



ADMINISTRATIVE LAW REVIEW



Volume 63

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Number 3

REPORT

Lobbying Law in the Spotlight:
 Challenges and Proposed Improvements.....419

ARTICLES

An Inductive Understanding of Separation
 of PowersJack M. Beermann 467

An Empirical Study of Judicial Review of Agency
 Interpretations of Agency Rules Richard J. Pierce, Jr. 515
 Joshua Weiss

Rule by ReasonablenessDavid Zaring 525

COMMENTS

The Department of Veterans Affairs' Entitlement Complex:
 Attorney Fees and Administrative Offset
 After *Astrue v. Ratliff*.....Stacy L.Z. Edwards 561

The Illusion of Interchangeability:
 The Benefits and Dangers of Guidance-Plus Rulemaking
 in the FDA's Biosimilar Approval ProcessJonathan Stroud 599

RECENT DEVELOPMENT

Fees From Mars: Why the FTC Needs to Regulate Mortgage
 Assistance Relief Services (MARS) Fees Alexander Lutch 645



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Volume 63

Summer 2011

Number 3

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in the FDA's Biosimilar Approval ProcessJonathan Stroud 599

RECENT DEVELOPMENT

Fees From Mars: Why the FTC Needs to Regulate Mortgage
Assistance Relief Services (MARS) Fees Alexander Lutch 645

REPORT

LOBBYING LAW IN THE SPOTLIGHT: CHALLENGES AND PROPOSED IMPROVEMENTS

REPORT OF THE TASK FORCE ON FEDERAL LOBBYING LAWS
SECTION OF ADMINISTRATIVE LAW AND REGULATORY PRACTICE
AMERICAN BAR ASSOCIATION

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JANUARY 3, 2011

[Editors' Note: On August 8, 2011, as an outgrowth of this report, the American Bar Association House of Delegates approved a resolution recommending revisions in the nation's lobbying laws. The resolution appears as the Appendix to this report.]

TABLE OF CONTENTS

Preface	424
Executive Summary.....	426
Lobbying Law in the Spotlight: Introduction.....	428
I. The Development and Present Scope of Lobbying Regulation	428
A. The Lobbying Disclosure Act.....	429
B. HLOGA and Beyond	432
II. Improving Registration and Reporting Under the Lobbying Disclosure Act.....	434
A. Current Trends and Concerns	434
B. Recommendations.....	439
1. Who Should Be Registered?	439
2. What Should Lobbying Firms and Organizations Disclose?.....	443
3. Client Disclosure of Lobbying Support	447
4. Particulars of “Lobbying Support”	448
5. Additional Findings.....	449
III. Recommendations for Strengthened Regulation of Lobbying- Related Activities	450
A. Lobbying Participation in Political Fundraising	450
1. Separation of Lobbying and Campaign Participation.....	451
2. Constitutional Considerations	452
3. Implementation Issues	455
B. Earmarks.....	457
C. Contingent Fees.....	460
D. Byrd Amendment	462
IV. Enforcement	462
Appendix	464

The views expressed in this report are presented only on behalf of the Task Force on Federal Lobbying Laws. They have not been approved by the Council of the Section of Administrative Law and Regulatory Practice, nor by the House of Delegates or the Board of Governors of the American Bar Association. Accordingly, they should not be construed as representing the policy of the Section or the Association. [Editors’ note: For the Association’s resolution, see the Appendix to this report.]

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i. The views contained in this report are those of the members of the Task Force in their individual capacities and do not necessarily reflect the views of their organizations, firms, or clients.

ii. The views contained in this report do not represent the views of the District of Columbia Bar, any Bar committee, any section of the Bar, or any section committee.

iii. The views contained in this report do not purport to represent the views of those persons identified as liaisons to the Task Force or their employing entities. Liaisons were invited to join the Task Force solely to offer, where appropriate, views and information that might assist the Task Force in forming its own conclusions and recommendations.



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January 3, 2011

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Dear Jon,

We are pleased to present the attached report of the Task Force on Federal Lobbying Laws, entitled “Lobbying Law in the Spotlight: Challenges and Proposed Improvements.” We believe it should make a useful contribution to the public debate about ways in which the federal government can improve its system of lobbying regulation, so that transparency in lobbying can be enhanced and conflicts of interest ameliorated (while fully honoring the First Amendment right of petition).

Beginning in October 2009, the Task Force held eleven meetings. Option and position papers were drafted and circulated, straw votes on central issues were conducted, and discussions were reopened where substantial disagreements persisted. The Task Force’s procedure was that no proposal went forward without broad support (at least two-thirds), and the recommendations reflected in this report are the result of those deliberations and that consensus. The breadth and depth of the Task Force’s recommendations testify to the expertise and experience of its members.

We appreciate Ron Levin’s invaluable service as Reporter for the Task Force. As Reporter he took charge of producing all the many drafts of the report as well as of the final product, for which he deserves very special acknowledgment. We also thank Bill Luneburg, who improved the entire report with background material, documentation, and a technical edit throughout the text. Section Director Anne Kiefer provided her usual high

2011]

LOBBYING LAW IN THE SPOTLIGHT

423

level of support assistance. Finally, his co-chairs thank Trevor Potter for his leadership and coordination of the entire endeavor.

We will look forward to the Council's consideration of our proposals in the near future.

Respectfully submitted,

Charles Fried
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PREFACE

CHARLES FRIED*

One of the first gestures of the incoming Obama Administration was to issue an executive order and memoranda with the intention of dramatically and drastically lowering the prestige, access, and influence of lobbyists. This initiative was one element of a broader wave of antilobbying enactments and proposals that have emerged in recent years at both the federal and state levels. Whatever the substantive merits and efficacy of these measures, they have grown out of a conviction—widely shared in the media, by political figures in both major parties, and by the public—that “special interests” have come to dominate and distort the processes of government. The result, it is thought, is that few important issues are decided rationally and deliberately on their merits, and the people’s work does not get done. And the agents and conduits of this nefarious influence are said to be the lobbyists. What is frequently overlooked by this sort of criticism, and by the accompanying urge to somehow make lobbyists disappear from the political scene, is an inescapable reality. Lobbying, and therefore lobbyists, are indispensable to the functioning of government, and they embody a constitutional right of the highest order, enshrined in the First Amendment: “The right of the people . . . to petition the Government for a redress of grievances.”

The government—whether it be the Executive or the Legislative Branch—simply cannot know the intricate details of the myriad aspects of national life that its actions might affect unless it has access to the expert contributions of the persons and interests involved. One cannot readily imagine legislators and administrators diligent and expert enough to learn on their own all they need to know to make the laws, and draft the rules and apply them in a way that accomplishes whatever good they seek. And even if one could, those affected by government have the constitutional right to make their contribution to the process, to make their views known, and to head off intended and unintended effects. The First Amendment says they may do this in the press and in public gatherings, and the Petitioning Clause says that the people may do this not only by spreading their views through broadcasting but also by seeking to address their governors directly.

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To be sure, the Constitution only gives the people a right to write and seek to call on those who govern them; whether officers and legislators must listen, answer their mail, or return their phone calls is another matter. The antilobbying measures of our day do not usually gainsay the right of lobbyists to ring the officials' bell; but some of them come quite close to decreeing that no one in the Executive Branch may come to the door. And this comes perilously close to infringing the very right the First Amendment establishes. Quite apart from that, some of these initiatives express a disdain for a whole class of persons, many of whom perform a useful and important function.

Notwithstanding some excesses, however, the critics of lobbying have raised issues that require serious attention. After all, many of these lobbyists are lawyers. Just as courtroom and law office lawyers advocate for and counsel their clients in the law that is, so do other lawyers serve as public policy advocates and counselors in the law that will or may be. As it is frequently put, ours is an honorable profession.

The proposals the Task Force offers are intended to restore the honor and enhance the efficacy of those in our profession who advocate for clients in the forum of public policy. Its proposals have two main themes. One is quite familiar: that public policy advocates should work in the open, just as their colleagues who advocate before courts work in the open, on the record. In aid of this goal, the Task Force proposes a number of improvements to the existing regime of disclosure, in ways that will make that regime more efficacious—not in silencing lobbyists, but in letting the public know who is talking to their government and about what.

The second theme is less familiar but no less important: to separate the function of urging elected officers of government to take action from the function of raising funds for and transmitting money to those officers. Nothing so contributes to the perception of lobbyists as agents of corruption, rather than as public policy advocates, as the confounding of these two functions. Conversely, nothing will go further to restoring the honor of this branch of our profession than a determined effort to separate, so far as constitutionally and practically possible, the roles of advocate and fundraiser. The Supreme Court has made abundantly clear that the contributing of funds to, and therefore the raising of funds for, elected officials is a constitutionally protected right. The Task Force does not propose to suppress that right. Rather, it proposes that, so far as practicable, those who advocate to elected officials do not raise funds for them, and those who raise funds for them do not advocate to them. If this guideline and related proposals of the Task Force are put into place, the status and value, perhaps even the efficacy, of public policy advocacy in our nation will be greatly enhanced.

EXECUTIVE SUMMARY

Lobbying plays an essential and consequential role in governmental decisionmaking, but its influence on legislative and executive actions also gives rise to apprehensions and controversy in society at large. The landmark Lobbying Disclosure Act of 1995 (LDA) took significant strides in the direction of promoting transparency and regularity in the practice of lobbying. Even in the wake of strengthening amendments in 2007, however, the LDA remains decidedly limited in scope and effectiveness. The present Task Force—a broadly based group of lobbyists, lawyers, public interest organization representatives, and academics—has developed a package of proposed reforms that would lay the groundwork for the next chapter in the development of lobbying regulation.

A principal focus of the Task Force's discussion has been on weak spots in the LDA that allow much lobbying activity to go unreported. For example, today a lobbying firm is exempt from having to register under the LDA unless it employs a lobbyist for whom lobbying activities constitute twenty percent or more of the time that he or she spends in working for a particular client. The Task Force recommends that this twenty-percent threshold test be eliminated, although monetary thresholds based on the amounts the lobbying firm expects to receive from the client should be retained. Furthermore, the LDA does not now require registrants to identify the specific legislative or executive offices to which they make a lobbying contact. Under the Task Force recommendation, that information would, in general, have to be reported.

Moreover, a modern lobbying operation is often a joint effort among multiple entities—not only a lobbying firm, but also firms that handle strategy, public relations, polling, coalition building, etc. At present, however, a lobbying firm reports only its own activities. Under the Task Force's recommendation, the firm and its client would each be responsible for reporting the activities of these additional entities that they have respectively retained. These additional “lobbying supporters,” however, would not be characterized as “lobbyists,” a label that carries a variety of collateral consequences. The hope is that, by not using that term to refer to lobbying supporters, the amended scheme would elicit more disclosure. Nevertheless, individuals who are principally involved in the “lobbying support” efforts would be identified by name on these reports. In addition, certain former high-ranking officials would be identified even if they were more incidentally involved in lobbying support.

The Task Force is also concerned about the leverage that lobbyists can acquire, and the unseemly appearances they create, when they participate in campaign fundraising for the same members of Congress whom they also

lobby. The Task Force proposes that a lobbyist should not be permitted to lobby a member of Congress for whom he or she has engaged in campaign fundraising during the past two years. Conversely, if the lobbyist engages in fundraising for a member, he or she should not be permitted to lobby that member for a two-year period. These prohibitions would not apply to personal monetary contributions to the campaign unless the total reaches a high aggregate figure. The proposed rules aim principally to limit lobbyists' fundraising from others, not to eliminate their ability to contribute to campaigns themselves.

Lobbying for earmarks also gives rise to risks of corruption and the appearance of corruption. The Task Force proposes that lobbyists who are retained to lobby for earmarks must certify in their LDA disclosure reports that they have not solicited contributions for the campaigns of the members lobbied, nor made contributions to those campaigns (or perhaps only nominal contributions). On a related note, the Task Force proposes that a lobbyist should not be permitted to enter into a contingent fee contract when the object of the lobbying is to obtain an earmark, individualized tax relief, targeted loan or grant, or a similar narrow financial benefit for the client. Additionally, the Byrd Amendment, which prohibits the use of funds appropriated by Congress to lobby for federal benefits, is in need of legislative or administrative clarification.

Finally, the Task Force believes that a major reason why the LDA is poorly enforced is that it is administered by House and Senate staff and the United States Attorney for the District of Columbia, rather than by an administrative agency that can deploy typical regulatory tools such as rulemaking, administrative penalties, administrative investigatory powers, etc. The Task Force recommends that responsibility for LDA enforcement be shifted to a regulatory body, such as the Civil Division of the Department of Justice, and appropriate authority conferred to make enforcement effective.

LOBBYING LAW IN THE SPOTLIGHT: CHALLENGES AND PROPOSED IMPROVEMENTS

AMERICAN BAR ASSOCIATION
SECTION OF ADMINISTRATIVE LAW
AND REGULATORY PRACTICE
TASK FORCE ON FEDERAL LOBBYING LAWS

INTRODUCTION

The Task Force on Federal Lobbying Laws presents herewith its final report on the condition of the nation's lobbying laws, together with its suggestions for improvements.

The Task Force was appointed in 2009 under the auspices of the Section of Administrative Law and Regulatory Practice of the American Bar Association (ABA). The Section has served for years as a focal point for discussions within the ABA on lobbying regulation. It has published a very successful compliance manual on federal lobbying law and practice (now in its fourth edition)¹ and has also sponsored lobbying reform proposals in the ABA House of Delegates.²

A preliminary version of this report was considered by the Council of the Section at the ABA Annual Meeting on August 7–8, 2010. The Council intends to consider a resolution based on the Task Force's work and forward it for adoption by the ABA's House of Delegates in August 2011.

I. THE DEVELOPMENT AND PRESENT SCOPE OF LOBBYING REGULATION

The first general law applicable to lobbying the federal government passed almost as an afterthought to the congressional reorganization efforts that followed World War II.³ Overshadowed in importance by the

1. ABA SECTION OF ADMIN. LAW & REGULATORY PRACTICE, *THE LOBBYING MANUAL: A COMPLETE GUIDE TO FEDERAL LOBBYING LAW AND PRACTICE* (William V. Luneburg, Thomas M. Susman & Rebecca H. Gordon eds., 4th ed. 2009) [hereinafter *THE LOBBYING MANUAL*].

2. See, e.g., ABA House of Delegates, *Recommendation 119*, AMERICAN BAR ASSOCIATION (Aug. 2006), http://www2.americanbar.org/sdl/Documents/2006_AM_119.pdf [hereinafter *Recommendation 119*] (advocating more expansive Lobbying Disclosure Act of 1995 (LDA) disclosure of lobbying coalitions and coverage of paid grassroots lobbying efforts).

3. See William N. Eskridge, Jr., *Federal Lobbying Regulation: History Through 1954*, in *THE*

Administrative Procedure Act and the Federal Tort Claims Act that were enacted the same year, the Federal Regulation of Lobbying Act of 1946 (FRLA)⁴ soon became almost irrelevant to the practice of lobbying and was largely ignored on all sides. The FRLA was in essence a disclosure regime administered by the Clerk of the House of Representatives and the Secretary of the Senate.⁵ It applied only to those seeking to influence members of Congress, but probably not their staffs, and without any coverage of the Executive Branch. The requirement to disclose lobbying activities extended to large and small expenditures (including cab fares), so that, even if a lobbyist fully adhered to the law's requirements (as few did), the level of detail required could easily overwhelm the ability of anyone examining the records to obtain an overall sense of lobbying in the nation's capital.⁶ In 1954, in *United States v. Harris*,⁷ the Supreme Court substantially weakened the Act by narrowly construing it.⁸ Thereafter, the Department of Justice abandoned any attempt to enforce the FRLA.⁹ Efforts to enact an effective federal lobbying statute continued for more than forty years without success.¹⁰

A. *The Lobbying Disclosure Act*

In the mid-1990s, a rare constellation of political events and publicized lobbying abuses resulted in the interment of the FRLA and the enactment of the Lobbying Disclosure Act of 1995 (LDA).¹¹ Like the FRLA, the LDA was, as originally adopted, purely a disclosure regime. It is applicable both to lobbying firms¹² and to entities that lobby on their own behalf.¹³ Where

LOBBYING MANUAL, *supra* note 1, at 5, 9–10.

4. Pub. L. No. 79-601, §§ 301–311, 60 Stat. 812, 839–42 (1946) (formerly codified at 2 U.S.C. §§ 261–270 (1994)) (repealed 1995).

5. For a succinct description of the Federal Regulation of Lobbying Act of 1946's (FRLA's) requirements, see Eskridge, *supra* note 3, at 10–11.

6. See William V. Luneburg & A.L. (Lorry) Spitzer, *The Lobbying Disclosure Act of 1995: Scope of Coverage*, in THE LOBBYING MANUAL, *supra* note 1, at 43, 44.

7. 347 U.S. 612 (1954).

8. See Eskridge, *supra* note 3, at 12–14.

9. *Id.* at 14–15.

10. See Thomas M. Susman & William V. Luneburg, *History of Lobbying Disclosure Reform Proposals Since 1955*, in THE LOBBYING MANUAL, *supra* note 1, at 23, 23–30 [hereinafter Susman & Luneburg, *History Since 1955*].

11. See William V. Luneburg, *The Evolution of Federal Lobbying Regulation: Where We Are Now and Where We Should Be Going*, 41 MCGEORGE L. REV. 85, 86 (2009) [hereinafter Luneburg, *Evolution*].

12. 2 U.S.C. § 1602(9) (2006) (defining “lobbying firm” to include persons and entities with one or more employees who are “lobbyists” as defined in the Act as well as self-employed “lobbyists”; in both cases such a firm works on behalf of others for compensation,

coverage requirements are met, such firms and organizations must register with the Secretary and Clerk¹⁴ and thereafter periodically file reports of lobbying activities,¹⁵ regardless of whether those activities are aimed at Congress, its staff, or the Executive Branch.

The duty of a lobbying firm or other entity to register largely depends on whether it employs a “lobbyist” as that term is defined in the Act.¹⁶ To qualify as a “lobbyist,” an individual has to (1) make more than one “lobbying contact” for the client over the course of its representation, and (2) spend at least twenty percent of his or her time for the client on “lobbyist activities.”¹⁷ A “lobbying contact” is a communication with a member or staff of Congress or with certain high executive branch officials (subject to some nineteen exceptions).¹⁸ “Lobbying activities” include not only lobbying contacts, but also efforts in support thereof.¹⁹ But a firm or entity is not required to register unless, in addition to employing a “lobbyist” as so defined, it meets certain monetary thresholds. In 1995, those were \$5,000 in income earned by a lobbying firm during a semiannual period, or \$20,000 in expenses for lobbying activities incurred over that same period by an entity that lobbies on its own behalf.²⁰ (As will be explained momentarily, the figures are higher today.) Businesses and various public

id. § 1602(10)).

13. *Id.* § 1603(a)(1), (2) (2006 & Supp. III 2009).

14. *Id.* The registration form is denominated the LD-1.

15. *Id.* § 1604 (including quarterly reports of lobbying activities—the LD-2 form—and semiannual reports of various contributions and disbursements to or on behalf of federal legislative and executive branch “covered” officials—the LD-203 form).

16. *Id.* § 1603(a). Note that the statutory definition of “lobbyist” differs from the concept of a “registered lobbyist.” The captions of the registration and reporting sections of the LDA refer to “registration of lobbyists” and “reports by registered lobbyists,” thus suggesting that the statute requires individual persons who meet the definition of “lobbyist” to register. *Id.* §§ 1603–1604. Actually, however, the operative provisions of the LDA require registration by the *employer* of such individuals (i.e. the lobbying firm or the organization that lobbies on its own behalf). Under specified circumstances, individuals who qualify as “lobbyists” are listed by that employer on either the registration form, its updates, or the quarterly reports of lobbying activities. Recent measures that govern federal lobbying, *see infra* Part I.B., are frequently directed at persons who have been listed in this fashion. *See, e.g.*, 2 U.S.C. § 1613(b) (Supp. III 2009) (lobbyist liability for breaching congressional gift rules); *id.* § 434(i)(7)(B) (disclosure of contributions bundled by lobbyists). The term “registered lobbyist” is commonly used to refer to persons who have been so listed. For example, the term is used in the Obama Administration’s executive orders and other implementation guidance applicable to lobbying, as well as in discussions of lobbying regulation in the media and in other contexts.

17. 2 U.S.C. § 1602(10) (2006).

18. *Id.* § 1602(8).

19. *Id.* § 1602(7).

20. *Id.* § 1603(a)(3)(A).

charities that lobby on their own behalf can opt to use definitions of lobbying provided in the Internal Revenue Code (IRC) to determine if these expense levels are met and for certain (but not all) disclosures where registration is required.²¹

The LDA registration form (the LD-1) requires certain basic information: the name and address of the registrant and its client; the names of lobbyists employed by the registrant and former congressional and executive branch positions held by those individuals; areas of projected lobbying activity; the names of organizations providing significant funding to the registrant for its lobbying activities on behalf of the client; and the names of foreign entities affiliated in various ways with the client and contributing organizations.²²

The periodic reports (the LD-2) update information provided on the registration form; give the total of income earned by a lobbying firm from the client over the covered period and aggregated expense totals for that same period in the case of a registrant that lobbies on its own behalf; specify general and specific areas of lobbying activities engaged in by lobbyists employed by the registrant; identify the houses of Congress and federal agencies with which a lobbyist made a lobbying contact for the client during the period; list those lobbyists active during the period; and specify foreign entities with interests in issues lobbied.²³ This information is very basic and conveys only a bare-bones outline of lobbying activities undertaken. However, in fairness to the drafters of the LDA, one of the perceived beneficial purposes of the statute was to give a better overall sense of lobbying activity than provided by the detailed itemization of expenses mandated by the FRLA.²⁴ It should be noted that grassroots lobbying does not trigger LDA registration and is not subject to disclosure where registration is required,²⁵ except in those instances where businesses or public charities elect to use IRC definitions of lobbying activity.²⁶

21. *Id.* § 1610(a), (b) (2006 & Supp. III 2009).

22. *Id.* § 1603(b).

23. *Id.*

24. *See* H.R. REP. NO. 104-339, pt. 1, at 4 (1995) (“Lobbyists who comply with this requirement [of the FRLA] file sheets of paper listing expenditures such as \$45 phone bills, \$6 cab fares, \$16 messenger fees, and even prorated salaries, in one case for as little as \$1.31. Some lobbyists provide lists of restaurants where they have paid for lunch. At the same time, however, the Act falls short of requiring disclosure of what the Act seeks most to know about lobbying—how much is spent overall and for what purpose.” (footnote omitted)).

25. *See* Lunenburg & Spitzer, *supra* note 6, at 57–59, 77.

26. *Id.* at 84–86.

The LDA also amended another statute, the Byrd Amendment,²⁷ which regulates a specific type of lobbying activity. That statute prohibits the use of funds appropriated by Congress to lobby for federal contracts, grants, loans, and cooperative agreements.²⁸ Before enactment of the LDA, the Amendment required contractors and awardees to file a complicated disclosure certification stating that no appropriated funds were used for prohibited purposes and detailing payments made from the contractor's or awardee's own funds to influence awards.²⁹ For awards made on or after January 1, 1996, the LDA simplified the disclosure requirements by requiring only a declaration that must (1) state the name of any lobbyist who has made lobbying contacts on behalf of the contractor and (2) contain a certification that the declarant has not made, and will not make, any prohibited payments.³⁰ However, the Byrd Amendment remains to this day vague in many important respects and a source of confusion for those to whom it may apply.³¹

B. HLOGA and Beyond

The series of scandals associated with lobbyist Jack Abramoff that came to light from 2004 to 2006³² so captured press and public attention that both Democrats and Republicans in Congress proposed significant changes to the LDA and other rules governing federal lobbying, including congressional gift and travel rules.³³ Following a tortuous process, the Honest Leadership and Open Government Act (HLOGA)³⁴ became law on September 14, 2007 on a bipartisan vote that followed intense partisan battles.³⁵ Thereafter, the LDA was more than a mere disclosure statute;

27. 31 U.S.C. § 1352 (2006).

28. *Id.* § 1352(a).

29. See Thomas M. Susman, *The Byrd Amendment*, in THE LOBBYING MANUAL, *supra* note 1, at 349, 353 [hereinafter Susman, *Byrd Amendment*].

30. 31 U.S.C. § 1352(b).

31. See Susman, *Byrd Amendment*, *supra* note 29, at 360.

32. Abramoff was sentenced to five years and ten months in prison on March 29, 2006, after pleading guilty to charges of fraud, tax evasion, and conspiracy to bribe public officials. The *Washington Post* covered the developments in detail. Those stories and a rich store of other information on the Abramoff scandals are found on the *Washington Post's* website. See Susan Schmidt et al., *Investigating Abramoff—Special Report*, WASH. POST, <http://www.washingtonpost.com/wp-dyn/content/linkset/2005/06/22/LI2005062200936.html>.

33. See Susman & Luneburg, *History Since 1955*, *supra* note 10, at 32–36; Robert F. Bauer & Rebecca H. Gordon, *Congressional Ethics: Gifts, Travel, Income, and Post-Employment Restrictions*, in THE LOBBYING MANUAL, *supra* note 1, at 477, 480–82 & Exhibit 23-1.

34. Pub. L. No. 110-81, 121 Stat. 735 (2007).

35. See Susman & Luneburg, *History Since 1955*, *supra* note 10, at 36–37.

registrants and their lobbyists commit criminal and civil offences by giving gifts in knowing violation of congressional rules.³⁶ Moreover, they must file a semiannual report (the LD-203) regarding their and their political action committees' (PACs') political contributions to federal candidates and certain disbursements that they make to or for the benefit of covered congressional and executive branch officials, certifying (subject to criminal and civil penalties) that those contributions and disbursements do not violate congressional gift and travel rules.³⁷ HLOGA also created an online reporting regime in which lobbying data is electronically filed and disclosed.³⁸

In addition, under HLOGA the LDA reporting cycle changed from every six months to every three months, resulting in a reduction of the monetary threshold for lobbying firm registration to \$2,500 and the threshold for entities lobbying on their own behalf to \$10,000³⁹ (both of which amounts increase with the Consumer Price Index (CPI) every four years; they are now, respectively, \$3,000 and \$11,500⁴⁰). Disclosure obligations for registrants were also broadened to capture more contributors to lobbying campaigns (i.e., those giving more than \$5,000 per quarter who also actively participate in the planning, supervision, and control of lobbying activities).⁴¹ Finally, political committees receiving more than \$15,000 (now \$16,000 based on CPI adjustment) in contributions credited to the fundraising efforts of LDA registrants or lobbyists must file periodic reports of that bundling under the Federal Election Campaign Act of 1971 as amended in 2007.⁴²

Enforcement of the LDA remains modest, to say the least. The Clerk of the House of Representatives and Secretary of the Senate have only the limited function of sending notices to those they believe may not be complying with the Act and thereafter notifying the United States Attorney for the District of Columbia of possible noncompliance.⁴³ Frontline enforcement authority in terms of seeking civil and criminal penalties is lodged solely in the United States Attorney.⁴⁴ To date there have been no formal enforcement actions filed and only three formal settlements entered

36. 2 U.S.C. §§ 1606, 1613 (2006 & Supp. III 2009).

37. *Id.* § 1604(d) (Supp. III 2009).

38. *Id.* §§ 1604(e), 1605(a)(9).

39. *Id.* § 1603(a)(3)(A).

40. *See id.* § 1603(a)(3)(B)(ii) (requiring adjustment every four years).

41. *Id.* § 1603(b)(3).

42. *Id.* § 434(i) (Supp. III 2009); *see* Trevor Potter & Matthew T. Sanderson, *Lobbyist Bundling of Campaign Contributions*, in *THE LOBBYING MANUAL*, *supra* note 1, at 471, 471–76.

43. 2 U.S.C. § 1605(a)(7), (8) (2006 & Supp. III 2009).

44. *See id.* § 1605(a)(8).

into.⁴⁵ Dissatisfied with the lack of enforcement action prior to 2007, Congress mandated that the Government Accountability Office (GAO) prepare an annual audit of lobbyist compliance with the Act⁴⁶ and that the Department of Justice semiannually report its enforcement activity to Congress.⁴⁷ To date, those reforms have yet to result in the filing of any enforcement actions, though the United States Attorney has made more effort to identify repeat LDA violators.⁴⁸

Finally, recent executive measures have extended lobbying regulation beyond the congressionally defined scope of the LDA. The Obama Administration took office promising to limit the influence of special interests on governmental decisionmaking.⁴⁹ Its initiatives have relied on the LDA concept of a “registered lobbyist” in (1) restricting gifts to executive branch officials;⁵⁰ (2) limiting the recruitment of former lobbyists into government positions;⁵¹ (3) requiring the posting on the Internet of communications from lobbyists related to applications for funding under the American Recovery and Reinvestment Act;⁵² and (4) prohibiting service of lobbyists on advisory committees and other executive agency boards and commissions.⁵³

II. IMPROVING REGISTRATION AND REPORTING UNDER THE LOBBYING DISCLOSURE ACT

A. *Current Trends and Concerns*

A continuing and pervasive concern of the Task Force has been to consider ways in which the registration and reporting system established by the LDA can be strengthened. Recent lobbying-related scandals, notably the Abramoff affair, provide the most visible illustrations of the need for

45. See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-499, 2009 LOBBYING DISCLOSURE: OBSERVATIONS ON LOBBYISTS' COMPLIANCE WITH DISCLOSURE REQUIREMENTS 17 (2010) [hereinafter 2009 GAO STUDY].

46. 2 U.S.C. § 1614 (Supp. III 2009).

47. *Id.* § 1605(b)(1).

48. See 2009 GAO STUDY, *supra* note 45, at 13.

49. See *The Obama-Biden Plan*, CHANGE.GOV, http://change.gov/agenda/ethics_agenda/ (last visited June 15, 2011).

50. See Exec. Order No. 13,490, §1, 3 C.F.R. 193, 194 (2010).

51. *Id.*

52. See Memorandum from the President to the Heads of Executive Departments and Agencies, Ensuring Responsible Spending of Recovery Act Funds, 2009 DAILY COMP. PRES. DOC. 177 (Mar. 20, 2009), *reprinted at* 3 C.F.R. 353 (2010).

53. Memorandum for Heads of Executive Departments and Agencies, Lobbyists on Agency Boards and Commissions, 2010 DAILY COMP. PRES. DOC. 513 (June 18, 2010), *reprinted at* 75 Fed. Reg. 35,955, 35,955 (June 23, 2010).

transparency. More broadly, however, the LDA reflects recognition that organized interest groups, which commonly act through lobbyists, exert enormous influence on the Legislative and Executive Branches of government.⁵⁴ Society has a recognized interest in shining light on lobbying activities so as to facilitate informed political dialogue about the extent and nature of this influence.

At the same time, lobbying is a legitimate form of petitioning the government for redress of grievances, and it can contribute in many ways to more informed and democratically responsive decisionmaking.⁵⁵ Providing a counterweight to official power, lobbyists often serve to keep government itself accountable. However, one need not posit that lobbying as such is sinister or suspect to believe that it should be accompanied by transparency that helps to assure accountability. In the only case to date in which the LDA has been challenged as invalid under the First Amendment, the court relied on this reasoning to uphold the Act.⁵⁶ The challenge, therefore, is to devise approaches to effective disclosure that do not impede the beneficial roles that lobbyists play.⁵⁷ Today, as attorneys increasingly find themselves providing analysis, advice, and advocacy in the policy realm, the Bar has a natural interest in ensuring that the regulatory balance is struck wisely.

54. In enacting the LDA, Congress made the following three findings:

- (1) responsible representative Government requires public awareness of the efforts of paid lobbyists to influence the public decisionmaking process in both the legislative and executive branches of the Federal Government;
- (2) existing lobbying disclosure statutes have been ineffective because of unclear statutory language, weak administrative and enforcement provisions, and an absence of clear guidance as to who is required to register and what they are required to disclose; and
- (3) the effective public disclosure of the identity and extent of the efforts of paid lobbyists to influence Federal officials in the conduct of Government actions will increase public confidence in the integrity of Government.

2 U.S.C. § 1601 (2006).

55. See, e.g., Nicholas W. Allard, *Lobbying Is an Honorable Profession: The Right to Petition and the Competition to be Right*, 19 STAN. L. & POL'Y REV. 23 (2008).

56. Nat'l Ass'n of Mfrs. v. Taylor, 582 F.3d 1 (D.C. Cir. 2009).

57. Compare Canada's Lobbying Act, R.S.C. 1985, c. 44 (4th Supp.) (Can.), which commences with the following preambulatory recitals:

WHEREAS free and open access to government is an important matter of public interest;
AND WHEREAS lobbying public office holders is a legitimate activity;
AND WHEREAS it is desirable that public office holders and the public be able to know who is engaged in lobbying activities;
AND WHEREAS a system for the registration of paid lobbyists should not impede free and open access to government

The Task Force believes that the LDA disclosure system is in need of improvement. The need stems in part from limitations in the law itself and in part from circumstances in the political environment that make compliance with the law less effective than it should be.

The Task Force's discussions highlighted several ways in which the universe of lobbying firms and organizations that are required to register could be and should be broadened. For example, an individual who spends less than twenty percent of his or her time on lobbying activities for a particular client during a given quarter is not captured by the LDA disclosure scheme,⁵⁸ although this gap in coverage allows quite a bit of lobbying activity to go unreported. Similarly, the LDA requires less information from those lobbyists and organizations that do register than it should. For example, the Act does not *require* these registrants to identify the specific congressional offices that they have lobbied.⁵⁹ Yet the objective of promoting the accountability of these offices should arguably be deemed as important a public purpose of the LDA as the objective of promoting the accountability of private actors.

Above and beyond these relatively straightforward debates about the proper scope of lobbying firms' and organizations' obligations under the LDA is a more fundamental problem to which the Task Force devoted much attention. In a modern, sophisticated lobbying operation, the work is frequently divided among multiple firms. For example, the client may retain a "strategy firm" to manage the lobbying campaign. The strategy firm, perhaps led by a former member of Congress or other well-known Washington figure, may make critical decisions for the overall effort. Yet, if no one employed by that firm engages in any lobbying contacts (i.e., direct communication with a "covered official" in the government), its actions will not have to be disclosed.⁶⁰ Similarly, the client may retain a pollster, a public relations firm to handle communications with the public, and other entities to increase the effectiveness of its lobbying efforts, none of whom makes lobbying contacts. These agents' roles will remain obscured from public view because the only disclosure obligation falls on the lobbyist's employer with regard to the actions of its "employees";⁶¹ independent

58. 2 U.S.C. § 1602(10) (Supp. III 2009).

59. See 2 U.S.C. § 1604(b)(2)(B) (2006 & Supp. III 2009) (requiring merely "a statement of the Houses of Congress and the Federal agencies contacted by lobbyists employed by the registrant on behalf of the client").

60. The employment of a "lobbyist" as defined in the LDA is one of the necessary triggers to registration. See *supra* note 16 and accompanying text. More than one lobbying contact is necessary for an individual to be counted a lobbyist. See *supra* text accompanying note 17.

61. See 2 U.S.C. §§ 1603(b)(6), 1604(b)(2)(A)–(C).

contractors do not fit within that term under the LDA.⁶² In this respect, the LDA system contains a substantial gap in coverage that warrants a remedy if the public is to have a grasp of the nature and scope of the typical lobbying campaigns conducted on behalf of the clients of LDA registrants.

The background factors that militate against broad compliance with the obligations that the LDA does impose begin with the low level of enforcement effort exerted to date by the Department of Justice.⁶³ The absence of meaningful consequences for failure to comply with the Act not only prevents this regulatory scheme from fulfilling its declared objectives; it also breeds further noncompliance. Potential registrants who might otherwise be willing to file required disclosure forms under the LDA could have trouble justifying such compliance if their competitors are seen to be violating the Act without consequences. Weak enforcement of the lobbying laws has been the target of public criticism for more than half a century; indeed it was one of the reasons behind the enactment of the LDA in the first place.⁶⁴ Moreover, in 2007 Congress expressed its frustration with the lack of enforcement by requiring annual audits of lobbyist compliance by the GAO and semiannual reports to Congress by the Department of Justice with regard to its LDA enforcement activity.⁶⁵ From all outward appearances, these statutory changes have had little effect on the Department's willingness to aggressively prosecute LDA violations.

Recently, the incentives to avoid LDA registration have increased. An objective of the LDA was to make registration and reporting relatively simple and straightforward in order to encourage broad compliance with the disclosure regime.⁶⁶ However, HLOGA shortened the reporting cycle; required registrants and lobbyists not only to certify their compliance with congressional gift rules, but also to obey those rules subject to civil and criminal penalties; mandated the semiannual reporting of political and other contributions; and imposed new requirements on political committees to report bundling of campaign contributions by registrants and their lobbyists.⁶⁷ This statute was followed by the Obama Administration's orders premised on the LDA definition of "lobbyist," including those

62. *Id.* § 1602(5)(A).

63. *See* 2009 GAO STUDY, *supra* note 45, at 13–17.

64. *See* William V. Luneburg & Thomas M. Susman, *Lobbying Disclosure: A Recipe for Reform*, 33 J. LEGIS. 32, 53 (2006) [hereinafter Luneburg & Susman, *Recipe for Reform*].

65. *See supra* text accompanying notes 46–47.

66. *See, e.g.*, H.R. REP. NO. 104-339, pt. 1, at 2 (1995) (“The Act streamlines disclosure requirements to ensure that meaningful information is provided and requires all professional lobbyists to register and file regular, semiannual reports identifying their clients, the issues on which they lobby, and the amount of their compensation.”).

67. *See supra* text accompanying notes 36–42.

banning gifts to high-level executive branch appointees, limiting appointment opportunities for former lobbyists, requiring Internet disclosure of lobbyist communications regarding stimulus and Troubled Asset Relief Program (TARP) funding, and restricting lobbyists from being appointed or reappointed by executive branch agencies to agency advisory boards and committees.⁶⁸ According to some (though not all) accounts, the collective consequence of these actions has been to encourage in some cases former registrants to terminate their registrations and to remove individuals from their lists of active lobbyists and, in others, to deter registration in the first place.⁶⁹ To the extent that lobbyists may have responded to this incentive, the result has been reduced transparency in government, as well as the unhappy consequence of leaving people who comply with the LDA worse off than those who bypass it, either lawfully or otherwise.

The Task Force's focus has not been on whether these restrictions have been wise,⁷⁰ but rather on the challenge of designing a lobbying disclosure system that takes account of their effects while not undercutting the principal purposes of the LDA. It believes, for instance, that information about the activities of at least some participants in a lobbying campaign might be more successfully achieved if the disclosure obligations imposed do not require characterizing them as "lobbyists."

In this and other contexts in this report, the Task Force has, consistently with its charge, focused on the *law* of lobbying regulation. The Task Force did not consider whether ethics rules could or should cover some of the

68. See *supra* text accompanying notes 50–53.

69. See, e.g., Bara Vaida, *Shedding the Scarlet 'L'*, NAT'L J., July 11, 2009, at 50; David D. Kirkpatrick, *Intended to Rein In Lobbyists, Law Sends Them Underground*, N.Y. TIMES, Jan. 18, 2010, at A1. One empirical study indicates that most of the deregistration in recent years predated the Obama restrictions and thus is attributable primarily to the impact of the Honest Leadership and Open Government Act (HLOGA). See CTR. FOR RESPONSIVE POLITICS, *THE DEREGISTRATION DILEMMA: ARE LOBBYISTS QUITTING THE BUSINESS AS FEDERAL DISCLOSURE RULES TIGHTEN?* (2010), available at <http://www.opensecrets.org/news/Deregistrationreport.pdf>. However, even if most registered lobbyists who could potentially have been induced to drop their registrations had already done so when the Obama restrictions were imposed, those restrictions do appear to have contributed to lobbyists' reluctance to be associated with that label. Thus, the restrictions probably do serve as a deterrent to future registrations.

70. The Task Force has not specifically evaluated the Administration's initiative to curtail lobbyists' service on agency advisory committees, but the Section of Administrative Law and Regulatory Practice has sent a letter to the Administration suggesting that this policy is in tension with the purposes of the Federal Advisory Committee Act. See Letter from William V. Luneburg, Chair, ABA Section of Admin. Law & Regulatory Practice, to Norman Eisen, Special Counsel for Ethics and Gov't Reform (Mar. 9, 2010), <http://www2.americanbar.org/sections/adminlaw/Blanket%20Authority/Letter%20to%20Norman%20Eisen%20on%20FACA%20March%2009.pdf>.

same territory. Those issues remain open for possible consideration by national and state bar associations.

B. Recommendations

To strengthen lobbying disclosure laws and adapt them to the new circumstances discussed above, we propose several revisions to the existing system for LDA registration and reporting.

1. Who Should Be Registered?

We propose the following criteria for determining whether a lobbying firm (i.e., a firm with an outside client) or lobbying organization (i.e., an entity that employs in-house lobbyists to work on its behalf) would be required to register:

A lobbying firm will be required to register if, on behalf of a particular client:

(a) employees of the firm in the aggregate make two or more lobbying contacts at any time on behalf of the client; AND

(b) the firm receives or expects to receive from that client for matters related to lobbying activities, at least the amount specified in 2 U.S.C. §1603(a)(3)(A) (currently \$3,000) in the quarterly period during which registration would be made.

A lobbying organization will be required to register if:

(a) employees of that organization in the aggregate make two or more lobbying contacts at any time on its behalf; AND

(b) the organization expends in connection with lobbying activities at least the amount specified in 2 U.S.C. §1603(a)(3)(B) (currently \$11,500) in the quarterly period during which registration would be made.

For purposes of these criteria, “employee,” “lobbying contacts” and “lobbying activities” would be defined as under current law (2 U.S.C. §§1602(5), (7) & (8)).

The most notable feature of these criteria is what they do not contain. We propose to broaden the provision in current law that pins registration in part on employment of an individual who makes more than one lobbying contact *and* whose lobbying activities constitute twenty percent or more of the time he or she devotes to services for the client during a quarterly period.⁷¹ Those two conditions are embedded in the LDA’s definition of “lobbyist”; we propose that Congress retain the first condition (two or more lobbying contacts) but delete the second (the twenty-percent rule). The second precondition to registration renders the LDA significantly underinclusive. For example, a law firm might divide work between a

71. 2 U.S.C. §§1602(10), 1603(a) (2006 & Supp. III 2009).

partner who engages in lobbying contacts, but spends less than twenty percent of her time on lobbying activities, and an associate who spends a great deal of time on the subject, but does not personally engage in any direct contacts with covered officials. Similarly, the firm might engage in considerable lobbying contacts, but divide up the work so that none of the individual employees exceeds the twenty-percent threshold. Finally, the twenty-percent test applies only to “lobbying activities,” which is a broad term, but nevertheless does not encompass significant aspects of a lobbying campaign such as providing strategic advice to clients and stimulating grassroots support for the lobbying campaign.⁷²

Although this change in the law would constitute an expansion of the scope of the registration requirement, its incidence would fall primarily on firms and organizations that engage in significant lobbying work, including direct contacts with covered officials. Such entities should not be surprised by a regulatory regime that makes their activities to influence the government a matter of public record. Moreover, on a practical level, many of these entities will already be familiar with LDA requirements and will be in a position to provide the necessary legal and accounting support necessary to fill out forms and undertake the other work necessitated by LDA registration.

The elimination of the twenty-percent test from the LDA definition of “lobbyist” does not necessarily mean that every individual who engages in more than one lobbying contact for a client will or should automatically be treated as a “registered lobbyist” for purposes of the LDA and other lobbying-related laws. As discussed above, under the structure of the LDA, registration forms are filed by employers, not by individuals. One’s status as a registered lobbyist depends on whether one has been listed by the employer on a registration or quarterly reporting form.⁷³ Specifically, § 1603(b)(6) of the LDA requires a registrant to list on the LD-1 “the name of each employee of the registrant who has acted or whom the registrant expects to act as a lobbyist on behalf of the client.”

In order to prevent an undue expansion in the number of individuals who would be characterized as registered lobbyists, we propose that § 1603(b)(6) be amended to provide that a person who meets the amended statutory definition of “lobbyist” need not be listed on a registration form unless the registrant anticipates that the person will spend (or has already spent) at least twelve hours engaged in lobbying activities or lobbying support for the client in a quarterly reporting period. This limitation would harmonize with our proposal in Part II.B.2 that the registrant should not be

72. See *supra* notes 25–26 and accompanying text.

73. See *supra* notes 16–17 and accompanying text.

required to list an individual as a lobbyist on a given quarterly report unless he or she actually did spend twelve or more hours on lobbying activities or lobbying support during that period. (As we explain in that section, however, the registrant would be expected to identify the person and disclose these activities even if the twelve-hour threshold test is not met.)⁷⁴

We propose to retain, at least in their essential characteristics, the other LDA criteria for registration, namely the requirements of two direct lobbying contacts with covered officials and a monetary expense threshold. (Notice, however, that the basis for registering is two contacts made by members of the firm or organization, but not necessarily by the same individual in both instances.) The benchmark of direct lobbying contacts corresponds to what has traditionally been deemed “lobbying in its commonly accepted sense.”⁷⁵ One implication of this criterion is that a campaign to influence government action that operates solely through efforts to stimulate public opinion at the grassroots level would not trigger LDA registration requirements. (Such a requirement, if imposed, would undoubtedly be very controversial, as past struggles over extending LDA coverage to grassroots lobbying have amply demonstrated.⁷⁶) As will be seen below, however, we do contemplate a system in which much of that activity would be disclosed if performed for a client that also meets the standard registration requirements.

As for the monetary threshold criteria, we believe they should remain in place as one factor used for determining the need to register under the LDA. Although the determination of how high to set the triggers intrinsically involves somewhat arbitrary line-drawing, monetary thresholds have been recognized since the enactment of the LDA as a reasonable means for separating professional lobbying operations, which fall within the intended rationale of the statute, from contacts by which occasional advocates, even those acting for compensation, reach out to the

74. In practice, employers may well often be conservative in their predictions as to whether particular employees will at some point surpass the twelve-hour benchmark. However, as under the current § 1603(b)(6), the absence of those employees from the public record of “registered lobbyists” would be only temporary, because their satisfaction of that criterion would ultimately have to be reported on the LD-2 for the period in which the requisite quantum of lobbying activities actually occurred.

75. *United States v. Harriss*, 347 U.S. 612, 620 (1954) (quoting *United States v. Rumely*, 345 U.S. 41, 47 (1953)).

76. See Susman & Luneburg, *History Since 1955*, *supra* note 10, at 30–31 (disagreement in the 104th Congress); *id.* at 32–36 (disagreement in the 109th Congress). The ABA has recommended that entities that engage in grassroots lobbying that results in more than \$25,000 in income or expenses within a three-month period should be required to register under the LDA and to make suitable disclosures pursuant to that status. *Recommendation 119*, *supra* note 2, at 1, 11–12.

government. The latter pose fewer risks of undue influence and have a stronger claim to being left unregulated by government. In principle, the Task Force does not seek to relax the monetary thresholds reflected in current law, but some adjustments in these amounts might as a practical matter be necessitated by the elimination of the twenty-percent-of-time criterion and the wider range of activities that would be reportable under the regime we are proposing.

A final issue relating to one of the monetary thresholds for registration, and the reporting obligations that follow, arises from a provision of the LDA (Section 15) that gives businesses, trade associations, and public charities the option to use the definition of lobbying applicable for Internal Revenue Service purposes in two contexts: (1) estimating lobbying expenses to determine whether the monetary threshold for LDA registration is met and, if so, to report quarterly lobbying expenses under the LDA; and (2) providing certain other information on the quarterly LDA report of lobbying activities.⁷⁷ In 1995, this option was included purportedly to simplify the reporting obligations of these entities by enabling them to make a single calculation for IRC and LDA purposes.⁷⁸ However, any advantage that the provision may offer in this regard comes at a significant cost in terms of the benefits of informative disclosure of lobbying activities.⁷⁹ Unlike the LDA, the IRC definition of lobbying does not, for example in the case of public charities, include lobbying of executive officials on nonlegislative subject matters. On the other hand, it does include lobbying at the state level, including grassroots lobbying. Thus, an entity that can rely on the IRC option can file reports that are seriously misleading, when compared with other LDA quarterly reports submitted by filers that cannot or do not use the IRC definitions. Moreover, after the 1998 Technical Amendments to the LDA, even those entities electing to use the Section 15 option must employ the LDA definition of lobbying in quarterly reports for lobbying activities involving Congress (outside the area of expense reporting).⁸⁰ Accordingly, even the original purpose of the provision—to avoid the need to track expenditures under two different definitions—has been significantly compromised. In order to promote more reliable comparisons among the lobbying disclosures of similar entities, the Task Force recommends that the IRC option be repealed.

77. See 2 U.S.C. §1610 (2006 & Supp. III 2009).

78. See, e.g., H.R. REP. NO. 104-339, pt. 1, at 23 (1995).

79. See U.S. GEN. ACCOUNTING OFFICE, GAO/GGD-99-38, FEDERAL LOBBYING: DIFFERENCES IN LOBBYING DEFINITIONS AND THEIR IMPACT (1999). For a more detailed description of the impact of the Internal Revenue Code (IRC) option on LDA disclosure, see Luneburg & Susman, *Recipe for Reform*, *supra* note 64, at 50–52.

80. See 2 U.S.C. § 1610(a)(2)(A), (b)(2)(A).

2. *What Should Lobbying Firms and Organizations Disclose?*

We propose the following standard for disclosure on quarterly reports filed by LDA registrants:

Once a firm or organization is required to register, it would have to disclose in its LD-2:

- (a) the bills and topics with respect to which lobbying activity was conducted;
- (b) all congressional offices, congressional committees, and federal agencies and offices contacted;
- (c) all individuals employed by the firm or organization who both made any “lobbying contact” and also devoted at least twelve (12) hours during the quarterly reporting period to “lobbying activities” or “lobbying support” (as hereinafter defined) on behalf of the client;
- (d) all other individuals employed by the firm or organization who engaged in “lobbying activities” or “lobbying support”; and
- (e) all other persons and entities retained by the registrant firm or organization that engaged in “lobbying support” along with a statement of—
 - (1) the nature of the “lobbying support” rendered with a short narrative summary of work performed;
 - (2) the amount paid to such other person or entity for “lobbying support”; and
 - (3) the names of individuals employed by that other person or entity who supervised the provision of “lobbying support” or devoted more than a specified number of hours to “lobbying support” during the quarterly reporting period.

A few points about this set of criteria should be highlighted. The first is that the required set of disclosures includes “lobbying support,” a term defined in detail below. Under current law, the term “lobbying activities” already includes “efforts in support of [lobbying] contacts, including preparation and planning activities, research and other background work that is intended, at the time it is performed, for use in contacts, and coordination with the lobbying activities of others.”⁸¹ Thus, although our concept of lobbying support is somewhat broader, the requirement in paragraph (d) does not entail a conceptual shift in the nature of the Act’s coverage. What is more innovative is the expectation in paragraph (e) that registrant entities will disclose not only support activities that they themselves perform, but also activities performed by outside firms that they retain. As noted above, this expectation responds to the modern reality that much of the effort in a lobbying campaign may be dispersed among

81. *Id.* §1602(7) (2006).

multiple entities. Required disclosure of this wider picture would directly serve the purposes of the LDA.

Second, the intent of the proposal is that only the persons described in paragraph (c), that is, an individual who both made at least one “lobbying contact” (a direct communication to a covered official) and also devoted at least twelve hours of his or her time during the quarterly period to lobbying activities or support, would be considered a registered (listed) “lobbyist” for purposes of other provisions of federal lobbying law (e.g. the congressional gift rule ban, the bundling provisions, etc.) and executive orders.

In contrast to the persons identified under (c), the individuals described in paragraph (d) and the firms described in paragraph (e) would not themselves be deemed lobbyists or lobbying firms, and they would not be required to register or file any reports (except that a limited class of persons providing lobbying support would have to file reports similar to the LD-203, as discussed below). As to this wider class, we think it preferable that they *not* be formally classified as “lobbyists.” Despite their importance to what can be accurately described as a lobbying campaign, such a characterization would not comport with their reasonable expectations. More importantly, such a characterization now carries a variety of collateral consequences, such as ineligibility for certain positions in government and on advisory committees, exposure to penalties for violation of congressional gift rules, etc. The prospects for enhanced compliance with the amended LDA will be increased if the broader disclosure requirements we propose are decoupled from that set of consequences.

There may be an argument for an additional exemption from this category of “registered lobbyist.” The exemption would benefit employees of a registrant organization that lobbies on its own behalf if they lobby only on a very sporadic and limited basis during the year. A company may, for example, have a large number of employees who make a single-shot, one-day visit to Congress to promote a cause favored by the firm. Arguably, the participants in such an exercise are simply not the kind of “lobbyists” that the HLOGA and Obama restrictions are intended to reach. The exemption could be circumscribed by an upper limit (such as spending ten to fifteen hours per year on lobbying contacts).

Third, another innovation in our proposal is the recommendation that disclosure forms must identify all congressional offices, congressional committees, and federal agencies and offices to which a lobbying contact was made. This is an extension beyond current law, which requires “a statement of the Houses of Congress and the Federal agencies contacted.”⁸² More extensive disclosure as proposed would directly serve the social

82. *Id.* § 1604(b)(2)(B) (2006 & Supp. III 2009).

interest in tracing the impact of lobbying on public decisionmaking. In theory, this interest could be promoted even more fully if lobbyists were required to identify every specific individual whom they contacted during a lobbying campaign and what was said during the contact. The obligation to keep track of conversations with multiple staff members in a given office would be burdensome, however, and it is not clear that the materiality of this level of detail would justify this burden. Thus, a requirement to identify particular offices contacted seems to be an acceptable middle ground.

To be sure, especially in these days of electronic communications, contacts are often made on a mass basis. An obligation to list the 535 members of Congress on a disclosure form could prove unwieldy. That difficulty could be alleviated by allowing filers to identify recipients of their contacts using generic descriptions such as “all members of Congress” or “all members of the Senate Finance Committee.” On the Executive side, the obligation to identify all “offices” contacted should also be manageable. It would not extend literally to any office in the vast bureaucracy of a large federal agency because the scope of covered executive branch officials in the LDA is limited to high-ranking officials.⁸³

We have a few additional proposals that do not relate directly to the criteria for disclosures. First, most of our recommendations in this section seek to improve transparency by *broadening* the scope of disclosure under the LDA. In at least one respect, however, a clearer understanding of lobbying realities can be achieved by facilitating a *reduction* in the number of persons who are identified in LDA records as lobbyists. Under the LDA, as we have noted, registrations are filed by employers of lobbyists, not by the individual lobbyists themselves.⁸⁴ Sometimes listings of lobbyists on the LD-1 and LD-2 forms become obsolete because, for instance, the listed individuals cease to be engaged in lobbying contacts or activities for the client or even leave for nonlobbying jobs. Yet those listings can persist

83. *See id.* § 1602(3) (2006), which includes:

- (A) the President;
- (B) the Vice President;
- (C) any officer or employee, or any other individual functioning in the capacity of such an officer or employee, in the Executive Office of the President;
- (D) any officer or employee serving in a position [on] the Executive Schedule [i.e., Cabinet and subcabinet policymakers and their counterparts in independent agencies], as designated by statute or Executive order;
- (E) any member of the uniformed services whose pay grade is at [the level of admiral or general]; and
- (F) any officer or employee serving in a position of a confidential, policy-determining, policy-making, or policy-advocating character [as determined by executive decision].

84. *See supra* note 16.

indefinitely where the registrant does not take the initiative to remove the name of the individual from its list of active lobbyists. Current practice does not afford such individuals themselves any easy way to leave the public rolls of current lobbyists. We propose, therefore, that the Clerk and Secretary should make available a simple form that individuals can file on their own initiative to deregister themselves as lobbyists. This step would serve to make the public record more accurate and, at the same time, enable individuals to disavow the sometimes unwelcome label of “lobbyist” after it has ceased to describe their actual status.⁸⁵

Second, a public disclosure database is only as good as its usability—and the LDA electronic records system is greatly in need of improvement. Because the system is not compatible with all office and personal computers’ operating systems, it creates inconvenience for both filers of lobbying reports and users of the information.⁸⁶ Users of lobbying reports should not have to re-key the information they download from the public databases in order to use it. In effect, the government’s failure to employ up-to-date technology imposes unnecessary economic burdens on citizens who should not have to bear those costs. Standardized, user-friendly software is already in use at other government agencies and should be incorporated into the LDA records system.

Moreover, the process of compiling information on particular individuals is sometimes made unnecessarily difficult because of the similarity between their names and those of other filers. That difficulty could be alleviated if users were able to track filings pertaining to any given individual by reference to a single identifying number (i.e., a unique identifier) that would retrieve information from both the House and Senate records. In fact, a numbering system of this general kind already exists. The congressional offices should, however, make such numbers publicly available and should enable members of the public to search the lobbying report databases using them.

85. In proposed guidance interpreting the presidential memorandum that generally prohibits lobbyists from serving on advisory committees and other boards and commissions, the Office of Management and Budget (OMB) has tentatively stated that the ban does not apply to registrants who “have not appeared on a quarterly lobbying report for three consecutive quarters as a result of their actual cessation of lobbying activities.” Proposed Guidance on Appointment of Lobbyists to Federal Boards and Commissions, 75 Fed. Reg. 67,397, 67,398 (Nov. 2, 2010). This qualification, however, mitigates only one of the collateral consequences of being listed on public records as a lobbyist.

86. For a general discussion of this system and some of the usability issues presented, see Craig Holman, *Public Access to Lobbying Records: The Online Lobbying Disclosure Databases*, in THE LOBBYING MANUAL, *supra* note 1, at 783.

3. *Client Disclosure of Lobbying Support*

As discussed above, modern professional lobbying campaigns often involve the participation of multiple firms. Their actions may provide polling, public relations work, coalition building, and even the major strategic planning for a lobbying campaign, and they may include the participation of well-known public figures whose involvement in the cause would be of great interest to the public. The full scope of these efforts is not now subject to disclosure under the LDA, which applies only to lobbying firms and organizations that lobby on their own behalf. Our proposal would partially alleviate this gap in coverage by the requirement (*supra* Section II.B.2, paragraph (f)) that those entities must disclose the lobbying activities and lobbying support of firms that these entities have retained to perform those functions. In many instances, however, the support activities would fall outside the scope of that requirement because they are arranged by the lobbying client, not by its outside lobbying firm.

As a further step toward disclosure of the extent of these multifaceted lobbying campaigns, we propose that the client of a firm that is required to register under the LDA should also be required to file reports, similar to the LD-2, disclosing lobbying support that it has procured or performed itself. These reports should be filed on the same quarterly schedule as the LD-2s and made available online with the same “searchability” as we propose to be provided for other lobbying reports. The disclosure should identify the firms that were hired, the individuals principally involved, the sums expended, and other information similar to that required of registrants on their LD-2s with regard to the same types of services. Since the lobbying firm may not even know the full cost or extent of these activities, the burden of disclosing them should logically fall on the client. Although the client that does the hiring may also not know who worked on its behalf, it should have the responsibility of obtaining that information from the firm that did the work. (A law firm would probably include on its bill the names of lawyers who worked on the matter; but a pollster or public relations firm, for example, would not necessarily offer the names as a matter of course, and the client would have to take the initiative in order to obtain the needed information.)

The rule of thumb should be that the client and the lobbying firm should each be responsible for reporting activities that they respectively procured. However, the client should not have to report activities of the lobbying firm itself because the latter would be required to report those activities on its

own LD-2 form.⁸⁷ Identification of the lobbying firm, which would enable a researcher to consult that firm's reports, should suffice.

As in the case of lobbying support arranged by the lobbying firm, individuals who engage in lobbying support activities arranged by the client should not have to be characterized as "lobbyists." Avoidance of that label should remove the disincentives to registration that we have described previously.

Although, in most instances, the client would need to identify only those individuals who are "principally involved" in lobbying support, that obligation should be supplemented by a requirement that, in general, any involvement by a former LDA-covered official should also be reported.⁸⁸ This requirement would reflect the distinctive significance that members of the public ordinarily attach to their participation. The requirement should be qualified by a reasonable cooling-off period and, possibly, by an exemption for lower-ranking former officials, such as committee staff whose governmental responsibilities bore no relationship to the matter being lobbied. The general point, however, is that material information about the identities of lobbying supporters should be reported, and in the case of former covered officials that category cannot be limited to those individuals who are "principally involved" in the lobbying support.

4. *Particulars of "Lobbying Support"*

We propose that the term "lobbying support" should be defined to include:

- (a) provision of strategic advice;
- (b) monitoring of legislative and administrative developments related to lobbying goals;
- (c) advice and assistance with earned media (press/communications) related to bills or topics disclosed by the registrant on one or more lobbying reports;
- (d) polling related to lobbying goals;

87. This allocation of responsibilities would ameliorate some duplicative, and potentially confusing, reporting now required under the LDA. The aggregated expenses reported on the LD-2s of entities that lobby on their own behalf include fees paid to registered lobbying firms, which themselves also report those fees as income earned on their LD-2s. Accordingly, a search of the LDA databases under a client's name may result in the researcher's adding those totals together. The result may be a misleading picture of the full lobbying effort expended on behalf of the client.

88. Covered legislative branch officials include members of Congress and congressional staff members. See 2 U.S.C. § 1602(4) (2006). See *supra* note 83 for a listing of covered executive branch officials. Currently, the LD-1s and LD-2s must report the covered positions previously (back to twenty years) held by active lobbyists for the client. See 2 U.S.C. § 1603(b)(6) (2006 & Supp. III 2009).

(e) expenditures for advice on or production of public communications (paid media, phone banks, mass e-mails, websites, advertising, etc.) related to bills or issues disclosed by the registrant on one or more lobbying reports; and

(f) expenditures for coalition building, that is, payments provided or received for the purpose of encouraging organizations to support or oppose the bills or take action with regard to the topics identified by the registrant on one or more lobbying reports, including, but not limited to, the costs of creating formal or informal coalitions of organizations for such purposes.

This definition is broadly drawn to embrace a multitude of support activities, reflecting the realities of modern lobbying campaigns. The list is basically self-explanatory.

As noted earlier, actions taken to shape public opinion at the grassroots level in favor of or in opposition to government action would not, on their own terms, trigger any registration requirement. However, if a client otherwise meets the registration triggers, expenditures for phone banks, websites, advertising, and the like should be disclosed as “lobbying support” under paragraph (e) of the above definition. Individuals who provide these services would not, however, themselves be deemed “lobbyists.” The definition is intended to be a bounded one. General image advertising would not have to be disclosed, but advertisements that specifically relate to the subject of a lobbying campaign should be.

Coalition building, disclosed pursuant to paragraph (f), is another vital component of lobbying as it is currently practiced. This is not to say that the coalition itself would necessarily need to register. The LDA does provide that a coalition or association can be the “client” for purposes of the Act,⁸⁹ and it will have to register if thresholds are met. However, a more informal entity that simply provides a loose structure for cooperation among clients is different. The difficult task of defining such an entity for regulatory purposes can likely be avoided, assuming that the law can be written to ensure that the members of the coalition do have filing obligations and will furnish the relevant information.

5. *Additional Filings*

As a general matter, our report envisions that activities that comprise lobbying support will be disclosed by a lobbying firm and its client, not by affiliated organizations or their employees that actually provide the support. The lobbying firm and the client will typically be repeat players who have good reasons to become familiar with LDA requirements; persons in the

89. 2 U.S.C. § 1602(2) (2006).

affiliate category might be involved with a lobbying project only on an incidental or sporadic basis.

Nevertheless, as to a limited class of lobbying supporters, we do propose a periodic filing requirement:

Persons identified on LD-2s as providing “lobbying support” should file semiannual reports, similar to the LD-203, if they meet any of the following criteria:

(1) they qualify as “bundlers” for the purposes of the Federal Election Campaign Act;⁹⁰

(2) they have made federal political contributions (including contributions to so-called 527 organizations) of more than \$10,000 in either the calendar year in which they provide the lobbying support or in the previous calendar year;

(3) they provide advice on lobbying strategy and that advice constitutes ten percent or more of their work for that registrant or client; or

(4) the person has previously served as a member of Congress or as a Senate-confirmed presidential appointee, or has served within the last five years as an employee of Congress or the Executive Office of the President.

The public interest in disclosure of information about these persons is relatively high because of the prominence or sensitivity of their roles in the lobbying enterprise. This interest in disclosure warrants an expectation that they should personally take responsibility for furnishing and vouching for the reliability of the information on an LDA form. Again, however, they would not for legal purposes be deemed “registered lobbyists,” a term that we are wary of expanding, for reasons discussed previously in this report.

III. RECOMMENDATIONS FOR STRENGTHENED REGULATION OF LOBBYING-RELATED ACTIVITIES

A. *Lobbying Participation in Political Fundraising*

The interplay of lobbying and the political money machine inevitably creates the potential for special interest influence and governmental decisions based on inappropriate criteria. In order to dampen the risks of corruption and the appearance of corruption inherent in this situation, the Task Force favors measures that would largely separate these two spheres of political activity.

90. There are two types of bundlers: those covered by Federal Election Commission Act regulations as they existed prior to HLOGA and a more extensive group encompassed by HLOGA. See Potter & Sanderson, *supra* note 42, at 471–73; Joseph E. Sandler, *Lobbyists and Election Law: The New Challenge*, in THE LOBBYING MANUAL, *supra* note 1, at 751, 760–61.

1. *Separation of Lobbying and Campaign Participation*

The Task Force distinguishes in this connection between lobbyists' personal monetary contributions to campaigns, on the one hand, and participation in campaign fundraising, on the other. There is precedent for prohibiting lobbyists' own contributions to candidates, including restrictions at the state level and in the pay-to-play area.⁹¹ However, the Task Force is not disposed to extend these precedents to the limits of their logic within the entire field of federal lobbying regulation. To prohibit lobbyists from contributing to a member's campaign in an amount that is no higher than ordinary citizens can lawfully make would implicate First Amendment interests. And, in any event, the dollar amounts attributable to any particular individual's own contributions to a single campaign are relatively low and thus are not the heart of the difficulty. Extending this same logic, we do not propose to prevent lobbyists from making contributions to any given party committee if the amount in question is no higher than ordinary citizens can make to such committees. Nor do we advocate restraints on lobbyists' ability to support campaigns of their choice in intangible ways, such as making endorsements and volunteering their time in get-out-the-vote efforts.

In contrast to the impact of personal contributions to a candidate, the multiplier effect of a lobbyist's participation in *fundraising* for a member's campaign (or the member's leadership PAC) can be quite substantial, and the Task Force believes that this activity should be substantially curtailed. A lobbyist who solicits and then "bundles" large numbers of individual donations for the benefit of a particular member of Congress, or who leads a fundraising effort on behalf of that member's campaign, becomes an extremely valuable asset to that politician. In many instances, this role enables the lobbyist to wield particularly strong influence when he or she makes a "lobbying contact" with the member. Even if the lobbying occurs first, the expectation that the lobbyist may later serve as an important figure in raising money for the member's campaign can result in undue influence in the legislative arena. Thus, a self-reinforcing cycle of mutual financial dependency has become a deeply troubling source of corruption in our government.⁹² In addition, public awareness of this interplay has contributed to an appearance of corruption and thus to widespread mistrust of the Legislature.

91. See Sandler, *supra* note 90, at 755–56 (discussing cases).

92. See Thomas M. Susman, *Private Ethics, Public Conduct: An Essay on Ethical Lobbying, Campaign Contributions, Reciprocity, and the Public Good*, 19 STAN. L. & POL'Y REV. 10, 15–21 (2008).

We propose, therefore, that an individual lobbyist should be prohibited from conducting certain fundraising activity to support the campaign of any member of Congress, or candidate for Congress, with whom that lobbyist has made a “lobbying contact” within the past two years. We also propose, conversely, that an individual lobbyist should be prohibited from making a “lobbying contact” with a member of Congress (including the member’s staff), or a candidate for Congress, if that lobbyist has conducted any covered fundraising activity for that person within the past two years. For this purpose, covered “fundraising” activity would include hosting or organizing fundraising events, serving on a campaign fundraising committee, sending communications (phone, print, e-mail) soliciting contributions for the member’s campaign, or participating in the “bundling” of campaign contributions for the member’s campaign. Further details of the proposal are set forth in Part III.A.3 below.

Occupying a middle ground between the two general types of political participation just discussed—contributing to individual campaigns and fundraising—is the role of a lobbyist’s cumulative contributions to multiple campaigns or party committees. In the aggregate, a lobbyist’s contributions to multiple campaigns may give rise to disproportionate political influence, particularly if the lobbyist contributes up to the legal maximum to all campaigns (as not many citizens do). We support reasonable measures that are designed to make this source of influence less likely. Specifically, under current law an individual’s aggregate contributions to all campaigns are subject to statutory caps, although the Federal Election Commission (FEC) adjusts the precise amounts of these caps for inflation over time.⁹³ At present the amounts are capped at \$45,600 per election cycle for contributions to all candidates and \$69,900 for contributions to all PACs and parties.⁹⁴ We believe that a lobbyist’s biennial aggregate contributions should be limited to half of the amounts allowed to other citizens by this statutory framework. If a limitation on the size of lobbyists’ donations to individual campaigns should prove necessary, as a practical matter, in order to implement these aggregate caps effectively, that step should also be considered.

2. *Constitutional Considerations*

Any discussion of legislation relating to campaign finance must devote some consideration to the substantial body of First Amendment doctrine

93. See Trevor Potter & Matthew T. Sanderson, *Federal Campaign-Finance Law: A Primer for the Lobbyist*, in THE LOBBYING MANUAL, *supra* note 1, at 429, 431–32.

94. *Id.* at 432.

that has grown up around this subject during the last several decades. The constitutionality of a proposal such as ours cannot be determined with certainty, nor evaluated here in detail,⁹⁵ but a discussion of two courts of appeals cases dealing with related issues will shed light on the range of judicial responses that might be anticipated.

In *North Carolina Right to Life, Inc. v. Bartlett*,⁹⁶ the Fourth Circuit upheld a North Carolina statute that prohibited lobbyists from contributing to campaigns of members or candidates for the General Assembly while the legislature was in session. The court found that this measure served the compelling state interest in preventing corruption and the appearance of corruption, noting that “[i]f lobbyists are free to contribute to legislators while pet projects sit before them, the temptation to exchange ‘dollars for political favors’ can be powerful”⁹⁷ and that “the appearance of corruption may persist whenever a favorable legislative outcome follows closely on the heels of a financial contribution.”⁹⁸ The court also rejected the objection that the statute forced lobbyists to forego one constitutional right (to petition the government) in order to assert another (to contribute to candidates and incumbents), citing to the analogous tradeoff required by the Hatch Act, which the Supreme Court has upheld.⁹⁹

In contrast is the recent decision in *Green Party of Connecticut v. Garfield*.¹⁰⁰ The Second Circuit reviewed a Connecticut statute that prohibited state contractors and lobbyists from contributing to legislators’ campaigns. The court found this ban allowable as to contractors, some of whom had been implicated in recent corruption scandals, but not allowable as to lobbyists. Since the latter had not been involved in the recent scandals, a total ban on contributions was impermissible.¹⁰¹ A limitation on contributions would adequately serve the state’s interests.¹⁰² Moreover, neither contractors nor lobbyists could be prohibited from *soliciting* contributions, as another part of the statute had provided.¹⁰³ The court said that solicitation is, after all,

95. For a survey of cases in this area, which have been largely, though not entirely, supportive of state law restrictions on lobbyists’ participation in campaign finance, see Sandler, *supra* note 90, at 756.

96. 168 F.3d 705 (4th Cir. 1999).

97. *Id.* at 716 (quoting *FEC v. Nat’l Conservative PAC*, 470 U.S. 480, 497 (1985)).

98. *Id.*

99. *Id.* at 717–18 (citing *U.S. Civil Serv. Comm’n v. Nat’l Ass’n of Letter Carriers*, 413 U.S. 548 (1973)). For additional case authority supporting regulation, see *Preston v. Leake*, 743 F. Supp. 2d 501 (E.D.N.C. 2010); *Institute of Governmental Advocates v. Fair Political Practices Commission*, 164 F. Supp. 2d 1183, 1189–94 (E.D. Cal. 2001).

100. 616 F.3d 189 (2d Cir. 2010).

101. *Id.* at 206–07.

102. *Id.* at 206.

103. *Id.* at 207–10.

“speech,” and thus was subject to strict scrutiny.¹⁰⁴ Although the district court had upheld the solicitation bans by contending that a contractor’s or lobbyist’s bundling of many contributions could exert improper influence, the court of appeals disagreed. It noted that the statute reached not only bundling, but also all other solicitations, including small-scale ones, and for this reason, among others, was not the “least restrictive alternative.”¹⁰⁵

These two court of appeals decisions aptly illustrate the uncertainties that accompany the case law in this area, but the Task Force believes that its proposal stands up well against the body of First Amendment doctrine as a whole. In the first place, the goal is not to regulate the lobbyist’s speech, in the sense of expression of opinion. The primary target is the *conduct* inherent in the kind of organized fundraising activities that can trigger inordinate influence for the lobbyist who engages in them on behalf of a member or other candidate. Under standard election law principles, a contribution to the campaign of a candidate, thereby augmenting *that candidate’s* ability to speak, is not equivalent to an expenditure of money to express one’s own views. Legislatures are generally entitled to somewhat more flexibility when they seek to regulate the former as opposed to the latter, especially since direct contributions to a campaign are deemed to carry a greater potential for corruption than are independent expenditures in support of the candidate.¹⁰⁶

Second, the Task Force’s proposal addresses a well-known—indeed notorious—real-world problem of inordinate influence and unseemly appearances. Presumably a legislative or judicial record could be assembled to substantiate it in a manner that could reassure a reviewing court, much as Connecticut’s experience with scandal among its government contractors became the basis for the portion of that state’s statute that the Second Circuit did uphold.

Third, our proposal (more fully elaborated below) has been constructed to address this problem in a balanced and limited fashion. We do not seek to eliminate the lobbyist’s own contributions to a legislator’s or other candidate’s campaign; even the aggregate limitations that we propose are not very confining. Indeed, in this regard our proposal is narrower than both the North Carolina and Connecticut laws involved in the cases discussed above.

To be sure, should the courts ultimately decide that the proposal sweeps too broadly, it could be narrowed in various ways without departing from

104. *Id.* at 208 (citing *Citizens United v. FEC*, 130 S. Ct. 876, 878 (2010)).

105. *Id.* at 209–10.

106. *See, e.g.*, *FEC v. Colo. Republican Fed. Campaign Comm.*, 533 U.S. 431, 437–38, 440–42 (2001); *Buckley v. Valeo*, 424 U.S. 1, 14–23, 45–47 (1976).

the basic concept. For example, in *Green Party*, the district court defended the Connecticut solicitation ban as a means of preventing lobbyists from bundling contributions by their “deep-pocketed clients.” “If that is the case,” the court of appeals responded, “then a less restrictive means to address the bundling problem would be simply to ban lobbyists from soliciting contributions from their clients.”¹⁰⁷ The solicitation ban in our proposal could potentially be circumscribed in that same fashion. Similarly, the Second Circuit suggested that a less restrictive alternative to the Connecticut statute would be “to ban only large-scale efforts to solicit contributions.”¹⁰⁸ This idea, too, might be taken into account in the development and refinement of our proposal. In the end, however, advance speculation about the degree of “narrow tailoring” that some reviewing court might eventually demand is somewhat fruitless. On the basis of what can be known now, the Task Force believes that its proposal is reasonably framed in relation to the problem it aims to alleviate, and for that reason stands a good chance of surviving First Amendment scrutiny, either in its entirety or at least in its essential features.

3. Implementation Issues

The Task Force has given extended consideration to several of the implementation questions that our proposed limitations on lobbyist fundraising would entail. Thus, we have identified several subsidiary principles that would seek to prevent circumvention of the basic objective of the plan, but that also would avoid unnecessary burdens on both lobbying and campaign fundraising activities. Elaboration of these details should be helpful to the ultimate construction of a plan that would be politically acceptable and also demonstrate the care in drafting that a reviewing court would expect. Other details, however, will probably have to be worked out in the drafting process. For example, the two-year cooling-off periods envisioned by our proposal may require some adjustments in order to avoid practical difficulties (such as problems that might ensue from expiration of a ban in the middle of a congressional term).

Challengers. A detail noted in our description of the basic proposal is that it should apply to *candidates* for Congress, in addition to incumbents and their staff. In many situations, of course, it could not apply on a completely equal basis because a lobbying contact with someone who is not a “covered official” is, by definition, impossible. However, where the circumstances do permit parity between challengers and incumbents, we believe it should be

107. *Green Party of Conn.*, 616 F.3d at 209.

108. *Id.*

maintained. Such parity would be important to the political acceptability of the proposal, and is not uncommon in election regulation. (For example, in *North Carolina Right to Life*, the Fourth Circuit squarely upheld an aspect of the North Carolina statute that forbade lobbyists from contributing to challengers.¹⁰⁹) It also has functional justifications. For example, an executive branch official who intends to run for Congress might be especially receptive to a lobbying contact today if motivated by the hope (or worse, the assurance) of fundraising assistance from the lobbyist in next year's congressional campaign. Similarly, a lobbyist's fundraising for a challenger today might lead easily to gratitude and reciprocation when the lobbyist later brings a legislative matter to the newly elected member.

Imputation. Another set of issues concerns the extent to which actions of an individual lobbyist should be imputed to the lobbyist's employer or other members of the same firm. We believe that, when a registered lobbyist makes a lobbying contact with a member, that contact should not prevent *nonlobbyist colleagues* from raising money for that member during the ensuing two years. To that extent, the disqualification is personal to the lobbyist. However, when a registered lobbyist makes a lobbying contact with a member and is thereby disqualified from fundraising for that member for the next two years, the same disqualification should apply to other registered lobbyists in the same firm. Without such a rule, the basic prohibition could be easily circumvented: one lobbyist in the firm could lobby for Senator A and raise money for Senator B, while a colleague could lobby Senator B and raise money for Senator A. Moreover, anyone who is employed as a registered lobbyist can reasonably be expected to anticipate that this status would lead to restraints on his or her future behavior. (The Hatch Act analogy suggested by the Fourth Circuit¹¹⁰ seems pertinent to this rationale.) The disqualification should also prevent the firm *as an entity* from raising funds for a member, staffer, or candidate, such as by sponsoring a fundraising event. The Task Force considered a less restrictive alternative—permitting the firm to raise funds for the member, but shielding the lobbyist from participating in that decision; however, it deemed that option unmanageable. When one bears in mind that individual nonlobbyist members of the firm would not be constrained in their fundraising, this proscription on the firm as an entity does not seem overly onerous.

In the converse situation, when a registered lobbyist has engaged in fundraising for a member, neither that lobbyist nor the employer firm or company as a whole should be permitted to lobby that member during the

109. *N.C. Right to Life, Inc. v. Bartlett*, 168 F.3d 705, 717 (4th Cir. 1999).

110. *Id.* at 717–18.

next two years. On the other hand, no ban should apply if a nonlobbyist at the same firm did the fundraising.

Fundraising. For purposes of these recommendations, fundraising activity “for the campaign” of a member should include fundraising for any other political committee controlled by that member, such as a leadership PAC. A track record of having recently lobbied a particular member should not foreclose a lobbyist from raising money for a national party committee, except that the lobbyist should not be permitted to designate that member as an ultimate recipient of the funds.

Fundraising for an organization that intends to spend independently, rather than to funnel the funds to the member’s own campaign, is not covered by our recommendation (due to First Amendment concerns), but consultation by the lobbyist with the member or the member’s personal or campaign staff about such fundraising should trigger the ban on lobbying the member.

Finally, these proscriptions should apply only to fundraising for election or reelection campaigns for Congress, not to an official’s campaign for the presidency or vice presidency.

“Solicitation” of financial support for a candidate should be distinguished from generally “talking up” the candidate. Established FEC rules defining solicitation could provide a backdrop for drawing this distinction.¹¹¹ Relatedly, consideration should be given to ways in which isolated or casual acts of soliciting contributions might be exempted from the general rules of disqualification envisioned by our recommendations. Such an exemption would assuage one of the concerns expressed by the Second Circuit in *Green Party*. The court gave the hypothetical example of a contractor (or presumably lobbyist) “advising his mother about whether she should contribute to a particular . . . candidate.”¹¹² We would support an exemption for family members and such other exemptions as are thought constitutionally necessary. Such limitations would, nevertheless, be consistent with the basic objective of the proposal, which is designed to dissipate the interplay between lobbying and a lobbyist’s substantial, rather than minimal, involvement in the fundraising process.

B. Earmarks

Earmarks in congressional legislation, and lobbyists’ role in promoting them, have elicited vigorous criticisms, particularly in recent years.¹¹³ The

111. See 11 C.F.R. § 300.2(m) (2010).

112. *Green Party of Conn.*, 616 F.3d at 209.

113. See, e.g., Kevin Bogardus, *Lobbyists and Watchdog Groups Form Coalition to Push for Earmark Reforms*, THE HILL, Sept. 28, 2010, <http://thehill.com/business-a-lobbying/121495->

controversy has developed to the point that outright abolition of earmarks is currently under serious consideration, although the prospects for their disappearance are uncertain at best.¹¹⁴ Regardless, the area seems ripe for reform. However, the connection between earmarking problems and lobbying problems is somewhat indirect, and consequently not all of the potential reforms lie within the purview of the Task Force.

Earmarks are provisions in appropriations bills that specifically direct that funds be spent on a particular local project or use. They can be seen in positive terms, as a normal expression of the congressional power of the purse. Earmarks can serve to ensure that the benefits of a spending bill will be shared widely, which may be unavoidable as a means of securing sufficient support for it to pass. It can also be argued that members of Congress, who understand the needs of their respective districts, often have an advantage in allotting expenditures over executive agency staff members who would otherwise make spending decisions. Furthermore, earmarks represent a small percentage of overall federal spending, and they often consist in reallocating spending rather than increasing the total amount. These facts cast doubt on any notion that earmark reform would contribute substantially to improvement of the nation's fiscal problems.

Nevertheless, the Task Force recognizes the force of several criticisms of earmarks. In some statutory contexts, they can result in an end-run around relatively rigorous, merit-based review processes, such as the peer review procedures used in the funding of scientific research. Moreover, earmarks often have been inserted into appropriations measures anonymously and with little or no review. Under these circumstances, members of appropriations committees or subcommittees often wield disproportionate influence, and money may be allocated to projects that would probably be rejected as wasteful if Congress were to examine them more closely. The lack of transparency and of effective procedural checks can also induce members to arrange for special interest spending at the behest of lobbyists, sometimes in response to campaign contributions or other favors, to the detriment of the public interest.¹¹⁵ The last of these dangers is directly relevant to the mission of our Task Force.

lobbyists-and-watchdogs-push-for-earmark-reforms.

114. The House Republican Conference voted in November to establish a two-year moratorium on earmarks, effective in the 112th Congress. *House GOP Unanimously Adopts Earmark Ban*, GOP.GOV CONF. BLOG (Nov. 18, 2010), <http://www.gop.gov/blog/10/11/18/house-gop-unanimously-adopts-earmark> (last visited Aug. 3, 2011). However, a similar moratorium was defeated in the Senate soon afterwards. Felicia Sonmez, *Senate Rejects Earmark Moratorium*, WASH. POST, Nov. 30, 2010, <http://voices.washingtonpost.com/44/2010/11/senate-rejects-earmark-morator.html>.

115. See, e.g., R. Jeffrey Smith, *Thin Wall Separates Lobbyist Contributions, Earmarks*, WASH.

Congress has recently taken steps to limit earmarks, but the situation has remained in flux.¹¹⁶ Even if it does not ultimately decide to institute a permanent ban on all earmarks, it could ban them in certain contexts, particularly where they supersede a plainly superior method of allocating funds. The House and Senate might also consider revamping their internal procedures to ensure that earmark requests will receive more timely public disclosure and will not be adopted without meaningful consideration by, and the concurrence of, a wider range of congressional participants. For example, the proposed Earmark Transparency Act of 2010, H.R. 5258 and S. 3335, would have created a single, searchable online database for all earmark requests and provided for a point of order to be raised against any bill or joint resolution, or amendment thereto or conference report thereon, unless it met these disclosure requirements. Measures of these kinds, however, are not squarely within the Task Force's mandate, and we make no specific recommendations with regard to them.

To address the specific issue of lobbyists' participation in promoting earmarks, we recommend that Congress require all individuals who are retained to lobby for earmarks to certify in their LD-203 filings ("Lobbyist Contribution Report") that they have not contributed to, nor sought individual or PAC contributions for, those members whom they have lobbied for earmarks during the current session of Congress. Employers of these lobbyists should be required to make a similar certification. If it is concluded that an outright ban on lobbyists' contributions to these

POST, Mar. 7, 2010, at A6, available at http://www.washingtonpost.com/wp-dyn/content/article/2010/03/06/AR2010030602374_pf.html; see also Pete Yost, *Prosecutors Recommend 57 Months for Ex-Lobbyist*, ASSOCIATED PRESS, Dec. 13, 2010, available at LEXIS.

116. Under HLOGA, members of Congress are required to post information about their earmark requests on their websites. See, e.g., Honesty and Open Government Act of 2007, Pub. L. No. 110-81, § 521, 121 Stat. 760-64 (2007). However, some members' disclosures seem to have been obscure and not consistent with the spirit of this requirement. See Matt Viser, *Uneven Response on House Earmarks*, BOSTON GLOBE, July 12, 2010, http://www.boston.com/news/nation/washington/articles/2010/07/12/uneven_response_on_house_earmarks. Also, in March 2010 the House Appropriations Committee instituted a ban on allowing earmarks to for-profit enterprises. See Press Release, U.S. House of Representatives Comm. on Appropriations, *Appropriations Committee Bans For-Profit Earmarks*, (Mar. 10, 2010), http://appropriations.house.gov/images/stories/pdf/2010_Earmark_Reforms_Release-3.10.2010.pdf. In the abstract, this measure was at least roughly consonant with the above-mentioned concerns about money influence and the appearance of corruption in the enactment of earmarks. In practice, however, this prohibition was sometimes circumvented through the creation of nonprofit affiliates to receive the earmarked funds. See Eric Lipton & Ron Nixon, *Companies Find Ways to Bypass Earmarks Ban*, N.Y. TIMES, July 5, 2010, at A1. In any event, only a small proportion of all earmarks have generally been bestowed for the benefit of for-profit enterprises. For more recent developments, see *supra* note 114.

members' campaigns is constitutionally problematic, Congress could instead decide to allow these contributions up to a modest amount, such as \$250. This measure would permit the lobbyist to make a symbolic statement of support for the campaign—which is sometimes deemed important to the constitutionality of limitations on campaign contributions—but it would also take a strong stand against the conflicts of interest inherent in the interplay between lobbying for earmarks and supporting political campaigns.

A measure regulating lobbyists' contributions will not, of course, deal definitively with the public policy issues surrounding earmarks. With or without lobbyists' involvement, members will continue to have strong incentives to pursue spending measures that benefit their particular districts, but have a questionable relationship with the broader national interest. Yet, by the same token, Congress could plausibly adopt this proposal in the interest of dispelling troubling conflicts of interest and appearances, without having first resolved broader questions about the proper role of earmarks in the appropriations process.

C. *Contingent Fees*

Approximately thirty-eight states broadly prohibit contingent-fee contracts for lobbying services.¹¹⁷ In addition, federal procurement contracts (other than those awarded by sealed bids) have for almost a century been required to contain a “Covenant against Contingent Fees,” whereby government contractors must, in general, warrant that contingent fees or commissions have not been used to secure the contract.¹¹⁸ It is true that these measures were to some degree a product of an earlier era in which public policy was driven by misgivings about lobbying itself, as distinguished from abusive lobbying.¹¹⁹ Nevertheless, even in our day, in which lobbying has become more professionalized, these longstanding prohibitions appear to rest on an apprehension that still has resonance. The apprehension is that lobbyists may be more likely to overreach, or engage in unethical behavior, if they know during the course of their efforts that they will not earn a fee unless their efforts are successful.¹²⁰ The

117. See Thomas M. Susman & Margaret H. Martin, *Contingent-Fee Lobbying*, in THE LOBBYING MANUAL, *supra* note 1, at 669, 670 n.7. Canada's Lobbying Act also forbids contingent payment arrangements for lobbying. Lobbying Act, R.S.C. 1985, c.44 (Can.) (as amended in 2006).

118. Susman & Martin, *supra* note 117, at 670–72.

119. *Id.* at 673–74.

120. *Id.* at 679–80.

impact of this pressure may, however, vary depending on the context in which the lobbying occurs.

Accordingly, the Task Force proposes a ban on contingent fees in lobbying in a relatively limited context—where the object of the lobbying is to obtain an earmark, tax relief, or similar authorization of a targeted loan, grant, contract, or guarantee. Where the lobbyist is seeking a narrow financial benefit for the client, the temptations for unethical behavior are probably at their greatest. The appearance of unseemliness, driven by public apprehensions about a possible corrupt exchange, is likely to be particularly strong in that setting also, as taxpayer dollars are directly involved. Indeed, in a number of situations involving earmarks, as discussed above, there are reasons to think that this type of legislative action should not be occurring in the first place. In those circumstances, the contingent fee contract could be faulted for possibly making the lobbyist more determined to press for the arrangement to be made.

The ban proposed here would not be cost-free. The opportunity to resort to a contingency-fee contract may enable some private persons to obtain representation that they could not otherwise afford. It might, for example, enable a town to assure citizens that it will not have to pay a lobbyist's bill unless it obtains the sought-for relief. In this regard, contingency-fee arrangements may promote norms of equal access to justice. However, the Task Force believes that, at least in the limited circumstances to which its proposal would apply, the benefits of a prohibition justify these costs, because the ban may head off overly aggressive advocacy as well as an improvident payment from the public treasury.

Finally, with respect to types of lobbying to which the ban would not apply, and also in the event the proposed ban is not adopted, we recommend that a lobbyist who enters into a contingent-fee contract should be required to file a copy of it as an attachment to the relevant LD-1 or LD-2 form. This requirement would induce responsible behavior by deterring fee arrangements that could not withstand public scrutiny. It would also serve the central purpose of the LDA, because a contingent fee by its nature would not otherwise be disclosed until the job is finished. Thus, early disclosure of the fee arrangement would result in the kind of timely transparency that the LDA is designed to elicit with respect to lobbying generally.

D. Byrd Amendment

As discussed in Part I.A, the Byrd Amendment remains an especially troublesome feature of lobbying regulation. Drafted hastily and with much less than the customary degree of public vetting, the Amendment contains a host of ambiguities. The Office of Management and Budget (OMB), which has implementation authority, issued “interim” rules many years ago, without public proceedings, and it has never finalized them.¹²¹

There are valid arguments for strengthening the Amendment, as well as for narrowing or repealing it, but in any event Congress should revisit the statute and make a searching reappraisal of its ends and means. Pending that legislative review, OMB should proceed to issue final rules that will dissipate much of the uncertainty and thereby facilitate compliance with the statute.

IV. ENFORCEMENT

As we suggested in Part II.A, the lack of vigorous enforcement of the LDA remains a matter of continuing concern for the Task Force.¹²² Indeed, without more effective enforcement, controversy over reform of the substantive requirements of the LDA and related legislation may prove academic.¹²³

Since the enactment of the LDA, the Offices of the Clerk of the House of Representatives and the Secretary of the Senate have forwarded thousands of cases to the Department of Justice for consideration of apparent noncompliance with the LDA, but the results of these referrals have been disappointing, to say the least. While the Department has sent out hundreds of noncompliance letters, there has been no significant follow-up in terms of commencing enforcement actions where LDA registrants do not rectify identified violations.¹²⁴ Moreover, there is no sustained effort to uncover cases of lobbyists who should register and file disclosure forms, but do not do so. The Department, in fact, “has never filed a criminal case or civil lawsuit to enforce the 15-year-old lobbying law and has reached out-of-court settlements in only three cases, which are now five years old.”¹²⁵ Even these three cases were unaccompanied by the kind of written

121. For a detailed discussion of these problems, see Susman, *Byrd Amendment*, *supra* note 29, at 349–60.

122. For an examination of LDA enforcement history and some options for statutory changes to improve enforcement efforts, see Luneburg, *Evolution*, *supra* note 11, at 119–30.

123. *Id.* at 119–20.

124. See 2009 GAO STUDY, *supra* note 45, at 16–17 & tbl.5.

125. Kenneth P. Doyle, *DOJ Official Cites Progress on LDA, Says Compliance Action Coming Soon*, BNA MONEY & POL. REP. (2010).

explanations that other agencies regularly provide with settlement orders, with the result that members of the lobbying community are unable to use them to infer the working law of the agency. (In fact, information on these three cases became public only as the result of a Freedom of Information Act request by a journalist; the Department never made a formal disclosure of them on its own initiative.)

The Department's continuing lackluster performance suggests that at least some of the obstacles to effective LDA enforcement are structural. The U.S. Attorney's office specializes in criminal and civil enforcement actions in court—a mode of adjudication that is disproportionate to the severity of most LDA violations. A well-designed LDA enforcement agency would be able to resort to proceedings such as rulemaking and administrative penalty actions, which are better suited to resolving issues and allegations of violation that are, in many instances, relatively small-scale in terms of overall importance. The rulemaking process would also be conducive to the promulgation of anticircumvention rules, which would serve to prevent regulated persons from doing indirectly what they are prohibited from doing directly. In short, the basic responsibility for enforcing the Act should be given a new home.

What agency, then, should be entrusted with this revamped set of powers? One potential candidate would be the FEC, which already administers a disclosure system that relates to a kindred part of the political process. Our proposed restrictions on lobbyists' fundraising for political campaigns, as outlined in Part III.A above, would arguably make an especially good fit with the FEC's other responsibilities. Much can be said for the FEC's capacity to dispose of routine, bureaucratic matters effectively at the staff level. At the agency-head level, however, the FEC's unique structure of evenly balanced partisan membership can lead to paralysis on policy questions, especially during periods when the philosophical premises of the commissioners are widely split (as at present).

A better solution, therefore, may be to entrust responsibility for LDA enforcement to an executive branch agency. One distinct advantage of such an assignment is that the new or reconstituted agency would have political accountability if it did a poor job of enforcing the Act. The capacity to call upon an administrator to defend the agency's enforcement record would create an incentive to deliver satisfactory results that does not exist at present. The recipient of this responsibility should be given an appropriate set of tools, including rulemaking and administrative civil penalty authority, as well as the capacity to conduct investigation of suspected violators. The Civil Division of the Department of Justice might, for example, be a reasonable candidate. Assignment to the Civil Division would be consistent with the Department's tradition of separating civil and

criminal responsibilities. Thus, the unit that wields rulemaking and adjudicatory authority should be able to consult, when necessary, with prosecutors (presumably in the Public Integrity Section), but it should not be able to threaten regulated parties with prosecution on its own.

In the end, the substantive and enforcement dimensions of LDA reform are somewhat interdependent. An improved set of procedures for implementing the Act seems essential. However, the level of enforcement of any regulatory program is often related to the moral authority and credibility of the program itself. We hope that implementation of our substantive recommendations will contribute to the creation of a revised LDA that will be broadly perceived as establishing a more rationally drawn, credible, and uniform body of rules than that which now exists. In turn, this development may lead to more vigorous enforcement of the Act against persons who do not comply with it.

APPENDIX

As an outgrowth of the foregoing report, and on the recommendation of the Section of Administrative Law and Regulatory Practice, the House of Delegates of the American Bar Association adopted the following resolution regarding lobbying regulation on August 8, 2011 (Resolution 104B):

RESOLVED That the American Bar Association urges Congress to :

(1) Amend the Lobbying Disclosure Act (LDA) by:

(a) narrowing the current threshold language under which a lobbying firm or organization need not register under the LDA unless it employs a person whose lobbying activities constitute twenty percent or more of the time that he or she spends in working for a particular client during a quarterly period, provided that Congress should establish reasonable threshold limitations on the obligation to list any particular individual as a federally registered lobbyist, including measures designed to avoid imposing undue financial burdens on small entities;

(b) requiring LDA registrants and their clients to disclose in quarterly reports the lobbying support activities in which they have engaged, as well as the lobbying support activities performed by firms that they have retained, including strategy, polling, coalition building, and public relations activities;

(c) requiring on quarterly reports the identification of (i) individuals principally involved in planning, directing, or coordinating lobbying

2011]

LOBBYING LAW IN THE SPOTLIGHT

465

support activities, as well as (ii) individuals with any level of involvement in such activities who have recently served as high-ranking federal officials; and

(d) requiring LDA registrants to disclose, subject to current exemptions, on quarterly reports all congressional offices, congressional committees, and federal agencies and offices contacted by lobbyists employed by those registrants.

(2) Provide that a federally registered lobbyist may not:

(a) lobby a member of Congress for whom he or she has engaged in campaign fundraising during the past two years;

(b) engage in campaign fundraising for a member of Congress whom he or she has lobbied during the past two years;

(c) make or solicit financial contributions to the reelection campaign of a member of Congress whom the lobbyist has been retained to lobby for an earmark or other narrow financial benefit; or

(d) enter into a contingent fee contract with a client to lobby for an earmark or other narrow financial benefit for that client.

(3) Transfer authority to enforce the LDA to a suitable administrative authority and empower that agency to utilize appropriate tools such as rulemaking, investigation, and imposition of civil or administrative penalties.

ARTICLES

AN INDUCTIVE UNDERSTANDING OF SEPARATION OF POWERS

JACK M. BEERMANN*

TABLE OF CONTENTS

Introduction.....	468
I. Separation of Powers Basics.....	472
A. Separation of Powers Particulars.....	473
B. Separation of Powers Leniency.....	481
II. General Separation of Powers Controversies.....	484
A. The Removal of Officers of the United States.....	484
B. The Vesting Clauses.....	491
C. Separation of Powers and the Judicial Branch.....	494
III. The Rejection of Conceptual Analysis.....	497
A. No Assignment of Powers.....	497
B. Overlapping Powers.....	499
C. The Importance of the Identity of the Actor.....	503
IV. The Assignment of Powers.....	506
A. General Principles.....	506
B. Textual Commitment.....	507
V. Some Minor Corollaries of the General Understanding.....	510
A. Informal Pressure.....	510
B. Underenforcement.....	512
Conclusion.....	514

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INTRODUCTION

Separation of powers is one of the least understood doctrines in U.S. law and politics. Underlying a great deal of separation of powers analysis is the conventional view that the United States Constitution requires a strict separation between the three branches of government and that efforts within one branch to influence or control the exercise of another branch's powers are illegitimate and should be rejected whenever possible. Although its simplicity might be appealing, this image of strict separation is inconsistent with the Framers' understanding of separation of powers¹ and with the law as developed by the Supreme Court in the face of the explosive growth of the regulatory state over more than a century. Every so often, a decision or series of decisions by the Supreme Court raises the specter of movement toward a strict view of separation of powers, but ultimately any such movement sputters to a halt, and in retrospect it usually turns out that the appearance of movement was more in the nature of wishful thinking than actual change. In fact, the Supreme Court has been remarkably consistent in rejecting judicial enforcement of strict separation of powers.

The Court's recent decision in *Free Enterprise Fund v. Public Co. Accounting Oversight Board (PCAOB)*,² striking down one feature of the structure of the Board on separation of powers grounds, may be another such decision. The opening paragraph of Chief Justice Roberts's opinion for the Court contains the strongest indication in recent years that the Supreme Court might embrace a strict view of separation of powers. The paragraph invoked three key elements of a pro-executive-power version of strict separation of powers that has become known as the unitary executive

1. This Article is about the current understanding and application of separation of powers norms and not about any originalist separation of powers doctrine. It is worth noting, however, that it does not appear that the Framers intended to adopt a strict version of separation of powers. In *Federalist 48*, James Madison described the general theory of separation of powers as follows:

It was shewn in the last paper, that the political apothegm there examined, does not require that the legislative, executive and judiciary departments should be wholly unconnected with each other. I shall undertake in the next place, to shew that unless these departments be so far connected and blended, as to give to each a constitutional controul over the others, the degree of separation which the maxim requires as essential to a free government, can never in practice be duly maintained.

THE FEDERALIST NO. 48, at 101 (James Madison) (J. & A. McLean eds., 1788).

2. 130 S. Ct. 3138 (2010). The Court upheld the process for appointing members of the Board but struck down the provision prohibiting the Securities and Exchange Commissioners from terminating members of the Board without cause. This is discussed in more detail below. *See infra* Part II.A.

theory: government power is divided into “three defined categories”;³ the executive power is vested in the President; and executive branch officials, even in independent agencies, are constitutionally understood as assisting the President in discharging his duties. Taken to its extreme, as the unitary executive theory does, the logical end of these three propositions would be to pronounce unconstitutional the independence of independent agencies and all efforts to insulate the execution of the law from complete presidential control.⁴

While previous Supreme Court opinions have adverted to the government’s three-branch structure in ways that point toward a strict separation of powers,⁵ the *PCAOB* opinion is notable for invoking the Vesting Clause of Article II.⁶ The Vesting Clauses of the Constitution’s first three articles provide a blueprint for the structure of the government, but they have not been particularly important to the resolution of actual disputes over the separation of powers.⁷ To the contrary, the Vesting

3. See *Free Enter. Fund*, 130 S. Ct. at 3146. The Court’s reference to “three defined categories” of governmental power was not new. In this particular case, the Court quoted a passage in the *Chadha* decision. See *INS v. Chadha*, 462 U.S. 919, 951 (1983) (“The Constitution sought to divide the delegated powers of the new Federal Government into three defined categories, Legislative, Executive, and Judicial, to assure, as nearly as possible, that each branch of government would confine itself to its assigned responsibility. The hydraulic pressure inherent within each of the separate Branches to exceed the outer limits of its power, even to accomplish desirable objectives, must be resisted.”).

4. See, e.g., Gary Lawson, *The Rise and Rise of the Administrative State*, 107 HARV. L. REV. 1231, 1242 (1994) (“[I]f a statute vests discretionary authority directly in an agency official (as do most regulatory statutes) rather than in the President, the Article II Vesting Clause seems to require that such discretionary authority be subject to the President’s control.”). But see *Kendall v. United States*, 37 U.S. (12 Pet.) 524, 610 (1838) (noting that executive branch officials are not all under the exclusive control of the President); Kevin M. Stack, *The President’s Statutory Powers to Administer the Laws*, 106 COLUM. L. REV. 263 (2006) (hypothesizing that delegation directly to an agency indicates congressional intent not to have the President in charge of administering the statute).

5. See, e.g., *Chadha*, 462 U.S. at 919.

6. U.S. CONST. art. II, § 1, cl. 1.

7. The Vesting Clauses of Articles I and II are invoked more often in concurring and dissenting opinions than in the Court’s majority opinions. The most prominent example of this may be Justice Scalia’s invocation of Article II’s Vesting Clause in his dissenting opinion in *Morrison v. Olson*, concerning the constitutionality of the Independent Counsel provisions of the Ethics in Government Act. See 487 U.S. 654, 698–99, 705 (1988) (Scalia, J., dissenting). In that opinion, after quoting Article II’s Vesting Clause for the second time, Justice Scalia exclaimed, “As I described at the outset of this opinion, this does not mean *some of* the executive power, but *all of* the executive power.” *Id.* at 705. The Vesting Clause of Article II is cited in majority opinions as the source of the nondelegation doctrine which, as described *infra* notes 97–99, embodies a relatively lenient constraint on Congress’s ability to confer discretion on the Executive Branch. See, e.g., *Touby v. United States*, 500 U.S. 160, 164–65 (1991); *Mistretta v. United States*, 488 U.S. 361, 371–72 (1989). The Vesting

Clauses lurk in the background while the Constitution's numerous structural and procedural provisions occupy center stage, creating a governmental system best described as separation of powers with checks and balances. The Court has never decided separation of powers controversies by determining the nature of a power and then assigning it to the appropriate branch as specified in the Vesting Clauses. Rather, by and large, the Court has strictly enforced the structural and procedural requirements for action by each branch while being very deferential to Congress when ruling on whether a more general principle of separation of powers has been transgressed. If the Vesting Clauses are brought to the foreground in the future, we might see a new form of separation of powers analysis, under which powers are assigned to branches and little or no interbranch interference is tolerated.

The Court in *PCAOB* did not deliver on the opening paragraph of the opinion's promise of a major reform in the law of separation of powers. The Court did not read Article II's Vesting Clause as requiring that the PCAOB be brought under complete presidential control or that PCAOB members be appointed by the President or be removable without cause by the President. To the contrary, the Court reaffirmed its longstanding general approach to separation of powers issues, showing great flexibility with regard to the appointment of the PCAOB members and tightening up only modestly with regard to their removal.⁸

The purpose of this Article is to provide a description of current separation of powers doctrine as embodied in precedent and common understandings of the practice of separation of powers in the government of the United States.⁹ The idea is to provide a general understanding of

Clause of Article III is invoked often in the Court's majority opinions concerning the scope of the judicial power.

8. See *Free Enter. Fund*, 130 S. Ct. at 3164. The Public Company Accounting Oversight Board (PCAOB) was created in 2002 as part of the Sarbanes-Oxley Act's reform of regulation of the accounting industry. See Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, § 101, 116 Stat. 745, 750 (codified at 15 U.S.C. § 7211 (2006)). The Board consists of five members appointed and removable only for serious cause by the Securities and Exchange Commission (SEC). 15 U.S.C. §§ 7211(e)(1), 7217(d)(3). The PCAOB's function is to enforce the aspects of the Sarbanes-Oxley Act and other laws and regulations that apply to the accounting industry. The PCAOB was modeled on private self-regulatory agencies such as the New York Stock Exchange, and although the Act declares that the PCAOB members are not government officers or employees, they clearly are for purposes of the Appointments Clause. Its members are very well paid for government officials, with pay ranging from \$547,000 to \$673,000. See *Free Enter. Fund*, 130 S. Ct. at 3147 n.1.

9. Because the goal of this Article is to take a fresh look at the practice and practical understanding of separation of powers in the government of the United States, I do not engage the voluminous scholarship that exists on the subject. Although the picture painted here may strike some readers as novel and somewhat unconventional, it shares some

separation of powers as it actually structures the distribution of power within the federal government of the United States of America. The Article is inductive, deriving separation of powers principles from the caselaw concerning how the government is structured, rather than deductive, which would entail deriving the proper structure from abstract principles. I have chosen this methodology for two related reasons. First, in my view, there is no set of abstract principles from which an appropriate governmental structure consistent with separation of powers could be derived. Second, even if it were possible to construct an appropriate governmental structure from separation of powers principles, it would not take into account the particulars of the Constitution of the United States and thus would be of limited utility in understanding how separation of powers actually works under that Constitution.

In my view, current law creates a pretty good governmental structure that is not patently inconsistent with a normatively desirable understanding of the meaning of the Constitution. But I do not mean to state a normative theory of separation of powers, understood either as an efficiently functioning government or a correct understanding of the Constitution's requirements. Rather, the idea of this Article is to describe and analyze separation of powers as actually practiced by the government of the United States under the constitutional constraints recognized by the Supreme Court. The *PCAOB* decision, as the Court's latest pronouncement on separation of powers fundamentals, is highlighted somewhat, although this Article's focus is well beyond *PCAOB*.

This Article proceeds as follows. Part I sets forth seven propositions concerning the law of separation of powers in the United States and elaborates on the first two to lay out this Article's general view of separation of powers. Part II addresses separation of powers controversies concerning the appointment and removal of executive officials and discusses the role of the Vesting Clauses in the Supreme Court's separation of powers jurisprudence. Part III sets forth the argument that conceptual analysis is not important to separation of powers law in the United States, i.e. that the law of separation of powers does not involve describing the nature of a governmental power and assigning it to the proper branch. Rather, as this

attributes with M. Elizabeth Magill, *Beyond Powers and Branches in Separation of Powers Law*, 150 U. PA. L. REV. 603 (2001), and Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573 (1984). John Manning paints a similar picture of separation of powers in an article written roughly contemporaneously with this one, although Manning's analysis of governmental powers is more conceptual than the one presented in this article. See John F. Manning, *Separation of Powers as Ordinary Interpretation*, 124 HARV. L. REV. 1939 (2011); see also Arnold I. Burns & Steven J. Markman, *Understanding Separation of Powers*, 7 PACE L. REV. 575 (1987).

Part elaborates, most governmental actions can be taken by more than one branch as long as each branch obeys the Constitution's structural and procedural provisions that apply to it. Part IV addresses how powers are actually assigned to branches, if conceptual analysis is not the key. Finally, Part V lays out some minor corollaries to the general understanding of separation of powers presented in this Article.

I. SEPARATION OF POWERS BASICS

Separation of powers is one of the pillars of government in the United States. The federal government and all state governments are structured around the principle of separation of powers.¹⁰ Yet, a general theory of separation of powers has proven elusive. There is, of course, the basic principle of separation of powers and the idea that each branch exercises its own powers and does not intrude on the powers of the other branches, but this understanding is not complete for several reasons. For one, it does not incorporate the principle of checks and balances, which is designed to prevent or hinder branches of government from acting unilaterally. Further, it does not account for the near impossibility of matching activities to their proper branch. Finally, it fails to recognize that different branches often take actions that, while procedurally and structurally distinct, function identically as a matter of substance.

Some basic propositions, elaborated upon in the course of this Article, underlie the view of separation of powers espoused here. They are:

(1) The bulk of separation of powers analysis comprises the application of the various specific procedural and structural provisions contained in the Constitution, and not an overarching theory of separation of powers.

(2) Building on proposition (1), the courts generally enforce the procedural and structural provisions of the Constitution strictly. When, however, a separation of powers controversy cannot be resolved with reference to a particular provision of the Constitution, the courts apply a very forgiving standard and are unlikely to find a violation of the general principle of separation of powers.

(3) The Vesting Clauses of Articles I, II, and III of the Constitution are not among the procedural or structural provisions of the Constitution that tend to be strictly enforced. They thus have little or no substantive bite. In

10. State separation of powers law is similar but not identical to federal law. In one area of significant difference, some state courts have recognized substantive separation of powers limits on legislative reform in areas of traditional judicial control, such as damages in personal injury cases. *See, e.g.,* *Best v. Taylor Mach. Works*, 689 N.E.2d 1057, 1078 (Ill. 1997) (statutory damages cap on noneconomic injuries violates Illinois separation of powers doctrine).

other words, it is rarely, if ever, possible to rely on a Vesting Clause to provide an answer to a separation of powers controversy.

(4) As a corollary to proposition (3), in general, separation of powers controversies are rarely, if ever, resolved by determining which branch of government is the proper branch to engage in a particular activity. In other words, separation of powers controversies are not resolved by determining the nature of a government action and then assigning the performance of that action to the branch with the power to engage in that category of action.

(5) Building on propositions (3) and (4), most government actions can substantively be performed by more than one branch. Each branch must observe the constitutional procedural and structural requirements that apply to it.

(6) Building on proposition (5), the identity of the actor performing the action and not the nature of the action itself usually determines what sort of action is being performed. For example, when Congress acts it is legislating, and when an administrative agency acts it is executing the law, even if the action taken is, in substance, identical.

(7) The strongest evidence that a power is assigned to a particular branch is an explicit textual commitment of that action to the branch, not a more general principle of separation of powers. When a power has been assigned to a particular branch, no other branch is allowed to exercise that function unless the Constitution explicitly permits it to.

These are the most important propositions to the understanding of separation of powers presented in this Article. There are, in addition, a pair of minor propositions that help understand how separation of powers understandings have developed. These are:

(8) Informal pressure on the holder of a power to exercise it in a particular way does not violate separation of powers; and

(9) Separation of powers norms may be underenforced judicially. In other words, the constitutional ideal may involve a stricter understanding of separation of powers than what the federal courts are willing to enforce.

A. *Separation of Powers Particulars*

I begin by elaborating on proposition (1): *The bulk of separation of powers analysis comprises the application of the various specific procedural and structural provisions contained in the Constitution, and not an overarching theory of separation of powers.*

Although the principle was clearly on the minds of the Framers, the Constitution of the United States, unlike many state constitutions, does not refer directly to separation of powers. Rather, the Constitution contains

numerous particular structural and procedural provisions that create a government under which, by and large, separation of powers is observed. By “structural and procedural provisions,” I mean those constitutional provisions that specify the structure of the government, such as the clause specifying that the Congress consists of the Senate and the House of Representatives¹¹ and those provisions that specify the procedures for taking a particular governmental action, such as the clause specifying that that bills must be presented to the President before they become laws.¹² While nearly all of the Constitution’s structural and procedural provisions bear some relation to separation of powers, some focus specifically on separation of powers issues.¹³

When separation of powers controversies arise, they almost always turn on the meaning and application of one or more of the Constitution’s particular structural or procedural provisions, rather than on a general separation of powers standard. Perhaps this is because the Framers foresaw many potential threats to separation of powers and addressed them in the Constitution. The best example of this is the Incompatibility Clause, which prohibits simultaneous service in Congress and another branch of government.¹⁴ Perhaps it would violate a general principle of separation of powers for a member of Congress to serve in the Executive Branch as

11. U.S. CONST. art. I, § 1.

12. *Id.* art. I, §7, cl. 2.

13. The key separation of powers provisions of Article I include the Incompatibility Clause, which prohibits members of Congress from also serving in any other federal office; the procedures in Article I for passing bills and presenting them to the President for signature or veto; the enumerated powers of Article I, § 8 (including the Necessary and Proper Clause); and the prohibition on bills of attainder. In Article II, the key separation of powers provisions include the prohibition against changing the President’s compensation during the term; the designation of the President as Commander in Chief; the clause allowing the President to require written opinions from department heads; the grant to the President of the power to make treaties and appoint officers of the United States, both with Senate confirmation; the provision empowering the President to receive foreign ambassadors; the imposition on the President of the duty to take care that that laws are faithfully executed; the provisions, now amended, providing for independent election of the President; and the provision making clear that the President and Vice President are subject to impeachment and removal for treason, bribery, and “other high Crimes and Misdemeanors.” Article III’s key separation of powers provisions include the specification that the inferior courts are “ordain[ed] and establish[ed]” by Congress; that the federal judges serve “during good Behavior” at a compensation that cannot be diminished; and that Congress has the power, subject to limits, to declare the punishment for treason. While there are numerous additional provisions that relate in some way to separation of powers, these are the most important.

14. U.S. CONST. art. I, § 6, cl. 2.

well.¹⁵ Because of the existence of the Incompatibility Clause, we will never need to explore that issue. Although separation of powers principles are relevant to construing the Clause, the primary element of analysis, should a dispute over congressional service arise, would be the Clause itself, not general principles.

The particular structural and procedural provisions of the Constitution establish a form of government that is best described as separation of powers with checks and balances. These provisions do not map neatly onto a particular set of legal doctrines because they are not all vital to the creation of such a governmental structure. The key structural elements of this form of government are: no simultaneous service in the Legislative and Executive Branches of government;¹⁶ independent election of the President and Congress;¹⁷ an independent judiciary with life tenure and protected compensation;¹⁸ the requirement that all laws be passed by both houses of Congress and presented to the President, who has the power to veto them;¹⁹ appointment of executive branch officials, ambassadors, and the like by the President with the advice and consent of the Senate;²⁰ the Constitution's specification of the President's military and foreign affairs powers;²¹ and the imposition on the President of the duty to faithfully execute the laws.²² While there are many additional elements that help shape the structure of the government, these features provide a fairly good outline. Change one

15. Even though the separation of legislative and executive personnel might seem fundamental to Americans, it is unclear whether it would really violate separation of powers to allow members of Congress to serve also as officers of the United States. Ronald Krotoszynski has pointed out that this aspect of the U.S. Constitution has not been adopted elsewhere. See generally Ronald J. Krotoszynski, Jr., *The Shot (Not) Heard 'Round the World: Reconsidering the Perplexing U.S. Preoccupation with the Separation of Legislative and Executive Powers*, 51 B.C. L. REV. 1 (2010). Congressional service as officers of the United States would not necessarily concentrate legislative and executive power in the same hands because passing laws would still require positive votes from hundreds of legislators not serving in the Executive Branch. But such a system would be difficult to police without a strict numerical limitation on the number of members of Congress allowed to serve in the Executive Branch. Thus, a complete ban may be the more sensible rule.

16. U.S. CONST. art. I, § 6, cl. 2.

17. *Id.* art. II, § 1; *id.* art. I, § 2, cl. 1.

18. *Id.* art. III, § 1.

19. *Id.* art. I, § 7, cl. 2–3.

20. *Id.* art. II, § 2, cl. 2. Appointment of judges by the President is not necessary for the system of separation of powers. Judicial independence is ensured by their tenure and protected compensation. However, given that the Appointments Clause allocates the power to appoint judges to the President, any effort by Congress to appoint judges or delegate their appointment away from the President is likely to fail as violating a particular structural or procedural provision of the Constitution.

21. *Id.* art. II, § 2, cl. 1.

22. *Id.* art. II, § 1, cl. 8.

of these provisions and the form of government would begin to look different from what we have; change a few and we have a different system.

There are separation of powers issues that do not turn on the application of one of the particular structural or procedural provisions, such as the degree to which Congress may limit the President's power to remove officials executing the law; the nondelegation doctrine, which regulates how much discretion Congress may delegate to others; and the limitations on adjudication outside of Article III courts. As we shall see, when analysis turns away from the application of a particular provision to a more general separation of powers standard, the courts tend to be very forgiving, finding a violation of separation of powers only in extreme circumstances.²³

Elaboration of proposition (2) will help understand this important aspect of separation of powers law. (2) *Building on proposition (1), the courts generally enforce the procedural and structural provisions of the Constitution strictly. When, however, a separation of powers controversy cannot be resolved with reference to a particular provision of the Constitution, the courts apply a very forgiving standard and are unlikely to find a violation of the general principle of separation of powers.*

During the 1980s, there was a revival of attention to basic principles of separation of powers. Devices Congress had used to augment its influence and control (and decrease that of the President) over the execution of the law were challenged in court on constitutional grounds.²⁴ By and large, success in these attacks turned on whether a particular provision had been violated. When an attack boiled down to an alleged violation of the general principle of separation of powers, it usually failed.²⁵

23. There is some chance that we are about to witness substantial changes in separation of powers analysis. In the *PCAOB* decision, the Court struck down a removal provision on separation of powers principles separate and apart from the Constitution's specific procedural and structural provisions. See *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3164 (2010). Perhaps the law will move in a stricter direction, but for now, that decision appears consistent with prior law and differs, if at all, at a certain rhetorical level, but not as a matter of substance.

24. See, e.g., *INS v. Chadha*, 462 U.S. 919 (1983) (striking down the legislative veto).

25. Justice Kennedy's concurring opinion in *Public Citizen v. U.S. Department of Justice*, 491 U.S. 438 (1989), may be the most explicit statement of this understanding at the Supreme Court. Justice Kennedy explained that the Court is strict when Congress attempts to interfere with the President's exercise of a textually committed executive power and is much more forgiving when the President can claim interference only with "the general grant to the President of the 'executive Power.'" *Id.* at 484 (Kennedy, J., concurring) (quoting U.S. CONST. art. II, § 1, cl. 1). Unfortunately, in my view, Justice Kennedy erred in that case when he concluded that it would violate separation of powers to apply the Federal Advisory Committee Act (FACA), 5 U.S.C. app. (2006), to the President's utilization of the American Bar Association (ABA) for advice on judicial appointments. See *Pub. Citizen*, 491 U.S. at 482–89. In Justice Kennedy's view, requiring the ABA Standing Committee on the Federal Judiciary to abide by FACA's organizational, openness, and recordkeeping

The best example of this is the decision in *INS v. Chadha*,²⁶ in which the Supreme Court invalidated the legislative veto. The legislative veto is a device designed to increase Congress's control over the execution of the laws. Laws containing legislative veto provisions allowed Congress or a subset of Congress, such as a single house or in extreme cases a single committee, to disapprove of executive action without participation of the President. The legislative veto had been employed in many contexts, including review of agency regulations and oversight of agency spending. In *Chadha's* case, after the Department of Justice decided to suspend *Chadha's* deportation, the House of Representatives invoked the legislative veto provision of the Immigration and Nationality Act²⁷ and vetoed the suspension. Under the terms of the Act, the House's vote was legally sufficient to invalidate the suspension, which would result in *Chadha* being deported pursuant to the presuspension finding of deportability.

The Court's reasoning in *Chadha* spelled the end of all legislative vetoes. The decision was not, however, based on a general principle of separation of powers. Rather, the Court held that the legislative veto violated two particular structural provisions of the Constitution: the presentment and bicameralism requirements.²⁸ Presentment requires that all laws passed by Congress be presented to the President for signature or veto. Bicameralism provides that any bill or other congressional action be passed by both houses before it can become law. Reliance on bicameralism invalidated all one-house vetoes.²⁹ Reliance on presentment invalidated legislative vetoes altogether.³⁰

The most difficult issue in *Chadha* was determining that bicameralism and presentment actually applied to the legislative veto. To do this, the Court had to construct a definition of legislation to which the two requirements apply. Had the Court constructed a substantive definition of

requirements "would constitute a direct and real interference with the President's exclusive responsibility to nominate federal judges." *Id.* at 488. Because nothing in FACA limits the President's choice of nominees, I disagree with Justice Kennedy's characterization of application of FACA as a "direct and real interference" with the President's appointment power. If anything, it is indirect since it does not address the appointments themselves but only a part of the process of deciding on a nominee. I do not mean to venture an opinion on whether application of FACA in this and other contexts constitutes an unconstitutional interference with the President's powers under the more general separation of powers standard.

26. 462 U.S. 919, 958–59 (1983).

27. 8 U.S.C. § 1254 (1994) (repealed 1996).

28. U.S. CONST. art. I, § 7, cl. 2–3.

29. *See Chadha*, 462 U.S. at 955 (discussing limited exceptions to the general bicameral requirement).

30. *Id.* at 958.

legislation and then stated that all such actions are subject to bicameralism and presentment, proposition (1) would be incorrect and proposition (2) would be beside the point. But the Court did not construct a substantive definition of legislation. Rather, it constructed a procedural and highly practical definition, stating that the House exercised legislative power in *Chadha* because it “took action that had the purpose and effect of altering the legal rights, duties, and relations of persons, including the Attorney General, Executive Branch officials and Chadha, all outside the Legislative Branch.”³¹ Stated more generally, Congress, or a subset of Congress, exercises legislative power whenever it acts in a way that changes anyone’s legal rights outside the Legislative Branch of government.

This understanding of the nature of the legislative power is built upon the underlying separation of powers premise that Congress does not have the power to do anything but legislate, at least when it wants its actions to have legal effect. Basically, the Court said that anything Congress intends to have legal effect constitutes the exercise of Congress’s legislative power and is thus subject to the bicameralism and presentment requirements. There is no conceptual analysis of the nature of legislative power whatsoever.³²

This aspect of the opinion has been criticized as formalistic.³³ This attack is more effective when combined with the sensible argument that the legislative veto actually supports separation of powers principles because it allows Congress to effectively supervise the exercise of delegated power. However, because this argument is built on general separation of powers principles, it was irrelevant to the Court’s decision.

Did *Chadha* take a formalistic view of legislative power? In one sense it did not. It did not depend on a highly abstract conceptual concoction concerning the nature of particular exercises of power. Rather, it fashioned an effects test under which the determination of whether a congressional action is legislative is made based on the purported impact of the action, not on its nature or form. In another sense, however, it was somewhat formalistic because the Court did not support its analysis with arguments drawn on the policies underlying separation of powers or on the practical effect of outlawing the legislative veto. Justice White’s dissenting opinion made the very practical, nonformalistic point, mentioned above, that the legislative veto can be restorative of separation of powers because it allows

31. *Id.* at 952.

32. The *Chadha* Court’s explanation for why agencies are not required to utilize bicameralism and presentment when they take actions that change people’s rights and duties is discussed *infra* Part III.A.

33. *E.g.*, Bernard Schwartz, “Apotheosis of Mediocrity”? *The Rehnquist Court and Administrative Law*, 46 ADMIN. L. REV. 141, 143–44 (1994).

Congress to supervise executive exercise of delegated power.³⁴ However, the invalidation of the legislative veto can be supported by the same argument—the legislative veto concentrated power in the hands of the entity exercising the veto. For example, allowing the House of Representatives unilaterally to veto the cancellation of Chadha’s deportation or override an agency regulation concentrates power in the House, and for all the reasons power is divided and subject to checks and balances, is inferior to requiring those actions to go through bicameralism and presentment.

The criticism of *Chadha* and similar opinions as formalistic is a plea for more flexibility, for allowing the Constitution to adapt to changes either in society or in the way the structure of government has developed. The main argument in favor of the legislative veto is that the Constitution should be allowed to adapt to the increase in delegation of discretionary power to agencies. What we have seen and shall see is that the Court is not receptive to this sort of argument when it appears that Congress has designed a process that is inconsistent with one of the specific structural elements of the Constitution that forms the separation of powers.

Because the Court found that the legislative veto violated the specific constitutional procedure for the exercise of the legislative power, it did not reach more general questions of separation of powers. Much the same can be said for the other separation of powers decisions in recent times. In this area, the Court is remarkably consistent—it strictly applies the particular structural or procedural provisions, and if it finds no violation of one of these provisions, it upholds the government action on a very forgiving standard. Decisions regarding the exercise of the appointments power are the best remaining examples here.

In several decisions, the Court has reviewed the constitutionality of the appointment of officers of the United States. In *Buckley v. Valeo*,³⁵ Congress specified an unorthodox procedure for appointing members of the Federal Election Commission. Appointments were made, two each, by the Speaker of the House, the President Pro Tempore of the Senate, and the President of the United States, all subject to confirmation by both houses of Congress.³⁶ This was contrary to the Appointments Clause, which specifies that officers of the United States are appointed by the President with the advice and consent of the Senate, or, if Congress specifies for inferior

34. *Chadha*, 462 U.S. at 967–68 (White, J., dissenting). Justice White consistently argued for flexibility in separation of powers analysis. See, e.g., *Bowsher v. Synar*, 478 U.S. 714, 759–60 (1986) (White, J., dissenting).

35. 424 U.S. 1 (1976).

36. *Id.* at 113.

officers, by the President, a department head, or court of law, acting alone.³⁷ Confirmation by both houses was also arguably contrary to the Constitution's specification that the power to "advise and consent" be held by the Senate alone. The Court had no trouble holding that officials appointed in this manner were not officers of the United States and thus could not exercise authority pursuant to the law.³⁸ Again, because it found the process contrary to the Appointments Clause, the Court did not find it necessary to consider more general separation of powers considerations.

The decision in *Clinton v. City of New York*,³⁹ invalidating the Line Item Veto Act,⁴⁰ followed the pattern of *Chadha* and *Buckley*. The Court found that the line item veto procedure created by the Act was inconsistent with the Constitution's process for making (and amending) law, and thus it was not necessary for the Court to address general separation of powers questions.⁴¹ The Line Item Veto Act specified that within five days after signing an appropriations bill or a bill containing targeted tax benefits the President could specify particular items in the bill for cancellation, which under the Act would then lose their legal effect.⁴² The Court viewed this as inconsistent with the Constitution's veto provision under which the President must sign or reject bills in their entirety, and with the process for making law under which bicameralism and presentment are required to alter anything in a bill that has been signed by the President.⁴³ Once the President signs a bill, each and every provision it contains becomes law, and there is nothing the President can do unilaterally to alter its legal effect. All the practical arguments about the necessity for an effective method of deficit reduction and the degree of discretion Presidents traditionally have over the actual spending of appropriated funds were not relevant to the basic structural reality.⁴⁴

37. U.S. CONST. art. II, § 2, cl. 2.

38. *Buckley*, 424 U.S. at 143. Other methods of appointment may be applied to officials of the other branches who do not exercise authority pursuant to the law. For example, Congress may appoint officials who help in the process of legislation. *See id.* at 137–38.

39. 524 U.S. 417 (1998).

40. 2 U.S.C. § 692 (2000), *invalidated by* *Clinton v. City of New York*, 524 U.S. 417 (1998).

41. *Clinton*, 524 U.S. at 448.

42. *Id.* at 436–37.

43. *Id.* at 447–48.

44. The President's exercise of the line item veto under the Act could be defended as execution of the law (the Line Item Veto Act) rather than amendment of the appropriations or tax benefit bill that had already been signed. The Court characterized the veto as the latter, and in this and perhaps other separation of powers controversies, the Court's characterization was decisive. For example, in *Bowsher v. Synar*, 478 U.S. 714, 726–27 (1986), the Court held that an official removable by Congress could not execute the law.

In all of these cases, the Court applies the *expressio unis* canon to the procedural and structural provisions of the Constitution, disallowing innovation with regard to those matters spelled out in the text of the Constitution.⁴⁵ This helps explain why innovations such as the legislative veto and the line item veto are unconstitutional, and why Congress may not require approval of presidential appointments by the House of Representatives.

B. Separation of Powers Leniency

As stated in proposition (2), once it is clear that no particular procedural or structural provision of the Constitution has been violated, separation of powers analysis becomes highly forgiving and deferential to Congress's determinations of appropriate governmental structure. Just how forgiving is best illustrated by the Court's nondelegation doctrine jurisprudence and by the controversy over the appointment and removal of the Independent Counsel (IC) in *Morrison v. Olson*.⁴⁶ The nondelegation doctrine is discussed in connection with propositions (3), (5), and (6), below. Here I elaborate on appointment and removal in *Morrison*.

The position of IC was created in reaction to corruption in the administration of Richard Nixon, during which special prosecutor Archibald Cox was fired when his investigation got too close to the President.⁴⁷ Under the relevant provisions of the Ethics in Government Act, Congress specified that on the request of the Attorney General, after finding cause to investigate whether an executive branch official had violated the law, an IC would be appointed by a special panel of the United States Court of Appeals for the District of Columbia Circuit.⁴⁸ The IC was not subject to direct supervision by the Attorney General or any other government official and could be removed only for cause and only by the personal action of the Attorney General.⁴⁹

But the official, the Comptroller General, could be removed only through the exercise of the legislative process. *Id.* at 730–32. Had the Court characterized Congress's role as legislative, perhaps it would not have invalidated the law at issue in *Bowsher*.

45. John Manning makes a similar point. *See generally* Manning, *supra* note 9.

46. 487 U.S. 654 (1988).

47. *See* Steven L. Carter, Comment, *The Independent Counsel Mess*, 102 HARV. L. REV. 105, 107–08 (1988) (discussing the background of the passage of the provisions providing for the independent counsel (IC)); Orrin G. Hatch, *The Independent Counsel Statute and Questions About Its Future*, 62 LAW & CONTEMP. PROBS. 145, 145 (1999) (“The primary impetus for our nation’s first independent counsel statute was the firing of then-Watergate Special Prosecutor Archibald Cox in 1973 by President Nixon.”).

48. *See* 28 U.S.C. §§ 49(a), 591(a) (2006).

49. *See id.* § 596 (a)(1).

Appointment by a court of law is permissible under the terms of the Appointments Clause if the IC is an inferior officer, which the Supreme Court found to be the case.⁵⁰ Once that was settled, the remaining question was whether the entire arrangement (including the appointment method, the lack of supervision and the removal restriction) violated separation of powers. In this regard, the operative question became whether the Act violated the separation of powers by reducing the President's ability to control the prosecutorial powers wielded by the IC too much. The Court asked "whether the Act, taken as a whole, violates the principle of separation of powers by unduly interfering with role of the Executive Branch."⁵¹

This discretionary and forgiving standard invited the Court to make an independent judgment concerning whether the traditional presidential control over the machinery of prosecution had been interfered with too much. Despite strong dissenting arguments from Justice Scalia that the presence of an IC would undermine the ability of the President to command the loyalty of executive branch officials who might be subject to an IC investigation,⁵² the Court found that the combination of some presidential control and other structural features surrounding the IC saved the Act from unconstitutionally infringing on the separation of powers.⁵³ The Court's scrutiny, under general separation of powers principles, was thus very deferential to the congressional judgment that the IC was necessary and not excessively intrusive into presidential prerogatives.

It should be noted that the Court's generally forgiving treatment of alleged separation of powers transgressions in *Morrison* extended beyond the removal question, which is governed only by the general "undue interference" standard and extended to interpretation and application of the Appointments Clause itself.⁵⁴ Although the Court strictly requires anyone exercising authority pursuant to the law to be appointed under the procedures required by the Appointments Clause, it has not been very strict when applying the provisions of the Appointments Clause that govern the appointment of inferior officers, including the basic determination of which

50. *Morrison*, 487 U.S. at 671.

51. *Id.* at 693.

52. *Id.* at 712–13 (Scalia, J., dissenting).

53. *Id.* at 695–96 (majority opinion) (citing the Attorney General's removal authority, the statutory requirement that the IC follow Department of Justice guidelines when possible, and additional features of the appointment and conduct of the IC).

54. Removal of officers of the United States is one of the most significant areas not governed by a particular procedural or structural provision of the Constitution. The separation of powers aspects of removal are discussed in connection with propositions (3) and (7), below. See *infra* Parts II.B, IV.A.

officers are inferior and who has the power to appoint them. The Court appeared to bend over backwards to determine that the IC was an inferior officer within the meaning of the Appointments Clause even though the IC was not subject to much in the way of supervision by any superior.⁵⁵ The Court has also deferred to Congress's judgment concerning the appropriate appointing authority for inferior officers by allowing Congress wide latitude in assigning appointment to a court and in designating departments and heads of departments for appointments purposes.⁵⁶

The *PCAOB* decision also illustrates this leniency concerning the definition of inferior officers and the designation of departments and department heads with appointive authority.⁵⁷ PCAOB members are appointed by the Securities and Exchange Commission (SEC), an independent, bipartisan agency headed by five commissioners, one of whom serves as Chair.⁵⁸ The constitutionality of this appointment process depended on two issues: first, whether PCAOB members are inferior officers; and second, whether SEC Commissioners are department heads. On both scores, the Court ruled in favor of SEC authority. The Court found that PCAOB members are inferior officers because they are subject to removal and supervision by the SEC, even though removal is only for pretty extreme cause, much more protective of Board members than the standard governing removal of most independent agency heads and the IC.⁵⁹ And on whether the SEC Commissioners are department heads capable of appointing inferior officers, the Court adopted a practical definition of *department* as including any "freestanding component of the Executive Branch, not subordinate to or contained within any other such component."⁶⁰ Under this definition, the Court determined that nothing in the Appointments Clause is inconsistent with such a department being headed by multiple commissioners.⁶¹

55. The IC was subject to removal for cause by the Attorney General and was required to follow Department of Justice policy to the extent possible. *See* 28 U.S.C. §§ 594(f)(1), 596(a)(1) (2006).

56. *See, e.g., Freytag v. Comm'r*, 501 U.S. 868, 892 (1991) (upholding appointment of inferior officers by the chief judge of the Tax Court).

57. *See Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3163 (2010) (determining that the SEC is a department for Appointments Clause purposes).

58. 15 U.S.C. § 78d(a) (2006).

59. *Free Enter. Fund*, 130 S. Ct. at 3162. After the Court determined that PCAOB members must be subject to at will removal by the SEC, it applied the standard it had announced in *Edmond v. United States*, to determine that PCAOB members were inferior officers subject to appointment by, inter alia, "Heads of Departments." *Id.* (citing *Edmond v. United States*, 520 U.S. 651, 662–63 (1997)); *see also* U.S. CONST. art. II, § 2, cl. 2.

60. *Free Enter. Fund*, 130 S. Ct. at 3163.

61. *Id.* at 3163–64.

This leniency concerning the interpretation and application of the provisions of the Appointments Clause is somewhat inconsistent with this Article's general description of separation of powers as consisting of strict application of particular procedural and structural provisions and leniency when no such provision applies. This must be motivated either by an undisclosed ranking of the relative importance of the Constitution's provisions or an understanding that the text and history of the Appointments Clause do not demand a different analysis. In any case, it is accurate to conclude that the Court is not always very strict when it interprets and applies the particular structural and procedural provisions, but once it arrives at an interpretation, it is not forgiving if it finds that the provision has been violated.

II. GENERAL SEPARATION OF POWERS CONTROVERSIES

A. *The Removal of Officers of the United States*

The Court's acceptance of congressional power to restrict the removal of officers of the United States both tests and illustrates the claim that the Court is generally lenient when applying separation of powers standards not embodied in a particular procedural or structural provision of the Constitution. No provision in the Constitution addresses the routine removal of officers of the United States. It would be implausible to argue that impeachment is the exclusive removal provision, as that would place the tenure of all officials on par with that of federal judges whose lifetime tenure (absent impeachment) is explicitly provided for in the text of the Constitution.⁶² This would also be incompatible with the long tradition of patronage, under which a new President would appoint loyalists to virtually every position in the federal government.

Because there is no constitutional clause governing the routine removal of executive branch officials, controversies over removal test the proposition that general notions of separation of powers have little bite. To appreciate this, a somewhat extended look at the Court's jurisprudence concerning restrictions on presidential removal of executive officials is necessary.

For many years, Congress statutorily required the advice and consent of the Senate for the removal of certain officials, and the House impeached President Andrew Johnson for refusing to obey one such provision.⁶³

62. See U.S. CONST. art. III, § 1.

63. See Jerry L. Mashaw, *Federal Administration and Administrative Law in the Gilded Age*, 119 YALE L.J. 1362, 1383–84, 1462–63 (2010) (describing the Tenure in Office Act, the impeachment of President Andrew Johnson for violating it, and the repeal of the Tenure in Office Act in 1887); see also *Myers v. United States*, 272 U.S. 52, 107 (1926) (describing a

However, in the early twentieth century, in *Myers v. United States*,⁶⁴ the Court categorically rejected any role for the Senate in the removal of officials, declaring such participation contrary to separation of powers, which continues to be established doctrine.⁶⁵ Much of the language of the *Myers* opinion, written by Chief Justice and former President William Howard Taft, supports relatively stringent review of congressional efforts to interfere with the President's supervision of the Executive Branch. The Court also relied on the Take Care Clause, implying that requiring Senate permission to remove an executive branch official would unduly interfere with the President's ability to faithfully execute the law.⁶⁶

The primary argument made in defense of the requirement of senatorial advice and consent for removal of executive officials was that since the Senate had the power to participate in the appointment of officers of the United States, the Senate could also participate in the removal, through similar advice and consent power. There is apparently good historical evidence that this was the understanding at the time the Constitution was adopted.⁶⁷ The Court rejected this argument based on constitutional text, the President's need to supervise officials engaged in the execution of the laws, and the Court's reading of particular constitutional history on the subject.⁶⁸

The Court distinguished senatorial participation in removal from participation in appointments on three bases. The first is that the only

statute passed in 1876 requiring the advice and consent of the Senate before the President could remove certain postmasters). As is discussed below, *Myers* held this provision unconstitutional.

64. 272 U.S. 52 (1926).

65. *See id.* at 176 (holding that the Tenure Act was unconstitutional and "that subsequent legislation of the same effect was equally so").

66. *Id.* at 122 ("The power of removal is incident to the power of appointment, not to the power of advising and consenting to appointment, and when the grant of the executive power is enforced by the express mandate to take care that the laws be faithfully executed, it emphasizes the necessity for including within the executive power as conferred the exclusive power of removal."). The Court further observed that without the power to remove, the President could not "discharge his own constitutional duty of seeing that the laws be faithfully executed." *Id.* at 135.

67. The dissenting opinions of Justices McReynolds and Brandeis in *Myers* argue, based on constitutional history and consistent practice, that the Constitution allows Congress to require the advice and consent of the Senate for the discharge of inferior officers. *See id.* at 178–239 (McReynolds, J., dissenting); *id.* at 240–95 (Brandeis, J., dissenting). Justice Holmes's brief dissent argues that senatorial advice and consent is appropriate because Congress created the office to which the requirement applies. In other words, the greater power to abolish the office includes the lesser power to require the Senate's advice and consent to discharge the officer. *Id.* at 177 (Holmes, J., dissenting).

68. *Id.* at 175–76 (majority opinion).

reason the Senate is allowed to participate in the latter is that the Appointments Clause explicitly so provides.⁶⁹ The lack of a textual reference to senatorial participation in removal strongly implies that the Framers did not anticipate any such participation, especially in light of the specific reference to Senate advice and consent on appointments. *Myers* refutes the notion that the advice and consent power over appointments implies an advice and consent power over removals. To the contrary, the Court explained that there were specific reasons for requiring the Senate's advice and consent over appointments, and those reasons do not apply to removal.⁷⁰ Second, the Court relied on the President's need to supervise the execution of the laws.⁷¹ While the President may not find it ideal that the Senate has power to reject nominees to executive positions, once an official is confirmed and appointed, the President's strongest guarantee of efficiency and loyalty is the removal power. If the President is forced to share that power with the Senate, the President is effectively sharing the executive power with the Senate. This is not true with regard to Senate participation in appointment, since once the nomination is confirmed, the Senate loses virtually all formal control over the official.

Third, the *Myers* Court found specific constitutional history in support of its view that the Senate could not participate in the removal of executive officials.⁷² The Court examined the debates surrounding the advice and consent power and the general issue of removal of officials and found strong evidence that the Framers meant to lodge the removal power exclusively with the President, mainly for the practical reason discussed above. The opinion relies for its bottom-line rejection of senatorial advice and consent for removals on this specific evidence more than on the general notion that removal is by nature an executive function. In fact, the Court concluded that Senate participation in removal was specifically rejected.⁷³

Therefore, *Myers* is not contrary to the portrait of separation of powers offered in this Article. The primary bases for finding a constitutional problem with senatorial advice and consent for removal were the effect on the President's ability to take care that the laws are faithfully executed and the specific rejection by the Framers of a role for Congress in removal. Thus, although there is language in *Myers* and perhaps other opinions that supports a more conceptual form of separation of powers analysis, the

69. *Id.* at 164.

70. *See id.* at 161–62.

71. *Id.* at 164.

72. *Id.* at 119–29.

73. *See id.* at 167 (citing the insistence of “Mr. Madison and his associates in the First Congress . . . that the power of removal of executive officers by the President alone was essential in the division of powers between the executive and the legislative bodies”).

bedrock separation of powers principle for which the decision stands is the same as under current law: that Congress may not take action that unduly interferes with the President's ability to execute the law. There are two rules in this area, one that dates back to *Myers* and one that dates back only to the *PCAOB* decision. First, Congress, or a subset of Congress, may not participate in the removal of executive officials through any sort of advice and consent requirement. Second, if an official can be removed only for cause by a lower level official, the official with removal power must be subject to at-will removal by the President.⁷⁴ Given the lenient attitude the Court has taken toward removal restrictions—largely reaffirmed in the *PCAOB* decision—the more conceptual elements of *Myers* are insufficient to undercut the explanation of separation of powers offered here.

Regardless of its basis or bases, the *Myers* decision's restrictive view of Congress's authority to restrict the removal of officials did not last long. After *Myers*, the Court twice approved restrictions on the removal of independent agency personnel,⁷⁵ once even reading the removal restriction into a statute that did not actually contain one.⁷⁶ On a conceptual level, the Court did not abandon the *Myers* Court's view that the President must have complete control over those engaged in executive functions. In *Humphrey's Executor*, the Court instead found that the President did not need control over officials engaged in what it termed "quasi-legislative" and "quasi-judicial" functions because agencies performing such functions "cannot in any proper sense be characterized as an arm or an eye of the executive."⁷⁷ These decisions apparently left intact the *Myers* Court's endorsement of

74. It is not clear whether the Court will apply this rule to administrative law judges (ALJs) who are often protected by two layers of for-cause restrictions. The Court stated that its analysis did not necessarily apply to ALJs because they might be employees rather than Officers of the United States and they "perform adjudicative rather than enforcement or policymaking functions." *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3160 n.10 (2010). If the characterization of ALJs as performing adjudicative functions ultimately determines that the rule against double for-cause restrictions does not apply to them, the analysis will be inconsistent with the Court's recent rejection of conceptual analysis as the basis of decisions concerning the constitutionality of removal restrictions. *See supra* Part IIA. Kevin Stack suggests that *PCAOB* does signal a return to the conceptual analysis of *Humphrey's Executor* insofar as the Court would not apply its ban on double for-cause removal restrictions to "dedicated adjudicators" such as ALJs. *See* Kevin M. Stack, *Agency Independence after PCAOB*, CARDOZO L. REV. (forthcoming 2011).

75. *See Wiener v. United States*, 357 U.S. 349, 356 (1958) (stating that the President may not remove a member of the adjudicatory War Claims Commission even though the statute does not explicitly address removal standard); *Humphrey's Ex'r v. United States*, 295 U.S. 602, 623 (1935) (ruling that Congress may restrict removal of Federal Trade Commissioner to "inefficiency, neglect of duty, or malfeasance in office").

76. *See Wiener*, 357 U.S. at 353–54.

77. *Humphrey's Ex'r*, 295 U.S. at 628; *see also Wiener*, 357 U.S. at 352.

complete presidential control over the removal of officials exercising purely executive functions, such as delivering the mail, or, presumably, investigating and prosecuting alleged criminals.

The distinction of *Myers* in *Humphrey's Executor* is the exact sort of conceptual analysis (sorting powers and assigning them to branches) that I claim is *not* the mode of analysis the Supreme Court applies today to separation of powers controversies.⁷⁸ Under *Humphrey's Executor's* reasoning, restrictions on the removal of officers of the United States engaged in purely executive functions would be unconstitutional while restrictions on the removal of officials engaged in other functions, such as adjudication, would not only be constitutional, they would be desirable to protect the adjudicators from undue presidential influence.⁷⁹ This changed, however, with the Court's approval of restrictions on the removal of independent counsels in *Morrison v. Olson*.⁸⁰ In that decision, the Court discarded the executive versus quasi-judicial and quasi-legislative mode of analysis of removal restrictions in favor of application of the general separation of powers standard: "the real question is whether the removal restrictions are of such a nature that they impede the President's ability to perform his constitutional duty, and the functions of the officials in question must be analyzed in that light."⁸¹ The President's constitutional duty is to "take Care that the Laws be faithfully executed."⁸² Thus, removal restrictions are unconstitutional only if, in the Court's judgment, they unduly hinder the President's ability to fulfill the constitutional role of the presidency.

Although the *PCAOB* decision did not, on its face, adjust the standard for evaluating the constitutionality of restrictions on the removal of officers of the United States, it appears to be at least a modest step toward stricter application of the standard. By law, *PCAOB* members are removable only by the SEC Commissioners and only for pretty extreme cause.⁸³ SEC Commissioners are removable by the President but only for cause under

78. *Humphrey's Executor* is thus inconsistent with the second half of proposition (2), at least with regard to separation of powers controversies concerning removal restrictions.

79. See *Wiener*, 357 U.S. at 356 ("Congress did not wish to have hang over the Commission the Damocles' sword of removal by the President for no reason other than that he preferred to have on that Commission men of his own choosing.").

80. 487 U.S. 654, 696 (1988).

81. *Id.* at 691.

82. U.S. CONST. art. II, § 3; see also *Morrison*, 487 U.S. at 669. In similar language, the Court declared that "we cannot say that the imposition of a 'good cause' standard for removal by itself unduly trammels on executive authority" and "we simply do not see how the President's need to control the exercise of that discretion is so central to the functioning of the Executive Branch as to require as a matter of constitutional law that the counsel be terminable at will by the President." *Morrison*, 487 U.S. at 691-92.

83. See 15 U.S.C. § 7217(d)(3) (2006) (listing conditions for removal).

the standard governing removal of Federal Trade Commissioners evaluated in *Humphrey's Executor*.⁸⁴ In evaluating this situation, the Court asked whether the Board was sufficiently accountable to the President.⁸⁵ Although the Court did not recite the general separation of powers question of whether the removal restriction unduly interferes with the President's ability to fulfill the constitutional functions of the presidency, that was clearly the motivation for concern over whether the President had sufficient control over the Board's activities.⁸⁶

At a rhetorical level, the *PCAOB* Court seemed very concerned that restrictions on removal of officials executing the law must not be so great that the President cannot, as a practical matter, control their work at least to some extent. The Court declared the for-cause restriction on SEC removal of Board members unconstitutional because the President could not remove SEC members without cause.⁸⁷ Under the Court's reasoning, Congress may entrust removal of officials to a subordinate of the President, but when it does so, either the official so entrusted must be removable at will by the President or the official subject to removal must be removable at will by the official with removal power. Because PCAOB members were removable only by the SEC, which is headed by commissioners removable only for cause by the President, the Court held that PCAOB members must be removable without cause.⁸⁸

This understanding is a particularized application of the principle that no branch may prevent another from fulfilling its constitutionally assigned function. In the case of removal, Congress could cripple the President's ability to take care that the laws are faithfully executed by preventing the President from removing incompetent, corrupt, or disloyal officials. Normally this standard is not very demanding and is rarely violated.

84. No statute actually provides SEC Commissioners with this protection from discharge, but the Court accepted the parties' agreement to this standard for purposes of the litigation. This is discussed further *infra* at notes 93–95 and accompanying text.

85. See *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3146–47 (2010).

86. See *id.* at 3147 (“[T]he President cannot remove an officer who enjoys more than one level of good-cause protection, even if the President determines that the officer is neglecting his duties or discharging them improperly. That judgment is instead committed to another officer, who may or may not agree with the President's determination, and whom the President cannot remove simply because that officer disagrees with him.”).

87. *Id.*

88. *Id.* at 3161 (holding the offending for-cause removal provision severable from the otherwise valid act).

However, in the *PCAOB* decision, the Court appears to have created a *per se* rule against double for-cause restrictions.⁸⁹

Does this signal a tightening of norms governing the permissibility of removal restrictions? It's much too early to tell, although, in general, an affirmative answer appears unlikely. There is one signal in the Court's opinion that is consistent with a tightening of standards—the Court's novel invocation in the separation of powers context of a potential lack of political accountability for PCOAB decisions if Board members are insulated from control by either the SEC or the President.⁹⁰ However, other signals point in the opposite direction, especially the Court's willingness to imply a for-cause restriction on removal of SEC Commissioners even though no statute protects SEC Commissioners from removal without cause.⁹¹

According to the applicable statute, the President, with the advice and consent of the Senate, appoints SEC Commissioners for five-year terms.⁹² Removal of Commissioners is not mentioned in the statute. The Court relied on an agreement of the parties that Commissioners may not be fired without cause, based perhaps on a long-term understanding that Congress intends to protect heads of independent agencies from at-will presidential removal.⁹³ This presents something of a puzzle. The basis for the Court's

89. *See id.* at 3164. Another way in which the *PCAOB* decision appears novel is that the Court itself reformed the removal provision, declaring that PCAOB members are removable without cause by the SEC. In the past, rather than reform the offending removal or appointment provision, the normal practice has been for the Court to declare that improperly appointed or removable officials cannot engage in execution of the law. *See, e.g.,* *Bowsher v. Synar*, 478 U.S. 714, 736 (1986) (holding that an official removable by Congress cannot execute the law); *Buckley v. Valeo*, 424 U.S. 1, 143 (1976) (stating that officials appointed by members of Congress cannot execute the law).

90. *See Free Enter. Fund*, 130 S. Ct. at 3155 (“Without a clear and effective chain of command, the public cannot ‘determine on whom the blame or the punishment of a pernicious measure, or series of pernicious measures ought really to fall.’” (quoting THE FEDERALIST NO. 70 (Alexander Hamilton))). This concern for clear lines of political accountability is the underlying normative basis for the Court's prohibition on federal commandeering of state and local officials to enforce federal law, which the Court created as a limitation on Congress's power to regulate interstate commerce in the 1990s. *See Printz v. United States*, 521 U.S. 898 (1997); *New York v. United States*, 505 U.S. 144 (1992).

91. *See Free Enter. Fund*, 130 S. Ct. at 3148–49 (“The parties agree that the Commissioners cannot themselves be removed by the President except under the *Humphrey's Executor* standard . . . and we decide the case with that understanding.”).

92. *See* 15 U.S.C. § 78d(a) (2006).

93. *Free Enter. Fund*, 130 S. Ct. at 3148–49. A test of this understanding would occur if the President discharged a member of the Commission without cause and defended a suit by the terminated commissioner on the basis that no statute protects the Commissioner's tenure. It would be surprising if the Court stuck to its view in *PCAOB* and held that a for-cause restriction on removal is implicit for independent agency members in the absence of legislation to that effect. Perhaps the Court would view it as implicit in appointment of

disapproval of double for-cause protection for officials exercising executive power is to ensure that the President has some level of control over the execution of the law. But with regard to single for-cause protection of independent agency heads, not only did the Court not express any reservation about the typical for-cause limitation on discharge of independent agency heads, it embraced it by consenting to an implied for-cause restriction for SEC members. If a strong principle of presidential removal existed, it would seem that Congress should at least be required to explicitly legislate protection from discharge for independent agency heads. Thus, if there is anything revolutionary about the *PCAOB* decision, it may be that the independence of independent agencies appears to have achieved a quasi-constitutional status, such that Congress would have to explicitly grant the President unlimited removal power to overcome the presumption of protection. This is clearly inconsistent with a newly restrictive view of separation of powers.

In sum, although the *PCAOB* decision may be somewhat stricter than had been the case with regard to restrictions on the President's power to remove officers of the United States, separation of powers jurisprudence has not been demanding when no particular procedural or structural provision of the Constitution is implicated. This brings us to proposition (3).

B. *The Vesting Clauses*

(3) *The Vesting Clauses of Articles I, II, and III of the Constitution are not among the procedural or structural provisions of the Constitution that tend to be strictly enforced. They thus have little or no substantive bite. In other words, it is rarely, if ever, possible to rely on a Vesting Clause to provide an answer to a separation of powers controversy.*

That the Vesting Clauses are not among the procedural or structural provisions that tend to be strictly enforced should be apparent from the preceding discussion. If they were, then when more specific provisions were found not to have been violated, like the Appointments Clause or the bicameralism and presentment provisions, the next step in the analysis would be to ask whether a Vesting Clause had been violated.⁹⁴ And it

Commissioners for five-year terms. If the Court held that Commissioners are terminable at will, then presumably it would be constitutional to require cause for the SEC to discharge PCAOB members.

94. Some scholars locate a general principle of separation of powers, and other nontextual limitations on governmental power, in Article I's Necessary and Proper Clause, theorizing that a law that violates separation of powers cannot be "*proper*" for "carrying into execution" any federal power. See Gary Lawson & Patricia B. Granger, *The "Proper" Scope of Federal Power: A Jurisdictional Interpretation of the Sweeping Clause*, 43 DUKE L.J. 267, 274 (1993). Lawson's and Granger's argument is based largely on state constitutional separation of

would follow that a Vesting Clause was violated whenever a branch was deprived of complete control over the performance of its assigned constitutional function. Proponents of expansive presidential power, under what has become to be called the unitary executive theory, take this tack.⁹⁵ They would argue, for example, that because the independent counsel provisions of the Ethics in Government Act dilute presidential control over the performance of the executive function of prosecution, they are unconstitutional under the Vesting Clause of Article II. Vesting Clause enforcement would require exactly the sort of analysis this essay argues rarely, if ever, occurs. A challenger would claim that Congress has taken a power that belongs to one branch and either unconstitutionally allocated it to a different branch or restricted the proper branch's complete control over its exercise. Regardless of whether it would have been more faithful to the Constitution for the law to have developed that way, it has not, and while the Vesting Clauses have important legal ramifications,⁹⁶ they are not enforced strictly, the way other structural provisions of the Constitution are.

The best illustration of this fact of constitutional analysis involves the nondelegation doctrine. The nondelegation doctrine embodies a fundamental separation of powers principle, that Congress may not delegate away its legislative power. In a sense it is a truism, since the Constitution empowers Congress and only Congress to pass laws (subject to the possibility of presidential veto and judicial invalidation). It has long been recognized that delegation of excessive discretion to executive branch officials, even without the authority to actually promulgate laws, implicates the legislative power as a matter of substance if not of form. Even with regard to such a fundamental element of separation of powers, because no particular clause prohibits delegation of discretion (and because the Vesting

powers provisions that used the word *proper* to refer to matters within the jurisdiction of a particular branch of government. See *id.* at 291–97. They argue that the Framers incorporated this jurisdictional understanding into the Constitution through the use of the word *proper* in the Necessary and Proper Clause. *Id.* at 298–308. Whether they and other scholars who express similar opinions are correct is irrelevant to this Article which attempts only to describe separation of powers as practiced and understood in current law.

95. See Steven G. Calabresi & Kevin H. Rhodes, *The Structural Constitution: Unitary Executive, Plural Judiciary*, 105 HARV. L. REV. 1153, 1165 (1992) (“The theories of limited congressional power to divest the President of control over the executive department are rooted in the Vesting Clause of Article II, which provides: ‘The executive Power shall be vested in a President of the United States of America.’” (emphasis added)).

96. The Vesting Clauses do settle important structural matters. For example, we know from Article I that only Congress has the power to pass laws, and we know from Article II that there is only one President of the United States. U.S. CONST. art I, § 1; *id.* art. II, § 1, cl. 1. But under the Court's jurisprudence, the Vesting Clauses do not have much to say about the proper allocation of government power.

Clause of Article I is not understood as such a clause) the standard the Court applies to nondelegation disputes is incredibly forgiving, bordering on a determination that the doctrine is nonjusticiable.⁹⁷ To avoid delegation of legislative power, Congress must legislate an “intelligible principle” for agencies to follow when filling in gaps and making policy under the law.⁹⁸ If the Vesting Clause of Article I were understood as having separation of powers bite, it would be expected that the nondelegation doctrine would be much less forgiving of executive exercise of discretionary power to promulgate rules and take other action with the force of law.⁹⁹

Because in *PCAOB* the Court began its analysis by quoting Article II’s Vesting Clause, and because the Court’s opinion asserted that “the executive power included a power to oversee executive officers through removal,”¹⁰⁰ the decision may appear on the surface to contradict the proposition that the Vesting Clauses are not important to separation of powers doctrine. On closer analysis, however, the decision is not substantially different from prior law. Had the analysis stopped here and concluded that *any* limitation on the President’s power to remove members of the PCAOB violated separation of powers, we would be characterizing the decision as the opening gambit in the “Roberts Court’s separation of powers revolution.” What we got instead, however, was a relatively moderate swing toward greater presidential power and an ambiguous tip of the hat to the Vesting Clause of Article II.

The Court’s unusually explicit reliance on the Vesting Clause and its characterization of the power to remove as an executive function did create an air of expectancy concerning the next step in the Court’s separation of powers jurisprudence. Further, the development under the influence of the Vesting Clause of the apparent per se rule that two levels of for-cause protection are unconstitutional raises the possibility that the Vesting Clause might, in the future, be treated as a specific structural provision prohibiting excessive limitations on presidential control over those aiding in the

97. Justice Scalia stated in *Whitman v. American Trucking Ass’ns*, “we have ‘almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law.’” *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 474–75 (2001) (quoting *Mistretta v. United States*, 488 U.S. 361, 416 (1989) (Scalia, J., dissenting)).

98. *Whitman*, 531 U.S. at 472.

99. The dispute over whether the Constitution absolutely prohibits delegation of legislative power is addressed below, with regard to proposition (6). See *infra* Part III.C.

100. *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3152 (2010).

execution of the law. So far, however, indications are that business as usual is the most likely direction for the future.

C. Separation of Powers and the Judicial Branch

The analysis thus far has concerned mainly the Vesting Clauses of Articles I and II. Because the procedures for exercising the judicial power are not highly specified in the text of the Constitution, the Vesting Clause of Article III may be more important than the Vesting Clauses of Articles I and II, and the nature of the judicial power may thus be more relevant to understanding separation of powers than that of the other governmental powers. The structural and procedural aspects of the judicial power that are specified in the Constitution include the maximum jurisdiction of the federal courts,¹⁰¹ the specification of the Supreme Court's original and appellate jurisdiction,¹⁰² the requirement of trial by jury in criminal matters,¹⁰³ the local venue requirement in criminal cases,¹⁰⁴ the evidentiary requirements for treason,¹⁰⁵ and allocation to Congress of the power to establish lower federal courts.¹⁰⁶

In addition to these matters that are spelled out in the Constitution, the Supreme Court has identified the essential attributes of the judicial power that are reserved to the Article III courts. These include the entry of a final judgment, presiding over jury trials, and imposing criminal punishment. The prohibition on bills of attainder makes judicial power over some aspects of criminal law exclusive,¹⁰⁷ and the restrictions on the suspension of the writ of habeas corpus give the judiciary some power over executive action involving imprisonment.¹⁰⁸ There are also limitations on Congress's power to allocate jurisdiction over core Article III cases to non-Article III tribunals.¹⁰⁹ The lack of specificity in the Constitution concerning the essential attributes of the judicial power means that most controversies over alleged allocation of judicial power to non-Article III tribunals are evaluated under standards similar to the general separation of powers standard that governs executive and legislative branch controversies that do not involve a particular procedural or structural provision.

101. U.S. CONST. art. III, § 2, cl. 1.

102. *Id.* art. III, § 2, cl. 2.

103. *Id.* art. III, § 2, cl. 3; *see also id.* amend. VI.

104. *Id.* art. III, § 2, cl. 3.

105. *Id.* art. III, § 3, cl. 1.

106. *Id.* art. III, § 1.

107. *Id.* art. I, § 9, cl. 3.

108. *Id.* art. I, § 9, cl. 2.

109. *See* *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850–51 (1986); *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 87 (1982).

There is a great deal of federal adjudication outside the Article III courts in institutions as varied as benefits agencies, such as the Social Security Administration; regulatory bodies, such as the National Labor Relations Board; and licensing agencies, such as the Nuclear Regulatory Commission. There are also non-Article III institutions that are explicitly characterized as courts, such as the United States Tax Court. The typical separation of powers controversy concerning Article III involves whether the establishment of a non-Article III federal adjudicatory institution violates Article III because it exercises judicial power that is constitutionally vested in the federal courts. The Vesting Clause is usually invoked, but it has little effect on the actual analysis or resolution of the controversies.

The general rule is that Congress has broad power to create non-Article III adjudicatory institutions to decide categories of cases that have traditionally been viewed as outside the core of Article III jurisdiction. The categories include public rights (rights against the U.S. government), cases arising in territorial courts, and cases arising in military courts. The most important category here is public rights.¹¹⁰ The theory underlying acceptance of non-Article III adjudication of public rights is that, because the United States could assert complete sovereign immunity or decide such claims in a nonadjudicatory administrative manner, the use of an adjudicatory process does not transform the decisionmaking process into an exercise of the Article III judicial power. This notion is reinforced by the fact that the Supreme Court has long understood claims against the sovereign to be outside the original intent of Article III.¹¹¹

Private rights adjudication in a non-Article III federal tribunal presents a more difficult Article III separation of powers question. In 1979, the Supreme Court invalidated a new system of bankruptcy adjudication because it allowed the non-Article III bankruptcy courts to adjudicate all claims involving the bankrupt estate, including state common law claims between the bankrupt and another private party.¹¹² Here we have a direct application of the Vesting Clause of Article III: non-Article III federal tribunals cannot exercise the judicial power of the United States.

110. The reasons behind acceptance of non-Article III territorial courts and courts-martial are idiosyncratic and do not aid in understanding separation of powers doctrine. Non-Article III territorial courts are necessary because when a state is formed in what was previously a territory, the need for federal judges decreases dramatically because most of the work done by the former territory's courts is taken up by the state courts. Courts-martial have long been part of the military structure and would not be considered part of the domain occupied by the Article III courts.

111. See *Hans v. Louisiana*, 134 U.S. 1 (1890).

112. *N. Pipeline*, 458 U.S. at 87.

Until relatively recently, it was unclear whether the Supreme Court would embrace a strict standard condemning all non-Article III adjudication outside the public rights, territorial courts, and courts-martial areas. Early cases placed restrictions on agency adjudication of private rights claims to preserve the Article III courts' dominant role in such adjudication.¹¹³ The closest that a highly restrictive view came to becoming law in recent years was in Justice Brennan's plurality opinion in the case invalidating the bankruptcy courts.¹¹⁴ Ultimately, the Court adopted a much more forgiving standard, allowing federal adjudication of private rights claims in non-Article III tribunals if the claims were closely related to a federal regulatory scheme and the statute did not allow the non-Article III tribunal to assume the "essential attributes" of Article III courts, such as the power to enter final judgments and the power to preside over jury trials.¹¹⁵ In language similar to that used in separation of powers controversies concerning the powers of the other branches, the Court stated that the fundamental question concerning the constitutionality of the assignment of adjudicatory power to a non-Article III tribunal is whether it "impermissibly threatens the institutional integrity of the Judicial Branch."¹¹⁶

In evaluating the constitutionality of adjudication in non-Article III federal tribunals, it is important to distinguish between the exercise of the judicial power of the United States and the mere use of an adjudicatory procedure. What marks out this distinction is a combination of procedural and structural aspects of the tribunal, most of which are not mentioned in the Constitution and are referred to in the Court's opinions as the "essential attributes of the judicial power."¹¹⁷ These essential attributes include the power to issue final judgments, the lack of judicial review or review only on a highly deferential standard, the power to issue writs of habeas corpus and preside over jury trials, and jurisdiction over state law claims.¹¹⁸ If a federal

113. See *Crowell v. Benson*, 285 U.S. 22, 64–65 (1932). In *Crowell*, the Court held that a federal agency could adjudicate private rights claims as a sort of adjunct to the federal courts, with deferential review of routine facts but de novo review of jurisdictional facts and questions of law.

114. *N. Pipeline*, 458 U.S. at 87.

115. See *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 851 (1986).

116. *Id.*

117. *Id.*

118. *Id.* at 852–53. In *Stern v. Marshall*, No. 10-179, 2011 WL 2472792, at *16 (U.S. June 23, 2011), the Court reaffirmed that the power to enter a final judgment in a state common law claim is an essential attribute of the Article III judicial power. Interestingly, in dicta, the Court expanded the category of "public rights" that may be adjudicated by non-Article III tribunals to include cases between private parties "in which the claim at issue derives from a federal regulatory scheme, or in which resolution of the claim by an expert

institution respects these boundaries sufficiently, the fact that it makes decisions using an adjudicatory process does not take it out of the realm of execution of the law and convert its actions to the exercise of the judicial power of the United States. What is special about this standard is that, because these attributes are not specified in the Constitution, the Vesting Clause, together with a conceptual understanding of the nature of the judicial power, plays a greater role here than in separation of powers controversies concerning the powers of Congress and the President.

III. THE REJECTION OF CONCEPTUAL ANALYSIS

A. *No Assignment of Powers*

Proposition (4) is the conclusion to this part of the discussion: (4) *As a corollary to proposition (3), in general, separation of powers controversies are rarely, if ever, resolved by determining which branch of government is the proper branch to engage in a particular activity. In other words, separation of powers controversies are not resolved by determining the nature of a government action and then assigning the performance of that action to the branch with the power to engage in that category of action.*

As we have seen, separation of powers controversies are usually resolved by asking two questions: first, whether a specific structural or procedural provision has been violated, and second, if not, whether the particular arrangement being challenged unduly interferes with a branch's ability to perform its assigned function in the government. None of the major separation of powers cases discussed above, except perhaps those concerning judicial power, were decided conceptually by asking whether a branch was exercising a power that properly belonged to another branch. There are powerful practical reasons for this, having mainly to do with the difficulty courts would face if they tried to construct mutually exclusive definitions of the three types of government powers.

Consistent with this analysis, the *Chadha* Court defined the legislative power in a practical way, basically by stating that anything that Congress does that purports to have legal effect outside the Legislative Branch falls within the legislative power.¹¹⁹ This reflects a fundamental separation of powers understanding that each branch has only the power assigned to it

government agency is deemed essential to a limited regulatory objective within the agency's authority." *Id.* at *18. The Court, in effect, recharacterizes the cases in which it has allowed non-Article III adjudication of claims between private parties as falling within this expanded definition of "public" rights. *Id.* In my view, this is a serious mischaracterization of prior cases. Unfortunately, *Stern* was decided too late in the process of editing this Article to allow for a complete analysis.

119. *INS v. Chadha*, 462 U.S. 919, 951–52 (1983).

by the Constitution, and that when it exercises governmental power each branch must follow whatever procedural or structural provisions apply to it. Congress must act legislatively. The courts may not go beyond the resolution of cases or controversies. The President may not act beyond the power delegated either by legislation or the Constitution itself. In this regard, one of the more interesting points the Court made in *Morrison v. Olson* is that because the Constitution specifies that courts of law may appoint inferior officers, appointment of officers of the United States is not, constitutionally speaking, an exclusively executive function.¹²⁰

This is not to say that the nature of the power is always irrelevant, although in the vast majority of cases it is. Sometimes conceptual analysis of the nature of a power may be lurking just below the surface of a controversy. Arguably, for example, the Court considers the power to remove officials executing the law as an executive function. Impeachment and conviction by the House and Senate is allowed only because the Constitution specifies it, not because it is a normal legislative function. This helps explain why the Supreme Court denied the Senate a role in removal in *Myers*¹²¹ and why the more recent decision in *PCAOB* placed the power to remove squarely within the executive power constitutionally vested in the President.¹²² Even here, however, it is best to say that the President's removal power depends not on the nature of that power but on the potential for any other arrangement to interfere with the performance of his constitutional powers and duties. After all, the Legislative and Judicial Branches have the power to remove their own officials, and even hire them despite the Appointments Clause. Thus, appointment and removal should not be viewed as executive functions per se, except when the officials involved assist the President in executing the law.

The *PCAOB* decision also illustrates that separation of powers decisions do not depend on assignment of a function to a particular branch. In that case, the Court found that the provisions governing removal of PCAOB members contravened the separation of powers.¹²³ Note, however, that the Court's decision was not that the power to discharge officers of the United States was in its nature an executive function but rather that the removal restrictions unduly impaired the President's ability to carry out his

120. 487 U.S. 654, 695 (1988) (“[T]he power to appoint inferior officers such as independent counsel is not in itself an ‘executive’ function in the constitutional sense, at least when Congress has exercised its power to vest the appointment of an inferior office in the ‘courts of Law.’”).

121. *Myers v. United States*, 272 U.S. 52, 176 (1926).

122. *See Free Enter. Fund v. Pub. Co. Accounting Oversight Bd.*, 130 S. Ct. 3138, 3152 (2010).

123. *Id.* at 3147.

constitutional obligation to “take Care that the Laws be faithfully executed.”¹²⁴ Removal can be accomplished legislatively as well. The Court has made it clear that when a legislature abolishes a governmental position and, in effect, removes the incumbent official from office, the legislative body is engaging in a legislative function.¹²⁵ Thus, even the separation of powers analysis relevant to removal of officials executing the law is best understood as based on general separation of powers principles rather than the allocation of authority to a particular official or branch of government.

B. Overlapping Powers

(5) *Building on propositions (3) and (4), most government actions can substantively be performed by more than one branch. Each branch must observe the constitutional procedural and structural requirements that apply to it.*

It is a fundamental reality of the U.S. government that more than one branch can create the identical substantive law. To provide a simple example of this, consider the specification of National Ambient Air Quality Standards (NAAQS). Congress has empowered, indeed required, the Environmental Protection Agency (EPA) to establish NAAQS for numerous pollutants.¹²⁶ The EPA does this by promulgating regulations pursuant to the procedures established by Congress. There is no doubt that Congress itself could establish the NAAQS via the legislative process of bicameralism and presentment. Assuming proper delegation of authority, Congress and the EPA have concurrent power to establish NAAQS, with the understanding that if Congress acts, its legislative determination supersedes any standard set by the EPA.

We know from *Chadha* that if Congress wants to establish a NAAQS or reject one established by the EPA, it must employ the constitutionally specified legislative process of bicameralism and presentment. *Chadha* also establishes that bicameralism and presentment do not apply to agencies even when they do the exact same thing as Congress might have done itself. This is because agencies are executing the law as established by Congress through bicameralism and presentment.¹²⁷ In addition to any substantive

124. The Court referred to both the Vesting Clause and the Take Care Clause, which illustrates how removal disputes test the theory offered here. “We hold that such multilevel protection from removal is contrary to Article II’s vesting of the executive power in the President. The President cannot ‘take Care that the Laws be faithfully executed’ if he cannot oversee the faithfulness of the officers who execute them.” *Id.*

125. *Bogan v. Scott-Harris*, 523 U.S. 44, 55–56 (1998).

126. Clean Air Act § 109(a), 42 U.S.C. § 7409(a) (2006).

127. *See INS v. Chadha*, 462 U.S. 919, 953 n.16 (1983).

and procedural requirements for agency action established by statute, there are three primary constitutional structural provisions that apply to the EPA. First, unless the EPA claims it is acting under a specific constitutional authorization—as the President does, for example, when recognizing a foreign government—the EPA must be executing the law, which means there must be a sufficiently specified delegation from Congress. To meet the constitutional requirement, the delegation must contain an intelligible principle directing the EPA's actions.¹²⁸ If there is no constitutionally valid delegation from Congress, then the EPA would be acting *ultra vires* in the same way that President Truman's seizure of the steel mills was held unconstitutional in the absence of a statutory delegation of authority in *Youngstown Sheet & Tube Co. v. Sawyer (Steel Seizure)*.¹²⁹ Second, the officials within the EPA must be appointed as officers of the United States as specified by the Appointments Clause. If the EPA officials are not appointed properly, they cannot exercise authority pursuant to the laws of the United States. Third, the officials must be subject to some measure of presidential control through removal provisions that do not unduly hinder the President's ability to supervise the execution of the laws.

Similarly, Congress and the Executive Branch have overlapping power over the status of aliens like Chadha. If Congress passes a law allowing the Department of Justice or Homeland Security to naturalize or otherwise modify the status of aliens, the exercise of authority under that law would be a classic case of executing the law. However, when Congress passes a

128. See, e.g., *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472–73 (2001) (citing *J.W. Hampton, Jr., & Co. v. United States*, 276 U.S. 394, 409 (1928)) (discussing the constitutionality of delegation to the Environmental Protection Agency to set National Ambient Air Quality Standards).

129. 343 U.S. 579 (1952). This is the clear implication of the Court's analysis in the *Steel Seizure* case, in which the Court grappled with President Truman's claim of inherent power to seize the steel mills in wartime to avert serious negative consequences to the war effort. The Court's decision appears to stand for the proposition that the President had not only seized the mills, but had also seized the Congress's legislative power, and that this he could not constitutionally do. In my view, it is more accurate to state that President Truman's action was illegal because it was *ultra vires*. In the Court's view, President Truman had no statutory or constitutional basis for seizing the mills. It is not that the order to seize the mills was an exercise of the legislative power. The President does not have legislative power beyond the veto granted in Article I. It is that lacking a constitutional basis, the only possible source of presidential power would arise from a statute passed by Congress which was also not present. In a sense, the nondelegation doctrine could be understood this way. Vague statutes lacking an intelligible principle simply do not successfully delegate power to the Executive Branch. On this understanding, the problem is not that such statutes improperly delegate legislative power, it is that they do not successfully enable executive action because they are not specific enough. Therefore, action taken purporting to rely on them is *ultra vires* because it has not been successfully authorized.

bill naturalizing a particular alien or declaring that a particular alien should not be deported, Congress has exercised its legislative power (and therefore must act pursuant to bicameralism and presentment).¹³⁰ Further, if, in a justiciable case or controversy, a federal court orders the Executive Branch to modify the status of a particular alien, the court would have exercised the judicial power.

The substantive power of the federal courts also overlaps with that of the other branches. For example, consider a controversy over whether a particular collective bargaining strategy constitutes an unfair labor practice under the National Labor Relations Act.¹³¹ All three branches have the power to make a decision on the subject. The National Labor Relations Board, as part of the Executive Branch, can determine that the conduct is an unfair labor practice.¹³² On judicial review, a federal court can make the very same determination. And Congress has the power to legislatively specify whether the practice is unlawful. Each branch is performing its assigned constitutional function and must observe the constitutional requirements for actions that apply to it.

Another example of overlap can be seen in the Commander in Chief power. Perhaps it is in the nature of the power to direct the military that this should belong to the President, but this is a very unsettled area of constitutional law. The Constitution explicitly grants Congress several powers over the military, including the power “[t]o make Rules for the Government and Regulation of the land and naval Forces” and the power to declare war.¹³³ Further, the appointment of military commanders is subject to the advice and consent of the Senate.¹³⁴ Thus, even what appears to be the quintessential executive function is subject to legislative checking and involvement. Over the years, some of the most extravagant claims for exclusive presidential power have involved this power, in

130. See *Chadha*, 462 U.S. at 954–55. This sort of legislation may not be permissible in most states in the United States that have bans on “special legislation” in their constitutions. For example, Article IV, section 13 of the Illinois constitution provides: “The General Assembly shall pass no special or local law when a general law is or can be made applicable.” ILL. CONST. art. IV, § 13. Because the federal Constitution has no such provision, Congress is free to legislate with greater particularity than most state legislatures, subject to other limitations such as the prohibition on bills of attainder, which, under certain circumstances, prevents Congress from singling out individuals for unfavorable action. U.S. CONST. art. I, § 9, cl. 3.

131. 29 U.S.C. §§ 141–197 (2006).

132. *Id.* §§ 158, 160.

133. U.S. CONST. art. I, § 8, cl. 11, 14.

134. *Id.* art. II, § 2, cl. 2.

apparent ignorance of the Constitution's dispersion of the power over the military between the Executive and Legislative Branches.¹³⁵

For another simple example, a majority in one house of Congress can prevent a bill from becoming law by voting it down, the President can prevent a bill from taking effect by vetoing it, and the Judiciary can prevent a statute from having legal effect by declaring it unconstitutional and enjoining its enforcement. Of course, there are structural limits on the power of each branch. For example, if a bill was passed in a prior Congress, bicameralism and presentment would be required to repeal it even for constitutional reasons. The President cannot exercise a "veto" over a law that is already in effect,¹³⁶ and the Judiciary may act only if presented with a justiciable controversy that implicates the constitutionality of the law.

The existence of overlapping powers is directly related to the general rejection of conceptual analysis in separation of powers law. While there may be small pockets in which conceptual analysis of the nature of a particular governmental power is relevant—such as in deciding on the essential attributes of Article III courts that cannot be exercised outside the Judicial Branch—these pockets are few and far between, because in most cases it simply is not obvious where a power properly belongs. Further, note that this is still a procedural matter, not a substantive limitation on

135. Consider, for example, Robert Bork's view that Congress lacked the power to legislatively prevent President Nixon from ordering attacks on Cambodian territory during the war in Vietnam. In Bork's view, congressional efforts to prevent attacks on Cambodia interfered with the President's power as Commander in Chief. As Bork stated in 1971:

I arrive, therefore, at the conclusion that President Nixon had full Constitutional power to order the Cambodian incursion, and that Congress cannot, with Constitutional propriety, undertake to control the details of that incursion. This conclusion in no way detracts from Congress's war powers, for that body retains control of the issue of war or peace. It can end our armed involvement in Southeast Asia and it can forbid entry into new wars to defend governments there. But it ought not try to exercise Executive discretion in the carrying out of a general policy it approves.

Robert H. Bork, *Comments on the Articles on the Legality of the United States Action in Cambodia*, 65 AM. J. INT'L L. 76, 81 (1971). For a contrary view, built on a history of congressional micromanagement of the conduct of wars during the early years of the nation, see Saikrishna Bangalore Prakash, *The Separation and Overlap of War and Military Powers*, 87 TEX. L. REV. 299 (2008).

136. There is substantial controversy over whether the President may refuse to enforce a law that in his or her opinion is unconstitutional. Compare Saikrishna Bangalore Prakash, *The Executive's Duty To Disregard Unconstitutional Laws*, 96 GEO. L.J. 1613, 1682 (2008) (arguing that the President must disregard unconstitutional statutes to fulfill the obligation to defend the Constitution), with Peter L. Strauss, *The President and Choices Not To Enforce*, LAW & CONTEMP. PROBS., Winter/Spring 2000, at 107, 123 (advocating that the enforcement of a possibly unconstitutional law should not depend solely on the President's views).

what decisions can be made by a particular branch of government. The fact that only a court has the power to issue a judgment does not tell us anything about the content of the judgment or whether the very same legal standard could have been made by an administrative agency, for example, via rulemaking. The substantive powers overlap even as each branch is governed by unique structural and procedural requirements.

C. *The Importance of the Identity of the Actor*

Now that it has been established that more than one branch can take the exact same substantive action without violating separation of powers, we can move on to proposition (6): *Building on proposition (5), the identity of the actor performing the action and not the nature of the action itself usually determines what sort of action is being performed. For example, when Congress acts it is legislating, and when an administrative agency acts it is executing the law, even if the action taken is, in substance, identical.*

In the *American Trucking* nondelegation decision, Justices Scalia and Stevens sparred over whether it is more accurate to state that Congress may not delegate any legislative power or to state that the nondelegation doctrine allows Congress to delegate a limited amount of legislative power.¹³⁷ In response to Justice Scalia's point that no delegation of legislative power is allowed, Justice Stevens argued that when the EPA establishes NAAQS, it exercises delegated legislative power.¹³⁸ Justice Stevens expanded on this argument by claiming that the nature of the government action and not the identity of the actor determines what action is being performed.¹³⁹

Justice Stevens's view that some delegation of legislative power is permissible is inconsistent with the Court's general practice in separation of powers cases, under which decisions often turn on the identity of the actor rather than the action taken. The procedural understandings of legislating and executing the law provide the basis for this conclusion. Continuing with the example of establishing NAAQS, when the EPA acted, it was executing the law, namely the Clean Air Act, which instructed the EPA to establish NAAQS.¹⁴⁰ The EPA's actions meet the definition of actions that

137. *See* *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 472 (2001) (quoting the Vesting Clause of Article I and finding the text "permits no delegation" of Congress's legislative power); *id.* at 488 (Stevens, J., concurring) ("I am persuaded that it would be both wiser and more faithful to what we have actually done in delegation cases to admit that agency rulemaking authority is 'legislative power.'" (citing *Mistretta v. United States*, 488 U.S. 361, 372 (1989))).

138. *Id.* at 489.

139. *Id.* at 488–89.

140. Clean Air Act § 109(a), 42 U.S.C. § 7409(a) (2006).

can be taken only by officers of the United States, namely the exercise of significant authority pursuant to the law. If Congress had not delegated power to the EPA to establish NAAQS, then chances are that any effort by the EPA to do so would be illegal, not because of the nondelegation doctrine, but because the EPA would be acting without legal authority, i.e. *ultra vires*. If Congress were to promulgate NAAQS on its own using bicameralism and presentment, it would meet the definition of legislation, since it would affect the rights and duties of people outside Congress. Thus, the same substantive action is execution when done by an agency and legislation when done by Congress.

Although it presents a somewhat more difficult case, even adjudication is subject to this analysis. When the Judiciary establishes a binding legal rule in the course of resolving a case or controversy, it is adjudicating, not legislating. If the legislature is dissatisfied with a nonconstitutional judicial decision, it can override the decision by legislating. An agency can promulgate regulations in reaction to an unfavorable judicial decision, and, under certain circumstances, can force a court to abandon what it considers the best interpretation of a federal statute in favor of a different, but reasonable agency interpretation.¹⁴¹ Even when a non-Article III judge presides over what looks like an adjudicatory procedure, that official is engaged in the execution of the law unless the non-Article III tribunal purports to have the power to employ the essential attributes of the judicial power.

When a non-Article III decisionmaker employs an adjudicatory process to resolve a claim against the government, that decisionmaker is executing the law, creating the claim, or waiving sovereign immunity as to a claim created elsewhere. The fact that an adjudicatory process is used does not mean that the decisionmaker is exercising the judicial power of the United States. These are the sort of claims that could be resolved in a nonadjudicatory process, and the fact that Congress or an agency decides to use an adjudicatory procedure does not mean that judicial power is involved, just as rulemaking is execution, not legislation. Due process may require an adjudicatory procedure in some cases, but it does not require an Article III decisionmaker.

The separation of powers issues regarding adjudication are more complicated because the Court has liberalized the use of non-Article III decisionmakers to include private rights that would have traditionally been resolved (in the federal system) by Article III judges. It can be argued that

141. See, e.g., *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 982–83 (2005) (holding that only a judicial precedent which unambiguously forecloses the agency's interpretation displaces a conflicting agency construction).

when a federal agency resolves, for example, a state law breach of contract claim between a commodities broker and a customer, the agency is exercising the judicial power of the United States.¹⁴² More than in any other area, including agency rulemaking under delegation from Congress, agency adjudication of private rights appears to involve the exercise of judicial power outside of the Article III courts.

Despite the apparent assumption of Article III powers by non-Article III tribunals, in allowing agency adjudication of private rights, the Court has applied a forgiving standard similar to the standard that governs separation of powers disputes when no particular structural or procedural provision has been violated. Because the Constitution does not enumerate the structural aspects of the judicial power, the Court's standard for evaluating the permissibility of non-Article III adjudication is not very specific, examining "the practical effect that the congressional action will have on the constitutionally assigned role of the federal judiciary" to ensure that agency adjudicatory power does not "impermissibly threaten[] the institutional integrity of the Judicial Branch."¹⁴³ Under this standard, the Court looks at a range of factors including:

[T]he extent to which the 'essential attributes of judicial power' are reserved to Article III courts, and, conversely, the extent to which the non-Article III forum exercises the range of jurisdiction and powers normally vested only in Article III courts, the origins and importance of the right to be adjudicated, and the concerns that drove Congress to depart from the requirements of Article III.¹⁴⁴

Applying this standard, the Court has required a realistic option of Article III adjudication, and has allowed non-Article III adjudication of private rights claims only when they are closely related to federal regulation.¹⁴⁵

142. *See* *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 858 (1986) (upholding such an arrangement).

143. *Id.* at 851.

144. *Id.*

145. *Id.* at 853. In reviewing the adjudication of private rights claims in non-Article III tribunals, the Court has also suggested that it would deny agencies the power to issue final judgments or punish contempt, and that nondeferential judicial review of agency decisions should be available. *Id.*

IV. THE ASSIGNMENT OF POWERS

A. *General Principles*

(7) *The strongest evidence that a power is assigned to a particular branch is an explicit textual commitment of that action to the branch, not a more general principle of separation of powers. When a power has been assigned to a particular branch, no other branch is allowed to exercise that function unless the Constitution explicitly permits it to.*

This proposition is very similar to proposition (4) but with stress on the commitments the Constitution's text makes to specific branches. The substantive powers of the federal government are shared among the branches. The powers each branch has over substantive areas of the law are overlapping, provided that each branch employs the procedural and structural requirements that apply to it.

Some matters in which the Constitution may assign powers to a particular branch are not textually specified. For example, only a court of law can issue a binding final judgment in a matter within the judicial power of the United States, and only an Article III court can preside over a jury trial. The Supreme Court has characterized these as the essential attributes of the judicial power that are exclusively held by the federal courts.¹⁴⁶ This last observation tests a primary proposition on which this Article is based: that separation of powers disputes are not resolved by inquiring into the nature of the power being exercised and then assigning the power to a branch. The reason for this is that the procedural and structural incidents of the judicial power are under-specified as compared with those that apply to the other branches. The Vesting Clause of Article III may be more important than the other Vesting Clauses in that it is relied upon to assign certain fundamental judicial attributes to the federal courts. In most cases, however, assignment of a power to a particular branch is based on a specific textual provision and not on general principles of separation of powers.

Even the substantive aspect of judicial power is subject to similar sharing, given that Congress can change the law and determine the outcome of legal controversies. Consider what happened to litigation over the effects of logging on the species of bird known as the spotted owl. After environmentalists and logging interests challenged the federal government's logging plans in court, Congress passed a statute essentially approving the government's plan.¹⁴⁷ The statute even mentioned the litigation by case

146. *Id.* at 851.

147. *See* *Robertson v. Seattle Audubon Soc.*, 503 U.S. 429, 433 (1992) (discussing the Northwest Timber Compromise).

name and number.¹⁴⁸ This was challenged as an infringement on the judicial function and the Supreme Court unanimously upheld Congress's action, proclaiming that Congress had changed the law and had not trampled on the Judiciary's power to resolve cases.¹⁴⁹ Had Congress not acted, the federal courts might have made the very same substantive decision, that the logging plans were consistent with the law, or it might have decided differently. As a matter of substance, all three branches had the power to make the exact same decision over the protection of the spotted owl from the effects of logging.

In addition to the practical difficulty of assigning powers to branches, there are positive constitutional reasons for not resolving separation of powers disputes by determining which branch is the one to properly exercise a particular power. A conceptual analysis would weaken the checks and balances aspect of separation of powers law. As the Framers made clear, the idea of separation of powers is not to assign a power to each branch and then give that branch a free hand in exercising that power. Rather, they understood that the whole idea of separation of powers is to condition government action on agreement among multiple centers of power. For this to work, each branch must have a way to check the others. If powers were clearly assigned to branches, checking might still occur though informal bargaining, but such checking is likely to be less robust than when more than one branch has a colorable claim of authority in a substantive area. For example, even if the President has exclusive control over foreign policy and Congress has exclusive control over appropriations, Congress might insist on presidential agreement to a foreign policy strategy before passing an appropriations bill favored by the Executive Branch. However, with multiple colorable claims of authority, much greater competition for control is likely to occur. This is the essence of separation of powers with checks and balances.

B. Textual Commitment

There are functions that can be performed by only one branch of government, usually because the text of the Constitution specifically assigns the function to a particular branch. For example, the President's exclusive control over the recognition of foreign governments is based on the textual commitment of the power to receive foreign ambassadors to the President in Article II, Section Three of the Constitution.¹⁵⁰ Similarly, because of

148. Act of Oct. 23, 1989, Pub. L. No. 101-121, § 318(b)(6)(A), 103 Stat. 701, 745.

149. *Robertson*, 503 U.S. at 438–39.

150. *See Goldwater v. Carter*, 444 U.S. 996 (1979).

textual commitment, only the House of Representatives can vote articles of impeachment¹⁵¹ and only the Senate can conduct trials in cases of impeachment.¹⁵² Only the President can nominate and appoint principal officers of the United States.¹⁵³ Only the two houses of Congress can pass bills and present them to the President¹⁵⁴ and only the President can sign or veto bills presented.¹⁵⁵

When a power has been assigned to a particular branch, other branches are not allowed to participate in the exercise of the power unless an additional constitutional provision allows it. Note that this element of proposition (7) does not depend on a substantive theory of the nature of the powers that belong to each branch. Rather, assignment is normally due to a specific textual provision rather than based on general separation of powers principles. Exclusivity is implied from a positive grant of power. For example, the specification of the process for making law through bicameralism and presentment strongly implies that only Congress has the power to perform that function. The Appointments Clause vests the power to nominate and appoint officials in the President except that with regard to inferior officers, Congress may legislate to allow department heads and courts of law to make appointments.¹⁵⁶ Participation by any others, such as members of Congress, in the appointment of officials is unconstitutional except when specifically authorized by the Constitution.¹⁵⁷ The Senate would not be allowed to participate in the appointment of officers of the United States were it not for the particular constitutional provision requiring the advice and consent of the Senate for such appointments, and the President would not be allowed to participate in the legislative process absent the presentment requirement spelled out in Article II. This explains why the House is not allowed to participate at all in the appointments process.

It might appear that this analysis depends on a conceptual understanding of separation of powers in the following sense. How do we know that the Senate could not participate in the appointment of officers of the United States without the specific reference in the Appointments Clause to the Senate's power of advice and consent? Is this because appointment is, by nature, an executive function, just as passing legislation is a legislative function in which the President would not be allowed to participate without

151. U.S. CONST. art. I, § 2, cl. 5.

152. *Id.* art. I, § 3, cl. 6.

153. *Id.* art. II, § 2, cl. 2.

154. *Id.* art. I, § 7, cl. 2, 3.

155. *Id.* art. I, § 7, cl. 3.

156. *Id.* art. II, § 2, cl. 2.

157. *Buckley v. Valeo*, 424 U.S. 1, 143 (1976).

the specific constitutional authorization of the veto? There is some truth to this challenge to my approach, but I do not think it refutes the approach in most cases. For example, even if the Appointments Clause did not exist, efforts by Congress to appoint executive branch officials might be unconstitutional under the general separation of powers standard, not because appointment is an executive function, but because it would prevent the President from accomplishing the constitutional functions of the presidency. In fact, as noted above, the Supreme Court has recognized that because the Appointments Clause invests the courts of law with the potential power to appoint inferior officers, the power to appoint officers of the United States is not exclusively an executive power.¹⁵⁸ The President's power to veto legislation would be more difficult to justify without a specific constitutional authorization, but, as the Framers recognized, the absence of the veto would threaten the presidency.¹⁵⁹

There is one area of significant uncertainty regarding this proposition, namely, restrictions on appointments such as bipartisanship requirements, qualifications, and other limitations on the President's power to choose freely whom to nominate and appoint. For those who rely on the Vesting Clauses to create a substantive form of separation of powers, this issue is easy—Congress should not be able to restrict the President's choice in appointments matters.¹⁶⁰ To them, only rejection by the Senate should limit the President's choice of who to appoint as an officer of the United States.¹⁶¹

Whether Congress has power to limit the President's choice of who to appoint has not been resolved in court. Perhaps this controversy is unlikely to arise in a justiciable form because the President, to receive continued cooperation from Congress, will observe the limitations even if he or she

158. *Morrison v. Olson*, 487 U.S. 654, 695 (1988).

159. *See INS v. Chadha*, 462 U.S. 919, 946–48 (1983) (discussing two bases for veto: the President's need to protect the presidency from legislative encroachment and the necessity of limiting Congress's propensity to pass ill-considered, faction-dominated legislation).

160. For an argument that all statutory qualifications for federal offices requiring Senate confirmation are unconstitutional, see generally Hanah Metchis Volokh, *The Two Appointments Clauses: Statutory Qualifications for Federal Officers*, 10 U. PA. J. CONST. L. 745 (2008).

161. For example, after the Katrina disaster, when the federal government's response was marred by Federal Emergency Management Agency's (FEMA's) apparent indifference and incompetence, Congress prescribed strict professional qualifications for the FEMA directorship. President George W. Bush objected to these in a signing statement on the ground that they would prevent him from appointing many qualified people of his choice and promised to "construe [the statute] in a manner consistent with the Appointments Clause of the Constitution." Presidential Statement on Signing the Department of Homeland Security Appropriations Act 2007, 42 WEEKLY COMP. PRES. DOC. 1742, 1742–43 (Oct. 4, 2006).

believes they are unconstitutional.¹⁶² To those who rely on the Vesting Clauses of the Constitution to create a strong form of separation of powers, these restrictions may appear unconstitutional as an interference with the President's appointment power. They can point out that the contrary view implies that Congress may restrict, for example, the President's use of the pardon power,¹⁶³ perhaps by substantively restricting it or by requiring certain procedures before a pardon may be issued. If the President's pardon power must remain unrestricted, it is plausible to argue that legal restrictions on the President's choice of nominees are unconstitutional.

This is one of those areas that the text of the Constitution does not definitively resolve. Because of the lack of direct textual resolution, congressional prescription of professional and political qualifications for presidential appointees is likely to be evaluated under the general separation of powers standard of whether the qualifications unduly hamper the President's ability to perform his constitutional functions, mainly to take care that the laws are faithfully executed. As in the vast majority of other situations in which this standard applies, the answer is likely to be no.¹⁶⁴

The discussion of these seven propositions forms the core of the understanding of separation of powers offered in this essay. In what follows, I discuss two minor propositions that are somewhat peripheral to the theory but still important enough to be worthy of mention.

V. SOME MINOR COROLLARIES OF THE GENERAL UNDERSTANDING

A. *Informal Pressure*

(8) *Informal pressure on the holder of a power to exercise it in a particular way does not violate separation of powers.*

When the Constitution assigns a function to a particular official or branch of government, only that official may perform the function. However, separation of powers does not prohibit officials in other branches from using their governmental power to exert informal influence over the carrying out of the function. For example, as we know, the President has the constitutional power to appoint officers of the United States and federal judges, and only the Senate has the advice and consent power. A member

162. If the President violates a statutory restriction and, with cooperation from the Senate, makes an appointment contrary to a statutory restriction, perhaps a party subject to regulation by the official involved would be able to argue that regulation is unlawful because the officials were not appointed in accordance with governing law. As far as I know, this has never happened.

163. U.S. CONST. art. II, § 2, cl. 1.

164. See *supra* Part I.B and accompanying notes.

of the House of Representatives may insist that the President appoint his chosen candidate, and might use power over the President's legislative agenda to "convince" the President to comply. A cursory look at the resumes of presidential appointees to agencies would reveal that many were congressional staff members before their appointments. There is also a longstanding tradition of Presidents allowing Senators to virtually choose federal judicial nominees who will sit in their states. As long as the President actually exercises the power to nominate and appoint, external informal involvement in the decisionmaking process presents no separation of powers problem.¹⁶⁵

There are lesser known manifestations of external influence on the execution of the law. In the appropriations area, congressional committees exert a great deal of influence over how agencies spend funds when they have discretion under appropriations statutes. For example, with regard to military spending, the armed services have at times treated committee reports as if they contain binding legal instructions on how to spend funds.¹⁶⁶ Congressional committees expect agencies to consult them before spending funds differently from what they were requested for.¹⁶⁷ Agencies and the President comply with these practices because they need continued cooperation from members of Congress and congressional committees. members of Congress also sit in on trade negotiations and accompany executive branch officials on trade missions. Again, as long as the actual exercise of executive power is performed only by officers of the United States, the fact that it is done under pressure from members of Congress has no constitutional significance.

165. For a general look at this, see Jack M. Beermann, *Congressional Administration*, 43 SAN DIEGO L. REV. 61 (2006).

166. John C. Roberts, *Are Congressional Committees Constitutional?: Radical Textualism, Separation of Powers, and the Enactment Process*, 52 CASE W. RES. L. REV. 489, 563–65 (2001).

167. The Supreme Court has made it clear that funding requirements contained only in congressional committee reports are not legally binding. *See Cherokee Nation of Okla. v. Leavitt*, 543 U.S. 631, 646 (2005); *Lincoln v. Vigil*, 508 U.S. 182, 192 (1993). Late in his presidency, George W. Bush instructed agencies not to treat as binding spending instructions contained in committee reports. Exec. Order 13,457, 3 C.F.R. 175–177 (2009). This Executive Order may be viewed as an example of improper midnight activity, since President Bush waited until the last year of his second term to issue an order that regulated internal executive branch activity. *See generally* Jack M. Beermann, *Presidential Power in Transitions*, 83 B.U. L. REV. 947 (2003) (finding the phenomenon of "midnight regulation" a fact of life in a term-based political system). Further, Congress continues to include unconstitutional legislative vetoes in appropriations legislation. It is unclear whether agencies informally comply with the veto provisions.

As one court has stated in a case in which a criminal defendant challenged his conviction on the basis that a member of Congress had informally asked the Department of Justice to investigate:

Legislators routinely express their opinions to executive branch officials about matters for which their departments or agencies are responsible. Defendant's position presumes that executive officials must disregard these views and remain entirely free of their influence in order to maintain the separation of powers, but this is impracticable, unnecessary, and bears no relation to the actual workings of the modern administrative state. Furthermore, the adoption of Defendant's conception of the separation of powers would surely hinder legitimate congressional oversight of executive agencies. This interaction among the branches is simply part of the vigorous engagement that gives rise to the system of checks and balances in our government.¹⁶⁸

While due process and the Administrative Procedure Act require insulation of decisionmakers from informal pressure in adjudicatory proceedings, it is difficult to imagine a separation of powers violation resulting from informal pressure on executive officials.

B. Underenforcement

(9) *Separation of powers norms may be underenforced judicially. In other words, the constitutional ideal may involve a stricter understanding of separation of powers than what the federal courts are willing to enforce.*

Scholars have long distinguished between actual legal norms and judicial enforcement of the norms.¹⁶⁹ The theory is that full judicial enforcement of some legal norms, such as separation of powers, may be unrealistic or even undesirable. To a legal realist, this may seem paradoxical or even plain wrong. How can there be an unenforced legal norm? Without enforcement, realism teaches that there is no such legal norm. The answer to this objection involves taking an institutional perspective.¹⁷⁰ Norms of judicial restraint and competence may lead judges to uphold laws that they might believe are inconsistent with the best view of what the Constitution requires. A judge might vote to uphold a law that she would have opposed on constitutional grounds as a legislator or President.

Courts might systematically underenforce separation of powers norms for a variety of reasons. The simplest reason is the difficulty of matching

168. *United States v. Mardis*, 670 F. Supp. 2d 696, 702–03 (W.D. Tenn. 2009) (citations omitted).

169. *See generally* Lawrence Gene Sager, *Fair Measure: The Legal Status of Underenforced Constitutional Norms*, 91 HARV. L. REV. 1212 (1978).

170. *See id.*

function to branch. The nondelegation doctrine provides the clearest example of this. The execution of the law virtually always involves discretion on the part of executive branch officials, and it would be very difficult to construct a legal standard to capture the norm against delegation of legislative power. Perhaps this is why Justice Scalia's opinion for the Court in *Whitman* stated that the courts have not felt "qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law."¹⁷¹

Further, separation of powers controversies often arise in the most politically sensitive and contentious areas, when Congress feels the need to break from tradition. The independent counsel provisions upheld in *Morrison* provide a good example of this. The Watergate scandal spawned several innovations that Congress apparently thought were necessary to restore the public's faith in government. Whether it is fear of a backlash or genuine concern that courts should not meddle in politically sensitive areas unless absolutely necessary, it is not surprising that judges might be restrained when asked to invalidate important legislation for violating a general separation of powers norm.¹⁷²

Underenforcement of separation of powers norms is most likely to exist in areas without clear constitutional rules such as an explicit procedural or structural provision. It might be truer to the Constitution, under whatever theory of constitutional interpretation one holds, to be much stricter with regard to delegation of discretion to the Executive Branch, restrictions on appointment and removal of officers of the United States, and adjudication outside Article III courts. Perhaps it would be truer to the Constitution to prohibit agency rulemaking, agency adjudication, and congressional specification of qualifications for executive office. But except to those with excessive confidence in their ability to extrapolate clear understandings from vagaries of the Vesting Clauses or nonspecific constitutional provisions, these are all areas in which there is no clear answer in the text of the Constitution.

This understanding is consistent with the way separation of powers law has developed. The Court strictly enforces most of the particular procedural and structural separation of powers provisions of the Constitution but is very lenient when the case boils down to whether there has been a violation of general separation of powers norms. A court

171. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474–75 (2001) (quoting *Mistretta v. United States*, 488 U.S. 361, 416 (1989)).

172. See generally Kevin M. Stack, *The Story of Morrison v. Olson: The Independent Counsel and Independent Agencies in Watergate's Wake*, in *PRESIDENTIAL POWER STORIES* 401 (Christopher H. Schroeder & Curtis A. Bradley eds., 2009).

concerned with restraint is likely, absent compelling circumstances, to feel more comfortable enforcing the specific requirements of the Appointments Clause and bicameralism and presentment than with invalidating legislation based on a vague, undefined separation of powers understanding. It may be that a “true” understanding of separation of powers would invalidate independent agencies and all restrictions on the President’s power to appoint and remove officers of the United States. It may even be that a majority of the Justices of the Supreme Court hold such views, but are unwilling to act on them for reasons of judicial restraint. The *PCAOB* decision may be a nudge in the direction of less discomfort with employing general separation of powers norms, but it remains to be seen whether the Court will move the law toward greater enforcement of general separation of powers norms.

CONCLUSION

Although the Court’s recent decision invalidating the provisions governing removal of members of the *PCAOB* contains hints of a movement toward strict application of separation of powers norms, at the end of the day, the Court preserved the basic structure of separation of powers. Under this basic structure, courts strictly enforce the particular procedural and structural provisions of the Constitution and are lenient when only the general notion of separation of powers is implicated. Key to this understanding is that the Vesting Clauses of the first three Articles of the Constitution are not among the strictly enforced provisions of the Constitution. Under separation of powers in the United States government, the branches have overlapping power in many substantive areas, ensuring a robust system of checks and balances. Separation of powers law looks very little at the substance of government action, demanding usually only that each branch follow the procedural and structural requirements that apply to it. Except in areas clearly governed by a particular procedural or structural constitutional provision, the law of separation of powers allows for a great deal of flexibility concerning the structure and operation of the federal government. Thus, while conceptual analysis of the nature of government power and assignment of each power to a particular branch may be theoretically satisfying, it does not represent the theory or practice of separation of powers in the United States.

AN EMPIRICAL STUDY OF JUDICIAL REVIEW OF AGENCY INTERPRETATIONS OF AGENCY RULES

RICHARD J. PIERCE, JR.* AND JOSHUA WEISS**

TABLE OF CONTENTS

Introduction.....	515
I. The Study and Findings.....	519
II. What Do the Findings Mean?.....	520

INTRODUCTION

In a recent essay, one of us (Pierce) described and analyzed ten empirical studies of judicial review of agency actions.¹ With one exception, the studies found that a court’s choice among six review doctrines had little, if any, effect on the outcome of cases. Courts at all levels of the federal judiciary uphold agency actions in about 70% of cases, no matter whether the court applies *Chevron*,² *Skidmore*,³ *State Farm*,⁴ *Universal Camera*,⁵ or de novo review.⁶ The one exception was the finding with respect to Supreme Court

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1. See generally Richard J. Pierce, Jr., *What Do the Studies of Judicial Review of Agency Actions Mean?*, 63 ADMIN. L. REV. 77 (2011).

2. *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984).

3. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

4. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34 (1983).

5. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951).

6. Pierce, *supra* note 1, at 83 (defining de novo review as an approach in which “the court resolves the issue before it as if the agency had never addressed the issue”).

applications of the *Auer*⁷ doctrine. The Supreme Court seems to take an extraordinarily deferential approach when it reviews agency interpretations of agency rules. William Eskridge and Lauren Baer found that the Court upholds 91% of such agency actions.⁸

The studies of judicial review of agency actions leave one important void. No study has previously calculated the rates at which district courts and circuit courts uphold agency interpretations of agency rules. Thus, we have no way of knowing whether all courts apply the *Auer* doctrine in the same extraordinarily deferential way that the Supreme Court does, or whether applications of *Auer* by district courts and circuit courts reflect instead the 70% rate of affirmation that seems to be the norm for all other doctrines. The main purpose of this Article is to fill that void and to answer that question.

In *Auer*, the Court announced that an agency's interpretation of an agency rule should be accorded "controlling" weight, "unless [it is] plainly erroneous or inconsistent with the regulation."⁹ The Court issued its opinion in *Auer* in 1997, but it quoted from its oft-cited 1945 opinion in *Seminole Rock* and applied the *Seminole Rock* test to the interpretation at issue in *Auer*.¹⁰ Thus, *Seminole Rock* and *Auer* announce the same test. Courts have been applying the *Auer/Seminole Rock* test for sixty-five years. Many judges and scholars have characterized the *Auer/Seminole Rock* test as analogous to the more recent *Chevron* test except, of course, that *Chevron* applies to agency interpretations of statutes, while *Auer/Seminole Rock* applies to agency interpretations of rules.¹¹

Judicial deference to agency interpretations of agency rules might be supported on at least three grounds. First, deference might be supported by the belief that the agency is more likely than a court to know what it intended when it issued a rule. We think that is a weak justification for deference, however. In many cases, the interpretation at issue was announced so long after the rule was issued that it is unlikely that the agency decisionmakers who issued the interpretation played any role in the decisionmaking process that led to the issuance of the rule. Moreover, most

7. *Auer v. Robbins*, 519 U.S. 452, 461 (1997) (applying the "plainly erroneous or inconsistent with the regulation" standard derived from *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945)).

8. See William N. Eskridge, Jr. & Lauren E. Baer, *The Continuum of Deference: Supreme Court Treatment of Agency Statutory Interpretations from Chevron to Hamdan*, 96 GEO. L.J. 1083, 1142 & tbl.15 (2008).

9. 519 U.S. at 461 (internal quotation marks omitted).

10. See *id.*; see also *Seminole Rock*, 325 U.S. at 414.

11. For an expanded explanation of these deferential standards, see 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE §§ 3.3, 6.11 (5th ed. 2010).

courts, including the Supreme Court, confer *Auer/Seminole Rock* deference on agency interpretations of agency rules even when the agency changes its interpretation, as long as the agency acknowledges that it is making a change and gives plausible reasons for the change.¹²

The second reason for deference is stronger. Deference is justified because the agency understands better than a court which interpretation will allow the agency to further its statutorily assigned mission. This is the familiar expertise-based comparative institutional advantage that has long been the primary justification for most doctrines that instruct courts to defer to agencies. We think this justification for deference is strong, but we can think of no reason why this justification for deference is more powerful in the context of agency interpretations of agency rules than in the context of agency interpretations of agency-administered statutes, agency policy decisions, or agency findings of fact. Yet the Supreme Court's pattern of decisions suggests that the Court confers more deference on agency interpretations of agency rules than on any other type of agency action.

The third reason is rooted in the differences in the jurisdictional reach of agency interpretations and judicial interpretations. Since an agency's jurisdiction is national and a circuit court's jurisdiction is regional, a high degree of judicial deference to agency interpretations of agency rules furthers the goal of maximizing national uniformity in implementing national statutes.¹³ Conversely, a low degree of deference would reduce national uniformity, since circuit courts are likely to adopt differing interpretations of agency rules.¹⁴ We also think this justification is strong, but it is no stronger in the context of agency interpretations of agency rules than in the context of agency interpretations of agency-administered statutes. Indeed, Peter Strauss relied on this reasoning to support his argument for a strong version of *Chevron* deference in 1987.¹⁵

John Manning has argued that courts should not defer to agency interpretations of agency rules.¹⁶ Since agencies are the source of the rules

12. See *id.* § 6.11, at 531–32 (suggesting a court will ask whether the agency gave its “fair and considered judgment on the matter”).

13. *Id.* § 3.4, at 167 (explaining that *Chevron* deference has enhanced consistency).

14. *Id.* (noting that *Chevron* also precludes judges from mistakenly labeling their findings as rulings of law).

15. See generally Peter L. Strauss, *One Hundred Fifty Cases Per Year: Some Implications of the Supreme Court's Limited Resources for Judicial Review of Agency Actions*, 87 COLUM. L. REV. 1093 (1987) (asserting that the *Chevron* rule helps to eliminate diversity and reduces the Supreme Court's need to monitor courts' decisions for accuracy).

16. See generally John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612 (1996) (contending that courts should apply the *Skidmore* test instead). In his concurring opinion in *Talk America, Inc. v. Michigan Bell Telephone Co.*, 131 S. Ct. 2254, 2266 (2011), Justice Scalia cited Manning's article with

they interpret, Manning argued that deferring to agency interpretations of ambiguous agency rules encourages agencies to maximize the ambiguities in the rules they issue. This incentive is powerful because an agency must use the resource-intensive and time-consuming notice-and-comment process to issue a rule, while it is not required to use any procedures to interpret a rule.¹⁷ Thus, the agency has an incentive to issue a broadly worded rule capable of bearing a wide range of interpretations and then to use the process of interpreting the rule to make most important decisions, thereby avoiding the cost, delay, and risks of using the notice-and-comment process in that recurring context.

The 91% rate at which the Supreme Court upholds agency interpretations of agency rules suggests that the Court has not found Manning's criticism of judicial deference to agency interpretations of rules persuasive. The Court provided at least a partial response to Manning's concern in its 2006 opinion in *Gonzales v. Oregon*,¹⁸ however. The Court announced and applied an "antiparrotting" canon in the context of an agency's interpretations its own rules.¹⁹ If an agency issues a rule that merely parrots the relevant statutory language, the agency's interpretations of the rule do not receive *Auer/Seminole Rock* deference.²⁰

The antiparrotting canon applies to rules that go beyond mere parroting of statutory language. Indeed, the rule at issue in *Gonzales* went beyond the statutory language in some respects, as the dissenting Justices pointed out.²¹ Thus, the antiparrotting canon deprives agencies of *Auer/Seminole Rock* deference unless the rule the agency is interpreting goes beyond the language of the statute by particularizing or clarifying the statutory language to some significant but uncertain extent. The antiparrotting canon still leaves the agency with some degree of discretion to engage in the practice that concerns Manning, however. The agency still has an incentive to use the notice-and-comment procedure to issue a broadly worded rule that contains many ambiguities, as long as the rule clarifies or particularizes the statutory language to the extent necessary to avoid the

apparent approval and indicated that he is open to the possibility of overruling *Auer* for the reasons Manning gives in his article.

17. PIERCE, *supra* note 11, § 6.4, at 433.

18. 546 U.S. 243 (2006).

19. *Id.* at 257–58.

20. *Id.* at 258.

21. *Id.* at 278–80 (Scalia, J., dissenting) (tasking the Court for focusing on irrelevant parroting in parts of the statute the agency did not purport to construe and ignoring the agency's interpretive choice among three possible meanings for an ambiguous statutory term).

“parroting” characterization. The agency could then use the interpretive process to make most important decisions.

We think the case for judicial deference to an agency’s interpretation of an agency’s rule is strong notwithstanding Manning’s critique. However, we are unable to identify any reason why courts should accord greater deference to agency interpretations of agency rules than to agency interpretations of agency-administered statutes, agency policy decisions, or agency findings of fact. Thus, we are puzzled by the Supreme Court’s apparent practice of conferring much more deference on agency interpretations of rules than on any other type of agency action.

I. THE STUDY AND FINDINGS

The main purpose of this study was to determine whether the Supreme Court is alone in its practice of conferring extreme deference on agency interpretations of rules, or whether district courts and circuit courts also accord some form of “super-deference” to agency interpretations of rules. Additionally, we designed the study to allow us to estimate the extent to which judicial applications of the *Auer/Seminole Rock* doctrine are affected by the political or ideological perspectives of the judges who apply the doctrine. For those purposes, we studied the thirty-four cases in which district courts applied *Auer/Seminole Rock* and the fifty-seven cases in which circuit courts applied *Auer/Seminole Rock* between January 1, 1999, and December 31, 2001, and the seventy-four cases in which district courts applied *Auer/Seminole Rock* and the fifty-four cases in which circuit courts applied *Auer/Seminole Rock* between January 1, 2005, and December 31, 2007.

We chose these two time frames because the first period was likely to involve review of rule interpretations adopted by a Democratic administration, while the second was likely to involve review of rule interpretations adopted by a Republican administration. That choice of time periods, in turn, allowed us to make some judgment on the effect of judges’ political or ideological preferences on the degree of deference they accord agency interpretations of agency rules.

The sample of cases we studied—219—is large enough to give us confidence that our findings are representative of the pattern of decisions in the total population of cases in which lower courts apply *Auer/Seminole Rock*. Courts upheld agency interpretations in 76.26% of the cases we studied. There was no significant difference between the rate at which district courts upheld agency interpretations (75.93%) and the rate at which circuit courts upheld agency interpretations (76.58%).

There also was no statistically significant difference between the rate at which judges voted to uphold interpretations of rules adopted by agencies

headed by members of the same party versus the rate at which judges voted to uphold interpretations adopted by agencies headed by members of the other party. Republican judges voted to uphold interpretations adopted by a Republican administration in 77.94% of cases, while Democratic judges voted to uphold interpretations adopted by a Republican administration in 78.57% of cases. Republican judges voted to uphold interpretations adopted by a Democratic administration in 74.51% of cases, while Democratic judges voted to uphold interpretations adopted by a Democratic administration in 74.42% of cases.

II. WHAT DO THE FINDINGS MEAN?

Our finding that district courts and circuit courts upheld agencies in 76% of cases in which they applied the *Auer/Seminole Rock* doctrine contrasts starkly with Eskridge and Baer's finding that the Supreme Court upholds agencies in 91% of such cases.²² The Supreme Court appears to be alone in the extreme deference it accords agency interpretations of rules. Our finding suggests that district courts and circuit courts apply *Auer/Seminole Rock* deference in about the same manner as they and the Supreme Court apply the other deference doctrines that have been subjected to empirical study. The prior studies of judicial applications of the other deference doctrines revealed rates of affirmation in the following ranges: *Chevron*, 64% to 81%; *Skidmore*, 55% to 71%; *State Farm*, 64%; and *Universal Camera*, 64% to 71%.²³ The overall rate at which district courts and circuit courts upheld agency actions through application of the *Auer/Seminole Rock* doctrine, 76%, is within the range of the findings of the studies of other doctrines, albeit at the high end of that range.

Our findings with respect to the overall rate at which district courts and circuit courts upheld agency interpretations of agency rules fit well with David Zaring's finding that courts uphold agency actions in about 70% of cases no matter what review doctrine the court applies.²⁴ Our findings are also consistent with the normative case for judicial deference to agency interpretations of agency rules we discussed in the Introduction.²⁵ The case for deference to agency interpretations of agency rules is strong, but it is no stronger than the case for judicial deference to agency interpretations of

22. Eskridge & Baer, *supra* note 8, at 1142 tbl.15.

23. Pierce, *supra* note 1, at 84.

24. David Zaring, *Reasonable Agencies*, 96 VA. L. REV. 135, 169 (2010) [hereinafter Zaring, *Reasonable Agencies*]. Zaring has also argued that this uniformity of results implies that a rule of reasonableness would make a preferable standard of review. See David Zaring, *Rule by Reasonableness*, 63 ADMIN. L. REV. 525 (2011).

25. See *supra* notes 13–20 and accompanying text.

agency-administered statutes, agency policy decisions, and agency findings of fact.

Our finding that the ideological and political preferences of judges had no significant effect on their votes in cases in which they were called upon to review agency interpretations of agency rules differs from the findings of many of the studies of judicial review of other types of agency actions. Many of the studies of judicial review of agency statutory interpretations and agency policy decisions found that between 15% and 31% of votes could be explained with reference to the ideological or political preferences of the reviewing judges.²⁶ By contrast, Zaring's study of 678 judges' votes in cases reviewing agency findings of fact produced the same result as our study of 441 judges' votes in cases reviewing agency interpretations of rules. Zaring found that the political and ideological preferences of judges had no significant effect on their pattern of voting in cases in which courts reviewed agency findings of fact.²⁷

It is possible that the difference between the findings of studies such as Zaring's and ours—that judges' political preferences had no significant effect on their voting patterns—and the findings of studies that found that judges' political preferences had a significant effect on their voting patterns simply reflects reality. In other words, judges may not be influenced by their ideological and political preferences when they review agency interpretations of agency rules and agency findings of fact, even though they are influenced by those same preferences when they review agency interpretations of statutes and agency policy decisions. We are skeptical of that explanation, however. We believe that all judges attempt to review agency actions without allowing their political and ideological preferences to influence their decisions. We can think of no reason why they would be more successful in pursuing that laudable goal in the process of reviewing some aspects of the agency decisionmaking process than others.

There is another plausible explanation for this difference between our findings and those of many of the prior studies. Most studies that found a strong connection between judges' political and ideological views and their votes in agency review cases relied primarily on a methodology different from ours. In those studies, the researchers first classified each agency

26. *E.g.*, Thomas J. Miles & Cass R. Sunstein, *The Real World of Arbitrariness Review*, 75 U. CHI. L. REV. 761, 788 tbl.3 (2008) [hereinafter Miles & Sunstein, *The Real World*]; Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823 (2006) [hereinafter Miles & Sunstein, *Do Judges Make Regulatory Policy?*]; Frank B. Cross & Emerson H. Tiller, *Essay, Judicial Partisanship and Obedience to Legal Doctrine: Whistleblowing on the Federal Courts of Appeals*, 107 YALE L.J. 2155, 2171 (1998).

27. Zaring, *Reasonable Agencies*, *supra* note 24, at 178–79.

action as “liberal” or “conservative,” and then compared the number of Republican judges who voted to uphold liberal and conservative actions with the number of Democratic judges who voted to uphold liberal and conservative actions.²⁸

We decided not to use that methodology because we lacked confidence that we could classify accurately as liberal or conservative all of the agency actions that fell within the large sample of agency actions we studied. We chose instead to use a methodology that did not require us to characterize the actions we studied. We categorized agency actions as Democratic or Republican based on the political party that controlled the Executive Branch at the time the agency adopted the interpretation at issue. Our methodology was simple to apply, and our findings are easy for other researchers to verify or refute. Our methodology is based on the implicit assumption that agencies in Republican administrations tend to adopt interpretations of rules that are consistent with the political and ideological preferences of Republicans and that agencies in Democratic administrations tend to adopt interpretations of rules that are consistent with the political and ideological preferences of Democrats. We recognize that the assumption we indulged is not universally true, but we believe it is generally true.

We are not prepared to argue that our methodology is superior to the methodology used in the studies that found that the political and ideological preferences of judges had a significant effect on their pattern of voting in cases in which they reviewed agency actions. At least in theory, the methodology used in those studies is better than the methodology we chose. The studies that found a significant difference in voting patterns based on judges’ political preferences attempted to measure the political and ideological content of each agency action directly, rather than relying on the imperfect surrogate for the political and ideological content of an agency action we chose—identity of the political party that controlled the Executive Branch at the time an agency adopted an interpretation of a rule.

Zaring has expressed concern that at least some of the difference in voting patterns that other researchers have attributed to the political preferences of judges may instead be attributable to errors in the inherently difficult process of characterizing agency actions as liberal or conservative.²⁹ We are not in a position to evaluate that possibility, but our finding that the

28. *E.g.*, Miles & Sunstein, *The Real World*, *supra* note 26, at 788–89 & tbl.3 (discussing review for arbitrariness); Miles & Sunstein, *Do Judges Make Regulatory Policy?*, *supra* note 26, at 846 tbl.6 (comparing the records of Supreme Court Justices); Cross & Tiller, *supra* note 26, at 2168 (noting that coding for political ideology tracks political scientists’ methods).

29. *See* Zaring, *Reasonable Agencies*, *supra* note 24, at 182.

2011] *A STUDY OF JUDICIAL REVIEW OF AGENCY INTERPRETATIONS OF RULES* 523

political preferences of judges had no significant effect on their voting patterns in cases in which courts reviewed agency interpretations of agency rules raises the same troubling question.

RULE BY REASONABLENESS

DAVID ZARING*

TABLE OF CONTENTS

Introduction.....	525
I. Testing Reasonableness	529
II. Surveying Reasonableness	535
A. Torts.....	537
B. Fourth Amendment.....	539
C. Financial Regulation.....	543
D. Conclusion	549
III. Defending Reasonableness	551
A. Critiques of Reasonableness.....	552
B. Implications of Reasonableness.....	555
C. Getting There	559
Conclusion	560

INTRODUCTION

To a reasonable creature, that alone is insupportable which is unreasonable, but everything reasonable may be supported.

—Epictetus¹

The rule of reason is sometimes said not to be much of a rule at all,² but in this Article I argue that reasonableness is tractable, cognizable, and

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1. EPICETUS, DISCOURSES, *in* 1 THE WORKS OF EPICETUS 9 (Thomas Wentworth Higginson trans., Cambridge Univ. Press 1890).

2. As James Gibson suggested, “reasonable care can be a frustratingly imprecise

ultimately the right way to design judicial review, especially when courts review the work of agencies.³ I do so because although administrative law doctrine has eschewed the rule of reason in theory, courts and scholars increasingly accept that review for reasonableness is really the only way to describe what courts do when they supervise the conduct of agencies.⁴ There are those who are accustomed to the old standards of review and those who want to reform those standards. This Article takes the latter view—it argues that reasonableness is both an acceptable and desirable way to review agency action, largely by analogizing it to other vibrant areas of law that succeed with a reasonableness standard. It builds on my earlier work, which established that the standards of review validate agencies roughly two-thirds of the time despite offering putatively different levels of scrutiny for various forms of administrative action.⁵ While that work focused on what agencies actually do, this Article focuses on what they *should* do, adds a comparative approach, and addresses possible critiques of the rule of reason.

If judges turned to the rule of reason and rejected the complicated standards of review that currently exist in administrative law, they would not be abandoning constraint. Instead, they would be embracing a broad standard with philosophical overtones (which admittedly does not sound very intuitive or constraining), a standard that has been specified in many different legal contexts and factual settings.

Administrative law has eschewed reasonableness in favor of elaborate standards of review encompassing no less than six different ways that courts

concept.” James Gibson, *Doctrinal Feedback and (Un)reasonable Care*, 94 VA. L. REV. 1641, 1643 (2008).

3. It is a controversy to which I have contributed, and this Article builds on my earlier, more descriptive work. See David Zaring, *Reasonable Agencies*, 96 VA. L. REV. 135, 186–87 (2010) (observing that regardless of the standard of review employed by courts, agencies win their appeals roughly two-thirds of the time, suggesting that courts apply a broad reasonableness metric to review agency action).

4. See *infra* Part II for a further discussion, but for example, in antitrust law alone there are those who have argued, with some alarm, that reason is sometimes applied “in the twinkling of an eye.” PHILLIP AREEDA, FED. JUDICIAL CTR., THE “RULE OF REASON” IN ANTITRUST ANALYSIS: GENERAL ISSUES 37–38 (1981). Or that “[t]he rule of reason’s application is arbitrary because there is no way of telling which way the scales of justice will tilt.” Thomas Kennedy, Comment, *Will America’s Pastime Be a Part of America’s Future?: An Antitrust Analysis that Enables Sports Leagues to Compete Effectively in the Entertainment Market*, 46 UCLA L. REV. 577, 588 n.49 (1998). Or that the “rule of reason has no substantive content” and “is curiously lacking in definition.” Thomas A. Piraino, Jr., *Making Sense of the Rule of Reason: A New Standard for Section 1 of the Sherman Act*, 47 VAND. L. REV. 1753, 1754 (1994). Antitrust, of course, is only one of the areas of the law that turns on reasonableness. For more, see *infra* Part II.

5. Zaring, *supra* note 3, at 186–87.

are to scrutinize agency action (seven if you also consider the doctrines surrounding review of agency interpretation of agency rules, which Richard Pierce and Joshua Weiss analyze in this volume of the *Administrative Law Review*.⁶ For all this doctrinal complexity, however, the validation rate of agencies varies little on the basis of the standard of review.⁷

The two-thirds average validation rate suggests that lawyers and judges are converging upon a single standard of review.⁸ If that standard is characterized as a reasonableness standard, it need not be thought of as lawless, unconstrained, or no rule at all. Reasonableness works all over the legal system. It undergirds the law of negligence, which depends upon the “reasonable person” standard; the Fourth Amendment, which prohibits “unreasonable searches and seizures”; antitrust law, which turns ever more increasingly on a “rule of reason” used to evaluate restraints upon trade; securities law; contract law; and the list could go on.⁹

In each of these well-established areas of law, reasonableness has become the core doctrine. It affords lawyers and judges, not to mention juries, the opportunity to make and specify law in particular contexts and permits the application of community standards to controversial conduct. Yet reasonableness is not so unpredictable as to make planning impossible. To be sure, reasonableness has always had its critics—it has been branded as too unspecific, and there is a vigorous jurisprudential debate about what, precisely, it means.¹⁰ But as the resilient legal system has shown time and again, reasonableness may enable the constitution of a standardized, coherent, and rich corpus of law premised on broad flexibility for decisionmakers, real jurisdictional and procedural constraints, and the power to use precedent to give content to and specify the broad meaning of the rule of reason.

6. See Richard J. Pierce, Jr. & Joshua Weiss, *An Empirical Study of Judicial Review of Agency Interpretations of Agency Rules*, 63 ADMIN. L. REV. 515 (2011).

7. Zaring, *supra* note 3, at 186–87.

8. See *id.*

9. See *infra* Part II for a discussion of each of these rules of reason.

10. Understanding what reasonableness requires has been a preoccupation of legal thinkers for decades. Rather than attempt to recount all the relevant sources, perhaps the interested reader could consider some humanistic approaches. See generally JOSEPH RAZ, PRACTICAL REASON AND NORMS (Oxford Univ. Press 1999) (1975). For a discussion, see generally Adam Gearey, *The Poetics of Practical Reason: Joseph Raz and Philip Larkin*, 19 LAW & LITERATURE 377 (2007). See also Jane Flax, *Postmodernism and Gender Relations in Feminist Theory*, in FEMINISM/POSTMODERNISM 39 (Linda J. Nicholson ed., 1990). For a discussion of the Flax and the feminist critique of reasonableness more generally, see Naomi R. Cahn, *The Looseness of Legal Language: The Reasonable Woman Standard in Theory and in Practice*, 77 CORNELL L. REV. 1398 (1992).

I explore three other implications of the case for reasonableness. First, a claim about what standards of review are supposed to do. Some envision those standards as checklists, or cues, for the courts.¹¹ These checklists and cueing functions are plausible but are frequently abandoned in practice and add complexity to a judicial inquiry pairing such standards with substantive law tests.¹² Rather than thinking of the standards of review as requiring the itemization of a list—check the text first, the legal work done by the agency second, and whether the action would be a good idea third—reasonableness review is much less cabined. And the reasonableness approach to administrative law is a challenge to the merits of the plausible reasons to do such cabining.

Second, reason's capaciousness broadens the permissible scope of legal inquiry. Reasonableness admits constraints, legal and otherwise, that we all think matter in realistic visions of the application of law, such as politics and community standards.

Third, rule by reasonableness takes judges and courts out of an exalted context where they do something different—parse complicated standards of review—than do juries, police officers, and financial bureaucrats, all of whom apply a broad rule of reason to their work.¹³ This is a useful demystification of law, and a reminder that courts are government officials too and that government officials often find rules of reason to be useful guides as to how to do their jobs.

In what follows, this Article compares administrative law's emerging embrace of reasonableness to other, more settled forms of government action, namely government searches and seizures and government supervision of the financial system. I also compare administrative law to negligence law. The Article concludes with some implications for lawyers and academics persuaded by the prominence of the reasonableness inquiry across various forms of law.

11. In administrative law, for example, the so-called *Chevron* two-step test requires courts to consult the plain text of the statute and then evaluate whether there is any ambiguity in that text. If ambiguous, a court will uphold an agency's interpretation if it is a reasonable one. See *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

12. To be sure, the standards of review in administrative law are both substantive in that they tell the court what to look for in agency action—say, arbitrariness—and how carefully to look for that arbitrariness—a hard look.

13. Financial regulation has its own set of elaborate rules for how the government is supposed to treat the banks, thrifts, and credit unions that it charters. But, as the financial crisis suggests, some of the elaboration of the rules of decisionmaking are a bit of a reach. While some believe that the financial crisis exemplifies how law gets abandoned when crisis hits, my own view is that the law did matter during the crisis. For a discussion, see generally David Zaring, *Administration by Treasury*, 95 MINN. L. REV. 187 (2010).

I. TESTING REASONABLENESS

Administrative lawyers have evinced increasing dissatisfaction and uncertainty about the standards of review that guide the discipline, and rightly so. Scholars and courts increasingly agree that the standards of review in administrative law are overly complex. And the courts are also doing something about it, turning away from current doctrine and toward a general reasonableness review that would replace the complicated standards reviewed here. This section of the Article reviews some of the problems with the current standards of review; those acquainted with the critiques will find it familiar, though the trends in citations to those standards identified are new and perhaps indicative that further research in the area is needed.

We now know that, regardless of the standard of review employed, courts validate agency policymaking between 60% and 70% of the time.¹⁴ The fact is a challenging one for current doctrine.

In theory, administrative law encompasses a complex review scheme that employs no fewer than six different standards of review depending on what precisely the agency did. In many cases, courts review agency factfinding under a substantial evidence standard, but in others they review under an arbitrary and capricious standard.¹⁵ Review of agency legal determinations triggers *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.* deference,¹⁶ *Skidmore v. Swift & Co.* deference,¹⁷ *Auer v. Robbins* deference,¹⁸ or sometimes no deference at all, as is the case when interpreting the Administrative Procedure Act or the Constitution.¹⁹ Finally, after pairing the correct standard of review with the sort of action the agency took, courts must

14. This assumes, of course, and somewhat controversially, that the distribution is normal.

15. Zaring, *supra* note 3, at 177–86.

16. 467 U.S. 837 (1984).

17. 323 U.S. 134 (1944).

18. 519 U.S. 452 (1997).

19. 463 U.S. 29 (1983). De novo review can also occur in other limited circumstances. See *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (holding that de novo review of agency determinations is limited to when “the action is adjudicatory in nature and the agency factfinding procedures are inadequate,” and “when issues that were not before the agency are raised in a proceeding to enforce nonadjudicatory agency action”). The agency’s organic statute, or its legislative history, may also authorize de novo review. See, e.g., Food Stamp Act, 7 U.S.C. § 2023(a)(15) (2006) (“The suit in the United States district court or State court shall be a trial de novo by the court in which the court shall determine the validity of the questioned administrative action in issue”); *Chandler v. Roudsbush*, 425 U.S. 840, 861 (1976) (finding that the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972, permits de novo review of administrative action).

perform a general arbitrariness review under the *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.* standard.²⁰ Sometimes *State Farm* review is called hard look review, and at other times it is called rationality review.²¹

Because it has never been easy for courts to distinguish between questions of law, questions of fact, and mixed questions of law and fact, subsequently apply the right standard of review, and then finally perform a catchall review for arbitrariness, it is worth asking if it makes sense to make all of these doctrinal distinctions.

The courts may not think so. They are increasingly sneaking reasonableness standards into their reviews in lieu of making the difficult distinctions required by contemporary standard of review doctrine. The United States Court of Appeals for the District of Columbia Circuit once concluded that, as among the three standards of review for legal questions, “the result is the same whether the court applies *de novo* review, deference under *Skidmore v. Swift & Co.*, or *Chevron* deference.”²² The Ninth Circuit, for its part, has stated that the “‘rule of reason’ . . . does not materially differ from an ‘arbitrary and capricious’ review.”²³ Judge Patricia Wald bemoaned the fact that “[a]fter fifty years . . . we have yet to agree on how this review should operate in practice. We are still struggling with where to draw the line between obsequious deference and intrusive scrutiny.”²⁴

In prior work, I pooled studies of agency validation that focused on this or that standard of review.²⁵ Pooling eleven studies consisting of 5,081 observations from across all judicial review standards results in an overall agency validation rate of 69%.²⁶ There is little variance among the rates of validation, regardless of the standard. The standard deviation among the studies was 7.54, meaning, roughly, that slightly less than two-thirds of the time the studies placed agency validation rates between 62.5% and 76.5%.²⁷

20. 463 U.S. 29, 52 (1983).

21. See, e.g., William Funk, *Rationality Review of State Administrative Rulemaking*, 43 ADMIN. L. REV. 147 (1991).

22. *Bullcreek v. Nuclear Regulatory Comm'n*, 359 F.3d 536, 541 (D.C. Cir. 2004) (citations omitted).

23. *Neighbors of Cuddy Mountain v. Alexander*, 303 F.3d 1059, 1071 (9th Cir. 2002) (citing *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1149 (9th Cir. 1998)).

24. Patricia M. Wald, *Judicial Review in Midpassage: The Uneasy Partnership Between Courts and Agencies Plays On*, 32 TULSA L.J. 221, 258 (1996).

25. The assumption was that, even if one study is unreliable, averaging a number of studies is more likely to approach something like the “market price” of appellate validation of agency action, regardless of the standard of review.

26. Zaring, *supra* note 3, at 171 tbl.1.

27. *Id.*

2011]

RULE BY REASONABLENESS

531

The implications are notable. While doctrinal enthusiasts might expect wide variance between strong deference and de novo review (given that in the one case—*Chevron*—courts are supposed to defer to any reasonable legal interpretation by the agency, and in the other case—certain questions of the Administrative Procedures Act (APA) and constitutional interpretation—courts are supposed to ignore the legal interpretation of the agency), this sort of variation simply does not exist in the reported cases.

Moreover, there appears to be an increasing level of dissatisfaction with the standards of review where they sit, especially among the federal appellate courts located outside of the District of Columbia.

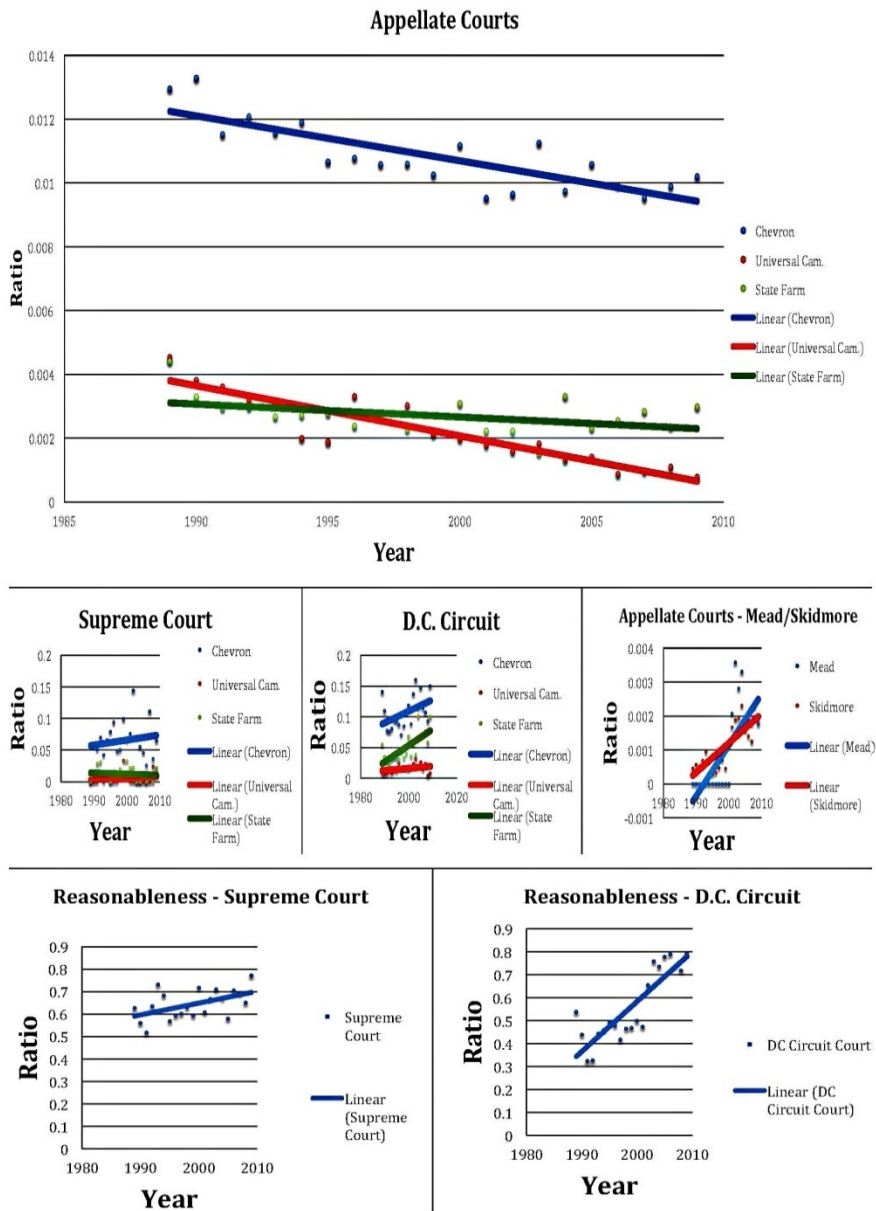


Figure 1: Standards of Review Citation Trends (Source: Westlaw)

When all the federal appellate courts are pooled, they have been citing *Chevron*, *Universal Camera Corp. v. NLRB*,²⁸ and *State Farm* in a lower and lower percentage (or “ratio”) of their total cases over the past twenty years. That trend has been arrested to some degree by the willingness of the D.C. Circuit and the Supreme Court, when taken alone, to continue to cite the fundamental cases in their review of decisions (again, the graphs in Figure 1 recount the percentage of cases in which the seminal standard of review cases are cited).

It has also naturally been arrested by an increase in citation to *United States v. Mead Corp.*²⁹ and *Skidmore* because the Court rendered the *Mead* decision less than twenty years ago, and in so doing revitalized, perhaps briefly, *Skidmore* deference. But at the same time, the terms *reasonable* or *reasonableness* appear in an increasing and very large proportion of all of the decisions of the Supreme Court and D.C. Circuit, one that dwarfs either court’s use of the other standards of judicial review. In fact, as the graphs in Figure 1 show, both courts cite the term *reasonable* or *reasonableness* in a growing majority of their opinions. In this sense, the Supreme Court is citing canonical administrative law cases less often. In the 2009 October term it cited the *Chevron* decision once and the *Skidmore*³⁰ decision once, as Kathryn Watts observed.³¹

One must not read too much into these trend lines, which stem from a growing docket in areas of nonadministrative law as much as anything within the subject matter, and are presented here more as food for thought than as comprehensive, controlled empiricism. However, the pattern suggests that the standard administrative law doctrines may become somewhat less helpful across a broad range of appellate concerns.

These trends—increasingly similar validation rates between the standards of review and a mixed picture of resort to those cases that set forth the baseline of those standards, even as resort to reasonableness grows and grows—have not gone unnoticed in the academy, which has evinced its own dissatisfaction with current doctrine. Jack Beermann leveled a number of well-judged criticisms of the *Chevron* two-step standard of review, which at its worst is in his view both incoherent and indecipherable.³² He

28. 340 U.S. 474 (1951).

29. 533 U.S. 218 (2001).

30. 323 U.S. 134 (1944).

31. Kathryn A. Watts, *Judicial Review*, in DEVELOPMENTS IN ADMINISTRATIVE LAW AND REGULATORY PRACTICE 2009–2010 43, 43–44 (Jeffrey S. Lubbers ed., 2011).

32. See Jack M. Beermann, *End the Failed Chevron Experiment Now: How Chevron Has Failed and Why It Can and Should Be Overruled*, 42 CONN. L. REV. 779, 788–839 (2010) (describing how “*Chevron* has failed” by looking to its intrinsic failings, failings in its application, and its costs and benefits).

exemplifies a growing dissatisfaction with the two-step approach to much of administrative law, and his dissatisfaction is widely shared.³³ Even one of the scholars most supportive of *Chevron*, Richard Pierce, has viewed the growing complexity of a regime he hoped held the promise of simplicity, clarity, and useful judicial deference with some dismay.³⁴

The result has been a growing call for reform. Beermann simply called for *Chevron's* abrogation.³⁵ Others supported a return to the pre-*Chevron* regime of so-called *Skidmore* deference, where courts afford agencies policymaking space essentially based on the quality of that policymaking.³⁶ Adrian Vermeule and Matthew Stephenson have complemented the dissatisfied turn in administrative law scholarship by arguing that the *Chevron* standard is actually incoherent on its own terms.³⁷ They plausibly posit that *Chevron* is not a two-step process at all; the two steps are interchangeable, and really what is going on in administrative law might best be thought of as a single step. In their words, "*Chevron* calls for a single inquiry into the reasonableness of the agency's statutory interpretation."³⁸

This sort of doctrinal revisionism can be developed still further.³⁹ If that one step that Vermeule and Stephenson think better describes *Chevron* review is the reasonableness step, it is not a step that only applies to *Chevron*. Rather, reasonableness is the standard that the courts should, and increasingly do, apply to every reviewable case in administrative law.⁴⁰ Reasonableness applies not only when agencies interpret the extent of their legal authority. It also applies to the other standards of review applicable to agencies, such as whether the agency chose informal or formal

33. See, e.g., William R. Andersen, *Against Chevron—A Modest Proposal*, 56 ADMIN. L. REV. 957, 960 (2004); Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 998–1003 (1992) (criticizing the sequence and the dividing line of the *Chevron* two-step analysis); J.B. Ruhl, *Complexity Theory as a Paradigm for the Dynamical Law-and-Society System: A Wake-Up Call for Legal Reductionism and the Modern Administrative State*, 45 DUKE L.J. 849, 925 (1996).

34. Richard J. Pierce, Jr., *What Do the Studies of Judicial Review of Agency Actions Mean?*, 63 ADMIN. L. REV. 77, 94–95 (2011).

35. See Beermann, *supra* note 32.

36. See, e.g., Cynthia R. Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452, 456 (1989). Nor would Beermann be necessarily opposed to such a formulation. See Beermann, *supra* note 32, at 849–50.

37. Matthew C. Stephenson & Adrian Vermeule, *Chevron Has Only One Step*, 95 VA. L. REV. 597, 598 (2009); see also Ronald M. Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1254 (1997) (arguing that the two *Chevron* steps are identical).

38. Stephenson & Vermeule, *supra* note 37, at 598.

39. Zaring, *supra* note 3, at 186–87.

40. See *id.* at 178 (positing that similar affirmance rates across cases suggests that courts “may use similar degrees of scrutiny regardless of the doctrinal basis of the review”).

adjudication, whether the agency engaged in notice-and-comment rulemaking or formal rulemaking, or whether the court takes a hard look at whatever the agency has done to see whether there is a degree of arbitrariness entwined within the agency's decisionmaking process.⁴¹

There has long been handwringing in academia regarding the possibility that “the rules governing judicial review have no more substance at the core than a seedless grape,”⁴² and that there are “serious questions” about whether they “make[] any sense.”⁴³ Academics have had an increasingly difficult time distinguishing between the various standards of review, and articles like Stephenson's and Vermuele's have questioned the stability of these doctrinal distinctions. Similarly, Judge Brett Kavanaugh of the D.C. Circuit argued that hard look review is better thought of as a review for rationality, and in that sense does not differ much from the second step of the *State Farm* inquiry.⁴⁴ Lisa Bressman identified a common practice used in the appellate courts to engage in *Chevron* avoidance; that is, to either not address *Chevron* or assume that it does not matter.⁴⁵ Current doctrine in administrative law has, as we have seen, been characterized by increasing real-world convergence and stern theoretical critique.

II. SURVEYING REASONABLENESS

It makes sense to think about administrative law doctrine, at least as it actually exists, as something more like a “reasonable agency” standard. A reasonableness standard captures what courts actually do, simplifies a complicated and sometimes bewildering area of doctrine, and makes room for the heuristics that we all suspect are actually applied to agency law.

41. *See id.*

42. Ernest Gellhorn & Glen O. Robinson, *Perspectives on Administrative Law*, 75 COLUM. L. REV. 771, 780 (1975); *see also* STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES 415 (5th ed. 2002) (noting the “many puzzles” involved with sorting through the standards); Ernest Gellhorn, *Justice Breyer on Statutory Review and Interpretation*, 8 ADMIN. L.J. AM. U. 755, 755 n.4 (1995) (questioning “whether the legal rules were worth serious study—or at least the amount of time usually invested in them in the classroom or casebooks”); Paul R. Verkuil, *An Outcomes Analysis of Scope of Review Standards*, 44 WM. & MARY L. REV. 679, 681–82 (2002) (“[R]eviewing judges are still struggling to make sense of these standards, especially as they apply to scope of review of facts or of law and policy.”).

43. GARY LAWSON, FEDERAL ADMINISTRATIVE LAW 364 (4th ed. 2007).

44. *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 247–48 (D.C. Cir. 2008) (Kavanaugh, J., dissenting) (arguing that step two of the *Chevron* inquiry and the *State Farm* hard look inquiry are exceedingly similar, if not identical).

45. Lisa Schultz Bressman, *How Mead Has Muddled Judicial Review of Agency Action*, 58 VAND. L. REV. 1443, 1464–68 (2005).

It also suggests a return to traditional common law roots. As the APA has been characterized as a common law statute in the past, the return would not be so wrenching.⁴⁶

But perhaps most importantly, as this section of the Article discusses, reasonableness works across a broad range of doctrines (and appears in an ever-increasing percentage of Supreme Court and D.C. Circuit opinions), which suggests that it could work for administrative law too. A review of some examples suggests how.

There are many areas of law that both depend upon a reasonableness standard and that no one thinks are lawless outposts of the legal system. Negligence, the foundation of tort law, turns on a reasonableness standard.⁴⁷ So does a great deal of Fourth Amendment law, to such a degree that Akhil Amar wrote that the animating theory of the Fourth Amendment does nothing more than “require that all searches and seizures be reasonable.”⁴⁸ The standards of financial regulation appear to be guided as much by reason as by any other formulation of the standard of agency of supervision—partly because so much of that supervision occurs outside and away from the doctrinal complexity that judges have imposed on other agencies. If reasonableness works in these areas, it is difficult to see why it would not do so in conventional administrative law. Moreover, appellate judges are good at assessing reasonableness, given that they apply it all the time in other contexts, such as when deciding whether the decision of the trier of fact was reasonable.

No one argues that there is no law to apply in negligence cases or Fourth Amendment cases (financial regulation is admittedly a bit more controversial). Instead, these areas of the law exemplify how doctrine—

46. Gillian Metzger has recently made this connection. See Gillian E. Metzger, *Ordinary Administrative Law as Constitutional Common Law*, 110 COLUM. L. REV. 479, 483, 487 (2010); see also Jack M. Beerermann, *Common Law and Statute Law in US Federal Administrative Law*, in ADMINISTRATIVE LAW IN A CHANGING STATE: ESSAYS IN HONOUR OF MARK ARONSON 45, 45–47 (Linda Pearson et al. eds., 2008) (positing that federal courts approach administrative law in a common law way); Kenneth Culp Davis, *Administrative Common Law and the Vermont Yankee Opinion*, 1980 UTAH L. REV. 3, 3–10 (describing the evolution of administrative common law). But cf. John F. Duffy, *Administrative Common Law in Judicial Review*, 77 TEX. L. REV. 113, 115 (1998) (admitting the common law character of administrative law, but suggesting that this character may be changing as more statutes governing agency conduct are enacted).

47. See, e.g., *Martin v. Evans*, 711 A.2d 458, 461 (Pa. 1998) (“Negligence is the absence of ordinary care that a reasonably prudent person would exercise in the same or similar circumstances.”).

48. Akhil Reed Amar, *Fourth Amendment First Principles*, 107 HARV. L. REV. 757, 759 (1994). For just one famous example, see *Terry v. Ohio*, where the Court held that officers must have reasonable suspicion that whomever they have stopped pose a risk to their safety or that of others before they can perform frisks. 392 U.S. 1, 30–31 (1968).

applied through a reasonableness standard—can evolve to provide a great deal of guidance to the particular kinds of facts and circumstances that might count as negligence or a reasonable search. What follows are not definitive accounts of how tort law, Fourth Amendment law, and financial regulation work—multiple treatises and armies of articles have been compiled on each subject—but attempts to show how these areas of the law can depend upon a reasonableness analysis, and how reasonableness works in practice.

A caveat before proceeding: While the reasonableness I propose here would be a standard of review that courts would apply to agency action, that is not precisely what reasonableness means in tort or Fourth Amendment law. The tort and Fourth Amendment doctrines call for an inquiry into the substance of the act—the thing that the tortfeasor or government official did. Standards of review are quasi-procedural in that they tell courts how to think about the record of the proceedings in the agency. Moreover, while in some negligence cases reasonableness is a question for the jury, in administrative law it is one for the judge. In my view, these distinctions are not too important. In tort law, Fourth Amendment law, and my version of administrative law, courts apply reason to evaluate the conduct of tortfeasors, police officers (or other government officials), or agencies. Indeed, because both the Fourth Amendment and administrative law concern the conduct of public officials, rather than private actors, the analogy there is especially close.

A. *Torts*

The premise of negligence law is that we owe everyone a duty to exercise reasonable care in the conduct of our affairs.⁴⁹ As one English court put it, “Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do.”⁵⁰ To avoid negligence liability, one must act as a “reasonable man under like circumstances,” according to the Restatement (Second) of Torts.⁵¹ How would a reasonable man act, though? In Prosser and Keeton’s view, the reasonable person is a person

49. JOSEPH W. GLANNON, *THE LAW OF TORTS: EXAMPLES AND EXPLANATIONS* 70 (3d ed. 2005).

50. *Blyth v. Birmingham Waterworks Co.*, (1856) 156 Eng. Rep. 1047 (Ex.) 1049; 11 Ex. 781 (Alderson, B.).

51. RESTATEMENT (SECOND) OF TORTS § 283 (1965).

who acts at all times with “ordinary prudence, . . . reasonable prudence, or some other blend of reason and caution.”⁵²

Courts have further refined this broad instruction over the course of centuries. Sometimes they have been presented with almost philosophical questions about reasonableness. It has been suggested that reasonable people must consider the foreseeable risks of injury that their conduct will impose on others in light of its utility,⁵³ and that actors must consider the extent of the risks posed by their actions.⁵⁴ Sometimes the guidance is expressed as a form of cost–benefit calculation, which itself has been the subject of many efforts to jurisprudentially specify what the requirement is. In cost–benefit terms, reasonable people should evaluate the likelihood of actually causing harm,⁵⁵ whether alternatives to their conduct would reduce the risk,⁵⁶ the cost of potential harm, and whether the potential costs outweigh the benefits.⁵⁷ This sort of abstract instruction might seem inscrutable, at least to enthusiasts for clear rules. But these theoretical inquiries do set the basic standards in place for interpretation. They are meant to make some sense of a broad standard, to impart some rules of decision to make sense of what reasonableness means. In turn, this sort of instruction is meant to make a reasonableness standard more generally tractable. The next step is to make it understandable in a variety of contexts—and that is what a host of reported decisions have done.

Above all, the reasonableness inquiry requires courts to make concrete decisions and provide clarity about the standards of conduct expected by reasonableness. We know what constitutes, for example, reasonable care for invitees⁵⁸ and for hosting events where alcohol is served,⁵⁹ either as a

52. PROSSER & KEETON ON THE LAW OF TORTS § 32 at 174 (W. Page Keeton ed., 5th ed. 1984).

53. RESTATEMENT (SECOND) OF TORTS § 291 (1965).

54. *Id.* § 293.

55. *Id.* § 293(b).

56. *Id.* § 292(c).

57. This cost–benefit calculation was embodied by Judge Learned Hand’s $B < PL$ formula. As Hand put it, negligence turns on “a function of three variables: (1) The probability that [an accident will occur]; (2) the gravity of the resulting injury, if [it] does; (3) the burden of adequate precautions. Possibly it serves to bring this notion into relief to state it in algebraic terms: if the probability be called P; the injury, L; and the burden, B; liability depends on whether B is less than L multiplied by P, i.e., whether B [is less than] PL.” *United States v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir. 1947). For a discussion of the formula, see Lewis F. Powell, Jr., *Foreward* to GERALD GUNTHER, *LEARNED HAND: THE MAN AND THE JUDGE*, at x (1994); Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 32–33 (1972) (endorsing the Hand formula).

58. *See, e.g.*, *Massey v. Tingle*, 867 So. 2d 235, 239 (Miss. 2004) (explaining that the owner of the premises “is not an insurer of the invitee’s safety, but does owe to an invitee the duty to keep the premises reasonably safe, and when not reasonably safe, to warn only

business or as a party thrower. There is a reasonable care standard for medical malpractice, and appellate decisions have described what medical malpractice in various specialties and subspecialties might look like.⁶⁰ Negligence law is even more specific, even as it reaches broadly; although it does not permit people to avoid judicial assessment on the reasonableness of their actions because of their limited abilities or even insanity,⁶¹ it does take the particular circumstances of a wide array of situations into account.⁶²

All of this is the sort of work that all law students, as first-year students of tort law or takers of the bar exam, are expected to master, a fact that is itself a testament to the tractability of reasonableness. Whatever its definitional ambiguities, reasonableness has proven to be a useful concept in torts—so useful that it has become the jurisprudential underpinning of that entire field of law.

B. Fourth Amendment

Criminal procedure, especially as it concerns the Fourth Amendment, is also premised on a reasonableness inquiry, or perhaps more accurately, a number of them. The Fourth Amendment itself provides that there is a right “against unreasonable searches and seizures.”⁶³ Interpreting what exactly *unreasonable* means turns, in different contexts, on the reasonable expectations of privacy on the part of the citizens and the reasonableness of the imposition by the government authority.⁶⁴ Conversely, where there is a

where there is hidden danger or peril that is not in plain and open view” (emphasis omitted) (internal quotation marks omitted) (citing *Corley v. Evans*, 835 So. 2d 30, 37 (Miss. 2003))).

59. See, e.g., *Hansen v. Friend*, 824 P.2d 483, 486 (Wash. 1992) (holding that social hosts have a duty of care not to serve liquor to minors and are liable for injuries that are proximately caused by breach of this duty).

60. See, e.g., *Johnson v. Riverdale Anesthesia Assocs., P.C.*, 547 S.E.2d 347, 348 (Ga. Ct. App. 2001) (holding that the applicable standard of care in a medical malpractice case is that employed by the medical profession generally and not what an individual doctor would have done under the circumstances (citing *McNabb v. Landis*, 479 S.E.2d 194 (Ga. Ct. App. 1996))).

61. *Vaughan v. Menlove*, (1837) 132 Eng. Rep. 490 (C.P.) 492–93; 3 Bing. (N.C.) 468, 471–72 (rejecting the argument that an individual with poor judgment ought to be able to avoid being held negligent because subjective reasonableness to them was less than the subjective reasonableness to the average person).

62. Similarly, legal malpractice depends not on a reasonable lay person’s knowledge of the law but rather a reasonable lawyer’s skills and training in assessing whether their standard was up to snuff.

63. U.S. CONST. amend. IV.

64. *Illinois v. Rodriguez*, 497 U.S. 177, 183–86 (1990) (recognizing that the ultimate Fourth Amendment foundation is reasonableness, not warrants).

“reasonable expectation of privacy,” the Fourth Amendment has been interpreted to require the issuance of a warrant before privacy expectations can be impinged upon.⁶⁵ Here, too, reasonableness has its ambiguities, but it has proven to be a workable concept that allows judges and other government officials to apply the protections of the Fourth Amendment to a vast array of contexts. The courts (in the Fourth Amendment context, it is often the Supreme Court that sets the rules) have also wrestled with philosophical and practical questions about what reasonableness, broadly defined, means. In what follows, I sample various ways that courts have used the reasonableness inquiry to specify what government officials may and may not search or take.

The courts have ruled that warrantless searches may be reasonable if done pursuant to an arrest.⁶⁶ Where justified by special needs beyond the normal need for law enforcement, the courts have also upheld warrantless searches in public schools, government offices, and prisons—in each case dispensing with a warrant and probable cause requirements in favor of a reasonableness standard that balances the government’s interest against the individual’s interest and privacy.⁶⁷ In the same way, privacy expectations have also been deemed less reasonable given a history of pervasive regulation of an industry; such a history has made administrative searches (such as spot inspections by United States Department of Agriculture or

65. *Katz v. United States*, 389 U.S. 347, 360–61 (1967) (Harlan, J., concurring). Although “reasonable expectation of privacy” was first formulated in a concurring opinion, the Court has cited it as a concise formulation of what the majority was after. *See, e.g., Terry v. Ohio*, 392 U.S. 1, 9 (1968); *cf. Mapp v. Ohio*, 367 U.S. 643, 655–56 (1961) (providing for the exclusion of evidence that is obtained through an unreasonable search). As Akhil Amar put it, “in the landmark *Katz* case, the Court, perhaps unconsciously, smuggled reasonableness into the very definition of the Amendment’s trigger: the Amendment comes into play whenever government action implicates a ‘reasonable expectation of privacy.’” Amar, *supra* note 48, at 769.

66. *See Harris v. United States*, 331 U.S. 145, 155 (1947) (finding the search of a four-room apartment without a warrant pursuant to an arrest of a man in the apartment to be a reasonable search and consistent with the Fourth Amendment); *see also Fahy v. Connecticut*, 375 U.S. 85, 86–87 (1963) (holding that where evidence has been unlawfully obtained in violation of the accused’s constitutional rights and has been erroneously admitted in evidence, there must be a reversal if there was a reasonable possibility that the evidence complained of might have contributed to the conviction).

67. One of the many treatises that could be cited here, in addition to the *Katz* and *Terry* cases, is the useful Congressional Research Service’s online treatise on the Constitution. *See CONG. RESEARCH SERV., NO. 103-6, THE CONSTITUTION OF THE UNITED STATES OF AMERICA: ANALYSIS AND INTERPRETATION 1204* (Johnny H. Killian & George A. Costello eds., 1996), <http://www.gpoaccess.gov/constitution/pdf/con015.pdf>.

Occupational Safety and Health Administration officials) without warrants more presumptively legitimate.⁶⁸

Determining what that individual's interest is—again, she is entitled to a reasonable expectation of privacy—has also produced a great deal of jurisprudence.⁶⁹ After the Supreme Court announced that reasonableness would encompass the content of the rights of the citizenry against searches in a series of cases in the 1960s,⁷⁰ judges have found that reasonable expectation of privacy is particularly strong in the home,⁷¹ while privacy expectations outside of the home, such as in automobiles, are less reasonable.⁷²

Applicants for warrants must establish probable cause to obtain one, and that too requires an inquiry into the reasonableness of the request. As the Supreme Court has said:

In determining what is probable cause . . . [w]e are concerned only with the question whether the affiant had *reasonable* grounds at the time of his affidavit . . . for the belief that the law was being violated on the premises to be searched; and if the apparent facts set out in the affidavit are such that a *reasonably* discreet and prudent man would be led to believe that there was a commission of the offense charged, there is probable cause justifying the issuance of a warrant.⁷³

Probable cause, for its part, is to be ascertained by “the factual and practical considerations of everyday life on which *reasonable and prudent* men, not legal technicians, act.”⁷⁴

68. *Skinner v. Ry. Labor Execs.' Ass'n*, 489 U.S. 602, 627 & n.8 (1989).

69. 4 WAYNE R. LAFAVE, *SEARCH AND SEIZURE: A TREATISE ON THE FOURTH AMENDMENT* § 9.5 (4th ed. 2004) (“Reasonable suspicion of crime or any comparable test will, of course, seem rather vague when unadorned by judicial interpretation based upon specific fact situations, as would the ‘reasonable grounds to believe’ test for arrest, or, for that matter, the ‘probable cause’ requirement of the Fourth Amendment. It is certainly asking too much to expect that the basic standard which is to serve as the starting point for analysis should from its inception provide a ready answer for every conceivable fact situation.”).

70. Although there, reasonableness was defined narrowly, and unreasonableness, in many cases, presumed. The Court before then, and on occasion afterwards, suggested that “searches conducted outside the judicial process, without prior approval by judge or magistrate, are per se unreasonable under the Fourth Amendment—subject only to a few specifically established and well-delineated exceptions.” *Coolidge v. New Hampshire*, 403 U.S. 443, 454–55 (1971) (internal quotation marks omitted) (citing *Katz*, 389 U.S. at 357).

71. *See, e.g.*, *Payton v. New York*, 445 U.S. 573, 602 (1980); *Alderman v. United States*, 394 U.S. 165, 176–77 (1969).

72. *See, e.g.*, *Katz*, 389 U.S. at 352.

73. *Dumbra v. United States*, 268 U.S. 435, 441 (1925) (emphases added).

74. *Brinegar v. United States*, 338 U.S. 160, 175 (1949) (emphasis added).

The ability to conduct a search without obtaining a warrant, if it is not covered by one of the reasonableness exceptions, depends on the reasonableness of the suspicion of the police officer.⁷⁵ In *Terry v. Ohio*, the case that made clear that police officers could search some people without warrants, the Court indicated that the inquiry would turn on whether the police officer's actions were reasonable, as tested by whether the police officer could point to "specific and articulable facts which, taken together with rational inferences from those facts," would lead to magistrate on review to conclude that the search was reasonable.⁷⁶ A reasonable suspicion of criminal activity, in other words, is the standard for these sorts of warrantless stops.

Here, too, a substantial body of reported decisions has arisen. Indeed, the very policing of whether a stop has occurred or not turned on whether "a reasonable person would have believed that he was not free to leave."⁷⁷ If a reasonable person would "feel free to decline the officers' requests or otherwise terminate the encounter," the stop is not a stop.⁷⁸

This reasonableness standard has been further specified and contextualized in Fourth Amendment law, just as it has in negligence law. It has gotten the courts, including the Supreme Court, into specific opinions on fingerprints, blood, urine samples, skin scrapings, voice and handwriting exemplars, conversations, and other evidence.⁷⁹ Reasonableness also governs the inquiry as to the appropriateness of various sorts of tracking devices.⁸⁰

All told, because of its centrality in Fourth Amendment doctrine, reasonableness is the standard underpinning many of our privacy protections in constitutional law. That inquiry has permitted the development of a very specific jurisprudence to deal with individual cases and questions of reasonableness in particular factual circumstances.

75. *Terry v. Ohio*, 392 U.S. 1, 20–21 (1968) (applying the reasonableness inquiry to stops and frisks); *United States v. Castellanos*, 731 F.2d 979, 983 (D.C. Cir. 1984) (holding that the test as to whether a "seizure" has occurred "is whether police engaged in a show of authority which would lead a reasonable person, innocent of any crime, to conclude he was not free to go under all the circumstances").

76. 392 U.S. at 20–22.

77. See WAYNE R. LAFAYE & JEROLD H. ISRAEL, CRIMINAL PROCEDURE § 3.8(c), at 206 (2d ed. 1992) (footnote omitted) (citing *United States v. Mendenhall*, 446 U.S. 544, 554–55 (1980) (plurality opinion)).

78. *Florida v. Bostick*, 501 U.S. 429, 436 (1991).

79. See CONG. RESEARCH SERV., *supra* note 67, at 1224.

80. *United States v. Pineda-Moreno*, 591 F.3d 1212, 1216–17 (9th Cir. 2010) (concluding that law enforcement agents' use of a tracking device attached to defendant's vehicle to continuously monitor the location of a vehicle is not a search).

It is accordingly unsurprising that Akhil Amar's theoretical conception of what the Fourth Amendment is supposed to do is premised primarily on the idea that the reasonableness inquiry explains what the Fourth Amendment is meant to do.⁸¹ Amar's insight—perhaps the leading theoretical exposition of the point of the Fourth Amendment and one inclined favorably toward the reasonableness analysis—again explains how reason does not mean that the government can do whatever it wants. Or, for that matter, that courts will be enabled to interpret the directive any which way.

C. *Financial Regulation*

Administrative law, at least as it is currently studied and taught, has been uncomfortably paired with financial regulation, which works differently than the litigation-intensive, rule-oriented world of health, safety, and environmental regulation.⁸² But financial regulation turns on a variety of reasonableness inquiries as well, although the rules defining the business of banking or ensuring that those institutions are safe and sound often appear to be convoluted and hypertechnical. Because reasonableness appears in many specific areas of financial regulation as the test to apply, particularly in those areas amended after the financial crisis, and is probably the unstated standard to which the overall performance of the regulators is measured, I offer it here as a third case study for the relevance of

81. Amar, *supra* note 48, at 759; *see also* Akhil Reed Amar, *The Future of Constitutional Criminal Procedure*, 33 AM. CRIM. L. REV. 1123, 1133 (1996) (“Shouldn’t ‘reasonableness’ under the Fourth Amendment be read in light of other constitutional values—of property, privacy, equality, due process, free speech, democratic participation, and the like—affirmed in other amendments? Shouldn’t Seventh Amendment juries play some role in determining Fourth Amendment reasonableness, just as they play a role in determining reasonableness generally in tort law?”). *But see* Carol S. Steiker, *Second Thoughts About First Principles*, 107 HARV. L. REV. 820, 825 (1994) (“[T]he modern Court’s (at least occasional) focus on warrants and probable cause as the touchstones of constitutional ‘reasonableness’ and on the exclusionary rule as a distinctive Fourth Amendment remedy can and should be defended against the more freewheeling ‘reasonableness’ inquiry . . .”). And for a new take on Fourth Amendment fundamentals, *see* Orin S. Kerr, *An Equilibrium-Adjustment Theory of the Fourth Amendment*, 125 HARV. L. REV. (forthcoming 2011) (manuscript at 10–12), available at <http://ssrn.com/abstract=1748222>, where Kerr posits that the Supreme Court adjusts the scope of protection in response to new facts and technological innovations in order to restore the status quo level of protection.

82. *See* Zaring, *supra* note 13, at 201 (“Between 1998 and 2008 . . . the EPA was a party to 199 cases in the D.C. Circuit; and the Department of Transportation was a party to thirty-five such cases. In contrast, Treasury was a party to only fourteen cases during that decade, . . . seven percent the EPA number.” (citations omitted)); *id.* at 193 (“[F]inancial regulation—which standalone parts of Treasury do for both banks and thrifts—is simply less litigious than is the sort of regulated industry oversight that other important agencies, such as the Environmental Protection Agency (EPA), perform.”).

reasonableness. Although the observation is made cautiously, a broad recognition that the rule of reason is the rule applied by financial regulators in much of what they do, even when they are doing something unlikely to be subject to judicial review, might enable scholars to take a more holistic approach to administrative law, one more inclusive of the agencies that do important work, but that makes an uneasy fit with the current doctrines. Although judicial review of agency action and the standards of financial regulation are unlikely to grow together soon, evaluating them on the same metric might reconnect administrative law scholarship with an important administrative enterprise that it has ignored for too long. And so financial regulation is included as an example of reasonableness regulation somewhat tendentiously because of its importance and seeming distance from the conventional tropes of administrative law (which, of course, turn more on reasonableness than I think has been recognized).

To the extent that modern financial institutions have increasingly ventured into the capital markets, they are subject to a reasonableness inquiry. Reasonableness defines what would be “material” information that must be disclosed to investors. The Supreme Court defined *materiality* in *TSC Industries, Inc. v. Northway, Inc.* by reference to what a “reasonable shareholder” would consider important.⁸³ The due diligence that must be done for public offerings uses a “reasonable” investigation standard.⁸⁴ And the stock exchange standards for suitability (when broker-dealers must ensure that investments are suitable for customers) also use a reasonable standard.⁸⁵

Reasonableness has become a centerpiece of the newest model of financial regulation. The Dodd-Frank Act is replete with requirements that regulators analyze their industry through a reasonableness lens. Under § 112(b) of the Act, core financial regulators must sign an annual statement to the effect that they are convinced that the government and the private sector are “taking all reasonable steps to ensure financial stability and to mitigate systemic risk.”⁸⁶ A number of anti-evasion devices in the statute

83. 426 U.S. 438, 449 (1976). Although that case involved a potentially misleading proxy statement, the *TSC* standard has been applied to most other securities contexts where materiality is the touchstone.

84. Securities Act of 1933 § 11, 15 U.S.C. § 77(k) (2006).

85. *FINRA Manual, NASD Rules: Rule 2310, Recommendations to Customers (Suitability)*, FIN. INDUS. REGULATORY AUTH., INC., available at http://finra.complinet.com/en/display/display_viewall.html?rbid=2403&element_id=3638&record_id=4315 (last visited Aug. 14, 2011).

86. Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. No. 111-203, § 112(b), 124 Stat. 1376, 1396 (2010) (to be codified at 12 U.S.C. § 5322).

also use reasonableness standards.⁸⁷ The Act grants “reasonable discretion” to various private sector derivative bodies charged with centralizing clearing of derivatives, information gathering, or providing swap execution facilities—these would be the derivatives-clearing organizations that are meant to provide a liquid market and more open price discovery of these relatively newfangled financial instruments that many institutions misvalued during the financial crisis (particularly housing-related derivatives).⁸⁸ It also allows the Federal Reserve to take enforcement actions against financial utilities and financial institutions if the it has “reasonable cause.”⁸⁹ A similar reasonable cause standard marks the Consumer Financial Protection Bureau’s enforcement powers; in defining what constitutes “abusive” practices that the Bureau can regulate, the Act uses a reasonable standard.⁹⁰ In one of the Act’s more controversial features, the Federal Reserve Board may limit the “interchange transaction fees” for debit cards, or what payment networks can charge merchants for using debit card networks, to those fees that are “reasonable.”⁹¹ And residential mortgage lenders must now ensure that borrowers have a “reasonable” ability to repay.⁹² It might be said that the consumer protection provisions of the Act almost entirely turn on reasonableness.

In addition, financial regulators, and the lawyers who appear before them, deal with bet-the-bank transactions, such as mergers and acquisitions and the attendant antitrust review—a review complicated by the size limitations imposed on banks—and as we know, those objectives depend on reasonableness as well.⁹³ Since such mergers have to win the approval of the Federal Reserve Board as well as the antitrust regulators, banking lawyers have participated in the review and approval process for these

87. See, e.g., *id.* sec. 619, §13(e), 124 Stat. at 1627 (to be codified at 12 U.S.C. § 1851).

88. *Id.* sec. 725, § 5b(c), 124 Stat. at 1687–85 (to be codified at 7 U.S.C. 7a–1(c)); *id.* sec. 728, § 21, 124 Stat. at 1697 (to be codified at 7 U.S.C. 24a); *id.* sec. 733, § 5h, 124 Stat. at 1713–14 (to be codified at 7 U.S.C. § 7b–3).

89. *Id.* § 807(e), 124 Stat. at 1814–15 (to be codified at 12 U.S.C. § 5466); *id.* § 808(e), 124 Stat. at 1817 (to be codified at 12 U.S.C. § 5467).

90. *Id.* § 1031(d), 124 Stat. at 2006 (to be codified at 12 U.S.C. § 5531).

91. *Id.* sec. 1075, § 920(a)(2), 124 Stat. at 2068 (to be codified at 15 U.S.C. § 1693o–2).

92. *Id.* sec. 1401, § 103, 124 Stat. at 2137–38 (to be codified at 15 U.S.C. § 1602). Creditors have to make a “reasonable and good faith determination” into the borrower’s ability to repay. *Id.* sec. 1411, § 129C, 124 Stat. at 2142 (to be codified at 15 U.S.C. § 1639c).

93. The Reigle–Neal Act prevents bank holding companies from obtaining more than 10% of the total deposits in institutions insured by the Federal Deposit Insurance Corporation (FDIC) via acquisition of out-of-state banks, though it can expand by other means, such as through internal deposit growth. See 12 U.S.C. §§ 1831u(b)(2)(A), 1842(d)(2)(A) (2006). For an extended discussion, see RICHARD SCOTT CARNELL ET AL., *THE LAW OF BANKING AND FINANCIAL INSTITUTIONS* 186–87 (4th ed. 2009).

transactions, which turn upon their own rule of reason—the rule that antitrust law applies to all restraints on trade.⁹⁴ Related to these issues is the sort of wise counsel that banking lawyers who understand the affiliation limitations on banks (that is, the limitations on the businesses that the bank holding companies can acquire in addition to holding chartered banks or thrifts) provide.⁹⁵

Finally, although the mechanism is difficult to specify, the reasonableness inquiry captures the constraints on financial regulators as well as anything else. During the crisis, those regulators all but threw out the rule book in pursuit of means to stabilize the financial system.⁹⁶ It is that stabilization

94. *Standard Oil Co. v. United States*, 221 U.S. 1, 66–67 (1911) (“[T]he construction which we have deduced from the history of the act and the analysis of its text is . . . that in every case where it is claimed that an act or acts are in violation of the [antitrust] statute the rule of reason, in the light of the principles of law and the public policy which the act embodies, must be applied.”). Courts have consistently moved away from per se rules in antitrust law and *California Dental Ass’n v. FTC*’s assertion that there is no “categorical line to be drawn between restraints that rise to an intuitively obvious inference of anticompetitive effect and those that call for more detailed treatment” but that “what is required, rather, is an enquiry meet for the case.” 526 U.S. 756, 780–81 (1999). This implies an analysis based in reasonableness for all restraints on trade, but one would not want to overstate the case. Horizontal price fixing is still per se illegal, and horizontal market division is all but per se illegal, if it is not in fact per se illegal.

95. Again, for an extended discussion, see CARNELL, *supra* note 93, at 425–94. And these are not the only things banking lawyers do, of course. These lawyers and their charges at the banks remain in close contact with the government, as the Treasury Secretary’s and Federal Reserve Chairman of New York’s contacts with the banks during the financial crisis revealed. One lawyer in particular, Rodgin Cohen, played an especially important role in maintaining this sort of contact with the government and mediating the government’s interests with those of the banks he represented during the financial crisis. This sort of close contact work is another responsibility of banking lawyers, and it is not one that creates actions suitable for review under traditional administrative law doctrines.

96. Steven M. Davidoff & David Zaring, *Regulation by Deal: The Government’s Response to the Financial Crisis*, 61 ADMIN. L. REV. 463, 468 (2009) (explaining that the response to the financial crisis was a real departure from the normal notice-and-comment form of rulemaking); Gary Lawson, *Burying the Constitution Under a TARP*, 33 HARV. J.L. & PUB. POL’Y 55, 57 (2010) (using the Troubled Asset Relief Program (TARP) as an example of the unconstitutionality of modern administrative law); Alexander Mehra, *Legal Authority in Unusual and Exigent Circumstances: The Federal Reserve and the Financial Crisis*, 13 U. PA. J. BUS. L. 221, 222 (2010) (evaluating the scope of the Federal Reserve’s § 13(3) lending powers and arguing that by purchasing assets and extending credit against corporate shares, the Federal Reserve exceeded the bounds of its statutory authority during the financial crisis); Richard J. Pierce, Jr., *Presidential Control Is Better Than the Alternatives*, 88 TEX. L. REV. *SEE ALSO* 113, 123–24 (2009), <http://www.texaslrev.com/sites/default/files/seealso/vol88/pdf/88TexasLRevSeeAlso113.pdf> (describing this process); Eric A. Posner & Adrian Vermeule, *Crisis Governance in the Administrative State: 9/11 and the Financial Meltdown of 2008*, 76 U. CHI. L. REV. 1613, 1624–30 (2009) (stating that some of Treasury’s actions during the financial crisis were probably not legal); Simon Johnson, *The Quiet Coup*, 303 ATLANTIC, May 2009, at 46, 49,

function, more than any other, which organizes the efforts of the varied collection of agencies that oversee the financial system.⁹⁷ Indeed, although there are many different regulators in the financial regulatory universe, and they have somewhat different roles, each of them is charged with ensuring that banks are safe and sound. Although that inquiry is both exceedingly technical and one that has its own terminology, one suspects that the gestalt of the inquiry does turn, in fact, on reasonableness.⁹⁸

available at <http://www.theatlantic.com/magazine/archive/2009/05/the-quiet-coup/7364/> (arguing that banks captured the policymaking process during the financial crisis). For a comprehensive look at what has been spawned by the crisis, see generally DAVIS POLK & WARDWELL LLP, FINANCIAL CRISIS MANUAL: A GUIDE TO THE LAWS, REGULATIONS AND CONTRACTS OF THE FINANCIAL CRISIS (2009), <http://www.davispolk.com/files/Publication/d1ab7627-e45d-4d35-b6f1-ef356ba686f2/Presentation/PublicationAttachment/2a31cab4-3682-420e-926f-054c72e3149d/fcm.pdf>.

97. For a discussion of these regulators, see Adam J. Levitin, *Hydraulic Regulation: Regulating Credit Markets Upstream*, 26 YALE J. ON REG. 143, 149 (2009) (“For federally chartered banks, the regulator depends on the type of charter. The Office of the Comptroller of the Currency (OCC), a bureau of the Treasury Department, has primary authority over entities with national bank charters (‘national banks’). Another Treasury office, the Office of Thrift Supervision (OTS) has authority over entities with a federal thrift charter, such as savings associations, savings banks, and savings and loans (‘national thrifts’). Although the OCC and the OTS are part of the Treasury Department, they are autonomous, and the Treasury Secretary lacks authority to compel the Comptroller of the Currency or the Director of the OTS to promulgate any rule. Additionally, an independent agency, the National Credit Union Administration (NCUA), has authority over federal credit unions.” (footnote omitted)); Lawrence A. Cunningham & David Zaring, *The Three or Four Approaches to Financial Regulation: A Cautionary Analysis Against Exuberance in Crisis Response*, 78 GEO. WASH. L. REV. 39 (2009) (describing the differences between the regulators); Howell E. Jackson, *A Pragmatic Approach to the Phased Consolidation of Financial Regulation in the United States* 3–4 (Harvard L. School Pub. Law & Legal Theory Working Paper Series, Paper No. 09-19, 2008), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1300431 (critiquing the divergent approaches within the United States); Roberta Romano, *The Political Dynamics of Derivative Securities Regulation*, 14 YALE J. ON REG. 279, 282 (1997) (“The regulation of financial markets in the United States is dispersed. Securities are regulated by the Securities and Exchange Commission (SEC) while derivatives on securities—financial instruments whose value is derived from an underlying security or index of securities—are regulated by a variety of agencies. Options on securities are regulated by the SEC; futures, and options on futures by the Commodity Futures Trading Commission (CFTC); and off-exchange-traded forward contracts, options, and swaps are typically not subject to any federal regulation (unless undertaken by an institution which is itself federally regulated, such as banks). This multiplicity of regulatory authority has been the principal bone of regulatory contention for decades, as regulators, interest groups and legislators have sought to shift jurisdiction to their preferred agency. Even when a regulator does not object to another’s jurisdictional grab, market participants have contested the agencies’ authority to do so in court.”); John C. Coffee, Jr., *Competition Versus Consolidation: The Significance of Organizational Structure in Financial and Securities Regulation*, 50 BUS. LAW. 447, 448–50 (1995).

98. Lawrence G. Baxter, *Capture in Financial Regulation: Can We Channel It Toward the Common Good?*, 21 CORNELL J.L. & PUB. POL’Y [hereinafter Baxter, *Capture in Financial*

Regulators manage all these charges without reference to the standards of review promulgated so complicatedly by the Supreme Court, or with reference to the cost–benefit analysis that has animated so much regulation and evaluation of regulations in other industries.⁹⁹ As Julie Hill has explained, “regulators likely use rules of thumb that are not memorialized in publicly available material” when they make their decisions about bank

Regulation] (forthcoming 2011) (manuscript at 6), available at <http://ssrn.com/abstract=1769203>. Compliance with basic safety and soundness rules involves interaction and negotiation with bank examiners who, every three to five quarters (they are charged with conducting annual examinations of the banks they supervise), enter the premises of banks, review their books and spreadsheets, internal controls, and other matters, and draw a conclusion as to whether the institutions have sufficient capital on hand. See generally Beverly J. Hirtle & Jose A. Lopez, *Supervisory Information and the Frequency of Bank Examinations*, 5 FRBNY ECON. POL'Y REV., Apr. 1999, at 1, 2–3 (1999), available at <http://www.frbsf.org/economics/economists/jlopez/hirtle.pdf> (describing the timing and process of bank examinations). In my view, compliance and supervision is done on a reasonableness basis—reasonable compliance with the basic rules—though the question is not entirely without doubt. The so-called CAMELS system exemplifies efforts to get some precision into otherwise rather broad question about safety and soundness, and marks how this sort of supervision has rules in place. CAMELS is a five-point scale on which the regulators evaluate the regulated entities on six different issue areas: (C)apital adequacy, (A)ssset quality, (M)anagement ability, (E)arnings, (L)iquidity, and (S)ensitivity to risk. *Risk Categories & Risk-Based Assessment Rates*, FDIC, <http://www.fdic.gov/deposit/insurance/assessments/risk.html> (last visited Aug. 14, 2011). For a discussion, see Peter S. Kim, *The FDIC's Special Assessment: Basing Deposit Insurance on Assets Instead of Deposits*, 14 N.C. BANKING INST. 381, 401–02 (2010); Jonathan R. Macey & Geoffrey P. Miller, *Bank Failures, Risk Monitoring, and the Market for Bank Control*, 88 COLUM. L. REV. 1153, 1226 (1988). For each of these issue areas, the regulators devise a five-point scale, and an overall five-point rating, with low scores being awarded to safe and sound banks. High-scoring banks may be subject to “prompt corrective action” notices, written agreements, cease and desist orders, or other enforcement mechanisms, all designed to get banks to replenish their capital and possibly to root out the practices or people at the bank that led to undercapitalization (the process by which each regulator chooses to make use of these various enforcement mechanisms is rather opaque). For a careful discussion and critique, see Lawrence G. Baxter, *Administrative and Judicial Review of Prompt Corrective Action Decisions by the Federal Banking Regulators*, 7 ADMIN. L.J. AM. U. 505, 567 (1994) (“Four features seem to be particularly important: absence of clear protection against improper classification decisions; uncertainty regarding the availability of judicial review; the anomalous coexistence of PCA [the prompt corrective action system] and formal enforcement powers; and anomalous inconsistencies between PCA and conservatorship/receivership powers.”). See also Gail Otsuka Ayabe, Comment, *The “Brokered Deposit” Regulation: A Response to the FDIC's and FHLBB's Efforts to Limit Deposit Insurance*, 33 UCLA L. REV. 594, 624 n.194 (1985) (“A ‘problem’ bank is a CAMEL 4- and 5-rated bank. A ‘near-problem’ bank is a CAMEL 3-rated bank.” (citations omitted)).

99. See generally Baxter, *Capture in Financial Regulation*, *supra* note 98 (manuscript at 20); Edward Sherwin, *The Cost–Benefit Analysis of Financial Regulation: Lessons from the SEC's Stalled Mutual Fund Reform Effort*, 12 STAN. J.L. BUS. & FIN. 1, 12–17 (2006) (arguing that regulation has become separated from that basic administrative law principle, the cost–benefit analysis).

safety and soundness.¹⁰⁰ In doing this, bank regulators are not just charged with insuring the safety and soundness of the system but rather have a pro-bank mandate as well to ensure that the banking system as a whole operates efficiently.¹⁰¹ Here too, the reasonableness inquiry is exceedingly difficult to detach from a governance enterprise; if it applies to banking regulation, perhaps reasonableness can work for the standards of review as well.

The foregoing does not mean that the only way to evaluate the performance of financial regulators is to consider whether they did a reasonable job; but rather that it is likely that it probably does characterize that evaluation in practice. That evaluation is rarely done by courts under the doctrines of judicial review of agency action but nonetheless characterizes the standards to which other government actors hold these agencies.

D. Conclusion

In tort law, the standard of reasonable care is the premise of the negligence law that is the most common basis for tort liability. In criminal procedure, the Supreme Court has concluded that the Fourth Amendment prohibits unreasonable searches and seizures and has defined the assessment of that term through a reasonableness standard. Under both of these standards, thousands of cases are adjudicated every year. Whole treatises have been written that focus on the evaluation of reasonable conduct in both contexts. And in financial regulation—especially in the post-Dodd–Frank version of it—reasonableness is the coin of the realm. We have, in short, collectively made our peace with the legal tractability of the reasonableness standard through many cases and bureaucratic disputes.

Reasonableness in the context of administrative law is not very different from the doctrinally familiar mandate that government officials may not act arbitrarily and capriciously—itsself a capacious concept.¹⁰² In reasonableness contexts, reported cases serve as guides for a more precise, fact-dependent and fine-grained inquiry into the sort of law that should be applied in any particular context.¹⁰³

100. Julie Andersen Hill, *Bank Capital Regulation by Enforcement: An Empirical Study*, IND. L.J. (forthcoming) (manuscript at 50), available at <http://ssrn.com/abstract=1773072>. Hill further stated, “The individual bank minimum capital requirements contained in the formal capital enforcement actions seem to hint that regulators employ non-public rules of thumb.” *Id.*

101. *See id.* (manuscript at 4–6).

102. *See supra* note 46 and accompanying text.

103. One way to think about this matter might be adduced from the way Akhil Amar approaches the reasonableness inquiry in the Fourth Amendment context, in which the “other parts of the Bill of Rights . . . identify constitutional values that are elements of

Moreover, the examples of reasonableness considered in this Article are not the only examples. Courts premise the materiality element of the antifraud laws on what “reasonable investors” would find material.¹⁰⁴ Sexual harassment is proven by showing harassment sufficiently “severe or pervasive” that it is both subjectively and objectively hostile or abusive, as judged by a “reasonable person” standard.¹⁰⁵ The “rule of reason” has been the law of the Sherman Act for well over a century—and the move from per se rules in antitrust to a general reasonableness test has been one of the features of modern antitrust regulation.¹⁰⁶ Reasonableness is also a standard interpretive tool used in contract law.¹⁰⁷

constitutional reasonableness. These other Clauses at all times stand as independent hurdles, above and beyond composite reasonableness, that every search or seizure must clear, but the Clauses can also serve other functions. They can furnish benchmarks against which to measure reasonableness and components of reasonableness itself.” Amar, *supra* note 48, at 805 (emphasis omitted) (footnote omitted).

104. SEC v. Texas Gulf Sulphur Co., 401 F.2d 833, 862 (2d Cir. 1968) (en banc) (defining a misrepresentation or omission as an act that conveys a false impression of the facts or is misleading, which in turn requires an inquiry “into the meaning of the statement to the reasonable investor and its relationship to the truth”). In *TSC Industries, Inc. v. Northway, Inc.*, the Supreme Court essentially adopted the reasonableness rule, holding that information should be deemed material if there exists “a substantial likelihood” that it “would have been viewed by the reasonable investor as having significantly altered the ‘total mix’ of information” available to the public. 426 U.S. 438, 449 (1976). For other illustrations of the use of reasonableness in securities regulation, see *Basic Inc. v. Levinson*, 485 U.S. 224 (1988); *Texas Gulf Sulphur Co.*, 446 F.2d at 1305; Jeffrey L. Davis, *Materiality and SEC Disclosure Filings*, 24 SEC. REG. L.J. 180 (1996). For a discussion, see Richard C. Sauer, *The Erosion of the Materiality Standard in the Enforcement of the Federal Securities Laws*, 62 BUS. LAW. 317, 320 (2007).

105. *Harris v. Forklift Sys., Inc.*, 510 U.S. 17, 21–22 (1993). In 1991, the Ninth Circuit propounded a “reasonable woman” standard for these sorts of cases. See *Ellison v. Brady*, 924 F.2d 872, 878–79 (9th Cir. 1991) (“We . . . prefer to analyze harassment from the victim’s perspective,” prohibiting “conduct which a reasonable woman would consider sufficiently severe or pervasive to alter the conditions of employment and create an abusive working environment.” (footnote omitted)). But after *Harris*, the Ninth Circuit redefined its test to cover a “reasonable person with the same fundamental characteristics.” *Fuller v. City of Oakland*, 47 F.3d 1522, 1527 (9th Cir. 1995). For a discussion, see Ann Juliano & Stewart J. Schwab, *The Sweep of Sexual Harassment Cases*, 86 CORNELL L. REV. 548, 582–83 (2001).

106. The Sherman Antitrust Act may be found at 15 U.S.C. §§ 1–7 (2006). The rule of reason used to interpret its hostility to restraints on trade was announced in *Standard Oil Co. v. United States*, 221 U.S. 1, 66 (1911) (“[T]he construction which we have deduced from the history of the act and the analysis of its text is . . . that in every case where it is claimed that an act or acts are in violation of the [antitrust] statute the rule of reason, in the light of the principles of law and the public policy which the act embodies, must be applied.”). See also Thomas C. Arthur, *A Workable Rule of Reason: A Less Ambitious Antitrust Role for the Federal Courts*, 68 ANTITRUST L.J. 337, 337 (2000) (“The traditional rule of reason was uniformly viewed as ‘a euphemism for an endless economic inquiry resulting in a defense verdict.’” (quoting

Appellate judges, finally, are accustomed to making reasonableness determinations in standards of review for nonagency action, making the importance of reasonableness a jurisprudential fact that they would not find surprising. In the federal system, triers of fact are also reviewed for reasonableness and have been so reviewed for decades.¹⁰⁸ Reasonableness review is thus a feature of federal civil procedure in addition to being the sort of standard that has permitted the creation of a useful and fact-sensitive jurisprudence in other areas of the law that benefit from fact-oriented elaboration.¹⁰⁹

It is, in sum, not an overstatement to suggest that reasonableness pervades legal analysis, and there is no doctrinal reason not to reclaim it for administrative law.

III. DEFENDING REASONABLENESS

This section responds to some criticisms of reasonableness review and explores several implications that the adoption of a reasonableness standard in administrative law might entail. One critique is theoretical: it posits that the extant standards of review prevent the politicization of administration and that reasonableness would not do so. Another is empirical: it takes the fact that agencies are affirmed roughly two-thirds of the time as an unstable, rather than permanent fact, and so argues that just because the standards of review have similar validation rates now does not mean that they are in fact similar. This section also weighs the function of standards of review more generally by arguing that implementing a reasonableness standard is practically possible and normatively desirable, in that it would simplify administrative law, which should be understandable and accessible.

Maxwell M. Blecher, Schwinn—*An Example of a Genuine Commitment to Antitrust Law*, 44 ANTITRUST L.J. 550, 553 (1975)). See generally Case Comment, *Sherman Act*, 124 HARV. L. REV. 179, 400–10 (2010) (discussing *American Needle, Inc. v. National Football League*, 130 S. Ct. 2201 (2010), a decision by the Supreme Court in light of the rule of reason).

107. See, e.g., Brent C. Shaffer, *Counseling the Client on the Reasonable Consent Standard to Assignments*, PRAC. REAL ESTATE LAW., July 2003, at 7, 7–8 (“Reasonableness is a relative term. Luckily, the courts have provided ample guidelines” for the “standards of reasonableness articulated by the courts in construing commercial lease assignments.”).

108. George C. Christie, *Judicial Review of Findings of Fact*, 87 NW. U. L. REV. 14, 23 (1992) (observing, albeit in a somewhat narrow context, that “the courts merely look for reasonable evidentiary support”).

109. For an accessible critique of the reasonableness standard (while acknowledging its appellate ubiquity), see Chad M. Oldfather, *Appellate Courts, Historical Facts, and the Civil–Criminal Distinction*, 57 VAND. L. REV. 437, 443 (2004) (“[T]he governing standards in both criminal and civil cases pose roughly the same question for the reviewing court. The court must first view the evidence in the light most favorable to the verdict, and then ask whether the verdict could have been reached by a reasonable jury.”).

It also considers some other implications of broad legal rules such as reasonableness in the context of administrative regulation.

A. Critiques of Reasonableness

One strong critique of reasonableness review in administrative law is that it would allow judges to enact their political preferences because nothing about reasonableness inquiries forecloses the utilization of such preferences, and because the general nature of the inquiry would ease the constraints on judges inclined to do so.¹¹⁰

But, as the record of reasonableness in other areas of the law suggests, a reasonable agency standard would not mean that administrative law is just a matter of politics. It is true that many scholars argue that politics play an important role in understanding how administrative law decisions are made.¹¹¹ Political scientists are particularly prone to such suggestions even though they now are struggling to import some constraints from law into their rational-actor paradigm.¹¹²

110. Sasha Volokh argues that doctrine can limit the whims of judges who would like to enact their political preferences but do not. Alexander Volokh, *Choosing Interpretive Methods: A Positive Theory of Judges and Everyone Else*, 83 N.Y.U. L. REV. 769 (2008). Although I am unconvinced by the style of the argument, it surely is true that cases with clear legal answers prevent judges from disregarding those answers in favor of their policy preferences.

111. See generally WILLIAM M. LANDES & RICHARD A. POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* (2004) (describing the incentives of judges as including reputation and leisure); JEFFERY A. SEGAL & HAROLD J. SPAETH, *THE SUPREME COURT AND THE ATTITUDINAL MODEL REVISITED* (2002) (arguing that judges essentially enact their policy preferences into law when adjudicating); Thomas J. Miles & Cass R. Sunstein, *Do Judges Make Regulatory Policy? An Empirical Investigation of Chevron*, 73 U. CHI. L. REV. 823 (2006).

112. See David S. Law & David Zaring, *Law Versus Ideology: The Supreme Court and the Use of Legislative History*, 51 WM. & MARY L. REV. 1653, 1740 (2010) (concluding that Supreme Court justices are more likely to consult legislative history in their statutory interpretation when the legislative history favors their “ideologically preferred outcomes”); Mark J. Richards et al., *Does Chevron Matter?*, 28 LAW & POL’Y 444 (2006) (concluding that it may, in fact, matter);. But see LEE EPSTEIN & JACK KNIGHT, *THE CHOICES JUSTICES MAKE* (1998) (arguing more generally that political decisions count for most of the inputs into Supreme Court decisionmaking). For discussions about the relevance of law by scholars who are not known for otherwise celebrating the importance of doctrine, see Barry Friedman, *Taking Law Seriously*, 4 PERSPECTIVES ON POL. 261, 266 (2006); and Matthew C. Stephenson, *Legal Realism for Economists*, J. ECON. PERSPECTIVES, Spring 2009, at 191. There are numerous other examples of law professors expressing their concern about the law-disregarding nature of social scientific scholarship. See, e.g., Carolyn Shapiro, *Coding Complexity: Bringing Law to the Empirical Analysis of the Supreme Court*, 60 HASTINGS L.J. 477 (2009). It would be incorrect to pin much of the vanguard of the criticism on Stephenson and Friedman, both of whom have expressed some skepticism about the binding nature of legal constraints in their scholarship. Perhaps it is sufficient to take the placements of both articles in respected peer-reviewed

Others are clear-eyed about whether judges are able to do whatever they want when they adjudicate.¹¹³ But this is the case now, and reasonableness would not change anything, even as the problems of the politicization of judicial review can be overstated.

At any rate, we expect politics to play a role in some decisionmaking. Richard Pierce has observed that it would be impossible to eliminate politics from law.¹¹⁴ Indeed, it has been mooted that perhaps politics may even have played a role in decisions as foundational as *Marbury v. Madison*.¹¹⁵ It may be that the ideological element of adjudication is distinct but not dramatic, as the area for disagreement reaches relatively few cases decided within a relatively narrow band of decisions. But even defined narrowly, the importance of the political perspectives of judges can be overstated. Few cases produce dissents, meaning that the judges usually agree on the outcomes of decisions.¹¹⁶ Indeed, sometimes the evidence for the politicization of adjudication is sparse, as it was for substantial-evidence cases before the D.C. Circuit between 2000 and 2004, which I reviewed and failed to find an ideological basis of the voting of the judges, if ideology is measured by the party of the appointing president.¹¹⁷

But if we think that politicization can be an overstated threat and legal rules can do something about it (some are unsure of even that, of course), reasonableness might be the right sort of constraint, allowing a little

journals as some evidence of the social scientific disciplines to take a more nuanced view of the constraining power of law. And of course, other, well-cited scholars in the social sciences make much of the importance of capable legal institutions for economic development. See Rafael La Porta et al., *Legal Determinants of External Finance*, 52 J. FIN. 1131 (1997); Rafael La Porta et al., *Law and Finance*, 106 J. POL. ECON. 1113 (1998); Rafael La Porta et al., *Corporate Ownership Around the World*, 54 J. FIN. 471 (1999).

113. My own view is that no one takes the law-is-irrelevant critique seriously. Political scientists, like all of us, reject the “law doesn’t matter” hypothesis every day in real life. We all register real estate sales and enter into employment contracts without checking on the political affiliations of the judges on the courts that might hear our claims. Indeed, it might be more accurate to say that we usually, with almost all of our conduct, presume that the law matters almost all of the time.

114. Richard J. Pierce, Jr., *The Role of Constitutional and Political Theory in Administrative Law*, 64 TEX. L. REV. 469, 471 (1985) (“[I]ncreased Presidential control of agency policy making is the only response to the problem of broad agency discretion that is consistent with constitutional and political theory.”). See generally Jerry L. Mashaw, *The Economics of Politics and the Understanding of Public Law*, 65 CHI.-KENT L. REV. 123 (1989).

115. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137 (1803); see Pierce, *supra* note 114.

116. Subject, however, to Miles’s and Sunstein’s observations that divided panels tend to adopt less ideological outcomes—on a whistleblower theory, one suspects, though the mechanism of this amelioration of ideology is not very clear. Miles & Sunstein, *supra* note 111, at 852.

117. Zaring, *supra* note 3, at 197.

political policymaking discretion but not too much. The duty of agencies to be reasonable, when compared with constitutional limitations on congressional action that are less rigorous (Congress must only have a “rational basis” to act, a term that the courts have interpreted extremely broadly), if anything, clarifies where the most political decisions are meant to be made. Congress has substantially more authority to act arbitrarily, even capriciously, through legislation, subject to the check of the ballot box. It may reverse policies without laying any groundwork for doing so or cater to interest groups, and it need not give reasons for its decisions or justify them with scrutinized findings.

Administrative law precludes agencies from doing any of these things under either current doctrine or a reasonableness inquiry. And the importance of a reasonableness, or reasonable-like, inquiry is why administrative lawyers know that they must be able to tell a good story about why the policy choice they made makes sense and does not work a forfeiture on the individuals affected by the regulatory action.

Nor would the adoption of a reasonableness standard mean that agencies would forever win 60%–70% of their cases. That is currently what the studies across various standards of review suggest, especially for the current era; courts upheld agencies at both slightly higher and slightly lower rates in some older studies.¹¹⁸ It could be—though I think it unlikely—that the validation rates will diverge soon. But the goal of this Article has been to suggest that there is no reason to eschew reasonableness regardless of the

118. *Id.* at 169. This will not surprise those who suspect that the D.C. Circuit took a different perspective to agency action in the 1960s and 1970s than it does today. It is quite a standard view among not just political scientists, but historians. *See, e.g.*, JEFFREY BRANDON MORRIS WITH CHRIS ROHMANN, *CALMLY TO POISE THE SCALES OF JUSTICE: A HISTORY OF THE COURTS OF THE DISTRICT OF COLUMBIA CIRCUIT* (2001). A number of judges have also suggested that the D.C. Circuit is different from other courts and has evolved over time. *See* E. BARRETT PRETTYMAN, JR. ET AL., *D.C. CIRCUIT, HISTORY OF THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT IN THE COUNTRY'S BICENTENNIAL YEAR* (1977) (Prettyman was a lawyer and a judge on the court); Susan Low Bloch & Ruth Bader Ginsburg, *Celebrating the 200th Anniversary of the Federal Courts of the District of Columbia*, 90 *GEO. L.J.* 549, 605 (2002); John G. Roberts, Jr., *What Makes the D.C. Circuit Different? A Historical View*, 92 *VA. L. REV.* 375, 388–89 (2006) (describing the era of conflict between the 1960s and 1980s on the court). It could change in the future. Indeed, the lack of variability across affirmance rates is striking and interesting, but subject to selection bias—we simply do not know if litigants bring only really strong *Chevron* cases and really weak *State Farm* cases, despite the fact that they are affirmed at the same rate, and it may be that we will never know. This is a limitation of these sorts of observational, opinion-based data, and one worth keeping in mind—I mention it here because it suggests that even now we may be, in a strength-adjusted basis, in a world where the various standards of judicial review do, in fact, have different effects.

uncanny convergence of agency validation rates. It has other useful characteristics and works well in other circumstances.

B. Implications of Reasonableness

Adoption of a reasonable agency standard has other advantages. Researchers could spend more time looking at the other questions that we all think affect litigation, such as the importance of the perspective of the judges on the panel, the reputation of the agency (which I have always thought might matter in cases before the D.C. Circuit), or the importance of the administrative action. Courts may, after all, take different approaches when confronted with rulemakings about global warming as opposed to adjudications about whether somebody should get a camping permit.

If reasonableness review is the right way to think about administrative review, it might make for a “flatter, simpler base” of administrative law (flatter and simpler is what tax professors and tax lawyers think might be the right way to write a tax code; they provide the trope here).¹¹⁹ More sorts of administrative action could be interpreted through the reasonableness lens, which is an intuitive one used by jurors and police officers, as well as by appellate judges. Perhaps such a perspective might be useful for administrative law.

Moreover, reasonableness may be upon us sooner than many doctrinalists would suspect. It is possible that *Chevron*, *State Farm*, and finally the fact-based standards of appellate review have already essentially evolved into the standard of reasonableness, similar to the way common law evolves.¹²⁰ As Kathryn Watts observed, the Supreme Court cited *Chevron* once and *Skidmore* once over the Fall 2009 term, and we have already seen that direct citations to the administrative law standards are occupying a shrinking proportion of the appellate docket, even as the D.C. Circuit and Supreme Court refer to reasonableness in a higher and higher percentage of those cases.¹²¹

119. See, e.g., Boris I. Bittker, *A “Comprehensive Tax Base” as a Goal of Income Tax Reform*, 80 HARV. L. REV. 925, 926–27 (1967) (supporting creating a comprehensive tax base with few exceptions in tax policy design); Daniel S. Goldberg, *To Praise the AMT or to Bury It*, 24 VA. TAX REV. 835, 847 (2005) (identifying why tax reformers might prefer “a more comprehensive tax base and one free of incentive provisions”).

120. See Jack Beermann, *Common Law and Statute Law in Administrative Law*, 63 ADMIN. L. REV. 1 (2011).

121. Watts, *supra* note 31, at 1–2.

Would that be a good thing? There is a worthy story to tell about the valuable features of the current standards of review. They have been designed to teach the appellate courts humility.

They also represent a tick-the-box approach to adjudication that is a plausible approach to the design of judicial review, even if it appears to fail in practice. The first step of the *Chevron* case, for example, forces courts to engage in a statutory interpretation exercise that Justice Scalia has championed as a way to tether them to the rule of law.¹²² There is little doubt that courts engage in more careful statutory interpretation now than they may have in the years before Scalia made his way onto the Supreme Court.¹²³ Moreover, as Richard Pierce observes, what we want courts to do when reviewing agency action is to be sure that they have paid attention to the statute, that their policy decision is not unreasonable, and that they have explained what they did and how they got from the statute to the policy.¹²⁴ Each of these factors would seem to be encouraged by the current standard of review regime, and although nothing about a reasonableness inquiry would preclude these factors, stating them gives courts more guidance about what they should exactly do.

In this sense, standards of review might serve as a cueing function for judges.¹²⁵ At their best, they offer a checklist of things the judges are supposed to ask agencies to do. A checklist, or decision-tree approach—indeed even one much more elaborate than the approach required by *Chevron*, *State Farm*, and their ilk today—might help judges make sense of the complicated real world of administrative action, which turns science and social science into policy and which in turn is executed by regulation. Checklist review or decision-tree review could ease the job of courts as they go down the path of trying to discern what exactly a judge did and why.

Though checklists and decision trees are appealing in theory, it is an open question as to whether the standards of review in practice really guarantee this kind of inquiry. The number of steps they push the agency

122. See, e.g., Antonin Scalia, *Common-Law Courts in a Civil-Law System: The Role of the United States Federal Courts in Interpreting the Constitution and Laws*, in ANTONIN SCALIA, *A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW* 3 (Amy Gutmann ed., 1997).

123. For one empirical study reviewing how much Justice Scalia's ascension to the court changed jurisprudence with regard to the use of legislative history in statutory interpretation, see Law & Zaring, *supra* note 112.

124. See Richard J. Pierce, Jr., *Making Sense of Procedural Injury*, 62 ADMIN. L. REV. 1 (2010).

125. Cf. Robert B. Ahdieh, *Law's Signal: A Cueing Theory of Law in Market Transition*, 77 S. CAL. L. REV. 215, 255 (2004) (“[R]egulatory cues do not rely on the application or threat of public sanction.”); Richard H. McAdams, *A Focal Point Theory of Expressive Law*, 86 VA. L. REV. 1649, 1651 (2000) (arguing that law's expressive function can serve as a “focal point” around which private actors can coordinate their behavior).

to do are three or so, even under *Pierce*'s paradigm, and two of those steps are usually conflated into one—the hard look requirements that the courts simply read into the arbitrariness provisions of *State Farm*.¹²⁶ Indeed, a body of precedent more attuned to the facts and circumstances of particular cases might help courts through the specifics of administrative law more than would the current complex web of doctrine.

All of this permits an inquiry into what the standards of review are supposed to do. And so there are some final implications to reasonableness worth considering.

Presumably, standards of review offer guidance to agencies as to what is appropriate administrative procedure and offer guidance to courts as to how to assess agency action in delineating the vision and decisionmaking between courts and agencies. *Chevron* also sets the terms of the separation of powers framework. It has been dubbed the anti-*Marbury v. Madison*, which is the case that instructed the Executive Branch that “[i]t is emphatically the province and duty of the judicial department to say what the law is.”¹²⁷ Deferential standards of review like *Chevron*, however, permit the agencies within the Executive Branch to draw definitive conclusions about what the law is on their own and with the acquiescence of the judiciary, or so some have argued.¹²⁸ *Chevron*, in theory, reworks the separation of power angle between courts and agencies into one between courts and Congress itself.¹²⁹

126. Because courts have given context to whatever it is that *arbitrary and capricious* means by devising their own common-law style standards, I think it is unimportant to limit what they do even though the reasonableness inquiry does not appear in the statutory text while other terms do.

127. *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803).

128. Cass R. Sunstein, *Beyond Marbury: The Executive's Power to Say What the Law Is*, 115 YALE L.J. 2580, 2589 (2006) (“We can now see that *Chevron* is properly understood as a kind of counter-*Marbury* for the administrative state.”); Cass R. Sunstein, *Chevron Step Zero*, 92 VA. L. REV. 187, 188–89 (2006) (“*Chevron* was quickly taken to establish a new approach to judicial review of agency interpretations of law, going so far as to create a kind of counter-*Marbury* for the administrative state. *Chevron* seemed to declare that in the face of ambiguity, it is emphatically the province and duty of the *administrative* department to say what the law is.” (footnote omitted)); Henry P. Monaghan, *Marbury and the Administrative State*, 83 COLUM. L. REV. 1, 2 (1983) (arguing that deference would not be an unconstitutional transfer of the Judiciary’s duty “to say what the law is,” but a recognition that Congress often implicitly delegates lawmaking authority to administrative agencies); Jonathan T. Molot, *Reexamining Marbury in the Administrative State: A Structural and Institutional Defense of Judicial Power over Statutory Interpretation*, 96 NW. U. L. REV. 1239 (2002) (discussing the views of Monaghan and Sunstein).

129. Kenneth Bamberger and Peter Strauss have made some arguments along these lines. They argue that the *Chevron* test “separates questions of statutory implementation assigned to independent judicial judgment (Step One) from questions regarding which the courts’ role is limited to oversight of agency decisionmaking (Step Two).” Kenneth A. Bamberger & Peter L. Strauss, *Chevron’s Two Steps*, 95 VA. L. REV. 611, 611 (2009).

However, if the separation of powers worked by *Chevron* is important, it is not clear as an empirical matter that a reasonableness standard would do anything differently. Moreover, reasonableness review is a sort of deference that gets courts out of the business of flyspecking agency action or substituting their own judgment for that of the agency.

A reasonableness standard, however, does not preclude deference to Congress's wishes. It might, in fact, make courts more sensitive to those wishes by making room for larger considerations than the purely legal ones of the statutory interpretation encompassed by *Chevron* step one and the zone of reasonable statutory interpretations included in step two.¹³⁰ Moreover, agencies remain subject to congressional control though a number of other means—through regular oversight, control of funding, and all of the other indicia on which positive political theorists focus when they address the questions of how congressional control of agency action is expressed.

Others have hoped that *Chevron* will resolve agency ossification, the prospect that overly aggressive judicial review prevents agencies from meeting their regulatory obligations.¹³¹ But no one thinks that after the promulgation of *Chevron* the length and complexity of rulemakings has declined.¹³² They have increased instead. Lengthier *Federal Registers*, of course, do not prove that the administrative state has become ossified by process—the jury is out on just how ossified the administrative state has become.¹³³ But it is fair to say that many of the standards of measuring ossification have not suggested that our current standards of review serve any purpose in reducing the procedural hoop jumping that marks those agencies subject to appellate review for their policymaking efforts.

130. Of course, this all assumes that courts do, in fact, treat *Chevron* as a heuristic that encourages fidelity to Congress's language. Based on the relatively stable validation rates of agency action, *Chevron* or no, its reference to the statute may not be so important after all.

131. The canonical article in this area is Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1453 (1992) (concluding that in complex scientific cases, courts apply a pass/fail standard to grade the agency).

132. As Elizabeth Foote has said, "by turning nearly every challenge on judicial review into a question of law as a matter of 'statutory interpretation,' the Supreme Court's *Chevron* doctrines likely generate more, not less, judge-made ossification of statutes than the [Administrative Procedures Act] regime that they displaced." Elizabeth V. Foote, *Statutory Interpretation or Public Administration: How Chevron Misconceives the Function of Agencies and Why It Matters*, 59 ADMIN. L. REV. 673, 677 (2007).

133. See generally Jason Webb Yackee & Susan Webb Yackee, *Administrative Procedures and Bureaucratic Performance: Is Federal Rule-making "Ossified"?*, 20 J. PUB. ADMIN. RES. & THEORY 261 (2010) (utilizing data that covers all active federal rule-writing agencies from 1983 to 2006 and concluding that the results "largely disconfirm the ossification thesis").

Finally, the standards of review should be performing some duty to the public. They should be clarifying what agencies can do and what courts can do. It is not clear that this duty to the public is being met, as *Chevron* turns into an increasingly confusing part of an increasingly elaborate and confusing series of standards of review. It seems clear that the laity is less likely to be able to interpret and parse current doctrine than it would if the courts relied on the reasonableness standard.

In this sense, the normative case for reasonableness lies in an intuition that administrative law should not be the province of obscure doctrinal geniuses. It is too important to calcify into obscurity with an impossible set of standards of review, and it is no place for smart judges to draw obscure curtains across the important watchdog role they play for Congress and the public. Administrative law is too important to be incapable of interpretation. Understanding that it really amounts to a fact-specific and context-sensitive reasonableness inquiry avoids this sort of obfuscation of a critical function in a bureaucratic state that still is committed to maintaining the separation of powers announced in the Constitution.

C. *Getting There*

Administrative law, with its broad and rarely amended procedural statutes and its commitment to limited judicial review, is the sort of doctrine particularly amenable to a rule of reason. And, as I have suggested both here and elsewhere, it appears that the courts may be moving toward a rule of reason.

How, though, might they get there, given the complex web of rules that have grown to require a variety of other steps? My own view is that amendment of the APA will not be required, and that the facts on the ground—the increasing embrace of reasonableness among practitioners and adjudicators of administrative action—will do what Congress need not, and what, I suspect, the Supreme Court will ultimately endorse. The rule of reason will become the rule of administrative law not by a Supreme Court decision overruling *Chevron*, *Skidmore*, and their ilk. The sea change of reasonableness—if it even is, in fact, a sea change—is the kind of amendment to the standards of review that will echo the common law standard that it represents. Change will happen slowly, and it will percolate up from appellate courts to the Supreme Court. If administrative law looks a lot like common law—and many scholars have argued that it does—then we can expect that the reforms urged in this Article will be embraced slowly, perhaps even imperceptibly, but inevitably and intelligently. While this Article is prescriptive and normative—I think that reasonableness is the right way to evaluate agency action, as well as the approach that the courts,

sub silentio, are increasingly adopting—it takes a somewhat fatalistic view about the character of reform. The courts will, I suspect, ultimately embrace a reasonableness standard of review and reject the complexity of the current set of standards under which they labor. That doctrinal move lies within their power and discretion in interpreting the APA, which itself is certainly capable of supporting a reasonable agencies approach.

CONCLUSION

It is time to embrace reasonableness and, in administrative law, open ourselves to its possibilities. Courts are increasingly moving away from the complex standard of review superstructure. There is another way, and it is a way that works elsewhere in the legal firmament, including in Fourth Amendment and negligence law. There is nothing lawless about reasonableness, it works in a number of different contexts, and it has both practical and theoretical advantages. Ignoring its promise does no favors to those areas of the law snarled in increasingly confusing and elaborate doctrinal curlicues.

COMMENTS

THE DEPARTMENT OF VETERANS AFFAIRS' ENTITLEMENT COMPLEX: ATTORNEY FEES AND ADMINISTRATIVE OFFSET AFTER *ASTRUE V. RATLIFF*

STACY L.Z. EDWARDS*

TABLE OF CONTENTS

Introduction.....	562
I. The VA Benefits Process and the History of Attorney Representation.....	567
A. The Modern Disability Compensation Claims Process.....	567
B. Blunders of the Civil War and the Resulting Attorney Restrictions	572
C. <i>Walters</i> and the Due Process Challenge	573
D. Growing Discontent and the Veterans Judicial Review Act....	575
E. Veterans Service Organizations as Alternatives to Legal Representation.....	577
F. The Veterans Benefits Act of 2006: Representation Before the Agency	579
II. Judicial Interpretation of Attorney Fee Agreements.....	580

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A.	VA Enforcement of Fee Agreements	581
B.	The “Fund” Argument	582
C.	Attorney Entitlement Tied to the “Award of Past-Due Benefits”	583
D.	<i>Ratliff</i> and Statutory Entitlement to Fees: A Matter of Direct Payment	584
III.	Administrative Offset and Attorney Fees: Intersecting Laws	586
IV.	VA Has No Authority to Shift the Entitlement Scheme	588
A.	Congress Envisioned Direct Payment	588
B.	VA’s Regulation	589
C.	Precedent Opinion 12-93: The Real Hurdle	590
D.	VA’s Abuse of Its Limited Authority	592
E.	An Anticipated VA Response	594
	Conclusion	596

INTRODUCTION

The Department of Veterans Affairs (VA) administers a benefits system designed to be largely paternalistic.¹ An important aspiration of this benefits scheme is that the process should be navigable by a veteran without savvy legal prowess or the assistance of an attorney.² Although the regulations governing attorney involvement have changed, the intentions behind them have not: VA insists it must protect veterans from lawyers.³ Congress, however, is less skeptical of legal representation and has enacted statutes designed to encourage lawyers to take the cases of deserving veterans that might prove too difficult to win otherwise.⁴

1. See, e.g., Kenneth M. Carpenter, *Why Paternalism in Review of the Denial of Veterans Benefits Claims is Detrimental to Claimants*, 13 KAN. J.L. & PUB. POL’Y 285, 285–86 (2003) (mentioning the nonadversarial, pro-claimant, and ex parte system of adjudication that contributes to the “paternalism” of veterans law).

2. See, e.g., *Hodge v. West*, 155 F.3d 1356, 1362 (Fed. Cir. 1998) (“This court and the Supreme Court both have long recognized that the character of the veterans’ benefits statutes is strongly and uniquely pro-claimant.”); see also *Henderson v. Shinseki*, 131 S. Ct. 1197, 1205–06 (2011) (“The contrast between ordinary civil litigation . . . and the system that Congress created for the adjudication of veterans’ benefits claims could hardly be more dramatic.”).

3. See, e.g., Accreditation of Agents and Attorneys; Agent and Attorney Fees, 73 Fed. Reg. 29,852, 29,866 (preamble to final rule issued May 22, 2008) (codified at 38 C.F.R. § 14.636 (2010)) (reflecting suspicions that contingent fee agreements present “a more specific risk of exploitation” because attorneys have a “better sense of the value of a particular veteran’s claim than the veteran does”).

4. See 38 U.S.C. § 5904(c)–(d) (2006) (allowing attorneys to collect fees and setting forth the requirements for Department of Veterans Affairs (VA) enforcement of fee agreements).

As part of this congressionally mandated incentive structure, the Equal Access to Justice Act (EAJA)⁵ is available as a way for plaintiffs, through VA's pockets, to pay the fees for lawyers who "win" against the government before the Court of Appeals for Veterans Claims (CAVC).⁶ The EAJA does not compensate attorneys for work done on the vast majority of veterans' claims, which never reach the courts but are instead adjudicated at the agency level.⁷ There is, however, a separate compensation scheme to encourage attorney participation in the adjudication of VA benefits.

To ensure lawyers were not discouraged from representing veterans at this first, crucial stage, Congress instituted a contingency fee system: an attorney who succeeds in gaining benefits can receive 20% of the veteran's past-due benefits award directly from the Secretary of Veterans Affairs.⁸ This largely straightforward system has raised few problems for attorneys and veterans—in most cases VA simply parcels out 20% to the attorney and then hands over the rest to the veteran. However, there is a small but critical area of complexity involving veterans who for whatever reason will

5. See 28 U.S.C. § 2412(b), (d) (2006) (allowing a court to award to a nongovernment prevailing party reasonable attorney fees when the position of the United States was not substantially justified); see also U.S. COURT OF APPEALS FOR VETERANS CLAIMS, ANNUAL REPORTS FOR 2000–2009, http://www.uscourts.cavc.gov/documents/Annual_Report_FY_2009_October_1_2008_to_September_30_2009.pdf (documenting that in 2009 the Court of Appeals for Veterans Claims (CAVC) granted 2,385 Equal Access to Justice Act (EAJA) fee applications and denied or dismissed only 38). This highlights the need for attorneys to hold VA accountable earlier in the adjudication process, at the agency level. See, e.g., Carpenter, *supra* note 1 (asserting attorney representation throughout the administrative appellate process is necessary to ensure the record is fully developed and veterans receives all benefits they are entitled to).

6. See 28 U.S.C. § 2412(d)(2)(F) (including the CAVC in the definition of *court*).

7. In 2010, veterans filed more than 1.1 million claims for disability. DEP'T OF VETERANS AFFAIRS, FY 2010 PERFORMANCE AND ACCOUNTABILITY REPORT I-3 [hereinafter VA FY 2010 P&A REP.]. 150,475 preliminary requests for appeal were also filed; of these only 57,925 appeals to the Board of Veterans' Appeals (BVA) were perfected. BD. OF VETERANS' APPEALS, REPORT OF THE CHAIRMAN FISCAL YEAR 2010 17–21, http://www.bva.va.gov/docs/Chairmans_Annual_Rpts/BVA2010AR.pdf. These figures illustrate that the vast majority of veterans claims are handled at the agency level.

8. See 38 U.S.C. § 5904(d) (mandating that to qualify for direct payment the fee agreement must specify direct payment, meet statutory requirements, and be appropriately filed with VA). Firms are free to charge a greater fee percentage so long as it is still deemed reasonable. See *id.* § 5904(a)(5) (establishing a 20% fee as presumptively reasonable and giving VA discretion to decide beyond that). However, VA does not "protect" these higher fees and it is up to the attorney to collect from the client. See Payment of Fees, 38 C.F.R. § 14.636(g)(2) (2010) ("A fee agreement . . . that specifies a fee greater than 20 percent of past-due benefits awarded . . . [is] considered to be an agreement in which the . . . attorney is responsible for collecting any fees . . . without assistance from VA.").

not receive the entirety of their award.⁹ In these cases, the question becomes whether attorneys are to receive 20% of the original award or 20% of the award after offset or withholding.

For veterans who still receive some portion of their award, the answer is on the books. By statute, contingency fees are to be calculated from any past-due benefits awarded on the basis of the claim;¹⁰ “award” does not mean amount payable to the veteran but the actual award prior to any withholding.¹¹ *Snyder v. Nicholson*¹² held that *award*, in the “parlance of veterans’ benefits,” means “the amount stated as the award for success in pursuit of a claim for benefits.”¹³ Thus, even though a veteran might receive only a portion of his award, the attorney will still receive 20% of the original.¹⁴ This all flows from the idea that contingency fees in veterans’ benefits cases belong, by statute, to the attorney—and are thus payable directly from the benefits awarded on the claim, rather than being calculated from the actual payment to the veteran.¹⁵

This result reflects Congress’s decision to promote attorney participation in the VA process by guaranteeing enforcement of a 20% contingency fee agreement should the veteran win the claim.¹⁶ But VA regulations institute a caveat: a contingency fee agreement will be upheld only if the award of past-due benefits “results in a cash payment to a claimant . . . from which the fee may be deducted.”¹⁷ By using *results*, VA asserts that contingency fee agreements lose their statutory protection if the claimant, by virtue of

9. It could be that the veteran is incarcerated and only entitled to a reduced portion of benefits during his confinement, *see* 38 U.S.C. § 5313, or perhaps the veteran is already receiving an offsetting benefit such as a pension, *see id.* § 5304(a) (restricting receipt of multiple types of benefits, such as both compensation and retirement pay). This Comment deals almost exclusively with the cases of veterans whose awards are offset toward their debt to the United States.

10. *Id.* § 5904(d) (setting forth the requirements for a fee to qualify for direct payment).

11. *Snyder v. Nicholson*, 489 F.3d 1213, 1219 (Fed. Cir. 2007).

12. 489 F.3d 1213, 1219 (Fed. Cir. 2007).

13. *Id.* (emphasizing “awarded” as clearly and unambiguously referring to what the veteran has won from the government).

14. *See id.* at 1219–20 (determining that while an incarcerated veteran may receive a temporary reduction in benefits received, his attorney is still entitled to, and should receive, 20% of the award—just as if the veteran was to receive full benefits).

15. *Cf. Astrue v. Ratliff*, 130 S. Ct. 2521, 2526–27 (2010) (holding that an attorney prevailing against the Social Security Administration has no statutory entitlement to an EAJA fee because the statute’s plain text awards fees to the *litigant* as the “prevailing party”).

16. *See Scates v. Principi*, 282 F.3d 1362, 1366 (Fed. Cir. 2002) (characterizing Congress’s establishment of direct payment as an “offsetting benefit” compensating for the mandatory low fee percentage). There are other types of fee agreements available to attorneys, though this Comment focuses on contingency fee agreements. *See infra* note 124.

17. Payment of Fees, 38 C.F.R. § 14.636(h)(iii) (2010).

indebtedness to the United States, does not receive any payment at all.¹⁸ If no “fund” of past-due benefits is created, VA maintains that there is no percentage of that fund to which an attorney can be entitled.¹⁹ VA further reasons that if the veteran, as assignor, has no right to receive payment of any part of the past-due benefits, then his attorney, as assignee, cannot have such a right either.²⁰ This policy has troubling consequences: by protecting only the fee agreements of veterans *not* in debt to the government beyond their claims’ values, VA in fact ensures that some of the neediest veterans cannot retain legal representation.²¹

VA’s line drawing, protecting the fee agreements of veterans who emerge from their administrative battles with even a little something left in their award but refusing to enforce the agreements of those who break even or still have debt, needs explanation. Administrative offset is a concept not yet squarely dealt with in veterans law,²² but the Supreme Court has recently provided an analytical framework in *Astrue v. Ratliff*.²³ Although *Ratliff* dealt not with contingency fees but with the award of EAJA fees, the decision offers a useful comparison. The Court decided that if the pertinent statute does not specify that fees are payable directly to the attorney, the fees will not be severed from the claimant’s overall award and will be applied to the claimant’s debt to the government.²⁴ That EAJA awards the prevailing party with fees “in which her attorney may have a beneficial

18. See VA Opinion of the General Counsel, Precedent Opinion 12-93 (Dec. 21, 1993) [hereinafter Precedent Opinion 12-93], <http://www.va.gov/ogc/docs/1993/PRC12-93.doc> (interpreting “results in a cash payment” to require a fund, whatever the amount, to be actually paid to the veteran); Summary of Precedent Opinions of the General Counsel, O.G.C. Precedent 12-93, 59 Fed. Reg. 4752, 4753 (Feb. 1, 1994).

19. Precedent Opinion 12-93, *supra* note 18.

20. *Id.* at cmt. 10 (declaring a contingent fee agreement as in “the nature of an assignment of the veteran’s right to receive the portion of past-due benefits covered by the fee agreement”).

21. An important assumption underlying this Comment is that while pro bono representation of veterans has always been permitted, statutes and regulations prohibiting compensation result in fewer lawyers practicing veterans law and thus more obstacles in obtaining representation. Pro bono attorneys and other free legal help can only take on so many cases, see *infra* note 122 and accompanying text, and the opportunity for compensation is of course an excellent—if not critical—incentive for attorney participation, see *infra* note 224.

22. See *Snyder v. Nicholson*, 489 F.3d 1213, 1220 n.2 (Fed. Cir. 2007) (declining to reach the validity of 38 C.F.R. § 20.609 (2007), which contains identical language to its successor, 38 C.F.R. § 14.636 (2008)).

23. 130 S. Ct. 2521 (2010).

24. See *id.* at 2529–30 (concluding that without statutory protection, the contractual nature of a fee agreement is in essence overridden by the agency’s duty to collect outstanding debts).

interest or a contractual right” does not resolve the essential question of whether the attorney was entitled by statute to direct payment prior to offset.²⁵ Enforceable entitlement to direct payment is thus not a question of contracts or interest but of statutory rights and protection.²⁶ While the Supreme Court was firm in its declaration that EAJA fees are fair game for administrative offset,²⁷ it also established that resolution of similar cases depends on whether the governing statutes provide that fees are payable directly to the attorney.²⁸ If so, such fees may not be taken by the government to satisfy the claimant’s obligations.²⁹

Although the recent ruling in *Ratliff* instructs courts to look to the underlying statute when determining if attorneys are entitled to receive direct payment of fees despite the operation of administrative offset, VA has instead decided to interpret its regulations so that attorney fees will not be paid if the claimant does not receive an actual cash payment.³⁰ This interpretation relies on two pieces of agency regulatory issuances: 38 C.F.R. § 14.636(h), which upholds contingency fees only under certain conditions,³¹ and Precedent Opinion 12-93, which reads administrative offset into the regulation and was issued by the VA Office of General Counsel (OGC).³²

25. *Id.* at 2526–27.

26. *Id.*; *see also* Hanlin v. United States, 316 F.3d 1325, 1329 (Fed. Cir. 2003) (explaining that “[t]he statute and the regulation set forth [VA’s] authority and obligation to act” and rejecting an implied-in-fact contract or promissory undertaking theory with regards to payment of attorney fees); *cf. Ratliff*, 130 S. Ct. at 2528–29 (remarking that contractual or assignment relationships are unnecessary if the statute provides a basis for entitlement).

27. *Ratliff* was in reality a unanimous decision; Justice Sotomayor wrote a concurring opinion, joined by Justices Stevens and Ginsburg, only to note that while the law was clear and she was compelled to find with the majority, she did not like it. *Ratliff*, 130 S. Ct. at 2529–33 (Sotomayor, J., concurring) (deploring the practical effect of undermining the aim of the EAJA).

28. *Id.* at 2527–28 (majority opinion) (“Congress knows how to make fees awards payable directly to attorneys where it desires to do so.”).

29. *See id.* at 2524 (summarizing that all funds payable by the United States are subject to offset unless exempted by statute).

30. Precedent Opinion 12-93, *supra* note 18.

31. Specifically, (i) the total fee cannot exceed 20% of the past-due benefits awarded, (ii) the amount must be contingent on whether the claim is resolved in favor of the veteran, and (iii) the award of past-due benefits must result in a cash payment from which the fee may be deducted. Payment of Fees, 38 C.F.R. § 14.636(h) (2010).

32. Precedent Opinion 12-93, *supra* note 18; *see also* 38 C.F.R. § 14.507 (classifying a written legal opinion of the Office of General Counsel as a “conclusive” interpretation and binding unless it is designated as “advisory only”); *cf.* 38 U.S.C. § 501 (2006) (giving the Secretary authority to “prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws”).

This Comment challenges VA's regulations as departing from the clear language of 38 U.S.C. § 5904(d) and undercutting Congress's intent to establish by statute an attorney's right to direct payment out of past-due benefits awarded. Part I briefly sketches the VA benefits system as it stands today, outlining the evolving role of attorneys and explaining the history of VA's grudging acceptance of their increased participation. Part II analyzes *Ratliff* and relevant Federal Circuit cases to explain how the courts have interpreted Congress's provisions for attorney involvement as evidence of its intent. Part III examines the underlying statutes that establish direct payment for attorneys and provide for administrative offset, as well as the accompanying regulations. Finally, Part IV explains why the VA's position on administrative offset is an unreasonable interpretation of the underlying statute and a measure exceeding its authority.

I. THE VA BENEFITS PROCESS AND THE HISTORY OF ATTORNEY REPRESENTATION

The history of veterans' benefits in America is rich and colorful. It illustrates how the country feels about its returning heroes and also tracks the changing societal perceptions regarding disability.³³ Attorneys have played a variety of roles in this history—sometimes foiling the system and other times championing it. This Part will first explain how the disability compensation system works today, next returning to the beginning of VA history to trace the involvement of attorneys as the process has changed.

A. *The Modern Disability Compensation Claims Process*

A veteran seeking disability compensation³⁴ must first, of course, make a claim—a process typically initiated by filing a request for benefits at one of the fifty-seven Veterans Affairs Regional Offices (ROs).³⁵ The RO must

33. For a more thorough introduction to the history of veterans benefits, see DEP'T OF VETERANS AFFAIRS, VA HISTORY IN BRIEF (2010) [hereinafter VA HISTORY IN BRIEF], http://www.va.gov/opa/publications/archives/docs/history_in_brief.pdf.

34. There are numerous claims for benefits other than disability compensation claims that can be made, such as pension claims or dependency and indemnity compensation claims. See PAUL M. SCHOENHARD, VETERANS AFFAIRS LAW (forthcoming 2011) (manuscript at 7-1 to -30, 9-1 to -14) (on file with author) (explaining these and various additional benefits, such as education assistance); Thomas J. Reed, *Parallel Lines Never Meet: Why the Military Disability Retirement and Veterans Affairs Department Claim Adjudication Systems Are a Failure*, 19 WIDENER L.J. 57, 73-82 (2009) (discussing the various types of benefits claims a veteran may file and their accompanying standards of proof and adjudication procedures).

35. See 38 U.S.C. § 5101(a) ("A specific claim . . . must be filed in order for benefits to be paid . . . under the laws administered by the Secretary."); Claims for Disability Benefits, 38 C.F.R. § 3.151 (2010) (espousing similar language). This Comment only purports to

review the application and assist the veteran with locating military service and medical records,³⁶ retrieving medical records from treatments at VA facilities,³⁷ and obtaining any records of other administrative disability adjudications the veteran has disclosed.³⁸ A veteran dissatisfied with the RO's determination of the existence, nature, or severity of the disability can then request a rehearing³⁹ or appeal the decision to the Board of Veterans Appeals (BVA).⁴⁰ This requires the filing of a Notice of Disagreement (NOD),⁴¹ which triggers the first opportunity for representation by a compensated attorney.⁴² Following receipt of an NOD, the RO issues a Statement of the Case, which sets forth the legal basis for the decision and summarizes the evidence considered.⁴³ This gives the veteran a chance to prepare evidence in rebuttal and informs the veteran of the additional procedural requirements needed to push the case through to the BVA.⁴⁴

The BVA is the final stage in agency adjudication and review.⁴⁵ The

sketch the basic path for resolution of a disability compensation claim; for an excellent and in-depth articulation of the process see SCHOENHARD, *supra* note 34, at 5-1 to -18; and Reed, *supra* note 34, at 82-97.

36. 38 U.S.C. § 5103A(c)(1); VA Assistance in Developing Claims, 38 C.F.R. § 3.159(c)(3).

37. 38 U.S.C. § 5103A(c)(2); 38 C.F.R. § 3.159(c)(2).

38. 38 U.S.C. § 5103A(c)(3); 38 C.F.R. § 3.159(c)(2).

39. 38 U.S.C. § 7105(d); Review of Benefit Claims Decisions, 38 C.F.R. § 3.2600(a). This may be undertaken by way of a Decision Review Officer. *See* 38 C.F.R. § 3.2600(a) (giving a claimant sixty days to request this sort of view as an alternative to the "traditional appellate process"). Although this route sounds like a tempting alternative to adjudication, it acts as a trap for the unwary veteran and can add years to a claim. *See, e.g.,* Benjamin W. Wright, Comment, *The Potential Repercussions of Denying Disabled Veterans the Freedom to Hire an Attorney*, 19 FED. CIR. B.J. 433, 438-39 (2010) (reporting that it takes, on average, 645 days for a Decision Review Officer to reach a decision).

40. 38 U.S.C. § 7105.

41. *Id.* § 7105(b); 38 C.F.R. § 3.2600.

42. 38 U.S.C. § 5904(c); Payment of Fees, 38 C.F.R. § 14.636(c). The assertion requires one caveat: attorneys may be compensated for work done prior to a veteran's decision to file a claim, encompassing tasks such as document review. *See, e.g.,* VETERANS BENEFITS MANUAL 1546 (Barton F. Stichman & Ronald B. Abrams eds., 2010)

43. 38 U.S.C. § 7105(d)(1); Statement of the Case, 38 C.F.R. § 19.29.

44. *See* 38 U.S.C. § 7105(d)(3) (giving the claimant sixty days from the mailing of the Statement of the Case to file a formal appeal, which must set out "specific allegations of error of fact or law" and clearly identify the benefits sought); 38 C.F.R. § 19.30 (specifying that to perfect an appeal the veteran must file VA Form 9); *see also* Victoria L. Collier & Drew Early, *Cracks in the Armor: Due Process, Attorney's Fees, and the Department of Veterans Affairs*, 18 ELDER L.J. 1, 16 (2010) (outlining the consequences of legal and procedural hurdles imposed in addition to the filing of a Notice of Disagreement (NOD)).

45. *See* DEP'T OF VETERANS AFFAIRS, FEDERAL BENEFITS FOR VETERANS: DEPENDENTS & SURVIVORS 103-04 (2010) (designating the BVA as the appellate body that "makes decisions on appeals on behalf of the Secretary of Veterans Affairs" as opposed to the

BVA may grant relief, deny relief, or remand the case to the RO for further development.⁴⁶ In so doing, the BVA must demonstrably base its decision on the entire record before the agency and consider all evidence and provisions of law and regulation.⁴⁷ If adversely affected by the decision of the BVA, the veteran has a right to appeal to the CAVC.⁴⁸

The CAVC's appellate jurisdiction is limited: the CAVC may not undertake de novo review of the BVA's findings of fact⁴⁹ and can set aside or reverse a finding of fact only if it is clearly erroneous.⁵⁰ To prevail at the CAVC the veteran will usually be forced to demonstrate the BVA mistakenly applied the law.⁵¹ Because the CAVC is only looking for legal errors and will ignore factual disputes unless glaringly incorrect, the presence of a lawyer at this stage becomes more essential to the outcome of a claim—especially because VA will almost certainly be represented.⁵²

From there, veterans' claims follow a more familiar course through the Court of Appeals for the Federal Circuit⁵³ and occasionally on to the Supreme Court.⁵⁴ These Article III courts can review the actual validity and interpretation of VA regulations and statutes.⁵⁵ However, in contrast even to the CAVC's very limited authority to consider facts,⁵⁶ these Article III courts may not disturb the factual determinations made below; the application of the law to the facts of a particular case is likewise precluded

CAVC, which is an "independent court" and not part of VA).

46. 38 U.S.C. § 7104; 38 C.F.R. § 19.4.

47. 38 U.S.C. § 7104(d); 38 C.F.R. § 19.7.

48. See 38 U.S.C. § 7266(a); see also *id.* § 7252 (giving the CAVC exclusive jurisdiction over appeals from BVA).

49. See 38 U.S.C. § 7261(c) ("In no event shall findings of fact made by [the BVA] be subject to trial de novo by the Court.").

50. *Id.* § 7261(a)(4).

51. The CAVC has considerably more latitude to review legal determinations than factual determinations. Compare *id.* § 7261(a)(1) (granting the CAVC blanket authority to decide all legal matters, including interpretation of the Constitution, the relevant statutes, and the governing regulations), and *id.* § 7261(a)(3) (enabling the CAVC to set aside VA decisions, findings, conclusions, and rules only if arbitrary and capricious, contrary to the Constitution, or in excess of statutory jurisdiction), with *id.* § 7261(a)(4) (allowing the CAVC to set aside findings of fact only if clearly erroneous).

52. See, e.g., Matthew J. Dowd, Note, *No Claim Adjudication Without Representation: A Criticism of 38 U.S.C. § 5904(c)*, 16 FED. CIR. B.J. 53, 79–80 (2006) (quoting the remarks of two CAVC judges who emphasize the imperative of legal assistance at this stage in benefits proceedings).

53. 38 U.S.C. § 7292(c).

54. *Id.*

55. See *id.* § 7292(d)(1) (giving the Federal Circuit power to interpret all relevant questions of veterans law and set aside regulations).

56. See *supra* note 51 and accompanying text (describing CAVC jurisdiction).

from review.⁵⁷

When a veteran's disability claim achieves final resolution and is granted by VA, two types of compensation benefits are offered: continuing monthly payments to compensate the veteran going forward⁵⁸ and a lump sum award of past-due benefits compensating the veteran for accumulated benefits since the effective date of the claim.⁵⁹ In general, the effective date is the day the claim was first filed at the RO—even if it takes years for the veteran's case to be resolved or if a veteran seeks to reopen an old claim based on clear and unmistakable error.⁶⁰ A lengthy adjudication process thus has vast implications for the amount of benefits eventually received by veterans as well as their quality of life in the meantime.⁶¹

57. See 38 U.S.C. § 7292(d)(2) (prohibiting the Federal Circuit from reviewing factual disputes except to the extent they involve constitutional issues). The Supreme Court could undertake a factual review, but I have assumed this is unlikely.

58. See Schedule for Rating Disabilities, 38 C.F.R. pt. 4 (2010) (setting forth the hundreds of disabilities qualifying for monthly compensation and tabulating the severity of each); see also DEP'T OF VETERANS AFFAIRS, VETERANS COMPENSATION BENEFITS RATE TABLES (2009), <http://www.vba.va.gov/bln/21/rates/comp01.htm> (listing the monthly compensation rates associated with each level of disability; for example, in 2009 a single veteran who was 20% disabled would receive \$243 a month). For an explanation of how to use disability compensation tables and rates, see SCHOENHARD, *supra* note 34, at 5-22 to -30.

59. Definitions, 38 C.F.R. § 20.3(n). In essence, past-due benefits reflect all the benefits the veteran was entitled to receive before a final decision was made on the claim. See, e.g., *Snyder v. Nicholson*, 489 F.3d 1213, 1217–18 (Fed. Cir. 2007) (explaining that the disability forms the basis of the claim, and “[a]ny compensation not paid to the claimant in a given month becomes a ‘past-due benefit’”). Thus, if a veteran filed a claim in January 2000, and was ultimately determined to be 10% disabled in January 2001, he would receive a lump sum reflecting the past-due benefits he did not receive for the past year as well as a monthly payment reflecting the compensation assigned to a 10% disability rating. Cf. Schedule for Rating Disabilities, 38 C.F.R. pt. 4; DEP'T OF VETERANS AFFAIRS, VETERANS COMPENSATION BENEFITS RATE TABLES (2009), <http://www.vba.va.gov/bln/21/rates/comp01.htm>.

60. See 38 U.S.C. § 5110 (qualifying the rule in that the effective date shall be the later of the date the claim was filed and the date entitlement to disability compensation began, and listing effective date rules for claims for increased ratings and claims filed within one year of discharge from the armed services); 38 C.F.R. § 3.400 (applying the statutory language).

61. Compensation rates are keyed toward inability to work due to a service-connected injury or condition. See Essentials of Evaluative Rating, 38 C.F.R. § 4.1 (2010) (the ratings “represent as far as can practicably be determined the average impairment in earning capacity” due to an injury occurring in service). However, the rating tables are not based on actual impairment but instead reflect a determination of averages: even though a particular veteran may be able to manage a successful career despite the loss of his leg—which carries a 50% disability rating—he is still entitled to that sum. *Id.* Although societal aversion to the overinclusion inherent in such a system is understandable, it is a vestige of the “old way” of thinking about veterans benefits as merit or need-based rather than as entitlements. See, e.g.,

Unfortunately, obtaining a final and accurate resolution of a veteran's case can take years. While the RO may be reasonably quick to give an initial decision,⁶² an appeal to the BVA usually takes five years or more.⁶³ This is partly due to the extraordinary number of claims VA receives—almost 1.1 million filed in 2010.⁶⁴ Inaccuracies only extend the process; VA's records show 84% accuracy for initial entitlement claims.⁶⁵ The Federal Circuit has expressed its particular frustration with frequent mistakes that go unnoticed (and sometimes uncorrected).⁶⁶ In large part, accuracy problems are linked to deficiencies in the development of claims—missing examinations, inadequate medical opinions, and lack of training completed by VA staff.⁶⁷ Fully developing the record before the agency is thus the key to a successful claim for benefits.⁶⁸

Peter Blanck, "*The Right to Live in the World*": *Disability Yesterday, Today, and Tomorrow*, 13 TEX. J. C.L. & C.R. 367, 370–72 (2007) (detailing the changes in how society views disability and compensation benefits).

62. VA FY 2010 P&A REP., *supra* note 7, at II-10 (finding that initial rating decisions take an average of 166 days).

63. The average veteran waits 656 days from the filing of an NOD to a final decision from the BVA. *Id.* at II-20. *See also* Wright, *supra* note 39, at 439 (explaining that the five-year approximation assumes that a veteran can immediately answer VA's denial and that it is more likely that a veteran will require time to prepare an appeal).

64. *See* VA FY 2010 P&A REP., *supra* note 7, at I-3 (mentioning that it is not just the volume but also the complexity of claims that continues to increase).

65. *Id.* at I-18.

66. *See, e.g.,* Dambach v. Gober, 223 F.3d 1376, 1381 (Fed. Cir. 2000) (noting that the particular case had been in contest for seven years and was first remanded because of an inaccurate doctor's report and then again to determine if the doctor was an independent medical expert, leading the court to urge in exasperation that it "would be appropriate for the Veterans Court to set a deadline by which this veteran's case will be concluded"); *see also* VA FY 2010 P&A REP., *supra* note 7, at II-165 (finding that at the Veterans Affairs Regional Offices (ROs) inspected in 2010, staff incorrectly processed 27% of the benefit claims reviewed). Of the errors caught by VA's quality assurance program, 14% went uncorrected despite staff statements to the contrary. *Id.*

67. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-06-120T, VA DISABILITY BENEFITS: ROUTINE MONITORING OF DISABILITY DECISIONS COULD IMPROVE CONSISTENCY (2005) (showing great discrepancies across ROs, with average compensation varying as much as 63% and the percentage of exam reports containing the required information varying from 57% to 92%); U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-561, VETERANS' BENEFITS: INCREASED FOCUS ON EVALUATION AND ACCOUNTABILITY WOULD ENHANCE TRAINING AND PERFORMANCE MANAGEMENT FOR CLAIMS PROCESSORS 3 (2008) (complimenting VA's standard training curriculum for claims processors but finding staff was not held accountable for meeting the requirements and there was no policy outlining consequences for those who fail to do so).

68. *See* Carpenter, *supra* note 1, at 285 (noting that it is not only the legal character of the representation that matters, but it is critical that representation take place before the record is closed). *See also* James T. O'Reilly, *Burying Caesar: Replacement of the Veterans Appeals*

B. Blunders of the Civil War and the Resulting Attorney Restrictions

America boasts a long tradition of providing benefits to veterans, stretching all the way back to Plymouth Colony.⁶⁹ The Civil War, however, sorely taxed America's resolve to support benefits programs for the returning heroes.⁷⁰ Widespread, blatant misuse of the era's benefits programs resulted in severe aversion to mixing veterans and attorneys.⁷¹

The Civil War left 1.9 million veterans eligible for assistance,⁷² and the government dedicated vast funds for their assistance—at one point in 1893 nearly half the federal budget.⁷³ Attorneys flocked to veterans law in droves. Far from being generally responsible, the new attorney bar succeeded in spawning “a morass of fraud” and digging a “bottomless pit of extravagance,”⁷⁴ complete with agents traveling the country persuading veterans to manufacture an infirmity and to blame it on the war.⁷⁵ Society was already straining, and it perceived attorneys as nothing but leeches on an already exhausted system.⁷⁶

This tide of attorneys did not pass unchallenged; Congress enacted attorney fee limitations to discourage lawyers from becoming unnecessarily involved in veterans law. The first fee limitation—\$5 per claim—was enacted in 1862 during the early stages of the Civil War; two years later this fee increased to \$10.⁷⁷ This limitation was designed “to protect the veteran from extortion or improvident bargains with unscrupulous lawyers”⁷⁸ and

Process is Needed to Provide Fairness to Claimants, 53 ADMIN. L. REV. 223, 240–41 (2001) (mentioning missed or unscheduled exams, unobtained records, and decisions not compliant with remand instructions that plague VA on appeal and add time and cost to the process).

69. See, e.g., VA HISTORY IN BRIEF, *supra* note 33, at 3 (relating that in 1636, Plymouth Colony provided money to those who were injured while defending the settlement).

70. See, e.g., Collier & Early, *supra* note 44, at 5–8 (describing the public sentiment that led to government distrust of attorneys involved in veterans' claims).

71. See, e.g., Blanck, *supra* note 61, at 369–85 (detailing the extensive fraud and the resulting public outcry against veterans perceived to be milking the system).

72. See VA HISTORY IN BRIEF, *supra* note 33, at 4. This number only includes Union veterans; former Confederate soldiers were ineligible for any federal veterans benefits until they were pardoned in 1958. *Id.* Of course at that point, there was only one Confederate veteran left. *Id.*

73. Blanck, *supra* note 61, at 374.

74. *Id.* at 376 (quoting *The Democrats and the Pensions*, N.Y. TIMES, Dec. 9, 1898, at 6).

75. *Id.* at 380.

76. *Id.* at 376–81.

77. See *Walters v. Nat'l Ass'n of Radiation Survivors*, 473 U.S. 305, 359–60 (1985) (Stevens, J., dissenting) (tracing this history of fee limitations). See generally Collier & Early, *supra* note 44, at 5 (explaining that \$5 made sense when the claims process consisted of filling out a form and the claims themselves were simple to handle and adjudicate); Dowd, *supra* note 52, at 60–61 (further exploring the history of VA fee agreements).

78. *Walters*, 473 U.S. at 360; see CONG. GLOBE, 37TH CONG., 2D SESS. 2101 (1862)

encompassed reasonable compensation for the attorney's time, which was mainly spent locating and filling out the proper form.⁷⁹ Fee limitations ensured that attorneys could not siphon away a veteran's benefits award, but they did not create an incentive for a lawyer to "win" for his client. Because the fee was collected regardless of whether the benefits claim was successful, the fee limitations instead created an incentive to maximize volume of claims.⁸⁰

But as \$10 became a less valuable prize, even a lawyer filing a high number of claims could not make much of a living. Eventually, there was no incentive at all for attorneys to meaningfully participate in the administration of veterans' benefits.⁸¹ Despite minor statutory changes over time, Congress made no mentionable change to attorney fees⁸² and left the \$10 limit intact for almost 120 years.⁸³ Thus, by the 1980s, few lawyers practiced before VA or even cared to.⁸⁴

C. Walters and the Due Process Challenge

Though veterans, legislators, and attorneys disputed the restrictions,⁸⁵

(expressing Congress's intention to "prevent the numerous frauds" by limiting compensation to a level in accord with "services actually rendered").

79. Justice Stevens estimated this to be equivalent to a \$580 fee in 1985. *Walters*, 473 U.S. at 361. The success of the claim was irrelevant to collection of the fees—attorneys received the fee just for filling out the paperwork and forwarding it along. *Id.*

80. George Lemon provides the best stand-out example: he handled more than 125,000 pension claims for \$10 apiece—a hefty sum by any standards. Blanck, *supra* note 61, at 380–81; *see also* Collier & Early, *supra* note 44, at 7–8 (estimating that "[a] minimum" of one-fourth of all claims submitted were illegitimate or fraudulent). This led to a "moral economy of veterans benefits" with complicated societal judgments as to who was worthy and who was faking. Blanck, *supra* note 61, at 376–85 (quoting historian Larry Logue) (citation omitted).

81. *See* James D. Ridgway, *The Veterans' Judicial Review Act Twenty Years Later: Confronting the New Complexities of the Veterans Benefits System*, 66 N.Y.U. ANN. SURV. AM. L. 251, 260 (2010) (observing that despite a few dominating claims agents, the restrictions on attorney fees allowed a "vast network" of Veterans Service Organizations (VSOs) to replace attorneys by the time of the Veterans Judicial Review Act (VJRA)).

82. Throughout, Congress's intentions were to protect veterans from predatory attorneys and claims agents. *See* Collier & Early, *supra* note 44, at 9 (discussing the retention of the fee limitations despite changes in the benefits system).

83. Dowd, *supra* note 52, at 61. *See also* Ridgway, *supra* note 81, at 256–57 & nn. 29–31 (crediting Vietnam veterans' fight over Agent Orange as breaking the "Iron Triangle" of VA, veterans affairs congressional affairs committees and various VSOs that were opposed to judicial review).

84. *See* VETERANS BENEFITS MANUAL, *supra* note 42, at 1544 (identifying the erosion of the value of a \$10 fee as a "virtual economic bar to the hiring of an attorney").

85. *See, e.g.,* Collier & Early, *supra* note 44, at 11–12 (documenting a general "[d]iscontent at the lack of effective representation for veterans" in the years prior to judicial

only one—ultimately unsuccessful—legal challenge occurred, resolved in 1985 by the Supreme Court in *Walters v. National Ass'n of Radiation Survivors*.⁸⁶ In *Walters*, the Supreme Court declared that veterans' due process rights were not violated by restrictions on representation.⁸⁷ It also rebuked the district court, which had held that the fee limitation denied veterans any realistic opportunity to obtain legal representation,⁸⁸ for being so hasty to cast out over a century worth of practice.⁸⁹

The Supreme Court found the district court's *Mathews v. Eldridge*⁹⁰ analysis absolutely lacking, taking special issue with its faulty weighing of the government interest.⁹¹ Primarily concerned with protecting Congress's purpose behind the statutory scheme, the Court was convinced that eliminating fee agreements would wreak havoc on the system.⁹² It stressed that the veterans' disability system did not contemplate adversarial proceedings—which was to be “expected” considering the enormous number of claims VA received each year.⁹³ The government's interest in maintaining an orderly, paternalistic system was thus significant.⁹⁴

Determining that the government's interest consisted in perpetuating a benefits process “as informal and nonadversarial as possible,” the Court found that introducing lawyers into the equation would only serve to frustrate that goal.⁹⁵ Although the opinion focused on protecting the

review). Senator Tom Daschle expressed his dissatisfaction with VA procedures and lamented its arbitrary, behind-the-times adjudication of claims involving Post-Traumatic Stress Disorder, exposure to herbicides such as Agent Orange, and encounters with radiation. See generally Tom Daschle, *Making the Veterans Administration Work for Veterans*, 11 J. LEGIS. 1 (1984). He was also critical of the idea that providing judicial review would make the system adversarial. See *id.* at 11–12 (arguing that the appeals process is “already adversarial” and that a veteran must face opposition that “acts as both defendant and judge”).

86. 473 U.S. 305 (1985).

87. *Id.*

88. Nat'l Ass'n of Radiation Survivors v. Walters, 589 F. Supp. 1302 (N.D. Cal. 1984), *rev'd*, 473 U.S. 305 (1985).

89. *Walters*, 473 U.S. at 322–23.

90. 424 U.S. 319 (1976).

91. See *id.* (admonishing the district court for “cavalierly dismissing a long-asserted congressional purpose”).

92. *Id.* at 324–25.

93. See *id.* at 309–10 (mentioning the 800,000 claims received in 1978).

94. See *id.* at 321–22 (finding that the government's interest has been consistently asserted since the Civil War).

95. See *id.* at 323–25 (listing as probable consequences of lawyer involvement a prolonged decisionmaking process, great financial cost, longer records, and “the possibility of judicial review” (quoting *Gagnon v. Scarpelli*, 411 U.S. 778 (1973))). The Supreme Court was dismissive of the district court's determination that the system was already adversarial. See *id.* at 324 n.11 (finding that the statements of a few veterans and attorneys were not

system, it also noted that Congress's "principal goal" was to ensure the veteran received the entirety of the award.⁹⁶ The Supreme Court's *Mathews* analysis was thus quite different from the district court's: it accorded "great weight" to the government's interest in a paternalistic system.⁹⁷

Correspondingly, it looked for an "extraordinarily strong showing" of probable error and probability that attorneys would "sharply diminish" that possibility—and found neither.⁹⁸ Although Justice O'Connor's concurring opinion remarked that the door was still open for the district court to consider individual claims and "as applied" due process challenges,⁹⁹ the Supreme Court's majority was clear: a \$10 fee limitation did not violate a veteran's due process rights. Congress, in 1988, changed the game.

D. Growing Discontent and the Veterans Judicial Review Act

In 1988, Congress departed from the decades of tradition the Supreme Court found so convincing in *Walters* and enacted the Veterans Judicial Review Act (VJRA), allowing for judicial review and attorney involvement.¹⁰⁰ Vietnam-era veterans, fed up with VA's inability to process

persuasive).

96. *See id.* at 326. For example, Congress had considered modifications to the fee limit but cautioned those changes needed to be "made carefully so as not to induce unnecessary retention of attorneys" or "disrupt unnecessarily the very effective network of nonattorney resources." *Id.* at 322 (quoting S. REP. NO. 97-466, at 49 (1982)). *Walters* recognized, as did the Senate, that VA's insistence that veterans must be protected from unscrupulous lawyers was "no longer tenable." *Id.* However, the Court specifically mentioned its fears that a claimant with a "factually simple and obviously deserving claim may nonetheless feel impelled to retain an attorney simply because so many other claimants retain attorneys." *Id.* at 326.

97. *Id.* at 329. For a thorough analysis of the difference between the district court's and the Supreme Court's *Mathews* analysis, see generally David R. DiMatteo, Comment, *Walters Revisited: Of Fairness, Due Process, and the Future of Veterans' Fight For the Right to Hire an Attorney*, 80 TUL. L. REV. 975, 983–93 (2006).

98. *Walters*, 473 U.S. at 326. The Supreme Court found the numbers telling: VSOs had a 16.2%–16.8% success rate at the BVA; attorneys had an 18.3% success rate. *Id.* at 327–28. The Court did indicate that the "availability of particular lawyers' services in so-called 'complex' cases" could be a factor in preventing error in those cases—but this concession was tempered by lack of knowledge as to how to define such cases or how many of them there were. *Id.* at 330. Even then, the Court pointed out, due process must be judged by the generality of cases; a process sufficient for the large majority of claims is deemed sufficient for them all. *Id.*

99. *See id.* at 337–38 (O'Connor, J., concurring) (reasoning that though the majority concluded denying legal representation was not per se unconstitutional, the district court should still consider individual claims alleging that VA did not fulfill its obligations).

100. Veterans' Judicial Review Act, Pub. L. No. 100-687, 102 Stat. 4105 (1988) (codified

claims fairly and accurately, are largely credited with sparking this drastic reform.¹⁰¹ Before the VJRA, there was no judicial review of VA decisions;¹⁰² the Secretary's say was final and only challenges to the constitutionality of the underlying statute were justiciable.¹⁰³ The VJRA created the CAVC, an entirely new court allowing for initial review outside of VA, and then provided for further review by Article III courts.¹⁰⁴

Besides adding much to the perceived fairness of benefits adjudication,¹⁰⁵ traditional judicial review allowed attorneys to become involved and represent veterans once the BVA issued its first final decision.¹⁰⁶ Congress also allowed for direct payment of attorney fees, so long as the agreement capped the fee at 20% of past-due benefits and the agreement was properly filed with VA.¹⁰⁷

The VJRA certainly gave the veterans their day in court but not necessarily much assistance before the agency.¹⁰⁸ While Congress and courts agreed that veterans should have the opportunity to secure legal representation during a claim, the VJRA was geared toward cases that extended beyond the intermediate appeal at the BVA.¹⁰⁹ Indeed, the new

as amended throughout sections of 38 U.S.C.). For a critical look at the benefits process before and after the Veterans' Judicial Review Act (VJRA), see Lawrence B. Hagel & Michael P. Horan, *Five Years Under the Veterans' Judicial Review Act: The VA is Brought Kicking and Screaming into the World of Meaningful Due Process*, 46 ME. L. REV. 43 (1994) (parsing the different views of various VSOs on the subject and concluding that, for the most part, the VJRA simply had the impact of making VA do what it was supposed to be doing all along).

101. See, e.g., WILLIAM F. FOX, JR., *THE UNITED STATES BOARD OF VETERANS' APPEALS: THE UNFINISHED STRUGGLE TO RECONCILE SPEED AND JUSTICE DURING INTRA-AGENCY REVIEW* 23 (2000) (identifying the Vietnam generation of veterans as having enough political clout to push for reform).

102. 38 U.S.C. § 211 (1982) ("[T]he decisions of the Administrator on any question of law or fact . . . providing benefits for veterans . . . shall be final and conclusive and no other official or any court of the United States shall have power or jurisdiction to review any such decision."), amended by Veterans Judicial Review Act, 38 U.S.C. §§ 7251–7252 (2006).

103. See, e.g., *Johnson v. Robison*, 415 U.S. 361, 367 (1974) (finding that a veteran may constitutionally challenge decisions of Congress even if he could not challenge decisions of VA).

104. See *supra* notes 49–52 and accompanying text (discussing the CAVC's limited jurisdiction to reverse findings of fact but authority to provide de novo review of the BVA's legal conclusions).

105. See, e.g., Wright, *supra* note 39, at 433–39 (discussing how veterans were fed up by unfairly decided and inaccurately processed claims and demanded judicial review).

106. See Ridgway, *supra* note 81, at 260 (criticizing fee restrictions as showing that "[a]lthough Congress opened the door to attorneys, it could not force them through it").

107. 38 U.S.C. § 5904(d).

108. See *Bates v. Nicholson*, 398 F.3d 1355, 1363 (Fed. Cir. 2005).

109. See Collier & Early, *supra* note 44, at 12 (citing judicial conclusions regarding the then-simple procedures and the adequacy of VSOs to handle the vast majority of claims).

access to courts was accompanied by a measure replacing the \$10 fee previously charged for representation before VA with a general prohibition against charging any fee at the agency level prior to the BVA's final decision.¹¹⁰ The VJRA thus entirely excluded compensated attorneys from initial VA proceedings, despite the expanded opportunities for representation at the courts.

VA assured veterans that, despite ousting attorneys from the initial stages of benefits adjudication, it remained committed to a paternalistic system.¹¹¹ Yet there was a definite drawback to VA's benevolence: its paternalism basically barred attorneys from representing veterans until after the administrative record was closed—and at that point no further fact-finding or development could occur.¹¹² Veterans, advocates, and even the CAVC pleaded with Congress to change the rules in favor of permitting meaningful attorney participation in VA adjudication.¹¹³ VA pushed back by pointing to the availability of Veterans Service Organizations.

E. Veterans Service Organizations as Alternatives to Legal Representation

Many of the restrictions on attorneys have been justified by references to other available representation. Veterans Service Organizations (VSOs), congressionally recognized organizations created to assist veterans with claims, have long been part of the benefits claims system.¹¹⁴ VSOs are statutorily prohibited from earning any fee or type of compensation (even at the judicial stage), which makes them an attractive option for many claimants.¹¹⁵

VSOs provide useful assistance to many veterans' claims, especially those

110. See 38 U.S.C. § 5904(c)(1) (2000), *amended by* 38 U.S.C. § 5904(c)(1) (2006). An attorney could continue representation after successfully winning a remand at the CAVC and be compensated for the time spent before the agency, but could not charge any fee prior to a BVA final decision. *Id.* Of course, this likely made no practical difference, as the disparity between \$10 and nothing was probably not determinative to a lawyer in 1988.

111. See, e.g., Carpenter, *supra* note 1, at 285 (documenting Congress's expectations that VA fully and sympathetically develop the veteran's claim to its optimum and then give the veteran the benefit of the reasonable doubt).

112. *Id.*

113. See, e.g., *Benefits Legislative Initiatives Currently Pending Before the U.S. Senate Committee on Veterans' Affairs: Hearing Before the S. Comm. on Veterans' Affairs*, 109th Cong. 28 (2006) [hereinafter *Benefits Hearing*] (statement of Donald Ivers, Former C.J., U.S. Court of Appeals for Veterans Claims) ("The [CAVC] has long been on record in support of a veteran's right to retain counsel at the initial stages of the process.").

114. 38 U.S.C. § 5902 (2006) (establishing representatives of VSOs such as the Vietnam Veterans of America and the American Legion as recognized "in the preparation, presentation, and prosecution of claims").

115. *Id.* §§ 5902(b)(1)(A), 5903(a)(1) (prohibiting compensation "of any nature").

that are straightforward and well supported.¹¹⁶ Despite familiarity with the VA system, however, the vast majority of VSO employees have no legal training and are thus largely incapable of developing the record with an eye toward the legal details that might secure a claim's success on appeal.¹¹⁷ This lack of legal training is one basis for the courts' recognition that veterans represented by VSOs are still essentially proceeding *pro se*.¹¹⁸

Even the *Walters* Court, which was extremely complimentary of VSOs, recognized that there would likely be some circumstances where legal experience would be necessary.¹¹⁹ The limitations of VSOs factored into Congress's decision to enact the VJRA.¹²⁰ Conversely, Congress cited the success of VSOs as a justification for discouraging attorney participation at the agency level.¹²¹

By 2006, however, Congress recognized that despite quality guidance from VSOs, attorney representation needed to be available much earlier in the benefits decision process.¹²² Complex claims, often involving multiple

116. *See, e.g.*, *Comer v. Peake*, 552 F.3d 1362, 1369 (Fed. Cir. 2009) (appreciating the "invaluable assistance" provided by aides from VSOs).

117. *Id.* (asserting that VSOs cannot offer the same services as an attorney).

118. *See id.* at 1369–70 (concluding that the assistance provided by a VSO officer, who is styled an "organizational aide," is "not the equivalent" of legal representation). *Comer* also notes that the purpose of a VSO "is to cooperate with the VA in obtaining benefits for disabled veterans," which makes their role "fundamentally different from attorneys who represent clients in adversarial proceedings." *Id.* In a rather tentative and recent development in veterans law, courts are modifying veterans' obligations and VA duties to assist in order to fit the style of representation. *See, e.g.*, *Andrews v. Nicholson*, 421 F.3d 1278, 1283 (Fed. Cir. 2005) (reinforcing that there is no requirement for sympathetic reading of pleadings filed by counsel); *Comer*, 552 F.3d 1362, 1369–70 (contrasting the abilities of VSOs and licensed attorneys).

119. *Walters v. Nat'l Ass'n of Radiation Survivors*, 473 U.S. 305, 330 (1985) ("The availability of particular lawyers' services in so-called 'complex' cases might be more of a factor in preventing error in such cases . . .").

120. *See* S. REP. NO. 100-418, at 30–31 (1988) ("The combination of no judicial review and a statutory limit of \$10 on the amount an attorney is permitted to receive for [representation] . . . has led many claimants over the years to believe that they have been denied their 'day in court.'").

121. *Id.* at 63–65 (reflecting the Committee's belief that "there is no compelling justification for attorney representation at the initial level" because in most cases a veteran simply needs to file a claim and the agency will handle the record-gathering).

122. *See generally* Wright, *supra* note 39, at 445–47 (noting that while some statistics show the number of remands and grants of benefits broken down by type of representation, no statistics show the differences between the amount of benefits finally won by *pro se* claimants, those represented by VSOs, and those represented by the attorneys). Also of concern was the VSO caseload and its effect on quality of representation—for example, as of 2006, the Los Angeles VA's office had only nine service officers handling the cases of 9,000. *See Benefits Hearing*, *supra* note 113, at 47 (concluding that "no matter how well trained," no VSO officer can effectively handle that many claims) (statement of Barton F.

or related disabilities, had the potential to become stuck in a revolving door of remands, mistakes, and appeals. Veterans saw attorneys as a positive force for change: legal expertise and development of the record were needed to hold VA accountable for proper and prompt resolution of claims.

F. The Veterans Benefits Act of 2006: Representation Before the Agency

Under the Veterans Benefits, Health Care, and Information Technology Act of 2006 (Veterans Act of 2006),¹²³ a veteran can hire¹²⁴ legal representation once an NOD is filed.¹²⁵ This permits legal representation prior to a BVA final decision—essentially, as soon as VA first says no. VA recognized that allowing attorneys to be compensated for work done before the agency much earlier in the process was a significant change to the statutory scheme, an “expression of congressional intent to remove all restrictions on paid representation” so long as an RO has made a decision and the veteran has filed an NOD.¹²⁶

The modern requirements of the benefits system demand increased attorney involvement. Although the VA process is still intended to be paternalistic,¹²⁷ it is uncertain if the system can adequately and timely

Stichman, Co-director, National Veterans Legal Services Program).

123. Veterans Benefits, Health Care, and Information Technology Act of 2006 (Veterans Act of 2006), Pub. L. No. 109-461, 120 Stat. 3403 (codified throughout 38 U.S.C.).

124. Although this Comment extensively discusses contingency fees, by no means are such agreements the only way in which an attorney can receive compensation for work done before the agency. Attorneys and their clients can agree on a flat fee, an hourly rate, a contingency fee, some combination, or perhaps something different entirely, so long as the fee is “reasonable.” Payment of Fees, 38 C.F.R. § 14.636(e) (2010). This Comment focuses on the legal representation available to impoverished and indebted veterans, and has largely assumed that with such limited means these veterans can only compensate attorneys through contingency fee agreements.

125. 38 U.S.C. § 5904 (2006). The Veterans Act of 2006 responds to fears, such as those articulated in *Walters*, 473 U.S. at 321–33, that attorneys will look for easy cases and thereby provide mostly meaningless “assistance.” By setting the point for attorney representation at the filing of an NOD, lawyers will not be able to assist claimants unless VA first denies their claim. This means that the *Walters* fears are only realized if VA messes up first—which obviously should not happen if the claim truly is easy to prove and simple to resolve.

126. See Accreditation of Agents and Attorneys; Agent and Attorney Fees, 73 Fed. Reg. 29,852, 29,868–69 (responding to comments accompanying the final rule issued May 22, 2008) (codified throughout 38 C.F.R. pts. 1, 4, 19, 20 (2010)).

127. See, e.g., *Henderson v. Shinseki*, 131 S. Ct. 1197 (2011) (noting the obviously paternalistic attitude of VA as evidenced by many statutory provisions relaxing procedural requirements for filing and appealing claims, and holding that a missed deadline is not in every case a bar to appellate jurisdiction).

respond to the increasing complexity of modern claims.¹²⁸ It is also becoming more apparent that VSOs, which prior to the Veterans Act of 2006 were primarily responsible for handling claims before the agency, might be unable to keep up their current workload without deleterious effects on the adequacy of their representation. It is more common to see claims that require outside medical opinions, private evaluations, extensive legal research, and more importantly, exhaustive record-checking.¹²⁹ As the process for achieving disability compensation benefits becomes more complicated, attorneys will become a more necessary part of the system.

The extent of attorney involvement and its perceived value have greatly changed since the Civil War. Congress now recognizes that veterans must have the option of hiring an attorney as soon as VA has denied their claims. As the benefits process has evolved to encourage legal representation, new issues, such as administrative offset, have emerged as complications in the relationship between VA and attorneys. VA's responses to these recent developments have often landed it in court.

II. JUDICIAL INTERPRETATION OF ATTORNEY FEE AGREEMENTS

The judicial history of VA's attempts to curtail attorney involvement illustrates why VA's decision to mix attorney fee regulations and administrative offset provisions is problematic. Despite its long-standing statutory mandate to uphold—and enforce through direct payment—attorney fee agreements, VA has historically attempted to skirt these obligations. This Part first outlines judicial decisions regarding fee

128. Traumatic brain injury, for example, is an increasingly tricky issue for veterans and advocates. See, e.g., Gregg Zoroya, *360,000 Veterans May Have Brain Injuries*, USA TODAY, Mar. 5, 2009, http://www.usatoday.com/news/military/2009-03-04-braininjuries_N.htm (remarking that traumatic brain injury science is so new that it cannot yet fully distinguish whether symptoms are attributable to a psychological post-traumatic stress disorder or a physical concussive injury). VA's handling of these cases reflects the unique difficulties they pose. See VA FY 2010 P&A REP., *supra* note 7, at II-165 (documenting VA's inability to correctly process 26% of the traumatic brain injury claims reviewed; about half of these errors occurred because VA did not order traumatic brain injury examinations or incorrectly evaluated the disability claims).

129. See Carpenter, *supra* note 1, at 294–95 (listing the vast expenditure of resources, including time, necessary just to adequately review a veteran's claim file, which is rarely arranged chronologically and often composes thousands of pages). From her time with a veterans law firm, the Author vividly recalls the above difficulties that Mr. Carpenter mentions. Most notably, the claims files from Puerto Rico were often almost entirely in Spanish. Of course, difficulties only accrue if VA can find the records in the first place: one audit disclosed that approximately 296,000 claims folders were in locations different than that displayed in the tracking system, and 141,000 folders were lost altogether with no effective process for locating them. VAFY 2010 P&A REP., *supra* note 7, at II-157 to -158.

agreements as to (a) whether enforcement is mandatory or discretionary, (b) whether VA may forego enforcement when the veteran has already been paid the entirety of his award, and (c) whether VA must pay attorney fees as a percentage of the total award or the actual payment to the veteran. This Part concludes with an analysis of *Ratliff*, which sets forth the Supreme Court's analysis for when an attorney is entitled to direct payment prior to any offset of the claimant's award.

A. VA Enforcement of Fee Agreements

In re Smith sought to address a recurrent issue that plagued direct payment fee agreements: VA enforcement.¹³⁰ The CAVC attempted to simplify the issue to an if-then analysis: if the veteran and the attorney have entered into a fee agreement that provides for direct payment from the Secretary, the payment is contingent upon successful resolution of the claim and does not exceed 20% of the past-due benefits award, and all or part of the relief sought is granted, then the Secretary may direct that payment be made.¹³¹ The analysis depended completely on satisfaction of the statutory requirements.¹³² The CAVC also noted that it is VA's regulation that goes one step farther by requiring that the award of past-due benefits results in a cash payment.¹³³

Instead of relying on the regulations, the CAVC turned to the statutory language to determine if the Secretary's enforcement of fee agreements was obligatory or discretionary. The court remained mindful that it was bound to look not only at the specific language at issue but at the statute's overall structure as well.¹³⁴ The CAVC found there was "no question" that Congress contemplated an obligatory direct payment to the veteran's attorney.¹³⁵ Beyond statements of congressional intent, however, the CAVC read the language of § 5904(d)(3) providing the Secretary "may direct payment" as referring to § 5904(d)(2)(A) language that the fee "is to be paid" to the attorney directly.¹³⁶ The Secretary thus did not have

130. *In re Smith*, 4 Vet. App. 487 (1993), *vacated in part on other grounds sub. nom. In re Wick*, 40 F.3d 367 (Fed. Cir. 1994).

131. *Id.* at 492 (recognizing that in no event may attorney fees be paid out of future benefits).

132. *Id.*

133. *Id.*

134. *Id.* at 493 ("If the statutory language is plain, and its meaning clear, no room exists for statutory construction [because] [t]here is nothing to construe.") (citing *Gardner v. Derwinski*, 1 Vet. App. 584, 587-88 (1991)).

135. *Id.* at 494 (quoting Congress's language as anticipating the Secretary "will pay the attorney's fees directly out of past-due . . . benefits").

136. *Id.*

discretion to withhold direct payment because *may* in this direct payment context was permissive rather than discretionary.¹³⁷ As to why Congress did not just make things easy and write *shall*, the CAVC decided that the permissive aspect was needed in light of the blanket prohibition against the assignment of any portion of past-due benefits found in § 5301(a).¹³⁸ The CAVC therefore concluded that VA “is under a legal duty to comply with a § 5904(d) fee agreement” with “no discretion to refuse.”¹³⁹

Under the CAVC’s analysis in *In re Smith*, so long as a fee agreement meets the statutory requirements VA is obligated to provide direct payment of attorney fees. By finding that Congress intended mandatory direct payment to attorneys, the CAVC limited VA’s discretion to add requirements for valid fee agreements and to forego enforcement of those fee agreements. Nevertheless, VA continued its attempts to read direct payment out of the statute in certain situations where past-due benefits were awarded.

B. The “Fund” Argument

VA has repeatedly tried to work “fund” language into its arguments regarding awards of past-due benefits.¹⁴⁰ This position essentially attempts to relate the attorney’s entitlement to the fund of benefits VA owes the veteran. For example, *In re Smith* found the Secretary in the unenviable position of having mistakenly paid the veteran the entire sum of past-due benefits awarded rather than withholding 20% for his attorney as requested by the fee agreement on file with VA—meaning there were simply no benefits left from which to direct payment to the attorney.¹⁴¹ The Secretary unsuccessfully argued that when a fund was not available from which to deduct the attorney’s fee, VA was immune from claims for attorney fees.¹⁴²

137. *Id.*

138. *Id.* The CAVC also found support in *Aronson v. Derwinski*, which found that “38 U.S.C. § 5301 does not constitute a limitation on the Secretary’s obligation” to provide direct payment from past-due benefits. 3 Vet. App. 162, 163–64 (1992). Pursuant to *In re Smith*’s characterization of attorney fee agreements as an exception to the general prohibition against assignment, VA could argue that *Ratliff* does not apply, since it rejected assignor–assignee relationships as exempting attorney fees from administrative offset. *Astrue v. Ratliff*, 130 S. Ct. 2521, 2528–29 (2010). However, given the overall statutory scheme and the judicial development of attorney entitlement in *Snyder*, it seems clear that the entitlement is not in the nature of an assignment. *See infra* Part II.C.

139. *In re Smith*, 4 Vet. App. at 494. The court emphasized that VA’s obligation was not one of liability, which would require a waiver of sovereign immunity, but of statutory origin. *Id.* at 497.

140. *See* Precedent Opinion 12-93, *supra* note 18 (expanding the fund argument).

141. *In re Smith*, 4 Vet. App. at 494–95.

142. *Id.* at 495.

Although VA has persistently argued this line of reasoning, it has continued to be unsuccessful in the courts. *In re Smith* rejected the depleted-fund argument by finding that a “necessary corollary” of the Secretary’s obligation to honor a § 5904(d) fee agreement was the attorney’s “corresponding right” to receive payment.¹⁴³ Though VA had mistakenly dispersed the entire fund of benefits to the veteran, that error had no bearing on the attorney’s entitlement to direct payment from VA of 20% of the past-due benefits awarded.¹⁴⁴

The CAVC thus expressly rejected the fund argument when it came to enforcement of fee agreements. Yet VA, still intent on utilizing the argument, decided to interpret *In re Smith* as only pertaining to situations where VA mistakenly depleted the fund by paying the entirety of the award to the veteran.¹⁴⁵ This led to VA’s assertion that when the fund was depleted through administrative offset, it was not obligated to pay attorneys directly through enforcement of fee agreements.¹⁴⁶

C. Attorney Entitlement Tied to the “Award of Past-Due Benefits”

The Federal Circuit’s 2007 decision in *Snyder v. Nicholson* diminished the validity of VA’s argument that attorney fees in some way depend upon the actual payment of benefits to the veteran.¹⁴⁷ *Snyder* presents an excellent example of the type of case that attracts lawyers: perpetual mismanagement and interminable appeals prevented resolution and ratcheted up the veteran’s past-due benefits to a final award of \$93,044.¹⁴⁸ The veteran was incarcerated, and pursuant to the governing statute,¹⁴⁹ the VA dispensed past-due benefits at a 10% level of compensation.¹⁵⁰ His counsel’s attorney fees were likewise calculated as 20% of the post-withholding past-due

143. *Id.* (noting that a § 5904(d) fee agreement creates a “joint entitlement” whereby the attorney is entitled to 20% of the fund and the veteran to 80%).

144. *Id.* In a fabulous remark, the CAVC found the Secretary’s argument that its error gave it immunity to have “all the appeal of the plea of the apocryphal felon who, upon having been found guilty of murdering his parents, sought mercy from the court because he was now an orphan.” *Id.* at 496.

145. Precedent Opinion 12-93, *supra* note 18, at cmt. 6.

146. *Id.* at cmt. 10.

147. *See Snyder v. Nicholson*, 489 F.3d 1213 (Fed. Cir. 2007) (distinguishing between actual payment to veterans and attorney entitlement to a portion of the veteran’s award).

148. *Id.* at 1214–15. Although *Snyder* involved an incarcerated veteran, its language is broad and interprets 38 U.S.C. § 5904 as it applies to all veterans subject to withholding. *See id.* at 1219.

149. 38 U.S.C. § 5313 (2006).

150. *Snyder*, 489 F.3d at 1216 (explaining that the maximum amount received in such a situation is “computed as if [the veteran’s] disability rating were only 10 percent”).

benefits, not as 20% of pre-withholding past-due benefits.¹⁵¹

The Federal Circuit in *Snyder* found resolution to be quite simple: the veteran may only get 10% of his award, but that does not change the attorney's entitlement to 20% of the claimed benefits that were awarded prior to offset and withholdings.¹⁵² The court thereby eschewed the CAVC's willingness to accept the VA's perception of "ambiguity" between the statutes authorizing a withholding of an incarcerated veteran's benefits and those providing for direct payment from past-due benefits.¹⁵³ The Federal Circuit then continued on to resolve the "primary dispute," which concerned the meaning of "total amount of any past-due benefits awarded on [the claim]."¹⁵⁴ Observing that the language of VA regulations respects a difference between the amount awarded and the amount payable,¹⁵⁵ the court summed up the law with succinct elegance: "the word 'award' is clear and unambiguous, and in the parlance of veterans' benefits it means the amount stated as the award for success in pursuit of a claim for benefits."¹⁵⁶

The Federal Circuit concluded by holding that, specifically in reference to § 5904, the "total amount of any past-due benefits awarded on the basis of the claim" means the sum of each month's unpaid compensation.¹⁵⁷ So long as a fee agreement was made pursuant to the statute, the agreement is entitled to protection by the Secretary and the fee "is to be paid to the attorney by the Secretary directly from any past-due benefits awarded on the basis of the claim."¹⁵⁸

D. Ratliff and Statutory Entitlement to Fees: A Matter of Direct Payment

In 2010, the Supreme Court used *Ratliff v. Astrue* to set forth the analysis for determining when statutory language acts to bar attorney fees from being lumped with a claimant's award and subjected to administrative offset.¹⁵⁹ In *Ratliff*, a Social Security claimant prevailed in her claim for

151. *See id.* at 1214–15 (reporting the long procedural history of *Snyder* and the calculation of attorney fees).

152. *See id.* at 1217 ("Literal application of these two statutes . . . seems to permit of no result other than reduced compensation for [the veteran] during his incarceration and a payment, per the attorney fee agreement, to [his attorney] equal to 20 percent of the total past-due benefits awarded . . .").

153. The CAVC had compared the statutes to "two ships passing in the night." *Snyder v. Nicholson*, 19 Vet. App. 445, 450 (2006), *rev'd* 489 F.3d 1213 (Fed. Cir. 2007).

154. *Snyder*, 489 F.3d at 1217 (quoting 38 U.S.C. § 5904(d)).

155. *Id.* at 1219.

156. *Id.*

157. *Id.* at 1218.

158. *Id.* at 1216 (quoting 38 U.S.C. § 5904(d)(2)(A)(i)).

159. *Astrue v. Ratliff*, 130 S. Ct. 2521 (2010).

benefits but a government debt was discovered that predated the effective date of the award.¹⁶⁰ This prompted the agency to apply the entirety of the award, including attorney fees, to reduce the amount of the claimant's debt.¹⁶¹ The claimant's attorney protested the proposed administrative offset, asserting the EAJA fees belonged to him and thus could not be applied to his client's debt.¹⁶²

The Court found the EAJA statute clear: fees are awarded "to a prevailing party."¹⁶³ Noting that certain other Social Security statutory provisions allow "for payment to *such attorney* out of" the benefits award,¹⁶⁴ the contrast showed the Court "that Congress knows how to make fees awards payable directly to attorneys where it desires to do so."¹⁶⁵ Thus, in keeping with the EAJA's clear entitlement scheme, EAJA attorney fees are primarily payable to the litigant and subject to administrative offset.¹⁶⁶

The *Ratliff* Court was careful to steer clear of theories espousing contractual and assignment-based rights as the basis for entitlement determinations.¹⁶⁷ It reasoned that even though the "practical reality" was that attorneys are the ultimate recipients of fees awarded by statute, it is the EAJA litigant that is technically the recipient of the award.¹⁶⁸ Indeed, the Court proposed that assignment agreements would be wholly unnecessary if there was simply a statutory right to direct payment to attorneys.¹⁶⁹ This attention to what does *not* create entitlement further underlines the Court's preoccupation with the statutory language. *Ratliff* decided that it is the statute that creates the entitlement to direct payment of attorney fees, and it is to the statute that courts must look.¹⁷⁰ It is not practice or policy that

160. *Id.* at 2524.

161. *Id.*

162. *Id.* at 2525. This position reflects one side of the circuit split. *See id.* (tallying the various decisions among the courts of appeals).

163. *Id.* at 2524 (emphasis added) (quoting 28 U.S.C. § 2412 (d)(1)(A) (2006)).

164. *Id.* at 2527 (quoting 42 U.S.C. § 406(b)(1)(A) (2006)).

165. *Id.*

166. *Id.* at 2524.

167. *See id.* at 2530 (explaining that these nonstatutory rights usually confer upon the attorney the entitlement that the statute confers on the prevailing litigant).

168. *Id.* at 2529. Justice Sotomayor explained somewhat more clearly that because the attorney fee award under EAJA is "payable to the prevailing litigant," EAJA does not obligate the government to pay the litigant's attorney. *Id.* at 2529–30 (Sotomayor, J., concurring). Any obligation on the part of the claimant to pay her attorney is thus not controlled by EAJA, but by contract law. *Id.* at 2530.

169. *Id.* at 2529 (majority opinion).

170. *See generally* Joseph A. Fischetti, Comment, *Ratliff v. Astrue: The Collision of the Equal Access to Justice Act and the Debt Collection Improvement Act*, 40 SETON HALL L. REV. 723 (2010) (presciently outlining what the Supreme Court eventually decided to do). Justice Sotomayor's concurring opinion reflected her additional concern for the policy implications

creates the basis for entitlement to attorney fees.¹⁷¹ Further, *Ratliff* made clear that if the direct payment of fees to attorneys is called for, those fees cannot be usurped by the government through administrative offset to pay the claimant's debt.¹⁷²

III. ADMINISTRATIVE OFFSET AND ATTORNEY FEES: INTERSECTING LAWS

While the intricacies of administrative offset are not within the parameters of this Comment,¹⁷³ the basics are discussed here to provide a backdrop for understanding the problematic intersection of administrative offset provisions with attorney fees statutes. In the most general of descriptions, claimants who have been granted government benefits might not actually receive them if they are in debt to the government.¹⁷⁴ Instead, those benefits will be applied to reduce the amount owed.¹⁷⁵ Essentially, administrative offset flows from the idea that it makes no sense for the government to pay its debtor.

In slightly more technical language, funds payable by the United States may be used to offset particular types of federal debt unless exempted by statute.¹⁷⁶ To utilize administrative offset, VA participates in the Treasury Offset Program (TOP),¹⁷⁷ a centralized collection program administered by the Department of the Treasury under the Debt Collection Improvement Act of 1996 (DCIA).¹⁷⁸ Until 2005, the portion of a claimant's award

of the decision. *Ratliff*, 130 S. Ct. at 2530 (Sotomayor, J., concurring). She expressed regret that the Court's enforcement of the statutory provision would operate to thwart the EAJA's central aim of creating incentives for lawyers to take on the cases of financially needy citizens with legitimate claims. *Id.*

171. See *Ratliff*, 130 S. Ct. at 2527 (majority opinion) ("Even accepting [the statute] as ambiguous . . . the provisions and practices [claimant] identifies do not alter our conclusion that EAJA fees are payable to litigants and are thus subject to offset where a litigant has outstanding federal debts.").

172. *Id.*

173. See Paras N. Shah, Comment, *Lockhart v. United States: Decapitating the New Deal & Ignoring the Plain Language of the Social Security and Debt Collection Improvement Acts*, 58 ADMIN. L. REV. 455 (2006), for a discussion of administrative offset in the more general realm of Social Security benefits.

174. See 31 U.S.C. § 3711 (2006) (giving an agency the power to collect a debt through administrative offset and listing proper notice requirements and other procedural issues).

175. *Id.*

176. *Id.* §§ 3701(a)–(b), 3716(h)(2).

177. 38 C.F.R. § 1.910 (2010).

178. 31 U.S.C. § 3701. See generally *Oversight of the Implementation of the Debt Collection Improvement Act: Hearing Before the Subcomm. on Gov't Mgmt., Info., and Tech. of the H. Comm. on Gov't Reform and Oversight*, 105th Cong. 89–99 (1999) (statement of Mark Catlett, Chief Financial Officer, Dep't of Veterans Affairs) (presenting VA's first efforts to utilize the

designated as attorney fees was not subject to administrative offset—only when Treasury modified its TOP regulations to include “miscellaneous payments” were attorney fees brought within its purview.¹⁷⁹

Unless attorney fees are in some way statutorily exempted from falling within the DCIA, they are subject to administrative offset as miscellaneous payments. This statutory exemption is satisfied by an indication that Congress intended attorneys to receive payment directly.¹⁸⁰ If direct payment is specified, an agency may not lump attorney fees together with claimants' awards; only the claimant's portion may be applied to reduce his or her debt. If not, then the entire award, including the attorney fees, qualifies for offset in accordance with the DCIA.¹⁸¹

Unlike Social Security benefits, which are subject to general administrative offset,¹⁸² VA can only collect on debts resulting from participation in VA programs.¹⁸³ In fiscal year 2010, VA referred \$860 million to TOP, 99% of its eligible debt.¹⁸⁴ Although there is no report detailing how many veterans are in debt beyond the value of their compensation claims, 366,000 veterans are currently in debt to VA.¹⁸⁵

Administrative offset happens often enough to be of concern to veterans and their lawyers. Almost all attorneys hired by veterans are compensated either through EAJA fees for work before the court or other fees for work before the agency.¹⁸⁶ After *Ratliff* decided that attorney fees awarded under

Treasury Offset Program (TOP)).

179. This recent development weakened the attorney's argument in *Ratliff* that the government's extensive past practice of providing for direct payment, even when the claimant was in debt, was evidence that attorney fees were not subject to offset. *See Astrue v. Ratliff*, 130 S. Ct. 2521, 2528–29 (2010) (declining to interpret past payment practices as estopping the government from conforming its current practices to the revised Treasury regulations).

180. *Id.* at 2527–28.

181. *See Astrue v. Ratliff*, 130 S. Ct. 2521 (2010).

182. *See, e.g., Shah, supra* note 173 (thoroughly explaining the administrative offset process for Social Security benefits and the theory behind the principle of offset in general).

183. *See, e.g., 38 U.S.C. §§ 5301, 5314* (2006) (exempting VA benefit payments from offset to collect any debt other than those owed to VA); *see also* DEP'T OF VETERANS AFFAIRS, VA HANDBOOK 4800.7: TREASURY OFFSET PROGRAM AND TREASURY CROSS SERVICING 5 (2003), available at http://www.va.gov/vapubs/viewPublication.asp?Pub_ID=161&FTtype=2 (providing VA employees an explanation of the Secretary's implementation of administrative offset).

184. VA FY 2010 P&A REP., *supra* note 7, at I-94.

185. E-mail from David Sturm, Assistant Dir., VA Debt Mgmt. Ctr., to Author (Jan. 24, 2011, 12:19 PM) (on file with Author).

186. *See, e.g., Wright, supra* note 39, at 445–46 (explaining that very few attorneys represent veterans pro bono because the opportunity cost is “tremendous,” and noting that contingency fee agreements and EAJA fees are the only meaningful compensation available).

the EAJA's language could be applied to offset debt through administrative offset, the statutory entitlement scheme for attorney fees earned before VA has become much more important. If contingency fee agreements are not protected by VA, few indebted veterans will be able to secure legal representation.

IV. VA HAS NO AUTHORITY TO SHIFT THE ENTITLEMENT SCHEME

A. Congress Envisioned Direct Payment

Legislative intent, expressed through the plain language of the statute, decides the entitlement scheme involving attorney work before the agency.¹⁸⁷ While Congress is somewhat permissive with veterans' fee agreements in general, requiring only that they be "reasonable," there are two important restrictions for agreements an attorney is seeking to be enforced by VA: the fees cannot exceed 20% of the total amount of past-due benefits awarded on the basis of the claim, and the fee agreement must be contingent on resolution of the claim in favor of the veteran.¹⁸⁸ Additionally, the agreement itself must specify the fee will be paid to the attorney "directly from any past-due benefits awarded on the basis of the claim."¹⁸⁹

If past-due benefits are awarded and such a fee agreement is in place, the Secretary will then "direct that payment of any fee . . . be made [from] past-due benefits."¹⁹⁰ The language shows Congress's intention to allow attorneys to be paid directly so long as the fee agreement meets statutory requirements. It thus sets up an unambiguous entitlement scheme very unlike the EAJA at issue in *Ratliff*.¹⁹¹ VA's regulations and opinions must be analyzed in light of both the statutory text and the importance placed on that text by *Ratliff*—an analysis that shows that VA has erected a regulatory scheme that distinctly differs from what is set forth by statute.

187. See *Astrue v. Ratliff*, 130 S. Ct. 2521 (2010).

188. 38 U.S.C. § 5904(d)(1), (d)(2)(ii) (2006).

189. *Id.* § 5904(d)(2). A fee agreement that does not specify the veteran's wish to pay the attorney directly leaves the agreement without statutory entitlement to enforcement. See *supra* note 8.

190. 38 U.S.C. § 5904(d)(3). VA has no discretion in the matter because it has "acknowledged [its] obligation" to pay directly to the attorney fees that comport with § 5904. *Aronson v. Derwinski*, 3 Vet. App. 162, 164 (1992); see *supra* notes 130–140 and accompanying text.

191. See *Ratliff*, 130 S. Ct. at 2527–28 (showing the Court's attention to the contrast between Social Security statutory language that allows for payment to attorneys and EAJA language that provides for payment to the prevailing party).

B. VA's Regulation

38 C.F.R. § 14.636 differs from 38 U.S.C. § 5904 by adding the requirement that a veteran receive a cash payment before VA will uphold and enforce an attorney fee agreement.¹⁹² It does not necessarily follow that the regulation is an impermissible expansion of authority. In fact, the extra language of 38 C.F.R. § 14.636, when viewed outside of the administrative offset context, makes good sense.

Congress has always been committed to ensuring that veterans are the final recipients of their disability benefits—not creditors, agents, or attorneys.¹⁹³ If the VA benefits maze had not become such a complicated mess with all the trappings of arbitrariness, it is possible Congress might never have enacted the VJRA.¹⁹⁴ Even as it loosened restrictions on attorney participation, Congress retained its provisions that compensated attorneys could only get involved once VA has first denied a claim and then be compensated only if the claim was ultimately successful.¹⁹⁵ This shows that Congress intended to permit attorneys to be compensated only when their services were actually necessary to properly resolve a claim and gain veterans the fullest benefits to which they are entitled.

The regulation, when interpreted as merely prohibiting attorneys from collecting fees when the veteran receives no tangible benefit from the representation, fits within Congress's overall statutory scheme for veterans' benefits. For example, the regulation mentions situations where a veteran is entitled to benefits but elects instead to receive a pension.¹⁹⁶ It is not difficult to see why an attorney should not receive 20% of a disability compensation award that is of no benefit to the veteran. Another example would be a veteran who is already considered 100% disabled and receiving the highest level of compensation but files a claim for hearing loss—even though the veteran's claim may be successful, the attorney has not actually gained anything for the veteran because benefits were already being received at the highest level available. If the regulation's language is interpreted to preclude attorneys from being compensated for largely moot work, 38 C.F.R. § 14.636 poses no threat to needy veterans' ability to retain legal representation.

Nonetheless, the regulation's language states "results in a cash payment,"

192. See *In re Smith*, 4 Vet. App. 487, 492 (1993) (recording the CAVC's awareness that the regulation imposes requirements beyond the statute).

193. See, e.g., 38 U.S.C. § 5301 (prohibiting assignment of veterans' benefits).

194. See *supra* notes 120–129 and accompanying text.

195. See *supra* notes 108–110 and accompanying text.

196. Payment of Fees, 38 C.F.R. § 14.636(h)(iii) (2010).

not “results in monetary benefit.”¹⁹⁷ In cases involving administrative offset, a successful attorney has unquestionably gained something of value for his client. Further, even though the claimant might not receive his past-due benefits award in cash, he has still in some sense been compensated—the payment was simply applied to reduce his debt to the government. Such a veteran has still received something of value, making it difficult to see why his attorney does not deserve compensation for the work done on the claim.

The validity of 38 C.F.R. § 14.636 has yet to be tested in courts,¹⁹⁸ but if it were simply VA’s decision to interpret “results in a cash payment” so as to keep attorneys from claiming portions of benefits awards that are of no use to a veteran, it is unlikely a court would find the regulation troubling. This, however, is not the case. VA has taken a different direction with its regulation by using it to change the statutory entitlement scheme for direct payment of attorneys.¹⁹⁹ Precedent Opinion 12-93 declares that 38 C.F.R. § 14.636 precludes the payment of attorney fees when administrative offset applies the entirety of a veteran’s award to offset debt to the government—even though affected veterans still receive something of financial value.²⁰⁰

C. Precedent Opinion 12-93: The Real Hurdle

Precedent Opinion 12-93 is the clearest statement of VA’s position regarding administrative offset and attorney fees.²⁰¹ It establishes that VA will only enforce fee agreements if they fit 38 U.S.C. § 5904 and 38 C.F.R. § 14.636(h), meaning the claimant must, at the end of VA proceedings, receive a payment of some amount, however nominal.²⁰² If the claimant is paid nothing, neither is the attorney. The set of facts that prompted the

197. *See id.*

198. *See Snyder v. Nicholson*, 489 F.3d 1213, 1220 n.2 (Fed. Cir. 2007) (postponing the discussion of whether 38 C.F.R. § 14.636 is valid).

199. Precedent Opinion 12-93, *supra* note 18.

200. *Id.*

201. *Id.* (resolving whether VA must enforce a fee agreement “when the claimant would not be entitled to payment of any portion of the past-due benefit award because his outstanding indebtedness to the United States exceeded the amount of the past-due benefits”). If an agency interpretation is delivered in policy statement, rather than a regulation, the interpretation is not entitled to full *Chevron* deference. *See Christensen v. Harris County*, 529 U.S. 576, 587 (2000) (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944) (holding that interpretations such as opinion letters are entitled to respect to the extent they have “power to persuade”). *See generally* Robert A. Anthony, *Three Settings in Which Nonlegislative Rules Should Not Bind*, 53 ADMIN. L. REV. 1313 (2001) (dissecting various precedents that dictate the proper level of deference in a given regulatory situation).

202. Precedent Opinion 12-93, *supra* note 18. VA focuses on “payment” language, which further distinguishes it from *Snyder*’s “awarded” language. *Cf. Snyder*, 489 F.3d 1213.

decision clarifies the issue. In Precedent Opinion 12-93, the veteran owed \$8,041.10 to VA after his participation in a loan program, which exceeded the amount of past-due benefits the RO awarded after finding his disability rating should be increased.²⁰³ His attorney had filed a fee agreement with VA that in every respect comported with statutory requirements. The attorney argued that he was entitled to 20% of the past-due benefits awarded, which left only the remainder subject to administrative offset.

Instead, VA decided that because the entirety of the debt would not satisfy the veteran's debt obligations, it must all be offset and 38 C.F.R. § 14.636 acted to preclude the attorney from claiming his portion.²⁰⁴ If, after all the dust has settled, the veteran owes more to VA than he is due to receive, there is no fund from which the fee can be deducted and paid out directly to the attorney.²⁰⁵ There must be a payment made, however small, for an attorney fee agreement to be enforced by VA. *Snyder* brings out a potential absurdity in this result—if at the conclusion of offset a claimant receives \$1 of a \$100,000 award, the attorney is entitled to 20% of the amount awarded on the claim (\$20,000), not 20% of the \$1 actually received by the veteran. But if at the conclusion of offset the claimant's debt is exactly settled, with nothing left over for the veteran—a mere \$1 difference in the final cash result—the attorney will receive nothing because the veteran received nothing. VA can sustain this position only by contending that the attorney's entitlement is inextricably linked to the veteran's cash payment.²⁰⁶

Precedent Opinion 12-93 struggled to prove VA's interpretation of attorney fee regulations was in accord with *In re Smith*.²⁰⁷ It largely relied on what VA perceived as the CAVC's favorable use of fund language.²⁰⁸ However, this reliance is misguided. It is true that the CAVC referred to the fund of past-due benefits awarded, but it did not use *fund* to refer to the amount of what would actually be paid to the veteran, as VA does.²⁰⁹ Instead, it saw the fee agreement as an instrument to “divide and define” the fund of past-due benefits—there was a fund for the attorney and a fund

203. Precedent Opinion 12-93, *supra* note 18, at cmt. 2.

204. *Id.* at cmt. 5.

205. *Id.* at cmt. 9.

206. See *supra* notes 147–148 and accompanying text (explaining how *Snyder* undermines this position by holding that *awarded* means amount awarded on the claim, not actually received).

207. *In re Smith*, 4 Vet. App. 487 (1993).

208. See Precedent Opinion 12-93, *supra* note 18, at cmts. 8 & 9 (arguing CAVC's quotation of the regulatory requirements shows there is “no reason to believe” that VA is precluded from collecting attorney fees in cases involving total administrative offset).

209. See *In re Smith*, 4 Vet. App. at 494.

for the veteran.²¹⁰ This supports the attorney as being directly entitled to his contingent fee; indeed, it mirrors the attorney's argument at issue in Precedent Opinion 12-93.²¹¹ VA either missed or ignored the CAVC's explanatory statement and instead decided no fund of past-due benefits is created in situations of offset.

Further, Precedent Opinion 12-93 overlooks the CAVC's discussion of the important congressional purpose behind § 5904(d) fee agreements, which was to assist all veterans in gaining legal assistance by enabling them to pay for it out of past-due benefits.²¹² VA policy instead makes it impossible for certain veterans to pay for representation. It does so by twisting a statute granting authority to set the amount of fees into a permit to alter the entitlement scheme providing for direct payment of attorney fees.

D. VA's Abuse of Its Limited Authority

The Federal Circuit interprets § 5904 as authorizing the VA to issue regulations and opinions that conform strictly to its language but go no further. For example, *Snyder* mentions that “[§] 5904 makes no mention of special provisions for attorneys who . . . undertake representation of incarcerated veterans.”²¹³ Likewise, § 5904 makes no mention of administrative offset, meaning that under *Snyder*'s statute-based analysis VA has no authority to make special rules attempting to merge administrative offset rules with those governing attorney fees. The Federal Circuit has also asserted plainly that certain and direct payment is a crucial part of the system as an “offsetting benefit” to make up for the lower contingency fees that are found in other practices.²¹⁴ Certainty of payment is part of the plan; by altering the statute beyond its authority, VA is discouraging attorneys from representing veterans with doubtful financial situations.²¹⁵

In enacting the VJRA, Congress envisioned attorney fee agreements in which the total “amount of the fee payable to the attorney is to be paid to

210. *Id.* at 495.

211. *See* Precedent Opinion 12-93, *supra* note 18, at cmts. 3 & 9 (asserting that if the veteran's fund is depleted, there is no fund for the attorney).

212. *See In re Smith*, 4 Vet. App. at 496 (highlighting importance of paid legal representation).

213. *Snyder v. Nicholson*, 489 F.3d 1213, 1216 (Fed. Cir. 2007).

214. *See Scates v. Principi*, 282 F.3d 1362, 1366 (Fed. Cir. 2002) (discerning congressional intent to provide incentive to take cases that are far less profitable than the average claim in practice).

215. *See Astrue v. Ratliff*, 130 S. Ct. 2521, 2529–30 (2010) (Sotomayor, J., concurring) (believing there to be no question that without economic incentives lawyers will not take on needy clients).

the attorney by the Secretary directly from any past-due benefits awarded on the basis of the claim.”²¹⁶ While the Veterans Act of 2006 changed the timeline for when attorneys can become involved, Congress did not alter its “is to be paid . . . directly” language.

Congress gave the Secretary the power to prescribe “reasonable restrictions on the *amount* of fees [an attorney] may charge a claimant,” and then further limited the power by declaring that a fee that does not exceed 20% of the past-due benefits awarded on the claim is presumptively reasonable.²¹⁷ This shows the Secretary’s ability regarding fee agreements is merely to regulate the amount that can be charged—not determine ultimate ownership of the contingent fee.²¹⁸ Although the Secretary may review a fee agreement filed with VA, the review power is simply for reduction if the fee is “excessive or unreasonable.”²¹⁹ Indeed, even VA recognizes that Congress’s intent in enacting § 5904 was to grant VA the power to regulate the amount charged—i.e., the fee percentage.²²⁰

So long as the attorney follows the procedures to file a fee agreement with VA, the VA is required to uphold and honor that agreement—with direct payment of fees.²²¹ Congress has established attorney ownership of such fees; there is nothing for VA to do. There is simply no ambiguity as to ownership.

Beyond setting reasonable restrictions on the amount of fees an attorney may charge, Congress intended to give the Secretary the authority to require attorneys practicing before VA to have minimum levels of experience and training, to collect from attorneys a periodic registration fee to defray the costs of attorneys practicing before VA, and to review fee agreements and reduce fees that are excessive and unreasonable.²²² No mention was made of VA’s ability to change an attorney’s entitlement to direct payment. In the Senate hearing, VA recognized the limited grant of authority, repeating that it would be authorized to “restrict the amount of fees attorneys may charge, and subject fee agreements . . . to review by the

216. 38 U.S.C. § 5904(d)(2)(A)(i) (1988).

217. 38 U.S.C. § 5904(a)(5) (2006) (emphasis added).

218. The Secretary is also permitted to regulate VA’s requirements for recognition and qualification of attorneys. *Id.* § 5904 (a)–(b).

219. *Id.* § 5904(c).

220. Accreditation of Agents and Attorneys; Agent and Attorney Fees, 73 Fed. Reg. 29,852, 29,866–68 (preamble to final rule issued May 22, 2008) (to be codified at 38 C.F.R. § 14.636) (stating Congress authorized VA to “prescribe in regulations reasonable restrictions on the amount of fees that an agent or attorney may charge a claimant” and that Congress “intended that claimants would have [a] choice in representation with respect to all claims for benefits”).

221. 38 U.S.C. § 5904(d)(2).

222. *Id.* § 5904.

Secretary.”²²³ Congressional intent is clear: it is important for the Secretary to have some latitude in deciding who can practice and how much they can charge, but VA has no authority to alter the statutory scheme of direct payment out of past-due benefits.²²⁴

Moreover, stripping an attorney of ownership of a contingency fee goes directly against Congress’s broader intent. It is important to remember that attorneys have never been completely locked out of the VA benefits system. Under no statutory scheme were attorneys absolutely prohibited from representing veterans; the representation just had to be essentially pro bono.²²⁵ And yet in enacting the Veterans Act of 2006, Congress was concerned with a veteran’s right to hire an attorney—which, given the history, must mean the ability to pay one.²²⁶

The ability to pay an attorney is integral to the statutory scheme of the Veterans Act of 2006, which intended to enable all claimants to have the benefit of legal counsel during VA administrative proceedings.²²⁷ This “benefit” in reality only accrues when the veteran can pay the attorney—and under the current law, the only way a veteran can “pay” an attorney is through a contingent cut from past-due benefits.²²⁸ If the entirety of an indebted veteran’s past-due benefits must go to reduce the government debt, VA has eliminated that veteran’s ability to pay and hire an attorney.

E. An Anticipated VA Response

VA’s most successful attempt to downplay the importance of attorneys and circumscribe their rights came in *Walters*, and it is reasonable to expect VA to rely on *Walters* if it opposes any regulatory changes promoting attorney participation in veterans law.²²⁹ *Walters* dealt with due process

223. See *Benefits Hearing*, *supra* note 113, at 12–13 (prepared statement of VA).

224. Courts have freely admitted that without economic incentive for attorney involvement most veterans will be forced to forego legal representation. See *Snyder v. Nicholson*, 489 F.3d 1213, 1216 (Fed. Cir. 2007) (remarking that because at the time attorneys were prohibited from collecting compensation before the BVA issued a final decision, “[a]s a practical matter, this means that veterans will not be represented by attorneys until their claims for benefits have been rejected by the Board”).

225. See *supra* Part I (tracking the progression of attorneys fees from the low limits established during the Civil War to the VJRA, which prohibited attorneys from charging any fee prior to a final BVA decision).

226. See, e.g., *Benefits Hearing*, *supra* note 113, at 1–3 (statement of Sen. Larry E. Craig, Chairman, S. Comm. on Veterans Affairs) (expressing Congress’s overwhelming agreement that veterans needed to have the ability and choice to hire an attorney).

227. *Id.*

228. See 38 U.S.C. §§ 5901, 5904 (2006) (limiting compensation to payment out of past-due benefits, a statutory exception to the general rule against assignment of benefits).

229. *Walters v. Nat’l Ass’n of Radiation Survivors*, 473 U.S. 305 (1985).

challenges to restrictions on legal representation and is thus largely irrelevant to the issue of statutory entitlement to direct payment of attorney fees.²³⁰ But it nonetheless merits some attention because it is the only case involving a veteran's right to counsel to reach the Supreme Court.

The VJRA, enacted only a few years after *Walters* and superseding its holding, pretty well proves the importance that Congress places on veterans' access to legal representation—an importance that is only heightened by the Veterans Act of 2006. Further, the issue in *Walters* was a veteran's constitutional due process right to a lawyer—and the present issue is a lawyer's *statutory* entitlement to a portion of the veteran's award.²³¹ Thus, *Walters* provides no real support for a potential VA position that attorneys are unnecessary and the claimants that would be affected by attorney fee policies have adequate access to VSOs.

Moreover, the accessibility of VSOs does nothing to change the statutory entitlement scheme and does not negate Congress's intent to allow veterans to compensate an attorney for work done on claims. Congress recognized the quality service offered for free by VSOs but widely felt that it could not limit veterans' options.²³² This concern was specifically about a veteran's ability to compensate attorneys at the agency level, as attorneys were already able to get EAJA fees for representation once in court.²³³ By foreclosing the ability for certain veterans to pay an attorney, VA is eliminating that class of veterans' ability to exert the freedom Congress intended to afford them. As Congress noted, not being able to hire a lawyer results in a “de facto bar [on legal representation] because the lawyer cannot get compensated for their time.”²³⁴ VA's regulatory scheme thus defeats a cherished principle of VA adjudication of veterans benefits: that the merits of a case, and not financial standing, would dictate a veteran's ability to retain legal representation.

230. For analysis on the future of due process challenges to VA's lawyering rules, see John W. Egan, Note, *The Department of Veterans Affairs and the Constitutional Implications of Judicial Review: Veterans' Due Process Right to Hire Counsel*, 16 FED. CIR. B.J. 31 (2006).

231. As to the state of a veteran's due process right to a lawyer, the scene has changed since *Walters*. *Cushman v. Shinseki*, 576 F.3d 1290, 1290–92 (Fed. Cir. 2009), displayed the Federal Circuit's initiative in holding “a veteran alleging a service-connected disability has a due process right to fair adjudication of his claim for benefits.” VA did not seek certiorari in *Cushman*, which has led Professor Jeffrey Lubbers to conclude that it represents the agency's current view. See Jeffrey S. Lubbers, *Giving Applicants for Veterans' and Other Government Benefits Their Due (Process)*, ADMIN. & REG. L. NEWS, Spring 2010, at 16, 19.

232. See *Benefits Hearing*, *supra* note 113, at 2 (acknowledging veterans may conclude that the free VSO services are a better deal, but deciding against limiting their options).

233. *Benefits Hearing*, *supra* note 113.

234. *Id.* at 23.

CONCLUSION

Unlike awards of attorney fees under EAJA, Congress did express its intent to provide for the direct payment of veterans' attorney fee agreements that comport with the requirements of § 5904(d). The Federal Circuit, as previously mentioned, sees certainty of collection as a congressionally created perk to compensate for the low fee percentage attorneys are allowed to charge when representing veterans who could not otherwise hire at attorney. In addition, *Snyder* works to discredit VA's "results in a cash payment" rule as grounds for the entitlement shifting promulgated in Precedent Opinion 12-93: once fee agreements meet the requirements of § 5904, VA is obligated to enforce them.²³⁵ If Congress did not specifically mention a special scheme for certain veterans regarding the payment of their attorneys, the Federal Circuit's opinion in *Snyder* suggests that there simply is not supposed to be one and VA cannot make one up. Likewise, *In re Smith* discounts VA's emphasis on the existence of the fund argument by explaining that a fee agreement "divides and defines" two separate funds with two separate entitlements.²³⁶ Given the Supreme Court's recognition in *Ratliff* that Congress knows how to provide for direct payment when it wants to,²³⁷ VA should work to either conform its regulatory interpretations to the statutory language or simply change the regulations themselves.

Congress provided for judicial review of VA decisions to ensure veterans were treated fairly and that all veterans received the benefits to which they were entitled.²³⁸ Later, perceiving that legal representation only before the courts was not enough, Congress expanded its statutes to promote legal representation before the agency. To this end, Congress allowed veterans to hire attorneys, who are compensated by a percentage of past-due benefits ultimately awarded. It likewise provided for direct payment of these fees to give attorneys incentives—namely, that of certain collection. Precedent Opinion 12-93 has stepped beyond VA's statutory power and has frustrated Congress's intent by eliminating an indebted veteran's ability to hire and pay an attorney. This opinion flouts the Supreme Court's decision in *Ratliff* by relying on regulations, rather than the underlying statute, to justify its administrative offset provisions for attorney fees.

If it does not amend its regulations, VA will force the most needy veterans to navigate one of the most complex benefits systems in the world without legal representation. VA must abandon its resistance to direct

235. *Snyder v. Nicholson*, 489 F.3d 1213, 1216 (Fed. Cir. 2007).

236. *See supra* note 28 and accompanying text.

237. *Astrue v. Ratliff*, 130 S. Ct. 2521, 2527 (2010).

238. *Barrett v. Nicholson*, 466 F.3d 1038, 1044 (Fed. Cir. 2006).

2011] *DEPARTMENT OF VETERANS AFFAIRS' ENTITLEMENT COMPLEX* 597

payment of attorney fees. The statute is clear and Congress's intent even clearer.

Congress knows how to specify direct payment when it wants to; it is time for VA to give force to Congress's intention to allow every veteran legal representation. VA is missing the point when it comes to attorneys' involvement in veterans law. The government's interest in veterans' cases is "not that it shall win, but rather that justice shall be done"²³⁹—an interest that is surrendered under the current regulatory scheme. The business of lawyers is justice, and every veteran who desires legal representation should be able to meaningfully seek it.

239. *Id.*

THE ILLUSION OF INTERCHANGEABILITY: THE BENEFITS AND DANGERS OF GUIDANCE-PLUS RULEMAKING IN THE FDA’S BIOSIMILAR APPROVAL PROCESS

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TABLE OF CONTENTS

Introduction: Reducing the Costs of Prescription Drugs via a New Generic Biologic Pathway.....	600
I. Background.....	607
A. History of Biologics Regulation	607
B. History of Recombinant DNA Protein Products.....	611
C. Hatch–Waxman	614
D. Preexisting Legal Framework	615
II. The Biosimilars Act and the Hatch–Waxman Act: The Two Parallel Pathways, Compared.....	618
A. Legislative History	618
B. The Biosimilars Act, Generally.....	620
C. Definition of Biologics	621
D. Bioequivalence, Biosimilarity, and Interchangeability	622
1. Biosimilarity.....	623
2. Interchangeability	626
E. New Approval Procedures: What an ABLA Might Look Like	627

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F. Notice-and-Comment or Guidance-Plus Rulemaking?	628
G. Judicial Review and Legislative Rules	633
III. Recommendations to the FDA	636
A. Classifying Biologics Through Legislative Rules	636
B. Flexible Guidance for Interchangeability and Biosimilarity Determination Requirements	640
C. Fundamental Assumptions: Proposing a Balancing Test in Clinical Trials	641
Conclusion	644

This is the patent age of new inventions, for killing bodies, and for saving souls, all propagated with the best intentions.

—Lord Byron¹

INTRODUCTION: REDUCING THE COSTS OF PRESCRIPTION DRUGS VIA A NEW GENERIC BIOLOGIC PATHWAY

On March 23, 2010, President Obama signed into law the ambitious Patient Protection and Affordable Care Act.² While media attention focused largely on the sweeping changes the bill makes to the nation's healthcare system,³ there was also a less-noticed rider to the bill, the Biologics Price Competition and Innovation Act of 2009 (Biosimilars Act).⁴ The Biosimilars Act grants the Food and Drug Administration (FDA) broad new authority to create an accelerated premarket approval pathway for

1. GEORGE GORDON BYRON, DON JUAN 39 (Leslie A. Marchand ed., Riverside Press 1958) (1819) (Canto I, Stanza CXXXII).

2. Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified as amended at scattered sections of the Internal Revenue Code and 42 U.S.C.) (better known as the Healthcare Reform Act).

3. See, e.g., Sheryl Gay Stolberg et al., *The Long Road Back: Tactics, Perseverance and Luck Resurrected a Bill*, N.Y. TIMES, Mar. 21, 2010, at A1 (discussing the political battle that preceded the passage of the PPACA).

4. Biologics Price Competition and Innovation Act of 2009 (Biosimilars Act), Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010) (to be codified throughout 42 U.S.C.). The Biosimilars Act will be codified as an amendment to the Public Health Service Act (PHSA), Pub. L. No. 78-410, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 262–300jj (2006 & Supp. III 2009)), which grants biologics approval to the Food and Drug Administration (FDA).

generic competition to biologics⁵ in an attempt to drive biologic drug prices down and reduce the overall costs of health care.⁶

Traditionally, inventors of medical products such as drugs and devices obtain patent protection at the United States Patent and Trademark Office (USPTO) for a twenty-year exclusive term⁷ and simultaneously must seek FDA approval to market their invention⁸ and for a trademark for their brand name.⁹

Because of the complicated and thorough approval process the FDA conducts, it is often expensive and time-consuming for the initial innovator to bring a drug to market.¹⁰ Likewise, it is often prohibitively expensive for a generic follow-on company to bring an analogue to market, after patent protection has expired, through duplicative and costly reapproval of the

5. See *infra* note 22 and Part II.C (discussing the old and amended definition of *biologics*).

6. See Randy Osborne, *Brand Biologics Grab 12 Years' Exclusivity, for Now*, 27 NATURE BIOTECHNOLOGY 677, 677–78 (2009) (decrying the twelve-year data exclusivity provisions of the bill as a coup for the innovator industry).

7. See 35 U.S.C. § 154(a)(2) (2006) (granting statutory authority to issue twenty-year patents).

8. Statutory authority for drug approval is found under § 505 of the Food, Drug, & Cosmetic Act (FDCA), Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.). Devices are regulated under § 510(k) of the Medical Devices Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C.), and biologics are generally regulated under PHS Act § 351, with historic exceptions for insulin, human growth hormone, and a few others that qualify as both biologics and drugs, which are regulated as new drugs under FDCA § 505. See David M. Dudzinski, *Reflections on Historical, Scientific, and Legal Issues Relevant to Designing Approval Pathways for Generic Versions of Recombinant Protein-Based Therapeutics and Monoclonal Antibodies*, 60 FOOD & DRUG L.J. 143, 154 (2005) (“In the 1940s, insulin was obtained in the same manner as many biologics, namely extraction from animals. Despite this similarity with biologics, insulin was regulated by FDA and not the Public Health Service.”).

9. Lanham Act, 15 U.S.C. § 1051 (2006) (granting statutory authority over trademarks). Thus, despite being codified at different section numbers, drug approvals are commonly referred to as § 505 approvals, biologics as § 355, and devices as § 510(k). Abbreviated approvals under Hatch–Waxman are referred to as § 505(b)(2) approvals.

10. Compare Joseph A. DiMasi, Ronald W. Hansen, & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 166 (2003) (estimating the cost of research and development (R&D) for new drugs at \$403 million), and Pharm. Research & Mfrs. of Am. (PhRMA), *Drug Discovery and Development*, PHRMA, <http://www.phrma.org/research/drug-discovery-development> (last visited Aug. 14, 2011) (estimating the R&D for a new drug is more than \$800 million and can top \$1 billion), with MERRILL GOOZNER, *THE \$800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS* 244–46 (2004) (maintaining these numbers are inflated and citing studies that estimate the true cost at \$115–240 million).

innovator drug, and it would be unethical to subject further human subjects to unneeded clinical trials.¹¹

To deal with these problems, in 1984 Congress enacted a law called the Price, Competition, and Patent Term Restoration Act, which is commonly referred to as the Hatch–Waxman Act.¹² The Act allows generic follow-on drugs to seek accelerated approval by the FDA. In exchange, the law grants limited data exclusivity¹³—and hence, often de facto market exclusivity¹⁴—for the original brand-name innovator.¹⁵ The Act utilizes a preexisting compilation of all relevant drugs and their clinical indications, the *Orange Book*, to list generic analogues.¹⁶ Most importantly, Hatch–Waxman allows generic drug manufacturers to use the same FDA approval data as the brand-name manufacturers had in an abbreviated approval application (thus eliminating the need for duplicative human trials and reducing cost for generic manufacturers).¹⁷ The result has been a decrease

11. See *supra* note 10.

12. Drug Price Competition and Patent Term Restoration (Hatch–Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. §§ 156, 271, 282 (2006)).

13. See Jessica Wapner, *Can Data Exclusivity Lead to Immortality?*, WORK IN PROGRESS (Jan. 28, 2011), <http://blogs.plos.org/workinprogress/2011/01/28/can-data-exclusivity-lead-to-immortality/> (“‘Data exclusivity’ . . . refers to protection of not only the drug but also the data. Under data exclusivity, manufacturers of generic drugs are prevented from using the original clinical trial data to support approval of their ‘biosimilar. . . .’”).

14. Market exclusivity is literal—it means simply having no competition for a product in the marketplace. *Cf. id.* (“[T]he new law gives new biologics at minimum 2.5 years and at most 7 years of additional solo time on the market.”).

15. See Hatch–Waxman Act, 21 U.S.C. § 355(c)(3)(E), 355(j)(5)(F) (2006) (awarding data exclusivity to innovator and first-to-file generic applicants).

16. See *id.* § 355(j)(2)(A)(iii)–(v) (requiring listings). Generic drugs are those that are therapeutically equivalent with the original brand-name drug. The *Orange Book* is a listing of the levels of therapeutic equivalence and interchangeability. FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2011), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf> (so called because the original *Orange Book* had an orange cover).

17. See FDCA, 21 U.S.C. § 355 (codifying the Hatch–Waxman Act’s amendment of § 505(2)(b) of the FDCA). These Abbreviated New Drug Applications, or ANDAs, are regulated under § 505(2)(b), and also allow for patent dispute resolution between the innovator and the follow-on, as well as an added 180-day “follow-on” market exclusivity over second or third follow-on companies as a financial incentive to provide the initial funding for the costly approval process. Applicants can also file “paper new drug applications,” or Paper NDAs, which allow a generic applicant to rely on publicly available scientific papers in lieu of self-funded studies. For more, see *infra* notes 124–26 and accompanying text. See also Dudzinski, *supra* note 8, at 216 (mapping out § 505(b)(2) for the differences between NDAs, Paper NDAs, and ANDAs approval pathways and generic versus innovator drugs).

in the cost of prescription drugs due to increased price competition after the expiration of the original drug's patent term.¹⁸

However, the FDA maintained that the pathway applied only to single-molecule drugs, so there were large exceptions for other types of analogous medical therapies.¹⁹ For instance, the FDA generally approves medical devices (such as pacemakers or stents)²⁰ under a separate pathway.²¹ There is also another category of therapeutic substances known as biologics, which includes nearly anything derived from living organisms, such as vaccines, blood, or cellular products.²² Importantly, a therapy can be both a “drug” and a biologic at the same time, such as insulin, human growth hormone, or other small-protein biologics.

Biologics are traditionally harder to produce and regulate than synthetically created single-molecule drugs because of their complexity, unpredictability (i.e., their ability to mutate or change shape),²³ and the fact

18. See Henry Grabowski et al., *The Market for Follow-On Biologics: How Will It Evolve?*, 25 HEALTH AFF. 1291, 1293 (2006) (discussing Hatch–Waxman’s long-term cost savings as it relates to potential biosimilars savings). Similarly, price competition for biologics could significantly lower the cost of health care. See Dawn Willow, *The Regulation of Biologic Medicine: Innovators’ Rights and Access to Healthcare*, 6 CHI.-KENT J. INTELL. PROP. 32, 36–37 (2006) (projecting cost savings).

19. Cf. FDCA, 21 U.S.C. § 355(j) (codifying the Hatch–Waxman Act’s amendment of § 505(2)(b) of the FDCA) (providing abbreviated approval for generic drugs). The FDA had taken the position that § 505(b)(2) of the FDCA (as amended by the Hatch–Waxman Act) gave it a pathway to approve “more than 80 section 505(b)(2) applications for drugs for indications ranging from cancer pain to attention deficit disorder.” See Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation and Research, to Katherine M. Sanzo et al. 4 (Oct. 14, 2003) [hereinafter FDA Interpretation], available at <http://www.fda.gov/ohrms/dockets/dockets/04p0231/04p-0231-c000001-exhibit-29-vol4.pdf> (position mooted by Biosimilars Act).

20. See, e.g., U.S. Patent No. 7,135,038 (filed Sept. 30, 2002) (drug eluting stent); U.S. Patent No. 5,243,977 (filed June 26, 1991) (pacemaker).

21. 21 U.S.C. § 360(k) (codifying the Medical Devices Amendments of 1976, Pub. L. No. 94–295, 90 Stat. 539, § 510(k), and granting the FDA authority for device review).

22. 42 U.S.C. § 262(i) (2006) (granting jurisdiction over “viruses, therapeutic serums, toxins, antitoxins, or analogous products,” and more that were intended for the “prevention, treatment, or cure of a disease or condition of human beings”); see *infra* Part II.C (discussing the amended definition of biologics). The FDA interprets *analogous* to include therapeutic proteins, monoclonal antibodies, and immunoglobulins. James N. Czaban et al., *Panacea or Poison Pill? Making Sense of the New Biosimilars Law*, 8 BNA PHARM. L. & INDUSTRY REP., May 2010, at 1, 2, available at http://www.bna.com/pdf/plir_05032011.pdf (categorizing the FDA’s interpretation as “broad”).

23. The three-dimensional structure of proteins affects how they bind to cells and other proteins. Imagine a long chain of magnets; a chain of identically opposite magnets would bind well with it. If the chain is twisted or overlapped, however, the binding changes drastically. See KATHERINE J. DENNISTON ET AL., GENERAL, ORGANIC, AND BIOCHEMISTRY

that they are often vaccines derived from live viruses with the potential to wreak large-scale havoc if they are not closely regulated.²⁴

But what was originally a largely separate category for those rare treatments that required live precursor sources (such as vaccines or sera) has today morphed into an over \$52 billion arm of the drug industry,²⁵ fueled in part by the creation of recombinant DNA technology and the so-called genomics revolution.²⁶ Recombinant DNA technology allowed for the laboratory creation of large amounts of proteins and other cellular products from living precursor cells, providing vast opportunities for biotechnology firms to create products on a commercial scale that are both “biologics” and “drugs” under the law.²⁷ Further, with the mapping of the human genome, scientists predict that emerging biologic drugs will be personalized

554–55 (3d ed. 2001) (describing the complicated structural interactions and the forces that can alter them). Each protein—like the pie-shaped character in Shel Silverstein’s *The Missing Piece*—has an often-unique object it wants to bind with. Cf. SHEL SILVERSTEIN, *THE MISSING PIECE* (1976).

24. See *infra* notes 49–51 and accompanying text (explaining how, prior to regulation, faulty batches of biologics caused a number of deaths).

25. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., RL 33901, FOLLOW-ON BIOLOGICS: INTELLECTUAL PROPERTY AND INNOVATION ISSUES 1 (2009).

26. See generally FRANCIS S. COLLINS, *THE LANGUAGE OF LIFE: DNA AND THE REVOLUTION IN PERSONALIZED MEDICINE* (2010) (discussing the future of genetics and the biotech industry).

27. Compare the statutory definition of *drug*:

The term “drug” means . . . articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

FDCA, 21 U.S.C. § 321(g)(1) (2006), with the statutory definition of *biologic*:

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

PHSA, *id.* § 262(i) (2006) (amendments italicized) (as currently amended by Biosimilars Act § 7002(b)). Noticeably, the definitions are not co-exclusive, and hence it is possible for the FDA to classify a biologic as both a biologic and a drug and to approve such a “biologic drug” under either an NDA or a Biologics License Application (BLA). See *supra* note 17 (NDAs) and *infra* note 162 (BLAs). Like a Venn diagram, there is substantial overlap between the two definitions—nearly all biologics, if read broadly enough, qualify as drugs. Indeed, this is what has led to some of the confusion and wargaming. For instance, some innovator drugs approved under an NDA would have preferred approval under a BLA, so their potential generic competition could not avail themselves of § 505(b)(2) abbreviated approval.

to an individual's own genetic traits and could vastly improve the quality of care over the current "one size fits all" model of chemically synthesized drug treatment.²⁸

Biologic drugs generally cost far more to manufacture than their single-molecule and chemically synthesized ("non-biologic") counterparts, because they are either "alive" or of a highly sensitive nature and must be created and closely monitored in a laboratory environment.²⁹ Additionally, the lack of a pathway for generic competition and rigorous, expensive, and ever-changing scientific standards for approval often result in de facto market exclusivity for the original brand-name manufacturer, further driving up the cost.³⁰ Biologic drugs average between \$10,000 to \$20,000 per patient, per year³¹ and can be as expensive as \$10,000 for a single dose.³² Hence, they significantly contribute to the cost of health care.³³ Industry experts and lawmakers expect the new regulatory pathway to increase price competition and decrease the cost of these drugs.³⁴

While it will be almost a decade before the FDA fully implements the new biosimilars law and issues controlling guidelines for industry practice,³⁵ debate has already begun over the feasibility of determining interchangeability and biosimilarity for biologics.³⁶ Indeed, the FDA has

28. See COLLINS, *supra* note 26, at XXIII–XXIV, 231–35, 237–50 (discussing biologic treatments targeted to individuals' genomes).

29. Jeremiah J. Kelly & Michael David, *No Longer "If," but "When": The Coming Abbreviated Approval Pathway for Follow-on Biologics*, 64 FOOD & DRUG L.J. 115, 119 (2009) ("[B]iological drug products are typically produced in vivo (in a biological system) and, as a result, are complex and less well understood."). Further, the manufacturing process has a serious effect on the final product—purification is required. *Id.*

30. *Id.* at 115 (advocating lowering the cost of prescription drug prices).

31. For example, as of 2005, the "annual cost of Raptival [was] over \$12,000 . . . annual cost of Rebif [was] over \$13,000 . . . annual cost of Humiral [was] over \$15,000 . . . Kineret costs over \$15,000." Dudzinski, *supra* note 8, at 144 n.5.

32. "[A] single dose of Xigris costs approximately \$10,000." *Id.*

33. See *The Law of Biologic Medicine: Hearing Before the S. Comm. on the Judiciary*, 108th Cong. 1, 24–25 (2004) (statement of Carole Ben-Maimon, President and CEO, Barr Research, Inc.) [hereinafter *2004 Hearing*].

34. See, e.g., Czaban et al., *supra* note 22, at 2 n.8, 3 (citing a Congressional Budget Office estimate of \$6–7 billion in cost savings over ten years, but cautioning that drug prices may not fall significantly).

35. The FDA is not required to issue biosimilar guidelines until at least 2020. See Biosimilars Act, Pub. L. No. 111-148, § 7002(e)(2)(B)(ii), 124 Stat. 119, 817 (to be codified at 42 U.S.C. § 262). For now, applicants "may" use § 505 for biologics applications. *Id.* § 7002(e)(2).

36. The FDA has already begun to gather public, industry, and academic input on how the guidelines ought to be fashioned. See *infra* note 45 and accompanying text.

already set aside \$5.7 million for fiscal year 2011 toward the development of a biosimilars program,³⁷ and one senior FDA official has announced publicly that at least one guidance document will be released “by the end of the year, without question.”³⁸

Some critics argue that any new biologics pathway will be so restrictive that it will do little to improve price competition.³⁹ Others argue it is a scientific impossibility to achieve interchangeability between some biologics (due to their variable nature as living organisms) and so the FDA’s efforts are doomed.⁴⁰ The traditional model for interchangeability under Hatch–Waxman (bioequivalence) is based on the assumption that a single-molecule drug may be chemically synthesized by another laboratory and will have the same effect.⁴¹ With biologics, however, protein folding, cellular mutation, and environmental factors (such as storage temperature or even light exposure) can all contribute to wildly unpredictable results in any given final product.⁴² Therefore, any determinations of interchangeability

37. Cathy Dombrowski, *FDA Biosimilars Program Gets Seed Money in Administration’s FY ‘11 Budget*, THE PINK SHEET (Feb. 8, 2010) (on file with author).

38. *BioCentury This Week: Biosimilars: Will the Path Work?* (WUSA, CBS affiliate television broadcast May 1, 2011) (comments of Rachel Behrman, Assoc. Dir., Medical Policy in the FDA’s Ctr. for Drug Evaluation and Research), available at <http://biocenturytv.com/fullplayer.aspx> (activate “Expand Video Library” hyperlink; activate “BC Show 33” hyperlink; follow “BioCentury 05.01.11 – [1] The Pathway” hyperlink).

39. See Letter from Bernie Sanders, Senator, Vermont, to Margaret Hamburg, Comm’r, FDA (Nov. 2, 2010), <http://www.fdalawblog.net/files/bcpi-act---sanders-ltr-11-2010.pdf> (calling the twelve-year period of data exclusivity a “defect” in violation of Article 20 of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects).

40. See, e.g., Letter from Arthur D. Levinson, Chairman and Chief Exec. Officer, Genentech, Inc., to Genentech Stockholders, in GENENTECH, INC., GENENTECH 2003 ANNUAL REPORT 4 (2003), <http://www.gene.com/gene/about/ir/historical/annual-reports/2003/editorial/lettertostockholders.pdf> (“Genentech does not believe that the technology currently exists to prove a generic biotech product safe and effective . . .”). Representative Jay Inslee’s (R-WA) proposal in the 110th Congress did not include determinations of interchangeability. See Patient Protection and Innovative Biologic Medicines Act of 2007, H.R. 1956, 110th Cong. § 2(a)(2).

41. Shein-Chung Chow et al., *Statistical Methods for Assessment of Biosimilarity Using Biomarker Data*, 20 J. BIOPHARM. STAT. 90, 91 (2010) (“[T]he assessment of bioequivalence as a surrogate for evaluation of drug safety and efficacy is based on the *fundamental bioequivalence assumption* that if two drug products are shown to be bioequivalent in average bioavailability, it is assumed that they will reach the same therapeutic effect or they are therapeutically equivalent.”) (emphasis in original).

42. See Kelly & David, *supra* note 29 (“A chief argument against abbreviated approval of follow-on biologics is the scientific difficulty in measuring the structural differences, and their effects, between the innovator and the follow-on product.”).

should not be premised on the old model, and it would be scientifically disingenuous or dangerous to regulate them so.

By formulating the Hatch–Waxman Act broadly, Congress has given the FDA wide flexibility to regulate. It has mandated the use of guidance documents, a less costly and time-consuming form of regulating than formal or even informal rulemaking.⁴³ This guidance mandate has the advantage of increased flexibility and a faster turnaround time than traditional notice-and-comment rulemaking.⁴⁴ Nevertheless, if the FDA does not use that flexibility judiciously, the Biosimilars Act may not achieve actual reductions in the cost of prescription biological drugs or significantly affect the cost of health care.⁴⁵

Part I of this Comment discusses the Hatch–Waxman amendments, analogous foreign biosimilars pathways, and the history of biologics approval. Part II discusses the new bill, compares the Hatch–Waxman pathway with the potential biosimilars pathway, and explores key differences between the two that could delay access to both innovator and generic drugs. Part III recommends using notice-and-comment procedures to establish product-class-specific guidance, while retaining flexibility within product classes for clinical requirements, and discourages the FDA from using two-sided biostatistical testing.

I. BACKGROUND

A. *History of Biologics Regulation*

In the nineteenth century, the United States and manufacturers developed and used vaccines (to prevent medical conditions such as smallpox) and antitoxins (to treat ailments like diphtheria).⁴⁶ These

43. See Administrative Procedure Act, 5 U.S.C. §§ 552, 553 (2006) (laying out procedural requirements for formal, informal, and other forms of agency rulemaking).

44. See *id.* The problem with supposedly “informal” rulemaking is that it has become “ossified.” See Jeffrey S. Lubbers, *The Transformation of the U.S. Rulemaking Process—For Better or Worse*, 34 OHIO N. U. L. REV. 469, 471–72 (2008) (discussing the ossification of informal rulemaking).

45. The FDA recently held a public meeting on biosimilars. FDA Public Meeting, Approval Pathway for Biosimilar and Interchangeable Biological Products (Nov. 2–3, 2010), <http://www.fda.gov/Drugs/NewsEvents/ucm221688.htm> [hereinafter FDA Public Meeting] (calling for stakeholder input before issuing biosimilarity and user-fee guidelines).

46. See JONATHAN LIEBENAU, *MEDICAL SCIENCE AND MEDICAL INDUSTRY: THE FORMATION OF THE AMERICAN PHARMACEUTICAL INDUSTRY* 3, 11 (1987) (discussing antitoxins); Rohit K. Singla, *Missed Opportunities: The Vaccine Act of 1813*, *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS*, 31 (Peter Barton Hutt ed., 2004),

therapies presented a host of problems as small patent medicine makers rushed to produce similar products that often had little or no effect, or were in fact harmful to consumers' health.⁴⁷ However, the regulation of drugs was widely thought to be a state law matter, and states were reluctant to spend money on something that was widely perceived as encroaching on personal liberties.⁴⁸

Without regulation of the sources of these treatments, mislabeling, fraud, and deaths were inevitable. For instance, in 1901 thirteen children died from tetanus.⁴⁹ Officials eventually attributed their deaths to a diphtheria antitoxin obtained from the blood of a local horse.⁵⁰ Coincidentally, a similar tragedy occurred in New Jersey around the same time—nine children died from tetanus after receiving a contaminated smallpox vaccine.⁵¹ This provoked Congress to regulate biologics under the 1902 Biologics Control Act, also known as the Virus–Toxin Law.⁵² Thus, Congress created the first premarket approval in United States history for biologics, but synthetic drugs and patent medicines remained largely unregulated.

Soon thereafter, the publication of Upton Sinclair's novel *The Jungle*,⁵³ with its grisly depictions of conditions in the Chicago meatpacking industry, led to the passage of the Pure Food and Drug Act of 1906 (PFDA).⁵⁴ The Act included grants of power to regulate drugs as well as food and granted those powers to the Bureau of Chemistry, thus splitting statutory regulation of biologics and drugs at an early juncture.⁵⁵ Congress had originally

<http://leda.law.harvard.edu/leda/data/229/rsingla.pdf> (discussing early smallpox vaccinations).

47. FRAN HAWTHORNE, *INSIDE THE FDA: THE BUSINESS AND POLITICS BEHIND THE DRUGS WE TAKE AND THE FOOD WE EAT* 36 (2005).

48. Singla, *supra* note 46, at 30–40 (discussing the early widespread opposition to mandatory vaccination).

49. Linda Bren, *The Road to the Biotech Revolution: Highlights of 100 Years of Biologics Regulation*, *FDA CONSUMER*, Jan.–Feb. 2006, at 50, 50–51.

50. *Id.*

51. *Id.*

52. Pub. L. No. 57-244, ch. 1378, 32 Stat. 728 (1902) (previously codified at 42 U.S.C. §§ 141–148, repealed and replaced by PHSA, Pub. L. No. 78-410, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 262–300jj (2006 & Supp. III 2009)) (creating the Center for Biologics Evaluation and Research (CBER) and regulating biologics).

53. UPTON SINCLAIR, *THE JUNGLE* (Bantham Reissue ed., Bantham Books 2003) (1906).

54. Pub. L. No. 59-384, ch. 3915, 34 Stat. 768 (1906).

55. *Id.*; *About FDA: History*, U.S. FOOD & DRUG ADMIN. (last updated July 29, 2010), <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

granted the Hygienic Laboratory, the predecessor of the National Institutes of Health (NIH),⁵⁶ the limited power to review biologics applications. However, after Congress passed the Public Health Service Act of 1944 (PHSA),⁵⁷ which was essentially a recodification of the earlier Biologics Control Act,⁵⁸ biologics review standards came to include “safety, purity, and potency.”⁵⁹

Meanwhile, the Food, Drug, and Insecticide Administration (FDIA) was created in 1927 to deal with drug regulation; it was eventually renamed the FDA.⁶⁰ As the need for broader drug regulation grew, in 1938 Congress vested the Secretary of Agriculture with the power to review new drugs and notify the public that they were safe under the Federal Food, Drug, and Cosmetic Act (FDCA), but preexisting drugs could be sold without premarket approval.⁶¹ This statutory grant of drug review and approval authority solidified the uneven two-track approach to approval of the two analogous (and sometimes overlapping) medical therapies. However, the usefulness of insulin, and the realities of the need for widespread production and sale of this biologic drug soon led to these two tracks crossing paths.

Insulin, which is a protein that naturally occurs in the body, was first discovered, understood, and isolated over a period from the latter half of the nineteenth century to 1921.⁶² In 1922, insulin was finally isolated in an injectable form in Canada.⁶³ Its usefulness at treating diabetes led to the widespread sale of insulin.⁶⁴ Soon after the patent expired, Congress passed the Insulin Amendments, which expressly required the FDA to approve

56. PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 879 (3d ed. 2007).

57. Pub. L. No. 78-410, ch. 373, 58 Stat. 682 (1944) (codified as amended at 42 U.S.C. §§ 262–300jj (2006 & Supp. III 2009)).

58. Biologics Control Act, Pub. L. No. 57-244, 32 Stat. 728 (1902) (previously codified at 42 U.S.C. §§ 141–148 (1942), repealed in 1944 by the PHSA).

59. PHSA, § 351(d), 58 Stat. at 702 (1944).

60. *Dudzinski*, *supra* note 8, at 151–52.

61. Federal Food, Drug, & Cosmetic Act (FDCA), Pub. L. No. 75-717, ch. 675, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.).

62. See Ian Murray, *Paulesco and the Isolation of Insulin*, 26 J. HIST. OF MED. AND ALLIED SCI. 150, 150–57 (1971).

63. See *id.* at 153.

64. See Frederic J. Geissel, *The U.S. Food and Drug Regulatory Process: Administrative Aspects of Certification of Insulins*, in INSULINS, GROWTH HORMONE, AND RECOMBINANT DNA TECHNOLOGY 201 (John L. Gueriguian et al. eds., 1981) (explaining the insulin industry’s growth).

insulin and insulin analogues despite the fact that developers derived it from animals, which qualified it as biologic as well as a drug.⁶⁵

Later in 1948, Congress transferred biologics responsibility from the Hygienic Laboratory to the National Microbial Institute in NIH.⁶⁶ In 1955, after some mishaps with polio vaccine, Congress transferred biologics again to the newly formed Division of Biologics Standards (DBS) within NIH.⁶⁷

In 1962, Congress finally authorized a true “premarket” approval process for drugs in response to the Thalidomide crisis, greatly expanding the FDA’s regulatory authority and bringing it in line with the longstanding premarket approval requirements of biologics.⁶⁸ Still, the two pathways were regulated by separate agencies.

In 1972, amid charges of conflict of interest and agency capture,⁶⁹ the DBS was given broader authority and was finally subsumed by the FDA and became the Bureau of Biologics.⁷⁰ This eventually morphed into the current Center for Biologics Evaluation and Research (CBER).⁷¹

Because of the way the FDA and the two-track approach to regulation has developed historically and the way that the FDA uses Centers to

65. See Insulin Amendments, Pub. L. No. 77-366, ch. 613, 55 Stat. 851 (1941) (codified at 21 U.S.C. § 356).

66. HUTT ET AL., *supra* note 56, at 879.

67. *Id.*

68. Drug [Kefauver–Harris] Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified in scattered sections of 21 U.S.C.) (creating premarket approval for all drugs requiring safety and efficacy testing in response to the Thalidomide crisis).

69. See Nicholas Wade, *Division of Biologics Standards: Scientific Management Questioned*, 175 SCIENCE 966, 968 (1972) (charging Division of Biologics Standards (DBS) with agency capture); see also Dudzinski, *supra* note 8, at 158 (“In the early 1970s, DBS was criticized after a series of well-publicized incidents where relatively ineffective vaccines reached the market.”).

70. Dudzinski, *supra* note 8, at 159.

71. See generally *Vaccines, Blood & Biologics*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/default.htm> (last visited Aug. 14, 2011) (listing the CBER resources and linking to guidance). When an innovator first seeks approval of a medical therapy at the FDA, the FDA must determine where the agency should examine the medical therapy. See *supra* note 8 (discussing the statutory authority for separate approval pathways). For example, the FDA generally sends devices to the Center for Device and Radiological Health (CDRH), while they generally send biologics to CBER and drugs to the Center for Drug Evaluation and Research (CDER). CBER handles reviews of most biologic applications, and the three Centers often work in conjunction on combination products. See generally *Combination Products*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/CombinationProducts/default.htm> (last visited Aug. 14, 2011) (providing guidelines for where examinations should take place).

generally handle certain technologies, when applicants seek premarket approval for a medical therapy, strategically they must ask (and FDA officials must answer) the following three important questions. The results are often confusing.

First, the *definitional question*: how is the product defined by statute?⁷² Second, the *examination question*: at what Center within the FDA will the product be examined?⁷³ Third, the *approval pathway question*: under what statutory premarket approval pathway should the product be regulated?⁷⁴

Until 1972, those questions were relatively easy to answer. Treatments derived from living precursors, for the most part, went to DBS (and later CBER at the FDA) and were approved under Biologics License Applications (BLAs).⁷⁵ Most chemically synthesized single-molecule drugs went to the FDA and the Center for Drug Evaluation and Research (CDER)⁷⁶ and were approved under New Drug Applications (NDAs).⁷⁷ Advances in biotechnology, however, soon blurred those lines.

B. History of Recombinant DNA Protein Products

For thirty years after World War II, the small-molecule drug sector grew rapidly, ballooning into a lucrative industry that treated all sorts of ailments, from infections and allergies to bad breath and bursitis.⁷⁸ Meanwhile, the field of biologics lagged far behind in generating new therapeutically effective products.⁷⁹

72. Is the product a drug, a biologic, or both? For the statutory definitions and a discussion of their substantial overlap, see *supra* note 27 and accompanying text. Or, is it a device or some combination thereof? See *generally Combination Products, supra* note 71.

73. Should the product go to CBER, CDER, or CDRH? See *supra* note 71 and accompanying text (naming the different centers and how the Office of Combination Products makes these determinations).

74. Should my product be examined under an NDA, an ANDA, or a Paper NDA? See *supra* note 17 and accompanying text. A BLA? See *infra* note 162 and accompanying text. A new Abbreviated Biologics License Application (ABLA)? See *infra* note 156 and accompanying text.

75. See *infra* note 162 and accompanying text.

76. See *supra* note 71 and accompanying text.

77. See *supra* note 17 and accompanying text.

78. Dudzinski, *supra* note 8, at 154 (“As American firms began to churn out dozens of new antibiotics, the period immediately after World War II heralded their collective embracing of the ‘small molecule paradigm’ as the *sine qua non* of the modern pharmaceutical industry and the birth of the ‘chemotherapeutic revolution.’”).

79. *Id.* at 160 (“Despite continuous scientific advancements and financial successes of the small molecule paradigm, dominance of the paradigm would be challenged by the biotechnology industry, especially after the late 1970s.”).

That is, until 1972, when the field of recombinant DNA was born.⁸⁰ Just a year prior, a paper published by Hamilton Smith, Daniel Nathans, and Walter Arber showed that you could cleave viral DNA with a specific enzyme.⁸¹ Then in 1972, Stanford Professor Paul Berg conducted a groundbreaking experiment where he used the enzyme to splice a segment of DNA from one organism into another organism (a prokaryote—a single-celled bacterium lacking a nucleus).⁸² In doing so, his team of scientists changed the genetic makeup of the organism. Thus, using this “recombinant” process, scientists could now modify or tailor the genes of host cells to turn bacteria into “living factories” that produced custom therapeutic proteins.⁸³

For instance, scientists quickly learned how to recombine insulin DNA in a particular way and then insert it into the DNA of a single cell bacterium.⁸⁴ In 1982, a company named Genentech developed such a process to produce a “better,” faster-acting form of insulin.⁸⁵ Around the same time, scientists also found a way to produce monoclonal antibodies⁸⁶ (human immune proteins meant to attack and neutralize viruses and bacteria).⁸⁷ They did so by taking a human immune cell called a *B cell*, which produces only one type of antibody, and fusing it with a cancer cell to engineer an immortal cell line which endlessly created one type of antibody.⁸⁸

80. See David A. Jackson, Robert H. Symons, & Paul Berg, *Biochemical Method for Inserting New Genetic Information into DNA of Simian Virus 40: Circular SV40 DNA Molecules Containing Lambda Phage Genes and the Galactose Operon of Eschericia coli*, 69 PROC. NATL. ACAD. SCI. U.S. 2904, 2904 (1972) (announcing the development of biochemical techniques to covalently join any two DNA molecules); see also Bo G. Malström, Professor, Royal Academy of Sciences, Award Ceremony Speech for the Nobel Prize in Chemistry (1980), <http://www.nobel.se/chemistry/laureates/1980/presentation-speech.html> (awarding the prize to Berg).

81. See WILLIAM S. KLUG & MICHAEL R. CUMMINGS, *CONCEPTS OF GENETICS* 577 (Sheri L. Snavely ed., 6th ed. 2000).

82. Jackson et al., *supra* note 80, at 2904 (explaining the experimental procedure).

83. Dudzinski, *supra* note 8, at 161. *Contra Corporate Chronology*, GENENTECH, <http://www.gene.com/gene/about/corporate/history/timeline.html> (last visited Mar. 2, 2011) (claiming Genentech founders Robert Swanson and Dr. Herbert Boyer pioneered the field).

84. Dudzinski, *supra* note 8, at 161 (“Genentech . . . immediately began development of recombinant insulin . . .”).

85. *Corporate Chronology*, *supra* note 83.

86. Dudzinski, *supra* note 8, at 161.

87. See KLUG & CUMMINGS, *supra* note 81, at 567–70 (explaining antibodies).

88. Dudzinski, *supra* note 8, at 161 (noting that Centocor was founded in 1979 to exploit such technology).

The discovery revolutionized the field of therapeutic biologic drugs.⁸⁹ Scientists, no longer forced to find sources in larger living creatures such as pigs, dogs, rats, or horses, could now culture single-celled bacteria that could produce small molecule therapeutic protein biologics on a commercial scale.⁹⁰ Indeed, the ensuing method was so easy that “high school pupils could easily learn it.”⁹¹ A field that had consisted almost solely of vaccines, blood, and insulin soon became crowded with new biologic protein drugs like erythropoietins (i.e., Epogen), and new “biotech” companies like Genentech, Amgen, and Biogen began to spring up.⁹² The FDA responded to the explosion of recombinant DNA research and the inevitable flood of applications by hiring a large number of new employees to increase expertise.⁹³

Further, in 1983, scientists at Columbia University, under the direction of Professor Richard Axel, developed a procedure that inserted the first recombinant DNA into larger-celled, more complex organisms (i.e., eukaryotes—whose cells have nuclei).⁹⁴ This quickened the pace of innovation by allowing scientists to mass-produce larger complex biologics as well.

Unfortunately for generic competition, however, the biologic drug industry was only in the nascent stages of development in 1982 and was little-discussed when Congress tackled the problem of escalating drug costs in the more heavily developed single-molecule drug industry.⁹⁵ They passed what is now widely known as the Hatch–Waxman Act and revolutionized how the FDA approves generic single-molecule drugs.⁹⁶

89. See KLUG AND CUMMINGS, *supra* note 81, at 577 (“Biotechnology is an outgrowth of recombinant DNA technology.”).

90. *Id.* at 593–97.

91. GOOZNER, *supra* note 10, at 21 (footnote omitted).

92. See *id.* at 16–29 (describing the growth of Amgen and the discovery and marketing of Epogen—artificial erythropoietin).

93. Dudzinski, *supra* note 8, at 161 (The FDA “recognized the ascendancy of recombinant DNA technology and anticipated commercialization of recombinant DNA products and regulatory findings; in response, FDA hired many physicians and scientists in order to amass institutional scientific expertise . . .”).

94. Eukaryotes are usually more complicated organisms that, like the human body, often require complicated intracellular structures to achieve their cellular functions. They are capable of building much more complicated protein structures and hence, capable of providing much more complicated therapeutic biologics through prokaryotic recombinant DNA processes. Dudzinski, *supra* note 8, at 166.

95. *Id.* at 167–68.

96. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. § 156, 271, 282).

C. Hatch–Waxman

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch–Waxman Act.⁹⁷ The Act gave the FDA broad and well-defined authority to issue abbreviated approval to generic drugs after approval of a brand-name drug.⁹⁸ Rather than having to wait for the first innovator drug's patent to expire and then having to repeat the process of approval all over again, generic companies could now file an abbreviated new drug application before patent expiration.⁹⁹ This allowed generic companies to lower their cost of entry to the market, increasing competition and hence lowered drug prices.¹⁰⁰

The effect of Hatch–Waxman on the prices of prescription drugs in the United States has been tangible and significant.¹⁰¹ For instance, “when Eli Lilly lost patent protection on the antidepressant drug Prozac (fluoxetine) in 2001, generic competitors garnered 70% of Prozac's market within 2 months.”¹⁰² The industry now estimates that generic drugs make up over 75% of total prescriptions filled in the United States.¹⁰³

Unfortunately, biologics had escaped the notice of lawmakers. In part because there was little generic competition once the FDA finally approved their biologic protein products, innovator companies were able to keep their drug costs high. In some cases, they currently charge upwards of

97. *Id.*

98. *Id.*; see also Kelly & David, *supra* note 29, at 115 (“Hatch–Waxman aimed to strike a critical balance in the Food, Drug & Cosmetic Act (FDCA) between incentives for drug innovation and the need for lower drug prices through increased competition.”).

99. FDCA, 21 U.S.C. § 355(j) (2006).

100. See Grabowski et al., *supra* note 18, at 1291 (discussing the effect of Hatch–Waxman and offering that proponents of the Hatch–Waxman approach predict that follow-on biologics will similarly lower prices).

101. See *id.*; see also Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w837 (2009), <http://content.healthaffairs.org/content/28/5/w832.full.html> (predicting large cost savings from follow-on biologic legislation).

102. Richard G. Frank, *Regulation of Follow-on Biologics*, 357 N. ENGL. J. MED. 841, 842 (2007).

103. Press Release, Generic Pharmaceutical Ass'n (GPhA), GPhA Tells FDA that Science-Based Biogeneric Approval Process Is Needed to Assure Lower Costs for Patients (Nov. 3, 2010), available at <http://www.gphaonline.org/media/press-releases/2010/gpha-tells-fda-science-based-biogeneric-approval-process-needed-assure-low> (noting that 75% of prescriptions filled are for generics, but they make up only 22% of total drug spending).

\$20,000 per year for biologic drug treatments,¹⁰⁴ supposedly to recoup the extensive start-up costs it takes to approve, market, and manufacture biologics.¹⁰⁵ At such high prices, it is clear that biologic drug prices have contributed significantly to rising healthcare costs.¹⁰⁶

In 2003, the European Union enacted the world's first regulatory system for follow-on biologics.¹⁰⁷ The European Medicines Evaluation Agency (EMA) Guidance on the Regulation of Biosimilars established a new nomenclature for generic competition: "similar biological medicinal products."¹⁰⁸ In 2008 Health Canada (HC) followed with Guidance on Regulation of Subsequent Entry Biologics, Canada's framework for the review of abbreviated applications for biologics.¹⁰⁹

In sum, the success of Hatch–Waxman, the growth of the biologics industry, and the international examples made the eventual statutory creation of a biologics generic pathway seemingly inevitable.¹¹⁰

D. Preexisting Legal Framework

In 1997, Congress passed the Food and Drug Administration Modernization Act, which under § 123(f) required the agency to conform

104. See *supra* notes 29–32 and accompanying text (describing the exorbitant cost of some biologic treatments).

105. See *Biologics and Biosimilars: Balancing Incentives For Innovation: Hearing Before the Subcomm. on Courts and Competition Policy of the H. Comm. on the Judiciary*, 111th Cong. 2 (2009) (statement of Rep. Henry Johnson, Jr., Chairman, Subcomm. on Courts and Competition Policy) ("Estimates put average development costs as much as \$1.37 billion. It is also without a doubt that the cost of pharmaceutical products, and in particular biologics, is huge.").

106. See *id.* ("In 2007, pharmaceutical expenditures accounted for \$231.3 billion in health care costs, and biologics represented \$40.3 billion of this total.").

107. Council Directive 2004/27, art. 10, 2004 O.J. (L 136) 34, 39 (EC).

108. European Medicines Agency, Comm. for Medicinal Products for Human Use, *Annex to Guideline on Similar Biological Medicinal Products Containing Biotechnology-Derived Proteins As Active Substance: Non-Clinical and Clinical Issues; Guidance on Similar Medicinal Products Containing Recombinant Human Soluble Insulin*, 3, EMA/CHMP/BMWP/32775/2005 (Feb. 22, 2006), available at http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003957.pdf.

109. See generally Draft Guidance for Sponsors: Information and Submission Requirements for Subsequent Entry Biologics (SEBs), Canadian Minister of Health: Health Products and Food Branch (Jan. 30, 2008), available at http://www.hc-sc.gc.ca/dhp-mps/alt_formats/hpfb-dgpsa/pdf/consultation/2009-03-seb-pbu-notice-avis-eng.pdf.

110. As Senator Hatch said, "When we adopted the 1984 Hatch–Waxman law, we were in an era of small molecule medicine and large patient population blockbuster drugs. Times have changed. It appears that we are rapidly entering an era of large molecule medicine and small patient population drugs." 148 CONG. REC. 15,677 (2002).

the drug (NDA) and biologic (BLA) approval processes in parallel.¹¹¹ Among other significant changes,¹¹² the Act did away with the expensive and cumbersome requirement for biologics license applicants to obtain a separate Establishment License Application (ELA) for their manufacturing facilities.¹¹³

Currently, the FDA approves drugs and some biologics under the so-called § 505 NDAs,¹¹⁴ while most biologics are approved with § 351 BLAs.¹¹⁵ That would traditionally mean that CDER handles the § 505 NDA applications and CBER handles the § 351 BLA applications. However, in the years running up to the new law, the FDA began transferring authority over certain classes of products from CBER to CDER, such as chemically synthesized biologic-analogues,¹¹⁶ monoclonal antibodies, and therapeutic proteins.¹¹⁷ The transfer likely reflected an FDA understanding that, given the growth of the biologic drug industry, some biologic drugs would be better regulated by CDER as a drug. It also reinforced the need for a generic biologics pathway to bring the two parallel pathways closer in line with one another.

111. Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 123(f), 111 Stat. 2296, 2324 (codified at 21 U.S.C. § 355) (“The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved [BLAs] . . . and products required to have approved [NDAs] . . .”).

112. The FDAMA did far more than require parallel approval processes:

FDAMA also completely rewrote 42 U.S.C. § 262(a) by codifying the BLA requirement for all biologics, [and] reaffirmed that all biological products are subject to the FDCA Section 123(g) of FDAMA, which stated that no licensed biologic requires a section 505 application, sparked controversy in that it could possibly be interpreted to mean that biologics could use the ANDA provisions of FDAMA. In response, the House passed a technical amendment clarifying that this section could not be construed to apply ANDA provisions to biologics, although this bill did not reach the Senate for consideration.

See Dudzinski, *supra* note 8, at 177.

113. Elimination of Establishment License Application for Specified Biotechnology and Specified Synthetic Biological Products, 61 Fed. Reg. 24,227 (May 14, 1996); Elimination of Establishment License and Product License, 64 Fed. Reg. 56,441 (Oct. 20, 1999).

114. 21 U.S.C. § 355 (2006).

115. *Id.* Devices are approved under 21 U.S.C. § 360.

116. FDA, INTERCENTER AGREEMENT BETWEEN THE CENTER FOR DRUG EVALUATION AND RESEARCH AND THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (1991), available at <http://www.fda.gov/CombinationProducts/JurisdictionalInformation/ucm121179.htm> [hereinafter INTERCENTER AGREEMENT].

117. See Drug and Biological Product Consolidation, 70 Fed. Reg. 14,978, 14,978 (Mar. 24, 2006) (explaining that the FDA transferred regulatory responsibility for protein products away from CBER to CDER).

For drugs, there are three approval pathways—a follow-on applicant can file (1) a normal NDA,¹¹⁸ (2) a Paper NDA,¹¹⁹ or (3) an Abbreviated New Drug Application (ANDA) (the so-called § 505(b)(2) approval), which uses the FDA’s earlier finding of safety and efficacy of the brand-name drug.¹²⁰

For biologics not considered an exception to the rule (e.g., human growth hormone),¹²¹ there is currently only one approval plan—a follow-on applicant must file a complete BLA.¹²² The follow-on applicant must then repeat all the clinical trials that the innovator conducted and cannot rely on old approval data to support the abbreviated application, with certain exceptions (e.g., Avonex approval, a rare exception that tends to prove the rule).¹²³

Full biologic approval is a significant and costly regulatory burden.¹²⁴ The applicant must file extensive pharmacology, pharmacokinetics, toxicokinetics, and tissue-distribution studies; toxicology studies; and a separate Good Laboratory Practices requirement.¹²⁵ Further, applicants

118. 21 U.S.C. § 355(b)(1); Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,950 (Apr. 28, 1992).

119. Publication of “Paper NDA” Memorandum, 46 Fed. Reg. 27,396, 27,396–97 (May 19, 1981).

120. 21 U.S.C. § 355(j)(1)–(2)(A).

121. These exceptions may be historical accident, although the statutory definitions of biologic and drug overlap:

Thus, by May 1981, FDA had divided protein-based therapeutics between the Bureaus, with human insulin, human growth hormone (and analogues), thymosin, ACTH, and endorphins under the purview of the Bureau of Drugs, while interferons, vaccines (for hepatitis B and influenza), and serum albumin fell under the jurisdiction of the Bureau of Biologics. There is little evidence of the deliberations and motivations for these distinctions, although one notes that the products in the Bureau of Drugs are physically smaller, and less complex proteins.

Dudzinski, *supra* note 8, at 163.

122. For more information on the pre-application process see James G. Kenimer et al., *Biologics*, in *FDA REGULATORY AFFAIRS: A GUIDE FOR PRESCRIPTION DRUGS, MEDICAL DEVICES, AND BIOLOGICS* 129, 137 (Douglas J. Pisano & David Mantus eds., 2004) (discussing clinical requirements in detail).

123. Avonex is a follow-on interferon beta-1b biologic. Biogen used comparability data with the first-to-file product, Betaseron, and received approval under § 505 from the FDA, despite the fact that the two have a different number of amino acids, one is glycosylated while the other is not, and there are two amino acid differences in the chain. *See Berlex Lab., Inc. v. FDA*, 942 F. Supp. 19, 21–22 (D.D.C. 1996) (unsuccessfully challenging the abbreviated approval).

124. *See* Grabowski et al., *supra* note 18, at 1292–93 (discussing R&D costs for drugs and biologics in terms of the Hatch–Waxman Act).

125. For an excellent discussion of those requirements, see Kenimer, *supra* note 122, at 129–52.

have to repeat the many requirements of Phase I (small trials meant to demonstrate safety only), Phase II (larger trials meant to demonstrate safety and efficacy), and Phase III human clinical trials (large, complex trials meant to demonstrate how safe and effective the treatment is compared to existing treatments).¹²⁶ Hence, the FDA needed an abbreviated approval pathway for biologic drugs to help alleviate this burden, spur competition, and increase widespread access to medicines.

II. THE BIOSIMILARS ACT AND THE HATCH–WAXMAN ACT: THE TWO PARALLEL PATHWAYS, COMPARED

A. Legislative History

In the years before the passage of the Biosimilars Act, legal scholars began arguing somewhat convincingly that the Hatch–Waxman Act itself authorized a generic pathway for biologics that qualified as drugs, regardless of whether the innovator product had been approved under § 351.¹²⁷ However, the FDA maintained that the Hatch–Waxman Act did not apply to generics of biologic products approved under § 351.¹²⁸ This led to the inevitable question: With all the advances in biotechnology, why would Congress not create a generic pathway for biologics?

Many detractors of a generic pathway argued to Congress that protein therapies and other biologics were simply too complex to safely allow for abbreviated generic follow-on applications.¹²⁹ Biotech companies have even argued that producing a generic biologic could not “be done because of the difficulty in producing biologics. In fact, they don’t believe there is such a thing as a generic biologic.”¹³⁰

126. *Id.*

127. *See, e.g.,* Dudzinski, *supra* note 8, at 171 (“It is questionable whether Title I of Hatch–Waxman applies only to ‘new drugs’ and excludes biologics because there was no biotechnology industry per se when it was enacted nor was the Act motivated by apparent concerns for generic biologics.”).

128. *See* FDA Interpretation, *supra* note 19 (finding so partly because the predictable atomic structure of single-molecule drugs allowed for a reliable determination of bioequivalence, while biologics, even small-protein biologic drugs, are harder to predict); *see also supra* text accompanying note 19.

129. *See 2004 Hearing, supra* note 33, at 72–73 (Statement of Dr. William Hancock) (arguing that results would always vary from batch to batch due to posttranslational modifications).

130. Deirdre Davidson, *Reform Eyed for Landmark Drug Law*, NAT’L L.J. LEGAL TIMES, Sept. 11, 2000, at 1.

On the other hand, advocates for the law countered that the FDA's standards for safety could remain high while "eliminating unnecessary requirements"¹³¹ and that it "will be essential" to create generic competition in order "to reduce costs to consumers and health care providers, and to stimulate continued innovation."¹³² Further, mechanisms of production and purification of biologics have progressed at a rapid pace, new technology has developed quickly, and advocates now argue that generic versions of biologics are well within a follow-on company's technical grasp.¹³³

Regardless of the arguments, the drive to legislate a new generic biologics pathway began in earnest in 2007 with the 110th Congress. The 110th Congress debated four competing bills, each variously generous to the innovator or generic industry.¹³⁴ By the end of the term, it appeared that members had reached a compromise deal. However, the bill failed passage when key members of the generic industry withdrew their support pending the election of Barack Obama, hoping instead for a better bill under a Democratic Administration, House, and Senate.¹³⁵

The Biosimilars Act was reintroduced in the 111th Congress in 2009 in modified form, and Congress finally passed it as part of the healthcare reform bill in 2010.¹³⁶

131. One of the FDA's primary institutional mandates (if not *the* primary one) is consumer safety. See *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use.").

132. *2004 Hearing*, *supra* note 33, at 60 (statement of Dr. Carole Ben-Maimon, President and CEO, Barr Research, Inc.).

133. *Id.*

134. See Kelly & David, *supra* note 29, at 124–30 (discussing—complete with tables and charts—the four bills; the Inslee bill, *supra* note 40; the Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. (2007); the Pathway for Biosimilars Act, H.R. 5629, 110th Cong. (2008); and the Access to Life-Saving Medicine Act, H.R. 1038, 110th Cong. (2007)).

135. Czaban et al., *supra* note 22, at 2. Whether the bill they ended up getting was in fact better remains to be seen.

136. See *supra* notes 3–4 and accompanying text (discussing the new Healthcare Reform Act). Senator Edward Kennedy originally introduced the bill during the 110th Congress, and it was reintroduced and adopted by the 111th Congress with a number of significant changes adopted from Eshoo's competing bill. Compare Biologics Price Competition and Innovation Act of 2007, S. 1695, 110th Cong. § 2(a)(2) (2007) (Kennedy bill) (defining biosimilar as "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product"), with Pathway for Biosimilars Act, H.R. 5629, 110th Cong. § 101(a)(2) (2008) (Eshoo bill) (adding that "biosimilar[s]" must be "highly similar"). Ironically, Congress largely rejected the bill put

B. The Biosimilars Act, Generally

The Biosimilars Act amends the definition of *biologic* under § 262(i) of the PHSA,¹³⁷ grants the FDA statutory authority to issue biosimilar and interchangeable determinations, and gives the agency broad deference in determining the procedural details of the scheme.¹³⁸ It also sets up a patent-challenge system¹³⁹ and offers exclusivity incentives for the first follow-on applicant to file.¹⁴⁰ It grants the agency ten years to come up with a comprehensive pathway to encourage and expedite follow-on generic applications in an effort to drive down the cost of health care.¹⁴¹ Additionally, the bill grants biologics innovator applicants twelve years of data exclusivity for their clinical studies.¹⁴² Further, the Act includes a complex patent-challenge system administered through the FDA, which is intended to reduce costly litigation by resolving patent disputes before they reach court.¹⁴³ Lastly, there is a user-fee provision that grants the FDA fee-setting authority in order to recoup some of the costs of the new regulations.¹⁴⁴ The twelve-year provision, the patent challenge system, and the fee-setting provisions are beyond the scope of this Comment.¹⁴⁵

forth by Rep. Henry Waxman, the eponymous sponsor of the Hatch–Waxman Act, perhaps because it granted only a three-year data exclusivity term. *See* Access to Life-Saving Medicines Act, H.R. 1038, 110th Cong. (2007).

137. 42 U.S.C. § 262(i) (2006) (defining “biological product”); Biosimilars Act, Pub. L. No. 111-148, § 7002(b), § 351(i), 124 Stat. 119, 814–15 (2010) (to be codified at 42 U.S.C. § 262(i)).

138. Biosimilars Act § 7002(a)(2)(k).

139. *Id.* § 7002(a)(2)(l).

140. *Id.* § 7002(a)(2)(k)(6).

141. *Id.* § 7002(e).

142. *Id.* § 7002(a)(2)(k)(7).

143. *See id.* § 7002(a)(2)(l) (laying out the new patent-challenge system). For more on the loopholes, quirks, and vagaries the new system presents, see Czaban, *supra* note 22, at 5–9 (calling the new patent challenge system the “Kabuki Theater of Biologics Patent Litigation”).

144. Biosimilars Act § 7002(f). The Prescription Drug User Fee Act (PDUFA) expires in 2012 and is limited to user fees for prescription drugs, but is anticipated to be reapproved in expanded form. *See* Prescription Drug User Fee Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491 (1992) (codified at 21 U.S.C. §§ 301, 343-1, 376, 379 (2006)) (detailing the strictures of the PDUFA); *see also* Alicia Mundy, *Generic Drug Makers Line Up Behind Proposal for FDA Fees*, WALL ST. J., Feb. 16, 2011, at B1 (“The Obama administration has supported user fees for generic drugs Obama’s budget . . . included \$40 million in anticipated revenue from such fees in 2012. Any such plan would require approval from Congress.”).

145. The contentious twelve-year data exclusivity provision in effect creates a strong new form of intellectual property protection for innovator biologics. *See* Interview with Hans Sauer, Assistant Chief Counsel, Biotechnology Indus. Org., in Washington, D.C. (Jan. 21,

C. Definition of Biologics

The Biosimilars Act changed the statutory definition of a biologic under the PHSA. The old definition, with the relevant amendments italicized, is as follows:

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, *protein (except any chemically synthesized polypeptide)*, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.¹⁴⁶

The addition of the language concerning proteins is vital, as the majority of biologic drugs approved as drugs in the past under § 505 with an NDA (e.g., insulin, human growth hormone) are variants of recombinant DNA proteins that occur naturally in the body.¹⁴⁷ Other than those grandfathered in,¹⁴⁸ it would appear that, moving forward, all innovator protein therapies not chemically synthesized will now likely be approved again under § 351 of the PHSA as biologics, using a BLA.¹⁴⁹ Whether CDER will retain examination authority over them remains to be seen.

Here, Congress granted the FDA an expanded definition of *biologics*, one that would encompass nearly all therapeutic protein products. The FDA

2011) (“It is a sad commentary on the state of the patent system that biotech firms felt the need to lobby hard for this alternative form of intellectual property to run to.”) (on file with author). However, the twelve-year provision is now statutory, and so the debate is largely academic. Besides, legal authors have already commented on the twelve-year provision *ad nauseum*. See, e.g., Maxwell R. Morgan, *Regulation of Innovation Under Follow-on Biologics Legislation: FDA Exclusivity as an Efficient Incentive Mechanism*, 11 COLUM. SCI. & TECH. L. REV. 93 (2010) (supporting the twelve-year provision).

146. 42 U.S.C. § 262(i) (as amended by Biosimilars Act § 7002(b)).

147. See *supra* Part I (discussing the history of regulation before the Hatch–Waxman Act).

148. See Biosimilars Act § 7002(e) (“An application for a biological product may be submitted under section 505 of the [FDCA] if [it] is . . . the subject of an application approved under such section 505 no later than the date of enactment of this Act.”).

149. The primary exception is directed at biologic-analogues of chemically synthesized drugs like Miacalcin, approved in 2005 before the legislation was drafted. Miacalcin is a “chemically synthesized polypeptide . . . cited as the reference product in the section 505(b)(2) application for Fortical, a recombinant salmon calcitonin product. The Fortical application was approved in 2005 . . . Congress thus had this precedent before it when drafting the language in question.” Jim Shehan, Vice President, Legal, Gov’t & Quality Affairs, Novo Nordisk, Inc., Address at the FDA Public Meeting (Nov. 2, 2010), http://www.novonordisk-us.com/Images/PDF/NN_Shehan_Testimony_October_27_FINAL.pdf.

has traditionally interpreted the “or analogous product” clause broadly,¹⁵⁰ including such things as monoclonal antibodies, therapeutic proteins, and immunoglobulin products. By specifically defining *proteins*, Congress has assumed this interpretation and made it statutory—making it clear that protein products are squarely biologics and will be subject to § 351 as amended, not § 505. So while many biologics will still qualify as drugs under the statutory definition, they most likely will be regulated under the new § 351(k) approval rules.

D. Bioequivalence, Biosimilarity, and Interchangeability

The Hatch–Waxman Act resulted in a highly detailed procedural pathway (the ANDA) that asks generic applicants to show their drug is “bioequivalent” to corresponding innovator drugs, meaning therapeutically equivalent.¹⁵¹ The FDA lists innovator and generic drugs in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the *Orange Book*), with an appropriate “equivalence” grade (generally, an A-type or B-type rating).¹⁵²

In contrast, the Biosimilars Act creates two statutory determinations for a follow-on biologic product: biosimilar and interchangeable. These can be analogized to the distinction in single-molecule drugs between products that are bioequivalent (i.e., those that receive a B rating in the *Orange Book*), versus products that are both bioequivalent and interchangeable (i.e., those that receive an A rating). In the former case, bioequivalence generally means the generic drug can only be prescribed for the same indications as the innovator, not substituted for it.¹⁵³ In the latter, the pharmacists can switch a patient’s prescription of one for the other without asking.¹⁵⁴ Further, the legislation gives the FDA the power to decide *not* to allow for

150. 21 C.F.R. § 600.3(h) (2010) (defining *analogous products*).

151. Hatch–Waxman Act, Pub. L. No. 98-417, § 101(2)(A)(iv), 98 Stat. 1585, 1586 (1984) (codified at 21 U.S.C. § 355(b), (j), (l); 35 U.S.C. § 156, 271, 282 (2006)). The applicant must provide “information to show that the new drug is bioequivalent to the listed drug referred to in clause (i)” with the exception that if the applicant admits the drug has a different active ingredient, additional studies are needed. *Id.*

152. ORANGE BOOK, *supra* note 16.

153. RICHARD R. ABOOD, PHARMACY PRACTICE AND THE LAW 141 (6th ed. 2011) (“For example, if the *Orange Book* lists four pharmaceutically equivalent drugs, two with a B rating and two with an A rating, the pharmacist may interchange the two drugs with A ratings.”).

154. *See id.* (cautioning that switching is only allowed if the drug is therapeutically equivalent or bioequivalent to the prescribed drug).

either biosimilar or interchangeable determinations for some classes of biologics.¹⁵⁵

Thus, the new law will lead to the creation of what is in essence an Abbreviated Biologics License Application (ABLA),¹⁵⁶ with the two standards resulting in far different, more unpredictable results than Hatch–Waxman.

1. *Biosimilarity*

The Biosimilars Act defines *biosimilarity* to require: (1) a follow-on product must be “highly similar” to the reference product in terms of structure, and (2) there can be “no clinically meaningful differences” between the biological product in terms of safety, purity, and potency.¹⁵⁷ This broad language allows the FDA to fashion clinical testing requirements based on (1) similar chemical structure and (2) statistical bioequivalence in clinical outcomes and efficacy. For instance, the FDA must define “clinically meaningful.”

To compare, for drugs NDAs must include data relating to (1) chemistry, (2) manufacturing, (3) controls, (4) labeling, (5) testing, (6) animal studies, (7) clinical studies, and (8) bioavailability¹⁵⁸ requirements.¹⁵⁹ ANDAs, on the

155. Biosimilars Act, Pub. L. No. 111-148, § 7002(a)(2)(k)(8)(E)(i), 124 Stat. 119, 808 (2010) (to be codified at 42 U.S.C. § 262(k)(8)(E)(i)).

156. Note that I have created the Abbreviated Biologics License Application (ABLA) term. Others have hypothetically called this future pathway “§ 351(k) approval” in keeping with the common practice of referring to approvals by their original statutory section number. *E.g.*, Steven A. Nash & Rebecca Workman, *A New Pathway for Follow-on Biologics*, 20 FED. CIR. B.J. 193, 194 (2010) (“[T]his Article will refer to an application for licensure of a biosimilar or interchangeable product as a ‘351(k) application.’”).

157. The PHSA was amended to include the following definition of *biosimilar*:

(2) The term ‘biosimilar’ or ‘biosimilarity,’ in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is *highly similar* to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are *no clinically meaningful differences* between the biological product and the reference product in terms of the safety, purity, and potency of the product.

Biosimilars Act, § 7002(b) (emphasis added) (internal quotation marks omitted).

158. *See* 21 U.S.C. § 355(j)(8) (2006) (defining bioavailability as “the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug product and becomes available at the site of drug action”).

159. This is derived from the FDA’s applications for drugs or biologics, which uses different nomenclature. *See* David J. Pizzi & Janet C. Rae, *Formatting, Assembling, and Submitting the New Drug Application (NDA)*, in FDA REGULATORY AFFAIRS: A GUIDE FOR PRESCRIPTION DRUGS, MEDICAL DEVICES, AND BIOLOGICS 81, 81–115 (Douglas J. Pisano & David Mantus eds., 2004) (including a chart mapping the various study requirements).

other hand, require (1)–(5) but can prove bioequivalence¹⁶⁰ comparative to the innovator drug in lieu of any of (6)–(8).¹⁶¹ Somewhat analogously, BLAs must submit data relating to (1)–(8) and must further submit establishment standards.¹⁶²

The Biosimilars Act provides that the FDA will derive determinations of biosimilarity from: (1) analytical studies showing the biological product is highly similar, (2) animal studies, including [an] assessment of toxicity, and (3) clinical studies sufficient to demonstrate safety, purity, and potency in relation to the innovator biologic.¹⁶³

These factors are analogous to drug bioequivalence, animal studies, clinical studies, and bioavailability requirements. This seems to encompass the full requirements, with an additional required showing of “highly similar.” However, a clause makes any of these three requirements optional at the FDA’s discretion.¹⁶⁴ Additionally, the ABLA applicants must submit data showing four other factors.¹⁶⁵

Thus, the burden of evidence for generic biologic applicants could be far higher than it is for generic drugs under Hatch–Waxman, even in relation to the higher burdens of biologics innovators.¹⁶⁶ ABLA applicants will also

160. See 21 C.F.R. § 320.24 (2010) (describing methods to demonstrate bioequivalence, including (1) pharmacokinetic studies, (2) pharmacodynamic studies, (3) comparative clinical trials, and (4) in vitro studies). For statutory authority, see 21 U.S.C. § 355(j)(8)(B).

161. Animal studies, clinical studies, and bioavailability studies are a combination of the precursor toxicology studies, phase I–III clinical trials, and pharmacokinetics, toxicokinetics, and tissue distribution studies. See Kenimer et al., *supra* note 122, at 136–43 (detailing clinical requirements).

162. See 21 C.F.R. § 601.2 (general BLA requirements); *id.* § 601.12 (2010) (supplements or changes to an existing license or BLA); see also Kenimer & Jessop, *supra* note 122, at 146–52 (explaining at BLA data requirements, including the data showing the establishment can reproduce batches in a safe, clinically pure, and consistent manner).

163. Biosimilars Act, Pub. L. No. 111-148, § 7002(a), 124 Stat. 119, 804 (2010) (to be codified at 42 U.S.C. § 201).

164. See *id.* § 7002(a)(2)(k)(2)(A)(ii) (“The Secretary may determine, in the Secretary’s discretion, that an element described [above] is unnecessary in an application submitted under this subsection.”).

165. *Id.* § 7002(a)(2)(k)(2)(A)(i). The four other factors are: (1) the products have the same mechanism of action (but only to the extent that it is known); (2) the intended conditions for use have been previously approved for the reference product; (3) the products have the same route of administration, dosing, and strength; and (4) the facilities used to process and package the product meet certain standards. *Id.*

166. See Grabowski et al., *supra* note 18, at 1293 (“Given that biologics made with different cell lines or manufacturing facilities might exhibit different efficacy and safety characteristics, it is likely that some clinical trial data will be required before a follow-on biologic is approved.”).

have to submit studies related to purity, manufacturing studies, mechanism of action, and possibly further animal, human, and other trials. In effect, ABLA applicants may be required to submit most or all of these data again just to achieve a biosimilar determination. ABLA applicants have reason to be hopeful, however. In July 2010 (after the passage of the Biosimilars Act), the FDA approved a generic of a complex carbohydrate drug without the need for any clinical trials proving safety or efficacy.¹⁶⁷ While the drug was technically not a biologic according to the FDA,¹⁶⁸ at least one senior FDA official has cited its approval as an example of how permissive the FDA's thinking on biologics abbreviated approval could be.¹⁶⁹

It also appears from the plain language that the highly similar determination itself is a much higher bar than Hatch–Waxman's bioequivalent standard. The biosimilars standards outlined above will require additional studies showing that the physical chemical structures of the two biologics are highly similar.¹⁷⁰ The FDA can waive toxicity or certain Phase II and Phase III trials upon a “good enough” showing of chemical similarity, but in practice the FDA is unlikely to waive most of these requirements, erring on the side of caution.¹⁷¹ This could mean applicants will have a relatively harder—and costlier—time achieving a biosimilarity determination than they currently have getting bioequivalent determinations for single-molecule drugs.¹⁷² Until the FDA issues guidance and grows comfortable with the process, these ABLAs are not likely to

167. *See Momenta Receives OK for Generic Version of Lovenox*, ABC NEWS.COM (July 23, 2010) (on file with author) (describing FDA approval of a generic version of enoxaparin (trade name Lovenox), a low molecular weight heparin, without requiring any safety or efficacy studies).

168. *Id.* (“Lovenox is technically not a biologic drug—a complex medicine made inside special, live cells rather than by combining chemicals. However, ‘functionally and effectively it is’ . . . because it is derived from animal materials and is heavily processed and purified.”) (quoting Tim Anderson, Analyst for Berstein Research).

169. *See BioCentury This Week: Biosimilars: Will the Path Work?*, *supra* note 38 (statement of Dr. Rachel Behrman, Assoc. Dir. for Med. Pol’y in CDER). Behrman cited Momenta's approval of M-Enoxaparin as exemplary of U.S. thinking on generic clinical requirements, as opposed to Europe, where they often require new safety and efficacy testing. As she stated, “We may be able to take the European experience [with biosimilars] and go one step further.” *Id.*

170. *See supra* note 157 (citing the highly similar standard).

171. *See generally* Supplements and Other Changes to an Approved Application, 69 Fed. Reg. 18,728, 18,729 (Apr. 8, 2004) (discussing the FDA's adoption of a risk-based approach to the regulation of pharmaceuticals to enhance safety).

172. *See* Grabowski et al., *supra* note 18, at 1293 (estimating costs of the average ADNA at \$1–2 million and estimating that costs of the average generic biologic approval have been \$10–40 million in Europe).

provide significant—if any—application cost savings.¹⁷³ That will probably take decades.

2. *Interchangeability*

Putting the lower-bar biosimilar determinations aside, the additional interchangeability standards seem even more difficult to meet, and the costs may not outweigh the benefits associated with generic status. The statute defines interchangeable as a biological product that “(i) is biosimilar to the reference product; [and] (ii) can be expected to produce the *same clinical result* as the reference product in any given patient.”¹⁷⁴

This is a higher clinical standard than the biosimilar “no clinically meaningful differences” standard.¹⁷⁵ Now the FDA must determine the level of statistical tolerance it will assign to the word interchangeable as opposed to equivalent.¹⁷⁶

Ironically, this could also indicate that biologics that have a *better* clinical result cannot achieve interchangeable status, regardless of evidence that the mechanism of action is the same, the dosage is the same, and the structure is identical. That remains true even if the generic is a slight improvement over the innovator biologic.

However, that is not the end of the interchangeability requirements. In addition:

for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of *alternating or switching between* use of the biological product and the reference product [*must*] *not [be] greater than* the risk of using the reference product without such alternation or switch.¹⁷⁷

Ostensibly, this additional “switching” test data requirement is out of a fear that an interchangeable determination could result in patients switching between biologics. Congress could have addressed this concern

173. See Bruce Babbitt, White Paper, *The Dawn of Biosimilar Development in the United States: Key Legislative Aspects and Next Steps for BioPharma Manufacturers*, 5 (PAREXEL Consulting 2010) (on file with author) (noting at present “very few companies are expected to pursue the interchangeability option as presented in the [Biosimilars] Act”).

174. Biosimilars Act § 7002(a)(2)(k)(4)(A)(i), (ii) (2010) (emphasis added).

175. *Id.* § 7002(a)(2)(k)(2)(A)(i)(I)(aa) (allowing biosimilarity to be shown through analytical studies showing the follow-on is “highly similar to the reference product notwithstanding minor differences in clinically inactive components” (emphasis added)).

176. Cf. ORANGE BOOK, *supra* note 16, at x (using for drugs “a 0.05 level of [statistical] significance”).

177. Biosimilars Act § 7002(a)(2)(k)(4)(B) (emphasis added).

in other ways. For instance, it could have added labeling requirements that patients cannot switch from one biologic or follow-on once a system of treatment has begun, or then only with a doctor's approval. Or they could have counseled doctors to only prescribe certain biologics at the beginning of treatment or changed the law so that a determination of interchangeability only applies to the initial prescription filled, not subsequent courses of the medication. To be sure, this would not have eliminated the risk associated with switching completely; the only way to do that would be to require cumbersome testing. However, by requiring such a high switching bar in addition to other safety requirements, the FDA is again erring on the side of caution. Thus, the statute imposes an unnecessarily high burden on follow-on applicants seeking interchangeability determinations.

Ominously, the FDA has indicated in the past that the mechanisms of switching may make it *impossible* to achieve an interchangeable determination.¹⁷⁸ This indicates the FDA may be predisposed to deny applicants seeking interchangeability in cases where switching is likely.

E. New Approval Procedures: What an ABLA Might Look Like

Hatch–Waxman dictates stringent guidelines of what clinical data applicants must provide with an ANDA and explicitly states that the FDA does not have the authority to require more clinical data than the statute requires.¹⁷⁹

Conversely, the Biosimilars Act grants the FDA exceedingly broad authority to increase or decrease the testing and data requirements. Indeed, the FDA can decide that science does not currently allow for *any* biosimilar or interchangeable determinations for non-protein products.¹⁸⁰

178. As one FDA official said in 2007, “For many follow-on protein products—and in particular, the more complex proteins—there is a significant potential for repeated switches between products to have a negative impact on the safety and/or effectiveness. Therefore, the ability to make determinations of substitutability for follow-on protein products may be limited.” Janet Woodcock et al., *The FDA's Assessment Of Follow-on Protein Products: A Historical Perspective*, 6 NATURE REVS. DRUG DISCOVERY 437, 440 (2007).

179. Hatch–Waxman Act, 21 U.S.C. § 355(j)(2)(A)(viii) (2006) (“The Secretary may not require that an abbreviated application contain information in addition to that required by [the Act].”).

180. See Biosimilars Act § 7002(a)(2)(k)(8)(E)(i).

The Secretary *may* indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (*not including any recombinant protein*) does not allow approval of an application for license as provided under this subsection for such product or product class.

This broad statutory grant will likely allow the FDA to adjust policies and procedural requirements as technology develops and requires different (and hopefully more efficient) testing methodologies to assure safety and efficacy of follow-on biologics.

It is currently unclear if the FDA will “rank” interchangeability determinations, the way Hatch–Waxman does equivalency, with an *Orange Book*-style rating.¹⁸¹ It should. It would be confusing to have two separate working definitions of *biosimilar/interchangeable* and *therapeutically equivalent* within the medical treatment field in the two separate pathways. Instead, the prudent thing to do is adopt a parallel (or at least analogous) definition of *interchangeable* for biologics. Having an indexed listing of all biologics and their associated biosimilars and interchangeables will increase certainty, help avoid frivolous litigation, and reduce development costs by increasing the quality and ease of co-extant biologics research.

To do this, the FDA should begin by forming an analogous *Orange Book* (say, a *Purple Book*) for biosimilarity and interchangeability ratings and rank biologics accordingly.

F. *Notice-and-Comment or Guidance-Plus Rulemaking?*

Traditionally, the Administrative Procedure Act (APA)¹⁸² confines agency rulemaking to one of three avenues: formal rulemaking, informal (notice-and-comment) rulemaking, and policy statements that do not have the force and effect of law.¹⁸³ Nonetheless, statutes can require more or less procedure and replace the rulemaking requirements of the APA.¹⁸⁴ Beyond the APA and the agency’s enabling statute, courts cannot normally impose further procedural requirements.¹⁸⁵ The agencies, however, are free to impose further procedures,¹⁸⁶ and the President, through the Office of

Id. (emphases added).

181. See ORANGE BOOK, *supra* note 16, at xiii–xxi (listing levels and rankings of equivalents).

182. Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified at 5 U.S.C. §§ 551–59, 701–06).

183. ANDREW F. POPPER ET AL., ADMINISTRATIVE LAW: A CONTEMPORARY APPROACH 66 (2d ed. 2010).

184. See *Marcello v. Bonds*, 349 U.S. 302, 310 (1955) (allowing exemptions from the Administrative Procedure Act (APA), but suggesting that they must be “express”).

185. *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (stating that “the [APA] established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures”).

186. *Id.* (“Agencies are free to grant additional procedural rights in the exercise of their discretion.”) See Recommendations of the Administrative Conference of the United States,

Management and Budget (OMB) and its rulemaking division, the Office of Information and Regulatory Affairs (OIRA) can and often does impose additional procedural hurdles.¹⁸⁷

Due to the increasingly onerous and time-consuming nature of “informal” notice-and-comment rulemaking, agencies are increasingly using policy and guidance documents, which offer some notice or opportunity for public comment but lack the many “ossified” constraints of informal rulemaking.¹⁸⁸ For instance, many agencies issue “guidance documents,” which lack many of the procedural hurdles of normal notice-and-comment rulemaking.¹⁸⁹ Ostensibly, they do this in an attempt to get around notice-and-comment rulemaking requirements.

These guidance documents may claim to lack the force and effect of law but may de facto have significant legal impact.¹⁹⁰ Some argue agencies do this in an attempt to avoid judicial review¹⁹¹ and to avoid other procedural

Agency Policy Statements, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), available at <http://www.law.fsu.edu/library/admin/acus/305922.html> (recommending “the ‘circumstances of particular proceedings’ that should move agencies to consider such additional procedures”).

187. See, e.g., OFFICE OF MGMT. & BUDGET, EXEC. OFFICE OF THE PRESIDENT, OMB BULL. NO. 07-02, FINAL BULLETIN FOR AGENCY GOOD GUIDANCE PRACTICES (2007) [hereinafter FINAL BULLETIN], at 20–22 (imposing procedure on guidance documents).

188. See David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L.J. 276, 284 n.33 (2010) (citing Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 166 (2000) (asserting that agencies are “avoiding ‘ossification’ . . . by increased use of ‘interpretative rules’ and ‘policy statements’”)); see also Lubbers, *supra* note 44, at 473 (“This precipitous drop in final rules published in the *Federal Register*—and the even more dramatic drop in proposed rules published for comment—are clear indications of the ossification of rulemaking or at least increased agency reluctance to use the APA’s rulemaking process.”).

189. For procedural hurdles that guidance documents retain see generally FINAL BULLETIN, *supra* note 187.

190. See, e.g., *Gen. Elec. Co. v. EPA*, 290 F.3d 377 (D.C. Cir. 2002) (striking down polychlorinated biphenyl (PBC) risk assessment guidance as having legal effect and hence requiring notice and comment); see also COMM. ON GOV’T REFORM, NON-BINDING LEGAL EFFECT OF AGENCY GUIDANCE DOCUMENTS, H.R. REP. NO. 106-1009, at 9 (2000) (“[A]gencies have sometimes improperly used guidance documents as a backdoor way to bypass the statutory notice-and-comment requirements for agency rulemaking and establish new policy requirements.”).

191. Gwendolyn McKee, *Judicial Review of Agency Guidance Documents: Rethinking the Finality Doctrine*, 60 ADMIN. L. REV. 371, 372 (2008) (“Agencies increasingly issue guidance documents . . . in lieu of engaging in the more costly, and binding, informal rulemaking process that ultimately affords regulatees with opportunities for judicial review.”); Franklin, *supra* note 188, at 307 n.160 (noting the lack of any provisions allowing for judicial review as evidence of a possible attempt to avoid it). But see Connor N. Raso, Note, *Strategic or Sincere?*

hurdles imposed by the Executive Branch and Congress.¹⁹² At a minimum, however, guidance documents allow agencies to make changes in their approval procedures with less unaccountability to the public.

This guidance practice has become particularly prevalent at the FDA in recent years.¹⁹³ In 1997, the FDA issued guidance laying out its so-called “Good Guidance Practices” (GGP).¹⁹⁴ The same year, Congress mandated that certain aspects of the 1997 GGP document become law and codified others.¹⁹⁵

Congress did this via the Food and Drug Administration Modernization Act (FDAMA), which required the FDA to solicit public input before issuing guidance documents.¹⁹⁶ In doing so, Congress endorsed a new form of significant rulemaking—a sort of “guidance-plus” requiring public comment but not the full range of APA requirements.¹⁹⁷

In 2007, the Executive Branch, through the OMB, took notice of the increasing use of these guidance documents by issuing the Final Bulletin for Agency Good Guidance Practices.¹⁹⁸ In it, OMB recognized that agencies often used guidance to produce significant regulation¹⁹⁹ and added

Analyzing Agency Use of Guidance Documents, 119 YALE L.J. 782, 782 (2010) (arguing that agencies do not often use guidance documents to avoid judicial review).

192. See LOUIS FISHER, CONG. RESEARCH SERV., RL33151, COMMITTEE CONTROLS OF AGENCY DECISIONS 21, 31 (2005) (finding that even post-*Chadha*, Congress finds many ways to exert control, through committees and budgetary means, over agency action). See generally LOUIS FISHER, CONG. RESEARCH SERV., RS22132, LEGISLATIVE VETOES AFTER CHADHA (2005) (reviewing *Chadha* and its impact on the veto systems in various legislatures); FINAL BULLETIN, *supra* note 187, at 20–22 (requiring added procedural requirements for agency guidance documents).

193. See U.S. FOOD AND DRUG ADMIN., *Biologics Guidances*, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/ucm2006010.htm> (last visited Mar. 3, 2011) (collecting FDA guidance documents).

194. The Food and Drug Administration’s Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997).

195. The FDA Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, § 405(h)(1)(A), 111 Stat. 2296, 2368 (codified at 21 U.S.C. § 371) (requiring the Secretary to publish a legislative rule codifying aspects of the 1997 GGP guidance).

196. *Id.* § 405(h)(1)(D) (“For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.”).

197. See Nina A. Mendelson, *Regulatory Beneficiaries and Informal Agency Policymaking*, 92 CORNELL L. REV. 397, 401 (2007).

198. See, e.g., FINAL BULLETIN, *supra* note 187.

199. *E.g., id.* at 2 n.2 (citing S. REP. NO. 105-43, at 26 (2007) (raising concerns about public knowledge of, and access to, FDA guidance documents, lack of a systematic process for adoption of guidance documents and for allowing public input, and inconsistency in the use of guidance documents)).

additional procedural hurdles for “economically significant guidance documents,” which have an economic impact of more than \$100 million on the U.S. economy.²⁰⁰ Notably, the bulletin stated that unless the guidance document is exempted due to an emergency or other appropriate consideration, the agency should observe the notice-and-comment procedures dictated by the bulletin.²⁰¹ The Judiciary has also voiced its displeasure at the practice of utilizing guidance documents to circumvent the legal requirements of rulemaking.²⁰² These rulemaking requirements are where Hatch–Waxman and the Biosimilars Act diverge significantly.

Hatch–Waxman demands that the FDA use notice-and-comment rulemaking procedures to implement the Act.²⁰³ Coupled with the Supreme Court’s decision in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, which forbade courts from imposing additional procedural hurdles on rulemakings,²⁰⁴ the FDA is required to use only notice-and-comment rulemaking to implement the provisions of Hatch–Waxman.

Conversely, the broad language of the Biosimilars Act confers sweeping authority to the FDA in regulating a detailed procedural pathway similar to

200. *Id.* at 7.

201. *Id.* at 21. In general:

- . . . when an agency prepares a draft of an economically significant guidance document, the agency shall:
- a. Publish a notice in the Federal Register announcing that the draft document is available;
 - b. Post the draft document on the Internet and make it publicly available in hard copy . . .
 - c. Invite public comment on the draft document; and
 - d. Prepare and post on the agency’s website a response-to-comments document.

But see id. at 21 (subjecting these requirements to the discretion of the agency head).

202. As the D.C. Circuit has opined:

One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.

Appalachian Power Co. v. EPA, 208 F.3d 1015, 1020 (D.C. Cir. 2000) (emphasis added).

203. Hatch–Waxman Act, 21 U.S.C. § 355 (2006) (“The Secretary of Health and Human Services shall promulgate, in accordance with the notice and comment requirements of section 553 of title 5, United States Code, such regulations as may be necessary for the administration of section 505 of the Federal Food, Drug, and Cosmetic Act, as amended by sections 101, 102, and 103 of this Act, within one year of the date of enactment of this Act.”).

204. *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978).

(or different from) the Hatch–Waxman pathways.²⁰⁵ The Biosimilars Act includes language suggesting the Secretary issue “final guidance” with “opportunity for public comment,”²⁰⁶ possibly endorsing this new guidance-plus form of rulemaking. Indeed, to the best of my knowledge, the FDA’s recent enabling statutes are unique in providing technically “nonbinding” guidance with public comment as a primary means of rulemaking authority.²⁰⁷

As such, the agency is encouraged to use these guidance-plus documents, which provide greater flexibility and avoid the burdens imposed by informal rulemaking but which some think unreviewable by courts.²⁰⁸

Significantly, the Biosimilars Act itself requires that the agency gather public comment before issuing any final guidance.²⁰⁹ It is unclear, however, what an opportunity for public comment alone entails. Possibly, this is a codification of the OMB Bulletin’s “public feedback” requirement, which does not require the agency to respond to the comments (as notice-and-comment does).²¹⁰ Thus, Congress has created and endorsed a new form of rulemaking through the Biosimilars Act and the FDAMA—one significant enough to require public comment, but one that does not demand the procedural requirements of notice-and-comment rulemaking and is not subject to the judicial precedent that guides (and burdens) notice-and-comment rulemaking.

In reality, the agency generally holds extensive public conferences and hearings and solicits comments from the public and stakeholders—indeed, it is in the FDA’s best interest to obtain as much input as possible when

205. See Biosimilars Act § 7002(a)(2)(k)(8)(A), (B)(ii) (2010).

206. *Id.* § 7002(a)(2)(k)(8)(A), (B)(i).

207. See Mendelson, *supra* note 197 at 401 (“With the exception of these FDA procedures, however, no other statute requires [comment] procedures for agency guidance documents.”).

208. See McKee, *supra* note 191, at 372 (arguing FDA guidances are unreviewable by courts). *Contra* Raso, *supra* note 191, at 793–95, 801, 802 (arguing guidance is reviewable by the courts).

209. See Biosimilars Act § 7002(a)(2)(k)(8)(A) (including the statutory words “after the opportunity for public comment,” which require the agency to elicit comment before final guidance issues).

210. FINAL BULLETIN, *supra* note 187, at 15 (“Public comments submitted under these procedures on significant guidance documents are for the benefit of the agency, and this Bulletin does not require a formal response to comments In some cases, the agency, in consultation with the Administrator of Office of Management and Budget’s (OMB’s) Office of Information and Regulatory Affairs, may in its discretion decide to address public comments by updating or altering the significant guidance document.”).

crafting procedures and testing paradigms for biologics.²¹¹ For the Biosimilars Act, it has already begun to do this.²¹² But that does not undercut the fact that Congress has endorsed this new form of rulemaking as a way to escape the procedural rigors—and possibility of judicial review—associated with notice-and-comment rulemaking.

To be clear, Congress has provided that the FDA can issue extensive regulations with far-reaching economic effects over a period of ten years using only guidance-plus documents, which ostensibly have no binding legal effect. Such guidance-plus documents cannot be considered mere policy documents. Scholars and the Congressional Budget Office expect the guidances to have billion-dollar consequences.²¹³ As such, it would be prudent—and in line with executive suggestion²¹⁴—for the FDA to issue full notice-and-comment rulemaking for the broad regulation implementing the statute.

G. Judicial Review and Legislative Rules

Any future biosimilars guidance-plus documents may be exempted from the APA § 706 judicial review provisions²¹⁵ because the organic biosimilars statute mandates the use of the guidance procedure.²¹⁶ However, even if the guidance-plus documents are held reviewable, courts will likely rule that these guidance-plus documents are policy documents and do not require informal rulemaking.²¹⁷

If the guidance-plus documents are ever challenged in court as invalid because they were not made pursuant to notice-and-comment procedures,

211. The FDA benefits from the community's and stakeholders' expertise. Public input increases public trust and decreases the likelihood of legal challenge.

212. See, e.g., FDA Public Meeting, *supra* note 45 (discussing the Biosimilars Act).

213. See Czaban, *supra* note 22, at 2 n.8, 3 (discussing costs and expressing ambivalence about potential savings for the cost of health care but citing the Congressional Budget Office's estimate of \$6–7 billion in savings); Grabowski et al., *supra* note 18, at 1291, 1293 (discussing costs generally, and providing the \$10–40 million average cost of abbreviated approval in Europe as instructive).

214. FINAL BULLETIN, *supra* note 187, at 15 (Although “this Bulletin does not require agencies to provide notice and an opportunity for public comment on all significant guidance documents before they are adopted, but it is often beneficial for an agency to do so when they determine that it is practical.”).

215. APA § 10(b), 5 U.S.C. § 706 (2006).

216. See generally Biosimilars Act § 7002(a)(2)(k)(5) (2010).

217. See 21 C.F.R. § 10.115(d) (2010) (declaring guidance lacks the force and effect of law).

the courts will have to determine if the guidances qualify as substantive legislative rulemaking—that is, whether they have the force of law.²¹⁸

To determine if an agency document qualifies as substantive rulemaking, the courts generally apply some form of a “legal effects test” like the one used in *Cement Kiln Recycling Coalition v. EPA*.²¹⁹ Here, potential clinical testing guidance documents will probably not have the force and effect of law because they only proscribe procedural, highly technical testing requirements for FDA approval.²²⁰ Also, the fact that the FDA may opt not to allow for determinations of biosimilarity or interchangeability in most cases militates toward finding that those regulations lack the force and effect of law.

Indeed, the D.C. Circuit has held that similar guidance documents at another agency (the Mine Safety & Health Administration) are not legislative.²²¹ Under the test previously used by the D.C. Circuit, the FDA guidance documents are not legislative. This is because the FDA: (1) is acting only pursuant to the organic biosimilars statute,²²² (2) only publishes most guidance on the FDA website and in the *Federal Register*, but not in the *Code of Federal Regulations*,²²³ (3) expressly disclaims any invocation of legislative powers,²²⁴ and (4) amends prior guidance but cannot amend

218. See *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (acknowledging that agencies’ interpretive choices may influence courts but do not bind them in every case).

219. 493 F.3d 207, 226–27 (D.C. Cir. 2007). In this case, the court applied a three-factor test to determine if a guidance was a rulemaking. First, how did the agency characterize the action? Second, did the agency issue the guidance in the *Federal Register* or the *Code of Federal Regulations*? Third, did the guidance have a binding effect on the parties or the agency? *Id.*

220. Accord Kelly & David, *supra* note 29, at 132 (regarding the 2009 proposals for biosimilars laws, “On its face, the guidance described in proposed legislation likewise fails the legal effects test because it would not have the force and effect of law.”).

221. See *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993). The four-part test announced by the D.C. Circuit is as follows:

(1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule.

If the answer to any of these questions is affirmative, we have a legislative, not an interpretative rule.

Id. at 1112.

222. Biosimilars Act §§ 7002–7003(2010).

223. See *infra* note 239 and accompanying text (comparing rules published in the *Code of Federal Regulations* with good guidance only noticed in the *Federal Register*).

224. See, e.g., FDA, GUIDANCE FOR INDUSTRY: STATISTICAL APPROACHES TO ESTABLISHING BIOEQUIVALENCE 1 (Jan. 2001), <http://www.fda.gov/downloads/Drugs/>

prior legislative rules.²²⁵ Therefore, any biosimilars guidance documents will likely be unreviewable by any court.²²⁶

However, even assuming for the sake of argument that the guidances are ultimately found to be reviewable and that a court might hold them invalid as legislative rules, the practical likelihood of court challenges is minimal.²²⁷ Further, any court challenge would also have to overcome finality and ripeness requirements,²²⁸ although the fact that the legislation calls for final guidance may undercut a finality challenge to some extent.²²⁹

As a result, the agency will likely be free to issue good guidance documents without the fear of judicial review or the threat of an adverse ruling, despite the fact that those documents will have an overwhelmingly substantive effect—for instance, if the agency determines that there can be no interchangeability for any class of biologics.

This means the agency has broad flexibility—and power—over the new biosimilar and interchangeable determinations. The Biosimilars Act gave the FDA the discretion to allow or deny *all* interchangeability determinations for *entire classes* of biologics.²³⁰ If the past is any indication,²³¹ the FDA will be reticent to aggressively implement the legislation, instead erring on the side of caution.²³² If it issues difficult or

GuidanceComplianceRegulatoryInformation/Guidances/ucm070244.pdf. Like most guidance, it includes the following disclaimer:

This guidance represents the Food and Drug Administration's current thinking on this topic. *It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.* An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

Id. (emphasis added).

225. *See, e.g., id.* The FDA has since discarded this guidance.

226. *But cf.* *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1019 (D.C. Cir. 2000) (holding similar Environmental Protection Agency guidance reviewable). If the FDA couches the guidance documents in the imperative, courts may find that they are binding and notice-and-comment procedures must be observed. *See id.* at 1023 (“[T]he entire Guidance, from beginning to end . . . reads like a ukase. It commands, it requires, it orders, it dictates.”). *See generally* JEFFREY S. LUBBERS, *A GUIDE TO FEDERAL AGENCY RULEMAKING* 73–104 (2006) (detailing the many ways in which guidance documents are subject to review).

227. *See Raso, supra* note 191, at 802 (“On balance agencies face a lower litigation risk from guidance documents because the lower probability of engaging in litigation outweighs the greater probability of winning once challenged.”).

228. *Id.*

229. A more substantive discussion of the ripeness and finality doctrines is beyond the scope of this Comment.

230. Biosimilars Act §7002(2)(k)(3) (2010).

231. *See Woodcock et al., supra* note 178, at 437–42 (offering a historical perspective).

232. To be fair, unsafe yet approved products have killed consumers in the past (e.g., Vioxx), so the FDA has good reason to be cautious. *See Hawthorne, supra* note 47, at 109–22

impossible-to-meet biosimilarity and interchangeability guidelines, the FDA may fail to achieve the explicit statutory purpose of the Biosimilars Act—a significant reduction in prescription drug costs through generic competition.²³³

III. RECOMMENDATIONS TO THE FDA

The FDA has ten years from March 3, 2010, to issue final guidelines for ABLA pathways under the amended § 351(k).²³⁴ In that time, the FDA should continue to gather as many comments from the public, scientists, and interested parties as possible.²³⁵ Then, it should provide notice in the *Federal Register* and allow further comment on proposed classifications and guidelines, following standard notice-and-comment procedures. Finally, it should issue clear notice-and-comment rules on product classifications and overall procedures but retain case-by-case guidance-plus flexibility in clinical testing requirements. Otherwise it runs the risk of attempting a major regulatory overhaul using only legally nonbinding policy documents. That would provide insufficient oversight and responsiveness to the public, which could lead to a regulatory scheme that does not fulfill the statutory purpose and actually hinders the growth of the generic biotech industry.

A. *Classifying Biologics Through Legislative Rules*²³⁶

First, the FDA should provide detailed notice-and-comment rules that indicate clearly how and where each individual type of biologic will be classified. Recently, the FDA issued a similar guidance for class-specific clinical testing in the drug field.²³⁷ Indeed, the Biosimilars Act itself suggests this when it discusses “product class-specific guidance.”²³⁸ These

(discussing the difficult decision to allow thalidomide for HIV treatment even though it causes birth defects).

233. See *supra* note 18 and accompanying text (discussing cost savings).

234. Under the statute, the sponsor of an innovator biologic *may* submit an NDA instead of a BLA during the transition period that expires in 2020. Biosimilars Act § 7002(e).

235. The FDA has begun to do this. *E.g.*, FDA Public Meeting, *supra* note 45.

236. Legislative rules are regulations promulgated by informal notice-and-comment rulemaking.

237. CDER, GUIDANCE FOR INDUSTRY, BIOEQUIVALENCE RECOMMENDATIONS FOR SPECIFIC PRODUCTS 1 (June 2010), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072872.pdf> (stating future drug bioequivalence guidance will be tailored to product classes).

238. Biosimilars Act § 7002(a)(2)(k)(8)(D):

final rules should be issued following the notice-and-comment rulemaking requirements of the APA and should be published in the *Code of Federal Regulations*, in addition to the *Federal Register*,²³⁹ to provide the biologics industry with a clear picture of the regulatory landscape, increase certainty in the market, and encourage generic manufacturers to apply for more licenses. The FDA has the authority to utilize stronger procedural safeguards than the statute requires, and the OMB has encouraged agencies to utilize full notice-and-comment procedures over guidance “whenever practical.”²⁴⁰ This is just such a situation.

The FDA should be careful to make these categories clear and well defined. They should avoid case-by-case ad hoc approvals to prevent wasteful clinical research, reduce approval costs, and increase certainty, hence allowing more effective interchangeability determinations. This will encourage follow-on companies to submit narrowly tailored, detailed clinical tests. It will also cut down on the paperwork and bureaucratic delay.²⁴¹

One common complaint with the FDA is a lack of predictability in the examination requirements²⁴²—a complaint the FDA can address by issuing clear guidelines with the force of law behind them. In fact, the industry has voiced fears that generic companies may not seek interchangeability determinations *at all* because of the high evidentiary bar²⁴³—something the FDA must work diligently to counteract. Doing so would also allow for judicial review of the broader substantive rulemaking involved, while

If the Secretary issues product class-specific guidance . . . such guidance shall include a description of . . . the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and . . . the criteria, if available, that the Secretary will use to determine whether a biological product meets [interchangeability standards].

239. When a “good guidance” rises to the level of a major regulatory shift, the FDA will usually publish the regulations in the *Code of Federal Regulations*. Compare 21 C.F.R. § 320.24 (2010) (ADNA bioequivalence requirements), and 21 C.F.R. § 601.2 (general BLA requirements), with Supplements and Other Changes to an Approved Application, 69 Fed. Reg. 18,728, 18,729 (Apr. 8, 2004) (to be codified at 21 C.F.R. pt. 314) (adopting a risk-based approach to the regulation of pharmaceuticals to enhance safety).

240. FINAL BULLETIN, *supra* note 187, at 15 (“Pre-adoption notice-and-comment can be most helpful for significant guidance documents that are particularly complex, novel, consequential, or controversial.”).

241. See *Hawthorne*, *supra* note 47, at 94–95 (describing how, before electronic filing, paper applications often arrived at the FDA’s Rockville offices in full U-Haul trucks).

242. See *id.* at 128 (“They keep changing the rules.”).

243. See, e.g., Bruce Babbitt, *supra* note 173 (“[A]t this very early stage of biosimilar development in the US very few companies are expected to pursue the interchangeability option . . .”).

possibly preventing a legal challenge to the entire scheme that could result if the FDA utilized only guidance-plus documents to regulate biosimilars and maintained that none of them had the force and effect of law.

The FDA should use legislative rules to divide the separate classes of biologics—small proteins, insulin-like analogues, monoclonal antibodies, blood products, progenitor cells, and others.²⁴⁴ In 2005, David Dudzinski catalogued the entire scope and various levels of complexity in protein biologic products.²⁴⁵ While he published his work before Congress began debate on the Biosimilar Act, it is still highly relevant.

He writes first that the FDA should recognize the distinction between: “‘*biologic*’ *biologics*” (i.e., vaccines, toxins, antitoxins, and viral and pathogen particles), which are highly unpredictable, truly dependent on source materials, and should not have generic analogues; and “‘*biologic*’ *drugs*” (i.e., protein macromolecules), which are more predictable, allow for independent manufacturers to arrive at the same result, and for which generics should be allowed.²⁴⁶

Dudzinski implicitly advocated for less strenuous biosimilarity and interchangeability standards for biologic drugs versus biologic biologics. The FDA should heed this advice and scale determinations of (and clinical requirements for) interchangeability and biosimilarity accordingly to streamline the application process. A classification matrix would allow the FDA the flexibility of determining varying testing standards within each class of macromolecule without making the process standardless and arbitrary. Otherwise, companies will have even less certainty about what they are required to file. Therefore, the FDA should institute a product classification system.

Indeed, the FDA’s recent behavior allowing small-molecule protein biologics to apply as drugs under § 505 indicates the FDA’s willingness to create a sliding scale of biologics categories.²⁴⁷ Under the grandfather provisions of the Biosimilars Act, these small-molecule protein manufacturers will probably be able to file § 505 applications until the new regulations become effective.²⁴⁸ However, biologic products that fall into similar categories but that the FDA has not previously approved under

244. The FDA has begun to do this. See *supra* note 117 and accompanying text.

245. Dudzinski, *supra* note 8, at 154.

246. *Id.* at 185–87.

247. See INTERCENTER AGREEMENT, *supra* note 116 (allowing protein products to file NDAs).

248. See Biosimilars Act, Pub. L. No. 111–148, 124 Stat. 804, § 7002(e) (2010) (to be codified at 42 U.S.C.) (legislating a grandfather or “safe harbor” provision for ten years).

§ 505 should also be allowed to file with CDER in the interim to increase certainty in the approval process and avoid inequitable results.

Dudzinski also catalogs those biologic drugs that are most likely to benefit from an abbreviated approval pathway.²⁴⁹ First, biological macromolecules can be broken down into four categories: polysaccharides, polynucleotides (DNA, RNA), lipids, and polypeptides (proteins). Amongst these known macromolecules, the easiest and most likely to benefit from generic pathway approval are polynucleotides and polypeptides, as they are the most widely used already and likely easiest to reproduce.²⁵⁰

He then divides known proteins with therapeutic benefits into categories based primarily on the size of the macromolecules, something the FDA should do. In shorthand, his five categories are (1) small proteins, (2) medium-sized proteins, (3) larger non-antibody-based proteins, (4) antibodies, and (5) very large molecules.²⁵¹ He bases the categories on complexity and ease of synthesis, in ascending order, and the FDA should do the same. By issuing clearly delineated product-class rules, the FDA can breathe certainty and efficiency into the regulatory process in a field where it is sorely needed. Laying out clear product classes with the force of law is the first step in creating a straightforward and predictable regulatory framework that puts generic applicants on notice of approval requirements and allows them to obtain FDA approval quickly and efficiently. Clear product classes will lead to lower healthcare costs and greater access to life-saving medicines for those who cannot afford brand-name prices.

249. Dudzinski, *supra* note 8, at 185–87.

250. *Id.*

251. *See id.* at 185–87. Dudzinski’s categories are as follows:

Therapeutic peptides containing eight to ten amino acids that are small in size (1000–1300 daltons), such as oxytocin, somatostatin, or gonadotropin. These small proteins are reproducible through chemical synthesis rather than the recombinant DNA and so are more likely to generate widely repeatable results.

Medium-sized proteins (such as insulin, glucagons, or bivalirudin) usually contain between twenty and seventy amino acids (3000–7000 daltons). These are more appropriate for recombinant DNA, as they are mostly copies of human proteins.

Larger non-antibody protein-based therapeutics (15,000 to 100,000 daltons) (e.g., human growth hormone, erythropoietin) which are harder to synthesize, but have been widely made for years using recombinant DNA, with high purity and yield.

Larger antibodies that have large stretches of nonactive (or “variable”) regions and active or “constant” regions (approximately 150,000 daltons).

Very large molecules (e.g., Factor VIII, a coagulation factor) have always been regulated as biologics and contain over 2300 amino acids (over 200,000 daltons).

Id.

B. Flexible Guidance for Interchangeability and Biosimilarity Determination Requirements

Second, the FDA should use the flexibility of guidance-plus documents to issue individualized biosimilarity and interchangeability testing requirements within each classification. Advances in testing technology and biologic understanding will inevitably allow the FDA to make those determinations using fewer clinical tests in the future, and they must have the regulatory agility to react quickly to those changes in order to avoid undue delay or ossification in the rulemaking.²⁵²

To paraphrase Dudzinski, not all biologics are created equal.²⁵³ Some will require less testing to prove interchangeability or biosimilarity. For instance, small macromolecules with eight amino acids and no glycosylation are currently easily reproducible in the laboratory.²⁵⁴ There is no reason why a generic company cannot produce an identical macromolecule like this on an industrial scale; testing standards should reflect this scientific reality.²⁵⁵ In the case of more easily predictable small-molecule proteins, studies of statistical bioequivalence are far less important than studies showing the chemical identities match.

Conversely, with some larger macromolecules where less is known about the mechanism of action, companies should be allowed to conduct large-sample population studies showing statistically bioequivalent outcomes that are at least as effective as the innovator biologic. However, for now the FDA should not grant extremely large macromolecules interchangeability (e.g., the very-large-class factor VII coagulants, live vaccines, and other endlessly unpredictable biologics). There is too much room for variability or mutation, and science cannot yet adequately predict the clinical effects of such biologics.²⁵⁶ Indeed, one top FDA official has said as recently as 2007

252. Rakoff, *supra* note 188 (claiming agencies can avoid ossification through the use of interpretative rules and policy statements).

253. Dudzinski, *supra* note 8, at 185.

254. FDA Public Meeting, *supra* note 45 (response of Jim Shehan, Vice President for Legal, Government & Quality Affairs, Novo Nordisk).

255. See *Assessing the Impact of a Safe and Equitable Biosimilar Policy in the United States: Hearing before the Subcomm. on Health of the H. Comm. On Energy and Commerce*, 110th Cong. 32, 35 (2007) [hereinafter Woodcock Statement] (statement of Janet Woodcock, Director of CDER) (finding the ability to predict clinical comparability of two products depends on their chemical structure and the ability to scientifically demonstrate structural similarity, using the Omnitrope approval as an example).

256. Proteins are subject to many unpredictable physical and chemical changes that can affect their efficacy. They are subject to post-translational modifications, three-dimensional structural changes (e.g., via their disulfide bonds), and protein aggregation. Even changing

that current science will allow for biosimilarity or interchangeability determinations for smaller but not larger protein products.²⁵⁷

In sum, issuing notice-and-comment rules for ever-changing scientific standards would be deleterious and should be avoided. Therefore, the FDA should instead employ guidance to lay out testing requirements.

C. Fundamental Assumptions: Proposing a Balancing Test in Clinical Trials

The FDA should also employ a balancing test between therapeutic and chemical biosimilarity. The FDA can scale the therapeutic testing based on the unpredictability of the macromolecule, thus maintaining a high level of consumer safety. For instance, for innovator biologics with a strong effect, unpredictable size and conformation, or wholly unknown mechanisms of action, the FDA should require further therapeutic clinical testing.²⁵⁸ On the other hand, where the size is small, the conformation known, or the mechanisms of action relatively well understood, the FDA should require a lesser showing of therapeutic similarity for biosimilarity or interchangeability determinations.

The FDA bases drug bioequivalence on the fundamental assumption that equivalent average testing data proves therapeutic equivalence.²⁵⁹ Similarly, the FDA should base biologic biosimilarity on the fundamental assumption that similar clinical outcome (i.e., more tolerant) average testing data balanced with data showing chemical structural similarity proves biosimilarity. Likewise, the FDA should premise biologic interchangeability on the fundamental assumption that biosimilar and safe average testing data proves that biologics will result in the same clinical outcome (i.e., interchangeability). This balancing of clinical data and chemical structural similarity reflects the spirit of the legislation and provides the most efficient regulatory pathway to generic competition. In addition, since the FDA will already have approved the innovator biologic for safety and it has probably

the temperature of protein can alter the structure and utility through a process called “denaturing,” as when you cook an egg and then cool it down. *See* DENNISTON ET AL., *supra* note 23, at 533–64.

257. Woodcock Statement, *supra* note 255 (“Although [a generic pathway for biologics] currently may be possible for some relatively simple protein products, technology is not yet sufficiently advanced to allow this type of comparison for more complex protein products.”).

258. *Accord* Grabowski et al., *supra* note 18, at 843 (“Analysts predict that more complicated molecules will have less competition from follow-on products, which will enter the market more slowly than traditional generic pharmaceuticals.”).

259. *See* CHOW ET AL., *supra* note 41, at 91 (defining the fundamental assumption).

been on the market for a number of years, there is a lesser need for a high showing of clinical safety in the biosimilar follow-on.

Importantly, the field of biostatistics has advanced rapidly in the past twenty years.²⁶⁰ In 1997, the FDA issued guidance allowing generic manufacturers to use population (PBE), individual (IBE), and average bioequivalence (ABE) studies.²⁶¹ These different methods can produce better biostatistical results within variable subject matter.²⁶² The FDA retracted the use of IBE and PBE for drugs in 2003 because researchers found that population and individual bioequivalence studies could be manipulated through poorly conducted controls.²⁶³ However, the FDA is now aware of these problems, can adjust to solve them, and so should use PBE, IBE, and scaled average BE, as well as other advanced statistical techniques, to anticipate high variability in biosimilar batches.²⁶⁴

The FDA should consider allowing follow-on biologics applicants to show PBE, or at least incorporate newer forms of biostatistical analysis as they emerge. These and other methods control for the inherent variability of results within biologic-drug-user populations. That is why they need flexibility to alter product-specific testing guidelines as appropriate statistical methods emerge—so the FDA can quickly implement them, creating certainty and letting generic company's statisticians utilize them to show biosimilarity and interchangeability. Using advanced statistical bioequivalence methods²⁶⁵ that control for interpopulation variability is more appropriate for variable biologics than it is for drugs.

260. *See generally* SHEIN-CHUNG CHOW ET AL., STATISTICS IN DRUG RESEARCH: METHODOLOGIES AND RECENT DEVELOPMENTS (2002) (discussing new bioequivalence statistical methods).

261. “The population [Bioequivalence (BE)] approach assesses total variability of the measure in the population. The individual BE approach assesses within-subject . . . as well as the subject-by-formulation interaction.” FDA, GUIDANCE FOR INDUSTRY: STATISTICAL APPROACHES TO ESTABLISHING BIOEQUIVALENCE 3 (Jan. 2001), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070244.pdf>.

262. *Id.*

263. SCOTT PATTERSON & BYRON JONES, BIOEQUIVALENCE AND STATISTICS IN CLINICAL PHARMACOLOGY 179 (2006) (“After FDA reviewed data from application of such techniques in practice, the IBE and PBE methods were removed from their guidance in 2003.”).

264. *Id.* at 186–88 (describing scaled BE as being useful for highly variable drugs and citing characterizations of the average bioequivalence (ABE) requirements for highly variable subject matter as “too stringent.”).

265. *See generally* CHOW ET AL., *supra* note 260 (presenting new biostatistical methods).

Most importantly, the FDA should allow for product-specific equivalence boundaries.²⁶⁶ Otherwise, the volatile nature of biologics (as compared with single-molecule drugs) will mean that aberrant or unexpected clinical results in certain tests, even if not statistically significant under some more advanced statistical models, could derail an abbreviated biologics application.

The FDA should use product-specific statistical equivalence boundaries (i.e., tolerance levels) similar to or more liberal than those they use for drugs²⁶⁷ in order to encourage generic applicants to file and so that they do not set the bar too high. Indeed, the nature of the word *biosimilarity* suggests it should be a lower bar than therapeutic equivalence. If, on the whole, the follow-on is as equally effective (or even more so) as the innovator, it should be afforded interchangeability status under the Biosimilars Act, regardless of the known or unknown mechanism of action or the actual conformational structure. If the generic applicant can show the chemical structure is highly similar, the FDA should apply the balancing test and allow a more permissive statistical tolerance level. This effectively balances consumer safety with the regulatory realities and statutory purpose of the law—to speed biologic generics to market.

Lastly, because of the statutory language mandating the “same clinical outcome” for interchangeability status, some researchers have advocated “two-sided” biostatistical testing, where the follow-on applicant must prove that his drug is not “worse,” but also not “better” than the innovator.²⁶⁸ Those in favor of two-sided testing argue that a biologic cannot be interchangeable if it does not produce a statistically equivalent outcome, even if that outcome is better.²⁶⁹ They argue that such a result proves that the follow-on is not interchangeable, but rather is different (in some biobeneficial way), and so the product does not deserve interchangeable status. They caution against the dangers of such products, which could show differing adverse consequences years down the road.²⁷⁰

266. Lei Lei et al., *Evaluating Statistical Methods to Establish Clinical Similarity of Two Biologics*, 20 J. BIOPHARM. STAT. 1, 62, 72 (2010) (“Given that biopharmaceutical products usually have more variation, product-specific equivalence boundaries may be the right choice.”).

267. ORANGE BOOK, *supra* note 16, at x (for drugs, “two one-sided tests at the 0.05 level of significance ensures that there is no more than a 5% chance that a generic product that is not truly equivalent to the reference will be approved”).

268. FDA Public Meeting, *supra* note 45 (response of Dr. Shein-Chung Chow). Statistical bioequivalence means using statistical regressions of population data to show that two groups are bioequivalent.

269. *Id.*

270. *Id.*

The FDA should not feel obligated to use two-sided testing. Where a follow-on biologic's clinical outcomes are more statistically effective than the innovator, the follow-on should be granted interchangeability status (as long as studies show that the follow-on is as safe as the innovator). This is well within a reasonable interpretation of the "same clinical outcome" language and better suits the statutory purpose of the Act—to allow generics to market.

CONCLUSION

It is up to the FDA to enforce Congress's will and vigorously pursue the explicit statutory purpose of the Biosimilars Act—lowering prescription drug costs by allowing for rigorous generic biologic competition. Accordingly, the FDA must work hard to allow generic competition with innovator products. It can do this through a well-defined classification system produced through notice-and-comment rulemaking that allows robust generic competition in the areas of biologics where barriers to market entry and cost of manufacture are high. This way, the FDA can encourage innovation *and* price competition while still maintaining the highest standards of consumer safety and remaining accountable to the public.

RECENT DEVELOPMENT

FEES FROM MARS: WHY THE FTC NEEDS TO REGULATE MORTGAGE ASSISTANCE RELIEF SERVICES (MARS) FEES

ALEXANDER LUTCH*

TABLE OF CONTENTS

Introduction.....	646
I. The FTC Acts to Prevent Abusive MARS Practices but Does Not Go Far Enough.....	649
A. The Context in Which Consumers Use MARS Justifies Regulation	649
B. The FTC Rule is an Attempt to Remedy the Problems in the MARS Industry	651
II. The FTC Should Limit Fees to a Percentage of the Reduction in Payments from Modification	653
A. The FTC Needs to Limit MARS Fees to Protect Consumers.....	653
B. The FTC Has the Authority to Regulate MARS Fees to Avoid Unfair Practices.....	656
1. Excessive Fees Cause Substantial Injury.....	657
2. The Benefits from Unregulated Fees are Insufficient to Overcome the Injury to Consumers	659
3. Consumers are Unable to Avoid the Injury from Excessive Fees	660
C. The FTC Should Adopt a Hybrid of the Illinois and Maine Approaches to Fee Regulation	663
Conclusion.....	666

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INTRODUCTION

The recent financial crisis has had far-reaching consequences—particularly for homeowners, who have felt the effects of falling real estate values and high unemployment.¹ In response to the difficulties that these homeowners have faced in keeping current with their mortgage payments, the government has provided free services to help those struggling to obtain loan modifications.² The government has also offered incentives for creditors to work with borrowers to avoid foreclosure.³ Despite these efforts, however, 2.9 million properties entered the foreclosure process in 2010,⁴ and over 2.7 million loan payments were more than sixty days past due nationwide in the first quarter of 2010.⁵ Many have criticized the government's efforts as being incapable of achieving lasting results and having helped far fewer homeowners than originally intended.⁶ Within this

1. For a discussion of the causes and effects of the financial crisis, see generally BETHANY MCLEAN & JOE NOCERA, *ALL THE DEVILS ARE HERE: THE HIDDEN HISTORY OF THE FINANCIAL CRISIS* (2010) (tracing the causes of the financial crisis to securitization of mortgages, aggressive mortgage origination practices, and insufficient investigation of the quality of securitized loans).

2. The government, through the U.S. Department of the Treasury (Treasury) and the U.S. Department of Housing and Urban Development (HUD), encouraged the creation of the "HOPE NOW" alliance, which provides outreach services and operates a hotline to advise homeowners. See generally HOPE NOW: SUPPORT AND GUIDANCE FOR HOMEOWNERS, <http://www.hopenow.com> (last visited Aug. 1, 2011).

3. As part of the Troubled Asset Relief Program (TARP), Treasury created the Home Affordable Modification Program (HAMP), which gives incentives for servicers to reduce the proportion of a borrower's loan payments to monthly income. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-787, HOMEOWNERSHIP PRESERVATION: FEDERAL EFFORTS TO COMBAT FORECLOSURE RESCUE SCHEMES ARE UNDER WAY, BUT IMPROVED PLANNING ELEMENTS COULD ENHANCE PROGRESS 4–5 (2010), <http://www.gao.gov/new.items/d10787.pdf>; see also Edmund L. Andrews, *Mortgage Plan Targets up to Four Million Homeowners*, N.Y. TIMES, Mar. 5, 2009, <http://www.nytimes.com/2009/03/05/business/economy/05loan.html> (explaining the incentives offered by HAMP, such as money from the government for reducing homeowners' payments to no more than 38% of a household's gross monthly income).

4. Janna Herron, *Banks Repossessed Million Homes in 2010*, WASH. TIMES, Jan. 13, 2011, <http://www.washingtontimes.com/news/2011/jan/13/banks-repossessed-1-million-homes-2010>. In Nevada, the state with the greatest number of homes entering foreclosure, one in every eleven homes entered the foreclosure process in 2010. *Id.*

5. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 3, at 3.

6. See, e.g., Robbie Whelan & Anthony Klan, *Banks Boost Mortgage Assistance*, WALL ST. J., Feb. 1, 2011, at A5 (comparing the roughly 2 million permanent loan modifications resulting from direct bank negotiations with borrowers to the 521,630 homeowners who had received help from HAMP); Alan White, *Latest HAMP Report: Treasury Program a Failure*, CONSUMER L. & POL'Y BLOG (Feb. 17, 2010, 10:49 PM), <http://pubcit.typepad.com/clpblog/2010/02/latest-hamp-report-treasury-program-a-failure.html> (describing statistics from Treasury as showing the HAMP program's failure, particularly because of the

context of high demand for assistance in avoiding foreclosure, the number of mortgage foreclosure rescue and modification services has increased dramatically.⁷

Mortgage assistance relief service (MARS) providers offer to help struggling homeowners avoid foreclosure by negotiating with creditors on their behalf, usually for loan modifications.⁸ These providers charge a fee for their services and often require payment before concluding successful negotiations on the homeowner's behalf.⁹ Thus, even if the provider fails to avoid foreclosure or negotiate a modification, it will still charge the homeowner—despite the fact that the homeowners who use the services are those who are often already on the verge of bankruptcy.¹⁰

The Federal Trade Commission (FTC) adopted a rule, pursuant to the 2009 Omnibus Appropriations Act¹¹ and Credit Card Accountability Responsibility and Disclosure Act of 2009 (Credit CARD Act),¹² which bars MARS providers from making certain false or misleading claims,¹³ institutes certain disclosure requirements relating to these services,¹⁴ and prohibits companies from charging up-front fees.¹⁵ The rule became effective on December 29, 2010.¹⁶

Section 322.5 of the FTC's rule, which prohibits MARS providers from charging up-front fees, will likely have a substantial effect on the industry

temporary nature of the achieved modifications). Part of the reason for HAMP's ineffectiveness is that it does not directly target redefault rates, which are a key element of servicers' calculations in assessing proposed modifications. Adam J. Levitin & Tara Twomey, *Mortgage Servicing*, 28 YALE J. ON REG. 1, 77–78 (2011).

7. NAT'L CMTY. REINVESTMENT COAL., FORECLOSURE RESCUE SCAMS: A NIGHTMARE COMPLICATING THE AMERICAN DREAM 4 (2010), <http://www.ncrc.org/images/stories/pdf/research/foreclosure%20rescue%20scams%20-%20%20nightmare%20complicating%20the%20american%20dream.pdf>. For example, the Federal Trade Commission (FTC) received 7,927 complaints about Mortgage Assistance Relief Services (MARS) in 2009, compared to 1 in 2008. *Id.* at 28.

8. Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,093 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322).

9. *Id.* at 75,114.

10. See *infra* note 79 and accompanying text (noting MARS consumers' desperation by the time they engage such services).

11. Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 626(a), 123 Stat. 524, 678 (2009).

12. Credit Card Accountability Responsibility and Disclosure (Credit CARD) Act of 2009, Pub. L. No. 111-24, § 511(a), 123 Stat. 1734, 1763–64 (2009).

13. Mortgage Assistance Relief Services, 16 C.F.R. § 322.3 (2011).

14. *Id.* § 322.4.

15. *Id.* § 322.5.

16. Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,092 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322). With respect to charging up-front fees, the rule became effective on January 31, 2011. 16 C.F.R. § 322.5.

and its customers.¹⁷ Specifically, this section of the rule prohibits any MARS provider from “collecting any fees until the provider negotiates, and the consumer executes, a written agreement for mortgage relief with the lender or servicer.”¹⁸ The rule requires providers to give borrowers a written description of the differences between their current situations and the proposed modifications and to notify consumers that they can accept or reject the proposed modifications.¹⁹ Thus, a borrower must accept the modification before she will owe any fees.

The FTC’s rule will hopefully curb the most abusive practices of MARS providers. The requirement that MARS providers present borrowers with a new payment plan before they can charge fees should stop these companies from taking money without ever contacting lenders—a practice which has been unfortunately common.²⁰ Further, the requirement that borrowers actually agree to the new arrangement, by giving the borrower the ability to reject a modification and avoid paying the MARS provider, should provide some incentive for MARS providers to negotiate an arrangement that will result in a material change for the borrower.

The rule as enacted, however, does not fully protect borrowers from all abusive practices. As the FTC notes in its Statement of Basis and Purpose, MARS consumers are generally inexperienced with such services.²¹ While the prohibition on advance fees goes a long way toward solving consumers’ problems, this inexperienced group of consumers needs further protections to ensure that MARS providers do not trick them into accepting modifications that leave them no better off—or potentially even worse off—than if they had not used such services. Given the numerous claims that the FTC has made against MARS providers for fraud and deception under

17. *See, e.g.*, Comments of the National Consumer Law Center, Notice of Proposed Rulemaking: Mortgage Assistance Relief Services, at 3 (Mar. 29, 2010), <http://www.ftc.gov/os/comments/mars-nprm/546727-00049.pdf> (“The single most important provision is section 322.5 . . . Requiring [MARS] providers to earn their fee before being paid will rid the market of those who specialize in nothing more than ‘take the money and run.’”). *But see* Comments of 1st American Law Center, Inc., Need to Protect Flaws in FTC Proposed Rule for Mortgage Assistance Services from Worsening Foreclosure Crisis, at 2 (Mar. 25, 2010), <http://www.ftc.gov/os/comments/mars-nprm/546727-00032.pdf> (arguing that the prohibition of up-front fees is one of the “largest flaws” in the proposed rule).

18. Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,114.

19. 16 C.F.R. § 322.5(b)–(d).

20. *See* Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,116 (justifying the rule change because this abusive practice “causes or is likely to cause substantial injury to consumers”).

21. *Id.* at 75,119.

the existing regulatory framework,²² it is clear that such providers often leave consumers worse off for having used their services.

Thus, this Recent Development argues that, while prohibiting MARS providers from charging up-front fees is a step in the right direction, the FTC should go further and require that fees be tied to the amount of savings the providers obtain for borrowers. This requirement would protect borrowers from paying a MARS provider more for its services than they end up saving. Such a fee structure would strengthen the resulting arrangement: a borrower will be in a better position after using MARS than before negotiating with a lender, making the borrower less likely to default. If a MARS provider fails to negotiate a beneficial modification, at least the borrower will not have given the provider any money that might otherwise have been used to pay down the borrower's debt.

Part I of this Recent Development describes the context of desperation in which MARS providers operate and outlines the components of the FTC's rule. Part II explains the insufficiency of the FTC's rule as adopted because it allows MARS providers to appropriate borrowers' savings from modifications, shows that the FTC has the authority to regulate fees, and suggests that the FTC adopt a fee regulation that is a hybrid of the regulations currently in place in Maine and Illinois. Without such regulation, there is a danger that MARS consumers who manage to obtain modifications will nevertheless redefault, making MARS effectively useless.²³

I. THE FTC ACTS TO PREVENT ABUSIVE MARS PRACTICES BUT DOES NOT GO FAR ENOUGH

A. *The Context in Which Consumers Use MARS Justifies Regulation*

The MARS industry has been plagued by abusive practices. In addressing the need for MARS regulation, FTC Chairman Jon Leibowitz noted that “scammers, often armed with official looking documents and false claims of connection to government programs for homeowners, sell legal services they can't—and don't deliver,” and that, “[h]undreds of thousands of consumers have lost hundreds of millions of dollars this

22. The Statement of Basis and Purpose notes: “The FTC and state law enforcement agencies have collectively filed over two hundred cases against MARS providers.” *Id.* at 75,116.

23. See *infra* Part II.A. (explaining that factors such as the typical MARS consumer's frail financial situation and desperation make disclosure-based regulation insufficient to ensure the usefulness of MARS services); *infra* note 33 and accompanying text (noting that many borrowers have redefaulted on loans following modifications).

way.”²⁴ The roots of this situation parallel those of the mortgage crisis that led to such high demand for MARS. In the case of the mortgage crisis, borrower ignorance about loan terms led to a situation in which many borrowers were not able to afford their mortgages and thus defaulted on their payments.²⁵ This operated in conjunction with questionable mortgage-origination practices through which lenders pushed borrowers into loans that were often not appropriate for them.²⁶ Many of the individuals previously involved in mortgage origination are now offering MARS.²⁷ Given that disclosure requirements at the lending stage failed to prevent the current foreclosure crisis,²⁸ it seems unlikely that disclosures at the modification stage will fare significantly better.

While the MARS industry has been defrauding consumers, servicers have been largely unwilling to modify loans.²⁹ This is in part because of

24. *Bogus Mortgage Relief Schemes Targeted by FTC*, BANKING & FIN. SERVS. POL’Y REP., Jan. 2011, at 19.

25. See Debra Pogrud Stark & Jessica M. Choplin, *A Cognitive and Social Psychological Analysis of Disclosure Laws and Call for Mortgage Counseling to Prevent Predatory Lending*, 16 PSYCHOL. PUB. POL’Y & L. 85, 88 (2010) (“The continued governmental policy of relying upon disclosure laws as the primary means to protect homeowners from predatory loans was based on the notion that with such laws a properly functioning mortgage market could be maintained This notion was proven to be false in light of the massive scale of predatory home lending that contributed to the high level of foreclosures”). Many homeowners also took out adjustable rate mortgages, meaning that their monthly payments would increase substantially once rates reset, in hopes of higher income in the future; many of these homeowners ended up defaulting when their rates reset. See, e.g., Brent T. White, *Underwater and Not Walking Away: Shame, Fear, and the Social Management of the Housing Crisis*, 45 WAKE FOREST L. REV. 971, 987–88 (2010) (describing homeowners’ “optimistic overconfidence” in taking out adjustable rate mortgages).

26. See generally MCLEAN & NOCERA, *supra* note 1 (tracing the causes of the financial crisis to, among others, cut throat mortgage-origination practices at subprime lenders). See also Jeff Sovern, *Preventing Future Economic Crises Through Consumer Protection Law or How the Truth in Lending Act Failed the Subprime Borrowers*, 71 OHIO ST. L.J. 761, 773–74 (2010) (noting that some mortgage originators misstated mortgage payments and then disclosed the true payments at closing, at which point borrowers were less likely to walk away from a mortgage).

27. See LAUREN K. SAUNDERS ET AL., NAT’L CONSUMER LAW CTR., *DESPERATE HOMEOWNERS: LOAN MOD SCAMMERS STEP IN WHEN LOAN SERVICERS REFUSE TO PROVIDE RELIEF* 12–13 (2009), http://www.nclc.org/images/pdf/foreclosure_mortgage/scam/loanmodscamsreport0709.pdf (describing connections between former subprime lenders and MARS providers and also giving examples of job postings by MARS providers explaining desirability of mortgage experience); Comments of 1st American Law Center, Inc., *supra* note 17, at 10 (“Traditionally [MARS providers] will focus on the hiring of underwriters, processors, and forensic loan auditors.”).

28. See, e.g., Sovern, *supra* note 26, at 773–76 (arguing that ineffective disclosures required by the Truth in Lending Act contributed to the foreclosure crisis).

29. See, e.g., Alan M. White, *Deleveraging the American Homeowner: The Failure of 2008*

poorly structured incentives for servicers, who often make more money through foreclosure than modification.³⁰ Further, even when borrowers do manage to obtain modifications, these are often insufficient.³¹ This shows the importance of the National Consumer Law Center's plea that the rule "require the modification to be *affordable* A modification that lowers the consumer's payments but is still unaffordable does not provide a genuine benefit to the homeowner."³² Further validating this concern is the number of borrowers who have redefaulted after obtaining loan modifications.³³ Thus, there is a great need for MARS regulation.

B. The FTC Rule is an Attempt to Remedy the Problems in the MARS Industry

In response to this need for regulation, Congress included in the Omnibus Appropriations Act of 2009 the requirement that ninety days after its enactment, "the Federal Trade Commission shall initiate a rulemaking proceeding with respect to mortgage loans"³⁴ With the Credit CARD Act, Congress amended this directive to explain, "such

Voluntary Mortgage Contract Modifications, 41 CONN. L. REV. 1107, 1117 (2009) ("Modifications for [November 2008] ranged from a negligible fraction of none for forty-seven [of eighty] servicers to 35% of all mortgages in foreclosure for one servicer.").

30. See Levitin & Twomey, *supra* note 6, at 69–71 (describing servicers' fee structures and explaining why these make servicers unwilling to negotiate modifications, particularly those that reduce mortgage principal).

31. See White, *supra* note 29, at 1124 ("[T]he typical voluntary modifications of 2008 were not unlike the subprime loan originations they were meant to resolve: borrowers were kept in debt exceeding home values and exceeding their ability to amortize, with deferrals of interest, balloon payments, and temporary low interest rates."). Such insufficient modifications have led to high redefault rates, exacerbating the problem of servicers' unwillingness to offer affordable modifications. See *id.* at 1124, 1129 (noting high redefault rates and explaining that servicers' models for assessing the costs of modifications account for redefault rates, where higher redefault rates suggest that a modification will be more expensive to the servicer).

32. Comments of the National Consumer Law Center, *supra* note 17, at 18.

33. See Charles Duhigg, *Fighting Foreclosures, F.D.I.C. Chief Draws Fire*, N.Y. TIMES, Dec. 11, 2008, at A1 ("This week, the Office of the Comptroller of the Currency reported that more than half of at-risk borrowers whose loan terms were changed this year by banks . . . had already redefaulted on their payments.").

34. Omnibus Appropriations Act, 2009, Pub. L. No. 111–8, § 626(a), 123 Stat. 524, 678 (2009). In directing that rules be promulgated in accordance with 5 U.S.C. § 553 (2006), the Act allows for a faster rulemaking process than typical under the Magnuson–Moss procedures set forth in 15 U.S.C. § 57a (2006). See *Legislative Solutions for Preventing Loan Modification and Foreclosure Rescue Fraud: Hearing Before the Subcomm. on Hous. & Cmty. Opportunity of the H. Comm. on Fin. Servs.*, 111th Cong. 113 (2009) [hereinafter *Hearing*] (prepared statement of the FTC) ("This new legislation allows the FTC to use the relatively streamlined notice and comment rulemaking procedures under Section 553 of the Administrative Procedure Act (APA) in promulgating these rules").

rulemaking shall relate to unfair or deceptive acts or practices regarding mortgage loans, which may include unfair or deceptive acts or practices involving loan modification and foreclosure rescue services.”³⁵ In response, the FTC adopted its rule regulating MARS, in which it defines a mortgage assistance relief service as:

[A]ny service, plan, or program, offered or provided to the consumer in exchange for consideration, that is represented . . . to assist or attempt to assist the consumer with . . . [n]egotiating, obtaining, or arranging a modification of any term of a dwelling loan, including a reduction in the amount of interest, principal balance, monthly payments, or fees.³⁶

The rule regulates MARS providers in three important ways. It (1) sets forth a list of prohibited representations³⁷ and required disclosures;³⁸ (2) prohibits advance fees;³⁹ and (3) imposes recordkeeping requirements.⁴⁰

The rule addresses some significant problems with the MARS industry,⁴¹ and the prohibition on advance fees is likely to curb some of the industry’s most abusive practices.⁴² Further, not only does this section of the rule

35. Credit CARD Act, Pub. L. No. 111–24, § 511(a), 123 Stat. 1734, 1763–64 (2009).

36. 16 C.F.R. § 322.2(i)(2) (2011).

37. *Id.* § 322.3. Significantly, this section of the rule prohibits a MARS provider from “[r]epresenting . . . that a consumer cannot or should not contact or communicate with his or her lender or servicer.” *Id.* § 322.3(a). This is meant to address the situation in which the MARS provider tries to hide its failure to provide any service to a borrower by cutting the borrower off from her servicer. *See* Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,106 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322) (explaining that the harm from such an instruction is the deprivation of information about “whether the provider is actually performing”). The rule also prohibits providers from “[m]isrepresenting . . . [t]he likelihood of negotiating, obtaining, or arranging any represented service or result.” 16 C.F.R. § 322.3(b)(1).

38. 16 C.F.R. § 322.4. Providers must disclose that a borrower may discontinue the use of the MARS provider’s service at any time, that a borrower may accept or reject an offer from her lender, and that if she rejects it, she will not have to pay for the provider’s services. *Id.* § 322.4(b)(i).

39. *Id.* § 322.5(a).

40. *Id.* § 322.9. These requirements are meant to aid in regulating the industry and investigating providers for legal compliance. Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,134.

41. For example, the restrictions on representations should help avoid situations in which MARS providers promise to achieve results and then leave borrowers worse off when they fail to do so because of the time wasted while borrowers assumed that the provider was achieving results. *See* Allison D. Matthews, Comment, *To Stop a Predator: Is a Complete Ban on For-Profit Foreclosure Rescue Operations the Best Way to Prevent Equity Stripping?*, 20 LOY. CONSUMER L. REV. 477, 487 (2008) (“Even if a consumer may never have to pay the consultant if service is not rendered . . . the foreclosure consultant still has wasted the homeowner’s valuable time, which could have been spent seeking legitimate guidance and aid.”).

42. *See supra* note 17 and accompanying text (describing the importance of an up-front

prohibit charging fees up-front, but it also requires the execution of a modification before a MARS provider can charge fees.⁴³ Thus, in theory, an informed MARS consumer should not pay a MARS provider who does not perform a beneficial service. The FTC declined, however, to impose any restrictions on the magnitude of the fees that MARS providers can charge.⁴⁴ This lack of regulation regarding the MARS fees themselves limits the effectiveness of the rule because it allows providers to continue to provide services that are worth less than the fees they charge.⁴⁵

II. THE FTC SHOULD LIMIT FEES TO A PERCENTAGE OF THE REDUCTION IN PAYMENTS FROM MODIFICATION

A. *The FTC Needs to Limit MARS Fees to Protect Consumers*

The FTC rule relies on mandatory disclosures to keep MARS providers from continuing their prior unfair practices.⁴⁶ The disclosures required in conjunction with execution of a modification may be insufficient to avoid situations in which consumers do not benefit from MARS.⁴⁷ One concern is that consumers may not fully process these disclosures and therefore may be willing to agree to a modification that is insufficient to achieve a lasting solution.⁴⁸ At the loan-origination stage, one author found that “brokers

fee ban to ensure that providers do not take fees up-front and then fail to provide any services).

43. 16 C.F.R. § 322.5(a). By making payment contingent upon execution of a modification, the rule avoids some disputes over what a MARS provider has actually represented that it will accomplish, since a borrower can theoretically reject a proposed modification if the provider fails to achieve the promised results.

44. Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,122. The FTC only explains why it did not adopt a static fee cap, not why it declined to adopt a dynamic cap such as this Comment proposes. *Id.*

45. *See infra* Part II.A. (outlining the need for regulation of MARS fees to ensure that such services provide value to consumers).

46. In particular, the rule requires disclosures about MARS generally and disclosures associated with executing a modification and charging of fees upon execution. 16 C.F.R. §§ 322.4, 322.5(b).

47. The disclosures required under the Real Estate Settlement Procedures Act (RESPA) in the context of mortgage settlement fees provide a cautionary example of the limits of disclosures. *See, e.g.,* Elizabeth Renuart & Jen Douglas, *The Limits of RESPA: An Empirical Analysis of the Effects of Mortgage Cost Disclosures* 1, 13 (Albany Law Sch., Research Paper No. 10-13, 2010), available at <http://ssrn.com/abstract=1635841> (describing RESPA’s goal of “rais[ing] market efficiencies and price competition by creating savvy shoppers” but finding that mortgage closing costs nevertheless increased dramatically in the decades following RESPA’s enactment).

48. There is a growing literature on the ineffectiveness of disclosures. *Cf.* William N. Eskridge, Jr., *One Hundred Years of Ineptitude: The Need for Mortgage Rules Consonant with the*

were virtually unanimous in saying that borrowers never withdrew from a loan after reading the final disclosures at the closing, and never used those disclosures for their stated purpose of comparison shopping for loans.⁴⁹ This is of particular concern in the loan-modification context, since borrowers are unlikely to have experience modifying loans or evaluating services that help them do so, meaning that disclosures are likely to be less effective.⁵⁰ Further, MARS is an “experience good”—a good whose quality a consumer cannot ascertain until after purchasing it—and is one for which repeat customers are unlikely.⁵¹ Where this is the case, a service provider has a reduced incentive to provide services that are satisfactory in the long term.⁵²

In addition to the difficulties in relying on disclosure, MARS providers do not have appropriate incentives to ensure that a borrower only accepts a worthwhile modification under the FTC’s rule. The rule requires that, for a MARS provider to receive payment, the consumer must receive and execute a modification.⁵³ The rule does not, however, refer to the terms of

Economic and Psychological Dynamics of the Home Sale and Loan Transaction, 70 VA. L. REV. 1083, 1086 (1984) (positing that “[f]ederally mandated disclosures do little to protect many homebuyers” in the context of loan origination). See generally Ronald J. Mann, “Contracting” for Credit, 104 MICH. L. REV. 899 (2006) (examining difficulties with ensuring that credit card disclosures create informed consumers); Florencia Marotta-Wurgler, *Does Disclosure Matter?* (NYU Sch. of Law, NYU Ctr. for Law, Econ. and Org., Law & Econ. Research Paper Series, Working Paper No. 10-54, 2010), available at <http://ssrn.com/abstract=1713860> (finding that increased accessibility of contract terms does not increase readership and that consumers are likely to purchase products regardless of the terms).

49. Govern, *supra* note 26, at 779.

50. See Omri Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure* 62 (Univ. of Mich. Law Sch. Empirical Legal Studies Ctr., Working Paper No. 9, 2010), available at <http://law.bepress.com/umichlwps/empirical/art9> (surveying the pitfalls of disclosures but acknowledging, “Where people make a decision regularly, they become expert at making those decisions”). Cf. Eskridge, *supra* note 48, at 1086 (“The typical homebuyer is not very knowledgeable about the market for homes, financing, and settlement services and tends to defer to more sophisticated intermediaries . . . who are more interested in closing transactions than in obtaining the best deal for the buyer.”).

51. Henry N. Butler & Jason S. Johnston, *Reforming State Consumer Protection Liability: An Economic Approach*, 2010 COLUM. BUS. L. REV. 1, 48–49 (noting that with “experience goods . . . the consumer learns the actual quality of the good after buying and using it”). It is difficult and troubling to imagine repeat MARS customers, given the dire circumstances that lead borrowers to use MARS.

52. There are few consequences for providers of experience goods that operate in a context where repeat customers are rare. The lack of repeat customers eliminates much of the incentive to satisfy customers, since there is no realistic threat that dissatisfied customers will take their business elsewhere in the future. See *id.* at 61 (differentiating between the effectiveness of this threat for various products, but noting that the ability of consumers to punish sellers by taking their business elsewhere is nonexistent for some experience goods).

53. 16 C.F.R. § 322.5(a) (2011).

the executed modification.⁵⁴ Thus, MARS providers' incentives are to obtain *any* modification, not the best modification possible.⁵⁵ Once providers negotiate for a modification from servicers, they can use their role as counselors to pressure consumers to execute the modification. If, on the other hand, the regulations required fees for MARS to relate to the modification achieved, then the provider would have an incentive to achieve the greatest savings possible for the borrower.

Such a contingent fee structure would be somewhat similar to that generally used by real estate brokers.⁵⁶ Real estate brokers receive a commission that is a predetermined percentage of the sale price of the property. This practice arose as a result of market conditions, not regulation.⁵⁷ Some have argued that this arrangement favors the seller, since higher sales prices result in higher commissions.⁵⁸ With MARS, however, tying fees to the modification obtained would align the provider's and borrower's interests while not harming the counterparty—i.e., the servicer—because unlike the broker, the provider only represents the borrower.

Arguments regarding the insufficiency of disclosure in informing consumers' decisions also explain why allowing a borrower to reject a proposed modification and avoid paying for MARS is insufficient. Many borrowers will not know whether they are getting a modification that justifies the cost of MARS and thus will be unable to make an informed choice.⁵⁹ Requiring that fees be based on the results achieved with a modification, however, ensures that even after accounting for MARS fees

54. Anecdotal information from before the rule's enactment suggests that MARS providers generally do not charge an outcome-based fee, and there is no reason to believe that this aspect of the industry's model will change after the rule's implementation. *See, e.g., SAUNDERS ET AL., supra* note 27, at 10–11 (listing examples of fees determined up-front that borrowers paid to MARS providers).

55. This is particularly the case because, unlike some other service providers, MARS providers face a low likelihood of having repeat customers given the remedial nature of their services. *See supra* note 52 and accompanying text.

56. *See* GEORGE LEFCOE, REAL ESTATE TRANSACTIONS, FINANCE, AND DEVELOPMENT 42–43 (6th ed. 2009) (explaining that brokers generally operate on a contingent fee basis, where compensation is calculated as a fixed percentage of the selling price of property).

57. *Id.*

58. Patricia A. Wilson, *Nonagent Brokerage: Real Estate Agents Missing in Action*, 52 OKLA. L. REV. 85, 104 (1999) (suggesting that there is an “inherent conflict of interest, which tends to favor the seller” under the standard broker's contingent fee arrangement).

59. *See supra* note 48 and accompanying text (describing the inadequacy of disclosure at ensuring rational decisionmaking).

the borrower will still receive a benefit from the modification. Moreover, such regulation of fees would fall within the FTC's authority to adopt regulations regarding unfair mortgage practices.⁶⁰

B. The FTC Has the Authority to Regulate MARS Fees to Avoid Unfair Practices

A MARS regulatory regime like the FTC's that does not limit the fees that providers charge leaves consumers in danger of paying fees unjustified by the services they receive.⁶¹ Regulation of fees is within the scope of the FTC's authority to regulate unfair practices since the agency can declare a practice unlawful if it finds "the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition."⁶² Thus, fee regulation would need to pass a three-prong test to fall within FTC authority: (1) it must regulate a practice that causes substantial injury;⁶³ (2) the practice must not have countervailing benefits;⁶⁴ and (3) the injury caused by the practice must not be reasonably avoidable by consumers.⁶⁵ The FTC addressed the concept of a fee cap in its Statement of Basis and Purpose, suggesting that it may not have the authority to enact such a cap.⁶⁶ However, in addressing the issue, the FTC described the downsides of a static cap on fees,⁶⁷ which is significantly different from requiring that fees be proportional to the outcome achieved.⁶⁸ The following discussion shows that the FTC does, in fact, have the authority to regulate fees.

60. Credit Card Accountability Responsibility and Disclosure (Credit CARD) Act of 2009, Pub. L. No. 111-24, § 511(a), 123 Stat. 1734, 1763-64 (2009).

61. *See supra* Part II.A. (outlining the risk that MARS providers' fees will exceed the savings achieved by a modification).

62. 15 U.S.C. § 45(n) (2006).

63. *Id.*

64. *Id.*

65. *Id.*

66. *See* Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,122 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322) (finding that the market should control MARS, and "the Commission's role is to remove obstacles to consumers making the informed choices that are necessary to a properly functioning market").

67. *See id.* at 75,122 n.351 (defending the decision not to adopt a fee cap by referring to disadvantages associated with "fixed maximum fee[s]," without weighing the costs and benefits of dynamic fee regulations).

68. The Statement of Basis and Purpose refers to a concern that "changes in market conditions and technologies render the fixed maximum fee too low . . . or too high." *Id.* A dynamic cap, such as one tied to the amount of savings that a borrower receives, has the advantage of adapting to changing circumstances.

1. *Excessive Fees Cause Substantial Injury*

A fee cap is necessary to avoid substantial injury. MARS providers' high-pressure sales tactics leave consumers vulnerable to agreements that involve excessive fees.⁶⁹ In enacting its prohibition on advance fees, the FTC tried to avoid the situation in which MARS providers charge up-front fees and do not provide the promised services.⁷⁰ This alone does not fully address the problem with MARS fees. It is likely—given that the rule does not regulate fees beyond banning up-front payments—that MARS providers will insist on a flat fee, with the amount determined up-front, for the provision of their services.⁷¹ While it is possible that a borrower might refuse to execute the modification if the predetermined fee is greater than her savings from the proposed modification, the borrower will only refuse if she actually understands that this is the case. If the borrower does not adequately understand the modification, she will likely focus on the fact that the modification has some initial reduction in payments. It is not unlikely, given the circumstances, that the borrower will end up executing the modification before realizing that the MARS provider's fee leaves her worse off.⁷²

Another FTC rule and the litigation surrounding it are instructive in evaluating the injury from excessive MARS fees. The consumer injury from the absence of a fee cap parallels the injury at issue in the adoption of the Credit Practices Rule, which survived challenge in *American Financial Services Ass'n v. FTC*.⁷³ That rule regulates six types of creditor remedies, including wage assignments and security interests in household goods.⁷⁴ In adopting its rule, the FTC determined that security interests in household goods and wage assignments constituted “unfair” trade practices.⁷⁵ The American Financial Services Association and South Carolina Department of Consumer Affairs challenged these parts of the rule, arguing that they exceeded the FTC's unfairness authority “because in the absence of seller

69. *Cf. id.* at 75,116 (“Consumers in financial distress suffer monetary harm . . . when, following sales pitches frequently characterized by high pressure and deception, they use their scarce funds to pay in advance for promised results.”).

70. *Id.* at 75,120.

71. This type of arrangement would make sense for a MARS provider, given that it will incur costs largely unrelated to its level of success and thus will want to know that it will recoup these costs upon execution of a modification.

72. *See supra* Part II.A. (arguing that disclosures alone do not ensure informed consumers).

73. 767 F.2d 957, 962 (D.C. Cir. 1985).

74. *Id.* at 963. The rule also regulates confessions of judgment, waivers of exemption, pyramiding of late charges, and cosigner liability. *Id.*

75. *Id.* at 964.

overreaching in the form of deceit, coercion or nondisclosure of material information, the FTC may not intercede in the market as an ‘invisible hand’ to obtain ‘better bargains’ for consumers.”⁷⁶ In upholding the rule, the court acknowledged the relevance of consumers’ already distressed circumstances in determining the injury resulting from such practices.⁷⁷ The MARS consumer’s circumstances are not unlike the debtor’s situation that the court describes, because in both cases the consumer is “most likely already enmeshed in a financial crisis.”⁷⁸ Homeowners who use MARS are generally unable to keep up with their mortgage payments.⁷⁹ If a MARS provider charges an excessive fee, the borrower, despite obtaining a modification, will likely still be unable to make her mortgage payments after paying the MARS provider’s fee and will end up losing her home.

The MARS consumer is also similar to the consumer protected by the Credit Card Practices Rule because both consumers may lose items with greater value to them than others. In *American Financial Services*, the court noted that when creditors seize household goods, “the replacement cost to the consumer is substantial, not to mention the sentimental value of the possessions and psychological impact of the loss on the consumer.”⁸⁰ The loss of a house through foreclosure similarly involves the forfeiture of a possession with a high replacement cost, particularly given the unique nature of real property.⁸¹ The fact that many homeowners attach great sentimental value to their homes and associated memories compounds this loss.⁸²

Finally, the MARS consumer is in a time-sensitive position that heightens the need for fee regulation rather than the rule’s up-front fee ban. If the MARS consumer avails herself of her right to reject the modification

76. *Id.*

77. *Id.* at 973 (comparing the minimal value of household items seized to the creditor with the consumer’s financial and psychological loss).

78. *Id.*

79. Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,117 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322) (“MARS providers direct their claims to financially distressed consumers who often are desperate for any solution to their mortgage problems and thus are vulnerable to the providers’ purported solutions.”).

80. *Am. Fin. Servs. Ass’n*, 767 F.2d at 973.

81. See, e.g., 1 JAMES C. BONBRIGHT, *THE VALUATION OF PROPERTY* 66 (1937) (pointing out that valuing a home at what the owner might receive as payment from someone else for it will not account for the full value of the home to the owner); ALFRED A. RING & JAMES H. BOYKIN, *THE VALUATION OF REAL ESTATE* 66 (3d ed. 1986) (noting the distinct valuation issues pertaining to real estate because of uniqueness and immovability).

82. See, e.g., John Fee, *Eminent Domain and the Sanctity of Home*, 81 NOTRE DAME L. REV. 783, 791–92 (2006) (arguing that just compensation for homes in eminent domain cases should be higher than market value and listing ways that homeowners attach personal, nonmonetary value to their homes).

that a provider obtains and thus avoids paying the provider,⁸³ she has nonetheless lost the time required to negotiate the modification. Given that the borrower is already in a time-sensitive position when enlisting a MARS provider's assistance, the lost time itself constitutes a significant injury to the borrower.⁸⁴ Thus, the MARS consumer's precarious financial position, the nature of the property MARS consumers stand to lose as a result of excessive fees, and the time-sensitive position of the MARS consumer mean that excessive MARS fees cause substantial injury to consumers.

2. *The Benefits from Unregulated Fees are Insufficient to Overcome the Injury to Consumers*

While excessive MARS fees cause substantial injury to consumers, allowing providers to determine fees without any government regulation provides little benefit. The potential harm of regulating the fees that MARS providers charge is that providers will cease to exist.⁸⁵ One must assess this harm with an awareness of the broader context in which MARS providers operate. The government provides free services to help borrowers negotiate modifications with their lenders.⁸⁶ A borrower can also attempt to negotiate on her own behalf.⁸⁷ Further, the FTC has noted

83. See Prohibition on Collection of Advance Payment and Related Disclosures, 16 C.F.R. § 322.5(b) (2011).

84. See *supra* note 41 (noting the time-sensitive nature of the typical MARS consumer's circumstances).

85. See Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,115 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322) (referencing comments in response to the proposed advance-fee ban in which MARS providers claimed that such a ban would drive providers out of business). There are reasons to encourage legitimate MARS providers, particularly because government-sponsored services have not been sufficient to help every borrower who needs assistance. See, e.g., *Hearing, supra* note 34, at 84 (prepared statement of Lauren Saunders, Managing Att'y, National Consumer Law Center) ("Though the free services offered by HUD-approved housing counseling agencies are unquestionably the first and best option for struggling homeowners, these counselors are overwhelmed and some homeowners report difficulties in getting through to them. For some homeowners, it would be well worth \$2,000 or \$3,000 to obtain an affordable modification . . ."); Andrews, *supra* note 3 (describing how various classes of borrowers are ineligible for government-sponsored help).

86. See *supra* notes 2–3 (discussing government-sponsored efforts, such as HAMP, which are meant to help borrowers struggling with their mortgage payments).

87. See *Hearing, supra* note 34, at 55 (prepared statement of Martha Coakley, Att'y Gen. of the Commonwealth of Massachusetts) (testifying that "most homeowners should be able to obtain a loan modification without having to hire someone to assist them"). *But cf.* Paul Kiel, *Borrowing Trouble: Some Lenders are Modifying Mortgages Only After Homeowners Waive Their Right to Sue*, SLATE, May 9, 2011, <http://www.slate.com/id/2293391/pagenum/all/> (describing servicers' efforts to force borrowers to waive their rights, such as the right to sue for faulty documentation, in order to obtain modifications and thus highlighting borrowers'

that MARS rarely result in modifications.⁸⁸ These factors lessen the overall benefit derived from the MARS industry.

In addition to the fact that the MARS industry is not essential, the most extreme consequences of regulating fees are only likely to occur where the benefits of MARS are minimal. In assessing the harm of providers no longer offering MARS in the context of the advance fee ban, the FTC decided that the harm was not sufficiently significant to outweigh the benefits of the advance fee ban.⁸⁹ While there is a greater possibility that fee regulation would cause MARS providers to disappear, since the ban only deals with the timing rather than the amount of the payment, MARS is only valuable where a borrower obtains a beneficial loan modification. A modification will not be beneficial, and thus will not justify using MARS, where the fee charged leaves the borrower still unable to make her mortgage payments. Thus, even if a fee cap like the one this Recent Development argues for⁹⁰ would drive MARS providers out of business, this is no great harm.

3. *Consumers are Unable to Avoid the Injury from Excessive Fees*

The final prong of the test for an FTC unfairness action requires that consumers be unable to reasonably avoid the injury from a practice.⁹¹ The direct injury to consumers from excessive fees for MARS is the money they lose to such fees. Given the frail financial status of the typical MARS consumer, however, this money will often mean the difference between being able to remain current on mortgage payments and defaulting.⁹² Thus, the real injury from excessive fees is magnified in many cases beyond the excess money paid to also include default on the consumer's mortgage payments and the concomitant consequences. Given the nature of MARS, disclosure of fees is insufficient to aid consumers in avoiding excessive fees for three reasons: (1) MARS providers have a history of high-pressure sales tactics; (2) MARS consumers generally agree to fees upon contracting with providers even though results come later; and (3) MARS consumers are unlikely to respond to disclosures.

need for assistance in negotiating for modifications).

88. See *Mortgage Assistance Relief Services*, 75 Fed. Reg. at 75,118 (“[T]he rulemaking record demonstrates that the vast majority of consumers fail to receive successful loan modifications or other forms of mortgage assistance promised.”).

89. *Id.* at 75,118–19.

90. See *infra* Part II.C. (proposing that fees be restricted to 15% of the borrower's savings and thus tying the fees to the modification obtained).

91. 15 U.S.C. § 45(n) (2006).

92. See *supra* note 79 and accompanying text (explaining the financially vulnerable position of the typical MARS consumer).

First, MARS providers' history of deception and high-pressure sales tactics lowers the likelihood that their customers will adequately evaluate the terms of the contract they enter into with the provider.⁹³ For example, in a complaint against a MARS provider, Illinois Attorney General Lisa Madigan alleged that the provider targeted Polish consumers who did not speak English and then asked them to sign contracts written only in English.⁹⁴ These high-pressure tactics operate in addition to MARS consumers' already vulnerable psychological position.⁹⁵

In prior rulemakings, the FTC has found this consumer vulnerability relevant to determining whether consumers can reasonably avoid an injury, and courts have upheld rules based on such findings. For example, the court in *Pennsylvania Funeral Directors Ass'n v. FTC*⁹⁶ evaluated the FTC's ban on "casket handling fee[s]" in the funeral services industry.⁹⁷ The FTC issued the ban because funeral service providers were charging fees to consumers who bought caskets from third parties in order to discourage them from doing so.⁹⁸ In assessing whether consumers could reasonably avoid the injury from such fees, the court stressed that "the FTC promulgated the original Funeral Rule . . . because of the particular vulnerability of funeral service consumers . . . [who] often do not have the time to 'shop around.'"⁹⁹ The court found this argument persuasive in showing that consumers could not reasonably avoid the injury caused by the fees.¹⁰⁰ Just as funeral service consumers are in a time-sensitive position that makes it difficult for them to compare prices, so too are MARS consumers, who must act quickly to avoid losing their homes.

93. See, e.g., *Hearing*, *supra* note 34, at 51 (prepared statement of Martha Coakley, Att'y Gen. of the Commonwealth of Massachusetts) (describing aggressive advertising strategies employed by MARS providers, including "unsolicited telephone calls"); Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,116 (referring to consumer injury resulting from "sales pitches frequently characterized by high pressure and deception"); NAT'L CMTY. REINVESTMENT COAL., *supra* note 7, at 26 (stating that "many law firms, former subprime lenders and other real estate professionals have diverted their talents to foreclosure assistance services"); SAUNDERS ET AL., *supra* note 27, at 8-9 (describing MARS providers' sales tactics, including the use of pressure and deceit).

94. Complaint for Injunctive and Other Relief at 6-7, *People v. Ill. Loan Modification, LLC*, No. 2010-CH-48287 (Ill. Cir. Ct. Nov. 9, 2010).

95. Cf. *Am. Fin. Servs. Ass'n v. FTC*, 767 F.2d 957, 974 (D.C. Cir. 1985) (describing various ways in which borrowers faced with threats upon default on consumer debts are particularly vulnerable because they are seeking any suggested "ways out" of debt).

96. 41 F.3d 81 (3d Cir. 1994).

97. *Id.* at 82.

98. See *id.* at 84 (describing how funeral homes began charging casket handling fees in reaction to increased competition in casket sales).

99. *Id.* at 91-92.

100. *Id.*

Second, because MARS consumers are particularly vulnerable, MARS providers will continue to insist upon a predetermined fee in the absence of regulation to the contrary, making it difficult for consumers to avoid excessive fees. Lenders and servicers have been unwilling to agree to significant modifications, such as reductions in loan principal.¹⁰¹ Thus, a MARS provider will want to protect itself against the probability that it will not achieve a modification worthy of a high fee by charging a fee unrelated to the modification achieved. Until the borrower has received a modification offer, however, she cannot determine whether this fee will be justified.¹⁰² Requiring that fees be assessed in relation to the terms of the modification executed would ensure that the borrower did not owe the MARS provider more than she had saved through using the provider. It would also save consumers from gambling on whether their MARS provider would end up obtaining modifications that justified the provider's fees.

Finally, disclosure is an ineffective way to aid consumers in avoiding harm.¹⁰³ The FTC dealt with the concept of consumer ability to avoid injury in the seminal case of *In re International Harvester Co.*¹⁰⁴ That case involved a company that made tractors with fuel-cap issues that occurred very infrequently but with potentially drastic consequences.¹⁰⁵ In explaining that consumers could not reasonably avoid injury, the FTC noted that the concept "depends, not just on whether people know the physical steps to take in order to prevent [the injury], but also on whether they understand the necessity of actually taking those steps."¹⁰⁶ Applying this logic to MARS, in order for consumers to be able to avoid the injury from excessive fees, they not only need to know that excessive fees will harm them, but also need to know how to identify and avoid excessive fees. To the extent that disclosures do not succeed in informing MARS consumers of the need to demand lower fees, disclosure alone will leave consumers unable to avoid the injury from excessive fees.

101. See, e.g., White, *supra* note 29, at 1127 (describing servicers' failure to agree to adequate modifications).

102. Further, the borrowers who use MARS are in a time-sensitive position and thus cannot afford to wait until the provider has obtained a modification offer in order to determine whether to accept the offer (in which case they will need to pay the provider's fee) or reject it. See *supra* note 41 (explaining the time-sensitive position of the typical MARS consumer).

103. See *supra* note 48 and accompanying text (discussing the ineffectiveness of relying on disclosures to ensure that consumers understand the terms of modifications).

104. 104 F.T.C. 949 (1984).

105. *Id.* at 1051.

106. *Id.* at 1066 (citation omitted).

C. *The FTC Should Adopt a Hybrid of the Illinois and Maine Approaches to Fee Regulation*

Given the abusive practices prevalent in the MARS industry and the inability of the FTC rule to fully address them, it is helpful to look at state efforts to regulate MARS for guidance on how to improve the rule. At least twenty-four states and the District of Columbia have laws regulating MARS.¹⁰⁷ Of the states that regulate MARS, both Maine and Illinois have specifically attempted to regulate the fees that providers can charge.¹⁰⁸ In 2009, Illinois enacted a statute that limits the fees that “distressed property consultants” can charge.¹⁰⁹ For modifications that reduce payments for five years or more, a consultant cannot charge more than “the lesser of the homeowner’s: (1) existing monthly principal and interest mortgage payment; or (2) total net savings derived from the lowered monthly principal and interest mortgage payment over the succeeding 12 months.”¹¹⁰ For modifications that do not last as long, fees cannot exceed “50% of the owner’s existing monthly principal and interest mortgage payments.”¹¹¹

Thus, fees in Illinois are limited in accordance with a borrower’s circumstances. Further, a consultant cannot “claim, demand, charge, collect, or receive any compensation until after the distressed property consultant has fully performed each service the distressed property consultant contracted to perform or represented he or she would perform.”¹¹² This means that a consultant cannot charge up-front fees.¹¹³

107. See SAUNDERS ET AL., *supra* note 27, at 20 (listing the various ways different states have regulated MARS).

108. Neither statute uses the *MARS* terminology, but each attempts to regulate a largely similar set of service providers.

109. 765 ILL. COMP. STAT. ANN. 940/70 (West 2009). The statute defines a “distressed property” as “residential real property . . . that is in foreclosure or at risk of loss due to nonpayment of taxes, or whose owner is more than 30 days delinquent on any loan that is secured by the property.” *Id.* 940/5. Thus, the statute does not appear to apply to consultants’ activities where a homeowner is not already behind on her mortgage payments.

110. *Id.* 940/70.

111. *Id.*

112. *Id.* 940/50(a)(1).

113. The Illinois prohibition on up-front fees, however, provides less protection than the FTC rule. The Illinois statute requires that a consultant complete the service she represented that she would perform before receiving payment. *Id.* This prohibition acts in conjunction with the borrower’s right to rescind her contract with the consultant “at any time until after the distressed property consultant has fully performed each service the distressed property consultant contracted to perform or represented he or she would perform.” *Id.* 940/15(a). The FTC rule, on the other hand, prohibits payment until the borrower has executed a modification, thus distancing the payment contingency from performance of represented services and making payment effectively depend instead on

The limitation on fees when the modification does not last for five years, however, is unrelated to the savings achieved by the modification. Given the difficulty borrowers have had in obtaining lasting modifications,¹¹⁴ this aspect of the statute is significant. Despite the statute's shortcomings, Illinois Attorney General Lisa Madigan has used the statute to aggressively address unfair MARS practices.¹¹⁵

Maine adopted its Debt Management Services Act in 2007.¹¹⁶ Under the Act, a "debt management service" includes one that is "[a]cting or offering to act as an intermediary between a consumer and one or more creditors of the consumer for the purpose of adjusting, settling, discharging, reaching a compromise on or otherwise altering the terms of payment of the consumer's obligation."¹¹⁷ The Act limits fees so that a provider can charge a "one-time initial or set-up fee" of at most seventy-five dollars¹¹⁸ and a "reasonable fee not to exceed 15% of the amount by which the consumer's debt is reduced as part of each settlement."¹¹⁹ Maine, like Illinois, has used its statute to combat unfair MARS practices in conjunction with other state and federal actions.¹²⁰

Having seen that the FTC has the authority to regulate MARS fees, it is helpful to look to the Illinois and Maine statutes for guidance regarding how the FTC ought to regulate such fees. The Illinois statute bans up-front

borrower satisfaction (assuming that a borrower will not execute a modification that she is not satisfied with). *See supra* note 43 and accompanying text.

114. *See supra* note 31 (explaining difficulties homeowners have encountered in trying to obtain modifications).

115. *See, e.g.*, Press Release, Ill. Attorney Gen. Lisa Madigan, Madigan Files Two Mortgage Rescue Fraud Lawsuits, Seeks Immediate Ban on Companies' Operations (April 6, 2009), *available at* http://www.illinoisattorneygeneral.gov/pressroom/2009_04/20090406.html (describing fees of MARS providers targeted by complaint and noting past judgments against providers of over \$1.8 million); *see also* Mary Ellen Podmolik & Katherine Skiba, *Feds Crack Down on Mortgage Rescue Fraud*, CHI. TRIB., June 18, 2010, at Sec. 1-31 (describing federal crackdown on MARS fraud as part of "Operation Stolen Dreams" as well as cases Attorney General Madigan filed in conjunction with federal efforts).

116. 2007 Me. Legis. Serv. 60 (West).

117. ME. REV. STAT. ANN. tit. 32, § 6172(2)(D) (2009). The statute includes an exemption for a "person admitted to the practice of law in this State as of the effective date of this chapter, except to the extent that debt management services constitute the exclusive activity of that attorney." *Id.* § 6172(3)(C).

118. *Id.* § 6174-A(1).

119. *Id.* § 6174-A(2)(B).

120. *See, e.g.*, Press Release, Office of the Me. Attorney Gen., Attorney General Sues Unlicensed Foreclosure Rescue/Mortgage Modification Companies (Nov. 24, 2009), *available at* http://www.maine.gov/tools/whatsnew/index.php?topic=AGOffice_Press&id=85238&v=article (alleging that certain MARS providers violated the state's fee restrictions and noting that the Bureau of Consumer Credit Protection had recovered over \$25,000 in restitution from providers).

fees entirely,¹²¹ while the Maine statute allows for a nominal initial fee.¹²² The FTC has banned up-front fees entirely, and this seems sensible given the low probability of achieving a successful modification and already cash-strapped nature of MARS consumers.¹²³ The Maine statute provides a preferable approach to the extent that it ties a MARS provider's maximum fee to a borrower's actual savings rather than her monthly payment.¹²⁴ This ensures greater adaptability of the fee regulation to a borrower's unique position. Further, this means that the MARS provider will attempt to achieve the greatest savings for the borrower, because greater savings mean a higher fee. Thus, the FTC should retain the rule's absolute ban on up-front fees, but should couple this with a ban on fees that exceed 15% of the savings achieved.

It is true that regulation of fees is more intrusive than disclosure requirements and even the prohibition on up-front fees because it gets to a fundamental element of the agreement between the consumer and the provider. Thus, such regulations as Illinois and Maine have adopted and this Recent Development has argued for may strike some as unneeded interference with consumer choice. According to such an argument, consumers should have the option of paying as much as they are willing to pay for services, without government interference. The FTC itself noted, "The purpose of the FTC's unfairness doctrine is not to allow the Commission to obtain better bargains for consumers."¹²⁵ A static, fixed price cap might well fit this description of excessive government intervention because such a cap ignores the individual characteristics of a transaction and needs frequent reassessment to ensure continuing applicability.¹²⁶ This is significant with MARS because the initial monthly payment and modification achieved will vary widely among different borrowers.¹²⁷ However, dynamic caps on MARS fees such as those in

121. 765 ILL. COMP. STAT. ANN. 940/50(a)(1) (West 2009).

122. Tit. 32, § 6174-A(1).

123. See Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75116 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322) (noting that the majority of borrowers do not receive modifications even when they use MARS and pointing out that MARS consumers already tend not to have enough money to pay all of their bills).

124. Tit. 32, § 6174-A(2)(B).

125. Mortgage Assistance Relief Services, 75 Fed. Reg. at 75,122 n.350.

126. See, e.g., *United States v. Trenton Potteries Co.*, 273 U.S. 392, 397 (1927) ("The reasonable price fixed today may through economic and business changes become the unreasonable price of tomorrow").

127. Further, such a price cap would need constant revisiting to determine its continued reasonableness. See *id.* at 398 (noting that inflexible price-fixing agreements in the antitrust context require "ascertaining from day to day whether [they have] become unreasonable through the mere variation of economic conditions").

Maine and Illinois have the benefit of adapting to each case because fees are determined in reference to the borrower's unique circumstances. When market conditions suggest a likelihood of unfairness and deception such as in the circumstances surrounding MARS, a dynamic fee cap may be both reasonable and necessary.¹²⁸

CONCLUSION

In the wake of a financial crisis that has left millions of homeowners unable to make their monthly mortgage payments,¹²⁹ a for-profit industry has grown to meet these homeowners' demand for services to help avoid foreclosure. The industry has been plagued by scams and the absence of federal regulation has frustrated efforts to combat these scams. Fortunately, Congress has recognized the need for regulation and has given the FTC the authority to issue rules regulating this industry. The FTC has issued a rule in its effort to curb these practices, and this rule goes a long way toward protecting homeowners from fraud, thus helping them avoid foreclosure. It is imperative that the FTC, now armed with regulation specifically addressing the MARS industry, continue its aggressive enforcement efforts.¹³⁰

The FTC now has help enforcing the MARS rule. On July 21, 2011, the FTC began sharing its enforcement authority with the Consumer Financial Protection Bureau.¹³¹ The Bureau also assumed the FTC's authority to prescribe rules and issue guidelines on that date.¹³² This Recent Development argues for the extension of the prohibition on advance fees for MARS to the establishment of regulations that require fees to be determined in accordance with the results that MARS providers achieve for borrowers. If the FTC does not adopt such regulations, then the Consumer Financial Protection Bureau ought to do so pursuant to its new rulemaking authority.

128. See *infra* Part II.A. (describing the market for MARS and showing the insufficiency of disclosures to combat unfair practices).

129. See *supra* note 4 and accompanying text (noting the staggering number of foreclosures in 2010).

130. Even before issuing its MARS rule, the FTC brought over thirty cases against providers under its general consumer protection authority. Press Release, FTC, FTC Issues Final Rule to Protect Struggling Homeowners from Mortgage Relief Scams (Nov. 19, 2010), available at <http://www.ftc.gov/opa/2010/11/mars.shtm>.

131. Mortgage Assistance Relief Services, 75 Fed. Reg. 75,092, 75,092 (Dec. 1, 2010) (codified at 16 C.F.R. pt. 322).

132. *Id.*



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