ARTICLES

THE EMPHASIS ON THE PRESIDENCY IN U.S. PUBLIC LAW: AN ESSAY CRITIQUING PRESIDENTIAL ADMINISTRATION

THOMAS O. SARGENTICH*

PREFACE

This piece is the final article written by our beloved colleague, Professor Thomas O. Sargentich, who passed away in April 2005. See In Memoriam, Thomas O. Sargentich*, 57 ADMIN. L. REV. i-vii (2005). Tom was working on this piece until his last few days, and it was ninety-five percent complete. At the behest of his family, we simply did a little cite-checking, updating, and polishing. But the substance of the piece is one hundred percent Tom's.*

Professor Sargentich was a nationally recognized scholar in the areas of administrative law and constitutional separation of powers. He was active in the American Bar Association's Section of Administrative Law and Regulatory Practice, serving as Co-chair of the Committee on Constitutional Law and Separation of Powers from 2000 to 2004 and, at various times, as a Vice Chair of that and other committees. His writings

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* Thomas O. Sargentich. Professor of Law and Director, LL.M. Program on Law and Government, American University Washington College of Law. For helpful comments on earlier drafts, I thank Ronald Levin, Jeffrey Lubbers, James Salzman, my other colleagues in the Program on Law and Government at American University Washington College of Law, including Jamin Raskin and Stephen Wermiel; my colleagues in the American University Law Faculty Seminar series; my co-presenters at a program of the Section of Administrative Law of the Association of American Law Schools in Washington, DC, in January 2003, including Elena Kagan whose scholarly and challenging work is the subject of this Article, as well as Saikrishna Prakash and our Moderator William Funk, in addition to all participants in the program. I have benefited from conversations with colleagues over many years with those in the U.S. Department of Justice's Office of Legal Counsel (OLC) from 1978 to 1983 (although I did not draft the 1981 OLC Opinion highlighted in this Article). All errors are my own.

covered numerous aspects of separation of powers and administrative law (see "Selected Works of Thomas O. Sargentich," In Memoriam*, at iii-iv).*

In this Article, Professor Sargentich addresses the role of the President with regard to administrative agencies and the growing prominence of a "mystique" of presidential power. Professor Sargentich explores these issues by critiquing the thesis of Dean Elena Kagan of Harvard Law School—published in Presidential Administration*, 114 HARV. L. REV. 2245 (2001)—that, as a matter of statutory interpretation, the President should be presumed to have power simply to order executive agencies to take action that the President deems desirable, even when congressional legislation has expressly delegated decisionmaking authority to the head of the agency and not the President.*

Professor Sargentich urges caution regarding this presidential mystique. He argues that this position relies upon a one-sided and exaggerated picture of executive virtues and an overly limited depiction of Congress, congressional committees, and administrative agencies. He suggests ways in which the presumption of presidential power over the agencies and the presidential mystique informing it diminish the vigor of pluralistic debate that is vital for informing governmental decisionmaking. And he argues for a richer vision and reality of checks and balances within American government.

In focusing on the need to recalibrate the balance of powers between the Congress and the President, Tom Sargentich had his finger on an issue that has increasing salience in many areas of our policies, foreign and domestic. We will miss his steady counsel on these and other issues, but we are pleased his last cautionary words will be printed in this Law Review, which he revered so much.

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INTRODUCTION

There have been continuing and justified concerns about the vast power of unelected agency officials in our democratic system.[1] Over the past two decades, much constitutional and administrative law discourse has emphasized the President as an actor whose oversight can legitimate the existence of far-reaching agency authority.

Emphasis on the Presidency is visible in numerous debates. For instance, discussions of judicial deference to an agency's legal conclusions often echo the Supreme Court's emphasis in *Chevron* that the President is more accountable to the public than are the courts.[2] To the extent that the President oversees agencies, it is said that courts should give deference to an agency's understanding of its authorizing statute to uphold the accountability principle.[3] Moreover, supporters of centralized executive oversight of agency regulations argue that it promotes the comprehensive rationality of the decisionmaking process.[4]

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1. *See* JAMES O. FREEDMAN, CRISIS AND LEGITIMACY: THE ADMINISTRATIVE PROCESS AND AMERICAN GOVERNMENT (1978) (discussing the recurrent crisis of the legitimacy of the United States administrative process).

2. Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 865 (1984).

3. *See* Jerry L. Mashaw, *Prodelegation: Why Administrators Should Make Political Decisions*, 1 J.L. ECON. & ORG. 81, 94-95 (1985) (arguing that, because agencies are more accountable to the public than the judiciary, agencies deserve deference when operating under broad statutory authority).

4. *See* Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 830-32 (2003) (outlining the basic argument for strong executive oversight of agency action and noting that proponents of this view argue that such oversight "avoids inconsistencies, redundancies, and unintended consequences in agency rulemaking" and also "ensure[s] that all relevant interests are identified and counted"); Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1081-82 (1986) (asserting that centralized executive review is desirable because "rulemakers should be accountable to the president before

In its most enthusiastic expression, a presidential model has become a full-blown presidential mystique, in which the special character of chief executive oversight is underscored. The mystique builds on the realities that the President is elected, whereas federal agency officials and judges are not, and that the President's election involves the nation as a whole, whereas Senators represent states and Representatives are elected from districts. Proponents underscore that the President alone has a nationwide constituency, to which he or she is uniquely accountable. In addition, the President is said to be more immune from capture by special interests in the private sector than members of Congress, who live in a hothouse of pork barrel spending for constituents, as well as administrators, who often become dependent on powerful voices in the private sector for political support and information.

The presidential mystique also underscores that the chief executive can act more quickly and effectively than Congress, given the latter's size and need for collective action. Moreover, the President, having the entire executive establishment as a domain of responsibility, is experienced in making tradeoffs among competing programs and policies. In contrast, agencies have more limited subjects of responsibility, and thus have less comprehensive, more parochial perspectives.[5]

Greater accountability to the public, less domination by special interests, greater effectiveness and comprehensiveness in orientation, less parochialism—these are the institutional virtues claimed by the presidency's strongest supporters as its comparative advantages over other governmental institutions.[6] Given these premises, it is unsurprising that a powerful presidential mystique has arisen.

No doubt, a certain emphasis on the presidency is likely to remain in academic and popular discourse. Respect for the chief executive's energy and uniqueness has a long history in U.S. political thought, dating at least

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issuing their rules and should be obliged to demonstrate the costs and benefits of their rules as thoroughly as circumstances permit"). *But see* Thomas O. McGarity, *Presidential Control of Regulatory Agency Decisionmaking,* 36 AM. U. L. REV. 443, 454-62 (1987) (detailing arguments against increased presidential control including unfaithful execution of the laws, a lack of accountability, concerns about due process and participation, and inconsistency with judicial review); Alan B. Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way to Write a Regulation,* 99 HARV. L. REV. 1059, 1064-71 (1986) (arguing against the Office of Management and Budget's (OMB) oversight of agency regulations because of costly delays, the ultimate decisionmaking authority ending up in the hands of OMB personnel, and the insulation of public debate).

5. *See* COMM'N ON LAW & THE ECON., AM. BAR ASS'N, FEDERAL REGULATION: ROADS TO REFORM 73-84 (1979) (explaining that elected officials, like the President, have the requisite overview and coordination to make judgments about competing claims and stand accountable at the polls for the results).

6. *See, e.g.*, *id.* at 76-78 (describing how the President's executive powers give him the ability to oversee administrative officers).

to Alexander Hamilton.[7] The real question is whether it is time to be somewhat more circumspect about the role of the presidency as the ultimate legitimator of the administrative process. In my view, it is important to inject a note of caution into comparative discussions of presidential attributes.[8] The basic problem is that the presidential mystique presents a one-sided, overstated picture of executive virtues as well as unduly negative stereotypes of other governmental and non-governmental actors. By seeking a more balanced assessment, we can shape a more realistically interactive picture of the system of checks and balances in which an administration operates.

A richer appreciation of the system of checks and balances is not only a beneficial result of a more balanced appreciation of presidential attributes, but also an affirmative challenge to the critic. "Checks and balances," frankly, is a concept that many people find unexciting. To be sure, James Madison made much of it,[9] and our constitutional structure of government is suffused with it. Yet the concept's longevity is a factor contributing to the difficulty many people have in appreciating it, for the idea of checks and balances often seems old-fashioned. Frequently, it is associated with the problem of a government that does too little to address pressing contemporary needs because it is checked and balanced to death, as it were. In the literature, concerns about stalemate and deadlock appear not infrequently in close juxtaposition to, if not as a direct result of, checks and balances in our structure of government.[10]

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7. *See* THE FEDERALIST NO. 70, at 341 (Alexander Hamilton) (Terence Ball ed., 2003) (arguing that such energy in the executive is vital, among other reasons, for "the protection of the community against foreign attacks" as well as "the steady administration of the laws").

8. For other analyses of the need to be cautious about presidential domination of the regulatory universe, see Cynthia R. Farina, *The Consent of the Governed: Against Simple Rules for a Complex World,* 72 CHI.-KENT L. REV. 987 (1997) [hereinafter Farina, *Against Simple Rules for a Complex World*]; Peter M. Shane, *Political Accountability in a System of Checks and Balances: The Case of Presidential Review of Rulemaking*, 48 ARK. L. REV. 161 (1995); Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965 (1997) [hereinafter Strauss, *Presidential Rulemaking*]. Professor Strauss has suggested that the advent of electronic rulemaking has increased the influence of the White House through review by the OMB's Office of Information and Regulatory Affairs (OIRA). "[OMB and OIRA] are the ones creating this new apparatus and to have all information travel through their gateway only adds to the possibilities of their influence. . . ." Richard G. Stoll & Katherine L. Lazarski, *Rulemaking*, *in* DEVELOPMENTS IN ADMINISTRATIVE LAW AND REGULATORY PRACTICE 2003-2004 160 (Jeffrey S. Lubbers ed., 2004) (attributing this portion of the chapter to Professor Strauss). He added that "[a]s agencies become more transparent, they become more transparent to the President as well as to the public . . . . Now the docket is immediately available on equal and easy terms to all who want it, including the President, and politics will give him the incentive to attend to it." *Id.*

9. *See generally* THE FEDERALIST NO. 51 (James Madison) (Terence Ball ed., 2003).

10. Add to these factors the existence of certain prejudices against the governmental actors who would receive greater attention if the presidential mystique was seriously questioned. These actors principally include agency officials themselves, the hated bureaucrats for some, as well as members of Congress, breezily referred to by the late John

This Article's thesis is that, while thinking more clearly about the limits of the presidency, we need to adopt a richer vision of checks and balances that sees them as more than merely the guardians of a minimal state or the cause of stalemate. Rather than assume that checks and balances are designed to guarantee an old-fashioned government, we should embrace a newer, more affirmative notion. Checks and balances are central to a deliberative democracy in which the peoples' different viewpoints are shared and debated to arrive at outcomes with broad appeal. No single preference is paramount, and no particular actor should be dominant. The representation of diversity is a key attribute of a well-functioning system of checks and balances. Such a vision calls for continuing criticism of our actual system of governance, requiring ongoing efforts to promote assertive self-government, wide-ranging representation, and deep respect for pluralism. It also critiques tendencies toward narrowing the terms of debate, shutting out contrary perspectives, and ratifying the preferences of a single power center.

This Article will develop these themes in response to a major claim in a recent landmark scholarly portrait of the presidency, Dean Elena Kagan's article, *Presidential Administration*.[11] As a compendium of authorities and arguments about the President in the administrative context, Kagan's piece is unparalleled. It whips into shape the presidentialist perspective by giving it wider appeal and stronger grounding than before. Its contribution reflects the author's first-hand experience as a senior legal and policy adviser in the White House during the Clinton Administration.[12] I will discuss its central contention—namely, the argument on behalf of a presumption of statutory interpretation holding that the President simply can direct agency heads to take certain regulatory actions in situations where statutes vest authority to act in agency heads, not the President. To Kagan's credit, while defending presidential directives, she highlights their problematic status in light of what she acknowledges to be the contrary traditional view of the President's role vis-à-vis agencies.

This Article will proceed in three parts. Part I will lay out the traditional view. Part II will sketch Elena Kagan's model of presidential administration during the Clinton Administration, which rejects the traditional view. Part III will critique Kagan's arguments against the

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Hart Ely as "clowns." JOHN HART ELY, DEMOCRACY AND DISTRUST 134 (1980). The presidential mystique is founded on the belief that administrative law discourse should pay particular attention to the head of state and head of government, united in the office of the President, rather than to bureaucrats and clowns. *Id.*

11. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001).

12. Dean Kagan served as Associate Counsel to the President from 1995 to 1996 and as Deputy Assistant to the President for Domestic Policy and Deputy Director of the Domestic Policy Council from 1997 to 1999.

traditional view, which turn on claims about legislative intent and institutional competence. When the discussion focuses on matters of institutional competence, the presidential mystique comes into full flowering.

I. THE TRADITIONAL VIEW

In this Part, I will discuss the traditional view of presidential power vis-à-vis agencies in regulatory matters. The traditional view holds that although the President can supervise and guide agency policymaking, the President cannot go so far as to displace the agency head's discretion to make decisions vested in that officer by law.[13] That is, the President cannot simply command or direct an agency head to issue a regulation, so long as the relevant statute vests authority to regulate in the agency head.[14] Rather, the agency head must exercise his or her own discretion in accepting the President's direction, assuming the action complies with statutory limits. For example, the agency head must actually decide to promulgate a regulation with the provision in question, thereby turning the President's advice into the agency's policy. Alternatively, the President can take the not entirely cost-free step of firing a recalcitrant agency head, assuming he or she is dealing with an at-will executive officer.[15] Again, what the President cannot do is merely assume that his or her own will is necessarily controlling when the statute vests regulatory authority in an agency head.

It should be clear that, as a matter of practice, Presidents commonly tell agencies what they want them to do. The traditional understanding sees these statements as expressions of the President's priorities, not as

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13. At the outset of her article, Dean Kagan highlights the "serious legal questions" that her challenge to the traditional view of agency head power raises. Kagan, *supra* note 11, at 2250. She describes the traditional view as follows:

> The conventional view further posits, although no court has ever decided the matter, that . . . Congress can insulate discretionary decisions of even removable (that is, executive branch) officials from presidential dictation—and, indeed, that Congress has done so whenever (as is usual) it has delegated power not to the President, but to a specified agency official.

Id.

14. For support of the traditional view, see Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. CHI. L. REV. 1, 25 (1995) ("[T]he President has no authority to make the decision himself, at least if Congress has conferred the relevant authority on an agency head."); Thomas O. Sargentich, *The Administrative Process in Crisis: The Example of Presidential Oversight of Agency Rulemaking*, 6 ADMIN. L.J. AM. U. 710, 716 (1993) ("[T]he power to regulate remains where the statute places it: the agency head ultimately is to decide what to do."); Peter L. Strauss, *The Place of Agencies in Government: Separation of Powers and the Fourth Branch*, 84 COLUM. L. REV. 573, 649-50 (1984) (explaining that "the agencies to which rulemaking is assigned," rather than the President, possess "ultimate decisional authority").

15. *See* Marshall J. Breger & Gary J. Edles, *Established by Practice: The Theory and Operation of Independent Federal Agencies*, 52 ADMIN. L. REV. 1111, 1141-44 (2000) (explaining the President's power, with some exceptions, to remove federal officials).

attempted displacements of agency head discretion. At the same time, the White House has on hand many tools of persuasion. At bottom, the traditional view holds in reserve a qualification on presidential power: The President cannot simply say to agency heads, "Regulate in this lawful way because I direct you to do so," and assume that the direction will be controlling by itself, so long as an agency head has the relevant regulatory authority under a statute.

There is no developed body of judicial case law elaborating the traditional view, for it operates in the background of intra-executive branch deliberations.[16] Yet, the Department of Justice embraced it in its 1981 memorandum validating the Reagan Administration's initial Executive Order on regulatory review.[17] It also has been affirmed in the literature and is widely thought to be valid, as Kagan's descriptive phrases "conventional view" and "generally accepted view" indicate.[18]

Of course, for numerous reasons, the likelihood that many agency heads will be willing to disregard presidential suggestions is limited. Presidential appointees naturally have a certain loyalty to the chief executive, and they presumably are in agreement with the President on matters of policy. Moreover, if an agency head desires a higher or different position that would require another presidential nomination, it is critical to stay on the good side of White House officials. Even if an appointee is tempted to negotiate strongly with the White House on a particular issue, the reality is that the President can remove an executive agency head for any reason.[19] To be sure, the actual firing of a recalcitrant executive agency head raises the costs to the President of getting his own way. There is an outer limit on the number or frequency of terminations that any administration can tolerate without suffering the negative political repercussions of instability.[20]

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16. At the same time, Dean Kagan acknowledges that "the courts never have recognized the legal power of the President to direct even removable officials as to the exercise of their delegated authority." Kagan, *supra* note 11, at 2271.

17. Proposed Executive Order Entitled "Federal Regulation," 5 Op. Off. Legal Counsel 59, 61 (1981) [hereinafter OLC Opinion] (explaining that Presidential supervision, though grounded in constitutional and implied statutory authority, is not limitless and is more justifiable in situations in which the authority of a subordinate official is simply guided or limited rather than wholly displaced).

18. Kagan, *supra* note 11, at 2250 & n.8 (referring to the conventional view and the generally accepted view of presidential power); *see also* James F. Blumstein, *Regulatory Review by the Executive Office of the President: An Overview and Policy Analysis of Current Issues*, 51 DUKE L.J. 851, 852 (2001) ("[I]t appears we are all (or nearly all) Unitarians now.").

19. *See* Breger & Edles, *supra* note 15, at 1141-44 (outlining the progression of the Supreme Court's position on the President's authority to remove appointees).

20. Needless to add, a pattern of firing senior officials also can make it difficult to recruit excellent candidates for office.

Yet, as Elena Kagan recognizes by giving the traditional view prominence in her discussion, it is not safe to assume that the view never will be important. There is always a possibility that an agency head might disagree sharply with the White House on some issue of special importance to the agency. Despite the costs involved, an agency head might be willing to signal dissent in a way that creates ill will toward the agency on the part of some people in the White House.

The traditional view would seem to be of greatest importance not in situations involving the President directly, but rather in negotiations with the White House staff, including the Office of Management and Budget (OMB). As with most large organizations, exchanges with the top office usually come in the form of interactions among senior staff. It does not require much imagination to see that agency heads can more easily invoke the traditional understanding in disagreeing with White House staff than in disagreeing with the President. It is not only easier to negotiate with White House staff but, in some circumstances, it would be expected. The key point is that, by insisting that he or she has the relevant regulatory authority, an agency head may gain greater space in bargaining for a position at odds with that desired by White House staff. Power relations can be subtly but distinctly affected by background norms like the traditional understanding.

Moreover, the traditional view should matter to outsiders who wish to critique what an agency has done. If it is clear that an agency head cannot just say, "The President made me do it," then the agency has to take responsibility for its policy decision. Outside critics in Congress, the media, and the public can more effectively hold the agency head's feet to the fire if they are drawing on assumptions built into the traditional understanding.

As a legal matter, the traditional understanding rests on the plain language that Congress employs in typical delegations of regulatory authority. A statute normally provides that the head of an agency is authorized to take action.[21] The text is controlling here, as is the usual case.[22]

Also, the structural realities underlying the creation of agencies support such a plain-language reading. Congress, by law, creates an agency in response to political pressures in an area of concern. For example, when

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21. *See, e.g.*, 42 U.S.C. § 7601(a)(1) (2000) ("The [EPA] Administrator is authorized to prescribe such regulations as are necessary to carry out his functions under this chapter.").

22. *See* Strauss, *Presidential Rulemaking*, *supra* note 8, at 984 ("In the text both of the Constitution and of Congress's statutes, it is the heads of departments who have legal duties vis-à-vis regulatory law. The President can ask about those duties and see that they are faithfully performed, but he and his department heads are to understand that the duties themselves are theirs. . . .").

the Department of Homeland Security was created by combining functions that had been dispersed in several agencies of government, Congress acted in response to political pressures to deal in a visible, institutional way with threats to the homeland following the terrorist actions of September 11, 2001. When Congress gives specific regulatory authority to an agency it creates, it confirms that this is the entity responsible for the functions under discussion.

The traditional understanding also finds support from legislative purpose, precedent, and pragmatic considerations. The purpose of Congress can be inferred from what Congress actually does, which is to vest discretion in an agency head. If Congress had wanted the President to have controlling authority, it could have so provided.[23] The precedents of relevance are those resting on the traditional understanding, including Department of Justice opinions and behavior reflecting the standard view itself.[24] The pragmatic considerations have to do with the apparent consequence of dropping the traditional view. It seems inconsistent to create a particular agency to deal with a problem and, at the same time, to overcome the agency's role by giving the President power to decide what the agency will do. Moreover, as I will discuss below, the traditional view rests on a conception of checks and balances that is non-presidentialist in orientation.

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23. *See* Croley, *supra* note 4, at 837 ("[B]y most acts of delegation Congress intends for agencies to apply *their* expertise in the course of exercising their discretion. Where instead Congress wants the president to have influence over particular decisions that agencies make, as opposed to agenda-setting influence in ordering their statutory priorities, Congress can so indicate by specifically delegating power to a White House agency. But in the normal course, Congress delegates regulatory power to agencies so that agencies, not the President, can exercise that power."); *see also* Robert V. Percival, *Presidential Management of the Administrative State: The Not-So-Unitary Executive*, 51 DUKE L.J. 963, 1008 (2001) (pointing out that "there are some circumstances in which Congress has specified that the legal effects of certain decisions entrusted to agency heads may be suspended by the president upon a finding of some sort of national emergency"). Percival argues that "[i]f the president has express authority to overturn the legal consequences of agency decisions in some circumstances, but not others, the argument for inferring congressional intent to permit the president generally to displace agency decisions is somewhat weaker." *Id.*

24. Peter Strauss points out that, in a somewhat different context, President Nixon's asking his Attorney General to fire Archibald Cox, the original Watergate special prosecutor, confirms that Nixon did not consider the Attorney General "the mouthpiece of the President, with no independent duties of his own. . . ." Strauss, *Presidential Rulemaking*, *supra* note 8, at 973. Neither did the Attorney General or Deputy Attorney General—who became Acting Attorney General—both of whom refused to fire Cox and subsequently resigned instead. The events of the Saturday Night Massacre "are sharply inconsistent with the proposition that the President's sole possession of constitutional 'executive power' means that any responsibility assigned to an executive department is his, and that he may exercise it." *Id.* at 974.

II. PRESIDENTIAL ADMINISTRATION DURING THE CLINTON YEARS

In this Part, I will discuss Dean Kagan's model of presidential administration during the Clinton Administration, which rejects the traditional view. Kagan begins by noting that, at different times, various entities, public and private, have had comparative primacy in establishing the direction and outcome of the administrative process, and "[i]n this time, that institution is the Presidency. We live today in an era of presidential administration."[25] Presidential administration "expanded dramatically during the Clinton years," with the result that agency regulatory activity became "more and more an extension of the President's own policy and political agenda."[26]

As Kagan acknowledges, the outlines of presidential administration began to emerge "sometime around 1980."[27] The critical forerunner was President Reagan's 1981 Executive Order on regulatory review, No. 12,291, which required executive agencies to submit to OMB's Office of Information and Regulatory Affairs any proposed major rule, accompanied by a "Regulatory Impact Analysis."[28] The Executive Order outlined criteria to govern the regulatory analysis. To "the extent permitted by law," an agency could regulate only if the benefits of doing so exceeded the costs and if the chosen alternative "involv[ed] the least net cost to society."[29] This 1981 Order was accompanied four years later by Executive Order No. 12,498, which required each agency to submit for review an annual regulatory plan listing proposed actions.[30]

The regulatory review experience during the Reagan Administration[31] and the first Bush presidency provide the background for Clinton-era developments. A 1993 Clinton Executive Order on regulatory review, No. 12,866, replaced the Reagan Orders while retaining key features of the earlier review system.[32] In particular, the Clinton Order retained OMB

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25. Kagan, *supra* note 11, at 2246.
26. *Id.* at 2248.
27. *Id*. at 2253.
28. Exec. Order No. 12,291, § 3, 3 C.F.R. 127, 128-30 (1981), *reprinted in* 5 U.S.C. § 601 (1994).
29. *Id*. § 2, 3 C.F.R. at 128.
30. Exec. Order No. 12,498, § 2, 3 C.F.R. 323, 324 (1985) (repealed 1993).
31. Elena Kagan writes that during the Reagan Administration, "roughly eighty-five rules each year were either returned to the agencies for reconsideration or withdrawn by the agencies in the course of review." Kagan, *supra* note 11, at 2278. Although that sum amounted to a small percentage of all reviewed rules, the group included many of the most important rules. *Id.* For a discussion of presidential review of agency rules during the Reagan Administration, see DeMuth & Ginsburg, *supra* note 4, at 1075-76; McGarity, *supra* note 4, at 443-44; Morrison, *supra* note 4, at 1063.
32. In an important respect, the Clinton Order was distinctive because it provided for presidential decisions to resolve disputes among agencies or between an agency and OMB. *See* Exec. Order No. 12,866, § 7, 3 C.F.R. 638, 648 (1993), *reprinted in* 5 U.S.C. § 601

review of major rules in the terms of cost-benefit analysis.[33] It also embraced an annual regulatory planning process. On the other hand, the Clinton Order limited the time available for OMB review,[34] and it softened the requirement of quantitative cost-benefit studies by referring to considerations of "equity," "distributive impacts," and "qualitative measures."[35] Furthermore, the Clinton Order substantially opened up the centralized review process to public view and comment.[36]

Kagan stresses that, unlike the Reagan Administration's efforts to reduce regulation, Clinton-era regulatory supervision had a "distinctly activist and pro-regulatory governing agenda."[37] Clinton thus appropriated the presidential mantle for those drawn to the positive uses of administrative power.[38] At the front-end of the regulatory process, the Clinton-era transformation consisted of "formal directives to the heads of executive agencies to set the terms of administrative action and prevent deviation from his proposed course."[39] At the back-end of the process, President

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(1994) (providing that such disputes were to be resolved to the extent permitted by law "by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials)"). Dean Kagan notes that a later provision more clearly indicated that the President will decide a matter in contest: "At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency . . . of the President's decision with respect to the matter." Kagan, *supra* note 11, 2288-89 (quoting Exec. Order No. 12, 866, § 7, 3 C.F.R. at 648). As a theoretical matter, Kagan stresses that the foregoing language presumes that the President is to make a final decision regarding a regulatory matter, regardless of a statutory delegation of rulemaking authority to an agency head; as a practical matter, she notes, the procedure made little difference during the Clinton Administration. *Id.* at 2289. She reports that the Administrator of OIRA from 1993 to 1998, Sally Katzen, could recall only one occasion in which a dispute between OMB and an agency went to the President as contemplated by this provision. *Id.* at 2289 n.174.

33. Exec. Order No. 12,866, §§ 2(b), 6(a)(3)(B), 3 C.F.R. 640, 645.

34. *Id.* § 6(b)(2), 3 C.F.R. at 646-47.

35. *Id.* § 1(a), 3 C.F.R. at 639.

36. Under the Clinton Order, only the Administrator of the OIRA could receive oral communications from persons outside of the executive branch, and agency officials had the right to be present at such meetings. *Id.* § 6(b)(4)(A)-(B)(i), 3 C.F.R. at 647. Moreover, OIRA was to forward all written communications from outsiders to the agency in question and maintain a public log of all written and oral communications about a rule under review. *Id.* §§ 6(b)(4)(B)(ii), 6(b)(4)(C), 3 C.F.R. at 647-48. Also, after publication of the regulation or a decision not to go forward with it, OIRA must disclose all written communications between itself and the agency. *Id.* § 6(b)(4)(D), 3 C.F.R. at 648.

Dean Kagan defends the Clinton-era practice of issuing regulatory directives with a degree of transparency, enabling the public and politically active groups to know what was going on. *See* Kagan, *supra* note 11, at 2331-33. In contrast, she criticizes the Reagan Administration's tendency toward secrecy, suggesting that "President Reagan usually tried . . . to veil his and his staff's influence over administration." *Id.* at 2333. After drawing this contrast, Dean Kagan notes that she is not claiming that Clinton always sought transparency or that he "never influenced agency decisions in ways designed to avoid leaving fingerprints. . . ." *Id.*

37. Kagan, *supra* note 11, at 2249.

38. *See id.* at 2341-44 (exploring the pros and cons of administrative "activism," a concept that implies "the imposition of a coherent regulatory philosophy across a range of fields to produce novel regulatory (or for that matter deregulatory) policies").

39. *Id.* at 2249.

Clinton "personally appropriated significant regulatory action through communicative strategies that presented regulations and other agency work product . . . as his own . . . ."[40] In implementing this system, "the White House in large measure set the administrative agenda for key agencies . . . ."[41]

Kagan notes that Clinton's own directives about regulations usually were not deployed within the regular OMB review system, but rather were outside of it.[42] She also points out that the number of Clinton's directives increased each year after the Democrats lost control of Congress in 1994.[43] She avers that President Clinton issued 107 directives to executive agencies about regulatory policy.[44] Through the use of directives, President Clinton "effectively placed himself in the position of a department head. . . ."[45] The President "ordered and announced the issuance of proposed regulations" for comment as well as "the issuance of final regulations" after the comment period.[46] Moreover, the President ordered and announced—"just as a department head might"[47]—agency action through guidance documents, policy statements, and the like.[48]

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40. *Id.*

41. *Id.* at 2248.

42. *See id*. at 2294 (pointing out that Clinton added a scheme for direct presidential intervention in particular regulatory matters to the system of presidential oversight).

43. *Id.* at 2312-13; *see* Timothy J. McKeown, *"Micromanagement" of the U.S. Aid Budget and the Presidential Allocation of Attention*, 35 PRESIDENTIAL STUD. Q. 319, 324-25 (2005) (citing Kagan and noting that presidential micromanagement of foreign aid budget matters also varied depending on "macrolevel phenomena in national and international politics").

44. *See* Kagan, *supra* note 11, at 2294. Clinton's closest advisors and Clinton himself saw such directives as "a central part of his governing strategy. . . ." *Id.* at 2295. Once the President issued a directive, White House staff monitored the agency "to ensure that agency officials complied in a timely and effective way with the directive's terms and exercised any discretion left to them consistently with its objectives." *Id.* at 2298.

45. *Id*. at 2306.

46. *Id*.

47. *Id*.

48. Although Dean Kagan's article was published in the early months of the second Bush Administration, she suggests that the new President is likely to carry over elements of Clinton's methods of control. *See id.* at 2318-19 ("[E]arly indications suggest that Clinton's methods of control will join Reagan's in Bush's arsenal . . . ."). She also predicts that there will be continuing "expansion of presidential administration" for example, as chronicled in her article. *Id*. at 2319. Indeed, this has come to pass with OMB's issuance of a far-reaching and controversial "Peer Review Bulletin" on December 16, 2004. *See* Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2664 (Jan. 14, 2005) (providing guidance "designed to realize the benefits of meaningful peer review of the most important science disseminated by the Federal Government"); OMB, EXECUTIVE OFFICE OF THE PRESIDENT, PROPOSED BULLETIN FOR GOOD GUIDANCE PRACTICES 1 (2005), http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf (proposing practices "to increase the quality and transparency of agency guidance practices and the guidance documents produced through them"); Press Release, OMB, Executive Office of the President, OMB Releases Draft Bulletin for Good Guidance Practices (Nov. 23, 2005), *available at* http://www.whitehouse.gov/omb/pubpress/2005/2005-30.pdf (announcing OMB's proposed bulletin on good guidance).

In short, regulatory oversight during the Clinton Administration took a new substantive turn: "President Clinton treated the sphere of regulation as his own, and in doing so made it his own, in a way no other modern President had done."[49] The President sought not only to influence but also to mandate the content of agency initiatives, including notice-and-comment rules and more informal means of policymaking. As Kagan writes, "President Clinton's principal innovation in the effort to influence administrative action lay in initiating a regular practice . . . of issuing formal directives to executive branch officials regarding the exercise of their statutory discretion . . . ."[50]

The foregoing description makes clear that, from the perspective of the Clinton White House, there basically was nothing left of the traditional view of the President's role vis-à-vis agencies. In practice, the line between strong efforts at persuasion and actual commands by the President can be a fine one.[51] Yet "a line remains," and by so often using directives, "President Clinton crossed from one side of it to the other."[52]

Perhaps out of concern that some might consider her position too extreme, Dean Kagan distinguishes her interpretation from that of "unitarian" executive branch theorists of the 1980s and 1990s.[53] To be sure, on several grounds the two models are similar. Both emphasize the President as a unique, democratic force for disciplining the use of

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49. Kagan, *supra* note 11, at 2281.

50. *Id*. at 2293.

51. *See id.* at 2298 (describing how politics and compromises lead to a line between command and persuasion that is, at times, hard to ascertain).

52. *Id.*

53. *See* Steven G. Calabresi & Saikrishna B. Prakash, *The President's Power to Execute the Laws*, 104 YALE L.J. 541, 550 (1994) (arguing that the founders of the Constitution fully embraced the "myth" of a chief administrator empowered to administer all federal laws); Steven G. Calabresi & Kevin H. Rhodes, *The Structural Constitution: Unitary Executive, Plural Judiciary*, 105 HARV. L. REV. 1153, 1165 (1992) (stating that unitary executive theorists believe that the Vesting Clause of Article II mandates "a hierarchical, unified executive department under the direct control of the President"); Lee S. Liberman, Morrison v. Olson*: A Formalistic Perspective on Why the Court Was Wrong,* 38 AM. U. L. REV. 313, 349-52 (1989) (discussing the theory of the unitary executive in the context of the Supreme Court's 1988 decision that upheld the constitutionality of the independent counsel statute); Geoffrey P. Miller, *Independent Agencies*, 1986 SUP. CT. REV. 41, 44 (arguing that, under the Constitution, Congress cannot deny the President removal power of a policymaking official who has refused a presidential order); Theodore Olson, *Founders Wouldn't Endorse America's Plural Presidency*, LEGAL TIMES, Apr. 17, 1987, at 11 (suggesting that the current "plural presidency" is the antithesis of the intent expressed by the framers of the Constitution for who should have the power to enforce the laws); David B. Rivkin, Jr., *The Unitary Executive and Presidential Control of Executive Branch Rulemaking*, 7 ADMIN. L.J. AM. U. 309, 309-10 (1993) (setting forth an argument that one does not have to abandon the original intent of the constitutional Framers to conclude that the President has oversight of all regulatory activities conducted by executive agencies). *But see* Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1, 118 (1994) (concluding that the theory of the "unitary executive" is a twentieth century creation, not the original intent of the Framers of the Constitution).

regulatory discretion. Under both, the President's disciplinary tools include the appointment of agency heads with backgrounds and philosophies congruent with the President's, as well as the oversight of agency budgets, legislative proposals, and testimony before Congress. Under both approaches, aggressive presidential oversight is justified on the premise that when the President guides agencies, he applies the values that the electorate has presumably validated.

The chief point of distinction between the perspective of Dean Kagan and unitarian executive branch theorists involves the constitutionality of independent regulatory agencies. The authorizing statutes of such agencies, among other things, limit presidential authority to remove the agency heads,[54] providing for their removal only for inefficiency, neglect of duty, or malfeasance in office. Unlike such officials, *executive* agency heads can be removed by the President for any reason, or at will.[55] The unitarian theorists argue that constraining the President's ability to remove any agency heads offends the constitutional text, structure, and original intent.[56]

This attack on independent agencies generated strong reactions from commentators defending Congress's authority to establish agencies having more independence from the President than typical executive agencies.[57]

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54. For a discussion of independent agencies, see Breger & Edles, *supra* note 15, at 1141-44.

55. *See* Humphrey's Ex'r v. United States, 295 U.S. 602, 631-32 (1935) (upholding a "for cause" removal provision in a statute dealing with an independent regulatory agency); *see also* Morrison v. Olson, 487 U.S. 654, 696-97 (1988) (upholding the independent counsel statute); Bowsher v. Synar, 478 U.S. 714, 727-32 (1986) (analyzing the constitutional status of Comptroller General in terms of the removal provision); Myers v. United States, 272 U.S. 52, 114 (1926) (upholding the President's power of removal at will of purely executive officers).

56. *See, e.g.*, Calabresi & Rhodes, *supra* note 53, at 1167-68 (defining the unitarian theory regarding the Vesting Clause, the Necessary and Proper Clause, and the Take Care Clause).

57. *See* Farina, *Against Simple Rules for a Complex World*, *supra* note 8, at 989-93 (challenging the notion that the President is uniquely positioned to hear the will of the people); Cynthia R. Farina, *Undoing the New Deal Through the New Presidentialism*, 22 HARV. J.L. & PUB. POL'Y 227, 227 (1998) [hereinafter Farina, *The New Presidentialism*] (stating that presidentialism is "a profoundly anti-regulatory phenomenon); Cynthia R. Farina, *The 'Chief Executive' and the Quiet Constitutional Revolution*, 49 ADMIN. L. REV. 179, 179 (1997) (describing the dangers and developments of presidentialism, or the "cult of the Chief Executive"); Martin S. Flaherty, *The Most Dangerous Branch,* 105 YALE L.J. 1725, 1788-92 (1996) (concluding that history does not support the current doctrine of a unitary executive); A. Michael Froomkin, *The Imperial Presidency's New Vestments*, 88 NW. U. L. REV. 1346, 1347 (1994) (asserting that a proper structural analysis of the Constitution emphasizes a "balance between Congress's role in structuring the executive and the President's inherent and default powers"); Abner S. Greene, *Checks and Balances in an Era of Presidential Lawmaking*, 61 U. CHI. L. REV. 123, 128 (1994) (defending Congress's regulation of presidential action by noting the need for a restoration of a proper system of checks and balances); Shane, *supra* note 8, at 213-14 (concluding that, by allowing agencies to remain attentive to multiple parties and not just the executive, there will be a proper amount of accountability); *see also* Percival, *supra* note 23, at 966

Underlying these critiques of unitarian presidentialism[58] is a commitment to active checks and balances between the legislative and executive branches, according to which neither branch should be exalted.

Although still a presidentialist, Kagan herself disagrees with the unitarian view that independent agencies and officers are unconstitutional.[59] She posits that Congress can, if it wants to, limit presidential control over administration.[60] The key requirement is that Congress needs to be explicit in constraining the President's power to control the heads of such agencies.[61]

Dean Kagan advances two main arguments in rejecting the constitutional critique of independent agencies. First, she does not consider that the Constitution's text, structure, and original intent are sufficiently clear to establish that the President has broad control over all execution of the law.[62] This is true, she argues, because of imprecision in the mandate of Article II, the fact that there has been great change in the field of presidential power, and the difficulty of reversing decades of practice by governmental institutions. Second, she does not believe that the Supreme Court is likely to abandon its decisions on the President's removal power that uphold the constitutional validity of independent agencies and officers.[63]

(asserting that, while the President has enormous power to influence agency heads' decisions because of the presidential removal power, this does not give the chief executive the authority to dictate substantive decisions); Mark Seidenfeld, *A Big Picture Approach to Presidential Influence on Agency Policy-Making*, 80 IOWA L. REV. 1, 49-50 (1994) [hereinafter Seidenfeld, *A Big Picture Approach to Presidential Influence*] (arguing that the President should not micro-manage agency policy decisions but rather use a "big picture approach" to influence agency policy more effectively); Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 6 (1994) (noting that Congress can limit the President's removal authority for independent agencies).

58. The term presidentialism has been used to refer to 1980s and 1990s unitary presidentialists. *See* Farina, *The New Presidentialism*, *supra* note 57, at 227 (defining the term presidentialism as "the unitary executive thesis"). I use the term more broadly to include Dean Kagan's views and will be more specific when referring to unitary presidentialists.

59. *See* Kagan, *supra* note 11, at 2326.

60. *Id.* (noting that Congress usually assigns "discretionary authority to an agency official, without in any way commenting on the President's role in the delegation . . . ").

61. *See* Kagan, *supra* note 11, at 2251 ("I accept Congress's broad power to insulate administrative activity from the President . . . ."); *id*. at 2320 ("I acknowledge that Congress generally may grant discretion to agency officials alone and that when Congress has done so, the President must respect the limits of this delegation."); *id*. at 2326 ("I do not espouse the unitarian position in this Article, instead taking the Supreme Court's removal cases, and all that follows from them, as a given."); *see also* Blumstein, *supra* note 18, at 875 (agreeing with Kagan's reading of the cases as providing a basis for insulating independent agencies from presidential administration).

62. *See* Kagan, s*upra* note 11, at 2326 (attacking the unitarian claim that plenary control is a constitutional mandate).

63. *See id.* (arguing that any framework attempting to explain presidential-agency relations must incorporate these holdings and their broader implications as part of its framework).

Dean Kagan not only endorses the constitutionality of explicit congressional restrictions on presidential power to remove particular agency heads, but concludes that her suggested statutory presumption in favor of presidential direction over agency action, discussed below, logically would not apply when such congressional restrictions have been imposed so as to turn an agency into an independent regulatory body.[64] Thus, Kagan is more supportive of the autonomy of independent regulatory agencies than are unitarian theorists, even while she aggressively embraces the President's interests in seeking to jettison the traditional view of presidential power vis-à-vis executive agencies.[65]

III. THE ARGUMENT AGAINST THE TRADITIONAL VIEW

Elena Kagan's critique of the traditional view rests on the notion that Congress has not specifically ruled out presidential directives to agencies. To oppose directives, one has to draw a negative inference from the assignment of regulatory authority to an agency. It is reasonable, Kagan contends, to adopt a presumption, as a matter of statutory interpretation, that when Congress assigns regulatory authority to an agency, it does so with an understanding contrary to the traditional view—namely, with an understanding that the President can direct the agency's regulatory behavior.[66]

A. Arguments Based on Legislative Intent

In this Section, I will consider arguments that go to the question of Congress's intent in enacting statutes that assign regulatory authority to agencies.

1. Traditional View Not Necessary or Logically Compelled

Kagan advances a pair of arguments to the effect that the traditional view is not necessary or logically compelled by statutory language. To begin, one might say that Congress's assignment of authority to an agency head represents the inevitable or necessary denial of directive power to the President based on the maxim of statutory construction, *expressio unius est exclusio alterius* ("the expression of one thing is the exclusion of

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64. *See id.* at 2323 (declaring that, where Congress has imposed such a restriction, "the limit on the President's directive power seems but a necessary corollary: a for-cause removal provision would buy little substantive independence if the President, though unable to fire an official, could command or, if necessary, supplant his every decision").

65. *See id.* at 2320 (urging that "most statutes granting discretion to executive branch—but not independent—agency officials should be read as leaving ultimate decisionmaking authority in the hands of the President").

66. *See id.* (specifying that when Congress delegates regulatory authority to an executive agency, it delegates discretionary power to the President).

another").[67] Kagan points out that this maxim needs to be applied with great caution.[68] As one commentator has stated, the *expressio unius* maxim "is a questionable one in light of the dubious reliability of inferring specific intent from silence."[69] Just because Congress mentioned an agency head's regulatory authority does not mean that it necessarily precluded presidential directives to the agency.

Another defense of the traditional view rests on the premise that Congress knows how to delegate power to the President in the regulatory sphere, as it has done so in various ways. Because Congress did not delegate directive power to the President in the statutes given meaning under the traditional view, it arguably chose not to delegate such power to the President.

Dean Kagan responds to this argument by insisting that it is not illogical for Congress both to delegate regulatory power to agencies and to allow presidential directives.[70] Yet, the fact that an interpretation is not logically compelled does not mean that it is not persuasive. After all, Congress does not explicitly address presidential power over agencies in the statutory language in question, so the most one could do is provide a persuasive case. Thus, the real battle does not hinge on what is logically compelled.

In rejecting the *expressio unius* argument, Kagan tips her hand about the hierarchical universe, with the President firmly on top, that she imagines as the model for agency oversight. She sees as analogous to an agency head's role the position of a Navy captain who makes decisions about a ship's

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67. *See* State *ex rel.* Riffle v. Ranson, 464 S.E.2d 763, 770 (W. Va. 1995) ("*Expressio unius est exclusio alterius* (express mention of one thing implies exclusion of all others) is a well-accepted canon of statutory construction."). The *expressio unius* maxim is premised upon an assumption that certain omissions are intentional. As the court explained in *Riffle*, "[i]f the Legislature explicitly limits application of a doctrine or rule to one specific factual situation and omits to apply the doctrine to any other situation, courts should assume the omission was intentional; courts should infer the Legislature intended the limited rule would not apply to any other situation." *Id.*

68. *See* Kagan, *supra* note 11, at 2328 n.322 (citing WILLIAM N. ESKRIDGE, JR., DYNAMIC STATUTORY INTERPRETATION 229 (1994), CASS R. SUNSTEIN, AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE 151-52 (1990), and Ill. Dep't of Pub. Aid. v. Schweiker, 707 F.2d 273, 277 (7th Cir. 1983), all of which cite to the phrase *expressio unius est exclusion alterius*, which equates statutory silence with denial of power, but may create erroneous statutory interpretation).

69. Cass R. Sunstein, *Law and Administration After* Chevron, 90 COLUM. L. REV. 2071, 2109 n.182 (1990); *see also* Max Radin, *Statutory Interpretation*, 43 HARV. L. REV. 863, 873-74 (1930) (calling the canon "one of the most fatuously simple of logical fallacies, the 'illicit major,' long the *pons asinorum* of schoolboys") (internal citation omitted). Thus, as the Seventh Circuit Court of Appeals succinctly observed, "Not every silence is pregnant; *expressio unius est exclusio alterius* is therefore an uncertain guide to interpreting statutes . . . ." *Ill. Dep't of Pub. Aid*, 707 F.2d at 277 (citations omitted).

70. *See* Kagan, *supra* note 11, at 2329-30 ("Only if Congress sometimes stipulated that a delegation of power to an agency official was subject to the ultimate control of the President—which Congress has not, to my knowledge—would a claim of this kind (that is, a claim relying on the negative implication of other statutes) succeed in defeating my argument.").

operation. She writes that few would think of the Navy captain as being free from a direct superior's power to give instructions to the captain "as to matters within the delegation."[71]

Yet we are not dealing with military personnel, and we should wonder whether the military is an apt analogy. The analogy begs the question whether there is a fully hierarchical relationship between the President and agency heads, or whether Congress should be understood to have created some space for agency discretion under law that is not subject to plenary presidential direction and displacement. That is the issue to resolve, not a point to assume.

2. Traditional View Not Realistic

To respond to the claim that the traditional view is persuasive, Kagan suggests that the President has so much power over executive agencies that it is most realistic to envision Congress as allowing presidential directives. First, the President nominates officers of the United States "without restriction";[72] second, the President can remove them at will; and third, the President "can subject them to potentially far-ranging procedural oversight."[73] These points are generally accepted by supporters of the traditional understanding.[74]

If one accepts that the President has these three powers, Kagan argues, it is realistic to suppose that Congress also allows the President to have a fourth power—namely, directive authority to control regulatory decisions.[75] Because the President can exercise procedural review of agency rules, "[a]n interpretive principle presuming an undifferentiated presidential control of executive agency officials" that includes procedural *and* substantive review "may reflect, more accurately than any other, the general intent and understanding of Congress."[76] Moreover, the "very subtlety" of the line between *influence* through appointment, removal, and procedural oversight

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71. *Id.* at 2329.
72. *Id.* at 2327.
73. *Id.*
74. *See* Peter L. Strauss & Cass R. Sunstein, *The Role of the President and OMB in Informal Rulemaking*, 38 ADMIN. L. REV. 181, 200 (1986) (substantiating the argument that Presidents have power over executive agencies by stating that the executive power to control and supervise has two components: (1) to consult with and demand answers from officials, and (2) to exercise authority in coordinating and overseeing the operating of the executive branch).
75. Kagan, *supra* note 11, at 2327-28 (advancing the argument that Congress knows that executive officials will give deference to presidential opinions, and therefore, by delegating to executive officials, Congress is delegating to the President).
76. *Id*. at 2328.

and *command* over the substance of regulatory action "provides reason to doubt any congressional intent to disaggregate them, in the absence of specific evidence of that desire."[77]

This argument takes advantage of our modern awareness of the manipulability of legal categories between procedural and substantive constraints on power. If the former are allowed, why not the latter? In addition, the argument calls into question the line between presidential influence and control, claiming that the distinction is too fine to be imputed to Congress.

Despite the difficulty of distinguishing procedural and substantive constraints on power, it is a familiar distinction. The key distinction under the traditional view in any event is the one between presidential influence or persuasion on the one hand, and presidential command and direction on the other. One need not accept all the procedural limits imposed by the President while rejecting all the substantive ones imposed by the President.

This point is confirmed in the 1981 opinion by the Office of Legal Counsel (OLC) of the Department of Justice (the OLC Opinion) validating the first Reagan Executive Order (the Order) on regulatory review.[78] This opinion invokes the distinction between procedural and substantive directives to agencies. In particular, it considers that the requirement of preparing a regulatory impact analysis of proposed and final rules is procedural in nature.[79] The opinion raises no serious objection to this requirement on the ground that it is "at most an indirect constraint on the exercise of statutory discretion."[80]

Yet the OLC Opinion also notes that the Reagan Order contains substantive requirements, which it examines more closely.[81] In particular, it notes that the Order's cost-benefit analysis requirement is "substantive" in character.[82] Assuming that authorizing statutes do not bar agencies from performing cost-benefit analyses, the OLC Opinion reasons that the key legal issue is "whether . . . the President may require executive agencies to

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77. *Id.*
78. OLC Opinion, *supra* note 17, at 59.
79. *See id.* at 59-60.
80. *Id.* at 62. Also, the requirement of reporting an analysis to the White House can be justified on the basis of the Opinion Clause, which empowers the president to "require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any Subject relating to the Duties of their respective Offices . . . ." U.S. CONST. art. II, § 2, cl. 1; *see also* Strauss & Sunstein, *supra* note 74, at 197 (stating that the Opinion Clause of the Constitution implies that the President can demand reports from agency heads in a particular form, but it does not imply directory authority).
81. *See* OLC Opinion, *supra* note 17, at 62 ("The order would impose requirements that are both procedural and substantive in nature.").
82. *See id.* at 63 ("Substantively, the order would require agencies to exercise their discretion, within statutory limits, in accordance with the principles of cost-benefit analysis.").

be guided by principles of cost-benefit analysis even when an agency, acting without presidential guidance, might choose not to do so."[83] The OLC Opinion analyzes this issue in terms of the traditional legal view that the President cannot displace an agency head's discretion. It notes that cost-benefit analysis leaves "a considerable amount of decisionmaking discretion to the agency."[84] Notably, the agency head remains responsible for calculating a rule's projected costs and benefits and for ascertaining whether the benefits exceed the costs. With such "considerable latitude" in decisionmaking left to the agency, the Order's "limited requirements" are not "inconsistent with a legislative decision to place the basic authority to implement a statute in a particular agency."[85] Accordingly, the Order's cost-benefit analysis requirement is acceptable because it does not "displace the relevant agencies in discharging their statutory functions. . . ."[86]

The reality-based critique of the traditional view presumes that there is no meaningful distinction between presidential influence on, and control of, agencies. To be sure, studies of the presidency have recognized that the distinction between presidential influence, supervision, advice, and persuasion on the one hand, and controlling, displacing, commanding, and directing on the other, can be subtle in practice.[87] The line, like many others, is not easy to draw.

Nonetheless, the basic distinction has content. It makes sense to say as a general matter that when a statute confers statutory authority on an agency head, the use of the authority should not be utterly displaced by the President. Consider in this regard the list of actions that centralized White House reviewers can and cannot do under the traditional view as suggested in the 1981 OLC Opinion. Centralized White House reviewers can, for instance, call for "the supplementation of factual data, the development and implementation of uniform systems of methodology, the identification of incorrect statements of fact, and the placement in the administrative record of a statement disapproving agency conclusions . . . ."[88] All of this is seen

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83. *Id.*
84. *Id.*
85. *Id.*; *see also* Strauss & Sunstein, *supra* note 74, at 201 ("But in view of the breadth of agency discretion in deciding on costs and benefits, and in making the ultimate trade-off, there is, in our view, no serious question about the facial legality of the order. This conclusion is buttressed by the various disclaimers in the order of any authority to displace delegated decisionmaking power.").
86. OLC Opinion, *supra* note 17, at 63.
87. *See* RICHARD E. NEUSTADT, PRESIDENTIAL POWER: THE POLITICS OF LEADERSHIP 10 (1960) ("Presidential *power* is the power to persuade.") (emphasis in original); *id.* at 32 ("Truman is quite right when he declares that presidential power is the power to persuade. Command is but a method of persuasion, not a substitute and not a method suitable for everyday employment.").
88. OLC Opinion, *supra* note 17, at 64.

as requiring discussion or disclosure by the agency in a manner that leaves intact the agency's ultimate regulatory authority. However, the supervisory and consultative role of centralized White House reviewers does not include authority to "reject an agency's ultimate judgment, delegated to it by law, that potential benefits outweigh costs, that priorities under the statute compel a particular course of action, or that adequate information is available to justify regulation."[89] These matters, no doubt, could become subjects of controversy between the agency and the White House, although the traditional understanding would come into play. To underscore the basic point, the OLC Opinion provides that, as to the latter set of subjects, White House reviewers are in an "advisory and consultative"[90] role with respect to an agency.

3. Traditional View Contrary to Congress's Interests

Another argument for the traditional understanding is that an agency's authorizing statute should not be seen to allow for presidential directives regarding the agency's regulatory activities because such a result would undermine Congress's institutional interests. Elena Kagan also summarily rejects this argument. She notes that Congress is not consistent in defending its own institutional interests in relation to the President.[91] Given Congress's silence on the subject of presidential power, why should we assume that Congress intends to protect its institutional prerogatives?[92]

Moreover—and here Dean Kagan casts doubt on her own enterprise of discerning legislative intent—there is a "fictive aspect" to any discussion of what Congress seeks when enacting a regulatory delegation.[93] Perhaps Congress literally has no intent on the matter of agency head authority in relation to presidential power. It may have "failed to consider" the issue, been "unable to reach consensus" about it, or "chosen to leave the decision to other actors to work out" for themselves.[94]

The problem with the argument that Congress often does not protect its own institutional interests is that this does not establish that Congress never does, or that it is not doing so here. To be sure, members of Congress often seem more concerned with partisan or constituency matters than with

89. *Id.* White House reviewers can engage in discussions with agencies in which they challenge the agency's premises and seek change in the agency's policies so long as they leave ultimate power to decide with the agency.

90. *Id.*

91. *See* Kagan, *supra* note 11, at 2230 (observing that Congress tends to defend its institutional interests poorly).

92. *See id.* (noting that Congress may have failed to consider the question of presidential directive authority).

93. *Id.*

94. *Id.*

protecting the legislature's power in the abstract.[95] Individual members may have comparatively little reason to pay personal attention to matters relating to Congress's institutional influence, given their preoccupation with amassing personal power to serve and impress their constituents.

Yet personal power depends at least partly on institutional influence. In those situations, it is rational for members of Congress to care about preserving their institution's relative clout. In particular, Congress is organized into committees that deal with particular agencies. Members of Congress obviously are aware of this reality when they delegate regulatory power to agency heads. Why would members of Congress want to undermine the relative power of their own committees vis-à-vis agencies, which would be the predictable effect of assigning directive power over executive branch rulemaking to the President who is, as Kagan recognizes, "Congress's principal competitor for power in Washington"?[96]

With respect to the contention about fictive legislative intent, it is problematic to proceed from a parsing of arguments about legislative intent to a debunking of such arguments in general. It is important to ask whether there is sufficient evidence of legislative intent on which to base a conclusion. After all, we are confronted with bare bones statutory provisions along the lines of, "Agency head *X* has rulemaking authority." It is possible that such a provision is accompanied, on the part of some members of Congress, by a lack of concern about presidential power, an inability to reach a consensus about it, or a desire to leave the issue to others.[97]

Yet these possibilities for individual members of Congress do not require a refusal to assign a collective purpose to the behavior of Congress as a whole. In fact, we commonly attribute a purpose to collective action in light of what a group does, even if individuals in the group cannot be assumed to have that purpose plainly in mind at the time they act. This approach has been defended in the context of upholding the cautious use of legislative history in statutory construction. Justice Stephen Breyer has

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95. *See id.* at 2314 ("The partisan and constituency interests of individual members of Congress usually prevent them from acting collectively to preserve congressional power . . . .").

96. *Id.* at 2330. It could be argued that Congress's power is not relatively diminished by a presidential assertion of general rulemaking power. Yet such a flat claim seems implausible. For one thing, if the traditional understanding is jettisoned, Congress cannot raise it as the basis of an objection to presidential influence on agencies. To be sure, Congress always can put countervailing pressure on an agency head faced with pressures from a president. But if the President indisputably has the ultimate power of rulemaking, Congress's pressure presumably will carry less weight than if the President has to tread with some care, as under the traditional understanding.

97. *See* Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467, 489 (2002) (arguing for a more limited view of delegations of rulemaking power to agencies).

argued by analogy that even if a member of a basketball team has no plainly identifiable, personal intent when he or she makes the moves of a much-practiced play, the fans can intelligibly speak about the team's general purpose in doing what it does.[98] The same approach is reasonable here.

The central question is what Congress's likely purpose is when its plain language assigns regulatory authority to an agency head. From such language, can we glean any intimations about the agency head's role? On its face, a statutory delegation to an agency head indicates that the agency head is to be the decisionmaker. Any scheme that would displace the agency head's discretion would appear to require specific justification. After all, what is the point of delegating power to an agency head if it can be displaced?

To put the point somewhat differently, an ordinary rulemaking delegation is not silent on the question of the agency head's authority. Although it is silent on the President's role, it does lodge discretion in an agency head—with the natural implication that to displace that official's discretion is to undermine the statute. To require an additional, explicit statement by Congress that the agency head's authority cannot be displaced puts an unwarranted burden on Congress in achieving its apparent aim.

B. Arguments Based on Institutional Competence

In this Section, I will consider arguments against the traditional view based on considerations of institutional competence. From Kagan's perspective, the fate of the traditional view ultimately turns on the President's comparative superiority in promoting accountable and effective decisionmaking. As she frames the issue, if presidential control of agencies advances accountable and effective administration, "then Congress should have to manifest any intent to limit that control," whereas if presidential control undermines those values, "then Congress should have to manifest the opposite desire" to promote presidential directives.[99] For Kagan, the President's superiority is so patent that we should adopt an interpretive presumption that is the opposite of the traditional view.

The accountability and effectiveness arguments about the presidency, it bears noting, have been used in other contexts to seek enhancements of the President's power. For instance, the contentions have been deployed on behalf of amendments to the U.S. Constitution designed to help the President "form a government"[100] and thereby formulate and carry out

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98. Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 865 (1992).

99. *See* Kagan, *supra* note 11, at 2330-31.

100. *See* Lloyd N. Cutler, *To Form a Government*, 59 FOREIGN AFF. 126, 139-43 (1981)

policies without negotiating with an independent Congress.[101] These arguments also underlie the ill-fated attempt to provide the President with a line item veto.[102]

Basic premises of the accountability-centered case for presidential uniqueness are associated with public choice theory. That theory conceives of public institutions in terms of the self-interested choices of actors within them.[103] A "rational" elected official seeks reelection to maintain his or her power base. Members of Congress endeavor to satisfy their constituents by trading public policies for support for reelection. On this view, it is naive to suppose that members of Congress have large or enduring commitments to the public interest. They possess a drive to remain in power, while their constituents aim to appropriate the benefits of governmental largesse or to avoid the burdens of governmental regulation. A similar dynamic occurs with respect to the President, although—and this point becomes critical—the accountability argument stresses the nationwide character of the President's constituency.

Constituencies are local in the case of members of the U.S. House of Representatives and state-based in the case of U.S. Senators. What follows from these facts? It is argued that members of Congress look at issues through a lens crafted locally or state-by-state.[104]

Contrast this situation with that of the President, who is the only nationally elected political figure (along with the Vice President). As such, the President is in the unique position of having an electoral incentive to represent the nation's public as a whole. As a consequence, it is asserted, the President alone can stand above the political fray of local pork barrel politics and special interest pleading.[105]

(making the argument that the Constitution should be amended to create the "capability of forming a Government"), *reprinted in* REFORMING AMERICAN GOVERNMENT: THE BICENTENNIAL PAPERS OF THE COMMITTEE ON THE CONSTITUTIONAL SYSTEM 11 (Donald L. Robinson ed., 1985).

101. *See* Thomas O. Sargentich, *The Limits of the Parliamentary Critique of the Separation of Powers*, 34 WM. & MARY L. REV. 679, 716-21 (1993) (critiquing the effectiveness and accountability arguments, which call for a more centralized government structure, on the basis that these arguments are both very vague and "evade substantive differences and choices in our political community").

102. *See* Clinton v. City of New York, 524 U.S. 417 (1998) (holding the Line Item Veto Act unconstitutional); *see also* Thomas O. Sargentich, *The Future of the Item Veto*, 83 IOWA L. REV. 79, 112 n.144 (1997) (citing accountability rationale in legislative history).

103. *See, e.g.*, Daniel A. Farber & Philip P. Frickey, *The Jurisprudence of Public Choice*, 65 TEX. L. REV. 873, 893 (1987) ("[T]he heart of the economic approach is the assumption that self-interest is the exclusive causal agent in politics.").

104. See, for instance, former Speaker of the House Tip O'Neill's famous aphorism, "All politics is local." SPEAKER TIP O'NEILL WITH GARY HYMEL, ALL POLITICS IS LOCAL: AND OTHER RULES OF THE GAME (1994).

105. *See* Steven G. Calabresi, *Some Normative Arguments for the Unitary Executive*, 48 ARK. L. REV. 23, 59 (1995) ("[T]he President is . . . the only official who is accountable to a national voting electorate and no one else."); *see also* Frank H. Easterbrook, *Unitary Executive Interpretation: A Comment*, 15 CARDOZO L. REV. 313, 318-19 (1993) (contending

In line with this approach, Elena Kagan emphasizes that because the President must win a national election, he or she must appeal to a national constituency that legislators lack.[106] Kagan acknowledges that specific regulatory issues often are not the subjects of national discussion in a presidential election campaign.[107] She places particular weight on the notion that, as a prospective matter, a President looks to majority sentiments in gauging how to act because the President has incentives to appeal to "a national constituency" and "the preferences of the general public, rather than merely parochial interests."[108] During a President's first term, he or she is acutely aware of the need for support for reelection, and during a second term, the President pursues nationally popular policies with the hope of becoming able to choose a successor and carve out a positive legacy for history.[109] The critical point is that, as a comparative matter, the President has a stronger relation to the public's majoritarian preferences than anyone else, including members of Congress, agency heads, or leaders of interest groups.[110]

With respect to effectiveness in governing, Kagan sees the President as uniquely able to make rational decisions about competing priorities in regulatory programs. She notes that enhanced presidential control advances "a number of so-called technocratic values: cost-effectiveness, consistency, and rational priority-setting."[111] Agencies, in contrast, are seen to have parochial perspectives in line with their limited statutory missions.

Kagan also emphasizes that in certain circumstances, such as those of the Clinton Administration, presidential directives can promote "dynamism or energy in administration,"[112] thereby helping to overcome the lethargy that can plague large bureaucracies.[113] While noting checks and balances on

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that members of Congress and independent agencies—which are more beholden to committee and subcommittee chairmen—are both "farther from the median of national opinion than are presidents . . . .").

106. *See* Kagan, *supra* note 11, at 2334 (asserting that presidential elections hinge on "general, rather than local, policy issues").

107. *See id*. (conceding that bare election results do not inevitably demonstrate wide support for a "candidate's most important positions, much less the sometimes arcane aspects of regulatory policy"). Kagan also notes that "[a]s the election of 2000 demonstrated, winning a national election does not necessarily entail winning more votes than any other candidate; still less, as the two prior elections showed, does it mean winning a majority of the national electorate." *Id.*

108. *Id*. at 2335.

109. *Id*. Here, too, she offers qualification, noting that each regulatory issue "probably will play a small role in the public's overall estimation of presidential performance. . . ." *Id.* at 2335-36.

110. *See id*. at 2336-37 (arguing that, as to political accountability, the President has "the comparative advantage" over other actors affecting the administrative process).

111. *Id.* at 2339.

112. *Id.*

113. *See id.* at 2344 (contending that the courts' increased demand on agencies to allow

power, she supports a "countertradition" favoring "enhanced government[]" and "executive[] vigor."[114] This countertradition, she argues, is advanced by a vigorous system of presidential control of regulatory decisionmaking.[115]

Clearly, the accountability and effectiveness arguments promote enhancements of chief executive power. The problem is that they are one-sided and unbalanced. They tend to exaggerate the broad accountability of the President and to understate the representativeness of Congress. They also overstate the policymaking effectiveness of the President while diminishing that of agencies. These exaggerations should give us pause. I will discuss each matter in turn.

1. The Accountability Argument's Exaggerations

Upon examination, the accountability argument in favor of eliminating the traditional view of the President's role vis-à-vis agencies takes the lessons of public choice theory only so far; in doing so, it offers a one-sided picture. The theory teaches that all public institutions tend to serve organized interests at the expense of the general public.[116] There is no reason to suppose that the presidency is immune from the influence of local or special interests.

Indeed, much experience confirms that presidents do respond directly to narrow, sub-national political interests, including those playing major roles in national campaigns and parties. Consider, for instance, the continuing attention that President Clinton paid during his administration to the interests of California's voters (or Florida's Cuban-Americans). The fate of California's electoral votes figured prominently in Clinton's campaign strategies in 1992 and 1996.[117] Consider also President George W. Bush's continuing concern for retaining the support of the rightwing of the Republican Party, which proved to be critical during the political primary season of 2000 in which Bush achieved preeminence in the field of

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interest group participation in rulemaking led to "ossification" of agency decisionmaking and "torpor" as a defining feature of administrative agencies).

114. *Id.* at 2342. Kagan associates this tradition with Alexander Hamilton and with modern theorists who have called for greater energy in government by means of concentrating power in the executive branch. *See id.* at 2343 & n.374 (citing sources denouncing tendency of "divided government" to lead to deadlock).

115. *See id.* at 2344 (arguing that the needs of the modern government call for "a need for institutional reforms that will strengthen the President's ability to provide energetic leadership in an inhospitable political environment").

116. When a group acts on incentives to organize despite the costs of doing so, it presumably is seeking to achieve certain discernible gains in the political process. The active pursuit of those gains leads to those well-organized groups having more power than the diffuse public.

117. *See* Sargentich, *supra* note 102, at 127-28 & nn.215-16 (recounting Clinton's frequent visits to California and his addressing of local interests, such as promises to protect local military bases from closing).

Republican presidential candidates,[118] during his first term, and during his 2004 re-election campaign.[119] As these examples suggest, it is unrealistic to suppose that presidents solely are accountable to some diffuse, majoritarian interest of the public in general.

Consider also the notion of a presidential "mandate" with reference to agency regulations. Even among issues that are discussed prominently in a presidential campaign, to what extent can one say that an election generates a clear majoritarian mandate on a particular matter of policy?[120] For one thing, a President can be elected without obtaining a majority of the popular vote—as in the cases of President Clinton in 1992 and 1996 and President George W. Bush in 2000. Moreover, presidential campaigns are heavily influenced by such general matters as the electorate's perception of national security needs, the state of the economy, or the personal appeal of candidates, as distinct from particular matters of policy.[121] Moreover, largely symbolic issues can dominate discourse during a campaign. Accordingly, it often is strained to suggest that such contests generate sharply-drawn majoritarian mandates as to particular policy issues.

For such reasons, Elena Kagan downplays the importance of a backward-looking mandate as the basis of a claim of special presidential accountability.[122] Yet what about the notion of a forward-looking

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118. *See* Thomas E. Mann, *For a Bipartisan War President*, CHRISTIAN SCI. MONITOR, Nov. 29, 2001, at 11 (referring to President Bush's "hypersensitivity to his conservative political base," especially prior to the terrorist attacks on the U.S. on September 11, 2001, and urging the President to "abandon his practice of always playing first to his political base").

119. For a critique of the first term of George W. Bush's presidency for serving right-wing interests, see CHARLES TIEFER, VEERING RIGHT: HOW THE BUSH ADMINISTRATION SUBVERTS THE LAW FOR CONSERVATIVE CAUSES (2004).

120. Three weeks after the November 2, 2004 presidential election, an article on the front page of *The New York Times* proclaimed an incongruence between the President's assertion of the mandate he received and the findings of the latest poll by the New York Times/CBS News. *See* Adam Nagourney & Janet Elder, *Americans Show Clear Concerns on Bush Agenda*, N.Y. TIMES, Nov. 23, 2004, at A1 ("At a time when the White House has portrayed Mr. Bush's 3.5 million-vote victory as a mandate, the poll found that Americans are at best ambivalent about Mr. Bush's plans to reshape Social Security, rewrite the tax code, cut taxes and appoint conservative judges to the bench . . . . Nearly two-thirds of all respondents—including 51 percent of Republicans—said it was more important to reduce deficits than to cut taxes, a central element of Mr. Bush's economic agenda.").

121. *See* Seidenfeld, *A Big Picture Approach to Presidential Influence*, *supra* note 57, at 20 ("Thus, presidential elections tend to turn more on the perceived state of the economy in an election year and the individual candidates' abilities to inspire confidence about the future state of the nation than on perceptions gleaned from particular regulatory stances taken by a candidate or the incumbent administration.").

122. *See* Kagan, *supra* note 11, at 2334 ("[E]ven assuming a popular majority for a presidential candidate, bare election results rarely provide conclusive grounds to infer . . . support for . . . [a] candidate's most important positions, much less the sometimes arcane aspects of regulatory policy.").

mandate—which Kagan stresses—that a President is qualitatively more likely than any other governmental actor to keep the public's interest in mind as he or she serves a national constituency?

Most basically, one needs to deal with the idea of a "national" constituency cautiously because presidents rely on certain distinct groups for support. Candidates need the contributions of financially established interests, and they are attentive to their electoral base. Those particular interests are not forgotten after Election Day. It is implausible to view the electorate as an undifferentiated body of nation-wide voters, each of whom carries equal weight with a President.[123]

Moreover, the very idea of a "national" presidential election is oversimplified. In reality, presidential elections consist of a series of state contests, the rewards of which are the state's electoral college votes. The nation was reminded of this reality after the November 2000 presidential election, when there was a period of uncertainty about the fate of Florida's electoral votes and, thus, the outcome of the election itself. In 2004, the presidential election was contested by both major presidential candidates in only a limited number of states, and the result turned on one state's electoral votes—namely, Ohio's.

None of this is to suggest that accountability to the public should be downplayed as a value in our constitutional system. As a normative matter, it should be highlighted—although not in a manner that glorifies the President's position. We also should remember that Congress makes its own unique, affirmative contribution to democratic accountability.

What is this contribution? In its broad-based representation of constituencies across the nation, Congress as an institution is arguably more representative of a wider range of public opinion than any single official, including the President, can hope to be.[124] To be sure, the voters for members of Congress are local in the case of the House of Representatives and state-based in the case of the Senate. Yet that does not necessarily mean that legislative institutions, acting as such, are unable to look out for the general public interest. No doubt, Congress may have a different take on that interest than the President. This possibility is not a negative factor as long as one respects the role of a democratic legislature

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123. *See* Shane, *supra* note 8, at 197 ("There is no evidence that the President, at any given moment, embodies that set of policy predilections across a wide set of issues that is held by a contemporaneous majority—or, more accurately, by contemporaneous majorities of Americans.").

124. *See id.* at 200 ("If bureaucratic accountability to elected politicians is to be used as a structural mechanism aimed at achieving direct responsiveness to public opinion, it would probably make more sense to intensify the influence that Congress—especially the House—has over the agencies. Members of Congress are eligible for reelection indefinitely; a common observation of the House is that its members are in a constant election campaign.").

whose members compete in numerous elections across the country and come together to hammer out positions accommodating a variety of views. In this sense, Congressional discourse serves the values of pluralism as captured by a cacophony of voices speaking for the diversity of life in the United States.[125]

The pluralism represented by Congress stands in contrast to a unified conception of the public good supported by the nation's voting majority. A unified conception does not fit well with the reality of tremendous heterogeneity in our society.[126] Particularly for those who are or who feel marginalized, the idea of a dominant majoritarianism is likely threatening. In truth, there are many warring notions of the good at play in our contemporary society, and this complexity is at odds with the supposition that an "accountable" government is one that responds to a unified majoritarian will. At a minimum, it seems admirable to foster an ongoing public dialogue that responds to the various communities and perspectives represented by both Houses of Congress as well as the President.

What should be said about the fact that members of Congress work in committees and that committee membership is not representative of the nation as a whole? It is true that committees attract members with special interests in the subject matters of the committees themselves. Why serve on a committee if you are not interested in its jurisdiction? Yet this reality does not defeat the claim that when Congress acts as a whole, with majorities of both the House of Representatives and the Senate in agreement, it represents a broad range of interests, geographical areas, and political orientations. If broad representation is the goal, congressional action is an important means of achieving it.

The accountability argument, then, embraces an oversimplified, one-sided slant in favor of presidential hegemony.[127] Kagan confronts this concern in a passage in which she discusses the system of checks and balances in the federal constitutional structure.[128] She sees the critique of

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125. The point is to recognize strengths of Congress, not to deny its limits, such as the current problem of gerrymandering by both parties, leading to non-competitive elections in the House of Representatives.

126. For a discussion of the value of diversity in modern debates about the revival of the republican ideal in liberal discourse, see Kathleen M. Sullivan, *Rainbow Republicanism*, 97 YALE L.J. 1713, 1714 (1988) (arguing for normative pluralism in which politics is "the interaction of groups that are more than simple aggregations of individual preferences, but less than components of a single common good").

127. *See* Robert R. M. Verchick, *Toward Normative Rules for Agency Interpretation: Defining Jurisdiction Under the Clean Water Act*, 55 ALA. L. REV. 845, 858 (2004) (concluding that "Elena Kagan acknowledges the possibility that a President might use his or her power to inappropriately cloud issues and avoid accountability, but she grossly underestimates the danger").

128. *See* Kagan, *supra* note 11, at 2337 n.347 (citing Farina, *Against Simple Rules for a Complex World*, *supra* note 8, at 989; Shane, *supra* note 8, at 212; and Strauss, *Presidential Rulemaking*, *supra* note 8, at 965 n.*).

her view as comparing the President with "a pluralist system, in which [the President] competes with all others to influence administration."[129] Kagan suggests that the framing of the issue as involving "presidentialism versus pluralism" distorts the inquiry more than her framing of the debate as "greater or lesser presidentialism within pluralism."[130] She argues that "we inevitably . . . live in a pluralist administrative system," and so threats to pluralism are not the issue.[131] "The real issue concerns the balance we should strike among all the institutions struggling for administrative power. . . ."[132]

The difficulty with this suggestion is that the real opposition raised by the presidential mystique is not that of presidentialism versus pluralism. It is thus not fully responsive to say that pluralism is inevitable, although it may be.[133]

The key choice is between presidentialism and non-presidentialism, or between accepting the presidential mystique and being critical of it. The former approaches seek systematically to enhance presidential power while casting doubt on the legitimacy and efficacy of other institutions of government. The latter approaches do not do so. They presume that the major political branches must be thought of as fully co-equal, that the various institutions of government—including the White House and Congress—have their respective strengths and weaknesses, and that there is no savior among them in the continuing search for accountable governance.[134]

In another context I have defended the principle of dialogue in the creation of public law, which underlies the Constitution's system of checks and balances.[135] The dialogue involves the main political institutions of the

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129. *Id.*
130. *Id*
131. *Id.*
132. *Id.*
133. *Cf.* Cass R. Sunstein, *Interest Groups in American Public Law*, 38 STAN. L. REV. 29, 47 (1985) [hereinafter Sunstein, *Interest Groups in American Public Law*] (discussing the federalists' rejection of either pure republicanism or pure pluralism and instead developing a "hybrid conception of representation," thus "achiev[ing] a kind of synthesis of republicanism and the emerging principles of pluralism. Politics rightly consisted of deliberation and discussion about the public good.").
134. Kagan is closer to the mark in framing the question as involving "balance among all the institutions struggling for administrative power." Kagan, *supra* note 11, at 2337 n.347. However, one could quibble about whether all the institutions actually are struggling for administrative power. The balance to be sought is not in the use of administrative power as such, but in the use of governmental power of whatever sort. Congress uses its legislative and allied oversight and investigative powers; the President uses executive power, including oversight of administration; agencies use their executive power pursuant to statute. Thus, the key balance at stake is not between the President and pluralism or among institutions struggling for administrative power, but among the various institutions of government, with each using its distinctive powers.
135. *See* Sargentich, *supra* note 101, at 720 (stressing the importance of preserving a "sense of competing social visions in order to take account of alternative experiences and

federal government—Senate, House of Representatives, and President—as contributors to broad public debate about national policy.[136] It is true that each institution has its distinctive constituency that will influence its voice. The key point is to put the voices together to develop diverse perspectives on public affairs. Such a dialogue can help create a healthy depth and breadth in policy discourse.

An active view of checks and balances fosters expansive access to power, for members of the public can have relationships with alternative institutions and still have their own voices heard.[137] Having various points of access to power is an intelligent response to the social diversity of the United States.[138] It is especially reassuring to citizens who oppose the policies of a given President, for whom the value of checks on the executive are obvious. Furthermore, vigorous debate fostered by a robust system of institutional interaction can help to prevent the dominance of particular special interests.[139] Without romanticizing the present, deliberation among actors with differing perspectives can broaden the voices heard and diffuse power.

One should not exaggerate in the opposite direction. The point is that the policy-based argument for eliminating the traditional view of the President's role vis-à-vis agencies tends to overstate the President's accountability to the public in general and, at the same time, to understate the accountability of Congress. By privileging the President's voice, the presidential mystique does not sufficiently acknowledge the principle of dialogue involving the people and all of the institutions of government in pursuit of the public interest.

2. The Effectiveness Argument's Exaggerations

The effectiveness-based argument for the presidential mystique builds on the notion that agencies have single-mission charters that generate narrow-gauged thinking about public policy.[140] The presumed narrowness of

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viewpoints").

136. *Id.* at 733.

137. *See id.* at 735 ("[I]ndividuals and groups may have a greater chance of winning the ear of some powerful official in their efforts to achieve representation.").

138. *See* Erwin Chemerinsky, *The Question's Not Clear, But Party Government Is Not the Answer*, 30 WM. & MARY L. REV. 411, 415 (1989) ("No group wins or loses all the time. As a result, no group need feel completely disenfranchised and better off working to overthrow the system of government. This stability is probably the most notable and desirable feature of the American system . . . .").

139. *See* Sunstein, *Interest Groups in American Public Law*, *supra* note 133, at 44 ("The system of checks and balances within the federal structure was intended to operate as a check against self-interested representation and factional tyranny in the event that national officials failed to fulfill their responsibilities.").

140. *See* Kagan, *supra* note 11, at 2339 ("Alone among the actors competing for control over the federal bureaucracy, the President has the ability to effect comprehensive, coherent change in administrative policymaking.").

agencies' perspectives is contrasted with the more comprehensive, government-wide orientation of the White House. Kagan's presidentialism sees presidential directives to regulatory agencies as tools for improving the comprehensive rationality of administration.[141]

For one who accepts that government can play an important role in helping to find solutions to social problems, it is difficult to doubt aspirations for greater energy in government. Ideally, a President can provide a useful measure of the coordination and energy that might be in limited supply in a far-flung executive establishment. But to exalt the presidential stance as singularly rational, comprehensive, and valuable is to disregard the possibility of presidential narrow-mindedness, fixation on particular goals to the detriment of broader objectives, or indebtedness to specific interests rather than a more idealized national perspective.[142] It is not unheard of for presidents themselves to be parochial in their commitments.

The familiar tension between arguably pursuing abstract rationality and actually making debatable decisions can be illustrated in terms of the operation of cost-benefit analysis itself. In broad terms, such analysis seems to be a model of rational thinking, enjoining action that promotes net benefits to society. Yet in addition to the concerns that these arduous analysis requirements add to the ossification of the rulemaking process,[143] consider the concrete manipulability of the analysis. In doing such analyses, often controversial judgments about valuing the effects of regulatory actions need to be made. A common example involves choosing the rate at which future benefits are to be discounted to arrive at a present-day valuation of benefits. Selecting the discount rate is a value-laden process. Moreover, it may be outcome-determinative in cases in which many of the gains from regulation are expected to arrive in the future. It is unrealistic to suggest that decisions about discount rates are unproblematically "rational," "consistent," and otherwise based on objective, government-wide criteria, as opposed to being significantly based on normative and frankly debatable judgments in particular instances.[144]

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141. *See id.* (discussing the President's "capacity to achieve set objectives, without undue cost, in an expeditious and coherent manner").

142. *See* Sunstein, *Interest Groups in American Public Law*, *supra* note 133, at 43 ("[T]he separation of powers scheme was designed with the recognition that even national representatives may be prone to the influence of 'interests' that are inconsistent with the public welfare.").

143. *See infra* note 146 and accompanying text (discussing the contribution of presidential oversight to agency ossification).

144. *See generally* Lisa Heinzerling, *Discounting Our Future*, 34 LAND & WATER L. REV. 39 (1999) (asserting that the federal government errs when it values future events less than present events for the purposes of regulation).

There remains the contention that the President can help to infuse into a torpor-laden bureaucracy the energy and dynamism sought from a forward-looking executive branch. That may be so. However, one person's energy can be another person's mistake. Even assuming the President assiduously adheres to legal constraints, a President can energetically impose on the bureaucracy a wrong-headed policy. The Reagan Administration provides numerous examples of energetic efforts to halt the development of rules protective of workers and the environment and to limit the scope of governmental attempts to reduce societal inequities.[145] Some might cite the decision of George W. Bush to review regulatory initiatives undertaken late in the Clinton Administration as a case of presidential rejection of valuable governmental initiatives.[146] Others will present different examples.[147]

Also, what Kagan calls the "necessary condition for presidential administration" designed to direct the regulatory process is "that it occur[s] in public."[148] Unfortunately, we know that much is held secret in the administration of George W. Bush.[149] There is simply no reason to suppose that other presidents will necessarily believe in transparency to the extent that, Kagan tells us, Clinton did.

Furthermore, the process of White House supervision mandated by executive order and statute imposes significant costs on the regulatory system. For that reason, some have seen White House review not as an energizer of agency rulemaking, but rather as another cause of the ossification of the regulatory process.[150]

Moreover, the idea that energy is missing from administration slants the analysis strongly against the values of agency responsibility. To be sure, many agencies face large backlogs with limited resources. Yet, over-

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145. Kagan acknowledges that the "desirability of such [presidential] leadership depends on its content; energy is beneficial when placed in the service of meritorious policies. . . ." Kagan, *supra* note 11, at 2341.

146. *See* Memorandum for the Heads and Acting Heads of Executive Departments and Agencies, 66 Fed. Reg. 7702 (Jan. 24, 2001) (instructing review of all regulations issued at the end of President Clinton's term of office that had not yet taken effect).

147. *See* TIEFER, *supra* note 119, at 121-23 (describing the Bush Administration's systematic dismantling of various environmental regulations).

148. Kagan, *supra* note 11, at 2362.

149. For a critical discussion of George W. Bush's presidency, including a tendency toward secrecy in government, see SENATOR ROBERT C. BYRD, LOSING AMERICA: CONFRONTING A RECKLESS AND ARROGANT PRESIDENCY (2004); KEVIN PHILLIPS, AMERICAN DYNASTY: ARISTOCRACY, FORTUNE, AND THE POLITICS OF DECEIT IN THE HOUSE OF BUSH (2004); TIEFER, *supra* note 119.

150. *See, e.g.*, Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1436 (1992) ("The net result of all of the aforementioned procedural, analytical, and substantive requirements is a rulemaking process that creeps along, even when under the pressure of statutory deadlines."); Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59, 62-63 (1995) (criticizing the OMB review process for increasing costs, delays, and inter-branch friction).

emphasis on these realities can prompt one to miss the stories about what agencies responsibly do, given the experience that they have gained.[151]

It also seems critical not to lose sight of the historical reality that agencies are created, at least in significant part, to address social issues that Congress believes are better addressed by administrators rather than by Congress or Presidents alone. By being somewhat shielded from the political process, agencies arguably are well-suited to address difficult issues on the merits without constant intrusions of raw politics into the process.[152] In the end, the values affirmed by agency decisionmaking should be kept more clearly in mind than they are by the presidential mystique.

CONCLUSION: PRESIDENTIAL ADMINISTRATION RE-EVALUATED

Dean Kagan has embraced presidential administration as a means of legitimizing broad delegations to agencies. In rejecting the stance of unitary presidentialists, she accepts the reality of independent agencies. She also bases her vision on an appreciation of energetic presidential leadership in the service of public purposes. In developing a new presidentialism, Kagan has brought the model to a high level of sophistication as a framework for justifying administrative power.

In discussing her approach, Kagan supports a presumption against the traditional view of presidential power vis-à-vis agencies. From her perspective, the understanding should be that the President can displace regulatory authority vested by statutes in agency heads. Kagan makes arguments based on legislative intent as well as institutional competence, with the latter constituting a policy-based defense of presidential directives to agencies as uniquely accountable and effective.

As argued in this Article, the traditional view has the advantage of reflecting a more straight-forward reading of statutory language delegating regulatory authority to agency heads. The fact that the traditional view barring presidential displacement of agency head discretion is not a necessary or logically compelled reading does not mean that it is not a serious or persuasive one. Also, the policy arguments for the presidential mystique exaggerate the presidency's positive qualities, while unduly diminishing the attributes of Congress and agencies. Indeed, the accountability and effectiveness claims present a picture of the President as

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151. *See* Shane, *supra* note 8, at 205 ("Each agency, because of its discrete jurisdiction and sustained immersion in particular categories of problems, is expected to develop a base of knowledge and methodological sophistication intended to protect against decision making based solely on passion or 'interest.'").

152. *See* Mark Seidenfeld, *A Civic Republican Justification for the Bureaucratic State*, 105 HARV. L. REV. 1511, 1576 (1992) ("Administrative agencies . . . fall between the extremes of the politically over-responsive legislature and the under-responsive courts.").

a white knight uniquely able to vindicate the public interest. Although it can be illuminating to speak in broad terms about presidential, legislative, and administrative decisionmaking, it seems important to portray each institution's attributes in even-handed ways. This is more in keeping with a critical understanding of the President's position and an active conception of checks and balances that broadens public involvement, diminishes the dominance of single viewpoints, and fosters diversity in democratic deliberation.

We should preserve an appreciation of richly divergent perspectives in a world of checks and balances, in which no single hierarchical voice should be seen to overcome all others. Of course, nothing can guarantee a rich polyphony[153]—but at least we can keep from being totally drowned out by the unifying voices of our age.

153. *See* Farina, *Against Simple Rules for a Complex World*, *supra* note 8, at 1037 (calling for structural polyphony in the performance of United States constitutionalism); Strauss, *Presidential Rulemaking*, *supra* note 8, at 965 n.* (reaffirming the need for structural polyphony).

THE MYTH OF "PRIVATIZATION"

CHRIS SAGERS*

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INTRODUCTION

Among the most written-about topics in administrative and constitutional law these days is "privatization," an area that in a relatively short time has spawned an immense body of literature. The work has become so prevalent and has so captivated the attention of leading thinkers in these areas that its conception of the nature of governance—its portrait of "privatizing" arrangements as the key focus of concern in understanding our allegedly changing political institutions—has the potential to define the academic lawyer's very understanding of government. Unfortunately, as it will be the purpose of this Article to show, it is also fairly problematic.

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* Assistant Professor of Law, Cleveland State University. I welcome all feedback at csagers@law.csuohio.edu. Because working out the ideas in this paper has had a bit of the flavor of a torchless search for the way out of a damp echoing cave, it was possible only with the occasionally searing and immensely appreciated feedback of Ben Barton, Anita Bernstein, Cary Coglianese, Errol Meidinger, Pierre Schlag, Frank Snyder, Paul Verkuil, and Phil Weiser.

One central criticism drives this Article: The very idea that there is such a thing as "privatization" and that it is a meaningful subject of study implies a sociological claim, which may seem obvious and unexceptional, but in fact is importantly mistaken. It implies that there is some distinction between the performance of certain functions by government institutions and performance by private ones, and it implies that the distinction is both real and of very deep significance. A purpose of this Article is to show that this distinction does not exist, and that by employing it, the literature has described the world in an inaccurate way. To that extent this Article joins with critiques of conceptual public-private dichotomies that have been a part of academic criticism for at least 150 years,[1] though I hope it will add something new and worthwhile to them. Importantly, though, this Article is not an exercise in legal doctrine. It is ultimately an attempt to suggest an alternative sociological picture of institutions of control. That is, the purpose is not simply to deconstruct the public-private distinction as a tool used by courts, policymakers, and law professors, but to offer a picture of governance that can get along without it.

In short, I hope to show that the basic choice in the organization of society is not between organization by government bureaucracy on one hand, and markets on the other—a choice that is assumed in the privatization literature. Rather, the basic choice is between two kinds of bureaucracy, which really do not differ much at all. Indeed, the chief difference seems to be that one of them lacks even a nominal obligation toward the public interest.

While I believe the real problem in the literature is a deep conceptual one, it begins superficially as a problem of definition. Though it is not often explicitly defined, "privatization" normally means, roughly, some conscious choice by an entity of traditional "government" to provide a service or good by enlisting the aid of an entity that is not part of traditional "government." As a concept it appears to find its origin in a popular article by Peter Drucker from the late 1960s.[2] From there, it found its way into

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1. *See infra* notes 65-69 and accompanying text (discussing the history of the public-private critique).

2. *See* Peter F. Drucker, *The Sickness of Government*, 14 PUB. INTEREST 3 (1969). Drucker, a business school professor and management consultant, argued that structural features inherent in government made it competent only to "focus the political energies of society[,] . . . to dramatize issues[,] [and] . . . to present fundamental choices," *id.* at 17, whereas all other goods-and-services provisions then being performed by government should be "reprivatized" to the "new, nongovernmental institutions that . . . sprang up and [grew]" during the twentieth century, *id.* at 17-18. In such a model, government would remain "the central, the top institution," but would only preside over the actual performance of social functions by private entities, like an orchestral "conductor." Though "reprivatization" in Drucker's mind is not a question of "ownership" in the literal sense of which organizations should own the relevant productive assets, he nevertheless saw "a special role [for] business . . . ." *Id.* at 17-23. Drucker's paper is strewn with anecdotal

any number of guru-esque management bestsellers[3] and advocacy-oriented government reports,[4] though it has an important antecedent in a policy begun in the Eisenhower Administration.[5]

In any event, this new literature largely considers "privatization" to be a legally formalistic phenomenon. It is accomplished by deliberate delegation of authority, in the form of some legal instrument (a government contract, a regulation, a statute, perhaps the creation of some free-standing nominally private entity, or some less formal policy instrument) by a formally constituted entity of traditional government.

On one hand, the instinct driving this large literature seems obviously correct. Incidences in which traditionally defined government acquires a good or service from nominally private sources occur in numbers and in ways that are fascinating and perhaps alarming (and perhaps occur more frequently now, as is generally claimed in the privatization literature), and they should be part of legal academic inquiries into the nature of contemporary governance. But the larger significance of those transactions probably is not very well captured in the literature because of its formalistic model and the assumption it implies of fundamental differences between "traditional government" and "private" entities. The problem with a formalistic approach is that the literature's ultimate goal is, or ought to be,

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claims in support of his argument about government failings, and about the managerial superiority of "private" or "autonomous" institutions, but beyond that he gives little actual proof other than his own opinions.

Of course, the deeper theme in Drucker's paper—that private trade and business associations serve the public interest better than government—was already a century old in 1969, however much he might imply that it was a new idea. Sanctification of private enterprise and aspirations for a private associative state go back at least to the mid-nineteenth century in the United States, and were dominant in public policy between the turn of the twentieth century and the New Deal. *See infra* note 64.

3. In recent times the best known of these was DAVID OSBORNE & TED GAEBLER, REINVENTING GOVERNMENT: HOW THE ENTREPRENEURIAL SPIRIT IS TRANSFORMING THE PUBLIC SECTOR (1992), a book that fueled a furor for privatization and making government more "business-like" throughout the last four presidential administrations.

4. Several of the best known reports were released during the Reagan Administration. *See generally* OFFICE OF MGMT. & BUDGET, ENHANCING GOVERNMENTAL PRODUCTIVITY THROUGH COMPETITION: A NEW WAY OF DOING BUSINESS WITHIN THE GOVERNMENT TO PROVIDE QUALITY GOVERNMENT AT LEAST COST (1988); PRESIDENT'S COMMISSION ON PRIVATIZATION, PRIVATIZATION: TOWARD MORE EFFECTIVE GOVERNMENT (1988).

5. *See* BUREAU OF THE BUDGET, BULLETIN 55-4 (1955) ("[T]he Federal Government will not start or carry on any commercial activity to provide a service or product for its own use if such product or service can be procured from private enterprise through ordinary business channels."). The policy is still in force, and is now contained in OFFICE OF MGMT. & BUDGET, CIRCULAR A-76: PERFORMANCE OF COMMERCIAL ACTIVITIES (2003). It has been the subject of no small controversy. The fact that "privatization" has this long lineage, which in some minds lends it legitimacy, has not been lost on recent administrations. *See, e.g.*, Letter from David H. Safavian, Administrator, Office of Mgmt. & Budget, to Richard B. Cheney, President of the Senate (Jan. 25, 2005), *available at* http://www.whitehouse.gov/omb/procurement/comp_src/fy2004_summary_rpt.pdf (reporting the status of the current President's "competitive sourcing" program, and noting that its origins lie in Eisenhower policy from 1955).

to understand social phenomena as they exist, and those phenomena are not necessarily well characterized by the law's own distinctions and definitions. In short, while the literature is content to study one comparatively small set of transactions in which entities of traditional "government" engage, the bulk of the important choices in our society are made by a whole *world* of institutions[6] that are not entities of traditionally constituted "government."[7] To try to understand it only by looking into legally formal delegations of particular functions leads to a narrow and metonymical picture of social governance, and seems also likely to produce shallow historiographical explanations.

This Article is accordingly an exercise akin to the "new institutionalism" in the social sciences of late, insofar as its basic critique is that the literature fails to model or try to understand the range of institutions that arrange social phenomena, as those institutions actually exist.[8] The literature

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6. For the most part I will use "institution" in a narrow sense, which may seem somewhat prosaic. I normally will use it to mean more or less formally organized associations of persons. I frequently will make reference to the very large range of more or less formal, more or less bureaucratic organizations in American society that have some power to engage in behavior that allocates social values. These entities include standard setting bodies, product design consortia, large corporations with respect to their personnel policies and large scale purchase and sales planning, law reform and policy advisory bodies, nominally "private" universities, non-profit corporations and unincorporated societies, churches, large voluntary social or professional organizations, and so on. I do this because the whole point of this Article is to show that not only is "privatization" not new or especially interesting, but for a long time American society has been virtually unique in the degree to which its important decisions have been in the hands of non-"government" bureaucracies. Thus, for the most part I will not much discuss other "institutions" that have influence in the arrangement of society, like custom or ethnicity. However, for an excellent critical review of the use of the term and its generally broader meaning in the social sciences, see Ronald L. Jepperson, *Insitutions, Institutional Effects, and Institutionalism*, *in* THE NEW INSTITUTIONALISM IN ORGANIZATIONAL ANALYSIS 143 (Walter W. Powell & Paul J. DiMaggio eds., 1991) [hereinafter THE NEW INSTITUTIONALISM]. In any case, this world of essentially formal governance institutions to which I make reference is explored in a substantial secondary literature. *See generally* SAMUEL N. KRISLOV, HOW NATIONS CHOOSE PRODUCT STANDARDS AND STANDARDS CHANGE NATIONS (1997); HARM SCHEPEL, THE CONSTITUTION OF PRIVATE GOVERNANCE (2005); Christopher L. Sagers, *Antitrust Immunity and Standard Setting Organizations: A Case Study in the Public-Private Distinction*, 25 CARDOZO L. REV. 1393, 1398-1402 (2004) [hereinafter Sagers, *Case Study*] (discussing the prevalence and influence of a class of nominally private regulatory entities known as "standard setting organizations"); Christopher L. Sagers, *The Legal Structure of American Freedom and the Provenance of the Antitrust Immunities*, 2002 UTAH L. REV. 927, 951-57 [hereinafter Sagers, *Legal Structure*] (discussing means by which nominally private entities can allocate social values in ways indistinguishable from "government").

7. A difficult problem in this Article is the awkwardness of referring to entities that are "public" or "governmental," and those that are "private" or "non-governmental," since a major purpose is to show that distinctions between these terms are illusions and distractions from meaningful social inquiry. Thus, this Article uses terms such as "traditional government" or "nominally private" or the like, which indicate only the everyday meaning given such terms in legal discourse. The terms have no value for my purposes as descriptions of actual sociological reality, but only as descriptions of how people commonly think of that reality.

8. A very good summary of which is in Walter W. Powell & Paul J. DiMaggio, *Introduction*, *in* THE NEW INSTITUTIONALISM, *supra* note 6, at 1.

concerns itself almost exclusively with a narrow class of formal transactions and the discrete doctrinal problems they are thought to pose. These are the sorts of problems that other social sciences have overcome (or at least recognized and attempted to address).[9]

This Article aspires to a few discrete goals. First, it will show that the concept of "privatization" and the public-private divide on which it is based are not meaningful and cannot guide academic inquiry. Importantly, this argument is not simply about academic method. The public-private distinction plays an important legitimating role in society and its use not only frustrates academic inquiry, it also conceals prevalent and very significant maldistributions of power. In any case, as will be explained at length below, deconstructing this distinction in this context will require two steps. First, the distinction as a jurisprudential proposition—a claim that the public and private sectors can be meaningfully conceptualized and distinguished—must be taken apart and seen for what it is: a normative commitment or aspiration that lacks moral or sociological content and tends to disguise disparities in freedom and power. But the distinction as it appears in the privatization literature also implies an economic argument: Provision of services in "markets"—that is, services provided under the pressures and incentives thought to characterize the "private" sector—will be quite different than functions performed by government. This argument also turns out to be problematic.

As a second major goal, this Article will argue that without concepts of public and private to define itself, study of "privatization" can be seen as simply one aspect of a much larger body of work. This is so in two respects. On one hand, it turns out that a large and diverse range of scholarship in one way or another relates to the private doing seemingly public things and, therefore, even though no one may really think of it in this way, it really ought to be thought of as part of the same endeavor as "privatization." But a whole range of other work, going well back into the nineteenth century, happens to address the same broad issues of institutions of social control, even though it may be unconcerned with any discrete set

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9. This Article therefore also finds company among the so-called "realists" of the founding generation of modern political science, whose chief endeavor was to see beyond the legally formalistic distinctions in which the study of government had been bound. *See generally* David Easton, *Political Science*, *in* 12 INTERNATIONAL ENCYCLOPEDIA OF THE SOCIAL SCIENCES 282, 289-90 (David L. Sills ed., 1968) (describing the change from legally formalistic to more holistic subjects of research during the late nineteeth century); Martin Landau, *The Myth of Hyperfactualism in the Study of American Politics*, 83 POL. SCI. Q. 378, 380-82 (1968) (describing the "realists"). As Easton says, a key development in this transition in political science was to insist "upon the need to abandon the habit of attributing causation to ideas and legal norms . . . ." Easton, *supra*, at 290.

of government transactions. Finally and most importantly, this Article concludes with a proposal for the sociological imagery with which the range of social control institutions might be better understood.

I. THE EXISTING "PRIVATIZATION" LITERATURE AND CERTAIN PRELIMINARY PROBLEMS

Perhaps the great scholarly interest in "privatization" reflects the recent zeal for it by politicians of all persuasions.[10] For instance, President George W. Bush began his first administration by promising no less than "[t]o . . . rethink [all of] government,"[11] and proposed privatization as a major tool for it.[12] No doubt scholarly concern also reflects the fairly brazen nature of some privatizing arrangements. We now have for-profit prisons whose owners are publicly traded corporations, and for-profit armies whose employees patrol, secure, interrogate, and kill foreign citizens, all while wearing U.S. deputy stars. Of all things, we came close to scrapping the National Weather Service in favor of a wholly private, for-profit system of weather information.[13] On its surface, in other words, the landscape of governance by nominally private institutions is gripping as much for those entities' power and ubiquity as for the fact that, to most Americans, they are all but invisible.

Most academics seem to think this "privatization" is happening much more than it once did. Many are fairly alarmed by it, though quite a few think that with appropriate corrections in policy or legal doctrine it can be harnessed as a force for good, and one that is well suited to our assertedly New Economy. Above all, virtually everyone seems convinced that it is *new* and that it is *very important*.

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10. "Privatization" agendas are hardly unpartisan, as they are often thought to be. *See infra* note 93 and accompanying text.

11. OFFICE OF MGMT. & BUDGET, THE PRESIDENT'S MANAGEMENT AGENDA FISCAL YEAR 2002, at 3 (2001) [hereinafter "BUSH MANAGEMENT AGENDA"].

12. He said it could help government harness the power of "innovation through competition." *Id.* at 4. Indeed, with a somehow endearing gumption the President explained that all of federal government reform could be "guided" by only "three principles"—that "Government should be: citizen-centered, not bureaucracy-centered; results-oriented; [and] market-based, actively promoting rather than stifling innovation through competition." *Id.*

13. In 2005, Senator Santorum of Pennsylvania introduced a bill that, while it would have preserved the Service, would have prohibited it from providing any information in competition with commercial information providers. *See* National Weather Services Duties Act of 2005, S. 786, 109th Cong. § 2 (2005); Maeve Reston, *Santorum Criticizes Weather Service, Has Sponsored Bill to Prevent Government Weather Notices, to Benefit Private Companies, Including Donor*, PITTSBURGH POST-GAZETTE, Sept. 10, 2005, at A6, *available at* http://www.post-gazette.com/pg/05253/569133.stm. Critics noted that a significant Santorum campaign contributor was a private weather information provider, and that still it would be taxpayer dollars generating weather information that would then become the sole re-saleable property of private companies. *Id.*

A. The Literature as It Exists

The resulting literature now includes a huge number of law journal articles,[14] quite a few of which are very long,[15] as well as an unusual number of law journal symposia[16] and many books.[17] Whether or not "privatization" is new, this literature to a large extent truly is—much of it dates from no earlier than 1990, and a surge of it began in about 2000,

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14. For a survey of which, see *infra* notes 22-41 and accompanying text. While by its nature this Article, for better or worse, must indulge in a certain sin—really long string-cite footnotes—it will make no attempt to list *all* the articles that have appeared, an effort that could itself consume a short law review article. Suffice it to say that there have been a *lot.* Online database searches identify several thousand articles that use the words "privatize" or "privatization" and more than 600 that contain these words in their titles.

15. Several of the leading articles in the area are in excess of 100 pages, for example, Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543 (2000) (132 pages); Gillian E. Metzger, *Privatization as Delegation*, 103 COLUM. L. REV. 1367 (2003) (135 pages); and many of them are more than fifty pages.

16. *See* Symposium, *Public Values in an Era of Privatization*, 116 HARV. L. REV. 1211 (2003); Sidney A. Shapiro, *Outsourcing Government Regulation*, 53 DUKE L.J. 389 (2003) (exploring the economics of privatization for government agencies); Symposium, *New Forms of Governance: Ceding Public Power to Private Actors*, 49 UCLA L. REV. 1687 (2002) (explaining the need for a reconceptualization of administrative law due to globalization); Symposium, *Redefining the Public Sector: Accountability and Democracy in the Era of Privatization*, 28 FORDHAM URB. L.J. 1307 (2001) (exploring the means by which government should fulfill its functions effectively and efficiently); Agnes P. Dover, *Single Subject Issue, Privatization and Outsourcing*, 30 PUB. CONTRACT L.J. 551 (2001); Jody Freeman, *Private Parties, Public Functions, and the New Administative Law*, 52 ADMIN. L. REV. 813 (2000) [hereinafter Freeman, *New Administrative Law*] (exploring the new direction of administrative law in the face of privatization); Symposium, *Constitutionalism, Privatization, and Globalization*, 21 CARDOZO L. REV. 1063 (2000) (describing the effects of privatization in a globalized world); Project, *Privatization: The Global Scale-Back of Government Involvement in National Economics*, 48 ADMIN. L. REV. 435 (1996) (surveying privatization efforts around the globe); Symposium, *Comparative Models of Privatization: Paradigms and Politics*, 21 BROOK. J. INT'L L. 1 (1995); Ronald A. Cass, *Privatization: Politics, Law and Theory*, 71 MARQ. L. REV. 449 (1988) (exploring the possible challenges and benefits of privatization); *see also* Symposium, *Association of American Law Schools: Private Parties as Defendants in Civil Rights Litigation*, 26 CARDOZO L. REV. 1 (2004) (describing the need to address civil rights violations by private entities in the post-September 11th world).

17. *See, e.g.*, BRUCE L. BENSON, TO SERVE AND PROTECT: PRIVATIZATION AND COMMUNITY IN CRIMINAL JUSTICE (1998) (discussing privatization of prisons); TIMOTHY BESLEY & MAITREESH GHATAK, PUBLIC-PRIVATE PARTNERSHIPS FOR THE PROVISION OF PUBLIC GOODS: THEORY AND AN APPLICATION TO NGOS (1999); PIERRE GUISLAIN, THE PRIVATIZATION CHALLENGE: A STRATEGIC, LEGAL AND INSTITUTIONAL ANALYSIS OF INTERNATIONAL EXPERIENCE (1997); JEROLD S. KAYDEN, PRIVATELY OWNED PUBLIC SPACE: THE NEW YORK CITY EXPERIENCE (2000) (exploring the history of privately owned public space in New York City); MARKET-BASED GOVERNANCE: SUPPLY-SIDE, DEMAND-SIDE, UPSIDE AND DOWNSIDE (John D. Donahue & Joseph S. Nye, Jr. eds., 2002) (focusing on accountability as a method of maintaining good governance); MARTHA MINOW, PARTNERS, NOT RIVALS: PRIVATIZATION AND THE PUBLIC GOOD (2002) (discussing the phenomenon of public money funding private entities, such as private schools); OSBORNE & GAEBLER, *supra* note 3 (exploring the need to reinvent government by focusing on the specific causes of poor governance); ELLIOTT D. SCLAR, YOU DON'T ALWAYS GET WHAT YOU PAY FOR: THE ECONOMICS OF PRIVATIZATION (2000); THE PROVINCE OF ADMINISTRATIVE LAW (Michael Taggart ed., 1997) (discussing privatization as a result of worldwide export of economic liberalism).

perhaps in response to campaign rhetoric of that year.[18] This literature extends throughout a variety of social science fields, and it is especially voluminous in law. It is useful for its collection of a large amount of sociological raw data—namely, a large collection of individual instances of conscious choices by government entities to provide some good or service through a non-government entity. The literature is mostly subject-matter specific. That is, each individual book or article normally focuses on the conscious government choice to perform some specific function through a nominally private entity. Much of the work has focused on contracting out welfare and other social services,[19] health care,[20] law enforcement and corrections,[21] military functions,[22] and sometimes seemingly more

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18. Of the law journal articles identified in online database searches, see *supra* note 16, nearly 200 have appeared since 2000, and nearly all have appeared since 1990. A large number of books have also appeared in that time. *See, e.g.*, *supra* note 17.

19. *See, e.g.*, Matthew Diller, *Form and Substance in the Privatization of Poverty Programs*, 49 UCLA L. REV. 1739 (2002) (exploring private, faith-based initiatives that replace public welfare programs); Marsha B. Freeman, *Privatization of Child Protective Services: Getting the Lion Back in the Cage?*, 41 FAM. CT. REV. 449 (2003); Michelle Estrin Gilman, *Legal Accountability in an Era of Privatized Welfare*, 89 CAL. L. REV. 569 (2001) (explaining how privatization of some aspects of welfare created accountability on the part of its recipients); Kathryn L. Moore, *The Effects of Partial Privatization of Social Security Upon Private Pensions*, 58 WASH. & LEE L. REV. 1255 (2001) (exploring the effect of partial privatization of the social security system on private pensions); Dru Stevenson, *Privatization of Welfare Services: Delegation by Commercial Contract*, 45 ARIZ. L. REV. 83 (2003) (discussing the discretion given to each agency to decide which services will be privatized and why); Luke Andrew Steven Demaree, Note, "*Tiny Little Shoes:" The Privatization of Child Welfare Services in Kansas*, 69 U. MO. KAN. CITY L. REV. 643 (2001) (summarizing the effect of privatization of child welfare services on the quality of that service).

20. *See, e.g.*, Sarah S. Bachman, *Why Do States Privatize Mental Health Services? Six State Experiences*, 21 J. HEALTH POL. POL'Y & L. 807 (1996); David M. Frankford, *Privatizing Health Care: Economic Magic to Cure Legal Medicine*, 66 CAL. L. REV. 1 (1992) (proposing that it is not useful to assess legal regulation of health care through a model of market competition); Jill R. Horwitz, *Why We Need the Independent Sector: The Behavior, Law, and Ethics of Not-for-Profit Hospitals*, 50 UCLA L. REV. 1345 (2003) (discussing the role of non-profit hospitals in providing services required by law and morality); Ronald L. Wisor, Jr., *Community Care, Competition and Coercion: A Legal Perspective on Privatized Mental Health Care*, 19 AM. J. L. & MED. 145 (1993) (exploring the possibility of privatization of mental health care providing better health care at a lower cost with a legal system that holds patient autonomy in high regard).

21. *See, e.g.*, BENSON, *supra* note 17; JOHN D. DONAHUE, THE PRIVATIZATION DECISION: PUBLIC ENDS, PRIVATE MEANS 150-78 (1989) (taking prison privatization as a case study); Alfred C. Aman, *Privatization, Prisons, Democracy and Human Rights: The Need to Extend the Province of Administrative Law*, 12 IND. J. GLOBAL LEG. STUD. 511 (2005) (addressing how administrative law in the United States can be used to correct human rights violations that arise from privatization, especially in the prison context); David Del Fiandra, Comment, *The Growth of Prison Privatization and the Threat Posed by 42 U.S.C. § 1983*, 38 DUQ. L. REV. 591 (2000) (exploring the effect of § 1983 on the expansion of privatized prisons); Dan M. Kahan, *Privatizing Criminal Law: Strategies for Private Norm Enforcement in the Inner City*, 46 UCLA L. REV. 1859 (1999) ("[P]rivatization . . . is essential to the future effectiveness of criminal law in our most crime-ridden communities, where it's clear that the state has neither an authoritative moral voice nor a monopoly on force, legitimate or otherwise."); Clifford J. Rosky, *Force, Inc.: The Privatization of Punishment, Policing, and Military Force in Liberal States*, 36 CONN. L. REV. 879 (2004). Mark N. Ohrenberger, Note,

mundane functions.[23] Some privatization writers have been especially concerned about private performance of seemingly inherent government functions, such as adjudication[24] and policymaking, whether through

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Prison Privatization and the Development of "Good Faith" Defense for Private-Party Defendants to 42 U.S.C. § 1983 Actions, 13 WM. & MARY BILL RTS. J. 1009 (2005) (advocating a good faith defense to § 1983 actions).

22. *See, e.g.*, Jon D. Michaels, *Beyond Accountability: The Constitutional, Democratic, and Strategic Problems with Privatizing War*, 82 WASH. U. L. Q. 1001 (2005); Steven L. Schooner, *Contractor Atrocities at Abu Ghraib: Compromised Accountability in a Streamlined, Outsourced Government*, 16 STAN. L. & POL'Y REV. 549 (2005) (discussing the effect of the Abu Ghraib scandal on the success of privatization); P. W. Singer, *War, Profits and the Vacuum of Law: Privatized Military Firms and International Law*, 42 COLUM. J. TRANSNAT'L L. 521 (2004) (exploring the effect of privatized military firms on the way the United States conducts war); Nathaniel Stinnett, Note, *Regulating the Privatization of War: How to Stop Private Military Firms From Committing Human Rights Abuses*, 28 B.C. INT'L & COMP. L. REV. 211 (2005) (noting that the goal of privatizing military functions is to respond to the demand for temporary, highly-specialized military services).

23. *See, e.g.*, KAYDEN, *supra* note 17; Dan Kramer, *How Airport Noise and Airport Privatization Effect* [sic] *Economic Development in Communities Surrounding U.S. Airports*, 31 TRANSP. L.J. 213 (2004); Darrell A. Fruth, Note, *Economic and Institutional Constraints on the Privatization of Government Information Technology Services*, 13 HARV. J. L. & TECH. 521 (2000). One interesting vein is an ongoing debate among military lawyers about privatizing military base housing and utilities. *See, e.g.*, Maj. Jeff A. Bovarnick, *Can a Commander Authorize Searches & Seizures in Privatized Housing Areas?*, 181 MIL. L. REV. 1 (2004); Philip D. Morrison, *State Property Tax Implications for Military Privatized Housing Program*, 56 AIR FORCE L. REV. 261 (2005); Jeffrey A. Renshaw, *Utility Privatization in the Military Services: Issues, Problems and Potential Solutions*, 53 AIR FORCE L. REV. 55 (2002); Stacie A. Remie Vest, *Military Housing Privatization Initiative: A Guidance Document for Wading Through the Legal Morass*, 53 AIR FORCE L. REV. 1 (2002). To say that these matters *seem* mundane definitely does not mean that they are. Often the very obscurity of particular policies renders them doubly pernicious. Privatization as a proposed solution to shortages of water for human use, for example, is a matter that many authors see as a looming global crisis. Of special recent concern have been fears that corporate entities, if entrusted with water distribution, would have incentives at odds with the public good and in particular would disserve the needs of third-world populations, a debate that largely began with the privatized water experiment of the government Chile in the 1980s. *See* CARL J. BAUER, AGAINST THE CURRENT: PRIVATIZATION, WATER MARKETS, AND THE STATE IN CHILE (1998). The Chilean experiment and other water privatization has been the subject of numerous legal works. *See, e.g.*, Craig Anthony (Tony) Arnold, *Privatization of Public Water Services: The States' Role in Assuring Public Accountability*, 32 PEPP. L. REV. 561 (2005); David J. Hayes, *Privatization and Control of U.S. Water Supplies*, 18 NAT. RES. & ENV. 19 (2003); Jennifer Naegele, *What Is Wrong With Full-Fledged Water Privatization?*, 6 J. L. & SOC. PROBS. 99 (2004); Robert Vitale, *Privatizing Water Systems: A Primer*, 24 FORD. INT'L L.J. 1382 (2001); Matthew S. Tisdale, Note, *The Price of Thirst: The Trend Towards the Privatization of Water and Its Effect on Private Water Rights*, 37 SUFFOLK U. L. REV. 535 (2004).

24. *See, e.g.*, Chris A. Carr & Michael R. Jencks, *The Privatization of Business and Commercial Dispute Resolution: A Misguided Policy Decision*, 88 KY. L. REV. 183 (2000); Christopher R. Drahozal, *Privatizing Civil Justice: Commercial Arbitration and the Civil Justice System*, 9 KAN. J. L. & PUB. POL'Y 578 (2000); Steven J. Eagle, *Privatizing Urban Land Use Regulation: The Problem of Consent*, 7 GEO. MASON L. REV. 905 (1999); Susan D. Franck, *The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing International Law Through Inconsistent Decisions*, 73 FORDHAM L. REV. 1521 (2005); Margaret L. Moses, *Privatized "Justice,"* 36 LOY. U. CHI. L. J. 535 (2005); Steven J. Ware, *Default Rules From Mandatory Rules: Privatizing Law Through Arbitration*, 83 MINN. L. REV. 703 (1999).

advisory consulting services,[25] drafting model codes,[26] or regulating directly through standard setting and certification.[27] Political trends also periodically focus attention on particular matters, like the privatization of Social Security[28] or education.[29] Finally, a number of articles have focused on special, doctrinal problems of privatized functions, like whether privately promulgated codes can be copyrighted,[30] whether private code-makers should enjoy antitrust immunity,[31] or whether delegates of public functions should be subject to open government statutes.[32]

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25. *See, e.g.*, DANIEL GUTTMAN & BARRY WILLNER, THE SHADOW GOVERNMENT (1976); Paul R. Verkuil, *The Nondelegable Duty to Govern* (Cardozo Legal Studies Research Paper No. 149, 2005), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=871455.

26. *See, e.g.*, Kathleen Patchel, *Interest Group Politics*, *Federalism, and the Uniform Laws Process: Some Lessons from the Uniform Commercial Code*, 78 MINN. L. REV. 83 (1983); Seven L. Schwarcz, *A Fundamental Inquiry Into the Statutory Rulemaking Process of Private Legislatures*, 29 GA. L. REV. 909 (1995); Robert E. Scott, *The Politics of Article 9*, 80 VA. L. REV. 1783 (1994); David V. Snyder, *Private Lawmaking*, 64 OHIO ST. L.J. 371 (2003).

27. Strictly speaking, people writing about standards and certification do not normally conceive their project as involving "privatization," and "privatization" scholars normally give little thought to standard setting. Presumably this is so because standard setting frequently occurs without any overt, de jure appointment by governments of standard setting bodies. In any case, the rise of private consortia and trade groups in high technology industries have fueled interest in this area, particularly in antitrust and intellectual property. Standard setting and its various problems are detailed extensively in two exceptionally thoughtful and comprehensive recent books: KRISLOV, *supra* note 6, and SCHEPEL, *supra* note 6.

28. *See, e.g.*, Patricia E. Dilley, *Taking Public Rights Private: The Rhetoric and Reality of Social Security Privatization*, 41 B.C. L. REV. 975 (2000); Richard L. Kaplan, *Enron, Pension Policy, and Social Security Privatization*, 46 ARIZ. L. REV. 53 (2004) (arguing that the Enron disaster helped derail attempts at Social Security privatization); Kathryn L. Moore, *Partial Privatization of Social Security: Assessing Its Effect on Women, Minorities, and Lower-Income Workers*, 65 MO. L. REV. 341 (2000). *See generally* Symposium, *Public Policy for Retirement Security in the 21st Century: Assuring the Future of Social Security: Privatization and Other Reforms*, 65 OHIO ST. L.J. 1 (2004).

29. *See* MINOW, *supra* note 17, at 1; Lewis D. Solomon, *Edison Schools and the Privatization of K-12 Public Education: A Legal and Policy Analysis*, 30 FORD. URB. L.J. 1281 (2003). *See generally* Symposium, *The Educational Divide: Gauging the Impact of Legal Challenges to School Vouchers and Parental Choice on America's Children*, 45 HOW. L.J. 247 (2001); David J. D'Agata, Comment, *School Privatization and Student Rights: A Comparison of Canadian and American Law Regarding Searches and Seizures Conducted in Privatized Schools*, 34 U. MIAMI INTER-AM. L. REV. 314 (2003) (explaining the legal implications of school privatization in the context of searches and seizures).

30. *See, e.g.*, Katie M. Colendich, *Who Owns "the Law"? The Effect on Copyrights When Privately-Authored Works Are Adopted or Incorporated by Reference Into Law*, 78 WASH. L. REV. 589 (2003); Shubha Ghosh, *Copyright as Privatization: The Case of Model Codes*, 78 TUL. L. REV. 653 (2004); Daniel J. Russell, Note, Veeck v. Southern Building Code Congress International, Inc.: *Invalidating the Copyright of Model Codes Upon Their Enactment into Law*, 5 TUL. J. TECH. & INT. PROP. 131 (2003).

31. *See* Sagers, *Case Study*, *supra* note 6.

32. *See, e.g.*, Craig D. Feiser, *Privatization and the Freedom of Information Act: An Analysis of Public Access to Private Entities Under Federal Law*, 52 FED. COMM. L.J. 21 (1999).

Most of this literature concerns privatizing policies of the United States federal and state governments. This is not really parochialism, because "privatization" in the United States is in some sense different than "privatization" in most of the rest of the world.[33] However, a subset of the literature takes a comparative approach[34] or focuses purely on privatizing in foreign regions.[35] Finally, not all work in this area is subject-specific. Some takes a more abstract, theoretical view,[36] though often the articles generalize mainly by collecting more than one subject-specific case study.[37]

While this literature is often as much journalistic as it is theoretical or constructive, it normally offers some suggestion for legislative or case law correction. Most of the policy-talk, oddly enough, begins with a presumption in favor of the status quo. Even the more careful analyses tend to take the current state of public-private relations—and even

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33. Namely, in most other places extensive state ownership of industry was common until at least the mid-twentieth century, and therefore "privatization" in most of the world literally means the transfer of state-owned *assets* to non-state entities. This obviously is the case in the former Soviet states, but is so even in Western Europe, a result of the early twentieth century success of socialist political programs, which only began to unravel in recent decades. In the United States, by contrast, government entities have almost never directly owned productive assets and have controlled significant industrial functions only in times of war. Therefore, "privatization" here can only mean the giving away of seemingly governmental *functions. See generally* DONAHUE, *supra* note 21, at 5-7.

34. *See, e.g.*, Kristen V. Campana, Comment, *Paying Our Own Way: The Privatization of the Chilean Social Security System and Its Lessons for American Reform*, 20 U. PA. J. INT'L ECON. L. 385 (1999).

35. *See, e.g.*, BESLEY & GHATAK, *supra* note 17; GUISLAIN, *supra* note 17; Bernard Black, Reinier Kraakman & Anna Tarassova, *Russian Privatization and Corporate Governance: What Went Wrong?*, 52 STAN. L. REV. 1731 (2000); Lisa Philips, *Taxing the Market Citizen: Fiscal Policy and Inequality in an Age of Privatization*, 63 J.L. & CONTEMP. PROBS. 111 (2000) (discussing "privatizing" effects and their impact on Canadian tax policy).

36. *See, e.g.*, DONAHUE, *supra* note 21, at 4; Harold I. Abramson, *A Fifth Branch of Government: The Private Regulators and Their Constitutionality*, 16 HASTINGS CONST. L.Q. 165, 167 (1989); Freeman, *New Administrative Law*, *supra* note 16, at 816 (urging that administrative law scholarship broaden its focus from delegation and agency legitimacy, which prevents those in the legal profession from appreciating the extent of private participation in governance and grappling with its implications for democracy); Dan Guttman, *Governance by Contract: Constitutional Visions; Time for Reflection and Choice*, 33 PUB. CONT. L.J. 321 (2004) [hereinafter Guttman, *Governance by Contract*]; Sheila S. Kennedy, *When Is Private Public? State Action in the Era of Privatization and Public-Private Partnerships*, 11 GEO. MASON U. CIV. RTS. L.J. 203 (2001) [hereinafter Kennedy, *Private Public?*]; Harold J. Krent, *Fragmenting the Unitary Executive: Congressional Delegations of Administrative Authority Outside the Federal Government*, 85 NW. U. L. REV. 62 (1990); Metzger, *supra* note 15; David Schneiderman, *Constitutional Approaches to Privatization: An Inquiry into the Magnitude of Neo-Liberal Constitutionalism*, LAW & CONTEMP. PROBS., Autumn 2000, at 83; Shapiro, *supra* note 16. *See generally* Symposium, *Constitutionalism, Privatization, and Globalization*, *supra* note 16. Some of these works, indeed, are extensive, highly abstract theoretical treatments, at least within particular areas. This is true especially of the outstanding work on private standard setting by Krislov and Schepel. *See* KRISLOV, *supra* note 6; SCHEPEL, *supra* note 6.

37. *See, e.g.*, Freeman, *supra* note 15, at 544-45; Chris Reeder, *Regulation by Contractors: Delegation of Legislative Power to Private Entities in Texas*, 5 TEX. TECH. J. TEX. ADMIN. L. 191 (2004).

perceived changes in the state of things, which sometimes are said to have produced "hybrid markets" or "hybrid public-private entities"—as pretty much satisfactory.[38]

B. Preliminary Problems Throughout the Literature

Several basic weaknesses affect this body of writing. They are important to this Article because they all in their own way contribute to the literature's fundamental problem, which is its assumption of a meaningful public-private divide. First, though it may seem to be a fairly superficial weakness, most of the large body of recent writing neglects prior work on non-state governance, going back at least to the 1920s.[39] Again, a purpose of this Article is to show the breadth of the issues raised by the very idea of "privatization" as an important focus of concern. For whatever reason, current literature has neglected much of the older material even though

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38. For example, Jody Freeman's large and influential output has gone farther than most in stressing that we must revise the way we currently see things—that we must understand the mechanisms of "governance" to comprise both public and private players. From that point on, however, her work seems to comprise mainly an optimistic defense of the status quo, along with a curious affinity for taking the middle way in all matters of doctrinal controversy that the status quo might pose. Her habit of presenting this as a matter of seemingly neutral, practical policy conceals what is in effect quite a conservative perspective. *See, e.g.*, Freeman, *New Administrative Law*, *supra* note 16, at 819 ("How and under what conditions we ought to constrain private actors depends . . . on the advantages they offer and the threats they pose . . . ."). Likewise, Alfred Aman believes the world to be so radically different than commonly perceived that an essentially new administrative law is required, which would be appropriate to the "complex nature of the hybrid markets that privatized governmental services create." Alfred C. Aman, Jr., *Privatization and the Democracy Problem in Globalization: Making Markets More Accountable Through Administrative Law*, 28 FORDHAM URB. L.J. 1477, 1500 (2001) [hereinafter Aman, *Democracy Problem*]. However, his work appears largely to argue that the primary policy matter of concern is how to make modest procedural and open-government rules apply to "hybrid" entities. *See, e.g.*, *id.*; Alfred C. Aman, Jr., *The Limits of Globalization and the Future of Administrative Law: From Government to Governance*, 8 IND. J. GLOBAL LEGAL STUD. 379 (2001).

39. *See, e.g.*, JOHN J. CORSON, BUSINESS IN THE HUMANE SOCIETY (1971); CLARENCE H. DANHOF, GOVERNMENT CONTRACTING AND TECHNOLOGICAL CHANGE (1968); GUTTMAN & WILLNER, *supra* note 25; JOHN D. HANRAHAN, GOVERNMENT BY CONTRACT (1983); DON K. PRICE, THE SCIENTIFIC ESTATE (1965); Robert L. Hale, *Law Making by Unofficial Minorities*, 20 COLUM. L. REV. 451 (1920); Kurt L. Hanslowe, *Regulation by Visible Public and Invisible Private Government*, 40 TEX. L. REV. 88 (1961); Louis L. Jaffe, *Law Making by Private Groups*, 51 HARV. L. REV. 201 (1937); Mark V. Nadel, *The Hidden Dimension of Public Policy: Private Governments and the Policy-Making Process*, 37 J. POL. 2 (1975). The United States government itself also has maintained a lively interest in these matters for several decades. Notably, the Government Accountability Office (GAO) (formerly the General Accounting Office) has issued reams of widely read reports over a long period, often quite cautionary in tone. *See, e.g.*, GENERAL ACCOUNTING OFFICE, CIVIL SERVANTS AND CONTRACT EMPLOYEES: WHO SHOULD DO WHAT FOR THE FEDERAL GOVERNMENT? (1981). Likewise, the Office of Management and Budget during the Kennedy Administration roundly criticized the influence of federal contractors in its influential "Bell Report," so named for that office's director of the time. *See* BUREAU OF THE BUDGET, REPORT TO THE PRESIDENT ON GOVERNMENT CONTRACTING FOR RESEARCH AND DEVELOPMENT (1962).

much of it is directly relevant. Interestingly, some of that prior work was to the effect that previous fetishes for privatization or making government more "business-like" were so much snake oil.[40]

Other weaknesses, moreover, seem more serious. To be fair, some of the problems to be discussed here are matters of jurisprudential first philosophy characteristic of much legal scholarship, in that the literature adopts the traditional model of the law professor as an uninvited amicus curiae.[41] They are nevertheless relevant because they help explain how the literature has misconceived its own subject matter.

As a consequence of the amicus model much of the work remains basically atheoretical, consisting mainly of extensive, more or less journalistic reporting on the wide range of arrangements said to "privatize" government functions. It often fails even to consider the plainest issues of *legal* theory raised by these arrangements (like whether there is a meaningful distinction between "public" and "private," or whether private ordering can be said to be meaningfully different from "law"), and it is not much given to social or political abstraction. Its main substantive contribution typically is to suggest some doctrinal correction to some existing legal rule that is relevant in some way, which assertedly will address the relevant concerns.[42] It assumes away the slim likelihood that

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40. *See, e.g.*, GUTTMAN & WILLNER, *supra* note 25; Charles T. Goodsell, *Reinvent Government or Rediscover It?*, 53 PUB. ADMIN. REV. 85 (1993) (reviewing DAVID OSBOURNE & TED GAEBLER, REINVENTING GOVERNMENT: HOW THE ENTREPRENEURIAL SPIRIT IS TRANSFORMING THE PUBLIC SECTOR (1992)); Jerry L. Mashaw, *Reinventing Government and Regulatory Reform: Studies in the Neglect and Abuse of Administrative Law*, 57 U. PITT. L. REV. 405 (1996).

41. To call this a problem has itself been the subject of hot debate, and it is an artifact of the unspecified means and ends of legal scholarship. Under these circumstances, it can be hard even to say what seems wrong with an existing body of work, and it can seem unfair to blame anyone for writing it in one way rather than another. I report with relief that I am not the only one who thinks these things, and one need consult neither radicals nor skeptics to find agreement on them. *See, e.g.*, Deborah L. Rhode, *Legal Scholarship*, 115 HARV. L. REV. 1327, 1330 (2002) ("The legal profession has no shared vision of what kinds of scholarship are most valuable or even most valued by the academy. . . . Any adequate assessment of the state of legal scholarship needs some working definition of its mission.").

42. Frequent topics include how and whether nominally private entities should be made subject to civil rights obligations. *See, e.g.*, Abramson, *supra* note 36; Kennedy, *Private Public?*, *supra* note 36; Paul Howard Morris, Note, *The Impact of Constitutional Liability on the Privatization Movement After* Richardson v. McNight, 52 VAND. L. REV. 489 (1999). The non-delegation rule is another frequent topic. *See, e.g.*, Krent, *supra* note 36; Metzger, *supra* note 15. The amicus model also provides some judicially manageable distinction between "public" and "private." *See, e.g.*, Metzger, *supra* note 15, at 1388-89. Again, this is not to say that contributions of legal theory have somehow been necessarily *bad*. Metzger's and Krent's papers on the non-delegation rule, for example, both seem very thoughtful and interesting. The problem is that they ask *only* those narrow questions of doctrinal theory, and do not inquire any further into the rich field of social and jurisprudential theory posed by "privatization." Admittedly, some doctrinal contributions have been more expansive. Alfred Aman probably has gone farther than anyone, urging disposal of "state-centered notion[s] of . . . public law," in favor of a "non-state focused approach to procedure" that would in effect "privatize the Administrative Procedure Act."

this advice will be welcomed by its intended recipients,[43] and for that matter the complex and problematic question whether, even if courts were to take any advice, changes in the rules they apply would have any effect on larger social phenomena. Even the most general, theoretically informed inquiries often merely offer practical advice to policymakers,[44] and sometimes the work really suggests no solutions or theoretical observations at all.[45]

Aman, *Democracy Problem*, *supra* note 38, at 1500. Aman so desires because "[w]here powerful institutions control important aspects of individuals' lives, there should be a legal commitment to a level of process necessary to assure transparency in the decision-making process regardless of the label we place on the entities involved." *Id.* Much of his background discussion is very interesting; in particular, his suggestion that "market democracy" may be sufficient assurance of "transparency" in many private arrangements, and his technical corrections to public contracting (which essentially would re-model contracting-out decisions as something quite seperate from contracts) are very thoughtful and commendable. But again, notice that although he does not say so explicitly, Aman's argument in effect boils down entirely to a purportedly more appropriate determination of whether a particular entity should be treated in the same way that government is treated, or whether, under the circumstances, it should not be. For reasons of political expediency he suggests this be done by a new federal statute modeled on the APA, rather than through case law. His primary suggestion is merely a doctrinal tweak to the public-private distinction. *See id.* at 1501.

43. The courts are unlikely to take direction on these matters from academic books and law review articles. As to the public-private distinction, for example, their approach is one of rigid and knee-jerking formality, and they have been using it for a long time with only rare deviation. They do so notably in applying the "state action" rule in civil rights cases. *See, e.g.*, NCAA v. Tarkanian, 488 U.S. 179 (1988); Flagg Bros., Inc. v. Brooks, Inc., 436 U.S. 149 (1978). *See generally* LAURENCE H. TRIBE, AMERICAN CONSTITUTIONAL LAW 1698-1703 (2d ed. 1988) (describing contemporary state action case law as the search for a distinction between "government" and "private" actors, and ultimately as the search for a "rule subject to constitutional scrutiny [that can] be restated at the decisionmaking level at which a government actor is responsible for its formulation"). Another notable area in which the distinction is applied very rigidly is in antitrust immunity for political conduct. *See, e.g.*, Mass. School of Law at Andover v. Am. Bar Ass'n, 107 F.3d 1026, 1036 (3d Cir. 1997) (holding the American Bar Association (ABA) immune from antitrust liability for its law school accreditation activities, on the theory that the "private" ABA had done no more than submit its opinion of plaintiff law school to state governments). Courts sometimes employ the distinction in areas like Establishment Clause cases. *See, e.g.*, Good News Club v. Milford Cent. Sch., 533 U.S. 98, 115 (2001) (asking whether in-school religious conduct violates the First Amendment by asking whether it was genuinely the conduct of the public school defendants). Most obviously for present purposes the courts have applied the public-private distinction in cases alleging unconstitutional delegations of regulatory power to private parties. *See* Krent, *supra* note 36, at 69 n.17. The exception that proves the rule is virtually an orphan in the Supreme Court's jurisprudence and is more than fifty years old. *See* Shelley v. Kraemer, 334 U.S. 1 (1948). The courts are abetted in this rigidity by the advice of many legal thinkers that the autonomy and "private" status of non-government associations is important to protecting individual liberty and constraining government abuses. *See, e.g.*, Roderick M. Hills, Jr., *The Constitutional Rights of Private Governments*, 78 N.Y.U. L. REV. 144 (2003); Robert K. Vischer, *The Good, the Bad and the Ugly: Rethinking the Value of Associations*, 79 NOTRE DAME L. REV. 949 (2004).

44. *See, e.g.*, DONAHUE, *supra* note 21 (offering transaction cost-based guidance as to which "public" functions can safely be contracted out and which should be retained in government control); Aman, *Democracy Problem*, *supra* note 38 (urging a revised conception of administrative law designed to cope with "hybrid" public-private governance entities).

45. For example, Professor Minow argues that healthy apportionment of public and

Yet more serious are certain philosophical precommitments generally shared in this literature. First, the literature states or implies a strong presumption of relatively stable definitional boundaries, and thus shares a metaphysical realism about legal institutions. Law deploys generalizations whose extensionality is thought to be meaningful and metaphysically "real"—in short, law *is* distinctions—and the privatization literature takes for granted that the distinctions are not subject to radical deficiencies of epistemology or metaphysics. Thus, it is presumed, things are *different*, in ways we can identify with confidence, and important policy consequences can be made to depend on the differences. Accordingly, the literature remains uncritically hung up on purely formal, conceptual distinctions between juridical entities, which assertedly exist and are assertedly distinct from one another.

Second, the literature systematically exaggerates (or at least leaves unexamined) the significance of legal doctrine itself. The over-emphasis seems based neither on any practical evidence nor on any serious theoretical examination, but rather it reflects a shared socialization among law school graduates. By our traditional approach to questions of policy, in which all lawyers are trained, we assume that law in application necessarily bears a close relationship to the social phenomena it purports to regulate. We should recall that we are also mostly socialized to identify law in the manner of the Holmesian "bad man"—that is, we perceive legal doctrine as a prediction of the future behavior of the particular appendage of government that is the courts.[46] Accordingly, our basic approach to policy is to assume that the behavior of the courts correlates closely with the social phenomena in question, but that assumption is rash.[47] Its relevance

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private roles can only be reached through public debate, performed according to a list of the proper values, which she specifies. This is essentially her only proposal. *See* MINOW, *supra* note 17, at 45-46.

46. *See* O. W. Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 459, 461 (1897) ("If you want to know the law and nothing else, you must look at it as a bad man . . . . [Under that perspective, the 'law' is] [t]he prophecies of what the courts will do in fact, and nothing more pretentious . . . ."). Because Holmes' "bad man" has been the subject of much discussion, see, e.g., Frederick Schauer, *Prediction and Particularity*, 78 B. U. L. REV. 773, 773 n.2 (1998) (collecting and discussing perspectives and critiques), let me be clear that what I mean by the "bad man" model is that law is nothing more than a prediction of the future behavior of a particular institution.

47. The character of the relationship is an empirical question, and indeed, a body of modern jurisprudence indicates that there is no strong relationship. Famously both law and economics and critical legal studies are said to share with a common predecessor, legal realism, a skepticism about the real significance of legal doctrine. In particular the Coase-ean tradition in law and economics and also much of the private ordering literature are to the effect that legal rules are often secondary at best to results actually observed in practice. Moreover, while the question remains one of untested empiricism, the astonishing infrequency of actual litigation in contemporary America must attenuate this relation even further. *Cf.* Marc Galanter, *The Vanishing Trial: An Examination of Trials and Related Matters in Federal and State Courts*, 1 J. EMPIRICAL LEG. STUD. 459 (2004) (documenting the decline in the number of cases that are resolved in court).

to this Article is that legally formal delegations to "private" entities and the issues of administrative and constitutional law they seem to raise seem significant only because the range of quite formal, bureaucratized social management functions already long in the hands of "private" entities—which dwarfs those recently "privatized"—is invisible if one looks for policy problems only in the positive "law." Thus, what makes more sense as a broad sociological analysis of institutions has remained narrowed in focus on the particular behavior of American bureaucrats over just the past several years.

Perhaps a resulting problem is that much of the privatization literature seems to have a poor grasp of its own historical background. As suggested at several points already, the legally formalistic definition of "privatization" normally excludes a significant range of social phenomena that are not substantively distinct from the government relationships under review. It also causes most writers to take for granted that "privatization" has become much more frequent in just the past several years.[48] Even the most thorough analyses, even when they acknowledge prior instances of conscious government delegation, typically claim that "privatization" as it now exists really began sometime around the advent of Thatcherism and was transported here only during the Reagan Administration.[49]

This raises several problems. First, even on the narrow definition of "privatization," it is false. Instances of privatization in the United States are not only old,[50] but have occurred in profusion for a long time.[51]

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48. Incidentally, with a disappointing predictability, the literature often explicitly or implicitly associates this "new" privatization with the "new" economy of the internet, globalized commerce, mass communications, and so on, with the underlying claim often being that privatization is a natural or at least inevitable thing, because traditional government neither can nor should perform all the complex social ordering that is now required. A certain cautionary history surrounds this sort of thing. *See, e.g.*, CHARLES P. KINDLEBERGER, MANIAS, PANICS AND CRASHES (4th ed. 2000); CHARLES MACKAY, EXTRAORDINARY POPULAR DELUSIONS AND THE MADNESS OF CROWDS (1841). Probably "privatization" authors should be more careful about leaping from the apparent affinity with high technology to the conclusion of novelty, especially in light of the recent cottage industry in professional critique of New Economy eschatology. *See, e.g.*, JEAN GADREY, NEW ECONOMY, NEW MYTH 3 (2003); Robert J. Gordon, *Does the "New Economy" Measure Up to the Great Inventions of the Past?*, 14 J. ECON. PERSP. 9 (2000) (downplaying the relative importance of recent technological advances).

49. *See, e.g.*, DONAHUE, *supra* note 21, at 4-6.

50. *See* HANRAHAN, *supra* note 39, at 79-80 (discussing military contracting at the time of the Revolutionary War); DONALD F. KETTL, SHARING POWER: PUBLIC GOVERNANCE AND PRIVATE MARKETS 6-7 (discussing the early growth of United States contracting practices).

51. *See* Guttman, *Governance by Contract*, *supra* note 36, at 322-23 & n.1. Even if it made sense to focus only on formal, conscious acts of government delegation, the existing literature's account of it is not very good, for that kind of "contracting out" was hugely employed by the federal government for four decades prior to the Reagan Administration. The United States military began a tradition of reliance on nominally private research entities and "management" consultants starting at about the time of World War II. This tradition expanded quite dramatically throughout the Great Society years, and resulted in the expenditure of billions of dollars, throughout the 1960s, through an agency within the

Elsewhere, private service of nominally public ends has occurred extensively and for many centuries.[52] The narrow account is also misleading to the extent it suggests that United States governments once managed some much larger range of social functions than they now do. On the contrary, Americans have long left much more to the private sector than other Western nations,[53] and prior to the 1960s American governments regulated much less of society than is now commonly perceived.[54]

It appears that a key piece of the evidence for "newness," whether explicitly acknowledged or not, has been that politicians talk about privatization, claim they have accomplished it, and congratulate themselves for it a *lot.* But political rhetoric must be among the most misleading hearsay, and in this particular case it has been very bad evidence of reality. For one thing, prevailing rhetoric has caused privatizing to be commonly thought of as a conservative policy, but that is not the case.[55] Also quite

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Department of Health, Education and Welfare called the Office of Economic Opportunity. *See* GUTTMAN & WILLNER, *supra* note 25.

52. A large body of literature shows how many pre nation-state princes relied upon nominally private entities for undertakings large and small. *See* Guttman, *Governance by Contract*, *supra* note 36, at 322 n.1; Franklin G. Snyder, *Sharing Sovereignty: Non-State Associations and the Limits of State Power*, 54 AM. U. L. REV. 365 (2004).

53. Americans regularly carry out an unusual range of important social functions through nominally non-state associations. Tocqueville famously observed that:

> Americans of all ages, all stations in life, and all types of disposition are forever forming associations . . . [They are] of a thousand different types—religious, moral, serious, futile, very general and very limited, immensely large and very minute. . . . In every case, at the head of any new undertaking, where in France you would find the government or in England some territorial magnate, in the United States you are sure to find an association.

ALEXIS DE TOCQUEVILLE, DEMOCRACY IN AMERICA 513 (J.P. Mayer ed., George Lawrence trans., Doubleday Anchor Books 1969) (1839). Indeed a number of these privately organized functions render the United States virtually unique in the industrialized world. For example, the United States is the only industrialized nation other than South Africa to retain a wholly private system of health care, resulting in very high administrative costs that consume a significant slice of the nation's entire gross domestic product. The attempt to socialize some healthcare functions has been among the most intensely fought political battles of the twentieth century. *See generally* DONALD L. BARLETT & JAMES B. STEELE, CRITICAL CONDITION: HOW HEALTH CARE IN AMERICA BECAME BIG BUSINESS—AND BAD MEDICINE (2004). Likewise, major functions of U.S. monetary policy remain in the hands of nominally private entities, not necessarily because it was better to do it that way, but because political compromise was needed to create the Federal Reserve. The Reserve's powerful Federal Open Market Committee (FOMC) directs the government's efforts to control the money supply through purchase and sale of its own securities. Krent, *supra* note 36, at 85. The private members of the FOMC are elected by the boards of directors of the Federal Reserve Banks, which are themselves nominally private; though the Executive Branch has some hand in peopling the Federal Reserve system, it has no direct involvement in the appointment or removal of the FOMC's private members. *Id.* at 84-85 & n.66.

54. *See generally* Robert L. Rabin, *Federal Regulation in Historical Perspective*, 38 STAN. L. REV. 1189 (1986) (detailing the rise of the formal regulatory state in the United States in the twentieth century).

55. The much ballyhooed Clinton-Gore "Reinventing Government" initiative had much in common with both the current president's agenda and with proposals of the Reagan Commission on Privatization. *See* BARRY D. FRIEDMAN, REGULATION IN THE REAGAN-BUSH ERA: THE ERUPTION OF PRESIDENTIAL INFLUENCE 176-77 (1995) (noting the similarity of

misleading can be politicians' self-congratulation and their recriminations. For example, despite the fanfare of its promises and the fears it engendered, the Reagan Administration's privatization agenda was much less successful than is commonly thought,[56] and the Clinton Administration failed to acknowledge that much of the downsizing for which it took credit was an inevitable side-effect of the "peace dividend" that followed the end of the Cold War.[57] Finally, one might remember the general predilection of politicians for faddish policy trends—what Jerry Mashaw calls "the management fraternities' panaceas *du jour*."[58] Those fads often are most remarkable for the speed with which they are first idolatrized and then forgotten, and the recent fetish for "privatization" is driven by them. Their lack of rigor degrades the reliability of the politicians' talk that they inform.

So is there anything actually *new*, or at least unique, about "privatization" as the literature has defined it? Surely it is *real* in some sense. Tax revenues can be expended through various channels that differ from one another institutionally, and presumably those different payment streams produce outcomes that differ from one another in various qualities.[59] Also, it is "important" in some sense, in that on a superficial political level it makes sense for voters to care about how some particular public service is provided. Likewise, it seems that while politicians frequently exaggerate their own privatizing efforts, political actors do in fact sometimes modify the personnel and streams of payments by which

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Clinton's regulatory agenda to his predecessors', including their privatization efforts); Daniel Guttman, *Public Purpose and Private Service: The Twentieth Century Culture of Contracting Out and the Evolving Law of Diffused Sovereignty*, 52 ADMIN. L. REV. 859, 861 (2000) [hereinafter Guttman, *Public Purpose*] (noting that the various means offered by the Clinton-Gore initiative had long been in use by the federal government). Likewise, Jimmy Carter's antigovernment theme of the mid-1970s may have been less strident than Ronald Reagan's, but it was nevertheless central to his electoral success. *See* DONAHUE, *supra* note 21, at 3.

56. *See generally* COMPTROLLER GENERAL, REPORT TO THE CONGRESS: CIVIL SERVANTS AND CONTRACT EMPLOYEES: WHO SHOULD DO WHAT FOR THE FEDERAL GOVERNMENT? 26-28 (1981) (complaining that outsourcing efforts between 1955 and 1981 had been largely ineffective); KETTL, *supra* note 50, at 47-51. As Kettl notes, by far the bulk of the Office of Management and Budget (OMB) Circular A-76 cost comparisons actually carried out during the Reagan Administration occurred within the Department of Defense (DOD), which along with three other agencies accounted for 96% of all of the alleged "savings." *See id.* at 49. All federal agencies other than DOD, the General Services Administration, and the Departments of Transportation and Commerce—either performed very few A-76 cost comparisons or ignored the directive entirely. *See id.* at 48.

57. *See* Paul C. Light, *Outsourcing and the True Size of Government*, 33 PUB. CONT. L.J. 311, 312-13 (2004).

58. Mashaw, *supra* note 40, at 408.

59. Notable examples include the varying incentives of actors within those channels and the consequences of the resulting differences in agency costs and productive efficiencies. *See* DONAHUE, *supra* note 21, at 79-98, 215-23.

government treasury expenditures lead to policy outcomes. It may even be that instances of this behavior have become statistically more frequent, and certainly they are more talked about than they once were.

But does that mean anything has *really* changed? Is this evidence that the world is changing, or just its decor?

In any case, as one final problem, the literature's formalistic definition of its own topic and the resulting failure to appreciate the larger picture has kept it isolated from other schools of thought to which it has obvious theoretical affinities. For example, privatization authors seem uninterested in the recent vein on the governmental role of non-state voluntary associations[60] or the historical literature on American associationalism generally.[61] Likewise they have neglected the older but still-thriving tradition that concerns "private ordering,"[62] the critique of private property

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60. In the legal literature, most of this work is to the effect that private groups, like families, social clubs, and churches, perform a function of such purely *social* significance in society that they should be understood as essentially governmental or sovereign. Its thrust is that these groups are fundamental to individual freedom and actualization and therefore deserve special legal status. *See, e.g.*, Hills, *supra* note 43 (arguing that such organizations should have the right to govern their own members); Snyder, *supra* note 52, at 399; Vischer, *supra* note 43. Interestingly, neither the American "privatization" work nor the "voluntary associations" work in the law reviews appears to be aware of the strong relevance of the political theory of Jürgen Habermas, and the general significance of private associations in European thought. At least one work, however, has given the matter extensive thought. *See* SCHEPEL, *supra* note 6, at 11-21.

61. A large literature recounts the rise and influence of private associations in American history, meaning in particular trade and professional associations. *See, e.g.*, ELLIS W. HAWLEY, THE NEW DEAL AND THE PROBLEM OF MONOPOLY 1-71 (1966) (chronicling the rise of business associationalism at the turn of the twentieth century, which culminated in the National Industrial Recovery Act in 1933); ROBERT F. HIMMELBERG, THE ORIGINS OF THE NATIONAL RECOVERY ADMINISTRATION: BUSINESS, GOVERNMENT AND THE TRADE ASSOCIATION ISSUE, 1921-1933 (2d ed. 1993); JAMES WILLARD HURST, LAW AND THE CONDITIONS OF FREEDOM IN THE NINETEENTH-CENTURY UNITED STATES 84-88 (1956) (noting the dramatic increase in the formation and activities of private political and trade associations beginning in the 1860s, and arguing that the trend reflected growing concern over concentration of capital and political power in private hands; as Hurst says, "[t]heir development reflected pervasive unease and dissatisfaction with emerging patterns of power and the lack of defined policy toward emerging issues"); BRADFORD SMITH, A DANGEROUS FREEDOM (1963) (chronicling the history of American associationalism and the constitutional right of assembly); Ellis W. Hawley, *Herbert Hoover, the Commerce Secretariat, and the Vision of an "Associative State," 1921-1928*, 61 J. AM. HIST. 116 (1974).

62. Work on "private ordering" is diverse. It has its roots in part in Coase, as much of it concerns the arrangements people make with one another in the absence or in spite of law, see, for example, ROBERT C. ELLICKSON, ORDER WITHOUT LAW: HOW NEIGHBORS SETTLE DISPUTES (1991), but also reflects legal realist concern for the power of private influence. *See* Margaret Jane Radin & R. Polk Wagner, *The Myth of Private Ordering: Rediscovering Legal Realism in Cyberspace*, 73 CHI.-KENT L. REV. 1295, 1295-99 (1998). Interest in these matters remains lively. *See, e.g.*, Avitai Aviram, *Regulation by Networks*, 2003 BYU L. REV. 1179; Yochai Benkler, *An Unhurried View of Private Ordering in Information Transactions*, 53 VAND. L. REV. 2063 (2000); Lisa Bernstein, *Private Commercial Law in the Cotton Industry: Creating Cooperation Through Rules, Norms and Institutions*, 99 MICH. L. REV. 1724, 1725 (2001); Jonathan R. Macey, *Public and Private Ordering and the Production of Legitimate and Illegitimate Legal Rules*, 82 CORNELL L. REV. 1123 (1997);

and contract of the legal realists,[63] and the even older critique of public-private dichotomies on which the realists appear to have drawn.[64]

II. DECONSTRUCTING PUBLIC AND PRIVATE

Again, each of these preliminary problems, in their own way, contributes to a deeper problem—the assumption that there is a meaningful difference between the government bureaucracies from which functions are "privatized" and the private delegates that receive them. In other words, the very idea that there is "privatization" or that it is importantly different from other institutional arrangements implies a commitment to some fairly strong public-private distinction.[65]

Public-private dichotomies are very old, and the idea that there is some meaningful and administrable difference between public and private affairs, as a jurisprudential proposition, is central to liberal political philosophy.[66] They are also omnipresent and come in a variety of guises—we perceive separate public and private spheres relating to our personal and family lives, sexual morality, spiritual and civic affairs, economic activity, and no doubt many other areas. But as mentioned above, the two respects in which it is important to address the distinction here are in its role as a conceptual jurisprudential proposition and in its role as an economic argument—in which it assumes that markets are importantly different from government bureaucracies.

Barak D. Richman, *Firms, Courts, and Reputation Mechanisms: Towards a Positive Theory of Private Ordering*, 104 COLUM. L. REV. 2328 (2004); Steven L. Schwarcz, *Private Ordering*, 97 NW. U. L. REV. 319 (2002); Steven L. Schwarcz, *Private Ordering of Public Markets: The Rating Agency Paradox*, 2002 U. ILL. L. REV. 1, 1-2 (2002); Barak D. Richman, *Community Enforcement of Informal Contracts: Jewish Diamond Merchants in New York* (Harvard John M. Olin Center Discussion Paper No. 384, 2002), *available at* http://www.law.harvard.edu/programs/olin_center/papers/pdf/384.pdf. An interestingly similar perspective is discussed in Neel P. Parekh, *When Nice Guys Finish First: The Evolution of Cooperation, the Study of Law, and the Ordering of Legal Regimes*, 37 U. MICH. J. L. REFORM 909 (2004).

63. Examined at length in BARBARA FRIED, THE PROGRESSIVE ASSAULT ON LAISSEZ-FAIRE: ROBERT HALE AND THE FIRST LAW AND ECONOMICS MOVEMENT (2001). The realist critique seems germane because the very idea of a donation of functions by "government" to "private" entities poses a public-private distinction of which several realists spent whole careers dissecting.

64. See, for example, Neil Duxbury's work on Rodolf von Jhering and Jhering's possible influence on the realists. Neil Duxbury, *Jhering's Philosophy of Authority*, 27 OX. J. LEG. STUDIES (forthcoming 2007), *available at* http://ojls.oxfordjournals.org or http://www.law.manchester.ac.uk/aboutus/staff/neil_duxbury/default.htm (discussing Jhering's critique of the public-private distinction and the affinity of his views with those of various realists).

65. A related discussion, which develops some of these same issues in more detail and raises others not discussed here, appears in Chris Sagers, *Monism, Nominalism and Public-Private in the Work of Margaret Jane Radin*, 54 CLEV. ST. L. REV. 219, 225-30, 240-47 (2006).

66. *See generally id.* at 225-30 (discussing the history and political significance of the public-private distinction).

A. The Public-Private Distinction as a Proposition of Sociology or Positive Law

An obvious challenge for scholarship in this area is that the line-drawing problem of the public-private distinction must be addressed by some doctrinal means by any proposed policy correction to privatization problems. More sophisticated scholarly efforts normally acknowledge the distinction's difficulty,[67] as its use in the courts has been among the most criticized doctrinal issues in modern times.[68] However, in privatization and elsewhere, legal academics frequently go on to assert that it nevertheless can be handled through some second-best or heuristic alternative.[69] Some of these efforts seem surprisingly formal and uncritical,[70] and even more

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67. *See, e.g.*, MINOW, *supra* note 17, at 29 (the distinction is "notoriously complex"); Metzger, *supra* note 15, at 1400 ("Line-drawing [in this connection] is . . . very difficult."); Paul R. Verkuil, *Public Law Limitations on Privatization of Government Functions*, 84 N.C. L. REV. 397, 402-21 (2006) (discussing the distinction in history and theory).

68. Charles Black famously described the Supreme Court's "state action" jurisprudence as "a conceptual disaster area" that "has the flavor of a torchless search for a way out of a damp echoing cave," Charles L. Black, Jr., *The Supreme Court, 1966 Term—Foreward: "State Action," Equal Protection, and California's Proposition 14*, 81 HARV. L. REV. 69, 95 (1967), and even the doctrine's defenders believe that in application in the lower federal courts it has been something of a disaster. *See, e.g.*, Ronald J. Krotoszynski, Jr., *Back to the Briarpatch: An Argument in Favor of Constitutional Meta-Analysis in State Action Determinations*, 94 MICH. L. REV. 302, 321-34 (1995) (arguing that problems in the doctrine stem not from the Supreme Court's jurisprudence, but from formalistic application by lower courts of talismanic slogans rather than pragmatic case-by-case applications intended by the Supreme Court). For further discussion, including elaboration on the many, routine, daily situations in which the distinction proves grossly inadequate, see Sagers, *supra* note 65, at 242-47.

69. *See, e.g.*, Aman, *Democracy Problem*, *supra* note 38, at 1491 (noting that Aman "[r]efus[es] to treat the public/private distinction as an either/or discourse . . . [because] . . . [b]right lines between markets and regulation . . . are . . . neither necessary nor desirable"); Margaret Jane Radin, Machine Rule: The Latest Challenge to Law 2 (Jan. 31, 2005) (unpublished manuscript, on file with author).

> I am a pragmatist about the public/private distinction, meaning that in my view it is not a conceptual or formal distinction, an either/or that is easy to deconstruct, but rather a contextual characterization that tends to work in practice most of the time. Most of the time, that is, what is public and what is private has been capable of being sorted out in a way that is functionally understood, in spite of the difficult borderline cases.

Id.; *cf.* RICHARD RORTY, CONTINGENCY, IRONY AND SOLIDARITY 84-85, 198 (1989) (identifying the public-private split as a well-established "practical measure" to "distinguish public from private questions" and thereby to protect private institutions important to personal life); Frank Michelman, *Private Personal But Not Split: Radin versus Rorty*, 63 S. CAL. L. REV. 1783, 1783-84 (1990) (discussing Rorty's position). A fairly common insight is that, while the distinction has no judicially administrable *legal* meaning, it remains meaningful in understanding governance, and as a concept in political debate and decisionmaking. *See, e.g.*, MINOW, *supra* note 17, at 22-32. Occasionally, for various reasons, an author will urge that the distinction does not matter. *See, e.g.*, Steven L. Schwarcz, *Private Ordering*, 97 NW. U. L. REV. 319, 324 n.25 (2002) (arguing that because his paper dealing with the legitimacy of "commercial private ordering" considers only public perceptions of legitimacy and not the actual location of regulatory power, he need not engage the distinction itself).

70. For example, Professor Freeman, who has produced an otherwise thoughtful and voluminous body of work, committed one of the most telling slips in this entire literature.

thorough efforts can be unsatisfying,[71] though often they can be quite subtle.[72] They are all understandable; one sometimes senses that these authors, consciously or unconsciously, are really struggling to avoid confrontation of a Marxist instinct, which under current circumstances would be quite unfashionable.

While she evidently distrusts legal formalisms and any bright lines between government and private sectors, she decries arguments either that "there is no such thing as 'public' and 'private'" or that "there is no such thing as an agency." She then adds that: "There is *clearly* such a thing as the Environmental Protection Agency, the Securities and Exchange Commission, or the Internal Revenue Service. You can visit their headquarters in Washington." Freeman, *supra* note 15, at 572 (emphasis added). Surely the fact that a particular brick-and-mortar building exists in a particular city is the most unimportant of sociological facts, so long as the question is the existence of some organization of human individuals and the delimitability of its "boundaries." Those phenomena seem to have little to do with any tangible object—if indeed they are real phenomena to begin with. Perhaps Professor Freeman meant this only as a shorthand way of implying that we can make use of our instincts heuristically, despite penumbral uncertainty, because of the obviousness of core cases. But the existence of an institution and its attributes are not made "clear" even by thorough, case-specific analysis of directionalities of power, flows of money, information and resources, allegiance to constituencies, or any number of non-legal norms—analysis of a sort largely absent from this literature.

71. For example, as mentioned above, see *supra* note 45, Professor Minow has suggested that public and private concepts have to be retained, and she thinks that appropriate lines between them can be set, apparently without much difficulty, but only through a process of public debate and not through legislation or adjudication. She says that debate can find workable solutions so long as it considers a list of appropriate values, which she supplies. She takes this view because, like most other thoughtful thinkers on the matter, she acknowledges the difficulty of the public-private distinction, and thinks its problems would make it too hard to come up with a priori doctrinal solutions to public-private partnership problems. "The lines themselves are historical inventions," she says, each being merely "a fiction, a convention of speech." MINOW, *supra* note 17, at 22, 29. Tellingly, however, and even aside from the radical problem of moral epistemology behind her list of appropriate values (how does she know they are the right ones?), her list contains such an evenly balanced collection of opposing ideals as to be thoroughly indeterminate. *See id.* at 45-46. Moreover, even having admitted its difficulties, she proceeds as if the "line" is meaningful and administrable, and can be a part of purely rational public exchange. For example, she takes as a chief purpose to show that there have been "crossing[s] [of] boundaries," a phrase she uses at least once every few pages, and ultimately she asserts that "the underlying concerns that the[] words ['public' and 'private'] signal should guide debate and decision." *Id.* at 33. Accordingly, she is comfortable, despite the distinction's "notorious[] complex[ity]," announcing that religious hospitals should not be considered "public" even when they are dominant in a community and predominantly federally funded. *Id.* at 29, 35. Her reasons consist only of her view that "[p]reserving their status as private entities is vital to promote freedom" and "[t]he simple receipt of public dollars does not convert a private entity into a public one." *Id.* at 35. To this extent, having acknowledged doctrinal indeterminacy and having tried to patch it with public debate, Professor Minow is left with a moral relativism characteristic of all apologetic defenses of democracy—and one inconsistent with the moral undercurrent running throughout her work and most of the privatization literature. Winding up in that position also betrays the public-private distinction's lack of any moral or sociological content.

72. *See, e.g.*, Metzger, *supra* note 15, at 1462-63 (suggesting a "private delegation" doctrine to judge the constitutionality of privatizations, as a means of properly differentiating exercises of governmental from non-governmental power; Metzger's test essentially depends on agency concepts, insofar as it asks whether the private deputy acts on "behalf" of government); Radin, *supra* note 69; *see also* Verkuil, *supra* note 67, at 402-21 (extensively discussing the history and current content of the distinction).

However, I believe that, even for their apparent reasonableness, these approaches are all quite wrong, and that it is useful to move a step beyond.[73] Indeed, with a little thought, one of the commonly made claims in the "privatization" literature can seem bizarrely false. It is not so that most cases posed under the distinction are obvious "core cases," and that, except in rare cases at the periphery, the distinction can be easily employed on some commonsense basis. On the contrary, though its failings are often hard to see (because belief in the distinction is so firmly embedded), they are omnipresent. In particular, as a proposition of legal doctrine the distinction frequently calls for different legal treatment of entities that are substantially similar. By generally rendering the laws that impose public-regarding obligations inapplicable to "private" entities, the distinction creates what may be a very large sphere of social action—in which major allocations of social goods are made—that is freed from our basic frameworks designed to ensure that those allocations are made in the common interest.

The critique can be stated more formally. In one standard version, the analysis begins with the Hohfeldian view that every "right" necessarily limits countervailing freedoms.[74] Because "rights" in our system are themselves laws given by our government, backed by official coercion, the seemingly private exercise of any such right in fact entails the exercise of public power.[75] Therefore, no difference seems left between public and private action that will robustly resist counterexamples.[76]

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73. To be clear, this Article does not aspire to doctrinal critique as such, and prescribes no doctrinal medicine. However, careful analysis of this one point of doctrine is useful to the larger conceptions of governance institutions discussed here and to why existing talk about "privatization" seems misdirected.

74. Wesley Hohfeld long ago observed that "rights" necessarily imply limits on countervailing freedoms. But as later theorists observed, this insight could prove to be quite subversive to traditional liberal accounts of our legal order. *See* FRIED, *supra* note 63, at 51-55 (discussing the logical end-point of the Hohfeld-inspired Progressive critique of "rights"); Sagers, *supra* note 65, at 236 n.62 (discussing this insight and Fried's interpretation of it).

75. Progressives in the early twentieth century were quick to seize on these implications of Hohfeld's work, particularly in their attack on liberty-of-contract case law (though Hohfeld may neither have agreed nor anticipated their view). As Barbara Fried notes, Hohfeld's views were recognized immediately by Progressives for their "seditious implications." *See* FRIED, *supra* note 65, at 53, 103-04.

76. One obvious difference might seem to be that an individual and a government official are differently *incentivized*, insofar as the individual's exercise of rights are necessarily personal. But are they really so different? While having no fealty personally to public choice doctrine, I would suggest that one undeniably appealing insight is its observation that government agents necessarily serve their own interests at least some of the time, and at least sometimes service of those interests is amplified through the agent's discretionary exercise of official power. Metzger's view that a "private" actor becomes in some sense "public" when it acts as government's "agent," see *supra* note 15, is not actually apt because it is not so much a defense of the distinction as it is a means of employing a distinction that is already presumed to exist and to be usable. After all, should she really be understood to argue that there is an important and robustly defensible difference between a

The distinction remains ubiquitous, however, and it will be useful to examine the several defenses made of it. First, the purely formal, institutional positivism often driving it is quite weak. For example, imagine that a standard-setting body composed of representatives of an industry promulgates a model standard for the design of their products, and then state and local governments adopt that standard as law through an unreflective rubber-stamp.[77] In no meaningful way did any body of traditional government formulate the underlying policy, even though in some superficial sense it would be easy to say so, and even though the public-private distinction would cause most lawyers to think it.[78] Recognizing the misleading character of this sort of formalism, most legal thinkers prefer the more nuanced distinction that, unlike private actions, the state's pronouncements are backed by legitimate coercion and, in particular, that the state may employ ultimate forms of violent coercion.[79] While maybe more intuitively appealing, this too turns out to seem quite weak. A wide array of nominally private associations can impose fines, expulsion, and other sanctions,[80] and to insist that the coercion open to state actors is importantly different from these sorts of penalties would be to insist that, say, a civil antitrust enforcement action is not "law" because it is not enforceable by death. Very similarly, it is not useful to distinguish

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"government agent" and the "agent" of a corporation that is itself an "agent" of the government?

77. This happens with *astonishing* frequency. *See* Sagers, *Case Study*, *supra* note 6, at 1398-1400 & n.15.

78. That this approach is weak has hardly prevented the courts from adopting it. *See* Mass. School of Law at Andover, Inc. v. Am. Bar Ass'n, 107 F.3d 1026, 1027 (3d Cir. 1997) (holding the ABA immune for law school accreditation activities, finding them to be merely appeals to government to deny bar admission to graduates of non-accredited law schools); Sanjuan v. Am. Bd. of Psychiatry & Neurology, Inc., 40 F.3d 247, 250 (7th Cir. 1994) (holding that although defendant psychiatric certification board's decisions were the basis of granting certain state benefits, the board was not a "state actor"); Sessions Tank Liners, Inc. v. Joor Mfg., Inc., 17 F.3d 295, 299-300 (9th Cir. 1994) (immunizing deliberate misrepresentations to a standard setting organization as valid attempts to influence government action); Lawline v. Am. Bar Ass'n, 956 F.2d 1378, 1383 (7th Cir. 1992) (holding the ABA immune for promulgation of model ethical rules); Sherman College of Straight Chiropractic v. Am. Chiropractic Ass'n, Inc., 813 F.2d 349 (11th Cir. 1987) (holding a chiropractic trade association immune for school accreditation activities); Zavaletta v. Am. Bar Ass'n, 721 F. Supp. 96 (E.D. Va. 1989) (holding the ABA immune).

79. Weber stated this argument explicitly in 1918. *See* MAX WEBER, *Politics as a Vocation*, *in* FROM MAX WEBER: ESSAYS IN SOCIOLOGY 77-78 (H.H. Gerth & C. Wright Mills, trans. 1958) ("Ultimately one can define the modern state sociologically only in terms of the specific *means* peculiar to it, as to every political association, namely, the use of physical force. . . . [A] state is a human community that (successfully) claims the *monopoly of the legitimate use of physical force*."). Arguably it appears in slightly different form in Austin's "command" theory of law in the early nineteenth century. *See* 1 JOHN AUSTIN, LECTURES ON JURISPRUDENCE 178 (London, John Murry 1830) ("Laws properly so called are a species of commands.").

80. Obvious examples include religious excommunication, expulsion from a trade group for violation of membership or conduct rules, denial of licensure or certification, or money penalties.

subjection to state versus non-state authority based on its "voluntariness." At least in our society, subjection to many forms of state authority is voluntary to some meaningful extent, and subjection to many forms of non-state authority is only "voluntary" in the same formal sense as was implied in the liberty of contract case law.[81]

A subtler approach might be to say that only those acts publicly perceived to be "legitimate" acts of government should be considered "public." Legitimacy might be an important element of government power in that it enables the authorities to rule with minimal coercion.[82] The problem is that allegedly "private" entities hold influence that is popularly legitimized in ways not meaningfully distinct from the legitimization of government. For example, Americans do not commonly question the coercive power of organized business entities over their employees. No one would seriously doubt that such power exists, and most would not doubt its legitimacy.[83]

Indeed, the most important critique of the distinction may be one that is brought into sharp relief by the subject of this Article. Though it is not often stated, a difference presumed to exist between the "public" and "private" is that, in the former, allocations of social values can be made in a *generalized* manner; whereas, in the latter, they are conceptualized as only the aggregate of individual transactions—namely, as (often somewhat mystically) idealized transactions of "market exchange." But this is also incorrect. Among the range of non-state entities making important allocations in American society, there are literally thousands—including standard setters, product design consortia, large corporations, voluntary professional associations, and so on—that are capable of making large

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81. *See* Sagers, *supra* note 65, at 243-44 & n.93; *see also* Snyder, *supra* note 52, at 378 (providing a persuasive argument on this point along with several illustrations).

82. *Cf.* DAVID EASTON, A SYSTEMS ANALYSIS OF POLITICAL LIFE 352-62 (1965); Nadel, *supra* note 39, at 18-19 (discussing this aspect of Easton's definition of "public" policy). Strictly speaking, this actually differs from Easton's definition of the subject matter of political science—the "authoritative allocation of values for a society . . . ." He says an allocation can be "authoritative" so long as it is likely to be accepted within a society, even it if is perceived to be illegitimate. *See* Easton, *supra* note 9, at 286-87.

83. The "legitimacy" here is driven by the logic of property. The proprietor may hire, fire, discipline, impose institutionalized norms, and socialize workplace behaviors (including whole attitudes, moralities, and personalities) because the proprietor *owns* the productive assets at issue and its revenues. By characterizing the coercive potential of property as simply a private right of ownership, the common view renders the employee's subjection voluntary and therefore, in the popular perspective, fair. Thus, property and "privateness" are themselves agents to legitimize otherwise contingent and debatable allocations of coercive influence. *See* Sagers, *supra* note 65, at 245-46 & n.100 (developing this argument and relating it to the larger concept of "power" generally).

allocations by generalized fiat. The effectiveness of these gestures does not depend on whether the acting entity is a "public" one, but only on whether it has *power* of some nature over some class of persons.[84]

Ultimately, the public-private distinction, like many other rules of law, is merely a normative commitment that happens to appear as an identification of pre-existing nature. Common defenses of this distinction do not explain its durability. In fact, the only clear explanation, and the only sense in which the distinction even approaches some meaningfully real metaphysical status rather than that of raw, normative politics, is from the view of the Holmesian bad man. The distinction has content neither as a proposition of morality nor as a description of sociological reality, but it does to some extent explain how courts decide cases.[85] Courts are institutionally constrained to enforce binding government statements, but not, for instance, pronouncements of the president of General Motors. But the distinction is hollow and uninteresting as a description of anything *except* for what the courts will do. As Mark Nadel says, "[w]hen we say that a member of the school board in Sheboygan, Wisconsin, is part of 'the authorities' but the president of General Motors is not, we cannot go very far in understanding political behavior or public policy."[86]

What remains might be the explanation behind this explanation—that is, the reason that such a seemingly feeble, clumsy and arguably harmful little doctrinal trick could enjoy such tenacious longevity. The apparent answer is not theorizable or systematic, and seems at least in part political. To some extent the distinction appears convenient to preserve a particular normative conception of the arrangement of society—that is, it is literally conservative. Moreover, it is easy to overlook the distinction's significance in setting the terms and limits of our political consciousness. While one surely can find strong statements of its *value* to liberal society,[87] there is perhaps less conscious awareness these days of its role in justifying the going order of things, and rendering fundamental criticisms of that order implausible, despite what otherwise might seem to be its ugliness. Indeed, though we give it little thought, whether the distinction has some

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84. For example, as even the Supreme Court has recognized, standard setting groups can have real power not only when their standards are adopted by actual governments, but also when standards are merely of their own independent effect. *See* Allied Tube & Conduit Corp. v. Indian Head, Inc., 486 U.S. 492, 498 n.2 (1988).

85. Though, indeed, the distinction is problematic even as a bad-man prediction. Courts frequently give (often outcome-determinative) weight to the government-like acts of nominally "private" entities. *See, e.g.*, Robert W. Hamilton, *The Role of Nongovernmental Standards in the Development of Mandatory Federal Standards Affecting Safety or Health*, 56 TEX. L. REV. 1329 (1978) (noting the influence of privately set safety and design standards in tort litigation); Sagers, *supra* note 65, at 244 & nn.94-95.

86. Nadel, *supra* note 39, at 19.

87. *See, e.g.*, Verkuil, *supra* note 67, at 405 ("[T]he [public-private] line is fundamental—it ultimately distinguishes liberal society from its despotic alternatives.").

meaningful reality goes to the very moral legitimacy of the liberal capitalist order. To the extent that the legitimating function in this respect is to disguise unequal distributions of power, this is again a Hohfeldian insight and one familiar from the work of some realists and critical legal theorists. Though legal discourse largely denies it, formal "rights" and "duties" are in practice vessels to be filled with the substance of prior endowments—endowments of skill, social position, wealth, or other phenomena that give substantive value (or lack thereof) to their holders.[88]

Importantly, however, defense of the distinction is not ideologically specific; indeed, critics and proponents of "privatization" both require the distinction as basic to their positions. Despite its weaknesses and the instinct of many to attack it in certain circumstances, there is no across-the-board political will to dispense with it.[89] Advocates on both left and right make use of the distinction in different contexts, and its invocation appears to be mainly a matter of political convenience.

B. Markets as Institutional Alternative to Government: The Public-Private Distinction as an Economic Argument

A second major theoretical critique is required. It is very commonly assumed that our two basic choices for organization of society are government bureaucracy and markets.[90] Thus, it is commonly taken for

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88. In this vein Professor Fried recalls a delicious observation of Anatole France: "The law, in its majestic equality, forbids the rich as well as the poor to sleep under bridges . . . ." FRIED, *supra* note 63, at 42.

89. *See* Sagers, *supra* note 65, at 230 (discussing the distinction's appeal across the political spectrum).

90. This is often said by social scientists. *See, e.g.*, CHARLES E. LINDBLOM, POLITICS AND MARKETS: THE WORLD'S POLITICAL-ECONOMIC SYSTEMS (1977); Douglass C. North, *A Transaction Cost Theory of Politics*, 2 J. THEORETICAL POL. 355, 361 (1990) ("[T]he basic separation between polity and economy has always, even amongst the most confirmed libertarians, left a residual of activities to be undertaken by government."); Oliver E. Williamson, *The Theory of the Firm as Governance Structure: From Choice to Contract*, 16 J. ECON. PERSP. 171, 174-75 (2002) (discussing comparative advantages of ordering by markets and government bureaucracy). Law professors do this as well. *See, e.g.*, Einer Elhauge, *Making Sense of Antitrust Petitioning Immunity*, 80 CAL. L. REV. 1177, 1195-98 (1992) (arguing that the rules making up the so-called *Noerr-Pennington* doctrine in antitrust law serve to ensure that resource allocations will be made either by democractically accountable actors or by markets kept healthy through antitrust); Einer Elhauge, *The Scope of Antitrust Process*, 104 HARV. L. REV. 668, 696-97 (1991) (arguing that the same rationale explains the so-called "state action immunity" in antitrust). The distinction is more or less basic in rhetoric surrounding "deregulation." *See* Peter C. Carstensen, *Evaluating 'Deregulation' of Commercial Air Travel: False Dichotomization, Untenable Theories, and Unimplemented Premises*, 46 WASH. & LEE L. REV. 109, 115-16 (1989) (criticizing facile use of the distinction). It has surfaced in interesting ways in judicial opinions. *See, e.g.*, Richardson v. McKnight, 521 U.S. 399, 410-11 (1996) (refusing to grant a private prison guard defendant in a § 1983 action the same immunity as would be enjoyed by traditional government prison employees, and basing the distinction on the "market" influences that govern private prisons but do not govern public ones). Indeed, this basic distinction and the mutual exclusivity of the two options is sometimes taken for granted even by sharp critics of neoclassical orthodoxy. *See, e.g.*, Herbert A. Simon, *Organizations and Markets*, 5 J. ECON.

granted in the privatization literature that when government cedes a function to the private sector, market forces will regulate it.[91] This plays a very important role in rhetoric and research on privatization because it is taken for granted that a systematic and fundamental difference between the two spheres is that actors within them are differently incentivized. However, though it may sound surprising to some, investigation remains highly incomplete of the aggregate of self-serving, essentially pecuniary instincts that, if left unfettered, are believed to orchestrate much of society's workings. The actual prevalence of such markets and the impact that other social institutions may have on them are questions of empirical sociology that remain almost completely unanswered.

It is worth observing first that the critique here need make no recourse to the well-known and contested sub-genre that critiques law and economics and price theory generally.[92] We may assume that price theory remains fully wholesome and above reproach in its own sphere—as a deliberately abstracted description of genuinely individuated transactions, incentivized by personal human desires, and constrained by competitive demand for scarce resources. The claim here is that price theory has little or nothing to say about at least some certain classes of social ordering decisions, and that

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PERSP. 25 (1991); *cf.* Herbert Simon, *Rationality as Process and as Product of Thought*, 68 AM. ECON. REV. 1, 6-7 (1978) (asserting that individuals make decisions based more on qualitative analysis of "discrete structural alternatives" than on quantitative analysis of equilibrium at the margins).

91. *See, e.g.*, Aman, *Democracy Problem*, *supra* note 38, at 1488-91.

92. Critique of the movement is hardly new, but there has recently emerged something of a small cottage industry in it. *See* AMITAI ETZIONI, THE MORAL DIMENSION: TOWARD A NEW ECONOMICS 1-87 (1988) (attacking the commitment of neoclassicism to individual utility maximization); NICHOLAS MERCURO & STEVEN G. MEDEMA, ECONOMICS AND THE LAW: FROM POSNER TO POST-MODERNISM (1997); Anita Bernstein, *Whatever Happened to Law and Economics?*, 64 MD. L. REV. 303 (2005); Gregory Scott Crespi, *The Mid-Life Crisis of the Law and Economics Movement: Confronting the Problems of Non-Falsifiability and Normative Bias*, 67 NOTRE DAME L. REV. 231 (1991); Reza Dibadj, *Beyond Facile Assumptions and Radical Assertions: A Case for "Critical Legal Economics*," 2003 UTAH L. REV. 1155; Eric M. Fink, *Post-Realism, or the Jurisprudential Logic of Late Capitalism: A Socio-Legal Analysis of the Rise and Diffusion of Law and Economics*, 55 HASTINGS L.J. 931 (2004). More familiar, older works would include Guido Calabresi, *The Pointlessness of Pareto: Carrying Coase Further*, 100 YALE L.J. 1211 (1991); Mark Kelman, *On Democracy-Bashing: A Skeptical Look at the Theoretical and "Empirical" Practice of the Public Choice Movement*, 74 VA. L. REV. 199 (1988); Duncan Kennedy, *Cost-Benefit Analysis of Entitlement Problems: A Critique*, 33 STAN. L. REV. 387 (1980); Duncan Kennedy & Frank Michelman, *Are Property and Contract Efficient?*, 8 HOFSTRA L. REV. 711 (1980); Donald N. McCloskey, *The Rhetoric of Law and Economics*, 86 MICH. L. REV. 752 (1988); Pierre Schlag, *An Appreciative Comment on Coase's* The Problem of Social Cost: *A View From the Left*, 1986 WIS. L. REV. 919; Pierre Schlag, *The Problem of Transaction Costs*, 61 S. CAL. L. REV. 1661 (1989). Now seemingly hoary old classics in this line would include Arthur Alan Leff, *Economic Analysis of Law: Some Realism About Nominalism*, 60 VA. L. REV. 451 (1974), and A. Mitchell Polinsky, *Economic Analysis as a Potentially Defective Product: A Buyer's Guide to Posner's* Economic Analysis of Law, 87 HARV. L. REV. 1655, 1671-81 (1974).

no one knows how much of society is governed by them.[93] As I hope is obvious at this point, the aim of this critique is that that world of which I have been speaking—the range of more or less formal and bureaucratized entities making important allocations in society—is to some greater or lesser degree exempt from market forces.

The common picture of "markets," in short, is that of economics as neoclassical price theory or as a science of human choice. Namely, in all sectors of human behavior not directly and effectively controlled by government, the dominant category of social ordering conduct is believed to be atomized, bilateral transactions between individuals, firms, or both. "Firms" in this picture, while seemingly out of place in a model of individuated market transactions, are really only contractual compromises occasionally needed to align incentives and reduce costs that arise in messy reality. Moreover, while it is recognized that certain other practical realities frustrate the *perfect* functioning of this system, it has so far seemed to triumph on the argument that the exogeneity of those market frailties leaves the basic *theoretical* account of markets intact, and still a useful depiction of society and guide for policy.[94]

Now, only the most prosaic idolater of free markets is surprised that real-world markets tend to accrete rules, standards and institutions, and courts and economists now largely believe such things are actually quite healthy.[95]

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93. Thus the following criticism may seem a little straw-mannish, in that it may seem to attack a model economists themselves do not adopt—economics does not necessarily model "markets" as free-standing institutions analogous to government agencies or business firms. Indeed, economists do not seem to think much about what "markets" are, and rather just assume their existence. In fact, it is probably quite wrong to claim that economists think of them that way, as it confuses self-serving instincts themselves with the collection of rules, standards, and structures needed in messy reality to make voluntary exchange work. Again, though, the criticism here is not a criticism of price theory, but rather of the sociological assumption that matters not constrained by traditional government are necessarily regulated by market forces. Admittedly, some tension exists between this Article and that body of economics arguing that many or all "non-market" transactions are explainable by price theory. *See, e.g.*, Jack Hirshleifer, *The Expanding Domain of Economics*, 75 AM. ECON. REV. 53 (1985) (discussing "imperialist" economic forays into a range of non-market interactions; introducing some criticisms, but finding ultimately that "[t]here is only one social science" and that eventually "economics," as improved by integrations from other disciplines, will "constitute the universal grammar of the social sciences."). Indeed, an explicit claim here will be that price theory, as a model of individual choices, cannot explain or predict events that occur under the influence of formally non-market social institutions. The basic prediction in this Article is that in fact a *huge* range of social choices are now made under such circumstances.

94. *See* Herbert A. Simon, *Organizations and Markets*, 5 J. ECON. PERSP. 25, 26 (1991) ("[Neoclassical price theory usually treats] [a]ccess to information, negotiation costs, and opportunities for cheating . . . as exogenous variables that do not themselves need to be explained . . . [Their] exogeneity . . . allow[s] the theory to remain within the magical domains of utility and profit maximization.").

95. Since the 1970s the courts have made clear that privately devised market rules and market-facilitating institutions will be given wide latitude under antitrust and other law, at least where they are needed or useful to the healthy functioning of markets. *See, e.g.*, Nw. Wholesale Stationers, Inc. v. Pac. Stationery & Printing Co., 472 U.S. 284 (1985)

However, even admitting this as a regrettably necessary concession to the costs of transactions, many social scientists seem to take for granted that markets together comprise basically an atomistic universe of individualized, efficiently incentivized, and predominantly low-cost person-to-person transactions, which orchestrate society through interactions between persons and firms and govern the internal organization of firms themselves.

This all seems increasingly implausible. First, a little-recognized but in fact profound empirical question goes normally unasked: Is it simply not known how many choices in society are made through market processes?[96] The answer is that it is not. It finally has begun to be suggested, in the face of centuries of orthodoxy, that individuated market transactions may be neither all that common nor all that important in the actual organization of society.[97] Admittedly, neoclassical thought has devised a means by which apparently non-market, intra-firm transactions can be brought within the theory. As a commonplace of the so-called "neoinstitutional" or

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(upholding restrictive membership rules of a retailer purchasing cooperative against antitrust attack, noting that they were necessary to the cooperative arrangement, and that the cooperative itself was useful to competition); Broad. Music, Inc. v. Columbia Broad. Sys., 441 U.S. 1, 18-23 (1979) (upholding a scheme of blanket licensing of the intellectual property of songwriters against antitrust attack, and noting that the arrangement alleviated otherwise prohibitive transaction costs and created the possibility of a market that otherwise would not exist); Rothery Storage & Van Co. v. Atlas Van Lines, 792 F.2d 210 (D.C. Cir. 1986) (upholding trade restraining terms in a contractual arrangement among household moving companies, and finding it to be a net efficiency-enhancing "integration" of a number of firms "by contract"); *cf.* Board of Trade of Chicago v. United States, 246 U.S. 231 (1918) (concerning trading rules of a commodities exchange).

96. Of course, one easy, knee-jerk response is that they all are because choice always necessarily implies the agency of individual human decisionmakers, and even if in some particular transaction the individual does not formally represent his own interest, he still will serve his own self-interested psychological instincts, perhaps at the expense of his principal's interests. *See, e.g.*, Simon, *supra* note 94, at 26 (characterizing the basic neoclassical argument as "that a proper explanation of an economic phenomenon will reduce it to maximizing behavior of parties who are engaged in contracting, given the circumstances that surround the transaction"); Oliver E. Williamson, *The Theory of the Firm as Governance Structure: From Choice to Contract*, 16 J. ECON. PERSP. 171 (2002) (asserting that the science of contract, in which parties align incentives and craft governance structures attuned to their exchange needs, is another means to study economic phenomena). But that is the whole point of the discussion here. The response is easy only if one first assumes that no matter how complex some world of institutionalized decisionmaking becomes, it can be explained by examining the individual motivations of some hypothesized contracting parties who created it.

97. *See, e.g.*, Paul J. DiMaggio & Walter W. Powell, *The Iron Cage Revisited: Institutional Isomorphism and Collective Rationality in Organizational Fields*, 48 AM. SOCIOLOGICAL REV. 147 (1983); Hanslowe, *supra* note 39, at 130 ("[I]t is plain that substantial proportions of economic activity are presently not governed by rules that come anywhere near approximating the power-neutralizing, classical, atomistically individualistic, liberal, competitive model."); Ronald L. Jepperson & John W. Meyer, *The Public Order and the Construction of Formal Organizations*, *in* THE NEW INSTITUTIONALISM, *supra* note 6, at 204; Simon, *supra* note 94, at 25 ("Counted by the head, most of the actors in a modern economy are employees."); *see also* ALFRED DUPONT CHANDLER, THE VISIBLE HAND: THE MANAGERIAL REVOLUTION IN AMERICAN BUSINESS (1977).

"transaction-cost" economics, when a firm resolves its make-or-buy choice in favor of "make," it nevertheless makes the resulting, internal hierarchical decisions exclusively as functions of negotiated contracts, which themselves are driven by individual incentives of the contracting parties who create or work within those firms, and are constrained only by exogenous material circumstances. In other words, the same socially optimizing forces that drive market transactions will drive the structure and behavior of firms and all other private entities. Therefore, a theory of even hegemonic firms in highly concentrated industries, which arrange some very large portion of society's basic decisions through internal fiat directives, can preserve almost undisturbed the centrality of markets and exchanges.[98]

It was only natural that this model of formal organizations, driven by rational choice theory, would be adapted to describe political decisions and to public bureaucracies in particular,[99] and that the posited "privatization" choice would be modeled as the government's own "make-or-buy" decision.[100]

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98. *See* Simon, *supra* note 94, at 26-27. It is worth noting explicitly that most transaction cost theorists see their theory of the firm as essentially an application of neoclassical theory; this fact often seems to be misunderstood. *See, e.g.*, OLIVER E. WILLIAMSON, MARKETS AND HIERARCHIES: ANALYSIS AND ANTITRUST IMPLICATIONS 1 (1975) (describing his work as "complementary to, rather than a substitute for, conventional analysis"); *see also* Terry M. Moe, *The New Economics of Organization*, 28 AM. J. POL. SCI. 739, 750 (1984) (describing most transaction cost theorists this way).

99. *See generally* Moe, *supra* note 98, at 758-66 (charting the then-nascent rise of transaction-cost applications to politics and public bureaucracy, while being cautiously optimistic about the movement's promise, despite concerns that important differences exist between political organizations and the profit-motivated firms that were the traditional subject of transaction-cost models).

100. Despite the general critique to follow, I think several recent works applying transaction cost approaches offer important and promising insights. In particular, political scientist John Donahue set out an encyclopedic tour of empirical evidence comparing public and private service providers, see DONAHUE, *supra* note 21, at 57-78, 101-212, along with careful analysis of their comparative institutional advantages, see *id.* at 79-98, 215-23, and the observation that the make-or-buy decision for government service boils down to consideration whether a particular function requires an input-based specification of public needs (i.e., provision by civil servants) or could adequately be gotten by output-based specification (i.e., from private sector providers), see *id.* at 45. A few other works have begun the task of applying the make-or-buy analysis, including one article by Oliver Williamson himself, see Oliver E. Williamson, *Public and Private Bureaucracies: A Transaction Cost Economics Perspective*, 15 J.L. ECON. & ORG. 306 (1999), and work by Professor Shapiro, see Sidney A. Shapiro, *Outsourcing Government Regulation*, 53 DUKE L.J. 389 (2003) (noting that the government has increasingly relied on the private sector to make and implement regulatory policy); Sidney A. Shapiro, *Matching Public Ends and Private Means: Insights from the New Institutional Economics*, 6 J. SMALL & EMERGING BUS. L. 43 (2002) (explaining that mechanisms to ensure private sector accountability are limited). These works are more preliminary, however, and they are also somewhat problematic. Namely, they fail to heed a warning from Terry Moe—that different sorts of organizations might differ in several fundamental respects that render simple application of transaction cost models ill-advised. *See* Terry Moe, *Politics and the Theory of Organization*, 7 J.L. ECON. & ORG. 106, 120-28 (1991). For example, despite his familiarity with Moe's work, Professor Shapiro explicitly chose to "assume that agency officials will

This approach has some serious problems. The most overwhelming and obvious problem is the profound number, range and complexity of institutions the model would attempt to explain as the conscious design of rationally maximizing individuals.[101] But maybe a larger problem conceptually is the model's implicit assumption that any formal association can be understood to have or serve some comparatively simple purpose, which by implication of the model necessarily maximizes the interests of those who form the organization. This might sometimes make some sense, as in a profit-maximizing business firm or an ad hoc product design consortium established by competing manufacturers. Very often, however, it will not. Often, the activities of a formal association will pose only highly uncertain or ambiguous welfare payoffs for its participants. Often, the various participants will have highly differing motives with respect to the organization's activities. Indeed, frequently individual participants may come to understand their interests in the organization only during the course of participation, and therefore could hardly maximize those goals during some period of contractual formation.[102] It also would seem simply inaccurate to characterize the evolution and accretion of all social entities with decisionmaking power as deliberate creations of individuals or firms. Institutions arise too organically for them all to be characterized as creatures of contract, even broadly defined. As a separate matter, price theoretic explanations of individual behavior will have little explanatory power of the behavior of actors within many formal institutions. Actors

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adopt institutional arrangements that promote legislative goals at the lowest transaction cost," and adopts as his purpose "to identify[] how transaction cost analysis would assist an administrator who seeks to determine in good faith when it is advisable to involve private parties in the implementation of regulation." Shapiro, *Outsourcing Government Regulation*, *supra*, at 399-400. The remainder of his article consists of "a typology of government-private relationships," many of which already exist, and an argument that "these choices constitute the same type of make-or-buy decision that economic actors confront . . . ." *Id.* at 400. Professor Williamson, for his part, argues that in evaluating privatization choices, governments must weigh "probity" along with more straightforward efficiency concerns. However, he too seems to take government "purposes" as essentially simple and unambiguous. Incidentally, both Shapiro's and Williamson's works arguably are fairly duplicative of Donahue's earlier and more comprehensive work; Shapiro distinguishes it by arguing that Donahue focused only on non-regulatory functions, whereas Shapiro is concerned with the outsourcing of actual regulation. *See id.* at 414-15 & n.92. However, the analysis Shapiro sets out still resembles Donahue's quite closely, insofar as it merely analyzes relative institutional advantages as between public and private regulatory work. Williamson seems to have been unaware of Donahue's work.

101. Admittedly, transaction-cost approaches attempt to accommodate the imperfection of human ability to contract—indeed, it assumes as a basic premise that all contracts are incomplete as a result of human bounded rationality. *See, e.g.*, Williamson, *supra* note 100, at 311. A great proportion of work in this area is devoted to strategies for organizational design that better addresses contracting inadequacies.

102. *See* Herbert A. Simon, *Human Nature in Politics: The Dialogue of Psychology with Political Science*, 79 AM. POL. SCI. REV. 293, 295 (1985) (noting that under realistic models of human problem solving, actors may even discover what their goals are in the course of the problem-solving process).

within those bureaucracies act subject both to restraints of the institutions' rules and norms, and they only rarely will exercise authority within their institutional roles solely for their own unambiguous benefit. Therefore, price theoretic models of individual or firm choice seem unlikely to explain either the "contractual" constraints of social decisionmaking institutions or the behavior of actors within them.

Finally, such a view again would have to remain uncritically committed to purely formal distinctions, this time between different "firms." "Firms" need not be understood, as they commonly are in both price theory and neoinstitutionalist economics, as hermetically differentiated entities that relate to one another only through unmediated market transactions. Indeed, deciding which components make up an "organization," however obvious it may seem in any particular case, is to some extent a bit of a nonsense exercise and an unnecessary one. Situations are easy to imagine in which purportedly distinct firms cooperate or interact so as to be no more than formally distinct, at least as to particular transactions.[103] Indeed, antitrust, administrative, and constitutional law now broadly permit private regulation of nearly the whole range of human affairs—even by collaborations of horizontal trade competitors—and the United States economy has been pervasively so governed for a long time.[104] Thus, "markets," such as they are, in fact are regulated directly through layers of bureaucracy that differ from "government bureaucracy" only in the legal instruments by which they are constituted and constrained, and in their permissible incentives. Bureaucratization is accomplished not only by the oligopolistic fiat of large firms in concentrated industries, but also by collaborations of firms, including standard-setting ventures or product design consortia. Moreover, even where the law would prohibit direct market constraints by distinct "firms" acting in horizontal coalition, nominally distinct firms often can accomplish the same thing by consolidation or joint venture.

Thus, even the one area of significant market activity left open to most human individuals—frequent small and infrequent large retail purchases of consumer goods and services—is in fact mediated not only by our system's

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103. Simon understated it in a pioneer work when he said that

> [i]n complex enterprises the definition of the unit is not unambiguous—a whole agency, a bureau, or even a section in a large department may be regarded as *an* organization . . . . [T]he smallest multi-person units are the primary groups; the largest are institutions (e.g., 'the economic system,' 'the state') and whole societies.

Herbert A. Simon, *Comments on the Theory of Organizations*, 46 AM. POL. SCI. REV. 1130, 1130 (1952).

104. *See* Sagers, *Legal Structure*, *supra* note 6, at 952-53 (discussing the legal treatment undercurrent law of nominally private entities with regulatory functions); *cf.* Sagers, *Case Study*, *supra* note 6, at 1398-1402 (discussing the range of "standard setting" activities by which nominally private organizations currently regulate much of human activity).

large number of official laws, but by a whole shadowy universe of constraints imposed hierarchically within firms and collaboratively across formal institutions of various kinds. None of this "private" regulation could be modeled to fit the neoclassical vision of atomized market conduct without substantially multiplying the number of assumptions needed for the theory to remain genuinely a work of price theory.[105] Therefore, it is increasingly hard to see how there even are such things as "markets" as traditionally understood.

In other words, the critique here is that "markets" can be understood as a meaningful regulatory alternative to traditional "government" only if we assume that the structure and behavior of all nominally "private" institutions with power over social choices can be explained by examining the personal choices of the individuals who create them by contract (thus analogizing them to "firms" in neoinstitutionalist economics). In light of the range and complexity of such institutions, however, this must sooner or later seem hopeless even to very conservative economic thinkers.

This critique is not entirely new. It builds not only on Herbert Simon's careful critique of neoinstitutionalist economics[106] and on the recent "new institutionalism" in sociology and organization theory,[107] but it was also important to the original American Institutionalists to examine the actual organs of economic decisionmaking, even to the extent they accepted price theory for its own sake.[108]

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105. Moreover, in addition to all of these more formal constraints, even the most individuated of consumer market transactions are mediated by hugely well funded and well researched marketing efforts that, as a major purpose of their very being, exploit market dysfunction and systematic consumer irrationalities. But this and other observations about demand and rationality really go to price theory itself as a psychological model of individual choice.

106. *See supra* notes 96, 100, 102, 104, 108-09.

107. *See* Jepperson, *supra* note 6, at 1 (charting the development of this movement and its general critique of atomistic, rational-actor models of social phenomena, its general disregard for the importance of institutions, and its confidence in the intentionality of organizations).

108. *See, e.g.*, Allan G. Gruchy et al., *Discussion*, 47 AM. ECON. REV. 13, 13-15 (1957) (summarizing the main goals of the Institutionalists). It may be that the Institutionalists have been fairly criticized for lack of analytical rigor. *See* Kenneth E. Boulding, *Institutional Economics: A New Look at Institutionalism*, 47 AM. ECON. REV. 1, 9-10 (1957) (asserting that the original institutionalists offered correct criticisms of contemporary economic thought, but not the correct answers).

III. AN ALTERNATIVE ACCOUNT OF THE MACROSOCIAL *WHAT* AND THE HISTORIOGRAPHICAL *WHY*; ALSO, ALAS, A BIT OF ABJECT MALTHUSIANISM

There remains, then, a need for an alternative theoretical account of the current world of human governance, to which the preceding arguments have all been leading. First, there looms the question of the macrosocial *what*—how exactly it is that values are apportioned in society—and the question of just how that phenomenon might be changing. I think the picture generally adopted of these matters, both in the privatization literature and more generally, is inaccurate.

The conventional vision of governance and how it is changing appears to be something like this: Traditional "government," composed of entities created through authoritative legal instruments, makes and enforces policy through authoritative announcements ("law") and through provision of goods and services. Individuals and non-state associations participate in various ways, some of which may be unwholesome, but actions of government ultimately are institutionally distinct from outside influence. Forces also exist in society outside this public sphere. A comparatively minor, non-theorizable component of non-state social ordering consists of social values, norms, customs, and rules of voluntary associations; these phenomena have some complex but essentially subordinate relationship to state ordering. A much more important aspect of non-state ordering, which regulates most human behavior that is not directly controlled by the state, is the world of market transactions. The market is unlike other non-state forces in that it is not very formally institutionalized in itself, it does not reflect any malleable, historically contingent social development, and it is not likely to be consciously varied in its operations through mere human intervention. Rather, the market is the cumulative product of inalienable human physical and psychological attributes and it operates automatically. It is the invisible hand.

On this view of human governance, a conscious choice by a government actor to provide a good or service via some nominally private entity is interesting mainly in that it might result in inefficiencies or defects in democratic desiderata.

In fact, a very different story can be told, using very different imagery. Traditionally constituted entities of "government" might constitute one and perhaps quite a small component of a (very roughly) horizontal, heterarchical range of focused points of influence. It exercises influence in part through legal pronouncements that work in the bad-man manner—they constrain the behavior of judges who act as gatekeepers on official coercion. Those pronouncements have at best a complicated relationship

with other social phenomena. Acting along with government in this heterarchical range is a limitless array of human associations and institutions, which exist along a continuum from the unorganized and even unconscious to the highly organized and government-like. Among the powers they represent are matters beyond law-like or regulatory prescriptions, including peculiar agenda-setting phenomena that are themselves a source of power.[109] Finally, acting among these influences are forces of systematic self-service that in the aggregate have some resource allocational influence. However, such "market" influences, to the extent that they exist, must be understood at a minimum to be highly mediated by state and non-state constraints. That is, given a range of options left open after other forces in society have already limited the possible options (and possibly modified the range of choices *psychologically* by modifying demand and limiting perceived options), an actor still may choose the behavior that maximizes its own welfare. The "market" on this view seems less like an independent, largely autonomous player in a vertically arranged hierarchy of governance bodies, and more like a piecemeal collection of interstitial influences weaving their way here and there through constraints set in other ways.

Within this alternative model of governance, "privatizing" changes that occur within traditionally constituted government entities could also be described differently than in the more familiar version. One of the more surprising insights in this study arises at this point.

First, it was mentioned above that United States governments have not actually given away some large range of functions they once performed, as is implied in much privatization rhetoric.[110] What has not yet been observed is that in fact United States governments have in some sense come to be responsible for inestimably *more* of society's functions than they once were, and most of that development has occurred in just the past few decades of allegedly ubiquitous privatization. This has occurred in some part because of the well-known expansion of federal regulation beginning in the 1960s, but more importantly it has occurred through the

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109. Among government actors, the agenda-setting process was described in the influential JOHN KINGDON, AGENDAS, ALTERNATIVES AND PUBLIC POLICIES (1995). As for the "power" implied in agenda-setting, Peter Bachrach and Morton Baratz observed in a set of studies in the 1960s that a source of social authority is the power to designate some topics the proper subject of controversy and rule others off the table. *See* Peter Bachrach & Morton S. Baratz, *Decisions and Nondecisions: An Analytical Framework*, 57 AM. POL. SCI. REV. 632 (1963); Peter Bachrach & Morton S. Baratz, *Two Faces of Power*, 56 AM. POL. SCI. REV. 947 (1962). To that end, they quote Schattschneider: "All forms of political organization have a bias in favor of the exploitation of some kinds of conflict and the suppression of others because *organization is the mobilization of bias.* Some issues are organized into politics while others are organized out." *Id.* at 949 (quoting E. E. SCHATTSCHNEIDER, THE SEMI-SOVEREIGN PEOPLE 71 (1960)).

110. *See supra* notes 50-54 and accompanying text.

enormous growth of the government's contract bureaucracy. Whatever sense in which it seems that functions given to contractors have been "privatized" is purely semantic. While it may be true that government treasuries now funnel a larger proportion of tax dollars through formally non-state vessels, they remain tax dollars distributed nominally under the supervision of oath-taking and government-paid bureaucrats and for purposes specified by bodies that in theory are democratically accountable.[111] This is an example of the problem this Article has explored: If one disregards the critique of the public-private distinction, it can be said that "government" no longer provides these outsourced functions. But that formulation reduces away most of the sociological reality here that is really interesting.

Second, this evolving institutional structure of traditional government has been a "conscious" phenomenon only in the most attenuated sense. In part, it occurred through a disaggregated collection of generally unrelated policy initiatives scattered throughout United States law and adopted throughout the twentieth century, almost all of which were invisible to the public and were visible in government only to those directly involved in specific programs.[112] In even larger part, it reflects the expansion of the

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111. Despite the ethos of "shrinking government" in which privatization rhetoric is wrapped, no one within government could really believe that government has gotten smaller. On the contrary, as many within the Beltway acknowledge, the rhetoric of "shrinking government" is tremendously misleading. The body of workers paid directly or indirectly via federal tax revenues or required by unfunded mandates is *enormous* and has grown much larger just since the late 1990s. The best regarded study concerning the true size of the government—co-sponsored by the Brookings Institution and the Wagner School of Public Service at New York University—shows that while politicians have continually congratulated their own efforts to shrink the government, the true size of the federal work force has actually grown substantially, especially since about 1999. While the formal, on-paper civil service has shrunk, the actual number of jobs for which the federal government and tax dollars are responsible—including jobs required by contracts, grants, and those state and local jobs required by federal mandates—is estimated at about 17 million. *See* Light, *supra* note 57, at 311-13.

112. These initiatives are numerous, sundry, and not much connected to one another. They include: (1) OMB Circular No. A-76, a policy dating to the Eisenhower Administration under which the federal government is theoretically barred from competing with the private sector in the provision of "commercial" goods or services, see *supra* note 5; (2) the Federal Activities Inventory Reform (FAIR) Act of 1998, Pub. L. No. 105-270, 112 Stat. 2382 (1998), (presently codified at the note following 31 U.S.C. § 501 (2000)), or "FAIR Act," which requires an annual accounting of all government functions that are "commercial," and is at least theoretically given teeth by the injunction of OMB Circular No. A-76 that agencies out-source commercial functions; and (3) a lengthy, century-long series of loosely connected federal policy steps to encourage private standard setting and to keep government entities out of the regulation of safety and design, including the government's role in nurturing the nominally private but very powerful American National Standards Institute, and adoption of the Federal Trade Commission Improvements Act of 1980, Pub. L. No. 96-252, 94 Stat. 374 (1980) (presently codified at 15 U.S.C. § 57a(a)(1)(B) (2000)), which among other things shielded standard setting entities from a proposed FTC rulemaking. Among the most surprising of these steps might be the National Technology Transfer and Advancement Act of 1995, Pub. L. No. 104-113, 110 Stat. 775 (1996), codified at 15 U.S.C. § 272 note, and implemented through OMB Circular No. A-

contract bureaucracy, and to this extent it occurred as a default or compromise, and again was not part of any overall plan. To some limited extent, it was part of a fairly conscious Cold War effort of the federal government to grow its defense capacities while escaping public attention,[113] but in recent years it appears much more commonly to have occurred as a last resort of front-line government managers simultaneously facing dwindling resources, public outcry against alleged "waste," and legislative demands for more services.[114] Contracting out can allow the bureaucrat to satisfy performance demands with expenditures that are much less publicly visible.[115] In any event, while government has largely lacked any overall vision of these events,[116] their practical effect has been greatly to expand the range of nominally private entities that are able to exploit bilateral power asymmetry.[117]

It seems likely that these trends will bear regrettable fruit. As is increasingly acknowledged by representatives of traditional government and others, government in recent decades literally has begun losing its ability to perform its own nominal functions. Its own contract bureaucracy has grown unmanageably large (to the extent that several federal agencies now admit they no longer know how many contractors they oversee), while government's own in-house managerial capacity has been decimated.[118]

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119. *See* 63 Fed. Reg. 8546 (Feb. 10, 1998). The NTTAA mandates that federal agencies use appropriate private standards both in procurement and regulation, *every* time such a standard exists.

113. *See generally* Guttman, *Governance by Contract*, *supra* note 36. Congressional desire in this respect is easy to understand—any politician, of any persuasion and with any constituency, can benefit by providing better services and can suffer by causing increased taxes. The executive desire is more interesting—it appears to have arisen not from any executive desire for power or political favor. Rather, front-line bureaucrats have, since at least the 1940s, found themselves faced simultaneously with ever-increasing congressional demands for service provision, on the one hand, and ever tighter controls on expenditures, on the other. *See* GUTTMAN & WILLNER, *supra* note 25.

114. *See generally* GUTTMAN & WILLNER, *supra* note 25.

115. Government can grow itself without accountability in this way because government contractor employees are not normally counted in tallies of the federal workforce and because there is no easily accessed means for accounting even for how many government contracts are in existence. Thus, an agency could take on additional responsibilities performed by civil service protected agency employees only with easy public accountability. By contracting the work out, however, the agency can claim to have provided additional public services without increasing the civil service workforce and without easily traceable public expenditures. *See* GUTTMAN & WILLNER, *supra* note 25.

116. The Government Accountability Office has tried to fill that gap. *See* GAO, COMPETITIVE SOURCING: GREATER EMPHASIS NEEDED ON INCREASING EFFICIENCY AND IMPROVING PERFORMANCE (2004); GAO, CIVIL SERVANTS AND CONTRACT EMPLOYEES: WHO SHOULD DO WHAT FOR THE FEDERAL GOVERNMENT? (1981).

117. For example, under the NTTAA, discussed, *supra* note 112, a standard setting body can constrain the behavior of its members and the industries or conduct within its purview not only through the persuasive power of its opinion but also because its opinion will be incorporated both in government regulatory rules and in government procurement specifications.

118. A bitter irony of recent downsizing efforts is that they have simultaneously

But the more important point, again, is that even this story is only one comparatively small piece of the overall picture of governance. Even those "private" entities whose social allocational influence comes from some legally formal relationship with government are only a portion of the overall complex of social ordering.

Thus, a picture of the macrosocial *what* could be adduced that is quite different from the picture of things contained in ordinary privatization talk. Again, in the popular imagination a sharp distinction divides "bureaucracy" and individualized market transactions. "Privatizing," especially in recent political rhetoric, means removing a function from "bureaucracy" and ceding it to the self-optimizing world of atomistic, highly incentivized competition. A better picture of the basic choice for allocation of social goods is between one kind of bureaucracy (government) or a different kind of bureaucracy (business organizations and other non-state rationalizing entities, some of which have some formal tie to traditional "government," but most of which do not). "Privatization" on this view is merely a shifting of personnel and flows of resources. It may rearrange incentives and alliances, but it is not a fundamental change in metaphysical character.

In any event, this leaves the matter of the historiographical *why*—why institutions have evolved in this manner and why both public and academic visions of them seem so misleading. This question seems much more speculative. As for the practical question of why institutions have evolved as they have, the location of social rationalization exclusively in bureaucracies seems mainly a compromise with brute practical circumstances—bounded human rationality, scarce resources, and expansions both in population and technology. The fullest and best theoretical treatment of this phenomenon is by sociologists Paul DiMaggio and Walter Powell, who argue that "the engine of organizational rationalization has shifted" from the desire for efficient markets to "individual efforts to deal rationally with uncertainty and constraint," efforts that take place within organizations of "key suppliers, resource and product consumers, regulatory agencies, and other organizations that produce similar services or products."[119] Moreover, they argue that these social institutions—these "efforts to deal rationally" with circumstances—seem to grow more similar over time, which reflects something important

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demanded: (1) reduction of civil service employees, including procurement officials, and (2) outplacement of the formerly civil service government services through procurement contracts. In other words, at the same time that government has been laying off its procurement officers, it has hugely increased the burden of oversight work *that is supposed to be done by procurement officers. See* Steven L. Schooner, *Competitive Sourcing Policy: More Sail Than Rudder?*, 33 PUB. CONT. L.J. 263, 284-85 (2004).

119. DiMaggio & Powell, *supra* note 97, at 147-548. Another excellent source is Marc A. Olshan, *Standards-Making Organizations and the Rationalization of American Life*, 34 SOC. Q. 319 (1993).

about society. Admitting that some of this "isomorphism" of organizations could be explained by competitive forces, as has been suggested elsewhere,[120] DiMaggio and Powell argue that much institutional isomorphism has become disconnected from the rationalizing influence of market competition. A larger implication of their work is that as institutions themselves come to have greater independent rationalizing force—as they grow in their bilateral power asymmetry vis-à-vis natural persons and other organizations—they increasingly displace the regulatory importance either of traditional government institutions or market pressures.

As for the psychological—the historiographical question of why people seem so reluctant to discard the image of governance divided between government bureaucracy and free markets—this too is mysterious and contested. Among historians, explanations abound for our domestic romance of the private; chief candidates are the Framers' fear of royal power[121] and their experience as colonists and pioneers in a new world.[122] But again it also must reflect very basic perceptions and political desires of contemporary Americans, which are ambiguous and not ideologically specific. To doubt a robust distinction of public and private and the would-be corollary of free markets obviously threatens conservative or libertarian individualism, but it also threatens progressive confidence in regulatory

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120. That is, in commercial markets firms are pressured by competition to choose organizational forms that give the greatest productive efficiency, and over time will tend toward the form that is most efficient. Notably, Alfred Dupont Chandler argued that organizational efficiencies explained the rise of managerial bureaucracy and the so-called "great merger movement," see CHANDLER, *supra* note 97, and economists of various stripes have made essentially similar arguments, see, e.g., FRANK H. EASTERBROOK & DANIEL R. FISCHEL, THE ECONOMIC STRUCTURE OF CORPORATE LAW (1991); Williamson, *supra* note 100. The origin of these arguments is Coase. *See* R.H. Coase, *The Nature of the Firm*, 4 ECONOMICA 386, 398-401 (1937).

121. *See* FORREST MCDONALD, NOVUS ORDO SECLORUM: THE INTELLECTUAL ORIGINS OF THE CONSTITUTION (1985). Historiographical debate has raged recently over whether the *founding* generation was genuinely individualistic in this sense, and it is said that in fact they held "republican" or some other generally communal views up until the turn of the nineteenth century. Explanations vary for founding-era republicanism, centering mainly on the philosophical predilections of the Founders, see, e.g., J.G.A. POCOCK, THE MACHIAVELLIAN MOMENT: FLORENTINE POLITICAL THOUGHT AND THE ATLANTIC REPUBLICAN TRADITION (1975), or the religion of the mass of Americans, see BARRY ALAN SHAIN, THE MYTH OF AMERICAN INDIVIDUALISM: THE PROTESTANT ORIGINS OF AMERICAN POLITICAL THOUGHT (1994). However, no serious disagreement exists that sometime in the early nineteenth century American political desiderata turned predominantly individualist and liberal in nature, and that we have never as a people turned back.

122. Daniel Boorstin describes a pragmatic individualism even in colonial America that led, among other things to a confidence in individual industry and distrust of the highly theorized European mercantilism of the day. *See* DANIEL J. BOORSTIN, THE AMERICANS: THE COLONIAL EXPERIENCE 152-58 (1958). He attributes the rise of this thinking to the "self evidence" of American experience in the colonies, during which population and material well-being expanded at great speed and for long periods. The colonists' ongoing success through self-reliant private industry made them skeptical of Old World models of government. *See id.*

oversight by democratic and public-regarding government institutions. In short, the vision of governance built into the privatization literature is a moral aspiration, not an empirical observation. That it might also happen to be false would not prevent it from seeming indispensable to most.

CONCLUSION

In summary, then, while it seems difficult to explain exactly why, the contemporary relationship of "public" and "private" seems quite different than that normally implied in "privatization" talk. If anything is meaningfully changing in society, the change is neither recent nor contained in the favored institutional arrangements of American bureaucrats of the late twentieth century. Rather, it seems much larger than those policy predilections and older—indeed *much* older—in that it reflects matters dating to the origins of Western capitalism in, say, the fifteenth century. The ancient and ongoing change is embodied in two very broad propositions, which I have been at pains to stress in this Article: First, that to the extent that they ever had even heuristic meaning, the distinctions between "public" and "private," and the corollary distinction between "law" and "non-law," are increasingly irrelevant. Second, that to the extent that they ever existed, it is increasingly the case that "free" markets no longer exist.

The consequence of these two propositions is that under the current state of human governance, the location of influence and decisionmaking for allocation of social goods normally must be within either one kind of bureaucracy (traditional government) or another (business firms or other non-state organizations). The only robust and meaningful difference between them is that one of them lacks even a nominal obligation to the public interest.

None of this is necessarily, unequivocally bad. Rationalization of social goods through non-state associations, however they happen to be organized, is not necessarily worse than rationalization through government direction or through markets and efficiently incentivized firms. However, that such a state of affairs has come to pass might suggest something about the material orientation of our development as a society. For whatever reason—one perhaps overly obvious explanation would involve technological change and population growth—our governance institutions have come to be organized in a way quite at odds with all aspects of the liberal individualism that has been our core political philosophy since at least the presidency of Thomas Jefferson. We have evolved to a state in which neither the individual franchise nor individual buying and selling decisions have any real significance at all, and all individual decisions are constrained by an astonishing array of restrictions set in ways that are

neither democratic nor efficiently incentivized. That such a thing has evolved, and that it has come about *despite* human intentions, might suggest that a complicated society with advanced technology and a large population is simply ill-suited for democratic capitalism.

ADMINISTRATIVE AGENCIES ARE JUST LIKE LEGISLATURES AND COURTS—EXCEPT WHEN THEY'RE NOT

ALAN B. MORRISON*

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INTRODUCTION

I have always found administrative law to be a difficult course to teach and for students to learn, a view that is shared by most people who have taught or studied it. There are many reasons for this, but one is that the course seems to lack an overall framework on which to hang the various quite disparate parts.

In the spring of 2004, I taught administrative law at New York University Law School (NYU Law School) in the most challenging setting one could imagine: The class was comprised entirely of first-year students. While preparing for a session in which I was hoping to explain why certain procedural requirements under the Administrative Procedure Act (APA)[1] were imposed on agencies when they are not applicable to similar actions taken by a legislature, an insight came to me. That afternoon I told the

* Senior Lecturer, Stanford Law School. Many thanks go to those who read early drafts of this Article and offered many valuable suggestions. These include David Vladeck, Andrew Stanner, Tino Cuellar, Justice Stephen Breyer, Bill Simon, and Jeffrey Lubbers. My research assistant Tim Hurley saved me many hours in finding citations for propositions that I knew to be true but could not substantiate. I also appreciate the careful work done by the editors of the *Administrative Law Review* in putting the manuscript into final form.

1. 5 U.S.C. § 551 (2000).

class that I had discovered the Rosetta Stone of administrative law: "Administrative agencies are just like legislatures and courts—except when they're not." The class started to laugh, and then I explained how my thesis applied to the issues we were discussing that day. They began to understand my point, increasingly so when I came back to it in other contexts. At our final meeting, after the class presented me with a T-shirt with those words printed on it, I pledged to write an article explaining what I meant. This is that article, and I dedicate it to the members of the class of 2006 at NYU Law School who pushed me so that I discovered these twelve magic words that may help unlock the mystery of administrative law.

By the time students take administrative law, they have some idea of how courts and legislatures work from middle school civics and constitutional law. However, most students have no meaningful conception of what agencies are or how they operate. Thus, the first part of these magic words conveys the fact that agencies act like both courts and legislatures; the fact that they are like only one, and not both, in a given proceeding comes out later. Early in the course, students learn that agencies were created as a practical response to the limits on what legislatures and courts could effectively do, both because of time constraints and legislators' lack of expertise in many areas of administrative regulation. The realization that agencies supplement the work of legislatures and courts enables students to analogize rulemaking to legislating and adjudication to judicial decisionmaking, thereby creating a starting place in understanding the administrative process. Then the phrase "except when they're not" tells students that the analogies only get them so far because there are significant differences between how agencies issue rules and make adjudications and how legislatures enact laws and courts decide cases.

The "except" phrase invariably raises the question: Is there a reason for those differences, or are they purely random? My answer, explained and illustrated below, is that various checks built into how legislatures enact laws and how courts decide cases either are lacking in administrative agencies, or agencies have organizational characteristics that require additional checks to counter-balance them. In other words, there are features in the legislative and judicial processes that are not present in the administrative process and, in order to restore a proper balance, other checks have been included to assure that agencies act in accordance with the law.

There is no evidence that Congress set out to create a complementary system of checks and balances to replace those found in the legislative and judicial areas. Rather, the system evolved in that manner because Congress

enacted the APA as a "compromise measure"[2] designed to afford "uniformity and fairness in administrative procedures without at the same time unduly interfering with the efficient and economical operation of the Government."[3] In hindsight, the APA has proven to be a solid compromise, overall neutral in its impact on agencies and outsiders, fitting within the accepted understanding that agencies would have considerable, but not unlimited, discretion. Although no one in 1946 could have predicted a world of administrative law in which almost as many claims would be made that agencies failed to regulate as that they overregulated, the deference that the APA gives to agencies has often come to the aid of those entities that seek to avoid or minimize regulation today, but who, in 1946, might have wanted more procedures and judicial review to prevent what they perceived as over-zealous regulators.[4]

These twelve words will not come close to explaining all of administrative law, not even all of federal administrative law. The world is too complicated to support unitary theories, and this theory post-dates, rather than precedes, the APA. It would be little short of a miracle if any concept perfectly fit the reality of administrative law. Indeed, all of the APA was not written at the same time,[5] and its meaning has evolved through court decisions over almost sixty years. As a result, the differences on which I focus will not address some of the differences between agencies on the one hand, and courts and legislatures on the other. Conversely, despite some of those differences, an agency will sometimes operate in ways much like a court or a legislature, depending on the function at issue. In short, this theory makes no pretense of being complete; rather, its primary goal is to help students understand how agencies operate and why they operate differently from courts or legislatures performing analogous functions.

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2. STEPHEN BREYER ET AL., ADMINISTRATIVE LAW & REGULATORY POLICY 21 (6th ed. 2006).

3. U.S. DEP'T OF JUSTICE, ATTORNEY GENERAL'S MANUAL ON THE ADMINISTRATIVE PROCEDURE ACT 5-7, 124 (1947) [hereinafter MANUAL] (quoting a letter that Attorney General Tom C. Clark sent to the chairs of the judiciary committees in both the House and Senate on October 19, 1945, endorsing the revised Administrative Procedure Act (APA)). The Manual further indicates that the Department of Justice had substantial involvement in the drafting of the APA as enacted, thereby validating the Manual as a reliable source for interpreting the Act, even with its potential for a pro-Government slant. *Id.*

4. When the APA has been found wanting for certain types of decisions, either because it imposes too many or too few procedures, Congress did not amend the APA, but instead amended the applicable substantive statute, which then trumped the APA, because that law "shall do so expressly." *Id.* at 122.

5. Government in the Sunshine Act, Pub. L. No. 94-409, § 4, 90 Stat. 1241, 1246-47 (1976) (adding ex parte rules to the APA).

Hopefully, this Article will have a secondary function. When scholars, legislators, practitioners, and judges analyze the administrative process and consider altering it, they should ask whether a proposed change is needed because some essential check that is available in either the legislative or judicial process is missing in administrative proceedings despite the APA. And, when there are calls for less agency process, the opposite question should be on the table: Will the agency still faithfully and effectively carry out its mission (or perhaps do a better job) because some unnecessary procedure or aspect of judicial oversight is removed? Similarly, when analogous issues are raised in litigation, courts should inquire as to whether the procedure in question provides a necessary check on the administrative process—to make it more like a court or a legislature—or whether it impedes the agency from performing its functions because, after all, agencies are not exactly like courts or legislatures. There are, of course, no general answers to those questions, but the questions are reminders that agency procedures exist to impose reasonable controls on agencies so that their results are, more or less, what legislatures or courts would have done.

Part I of this Article addresses the legislative and judicial processes and identifies the main checks that are imposed on them. I have confined my analysis to the federal system, but state administrative law regimes could usefully be viewed in similar terms. In Part II, I describe the controls placed on agencies during rulemaking and the functions that those controls play. In Part III, I go through the same process for formal adjudications and, in Part IV, I do so for informal and "semi-formal" adjudications.

Today, most agencies implement their mandates using both rulemaking and adjudication (both formal and informal), although some use more of one than the other. This combination of methods might raise issues of separation of powers if found in courts and legislatures,[6] but the combination is essential for modern agencies to carry out the responsibilities assigned to them. Thus, when I speak of an agency carrying out a legislative or judicial task, I am referring only to the particular role that it is playing in a particular situation, and not placing it in a general category. As discussed below, the fact that agencies issue both rules and adjudicate cases further complicates Congress's efforts to ensure separation of the prosecutorial and adjudicative functions in formal adjudications. Except where relevant to a separation of functions analysis, the reality that agencies both issue rules and make adjudications will not be

6. *See* Alan B. Morrison, *A Non-Power Looks at Separation of Powers*, 79 GEO. L.J. 281, 282 (1990) (describing the Framers' intention in creating a separation of power as a way to avoid the tyranny that could result from vesting too much power in any one branch).

repeated. This will simplify the discussion and avoid debates over whether an agency is or is not performing executive branch functions of the kind found in cases such as *Humphrey's Executor v. United States*.[7]

Before embarking on that path, there is one other qualification. To most lawyers, and probably most law students, the term "administrative agency" means an agency that regulates economic transactions, such as the Federal Communications Commission (FCC) or the Securities and Exchange Commission (SEC), or an agency that deals with issues of health, safety and the environment, like the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), or the Environmental Protection Agency (EPA). But the APA definition of agency is much broader and includes all entities within the executive branch, except the president and his closest advisers.[8] It ranges from the Central Intelligence Agency to the Departments of Justice (DOJ), Agriculture, and Commerce; from the Small Business Administration and the National Institutes of Health to the regulatory agencies noted above.

As so defined, agencies are not a recent phenomenon, although their functions have increased dramatically since 1789. President George Washington had agencies, referred to as departments, with the titles of War, State, Treasury, and Justice. Like agencies today, they were part of the executive branch. Because they did not engage in what we would today refer to as regulation—either by issuing rules or adjudicating cases within the agency—they did not raise any of the separation of powers, due process, or other issues that are now dealt with in the APA and other laws. For modern examples, many of the decisions made by officials at the Departments of Defense and State are not regulatory in nature—training and deploying troops or negotiating agreements with foreign governments fall into the "non-regulatory" category—and the procedural and substantive checks supplied by the APA would not be necessary or even appropriate for them. Indeed, there are limited exemptions from both rulemaking and judicial review for certain functions of those departments.[9] Similarly, for decades before the passage of the APA, agencies in the executive branch filed criminal and civil cases in court, collected taxes and tariffs, gave out federal funds for a variety of purposes, managed federal property (such as forests and national parks), and even seized unsafe food and drugs, with or

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7. 295 U.S. 602, 611 (1935) (discussing the Federal Trade Commission's quasi-judicial and quasi-legislative functions).

8. 5 U.S.C. § 551(1) (2000) (defining agency as "each authority of the Government of the United States, whether or not it is within or subject to review by another agency . . .").

9. *Id.* § 553(a)(1) (exempting military and foreign affairs functions from rulemaking procedures); *id.* § 701(b)(1)(F)-(G) (exempting military courts and commissions from judicial review).

without court assistance. These functions and more were carried out under substantive laws that gave the agencies the authority to act, in some situations with procedural requirements imposed on them.

Until agencies began to regulate directly, by providing detailed prescriptions about what regulated entities may and may not do, there was little need for procedures to deal with concerns about possible separation of powers and due process violations. Even after the APA was enacted, agencies' purely executive functions were not covered by specific APA procedural requirements, although they were subject to the substantive and procedural requirements of the statutes authorizing them. But for agencies that did most of their work through regulation (regardless of the form), and for those executive agencies that were assigned regulatory responsibilities that directly impacted non-governmental entities, the APA became the "rules of procedure" at the agency level and the basis for judicial review, unless Congress otherwise provided. Thus, most of this Article discusses agencies acting in their regulatory capacity, either through rulemaking or formal adjudication, to which the APA directly applies. At the end, I return to informal adjudications, for which the APA has no specific procedures, and discuss what impact the APA has on them and what remaining controls, including limited judicial review, are available.[10]

I. THE LEGISLATIVE AND ADJUDICATIVE PARADIGMS

Under the Constitution, a law is enacted by a process in which elected members of the House of Representatives and the Senate agree on the text of a bill and either the president signs it or both Houses override a presidential veto by a two-thirds vote.[11] Each Chamber has its own rules, but those rules have an internal effect only. Thus, for example, the House forbids substantive legislation in an appropriations bill, but if a bill contains forbidden provisions when it is introduced or they are added by an amendment, the validity of the law once it is enacted is not affected. Similarly, if there are violations of rules setting maximum time limits for voting—or minimum time limits before a bill that a committee has approved can be considered on the floor—but the bill has the requisite number of votes for approval, these violations are irrelevant. And if a bill is enacted but premised on a clear factual error—for example, that two plus two equals five, not four—the bill is still law once the president signs it.

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10. Although the APA is primarily concerned with controlling what agencies do, it also requires agencies to take action in some situations, *id.* § 555(e), and it provides for judicial review for agency action (inaction) that is "unlawfully withheld or unreasonably delayed," *id.* § 706(1).

11. For simplicity, the veto override will not be referred to again because nothing in this Article turns on which method is used for a bill to become law.

Not only is there no judicial review of claimed violations of procedural requirements for legislation, but substantive review is limited to claims that the law violates some express provision of the Constitution. The most important limitation is that, in contrast to the states, Congress does not have plenary legislative powers, but is confined to those subjects set forth in Article I. Until the twentieth century, those limitations were significant, but with the modern Supreme Court's expansive view of the Commerce Clause,[12] and its willingness to allow Congress to condition the acceptance of federal funds on the recipient's consent to conditions that Congress could not otherwise impose directly under Article I,[13] there are relatively few substantive limitations on congressional power. Among those limitations, some are procedural in nature, principally based on separation of powers considerations;[14] others are reviewable because they may violate principles of federalism;[15] others may transgress prohibitions in the Bill of Rights;[16] and others may be challengeable on due process or equal protection grounds.[17] Although opinions differ on how free courts should be to disagree with Congress on matters of constitutional interpretation, there is no dispute that the grounds for challenging most duly enacted federal laws are quite confined.

The very limited nature of external checks on the result of the legislative process is understandable because of the significant checks already built into the lawmaking process. The most obvious and potent check requires the concurrence of the two branches of the legislature and the president before a bill can become a law. Further, within Congress, the two Houses are elected for different terms—two years for the House and staggered six year terms for the Senate—and by different constituencies—the House by local districts and the Senate by the entire state.[18] Although not constitutionally based, the committee structure and the rules of each House also result in significant brakes on the process. If there is one truism about elected officials, it is that they are always considering the impact of their votes on their chances of reelection or, for those not running, the impact of their votes on the member of their political party whom they hope will replace them. This serves as an additional check on congressional power.

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12. *See* Wickard v. Filburn, 317 U.S. 111, 120-22 (1943) (recounting the development of Commerce Clause jurisprudence).

13. South Dakota v. Dole, 483 U.S. 203, 206 (1987).

14. INS v. Chadha, 462 U.S. 919, 951-59 (1983).

15. United States v. Morrison, 529 U.S. 598, 617-19 (2000) (invalidating a statute under both the Commerce Clause and Section Five of the Fourteenth Amendment).

16. Buckley v. Valeo, 424 U.S. 1, 12-15 (1976).

17. Mathews v. Eldridge, 424 U.S. 319, 323 (1976); Bolling v. Sharpe, 347 U.S. 497, 498 (1954).

18. In states with only a single House member, the district is the state, in which case only the term of office differs.

For the judicial branch, the Constitution permits federal judges to decide only the limited types of lawsuits described in Article III, a rough analogy to the limits on legislative powers imposed on Congress by Article I. The principal bases for federal court jurisdiction are claims that arise under federal law (mainly statutes, treaties, and the Constitution), cases involving the United States, cases where the opponents are either citizens of different states or where one party is an alien, suits between two states, or suits based on admiralty law. In addition, Congress has imposed a further restriction in diversity and alienage actions—the amount in controversy must exceed $75,000.[19] Furthermore, the Supreme Court has interpreted the "case or controversy" language in Article III to forbid advisory opinions, to impose fairly strict requirements of standing and ripeness, and to limit the ability of federal courts to decide "political questions." Although the lower federal courts may decide issues of state (or foreign) law in resolving cases before them, the Supreme Court may decide only issues of federal law.[20] In addition, in "suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved."[21] And to assure that the decisions of juries on factual matters are not overturned by judges, that same amendment states that "no fact tried by a jury shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law."[22] Moreover, at the direction of Congress, and subject to override by a duly enacted statute, the Supreme Court has issued detailed rules of procedure for all cases in the lower federal courts.[23] All of these provisions check the powers of the federal courts to various degrees.

One difficulty with considering these restrictions to be a real check is that they are enforced by the federal courts, which are the very institution they are designed to control. Any law student who has spent more than a passing moment examining the meaning of the case or controversy requirement in Article III knows how malleable it is and how the Supreme Court can choose to decide—or not to decide—a dispute more or less at will, although, overall, the outcomes do not range that widely. The question of whether a given lower court ruling is based on federal or state law generally is not in dispute, but in some cases, such as those involving the contested presidential election of 2000, it was far from clear that the Court was simply applying federal law. When the Court was faced with the question of the meaning of the re-examination clause, and whether a

19. 28 U.S.C. § 1332(a) (2000).
20. *Id.* § 1257(a).
21. U.S. CONST. amend VII.
22. *Id*.
23. 28 U.S.C. §§ 2071-2074.

particular determination was one of fact or law,[24] it was the Court that decided where the boundaries lay, and it gave a broader rather than a narrower role for federal judges in both instances. In June 2005, the Court declined to construe a statute granting supplemental jurisdiction to the federal district courts narrowly, despite the fact that there was no indication that Congress had contemplated such an expansive reading.[25] Thus, although there are statutory and constitutional limits that govern the federal courts, the other two branches of government have no formal mechanism by which to guard against possible excesses.

Indeed, unlike the other two branches, federal judges not only do not have to stand for reelection or even reappointment but, under Article III, they "hold their Offices during good behavior," a standard that essentially requires a finding that a judge has violated a criminal statute before she or he can be removed. Even then, it can be done only by the cumbersome process of impeachment, which has happened only fourteen times in more than 200 years. Thus, federal judges essentially have life tenure, which makes them unaccountable in the ordinary political sense.

Nonetheless, although lacking many formal controls, the federal judiciary is reigned in by several means. The most prominent is the right of a losing party to seek review in a higher court. That has the greatest effect on district courts, whose decisions are generally appealable as of right to the courts of appeals, although the standard of review on many issues makes it difficult to overturn the ruling below. As for Supreme Court review, that is entirely discretionary, with very few exceptions. With the Court receiving more than 8,000 petitions each year, and agreeing to hear only about 80, the chances of the Court taking a case are very small.

Moreover, the traditions of an independent judiciary and the practices arising from the common law provide significant checks on the ability of federal judges to disregard the law and decide a case the way that a legislator would decide whether to support an amendment to a bill. Cases are confined by the pleadings, and the decisions must be based on the record, using rules of evidence that exclude unreliable types of proof. Judges are forbidden from conducting their own factual investigations or receiving information from one party that is not available to the others. Also, judges may not participate in a case in which they have a financial or other personal stake or in which, for any other reason, their "impartiality may be reasonably questioned."[26] In cases that are tried by a judge alone,

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24. Cooper Indus., Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424, 437-40 (2001); Gasperini v. Ctr. for Humanities, Inc., 518 U.S. 415, 418-19 (1996).

25. Exxon Mobil Corp. v. Allapattah Servs., Inc., 545 U.S. 546 (2005).

26. 28 U.S.C. § 144. If a lower federal court judge refuses to recuse himself under this statute, that may be reviewed on appeal. However, in a recent Supreme Court case in which Justice Antonin Scalia was asked to step aside because of his participation in a duck hunting

Rule 52(a) requires the judge to issue findings of fact and conclusions of law, and all rulings are made in writing or in open court where the parties and lawyers are present. Although there is no formal requirement that judges explain their decisions, the common law practice of doing so—to inform the parties of why the judge ruled, to assist in the development of the law, and to justify the decision if an appeal is taken—are deeply ingrained in our legal culture. To be sure, the press of judicial business has increasingly led to the issuance of many "unpublished opinions" at the appellate level, but even they at least explain to the parties the general basis for the decision. The bottom line is that, while the formal constraints on judicial decisionmaking are not extensive, the traditions of judging significantly confine the way that judges decide cases in the real world, producing a similar effect to that by which Congress is controlled, albeit by very different means.

II. AGENCIES AS LEGISLATURES

The activities of administrative agencies fall into two broad categories: rulemaking and adjudication. In this Part, I discuss the former, which is sometimes described as "quasi-legislative" because the product is a rule that generally looks and acts like legislation, with differences described below.[27] I decline to use the "quasi" modifier because "[t]he mere retreat to the qualifying 'quasi' is implicit with confession that all recognized classifications have broken down, and 'quasi' is a smooth cover which we draw over our confusion as we might use a counterpane to conceal a disordered bed."[28] One further introductory point: a single individual heads most agencies, although commissions with between three and five members run some agencies. For purposes of this Article, nothing turns on that difference, and I therefore treat all agencies as headed by one person, unless otherwise stated.

The essential elements of the term "rule," as defined in the APA, are that it is "the whole or a part of an agency statement of general or particular applicability and future effect . . . ."[29] Thus, a rule could be general, as in the Occupational Safety and Health Administration rule directing all employers to

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trip with a party in the case (Vice President Richard Cheney), he rejected the motion on his own, which is consistent with Supreme Court practice under which the individual who is the subject of the motion, rather than the entire Court, decides the question. Cheney v. U.S. Dist. Court for the Dist. of Columbia, 541 U.S. 913 (2004). Disclosure: I was lead counsel for the Sierra Club, which made the motion seeking Justice Scalia's recusal.

27. *See* 5 U.S.C. § 553(c) (2000) (defining two kinds of rulemakings under the APA: formal rulemaking, which closely resembles a formal adjudication (or a trial), and informal rulemaking, which resembles a legislative process). This part is limited to informal rulemakings.

28. FTC v. Ruberoid Co., 343 U.S. 470, 487-88 (1952) (Jackson, J., dissenting).

29. 5 U.S.C. § 551(4).

do (or not to do) some particular act to further workplace safety. Or, it could apply only to the particular use of a specific workplace substance and hence affect only a portion of all employers.[30] In either case, a statute enacted by Congress could do the same thing. Like a statute, once a rule is in place, it must be obeyed unless a court overturns it or the agency revokes it. Thus, for example, if an agency with jurisdiction over roads in the National Parks issues a rule setting a speed limit of 35 miles per hour in certain locations, a driver must follow that rule just as if it were enacted by Congress.

Perhaps the more significant aspect of the definition of rule is the "future effect" phrase. The Supreme Court has read this phrase to prohibit agencies from giving substantive rules retroactive application.[31] This is consistent with the Supreme Court's refusal to give statutes retroactive application, unless Congress clearly intended that result, because of the constitutional issues raised by retroactivity.[32]

Unlike substantive rules, which set standards to be followed by the public and the agency, an interpretative rule is primarily a guidance document that tells the world how an agency construes a particular provision in an existing statute and, for reasons to be discussed below, generally is given limited deference by courts. The result is that the failure of a private party to follow an interpretative rule does not automatically subject that person to liability. To be sure, if the Internal Revenue Service issues an interpretative rule explaining the meaning of a phrase in the tax code, that rule may have an impact on how a court decides a case, even for a transaction that took place before that rule's issuance. That would not be a prohibited retroactive application because, almost by definition, an interpretation of an existing law—or rule—is retroactive, at least in part. To the extent that there is a retroactivity issue, it is mitigated, if not avoided, by courts giving interpretative rules less deference than other rules because it is ultimately the meaning of the existing statute that governs, and the rule provides merely some help in discerning that meaning. An agency's ability to issue interpretative rules that impact the meaning of existing statutes distinguishes it from Congress, which has no interpretative powers regarding laws that have already been enacted. For that reason, courts have refused to give any weight to the views of Congress on a law that it has already passed, except in the context of an amendment to that law.[33]

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30. *See* MANUAL, *supra* note 3, at 13 (making it clear that if an agency action is a rule, the fact that it applies to a single entity does not take it out of the requirements of § 553 and citing examples of a corporate reorganization approved by the SEC or a determination of future rates for a single utility as constituting rulemaking).

31. Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 216 (1988).

32. Landgraf v. USI Film Prod., 511 U.S. 244, 265-66 (1994).

33. Tennessee Valley Auth. v. Hill, 437 U.S. 159, 189-93 (1978).

As noted above, Congress is limited in the subjects on which it can legislate to those enumerated in Article I, Section Eight, and therefore the agencies that it creates are also limited to those subjects. In practice, agencies will have even more limited missions, some confined to a single industry (such as airlines or nuclear power plants), while others have a broader reach (such as the environment or occupational safety), although with more limited mandates. But whatever the mission, the agency is limited to it, and in many cases to certain aspects of that mission as circumscribed by Congress. And just as the courts check Congress to assure that it does not stray beyond the constitutional subjects allotted to it, so too do the courts review agency actions to prevent them from going beyond the topics assigned to them by Congress. Most of those borders are subject matter limitations, but agencies lack the authority to issue substantive rules that affect the primary conduct of others in some situations because they have been directed to proceed through adjudications. Finally, the non-delegation doctrine prevents Congress from simply turning over a subject area to an agency without an "intelligible principle."[34] The doctrine has a very limited effect today, much like the nominal limits on the powers of Congress under Article I, Section 8—there are some vague boundaries to ensure that Congress or the Constitution, respectively, retain some ultimate control over what has been delegated.[35]

Here the similarities end, and the differences start to take on significance. The most striking difference between agency rulemaking and congressional legislation is that the APA, in 5 U.S.C. § 553, imposes significant procedural requirements on agencies issuing rules and, unlike comparable procedural rules of Congress, courts enforce them. Section 553(a) requires agencies to publish a notice of proposed rulemaking in the *Federal Register* and allow for written public comment on the proposed rule, which is normally at least thirty days, and often considerably longer.[36] The notice must include the text of the

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34. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001).

35. *See* Gonzales v. Raich, 545 U.S. 1 (2005) (upholding the power of Congress under the Commerce Clause to forbid possession of marijuana grown locally and not held for sale). Although two recent Supreme Court cases have invalidated federal statutes enacted under the Commerce Clause, the Court has not found a violation of the non-delegation doctrine since 1935, which suggests that the concept is practically, if not legally moribund. BREYER ET AL., *supra* note 2, at 71-74.

36. *See* 5 U.S.C. § 553 (2000) (listing exceptions to these requirements for certain subjects—those involving a military or foreign affairs function or those relating to agency management or personnel, or to public property, loans, grants, benefits or contracts, §§ 553(a)(1) & (2)—and for interpretative rules, general statements of policy, or agency rules of organization, procedure or practice, § 553(b)(A)). The latter exclusion is only from the notice and comment requirement, whereas the former is from all of § 553. Agencies may, and some often do, treat rules in these areas like all other rules and provide notice and an opportunity for public comment. The meaning as well as the advisability of these exclusions has been the subject of considerable litigation and debate. Their existence does not alter the thesis of this Article, but makes the procedural point in the text inapplicable to this subset of agency activities.

proposed rule, along with a statement of basis and purpose. Section 553 requires agencies to identify in the notice the principal factual bases for the proposed rule, which often is done through a public file (paper or now, more likely, electronic) that contains the key documents and, subsequently, the comments submitted in response to the notice. Once the agency has evaluated the comments, it may issue a final rule that must have an accompanying statement describing the changes made in response to public comments, identifying the main issues raised by the comments, and explaining why it did not adopt the principal alternatives by those who suggested changes. If the agency makes changes that could not have been reasonably anticipated by the notice, the agency must provide the public an opportunity to comment on those changes through a supplementary proceeding. The rule cannot be effective sooner than thirty days after its publication. However, these procedural requirements can be avoided if an agency finds "good cause" for dispensing with them and "incorporates the finding and a brief statement of reasons therefor in the rules issued" on the ground that compliance would be "impracticable, unnecessary, or contrary to the public interest."[37] And, like the rest of § 553, the courts limit the good cause exception so that agencies do not engage in wholesale violations of the requirements imposed by § 553.[38] Finally, interested persons have an absolute right to ask an agency to issue, amend, or repeal a rule, as well as a right to sue the agency if it fails to do so in a timely manner.[39]

By contrast, when Congress legislates, it is not required to provide public notice of what it is going to do and why, or provide any opportunity for public input of any kind, although it often provides both. With no requirement that it tell anyone what it is doing or why, or give interested persons a right to tell it why it should not do what it is about to do, Congress can change its mind on any part of a bill that has been introduced, at any time, for any reason or no reason at all. New matters can be included when the two Houses meet to reconcile their differences in a bill, and provisions that have been part of a bill in both Houses can suddenly vanish, with no procedural check whatsoever. Bills can also provide that they are effective upon enactment (typically when signed by the president), and the Supreme Court even has allowed some substantive laws to have limited retroactive effect.[40]

Why should the APA's rulemaking section contain notice and comment procedural requirements, enforceable by the courts, when there is nothing comparable to those requirements before laws, which are the functional

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37. 5 U.S.C. § 553(b)(3)(B).
38. New Jersey v. EPA, 626 F.2d 1038, 1049-50 (D.C. Cir. 1980).
39. 5 U.S.C. §§ 553(e), 555(e), and 706(1).
40. *See, e.g.*, United States v. Carlton, 512 U.S. 26, 30-32 (1994) (allowing a bill to close tax loopholes retroactively).

equivalent of rules, can be enacted? The answer is that the legislative process contains a built-in check that is designed to accomplish the same ends, but through different means: A bill must pass both Houses of Congress and be signed by the president before it can become a law. Requiring the concurrence of all three, at least in theory, prevents rash decisionmaking, provides alternative sources of information and viewpoints, and creates several avenues for public input on pending legislation. Because the three components that must approve a bill are elected by different means and with different, though partially overlapping, constituencies, the legislative process provides a check that is largely political rather than procedural. Because there are three components required for adopting any law, the opportunity for public input and democratic participation by interested persons is increased, albeit not guaranteed. And if the pressure from outside becomes significant, the same process that produced a law can amend or repeal it, with no required procedures to slow down the process.[41]

I make no claim that the legislative and administrative processes were designed to prevent the same kinds of problems. Whatever its purpose, APA rulemaking as supplemented by judicial review over the procedural and substantive aspects of a final rule does, as a practical matter, compensate for the absence of political checks that are a central feature of the legislative process. "In a sense, notice-and-comment procedures serve as a Congressionally mandated proxy for the procedures which Congress itself employs in fashioning its 'rules,' as it were, thereby insuring that agency 'rules' are also carefully crafted (with democratic values served by public participation) and developed only after assessment of relevant considerations."[42] Thus, although Congress does not have to provide public notice comparable to what agencies must do under § 553, the general public nature of legislative proceedings, coupled with the bicameralism and presentment requirements, provides reasonable assurance that the public will have an opportunity to be heard on significant legislative issues. In addition, there are other political checks in the rulemaking process—important members of Congress may object, and Congress can always enact a law overturning a rule—but those are utilized relatively rarely and cannot be counted on to rectify most errors in the rulemaking process.[43]

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41. Section 551(5) defines rulemaking as the "process for formulating, amending, or repealing a rule," and the cases are clear that all of the rulemaking requirements applicable to issuing a rule apply to repealing it. *See, e.g.*, Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983) (finding National Highway Traffic Safety Administration's rescission of a regulation arbitrary and capricious for failing to provide an adequate basis and explanation).

42. Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 951 (D.C. Cir. 1987) (Starr, J., concurring in part and dissenting in part).

43. For a category of "major rules"—those with an annual impact of $100 million or more on the economy—Congress has provided that they may not go into effect for sixty

Other differences between what an agency must do to have a rule sustained as compared to what Congress must do are explainable by the lack of the tripartite check built into the legislative process. For example, Congress does not have to explain what it is doing or why it is doing it, either in advance or as part of the final product. Nor does it have to justify in any respect why it chose one alternative over another. Similarly, there is no requirement that Congress make available its evidence for public comment, or in most cases, that it even have evidence to sustain a law, including a law that imposes burdens (or gives benefits) to one party and not another. The lawyers defending the statute can offer any reasons they can create to persuade the court that the decision was rational.[44]

By contrast, if an agency issued a rule without an explanation, that would violate § 553(b). If it tried to defend a rule in court on a ground on which it did not rely when it issued the rule, the courts would require at least a remand if not outright reversal, even though a court of appeals could properly affirm a district court decision on a different ground than the one the court relied on below.[45] The short explanation for these differences is that the APA does not replicate the Constitution, but the more important inquiry is why the APA included these additional requirements. The answer is that, because agency decisions lack the tripartite political check present in lawmaking, Congress has imposed alternative checks on the rulemaking process to assure that agencies remain faithful to the authority Congress delegated to them. As to the requirement for a reasoned explanation, it exists to assure that the agency has in fact considered the relevant issues and properly exercised its discretion, including any relevant expertise, and not acted for reasons not authorized by Congress.

One of the central premises of the rulemaking process is that agencies will be receptive to public comments and make appropriate changes; otherwise, the process would be a farce. But to make a change, an agency head must be open to change which, in turn, logically means that the official has not irrevocably made up her mind on the desirability and contents of a proposed rule. The courts have indicated that if a regulator prejudged a rulemaking, at some point it would require her to step aside, although to date, no court has imposed that remedy.[46] Moreover, generally

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legislative days after they are transmitted to Congress to give Congress time to enact a law overriding the rule. 5 U.S.C. §§ 801-808. The law has been in effect for about ten years, and Congress has exercised its power under this provision only once: to reject the ergonomics rule issued in the last days of the Clinton Administration. Because the Bush Administration opposed the rule, opponents only had to obtain a simple majority in both Houses to overturn it. Presidential Signing Statement on S.J. Res 6, Mar. 20, 2001, *available at* http://www.whitehouse.gov/news/releases/2001/03/20010321.html.

44. Vance v. Bradley, 440 U.S. 93, 109 (1979).

45. SEC v. Chenery Corp., 318 U.S. 80, 88 (1943).

46. *See* Ass'n of Nat'l Advertisers v. FTC, 627 F.2d 1151 (D.C. Cir. 1979), *cert.*

applicable conflict of interest statutes would require a decisionmaker to disqualify herself if she had a financial conflict of interest, although in most cases the decisionmaker avoids those problems by divesting all investments that have a potential for conflicts of interest on a tax-free rollover basis before the issue arises.[47]

The situation is quite different in Congress (and for the president). A representative from a farm state, for example, is likely to have campaigned on the continuation of price supports and subsidies, and no one would suggest that he should not vote on a farm bill simply because his mind is not subject to change based on reasoned discussion. In many cases, the member of Congress was elected precisely because of his views, which will often be closely aligned with those whom he represents. To disqualify those members from voting would effectively disenfranchise their constituents. A legislator's personal financial interests also do not disqualify him from voting on a bill, nor should they, except in the most extreme case. Annual financial disclosure is part of the reason why an additional check is not needed, as are regular elections and the fact that each member has only one vote.

Agency officials participating in rulemaking are in a rather different position because they are carrying out the will of the people, as reflected in laws enacted by Congress, rather than making their own judgments. Moreover, they are either the sole decisionmakers or one of a small group of decisionmakers. Therefore, they are required to step aside in proceedings in which they have a financial interest.[48] Recusals are also necessary because voters and Congress cannot remove agency officials—only the president can.[49] Again, this check is more pronounced than in the legislative context, but not so much that it interferes with the administration of the laws, which Congress has directed the elected president and his appointed agency officials to implement.

Another difference relates to what are known as ex parte communications, such as those that are not on the record. In informal rulemaking, the record is not like a trial record, but consists of the documents placed in the agency file, material referred to in its notice of proposed rulemaking, comments submitted by the public, and anything else on which the agency relied in making its final rule.[50] If today an agency

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denied, 447 U.S. 921 (1980).

47. *See* 26 U.S.C. § 1043 (2000) (allowing a tax-free rollover for executive branch officials required to divest to avoid financial conflicts of interest).

48. 18 U.S.C. § 208 (2000).

49. *See* Humphrey's Ex'r v. United States, 295 U.S. 602, 604, 618 (1935); Myers v. United States, 272 U.S. 52 (1926).

50. Formal rulemaking is on the record, and so the discussion in text would not apply to it. Instead, the ex parte prohibitions in § 557(d) would apply.

receives a written communication, whether or not it is labeled a comment, the agency will almost always place it in the public file so that everyone can see it, although that was not always true. A more difficult question arises when an agency official receives oral comments about a pending rulemaking. A cautious official would reduce the conversation to writing and place a copy in the file, but what if the conversation took place after the comment period had closed, or the memo to the file became available only after that date? Must the agency re-open the proceeding, and what happens if it does not do so, or if the agency official does not include a memo to the file? The answers from the courts are not entirely clear, except to suggest that timing does matter (pre-notice—no problem; after comment period—much bigger problem); the nature of the rulemaking may matter (will the rule produce winners and losers, or is the impact much more diffuse?); and does the ex parte communication add new material or simply rehash points previously made?[51] Again, at some point, the courts seem willing to step into a rulemaking to assure that everyone works from the same record and that certain participants do not receive unfair access to the decisionmakers so that agencies will produce democratically made rules.[52]

Neither Congress nor the president is subject to any such restrictions in the legislative process. They are free to talk to anyone, at any time, about anything, and many would insist that they have a responsibility to do just that, and that ex parte rules would prevent them from carrying out their constitutional mandates as elected officials if their access to information was impeded in any way.[53] The election system plus a vigilant press provides additional necessary checks, as does the tripartite system of enacting laws, including the fact that no one member of Congress can act without the concurrence of a majority of both Houses and the president. Because those checks apply to agency heads in rulemaking only to a very limited degree, alternatives are needed to assure fairness in the process.

There is another check built into the administrative process that is never found in the legislative arena. If a group of concerned citizens exercising their First Amendment right to petition the government made a detailed written proposal to Congress to amend a law that they consider harsh or unwise, they might get a polite reply promising to look into the matter, but

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51. *See* Action for Children's Television v. FCC, 564 F.2d 458 (D.C. Cir. 1977); Home Box Office, Inc. v. FCC, 567 F.2d 9 (D.C. Cir. 1977), *cert. denied*, 434 U.S. 829 (1977); Sangamon Valley Television Corp. v. United States, 269 F.2d 221 (D.C. Cir. 1959).

52. The special status of the White House and OMB in rulemaking is beyond the scope of this Article.

53. *See* Public Citizen v. U.S. Dep't of Justice, 491 U.S. 440, 467 (1989) (finding that Congress did not intend to apply Federal Advisory Committee Act requirements to the confidential advice given by the ABA Committee regarding Presidential appointments to the federal bench).

almost nothing would ever happen. To my knowledge, no one has had the temerity to sue members for not acting on the petition, but if someone did, the Speech and Debate Clause,[54] among other defenses, would result in the lawsuit's rapid removal from the court's docket. If that same group of citizens filed their petition with a federal agency with jurisdiction over the subject of their petition seeking a new rule or an amendment to an existing rule and the same kind of non-response ensued, the court could not dismiss the case out of hand. Section 553(e) requires agencies to give interested persons "the right to petition for the issuance, amendment, or repeal of a rule," and the definition of agency action in § 551(13) includes the "failure to act." Furthermore, § 706(1) directs courts reviewing claims under the APA to "compel agency action unlawfully withheld or unreasonably delayed." The result is that the courts uniformly recognize that at some point, they have the power to require agencies to reach a final decision on a request for rulemaking, although they have shown a reluctance to do so except in extreme cases.[55] Aside from states where the initiative process is available to force a decision on a bill that is stalled in the legislature, the only remedy that citizens have is the ballot box—a remedy that does not apply to unelected administrators and that would apply very weakly to the president who appoints them, as it is almost inconceivable that a substantial number of voters would oppose the president for that reason alone, even assuming they made the connection.

A final requirement imposed on agencies is that they act consistently. They are not forbidden from changing their minds, but if they do so, they must explain why—or at least how they reconcile the disparate treatment of similar matters.[56] Congress is under fewer restraints in terms of consistency, even among what appear to be similarly situated groups. As with many of the other differences, the checks built into the legislative process that are not present for agencies explain much of this, with the rest explained by the need to control agency discretion without having the courts become, in effect, super-administrators. Insisting on consistency, or at least reasoned distinctions, is a lesser form of control that results in fewer intrusions on the agency than would direct review of substantive decisions. The tradeoff is reduced judicial scrutiny and greater agency discretion.

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54. U.S. CONST. art. I, § 6, cl. 1.

55. *See* Public Citizen Health Research Group v. Chao, 314 F.3d 143, 145 (3d Cir. 2002) ("[W]hile competing policy priorities might explain slow progress, they cannot justify indefinite delay and recalcitrance in the face of an admittedly grave risk to public health.").

56. *See* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983); SEC v. Chenery Corp., 318 U.S. 80 (1943).

There are other differences between legislatures enacting laws and agencies issuing rules, but they generally follow the same pattern. While there is a basic similarity in the two processes, there are additional requirements imposed on agencies that largely can be explained by the fact that various checks that control the legislative process are absent from rulemaking. These requirements thus fill a void in the system of checks and balances, but while they do not replicate the legislative process, they do produce a rough approximation of it.

This discussion of the utility of procedural requirements in reining in agencies should not be read as a paean to procedures as an unmitigated good. Assuming that additional procedures, such as a trial-type hearing, produce "better" results in some cases, they also inevitably bring with them added costs and delays. Indeed, when the Office of Management and Budget (OMB) proposed requiring substantial additional peer review requirements for certain categories of scientific information used in rulemaking and other agency proceedings, one of the major objections was the cost and delay that the added requirements would impose. The final OMB guidelines were much less demanding, largely in recognition of those problems.[57]

Whether the benefits of additional procedures outweigh the costs is, at least in the rulemaking context, a question that the Supreme Court concluded in *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*,[58] was one that Congress had decided, and it was not up to the courts to impose additional procedural requirements not found in the APA. The ruling finds support from the fact that the APA itself was a compromise between those who wanted agencies to be tightly controlled and those who wanted them to be generally free of restraints in carrying out their missions.[59] This "procedural hands-off" approach is most clearly justified for rulemaking and formal adjudications, where Congress has spoken directly on what the proper procedures should be. However, as discussed in Part IV, it should be less applicable to informal adjudications, where Congress has provided no directions at all, and hence the inference that courts would overturn a compromise is not a compelling rationale for courts to back away from assuring some degree of procedural regularity and basic fairness.[60]

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57. *See* 69 Fed. Reg. 74,976 (Dec. 15, 2004).
58. 435 U.S. 519 (1978).
59. *See supra* note 4 and accompanying text.
60. This argument does not apply to statutory schemes such as those for immigration matters and social security disability, which I label "semi-formal adjudications," where there is clearly a compromise on what procedures are and are not necessary or even appropriate. *See infra* Part IV.

III. AGENCIES AS ADJUDICATORS

A. Adjudications in General

Under the APA, any agency action that is not a rulemaking is an adjudication, although it takes a little work to see how that happens because the definitions in 5 U.S.C. § 551 are not arranged alphabetically or in another logical order. The all-inclusive term under the APA is "agency action," defined to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[61] Under § 551(7), "adjudication means agency process for the formulation of an order,"[62] and under § 551(6) an "order means the whole or a part of a final disposition . . . of an agency in a matter other than rule making, but including licensing."[63] Thus, unless the final product of an agency action is a rule, it must be an order, which is the product of an adjudication.

Adjudications sound like court cases in an agency setting, and in some cases, they resemble what goes on in a courtroom. If the statute requires that the proceedings be held on the record, they are "formal adjudications," governed by §§ 554, 556 and 557, which are more like court cases. But there are other forms of adjudications under the APA (because they are not rulemakings) that look much less like court cases and in some instances do not resemble court adjudications at all. Because they are not formal adjudications, and therefore do not have to follow the requirements applicable to that category of APA actions, they are generally referred to as informal adjudications. They are, in essence, the residue of everything that is neither a rulemaking nor a formal adjudication. Because every agency action, including such mundane matters as granting, or denying, a pass to enter a government building, ordering a carton of toilet paper, denying Social Security or other government benefits, or ordering an alien to leave the country, culminates in an "order" under the APA, the proceeding leading to it is an adjudication. Where there are no APA procedures applicable to those adjudicative-type decisions, they are known as informal adjudications, although the APA does not use that term.[64]

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61. 5 U.S.C. § 551(13) (2000).
62. *Id.* § 551(7).
63. *Id.* § 551(6).
64. Under § 554(a), the test for whether a proceeding must be conducted as a formal adjudication is whether the substantive statute governing the matter requires that it be "determined on the record after opportunity for agency hearing," which the Supreme Court has construed as requiring that the applicable statute include those precise words, or perhaps something very close to them. United States v. Florida E. Coast Ry. Co., 410 U.S. 224, 229 (1973). The Administrative Law Judges (ALJ) who work for the Social Security Administration take the position that their proceedings are "APA proceedings," although they do not claim that they are governed by §§ 554, 556, or 557. *See* Robin J. Arzt,

I will return to informal adjudications in Part IV, but for now it may be helpful to know that although the APA itself prescribes no specific procedures for informal adjudications, some statutes specific to certain substantive laws do contain other procedural requirements. The two most prominent of these statutes deal with Social Security disability benefits and immigrants, both of which have their own set of procedures that are more formal than what the APA alone would require, but less formal than a formal adjudication. I shall refer to these alternative, non-APA based proceedings as "semi-formal adjudications," to distinguish them from the truly informal adjudications and from formal adjudications.

Because agency adjudications are similar to court adjudications, contrasting court cases with legislation may help illuminate the nature of agency adjudications. Legislation is generally prospective only, prescribing consequences for conduct that will take place in the future. Court decisions, on the other hand, ascribe consequences to events that have already taken place, such as deciding whether A or B breached a contract or whether C negligently injured D and owes monetary damages for that conduct. Sometimes, courts issue orders that are purely prospective—E can no longer occupy a strip of land because it is on F's property—but, even then, the facts at issue arose before the case was filed, and hence the adjudication can be seen as looking back to determine the future consequences of prior conduct.

As noted in Part II, agency rules are forward-looking, like legislation, while many agency adjudications are, like court adjudications, backward-looking, in that they focus on prior conduct, often involve disputed issues of fact, and impose consequences based on that conduct.[65] Some agencies have the power in an adjudication, similar to the power that courts possess, to order the payment of money, either to the Government or to a third party, subject to judicial review.[66] More typically, agencies will issue orders that resemble court-issued injunctions, though they may be called something else, such as "cease and desist orders" (Federal Trade Commission (FTC)), "exclusion orders" (SEC), or "deportation orders"

Adjudications By Administrative Law Judges Pursuant to the Social Security Act Are Adjudications Pursuant to the Administrative Procedure Act, 22 J. NAT'L ASS'N ADMIN. L. JUDGES 279 (2002). Because Social Security cases rarely, if ever, raise issues of ex parte communications or separation of functions, and there is generally no agency attorney on the other side from a claimant, there seems to be little practical significance to claimants or the agency as to the characterization of Social Security hearings and how they operate. Because they are not literally required to be on the record, they are informal—not formal—adjudications.

65. *See* MANUAL, *supra* note 3, at 14-15 (making this very point).

66. The National Labor Relations Board (NLRB) has authority to order reinstatement, plus back pay under 29 U.S.C. § 160(c) (2000), and the Commodity Futures Trading Commission may order fines of the higher of $100,000 or the gain of the wrongdoer, as well as restitution to persons injured by the wrongful conduct. 7 U.S.C. §§ 9(3)-(4) (2000).

directing an alien to leave the country (U.S. Citizenship and Immigration Service). Some orders, as in Social Security disability cases, can result in payments both for the past and, assuming no change in the claimant's status, for the future, with the latter often overshadowing the former in terms of significance.

But there are whole groups of adjudications, mainly but not exclusively in the informal category, in which the relief sought is prospective and in which the agency does not make its decision based on what happened in the past, but rather on what the party requesting or opposing the order argues is likely to happen in the future. In that sense, the relief looks more like a rule (future effects, based on predictions of the consequences of various alternatives) than an adjudication. The prime example of this phenomenon is the issuance of a license, such as for a television station by the FCC. In this instance, Congress specifically dealt with the issue in § 551(6) by including licensing as proceedings that produce orders, and excluding rulemaking from that process. In addition, the APA defines license broadly to include "an agency permit, certificate, approval, registration, charter membership, statutory exemption, or other form of permission."[67] Thus, when the FDA allows a new drug to go on the market, the EPA approves a discharge permit, or Customs allows a product to enter the country without charging a duty, the agency has engaged in an adjudication even though, as described in Part IV, the procedures that it followed did not remotely resemble what takes place in a courtroom.

B. Formal Adjudications

While many agencies implement laws that contain criminal penalties, the agency law enforcement proceedings carried out through formal adjudication are civil. Most adjudications involve a request for some form of injunctive relief, which can have far more significant consequences for a business than a fine of a few thousand dollars. Thus, an FTC antitrust cease and desist order can fundamentally alter the manner in which a company, or perhaps an entire industry, operates. The SEC can prevent an individual from continuing in the investment business or conclude that a company's financial statements are false and misleading, thereby guaranteeing stockholder suits. The National Labor Relations Board (NLRB) can require an employer to recognize a union, triggering the duty to bargain and, in all likelihood, add payroll costs and impose significant burdens on its relationships with its employees. In short, there is no doubt that these civil adjudications can have significant economic consequences, even without the payment of money.

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67. 5 U.S.C. § 551(8).

Formal adjudications are the most judicial-like of agency proceedings, but there are a number of significant differences—some that are obvious, and some that are less so. To understand the differences, it is important to understand the variety of reasons why Congress has assigned these judicial-like proceedings to agencies instead of the federal courts, which is where they generally would go because it would be federal law that would be at issue.[68]

One reason is numbers. In fiscal year 2005, in the 92 United States District Courts, there were 322,848 civil cases filed, 338,314 terminated, and 5,294 in which a trial was held.[69] By way of comparison, the Secretary of Labor, who enforces the Longshore and Harbor Worker Workers Compensation Act,[70] handles 72,000 cases for injured workers annually under that law alone.[71] Similarly, the NLRB in fiscal year 2005 received 24,720 unfair labor practice charges and, after review by its professional staff, filed 1,373 complaints, setting the cases for hearings.[72] Recognizing that all cases are not equal in difficulty or complexity, the Longshore cases would, if added to the federal civil docket, result in an increase of over 18% in civil cases, and if all the NLRB cases set for hearing were tried, that would constitute more than 25% of all federal civil trials—and this is just from one agency (the NLRB) and one part of another agency (the Department of Labor). Of course, Congress could add more federal judges, but their appointments are for life, and they are much more expensive to support than judges who work for agencies. In addition, for political and other reasons, Congress has been very reluctant to create more federal judgeships, and at least some people who choose to become federal judges now would not do so if their dockets were filled with the kinds of cases that agency judges now handle.

Second, agencies develop an expertise in their subject areas that allow them to operate more efficiently and consistently because they handle those cases on a regular basis. In addition, their familiarity with an industry or,

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68. Under 28 U.S.C. § 1331 (2000), there would automatically be subject matter jurisdiction in the district courts for all claims arising under a federal statute and, under 28 U.S.C. § 1441(b), a case raising such a claim could always be removed from state to federal court. Under some statutes creating federal causes of action, such as 42 U.S.C. § 1983 (2000), the claims can be filed in state court and some plaintiffs choose to file there, because, for example, the lawyer is more familiar with state practice and the local courthouse may be more convenient than the federal court.

69. Judicial Facts and Figures, Fed. Court Mgmt. Statistics, tbls. 6.1, 6.4, http://www.uscourts.gov/judicialfactsfigures/contents.html (last visited Feb. 11, 2007).

70. 33 U.S.C. § 902(6) (2000).

71. H.R. REP. NO. 109-161, at 4 (2005).

72. NLRB, SEVENTIETH ANNUAL REPORT, 2-3 (2005), *available at* http://www.nlrb.gov/nlrb/shared_files/brochures/Annual%20Reports/Entire2005Annual.pdf.

in the case of the NLRB, the relationships between employers and employees, enables them to craft better solutions and appreciate what is at stake better than many generalist judges.

Third, under the Federal Rules of Civil Procedure, the courts use the same rules for all cases. Because many federal court cases involve significant financial interests or major public policy questions, the Rules are designed so that litigants receive full procedural rights, so that all the relevant facts can be brought forth at trial, and so that juries are screened from marginally relevant and highly prejudicial evidence. However, the types of issues subject to agency adjudication differ from those in most federal court cases, and there are no juries. Therefore, Congress has concluded that more flexibility and less formality are appropriate in most agency adjudications.

Fourth, many agencies have the authority to carry out their missions either by issuing rules or by bringing individual cases in an administrative forum. If, however, all of those cases had to go to court, it would change the nature of the choices that administrators have and reduce their flexibility in deciding the best way to resolve a policy issue. There may be other reasons for placing certain kinds of adjudications in agencies rather than courts, but these will suffice to understand the general point.

There are two readily apparent differences between court and agency adjudications: The judges are different, and there is never a jury in an agency proceeding. In formal adjudications, the presiding officer is normally an administrative law judge (ALJ) who generally specializes in the work of that agency and sometimes even has a sub-specialty if the agency enforces several different statutory regimes. While ALJs can be appointed from the private sector, most of them are lawyers who have been with the agency (or some other agency) for much of their careers, and their elevation is a capstone. Their appointments lack a specific term, but they are protected from removal except for "good cause" in a proceeding brought before the Merit Systems Protection Board.[73] They also can lose their jobs because of national security concerns or a reduction in force,[74] in contrast to federal judges who are appointed "during good behavior," which means for life absent the commission of an impeachable offense.[75] In federal court, not every case has a jury, but for those in which there is one, that substantially affects the dynamics of the litigation.

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73. *See* 5 U.S.C. §§ 3105, 7521 (2000).
74. *See id.* § 7521(b).
75. Article III protects federal court judges, but not ALJs, from salary diminutions. As a practical matter, it is almost inconceivable that the salaries of ALJs would be cut, unless there was an across the board reduction in pay for all federal employees because of a national recession. ALJs also do not wear robes, but nothing turns on that difference.

In significant part because there are no juries, the rules of evidence are relaxed in adjudications, less so in formal adjudications, and more so the more informal the process. Under the Federal Rules of Civil Procedure, there is extensive discovery but, in keeping with differences in the nature of administrative adjudications and the desire for less formality, discovery in agency proceedings is less prominent and the opportunities for it are diminished, sometimes quite significantly.

These differences from court adjudications are fairly apparent and the reasons for them not hard to understand. But the more interesting differences are more subtle and generally result from the fact that, unlike courts whose only function is to adjudicate, agencies have rulemaking and, most problematically in this context, law enforcement functions that do not sit easily with the role as a neutral adjudicator. The focus of the remainder of this subpart will be on why Congress created special rules for agencies that enforce their laws through formal adjudications within their own agency.

Most formal adjudications at an administrative agency are commenced by the filing of a complaint or similar pleading. It is generally prepared by a member of the staff of the agency who will decide the merits of the complaint at the end of the administrative process.[76] In contrast, if the federal government initiates a civil complaint in federal court, the person who files the complaint works for the executive branch (normally the DOJ), and adjudication takes place before a judge who is a member of the judicial branch. In a case in which a state body both investigated charges against doctors and then adjudicated those charges, the Supreme Court has upheld such a mixing of functions within an agency in the face of a due process challenge.[77] But simply because such an arrangement does not violate due process does not mean that there are no problems with it. To alleviate the problems, Congress has imposed restrictions, known as separation of functions requirements, that create a substantial, albeit less than complete, separation between those performing adjudicative functions and those performing enforcement functions.

Before examining the congressional response, it is worth asking why Congress would have wanted the combination of functions that creates this problem. In fact, in some situations, Congress has provided additional protection for those subject to the agency's jurisdiction by creating a separate agency that carries out the administrative adjudications.[78] In other

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76. Aggrieved parties, such as those denied a license or some government benefit, may in some circumstances also have the right to commence a formal adjudication, in which case agency staff will defend the agency (or sub-unit within the agency) whose decision is being challenged.

77. *See* Withrow v. Larkin, 421 U.S. 35 (1975).

78. If an employer does not agree to the proposed finding of a violation by the

statutes, Congress has provided that a separate office within the agency make the decision as to whether to file a complaint,[79] and it even has required the Federal Election Commission to go to court for its law enforcement activities.[80] In most cases, however, Congress has preferred the combination of functions, concluding that it is not only less costly and more efficient than the alternatives, but that it is also the best way to enforce the laws assigned to that agency.

The FTC presents a good example of why an agency should control the cases that its staff files. A principal reason for wanting such control is to manage the agency's resources, especially today when funding is scarce. For example, if agency staff could bring a massive antitrust case, such as a challenge to a corporate merger or an allegedly anticompetitive industry practice, it could tie up huge amounts of staff time and money for many years. If the Commissioners thought there was a higher priority use of those funds, but had no say in whether the case should be filed, they would lose significant power over how the agency operated. It might also force the Commissioners themselves to devote a major portion of their time to that case instead of other activities. This is the kind of discretion that law enforcement agencies, such as the Antitrust Division of the DOJ, have traditionally exercised in filing cases in court, and it would be counter-productive for Congress to have created an agency like the FTC to improve efficiency, but foreclose agency control over its docket through a strict separation of functions law.

Second, agencies often have choices about whether to proceed by rulemaking or adjudication, but if the staff controls the adjudication, the agency, in effect, no longer has that choice. Third, even if the Commissioners agree that adjudication is the correct method for proceeding, and even if they agree with staff that the general subject area has a high priority, they may conclude, for any number of reasons, that one case is not the best one to bring to test a legal theory. Again, a decision of that kind should be made by the agency officials with the expertise and ultimate responsibility for the laws assigned to it, even though they eventually may have to pass on the merits of the case after the record has been developed. Thus, there are substantial advantages, some of which were reasons for the creation of the agency in the first place, and why Congress chose not to have a complete separation of functions between those who bring the case and those who will decide it.

Secretary of Labor, the separate and independent Occupational Safety & Health Review Commission adjudicates the matter. 29 U.S.C. §§ 659(c), 661(a)-(b) (2000).

79. The General Counsel of the NLRB has the authority to commence proceedings before the Board. *Id.* § 153(d).

80. *See* 2 U.S.C. § 438 (2000) (listing powers of the Federal Election Commission, with no provision for administrative adjudications).

Before turning to the specific safeguards that Congress has enacted to deal with this problem, there are some ancillary protections that ameliorate it to some degree. For instance, although the FTC Commissioners must approve the filing of a complaint leading to a formal adjudication, it will be several years before the case comes back to them. Because they will have a number of cases on their docket, their recollection of what the staff told them about that case likely will be hazy. Because Commissioners serve staggered five-year terms, it is quite likely that some, perhaps even a majority, will not still be there when the case returns, and their replacements will have no prejudgment problem at all.[81] Moreover, the agency that decides a formal adjudication must do so on the basis of the record compiled by the ALJ who hears the case and whose findings of fact the agency must give substantial deference upon review.[82]

There are two sets of restrictions that deal with this intermingling problem. First is the creation of a strict separation of functions between the initial adjudicators and the enforcers. Thus, the person who is hearing the evidence and making the initial recommendations on factual and legal findings (an ALJ or anyone working for her) cannot be simultaneously involved in the same or a factually similar case on the enforcement side and vice-versa.[83] Nor can such a person report to anyone who is involved with those other functions, other than members of the agency itself. [84] Note that Congress stopped short of requiring separate staffs for enforcers and adjudicators, and so they can move back and forth, but just not in the same or similar pending cases. There is, of course, nothing that precludes an agency from making the separation more secure, but the APA does not require it, and reasons of efficiency and overall advancement of the agency's goals often counsel against it. Considerations of efficiency have no place in the organization of a judicial system, where there is complete separation of functions. But at the agency level, the important differences

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81. Formal adjudications can be undertaken by agencies headed by a single individual, as well as by agencies with three or more persons. In practice, however, most formal adjudications take place at multi-member agencies. The point in the text regarding staggered terms does not apply to single member agencies but, if there is a change in the single agency head, the prejudgment issue vanishes.

82. *See* Universal Camera Corp. v. NLRB, 340 U.S. 474, 487-88 (1951) (requiring examination of the record as a whole, including the ALJ's findings).

83. 5 U.S.C. § 554(d) (2000). *See generally* Michael Asimow, *When the Curtain Falls: Separation of Functions in the Federal Administrative Agencies*, 81 COLUM. L. REV. 759 (1981).

84. 5 U.S.C. § 554(d)(2). The APA allows the agency itself, or any member thereof, to serve as the initial adjudicator, in which case the separation of functions rule is inapplicable. *Id.* § 556(b)(1)-(2). However, the option is rarely, if ever, utilized because agency members have more important work to do than listening to live witnesses in a trial-type proceeding.

between it and a court compelled Congress to create an alternative response to prevent the most serious abuses that might arise from the combination of functions.

The second set of restrictions involves a ban on ex parte communications, a practice universally accepted in court proceedings. Thus, for a DOJ lawyer who works in the executive branch and who has a case before a federal judge who works in the judicial branch of the same government, strict compliance with an ex parte rule is not a problem. What makes application of the principle more complicated at the agency level is that the law enforcers (staff attorneys) and the adjudicators (the ALJ and the agency officials) all work for the same agency. Moreover, the staff attorneys have regular contact with the Commissioners regarding a wide variety of matters, such as whether to start an investigation and whether to file a formal complaint. Applying the strict ex parte rules to agency attorneys would make it almost impossible for them to do their jobs.

Nonetheless, Congress has concluded that given the adversarial nature of formal adjudications and consequences to the party defending against the agency, some ex parte restrictions should apply in that context. Thus, in formal adjudications, the APA forbids ALJs or other presiding officers, with limited exceptions, from "consult[ing] a person or party on a fact in issue, unless on notice and opportunity for all parties to participate."[85] In addition, Congress dealt more specifically with the issue of ex parte communications by adding § 557(d), which applies to all on the record proceedings, including formal rulemakings. Unlike § 554(d), which applies to any person or party, § 557(d) applies only to "an interested person outside the agency."[86] However, it includes not just the ALJ but the agency itself and "any other employee who is or may be reasonably expected to be involved in the decisional process of the proceeding."[87] And it is not, like § 554(d), limited to issues of fact, but appears to apply across the board to any communication by an interested person outside the agency. However, an agency attorney who tried a case is not covered by the rule and thus could discuss the case with the agency head, perhaps even raising new arguments or facts not presented to the ALJ, subject to the not insignificant limitation that the agency decision must be based on the record and defended in court on that basis. In practice, communications on factual matters related to a case are unlikely to occur because of concerns about whether they would be challenged in judicial review. In sum, the ex parte rules apply to all communications of fact by anyone to the ALJ, who

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85. 5 U.S.C. § 554(d)(1). As provided in the introductory phrase in § 554(a), the whole of § 554 applies only to formal adjudications, which excludes formal rulemakings.

86. *Id.* § 557(d).

87. *Id.*

makes the findings of fact that are given substantial deference by the agency; and agency personnel who worked on the investigation or trial of the case or "a factually related case" may not communicate with the agency officials who have ultimate decisional authority.[88]

Similar issues arise when a claim is made that an agency official is biased and should not participate in a formal adjudication. The final sentence in § 556(b) provides the specific means by which a claim of bias can be filed and is decided, but the procedures apply only to the ALJ or other person presiding at the formal hearing. Does this mean that agency officials could, for example, own stock in a company that is a party to the proceeding or, more problematically, one of its competitors? Or suppose that the agency official had firmly and irrevocably committed himself to a position with respect to the principal issue in the case? Case law, admittedly pre-*Vermont Yankee*, required an FTC Commissioner to step aside in such circumstances,[89] with no question that somehow Congress had authorized him to sit in a case "in which his impartiality might reasonably be questioned."[90] Perhaps the line on whether an agency member's views constitute improper pre-judgment should be drawn in a different place for a formal adjudication than for a judicial proceeding. If it is, it is because agencies make policy as well as adjudicate factual and legal disputes and, therefore, it would be unwise, even if theoretically possible, to hold agency officials to the same standard as applies to judges. Although agencies are like courts, they are not courts, and agency officials should not be treated exactly like judges.[91]

The four *Morgan* cases in the Supreme Court[92] illustrate another way in which agencies conducting even formal adjudications are different from courts, and for good reasons. The substantive issue in *Morgan* was the

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88. Given this quite carefully developed ex parte communications regime, including its application only to formal proceedings and the exclusion of formal rulemaking from the prohibition on factual inquiries under § 554(d), it is at least arguable that if a court attempted to impose similar requirements in the context of an informal rulemaking, *Vermont Yankee* would be invoked to prevent that from happening. On the other hand, basic notions of administrative fairness—and perhaps even due process—might lead a court to imply some protections in particularly egregious cases of ex parte communications, especially when, although the proceeding is a rulemaking, the result is more like an adjudication because it is principally a contest between two competitors over some government privilege. On applying this analysis to informal adjudications where Congress has been completely silent on what procedures apply, see discussion *infra* Part IV.

89. Am. Cyanamid Co. v. FTC, 363 F.2d 757, 767-68 (6th Cir. 1966); *see also supra* notes 73, 76 (addressing bias in rulemaking and the impact of *Vermont Yankee*).

90. 28 U.S.C. § 455(a) (2000) (requiring all federal judges, including Supreme Court Justices, to disqualify themselves in cases where their impartiality may reasonably be questioned).

91. Except for the Supreme Court, if one judge does not sit on a case, another can take her place, which is not true for agencies.

92. *See* United States v. Morgan, 313 U.S. 409, 413-14 (1941) (citing prior *Morgan* cases).

validity of an order by the Secretary of Agriculture establishing a fixed, maximum rate allowed to be charged for livestock in Kansas City.[93] The Secretary delegated the task of taking evidence to an Assistant Secretary in the pre-APA equivalent of an on-the-record hearing, but reserved the decisional authority for himself.[94] The administrative law question was whether the Secretary actually had to read the record or briefs, or if he could do nothing more than sign what his staff had presented to him.[95] The Court deemed his signature sufficient.[96] The model approved by the Court is a far cry from the judicial model, in which trial judges hear the witnesses, read the briefs, and review carefully their opinions, even if they do not actually write the drafts. Leaving aside questions of how evidence of what the Secretary did, or could have done in conducting the review, would be gathered without requiring the Secretary to be deposed, the result is a recognition of the fact that agency heads who make final adjudication decisions are acting rather differently from courts because of the significant institutional differences between them.[97]

Morgan was a pre-APA case, but even with the procedures that now apply under §§ 556 and 557, the result would be substantially the same, although now the ALJ (or whoever heard the evidence) would be required to make recommended findings of fact and conclusions of law, to which any party could object, before the case went to the agency. In that system, the ALJ functions like a magistrate judge to whom a district judge had referred a matter for the taking of evidence pursuant to 28 U.S.C. § 636(b).[98] Once the matter came back to the district judge, she would be expected to read the briefs and the relevant portions of the record, perhaps with the help of a law clerk, and reach a judgment on whether to affirm the recommendations or not. Under *Morgan*, however, (and now the APA), the Secretary may rely on staff to do as much or as little of that work as she deems appropriate.

There are several reasons why that difference in expectations is entirely appropriate. First, agencies generally have many more matters to decide than district judges—some adjudications and some rulemakings—and often with records of enormous length. Unlike judges, whose only job is to

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93. *Id.* at 413.
94. *Id.* at 415-16.
95. *Id*. at 416.
96. *Id*. at 416-17.
97. In *Nat'l Nutritional Foods Ass'n v. FDA*, 491 F.2d 1141, 1143, 1145-46 (2d Cir. 1974), the court assumed that it was impossible for the new Food and Drug Administration (FDA) Commissioner to have given any meaningful review to the massive record in the formal rulemaking there in the thirteen days in which he was in office before he approved the rules being challenged, but held that this impediment was irrelevant.
98. Even there, the analogy is not exact because the district judge would be required to review contested factual findings de novo, 28 U.S.C. § 636(b)(1), whereas the substantial evidence standard would apply to an agency's review of the ALJ's factual findings.

adjudicate, agency heads have a multitude of other responsibilities, including keeping the relevant committees of Congress happy. If the agency head had to do what a trial judge is expected to do in every case, the efficiencies gained in moving adjudications from a court to an agency would be largely lost. Second, federal judges enjoy life tenure, but agency heads work for a few years and leave. If every new agency head had to start from scratch with every case on the docket, almost no cases would be decided. Third, much is made of the expertise of agencies, often as a reason to sustain their decisions. It is not, however, agency heads who usually have the expertise—they may have just arrived on the job when a decision must be made. Rather, it is the staff—generally career people—who have the knowledge of the agency. Thus, it makes sense to give them significant roles in the decisionmaking process, while leaving to the secretary, who is exercising the discretion provided by law, the final say. Finally, although the term adjudication suggests a judicial analogy, a more apt analogy is the manner in which decisions are formally assigned to the president.[99] No one expects the president to read an entire record, or even all of the main written submissions, and no one should expect—or want—agency heads to do so either. Of course, some matters may be so important that a secretary will pay much closer attention to them than normal; however, that is a matter of choice, not a requirement.[100]

Another respect in which agencies are not like courts relates to issues of judicial review of questions of law. Suppose an agency in a formal adjudication decides a legal question, such as whether newsboys are employees or independent contractors under the National Labor Relations Act and suppose further that an identical question was posed to a district judge in a traditional lawsuit. Assuming in both cases that the facts were stipulated, the district court's decision, either on summary judgment or after trial, would be reviewed de novo by the court of appeals on the legal issue presented. However, if the case originated with the NLRB, the court of appeals would follow the two-step analysis articulated in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[101] as modified by *United States v. Mead Corp.*[102] Under that test, if the statute was clear, the inquiry

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99. 13 U.S.C. § 1341 (2000) (stating the duty of the President to report census data to Congress, based on recommendations of the Secretary of Commerce).

100. The same principles apply to agency rulemaking, but there the analogy to the legislative model sustains the lack of requirement of personal involvement: No one assumes that members of Congress write any of the legislation that becomes law, nor does anyone assume that members of Congress even read most of it.

101. 467 U.S. 837, 842-43 (1984).

102. 533 U.S. 218, 230-32 (2001). In its recent decision in *Gonzales v. Oregon*, 546 U.S. 243 (2006), the Court also placed considerable emphasis in deciding the appropriate amount of deference to be accorded on whether Congress delegated to the agency the authority to resolve specific ambiguities in the statute.

would end. If, however, the statute was ambiguous, the agency would be entitled to substantial deference in its interpretation of the law, provided that it fully considered its conclusion and explained the basis for it which, for the NLRB, is likely to have occurred if the proceeding were a formal adjudication.

There is a reason for the significant difference in the deference accorded an agency's view on a question of a law and the views of the district court: Congress delegated to agencies the power to fill in the inevitable uncertainties in the law. Agencies fill in these gaps as part of their responsibility to implement the law, which includes bringing policy considerations and agency expertise to bear in choosing among various alternatives. District courts, on the other hand, have no such mandate on questions of law because they are not policy implementers and have no specialized expertise in the subject areas of cases that come before them. Thus, because agency officials have policymaking roles and relevant expertise that they properly utilize in deciding questions of law during formal adjudications, their rulings on questions of law are given deference, while the rulings of district judges, who neither create policy nor possess the requisite substantive expertise, are not.[103]

In some formal adjudications, there will be conflicting testimony that the ALJ, and eventually the agency, must resolve. If challenged in court, the agency's factual findings are given considerable deference and will be upheld if supported by "substantial evidence."[104] Although other words are used in Rule 52(a) of the Federal Rules of Civil Procedure to guide the courts of appeals in reviewing findings of fact made by a district judge sitting without a jury—they may not be set aside unless "clearly erroneous"—there appears to be little real world difference between the two standards or, for that matter, between them and the "arbitrary, capricious, [or] abuse of discretion" standard specified in § 706(2)(A), which is used when reviewing the factual findings contained in agency rules or informal adjudications.[105] There is one exception to the limited review of findings of fact that has not been used since its creation by the Supreme Court in *Crowell v. Benson*,[106] but neither has it been overruled.

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103. *Chevron* deference also applies to legal questions arising in agency rulemakings (*Chevron* itself was such a case), but there is no appropriate analogy with comparable decisions of district courts because courts do not issue legislative-type rulings in adjudicated cases. Congress does enact statutes, but since those statutes are themselves "the law," the courts do not review their legality, except for claims of unconstitutionality. *Chevron* also may apply to informal agency adjudications, although they rarely have the requisite formality to satisfy *Mead*. Although what I have called semi-formal adjudications are more likely to satisfy *Mead*, even they may not clear the formality hurdle.

104. 5 U.S.C. § 706(2)(E) (2000).

105. *See* Ass'n of Data Processing Orgs. v. Bd. of Governors, 745 F.2d 677, 686 (D.C. Cir. 1984) (discussing the scope of review in judicial proceedings).

106. 285 U.S. 22, 54, 62 (1932).

The Court there required de novo review of certain factual findings by the agency that the Court concluded were "jurisdictional."[107] Although the rationale for choosing those facts, as opposed to others that were arguably as much of the predicate for the agency's power to act, is not clear, the Court was faced with a claim that Congress lacked the power to assign the adjudication to an administrative agency.[108] The conclusion, therefore, that certain facts had to be tried de novo in the district court provided some assurance that the agency would not stray too far from the congressional mandate.

Finally, in another example of the Supreme Court's unwillingness to give deference to an agency's interpretation of its enabling statute in certain situations, the Court in *FDA v. Brown & Williamson Tobacco Co.*[109] declined to accept the agency's determination that it had the authority to regulate cigarettes as either drugs or medical devices. The Court gave a number of reasons for its ruling, but there is at least a strong undercurrent that the controversial decision as to whether and how to regulate tobacco was one that should be made by Congress explicitly, and not by the FDA alone, by interpreting its existing authority.[110] In the analogous area in which courts review whether Congress has exceeded its limited legislative powers under Article I, Section Eight, the Supreme Court has not treated such cases any differently from other constitutional issues involving Congress, generally according them the presumption of correctness even though, almost by definition, it is reviewing whether Congress exceeded its powers, just as it reviewed whether the FDA exceeded its power by issuing the tobacco rules.

IV. INFORMAL AND SEMI-FORMAL ADJUDICATIONS

If a proceeding is not intended to produce a rule, and if the agency is not required to have an on the record hearing, then the proceeding is considered an informal adjudication, as that is all that remains of the administrative universe under the APA. As the catch-all, informal adjudications include a wide range of agency decisions, some on very complex and very important matters, and others on relatively simple issues that have modest consequences. However, unlike formal proceedings or informal rulemakings, there are no specific procedural requirements in the APA that agencies must follow when engaging in informal adjudication.[111] This

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107. *Id.* at 54.
108. *Id.* at 57.
109. 529 U.S. 120, 155 (2000).
110. *Id.* at 131-33.
111. Some protections that apply to all APA proceedings may be found in 5 U.S.C. § 555 (2000), including the right to appear before an agency (within limits), the right to retain copies of data submitted to an agency, the right to inspect a copy of any transcript of

leaves interested persons with only the procedural protections in the applicable substantive statute, plus any found in the agency's regulations. The danger from this kind of procedural void was brilliantly captured by Representative John Dingell, when he was chair of the House Energy and Commerce Committee: "Most people think of the procedure as just being kind of amorphous, and you don't have to worry about it. The procedure is exquisitely important . . . . I'll let you write the substance of a statute, and you let me write the procedure, and I'll screw you every time."[112] As described below, the courts have not been willing to allow agencies full carte blanche, but neither have they imposed substantial procedural requirements. In so doing, the courts have attempted to tailor the procedures to the nature of the proceedings, resulting in an almost case-specific approach within the general category of informal adjudications. Because the "law of informal adjudications" is not based on the text of the APA, but rather on case holdings, it is necessary to explore these cases in greater detail here than was done in the rest of the Article.[113]

This choice between quite formal procedures and almost no procedures sometimes leaves the courts in an awkward position, especially when important personal rights are at stake. The result was that the Supreme Court, in *Wong Yang Sung v. McGrath*,[114] construed the Immigration and Naturalization Act to require an on the record hearing in a deportation case, in large part because of what was at stake and the absence of an intermediate position. In response, Congress provided a set of specific procedures that do not require a full on the record trial, but that do provide more protection for aliens than would exist if the proceeding were only an informal adjudication.[115]

Because the APA is simply the default procedural option, if Congress specifies the procedural rules to be followed under a given statute, the APA no longer sets the maximum or minimum. In providing these additional protections, Congress has been informed by, although not necessarily controlled by, the requirements imposed by the mandates of the Due Process Clause. Surely, an alien who has been in this country for many

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testimony that person gave, and limits on agency subpoena power. However, they are quite different from the requirements of § 553 for informal rulemaking and §§ 554, 556, and 557 for formal adjudications.

112. Craig Oren, *Be Careful What You Wish For: Amending the Administrative Procedure Act*, 56 ADMIN. L. REV. 1141, 1141 (2004) (citing *Regulatory Reform Act: Hearing Before the Subcomm. on Administrative Law and Government Relations of the House Comm. on the Judiciary*, 98th Cong., 1st Sess. 312 (1983)).

113. For a fuller treatment of the limits imposed on informal adjudications, see Ronald Krotoszynski, *Taming the Tail That Wags the Dog: Ex Post and Ex Ante Constraints on Informal Adjudication*, 56 ADMIN. L. REV. 1057 (2004).

114. 339 U.S. 33, 48-53 (1950).

115. The current rules for hearings in deportation (and inadmissibility) cases are found in 8 U.S.C. § 1229a (2000).

years and is about to be deported would have a due process claim to some kind of procedural protections, perhaps including a hearing, as would a person receiving disability benefits before the government could take them away from her.[116] What those rights would be in the absence of a statute is beyond the scope of this Article, but there can be no doubt that the Due Process Clause operates to constrain agencies in ways that it would not constrain legislatures.[117]

Another very significant example of less-than-formal procedures involves adjudications at the Social Security Administration, mainly in the area of disability claims. Again, Congress specified what procedural rules to follow, attempting to balance the need for formality to protect individual rights, against the costs and delays inherent in an on the record proceeding. Like the Immigration and Naturalization Service (INS) proceedings, there is a hearing at which live witnesses are heard, in contrast to both informal adjudications and informal rulemakings, where there is no right to an oral hearing of any kind.[118] These statutory procedures, which are considerably less protective of individual rights than the procedures that would be followed in court or in a formal adjudication, will be upheld as long as they are consistent with due process.

In contrast to the INS and Social Security cases, which are governed by what I call semi-formal rules of adjudication, there are no procedural rules in the APA for the "everything else" that comprises informal adjudications.[119] In theory, the courts could have stayed out of informal adjudications altogether, providing no judicial review, but the Supreme Court clearly rejected that option in *Citizens to Preserve Overton Park v. Volpe.*[120] At issue there was a decision by the Secretary of Transportation to fund a highway that would run through a park in Memphis, Tennessee, in alleged contravention of a statute requiring the Secretary to choose other routes if feasible and to assure that any damage to the park was minimized to the extent feasible.[121] The Court rejected arguments by plaintiffs requesting de novo court review, review under the substantial evidence

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116. *See* Mathews v. Eldridge, 424 U.S. 319, 323, 348-49 (1976) (holding that an agency's administrative procedures for termination of disability benefits, which did not include a full evidentiary hearing prior to the termination of the benefits, fully complied with due process requirements).

117. *Compare* Londoner v. Denver, 210 U.S. 373 (1908), *with* Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441 (1915).

118. *See* 42 U.S.C. § 405(b) (2000) (describing the rules and regulations for hearings and investigations concerning administrative determinations in social security benefits cases).

119. Michael Asimow used the term "Type B" adjudications to cover what I call semi-formal adjudications. Michael Asimow, *The Spreading Umbrella: Extending the APA's Adjudication Provisions To All Evidentiary Hearings Required by Statute*, 56 ADMIN. L. REV. 1003, 1004 (2004).

120. 401 U.S. 402, 410, 422 (1971).

121. *Id.* at 406-07.

standard, and a requirement that the agency make formal findings to support its decision.[122] The Court did, however, require the agency to explain the basis of its decision, in particular how it had satisfied the statute, which the Court found had been enacted for the very purpose of changing agency practice and providing greater protection for parklands.[123] The Court also indicated that, in the absence of a written basis for his decision, deposing the Secretary might be possible as a last resort.[124]

There are several points to note regarding *Overton Park.* First, the Court rejected the no-review option as inconsistent with the presumption of reviewability in the APA.[125] Second, it refused to impose additional procedural requirements directly on the agency, although the practical effect of its ruling—that the agency must explain what it did and why—may be the functional equivalent of requiring findings of some kind in future cases, although perhaps not "formal findings," whatever difference there may be. Third, it made clear that there would be sufficient judicial review to assure that the agency stayed within its congressional mandate, but that the Court would not substitute its judgment for that of the agency. This is consistent with the notion that courts engage in judicial "re-view" and not judicial "re-do;" they serve as a backup to provide some control over agencies, but the principal responsibility belongs to the agency with Congress acting as the ultimate check if it has the votes to pass a statute overruling the agency.

As discussed above, several years after *Overton Park*, the Supreme Court in *Vermont Yankee*[126] set aside a decision of the District of Columbia Circuit imposing additional procedural requirements in an informal rulemaking. While upholding the obligation of the courts to review such decisions, the Court concluded that, in choosing less formal processes, Congress intended to preclude the courts from adding further procedural requirements, such as a hearing.[127]

In *Pension Benefit Guaranty Corp. v. LTV Corp.*, the Court subsequently applied that approach to an informal adjudication decision by the Pension Benefit Guaranty Corporation (PBGC) that restored a previously terminated pension plan to operative status over the claim of the plan sponsor that the PBGC provided inadequate procedures in reaching its decision.[128] Citing *Vermont Yankee* and finding that it trumped *Overton Park*, the Court concluded that a party to an informal adjudication has only

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122. *Id.* at 414.
123. *Id.* at 415-16.
124. *Id*. at 420.
125. 5 U.S.C. § 701 (2000) (detailing the application of the APA).
126. Vermont Yankee v. Natural Res. Def. Council, Inc., 435 U.S. 519 (1978).
127. *Id*. at 546.
128. Pension Benefit Guar. Corp. v. LTV Corp., 496 U.S. 633, 653-56 (1990).

those rights provided by the substantive statute at issue (and presumably any regulations issued under it) and those contained in § 555, although that provision does not mention informal adjudications, nor does it have any procedures that arguably govern them. The Court did leave open the possibility of requiring procedures where, as in *Overton Park*, the administrative record was inadequate to enable the court to engage in meaningful judicial review,[129] and it further left the door open to a due process challenge, which LTV had not raised.[130] The case otherwise seemed to close the door on efforts to have courts require additional procedures in informal adjudications.

Several points should be noted about the decision that raise questions about whether it should be read as broadly as its language suggests. First, LTV's principal procedural objection was that it was not apprised of the basis for PBGC's decision and thus not given an opportunity to adduce evidence to support its position. Yet footnote four in the opinion[131] shows that LTV was given notice of the decision before it was made and that it met twice with PBGC officials before the decision was finally issued, thereby calling into question what function the allegedly missing procedures would have provided. Moreover, the principal issues raised by LTV were legal, and thus it is difficult to understand how the additional procedures would have aided it. And, as the Court noted,[132] PBGC agreed with LTV regarding one of its plans, further suggesting that the agency took into account any facts provided by LTV relevant to the restoration of the remaining plans. Finally, the fact that PGBC is a financial guarantor, not a regulator, may have affected the Court's view of what procedures it should apply, despite the absence of a claim that the PGBC's actions were not subject to the APA.

Despite the sweeping language in *Pension Benefit Guaranty Corp.*, the Supreme Court—and, more likely, the lower courts—will retreat from the result, if not the reasoning, when justice requires it in individual cases. Agencies are required to follow their own regulations, including procedural ones,[133] and courts may be inclined to construe them broadly to avoid

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129. *Id.* at 655.

130. *Id.* at 655-56. As Professor Krotoszynski points out in his article, the breadth of the definition of agency action extends so widely that it would include "a decision to turn on the lights or lower an agency's office building temperature by two degrees . . . ." Krotoszynski, *supra* note 113, at 1069. However, the likelihood of a successful due process challenge in that situation is very small. *Id.* at 1073-74. The main point of his examples is that the scope of informal adjudications is almost limitless and thus that the same procedures are not necessary for every type of decision falling within the category of informal adjudication.

131. *See Pension Benefit Guar. Corp.*, 496 U.S. at 643 n.4 (providing details about the communications between the two parties).

132. *See id.* at 652 n.9.

133. Vitarelli v. Seaton, 359 U.S. 535, 539-40 (1959); Service v. Dulles, 354 U.S. 363, 388-89 (1957).

serious injustice. That inclination is made more likely because the Due Process Clause also remains available where substantial liberty or property issues are at stake. Thus, in cases (unlike *Pension Benefit Guaranty Corp.*) where an agency relies on secret information, or the agency does not disclose the reasons why it took certain action, it is hard to imagine that the courts will not find some way to assure basic fairness, even when a proceeding falls into the informal adjudication category. At the very least, the opinion makes clear that a remand to the agency for further explanation is a proper tool for the courts,[134] and on remand it may be possible to obtain the protections sought, even if they are not in the preferred procedural form.

Although the breadth of *Pension Benefit Guaranty Corp.* seems excessive, its acceptance of the basic thrust of *Vermont Yankee* seems appropriate in a number of circumstances. Thus, directing an agency to hold a hearing adds an affirmative requirement, as compared to a prohibition such as forbidding the agency from using secret evidence, even though the proceeding is not on the record. Some of these procedural requirements are contained only in the provisions of the APA regarding formal adjudications—such as the prohibitions on ex parte communications, the rules on disqualifications for ALJs, and the rules on separations of functions. If informal adjudications were like formal adjudications and like court adjudications, they too would apply. But when agencies conduct informal adjudications, they undertake a wide variety of tasks, many of which seem quite remote from the kind of decisions that courts make, and hence it should be up to Congress, not the courts, to decide which procedures agencies must use in making certain decisions.[135]

Overton Park provides a good example. In some ways, the decision whether to allow a road to be built through a park and, if so, under what conditions, looks more legislative than judicial—its impact will be in the future, and its discretionary and multi-factored approach is not the kind of activity ordinarily undertaken by judges. Yet, by default and because informal rulemaking does not apply to a process designed to approve (or reject) a specific project, it is an informal adjudication under the APA. Seen in that light, a literal application of the rules on ex parte communications, a neutral decisionmaker, and a strict separation of functions would be out of place, if not unworkable.

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134. *Pension Benefit Guar. Corp.*, 496 U.S. at 654.

135. Nothing prevents agencies from imposing additional procedural requirements on themselves for some categories of cases, or even in specific cases. *See* Paul Verkuil, *A Study of Informal Adjudication Procedures*, 43 U. CHI. L. REV. 739, 780-81 (1976).

On the other hand, it would not make sense to apply the legislative analogy of no specific controls because Congress passed a statute designed to limit agency discretion in approving highways that would affect the public's use of parks. Of those requirements, separation of functions is the most problematic since it would, in effect, require the agency to separate the staff that did the information gathering and analysis from the person who has the decisional authority, even though what is at stake is the money to build the highway and the route that it will follow. In many informal adjudication cases, there will be no factual dispute, and yet a separation of functions mandate, taken from the judiciary where there are often factual disputes, would be universally required. As for ex parte communications between the staff and the decisionmaker, whether through memos or in conversations that are not recorded and not available to all interested parties, they are almost certain to take place as they should in a properly functioning agency. But if either a proponent or an opponent of the highway communicated with the secretary, and if that communication contained factual information not available to others interested in the application, that might be a different matter, especially if the secretary relied on it in making his decision. While due process might not preclude that from happening, the courts have insisted on basic notions of fairness, even in the most legislative-like proceedings. Thus, if a court finds such basic unfairness, it can properly rely on its direct authority in the APA to set aside a decision as "arbitrary, capricious, [or] an abuse of discretion . . . ."[136]

The same is true of a neutral decisionmaker. Administrators of regulatory agencies surely have their ideas on how the agency should be run; indeed, that is often why they are chosen. But they are bound by the laws that govern their actions, and if an agency head has "unalterably closed" his mind on a topic, then it would be "arbitrary, capricious, [or] an abuse of discretion" for that official to make that decision and someone else should make the decision instead.[137] As noted previously, rules that are designed to assure fairness in the judicial process do not apply, or do not apply to the same extent and in the same manner, in the informal

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136. 5 U.S.C. § 706(2)(A) (2000). The notion that there should be "one administrative record for the public . . . and another for the Commission" is unthinkable. Home Box Office v. FCC, 567 F.2d 9, 54 (D.C. Cir. 1977). Even though the context in *Home Box Office* was rulemaking, the idea would appear to apply to at least some informal adjudications, and no case has held to the contrary.

137. Ass'n of Nat'l Advertisers v. FTC, 627 F.2d 1151 (D.C. Cir. 1979). Again, the context was informal rulemaking, but the concept should apply to informal adjudications as well.

adjudicative context at the agency level because the nature of the functions being performed are different and the need to strike a different balance is based on the differences between courts and administrative agencies.

Finally, an agency is likely to receive little, if any, deference on judicial review of questions of law arising in informal adjudications. The Supreme Court in *Mead* ruled that deference is generally permissible only when the agency reaches its interpretation in a more or less formal proceeding, in which input from outside the agency is sought—a rarity in informal adjudications. In addition, the basis of *Chevron* and *Mead* is that Congress presumably intended to allow agencies to fill in the gaps in the statutes that they administer.[138] However, in cases like *Overton Park*, where it was clear that the law was passed in order to confine, and not free, the agency's discretion over parks, the rationale is inapplicable and no deference is permitted. Also, when federal agencies make decisions that tread on areas traditionally left to the states, the Supreme Court has insisted that the delegation to the agencies must be clear before deference can come into play.[139]

There is one other set of decisions that, by default, are within the category of informal adjudications, but for which there are no procedural rules and no (or almost no) judicial review. *Heckler v. Chaney*[140] is the prime example of this category. The plaintiffs, death row inmates, alleged that the FDA had approved certain drugs for lethal injections that did not meet the statutory requirements of safety and efficacy because they produced unnecessary pain during the execution process.[141] The inmates sought an order directing the FDA to commence enforcement proceedings recalling the drugs as unlawful under the statute.[142] The FDA refused to commence such proceedings on the ground that the decision was one related to the allocation of its law enforcement resources and, as such, was not subject to judicial review.[143] The Supreme Court agreed, finding that the statute did not provide judicially manageable standards for deciding whether an agency had made a reasonable resource-allocation decision.[144]

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138. *See* STEPHEN BREYER, ACTIVE LIBERTY: INTERPRETING OUR DEMOCRATIC CONSTITUTION 106-07 (2005).

139. *See* Gonzales v. Oregon, 546 U.S. 243 (2006) (practice of medicine).

140. 470 U.S. 821 (1985).

141. *Id.* at 823.

142. *Id*.

143. *Id*. at 824.

144. Justice Brennan's concurring opinion left open the possibility that if the agency had refused to proceed for a legally indefensible reason—for example that the statute did not apply—the courts might review that determination and remand to the agency for reconsideration under the correct interpretation of the law. *See id.* at 839 (Brennan, J., concurring). Neither the APA nor any other substantive law required the FDA to account for its actions and inactions, or explain what its priorities are. That kind of reporting requirement would be far less intrusive than the relief sought in *Heckler*, but also would

In reaching the result in *Heckler*, the Court relied on the narrow exception to judicial review contained in § 701(a)(2) for actions "committed to agency discretion." There is, however, another way to look at the case that is consistent with the concept that the APA and judicial review are primarily designed to control the regulatory actions of agencies. Because the agency's decision in *Heckler* was to take no action, it did not fall within the broad category of agency regulatory action that the courts are called on to police. To be sure, under the APA's definitions, the decision not to seek the recall was an informal adjudication, but the action much more closely resembled the kind of executive branch prosecutorial decisions that federal officials made for more than 150 years before the APA was passed when compared to the type of regulatory actions that led to the enactment of the APA. That perspective alone might not lead to the conclusion that there should be no judicial review. However, the fact that the decision was not the kind that the APA sought to control through procedures and judicial review, and because the agency was not functioning like either a legislature or a court, provide alternative support for the result in *Heckler*, even if it is not the reasoning used by the Court to reach that conclusion. Stated another way, the Court's refusal to provide for judicial review was not inconsistent with the purposes of the APA's provisions for judicial review and their limited exceptions.[145]

CONCLUSION

There are two approaches that can be used in examining the practices regarding administrative agencies and comparing them to courts and legislatures. First, one can look at an agency that is issuing a rule and ask why the additional requirements of § 553 were imposed, instead of allowing the agency to do what a legislature would do in enacting a statute that might closely resemble the agency's rule. The answer would be that the agency process lacks the essential checks and balances found in the legislative arena—the concurrence of two bodies separately elected, plus the president. Thus, Congress has provided alternative checks, generally of a procedural variety, to offset the fact that one person alone will make the decision for the agency. The techniques used to control agencies, as compared to those used to control legislatures and courts, are different because the way that agencies operate produces different sets of problems

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inform the public what agencies are doing and allow for more meaningful congressional oversight.

145. Another way to look at *Heckler* is that it involved inaction rather than action. The problem is that the definition of "agency action" in § 551(13), which triggers the definitions of rule, order, and adjudication in subsections (4), (6), and (7), includes "failure to act," which forecloses that avenue. *See* 5 U.S.C. § 551 (2000).

that require different solutions. But the theory of providing an alternative check on the agency is a constant and, when applied to a particular procedure or other check, explains its existence. In other words, just because a legislature could do something in a particular way, it does not necessarily follow that an agency, carrying out legislative-like functions when issuing rules, should be allowed to do so without additional procedural checks.

Alternatively, one can examine the question from the congressional perspective. Thus, because agencies function differently from courts, some of the judicial checks, such as strict on the record proceedings or complete separation of functions, will not be workable in an agency. Therefore, to both provide for similar, albeit not identical, checks at the agency level, it is necessary to adopt additional agency procedures to assure that the essence of a neutral judiciary is protected at the administrative level without losing the advantages of having an entity that makes policy, enforces policy, and decides whether third parties have complied with that policy. Or, stated another way, just because a court could not do something under well-established norms does not mean that an unchecked agency also should be able to do so. The reason why the last sentence in both of the preceding paragraphs is correct is that "Administrative Agencies Are Just Like Legislatures and Courts—Except When They're Not."

PANDEMIC INFLUENZA: ETHICS, LAW, AND THE PUBLIC'S HEALTH

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Editor's Note

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INTRODUCTION

Highly pathogenic Influenza A (subtype H5N1) (H5N1 or virus) has captured the close attention of policymakers who regard pandemic influenza as a national security threat.[1] The virus already is endemic in avian populations in Southeast Asia, with serious outbreaks now in Africa, Europe, and the Middle East.[2] H5N1 has moved steadily to many regions of the world, surfacing in Europe as far north as Germany, as far west as France,[3] and as far south as the Mediterranean and Adriatic seas.[4] The virus has spread to the Middle East in Iraq, Iran, Saudi Arabia, and Egypt.[5] It has emerged in impoverished countries such as Nigeria and transitional economies such as India.[6]

Modeling suggests that the virus will eventually affect the entire globe through a number of transmission mechanisms such as commerce, migratory birds, and a highly mobile population.[7] International trade and travel will play a major role in the spread of the virus. The majority of the outbreaks in Southeast Asia have already been attributed to the movement of poultry and poultry products.[8] Frequent travel makes it difficult to contain a pandemic. However, even if trade and travel were severely

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1. *See* U.S. DEP'T OF HEALTH AND HUMAN SERVS., HHS PANDEMIC INFLUENZA PLAN 60 (2005) [hereinafter HHS PANDEMIC INFLUENZA PLAN], *available at* http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf; HOMELAND SECURITY COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA 2 (2005) [hereinafter NATIONAL STRATEGY FOR PANDEMIC INFLUENZA], *available at* http://www.whitehouse.gov/homeland/nspi.pdf.

2. *See* World Health Organization (WHO), *Avian Influenza—Spread of the Virus to New Countries*, Feb. 21, 2006, http://www.who.int/csr/don/2006_02_21b/en/index.html.

3. *See id*.

4. *See id*.

5. *See id.*

6. *See id.*

7. *See* Ira M. Longini et al., *Containing Pandemic Influenza at the Source*, 309 SCI. 1083, 1083 (2005); H. Chen et al., *Establishment of Multiple Sublineages of H5N1 Influenza Virus in Asia: Implications for Pandemic Control*, 103 PROC. OF THE NAT'L ACAD. OF SCI., 2845, 2845 (2006) [hereinafter *Implications for Pandemic Control*].

8. *See Implications for Pandemic Control*, *supra* note 7, at 2845, 2849.

restricted, it is possible that migratory birds still would bring the virus to other continents.[9]

At present, the spread of the H5N1 strain is mainly confined to animal populations. While the virus is highly contagious among birds,[10] it is still rare in humans because of a significant species barrier.[11] Confirmed cases of human infection have nonetheless been reported. As of May 29, 2006, 224 cases of H5N1 have been reported, with 127 deaths.[12] Most of these cases are attributable to close contact with infected poultry, particularly at poultry farms and markets, cock-fighting venues, or when poultry is used as backyard pets.[13] While a few cases of human-to-human transmission have occurred, principally resulting from intimate household contact, transmission is not common beyond one person.[14] The virus appears to be highly pathogenic when occurring among humans, with a reported death rate exceeding 50%.[15] However, because of possible under-reporting, the prevalence, transmissibility, and fatality of H5N1 remain uncertain.

A series of compounding possibilities make it likely that a new influenza pandemic could emerge, although the timeframe and virulence are uncertain. The first five of the following six essential prerequisites for a pandemic have already occurred: (1) a novel viral subtype is identified in animal populations such as swine or poultry, (2) the virus spreads to animals in a wider geographic setting, (3) the virus jumps from animals to humans inefficiently, (4) the virus more efficiently spreads from animals to humans, (5) inefficient human-to-human transmission is documented, and (6) efficient human-to-human transmission emerges. Through adaptive mutation or viral reassortment, the H5N1 virus could become highly transmissible among humans, thus leading to a pandemic outbreak.[16]

Recent evidence that an avian influenza virus caused the 1918 pandemic lends credence to the theory that current outbreaks could have pandemic

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9. *See* Dennis Normile, *Evidence Points to Migratory Birds in H5N1 Spread*, 311 SCI. 1225, 1225 (2006).

10. *See* Laurie Garrett, *Avian Flu Update*, FOREIGN AFF., Sept.-Oct. 2005, *available at* http://www.foreignaffairs.org/20050701faessay84401/laurie-garrett/the-next-pandemic.html.

11. *See* The Writing Committee of the World Health Organization Consultation on Human Influenza A/H5, *Avian Influenza A (H5N1) Infection in Humans*, 353 NEW ENG. J MED. 1374, 1379 (2005) [hereinafter *Avian Influenza A (H5N1) Infection in Humans*].

12. *See* WHO, *Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO*, May 29, 2006, *available at* http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_05_29/en/.

13. *See* Tran Tinh Hien et al., *Avian Influenza A (H5N1) in 10 Patients in Vietnam*, 350 NEW ENG. J. MED. 1179, 1181, 1183 (2004).

14. *See* WHO, *Avian Influenza: Significance of Mutations in the H5N1 Virus*, Feb. 20, 2006, *available at* http://www.who.int/csr/2006_02_20/en/index.html.

15. Samson S.Y. Wong & Kwok-yung Yuen, *Avian Influenza Virus Infections in Humans*, 129 CHEST 156, 156 (2006).

16. *See* Robert G. Webster et al., *H5N1 Outbreaks and Enzootic Influenza*, 12 EMERGING INFECTIOUS DISEASES 3, 3-4 (2006).

potential.[17] Historically, the number of deaths during a pandemic has varied greatly depending on the number of people who become infected, the virulence of the virus, and the effectiveness of preventive measures.[18] Such variables lead to great difficulty in establishing accurate predictions of mortality, and as a result, estimates differ considerably. A mild pandemic, like the 1957 and 1968 pandemics, is likely to cause the death of 89,000 to 207,000 people in the United States[19] and 2 million to 7.4 million people globally.[20] Conversely, other studies that extrapolate from the severe 1918 pandemic indicate that in the absence of intervention, an influenza pandemic would lead to 1.9 million deaths in the United States and 180 million to 369 million deaths globally.[21]

Characteristic	Moderate (1957/68-like)	Severe (1918-like)
Illness	90 million (30%)	90 million (30%)
Outpatient medical care	45 million (50%)	45 million (50%)
Hospitalization	865,000	9,900,000
ICU Care	128,750	1,485,000
Mechanical Ventilation	64,875	742,500
Deaths	209,000	1,903,000

Department of Health and Human Services (HHS) Health Outcomes: Number of Episodes of Illness, Healthcare Utilization, and Death Associated with Moderate and Severe Pandemic Influenza Scenarios[22]

17. *See, e.g.*, Jeffrey K. Taubenberger et al., *Characterization of the 1918 Influenza Virus Polymerase Genes*, 437 NATURE 889, 889 (2005) (asserting that the 1918 influenza virus polymerase genes more closely resembled avian-like flu strains than those of a reassortant virus); Terrence M. Tumpey et al., *Characterization of the Reconstructed 1918 Spanish Influenza Pandemic Virus*, 310 SCI. 77, 79 (2005).

18. *See* WHO, *Avian Flu vs. Pandemic Flu* (2005), *available at* http://www.wvdhhr.org/healthprep/common/avian_vs_pandemic_flu.pdf.

19. *See* Laurie Garrett, *The Next Pandemic?*, FOREIGN AFF., July-Aug. 2005, *available at* http://www.foreignaffairs.org/20050701faessay84401/laurie-garrett/the-next-pandemic.html (describing the Centers for Disease Control and Prevention's (CDC) prediction of the impact of a "medium-level epidemic"); U.S. DEP'T OF HOMELAND SEC., FLU PANDEMIC MORBIDITY/MORTALITY, *available at* http://www.globalsecurity.org/security/ops/hsc-scen-3_flu-pandemic-deaths.htm [hereinafter FLU PANDEMIC MORBIDITY/MORTALITY] (last visited Feb. 1, 2007).

20. *See* WHO, AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT, (2005) [hereinafter AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT]; World Health Organization, *supra* note 18.

21. *See, e.g.*, FLU PANDEMIC MORBIDITY/MORTALITY, *supra* note 19 (discussing studies performed by the Departments of Homeland Security and Health and Human Services); Michael T. Osterholm, *Preparing for the Next Pandemic*, 84 FOREIGN AFF. 24, 26 (2005). Notably, seasonal (interpandemic) influenza causes worldwide yearly epidemics resulting in 1 to 1.5 million infections. *Id.*

22. Estimates are based on extrapolation from past epidemics in the United States and can be found in the HHS Pandemic Influenza Plan. For the original table, along with other information regarding HHS's planning assumptions, see HHS, *Pandemic Planning Assumptions*, http://www.pandemicflu.gov/plan/pandplan.html (last visited Feb. 9, 2007).

An influenza pandemic would also result in massive economic disruption. So far, the virus's global economic impact has been fairly limited. The rural areas of Southeast Asian countries currently are experiencing the principal economic effects, which relate mostly to the losses of poultry and to governmental control measures such as the culling of birds. In Asia, the total direct economic costs due to the H5N1 outbreak amount to $10 billion.[23] Small and medium-sized farmers, who often have no alternative sources of income, have felt the impact the H5N1 outbreak most acutely. Further, the H5N1 outbreak has severely affected trade in poultry at the domestic, regional, and international level because many countries prohibit the importation of poultry meat from affected regions.

Since great uncertainties exist about the timing, virulence, and general scope of a future human influenza pandemic, any estimate of the economic impact is merely suggestive. On a global scale—extrapolating from the economic disruptions associated with Severe Acute Respiratory Syndrome (SARS)—a 2% loss of global gross domestic product (GDP) ($800 billion) can be expected.[24] If the outbreak were more severe, it could result in a global GDP loss of 6% or $3.2 trillion.[25] Within the United States, a severe pandemic would lower the U.S. GDP by as much as 5%, and a milder pandemic might reduce the U.S. GDP by about 1.5%.[26] In addition to these direct costs, a global flu pandemic would implicate a considerable loss of global work output.[27] Commerce would sharply decline as people avoid public spaces. The labor supply would shrink as workers become ill or stay home to care for others. The lack of an active workforce would place at risk essential goods and services such as food and water, electricity and gas, and transportation systems.

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23. *See* WORLD BANK, *Report by Global Program for Avian Influenza and Human Pandemic*, *in* ECONOMIC IMPACT OF AVIAN FLU, *available at* http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/EASTASIAPACIFICEXT/EXTEAPREGTOPHEANUT/0,,contentMDK:20713527~pagePK:34004173~piPK:34003707~theSitePK:503048,00.html (last visited Feb. 1, 2007); UNITED NATIONS ECONOMIC & SOCIAL COMMISSION FOR ASIA AND THE PACIFIC, *An Effective Regional Response to the Threat of a Pandemic*, *in* 2 SOCIO-ECONOMIC POLICY BRIEF 1 (2005), *available at* http://www.unescap.org/esid/hds/avianflu/policy-brief-n1-Oct2005.pdf.

24. *See* THE WORLD BANK EAST ASIA AND PACIFIC REGION, SPREAD OF AVIAN FLU COULD AFFECT NEXT YEAR'S ECONOMIC OUTLOOK, *available at* http://siteresources.worldbank.org/INTEAPHALFYEARLYUPDATE/Resources/EAP-Brief-avian-flu.pdf (last visited Feb. 1, 2007).

25. *See* SHERRY COOPER, THE AVIAN FLU CRISIS: AN ECONOMIC UPDATE, *available at* http://www.bmonesbittburns.com/economics/reports/20060313/report.pdf (last visited Feb. 1, 2007).

26. *See* CONGRESSIONAL BUDGET OFFICE, A POTENTIAL INFLUENZA PANDEMIC: AN UPDATE ON POSSIBLE MACROECONOMIC EFFECTS AND POLICY ISSUES (2006), *available at* http://www.cbo.gov/ftpdocs/72xx/doc7214/05-22-Avian%20Flu.pdf [hereinafter A POTENTIAL INFLUENZA PANDEMIC] (summarizing the United States government's preparations for an avian flu pandemic).

27. *See* THE WORLD BANK EAST ASIA AND PACIFIC REGION, *supra* note 24.

Further, therapeutic countermeasures (e.g., vaccines and antiviral medications) and public health interventions (e.g., infection control, social separation, and quarantine) form the two principal strategies for prevention and response. Many of the barriers to effective interventions are technical and have been thoroughly discussed elsewhere.[28] This Article focuses on the formidable legal and ethical challenges that have yet to receive sufficient attention.[29] Part II examines the major medical countermeasures under consideration as an intervention for an influenza pandemic. This Part evaluates the known effectiveness of these interventions and analyzes the ethical claims relating to distributive justice in the allocation of scarce resources. Part III discusses public health interventions, exploring the hard tradeoffs between population health on the one hand, and personal (e.g., autonomy, privacy, and liberty) and economic (e.g., trade, tourism, and business) interests on the other. This Part focuses on the ethical and human rights issues inherent in population-based interventions. Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but also reflects profoundly on the kind of society we aspire to be.

I. MEDICAL COUNTERMEASURES: VACCINES AND NEURAMINIDASE INHIBITORS

A. General Considerations

Industrialized countries place great emphasis on scientific solutions. Vaccination and, to a lesser extent, antiviral medication (neuraminidase inhibitors: oseltamivir (Tamiflu®) or zanamivir (Relenza®)), are perhaps the most important medical interventions for reducing morbidity and mortality associated with influenza.[30] In the $6.7 billion Department of Health and Human Services (HHS) influenza plan, $4.7 billion is allocated

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28. *See* World Health Organization Writing Group, *Nonpharmaceutical Interventions for Pandemic Influenza*, *International Measures,* EMERGING INFECTIOUS DISEASES 81, 81 (2006) [hereinafter *Nonpharmaceutical Interventions for Pandemic Influenza*] (noting that difficulties in influenza control include "peak infectivity" early in illness and short intervals between cases, among other factors).

29. *See, e.g.*, Jaro Kotalik, *Preparing for an Influenza Pandemic: Ethical Issues*, 19 BIOETHICS 422, 424 (2005). For an example of this lack of attention to law and ethics, see HHS, MEDICAL OFFICES AND CLINICS PANDEMIC INFLUENZA PLANNING CHECKLIST (2006), *available at* http://www.pandemicflu.gov/plan/medical.html#3. This document purports to be a "checklist to help medical offices and ambulatory clinics assess and improve their preparedness for responding to pandemic influenza." *Id.* However, it does not address the myriad legal and ethical issues that will arise.

30. *See* Timothy C. Germann et al., *Mitigation Strategies for Pandemic Influenza in the United States*, 103 PROC. OF THE NAT'L ACAD. OF SCI. 5935, 5935 (2006); Anthony B. Iton, *Rationing Influenza Vaccine: Legal Strategies and Considerations for Local Health Officials*, 12 J. PUB. HEALTH MGMT. PRAC. 349 (2006); Klaus Stöhr & Marja Esveld, *Will Vaccines be Available for the Next Influenza Pandemic?*, 306 SCI. 2195, 2195 (2004).

for cell-based vaccine technology and stockpiling experimental vaccine, and $1.4 billion for antiviral medicines.[31] Congress recently appropriated $3.8 billion to address pandemic influenza.[32] While Congress appropriated less money than HHS requested, Congress preserved the focus on medical countermeasures. The overwhelming majority of this money is to be spent on the development and purchase of vaccines and antivirals.[33]

Internationally, countries have followed suit, devoting the majority of their resources towards medical countermeasures. For example, Russia is planning to have an antiviral stockpile sufficient to cover their entire population.[34] Other countries have set less ambitious coverage goals (such as Belgium—30%, Germany—20%, Italy—10%)[35] but still will be forced to allocate large amounts for antivirals. Most industrialized countries also are investing significant sums for vaccine development and stockpiles.[36]

Despite the promise of medical countermeasures, there is a chronic mismatch of public health needs and private control of production. Vaccine production has been unreliable even for seasonal influenza, which is the leading cause of vaccine-preventable mortality; only a fraction of the recommended population is vaccinated each year.[37] For example, the United States lost half of its seasonal influenza vaccine supply in 2004-2005 when the United Kingdom withdrew Chiron Corporation's license because of bacterial contamination.[38]

The best way to ensure pandemic preparedness is to increase the baseline for seasonal countermeasures. The World Health Organization (WHO) asserted that better use of vaccines for seasonal epidemics would help to ensure that manufacturing capacity meets demand in a future pandemic.[39] Even though this approach is a good long-term solution, more immediate

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31. *See* A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26; Stephen Spotswod, *HHS Flu Plan Aims to Lift Vaccine Supply,* U.S. MED. (2005), *available at* http://www.usmedicine.com/article.cfm?articleID=1210&issueID=82.

32. *See* Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, Pub. L. No. 109-148, 119 Stat. 2680, 2782-87 (2005); *see also* A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26.

33. HHS, *Pandemic Planning Update*, Mar. 13, 2006, at 2.

34. *Bird Flu: Country Preparations*, BBC NEWS, Feb. 21, 2006, http://news.bbc.co.uk/2/hi/health/4380014.stm.

35. *Id.*

36. *Id.*

37. Scott A. Harper et al., *Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices*, 54 MORBIDITY & MORTALITY WKLY. REP. 1, 2-3 (2005); Kathleen M. Neuzil & Marie R. Griffin, *Vaccine Safety—Achieving the Proper Balance*, 294 J. AM. MED. ASS'N 2763, 2763 (2005).

38. SUSAN THAUL, VACCINE POLICY ISSUES: CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS 7 (2005) [hereinafter CRS REPORT].

39. *See* WHO, World Health Assembly, STRENGTHENING PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE 5 (2005), *available at* http://www.who.int/csr/disease/influenza/A58_13-en.pdf.

solutions are needed.[40] Moreover, supply is difficult to increase because of the lack of market incentives, intellectual property concerns, regulatory hurdles, and liability fears, as discussed below.

Despite these concerns, the global distribution of influenza vaccines is increasing rapidly, but questions remain about global distributive justice. In 2003, over 291 million doses were distributed globally.[41] This is almost forty million doses more than in 2001.[42] Unfortunately, only 35% of all doses reach the developing countries. Moreover, 85% of the world's supply of influenza vaccine is produced by companies located in eight industrialized countries: France, Germany, Italy, the Netherlands, the United Kingdom, the United States, Canada, and Australia.[43] Consequently, 40% of the doses used in central and eastern Europe, 60% of the doses used in the Western Pacific and Southeast Asia, and almost 100% of the doses used in Latin America, the eastern Mediterranean, and Africa are imported from one or more of the vaccine-producing developed countries.[44] It is quite likely that in the face of a new pandemic, governments will not export any of their nationally produced vaccines until domestic demand is satisfied.[45] For example, to ensure coverage for approximately half of its population, Canadian health officials have negotiated a contract with their domestic producer to provide five million doses of influenza vaccine.[46] Health officials in other countries have tried to reach similar agreements without success.[47] Further complicating matters is recent evidence that H5N1 floods the bloodstream with the virus, further calling into question the effectiveness of antivirals and vaccines.[48]

Moreover, the U.S. government has become too focused on specific pathogens, disproportionately devoting resources towards developing medical countermeasures for the disease of the moment. Whether the threat is anthrax, smallpox, bioterrorism, or influenza, the government targets the immediately salient threat rather than strengthening the public health infrastructure so that it can recognize and respond to a range of risks.

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40. *See id.*

41. *See* WHO, *Global Distribution of Influenza Vaccines, 2000-2003*, 40 WKLY. EPIDEMIOLOGICAL REC. 79, 357, 366 (2004), *available at* http://www.who.int/wer/2004/en/wer7940.pdf.

42. *See id.*

43. *See* David S. Fedson, *Pandemic Influenza and the Global Vaccine Supply*, 36 CLINICAL INFECTIOUS DISEASES 1552, 1553 (2003), *available at* http://www.journals.uchicago.edu/CID/journal/issues/v36n12/20633/20633.web.pdf.

44. *See id. See generally* JOHN M. BARRY, THE GREAT INFLUENZA: THE EPIC STORY OF THE DEADLIEST PLAGUE IN HISTORY (2004).

45. *See* BARRY, *supra* note 44; Stöhr & Esveld, *supra* note 30, at 2196.

46. *See* Fedson, *supra* note 43, at 1154-55.

47. *See id.* at 1555.

48. *See* G. F. Rimmelzwaan et al., *Pathogenesis of Influenza A (H5N1) Virus Infection in a Primate Model*, 75 J. VIROL. 6687, 6688-89 (2001).

States would bear a high proportion of these costs.[49] This "one bug, one drug" mentality is ineffective because it is impossible to predict and prepare for the wide variety of threats that society could face.[50] Developing medical countermeasure technologies and public health interventions that could respond to a wide range of emerging biological threats would be a better use of resources.

B. Planning and Market Incentives

The nation's goal must be to build a system that will ensure a stable, economically viable supply of vaccines capable of meeting potentially massive public needs in a just manner. Public and private strategies rather than private markets are most likely to succeed because of the unique risks and constraints of vaccine production.[51] Private market forces create suffer failures such as high investment costs, limited or variable markets, and regulatory non-compliance, each of which inhibits vaccine development. As vaccine manufacturers leave the industry, they create a risk of severe shortages. In 1967, twenty-six companies were licensed to distribute vaccines in the U.S. market, but less than half of this number are licensed today.[52] Only four companies currently supply influenza vaccines, with only two manufacturing domestically—MedImmune (live attenuated influenza virus, intranasal (FluMist®)) and Sanofi Pasteur.[53]

The Institute of Medicine recommends a National Vaccine Authority (NVA) to advance the development, production, and procurement of vaccines.[54] With or without an NVA, the government can create incentives by boosting demand through seasonal vaccine awareness programs, issuing purchasing contracts, and providing price guarantees or subsidies. Recognizing the need to increase output and availability, the G7 Finance Ministers recently announced a pilot Advance Market Commitment for vaccines of public health importance.[55]

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49. *See, e.g.*, HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 6 (illuminating some of the responsibilities that states and local planners might face, including: distributing information, planning for vaccine distribution, and implementing immunization registries).

50. Kendall Hoyt, *Bird Flu Won't Wait*, N.Y. TIMES, Mar. 3, 2006, at A23.

51. *See* WHO, VACCINES FOR PANDEMIC INFLUENZA 10 (2004) [hereinafter VACCINES FOR PANDEMIC INFLUENZA].

52. *See* Patricia M. Danzon et al., *Vaccine Supply: A Cross-National Perspective*, 24 HEALTH AFF. 706, 706 (2005).

53. *See* David Brown, *How U.S. Got Down to Two Makers of Flu Vaccine*, WASH. POST, Oct. 17, 2004, at A01.

54. *See* COUNCIL OF THE INSTITUTE OF MEDICINE, APPENDIX 1: STATEMENT ON VACCINE DEVELOPMENT 262 (2001).

55. CTR. FOR GLOBAL DEV., GLOBAL HEALTH POLICY: G-7 TO PILOT ADVANCE MARKET COMMITMENTS 1 (2005), *available at* http://blogs.cgdev.org/vaccine/archive/2005/12/.

Even if vaccination supplies adequately meet mass needs, the distribution of the vaccines to the population remains problematic. Each year, drug companies produce millions of influenza vaccines but never distribute them.[56] Pandemic influenza would require mass vaccination in a short window of time, probably within months of the advent of an outbreak. Federal stockpiles must meet needs at the local level, requiring systems for transportation, storage, and safe administration of the vaccine. If two doses are required to achieve immunity, health service providers may need a call-back system or immunization registry. At present, the federal strategic plan fails to resolve these vital issues, instead delegating them to the states.[57]

C. Sound Regulation

The vaccine industry must overcome rigorous regulatory hurdles to achieve safety and efficacy while avoiding increased costs and delays. To start, vaccines contain living organisms, making the threat of contamination greater than with drugs. Therefore, vaccines must adhere to higher purity standards than pills because they often are administered by injection.[58] Accordingly, the Food and Drug Administration (FDA) plays an active role during the development of the vaccine, as well as in its licensing.[59] Before licensure, the FDA reviews the data from clinical trials to assess the product's safety and effectiveness.[60] After licensure, the FDA conducts regular manufacturing practice inspections to ensure that the manufacturing facility produces a consistent product.[61] Violations found during these inspections can result in the loss of a manufacturing license; companies must go through a lengthy reapplication process before the FDA allows them to continue producing vaccines for public consumption. Additionally, the FDA requires manufacturers to test each lot of vaccine for contaminants before public release.[62]

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56. *See* HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 24 (citing the need for the availability of at least 81 million treatments, which is enough for about 25% of the U.S. population).

57. *See id.* at 7 (declaring that states and communities should have their own plans in case of an outbreak); *see also* NATIONAL STRATEGY FOR PANDEMIC INFLUENZA, *supra* note 1, at 24 (positing that one pandemic response action would be to administer the vaccine according to state and local distribution plans).

58. CRS REPORT, *supra* note 38, at 1.

59. *See id.* at 11-14 (presenting some of the Food and Drug Administration's (FDA) review methods, including fast-track drug development and accelerated approval).

60. *Id.* at 14.

61. *See id.* at 7 (describing the FDA's emphasis on the safety and effectiveness of the vaccines).

62. *See id*. at 2-3 (stating that each lot is evaluated based on its purity and potency).

Departing from these onerous regulations, the FDA amended its drug and biological product policies in 2002 in response to the possibility of a serious and immediate health threat.[63] Under the so-called "Animal Rule," the FDA may approve drugs and biological products for marketing based on animal studies when human studies are unethical or infeasible.[64] The revamped procedure streamlines the process for quickly developing medical countermeasures in the face of a bioterrorism attack or pandemic outbreak.[65] While this may be an effective regulatory strategy, critics are concerned that the relaxed requirements could put large numbers of human lives at risk[66] because animal models often do not accurately predict human responses to drugs or biological products.[67] Using multiple species testing can mitigate, but not entirely remove, this concern.[68] Thus, the first human users essentially will be involved in a clinical trial. While an immediate threat may justify the need for a streamlined approval process, more public education is required, and care must be taken to avoid abusing the process.

In addition to the federal regulatory regime, states also regulate vaccines. For instance, three states, California,[69] Iowa,[70] and New York,[71] regulate thimerosal-containing vaccines, while bills are pending in other states. Because influenza vaccines contain thimerosal, this legislation could undermine federal plans. In addition to federal and state regulation, agencies in other countries regulate vaccines. Therefore, industry faces multiple, overlapping regulatory requirements, which must be reconciled.

Recognizing that this problem of overlapping regulatory requirements is an issue nationally and internationally, the FDA and the European Medicines Evaluation Agency (EMEA) recently published "regulatory pathways for licensing of pandemic vaccines."[72] Since manufacturers must

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63. 21 C.F.R. §§ 314.600-314.650, 601.91 (2005).

64. *See id.* § 314.610 (showing that the animal tests must prove that the drug product is "reasonably likely" to benefit humans).

65. *See id.*

66. Andrew Pollack & William J. Broad, *Anti-Terror Drugs Get Test Shortcut*, N.Y. TIMES, May 31, 2002, at A1.

67. Kathi E. Hanna, *Extraordinary Measures for Countermeasures to Terrorism: FDA's "Animal Rule,"* 32 HASTINGS CTR. REP. 9, 9 (2002).

68. *Id.*

69. CAL. HEALTH & SAFETY CODE § 124172 (West 2006).

70. IOWA CODE ANN. § 135.39B (2006).

71. *See* N.Y. PUB. HEALTH LAW § 2 (McKinney 2005) (prohibiting women who know they are pregnant from being vaccinated with an influenza faccine that contains more than 1.25 micrograms of mercury per 0.50 milliliter dose, provided that the Commissioner of Public Health makes a yearly determination that an adequate supply of such low mercury vaccines exists). This provision goes into effect in 2008. *Id.* § 3.

72. *See* VACCINES FOR PANDEMIC INFLUENZA, *supra* note 51, at 13 (stating that this gives companies a more predictable environment for developing and producing the vaccine).

be licensed and begin commercial production in advance of, or soon after, the start of a pandemic, regulatory requirements should be timely, efficient, and well-coordinated.

D. Scientific Information and Intellectual Property

The rapid global dissemination of scientific information will be necessary to effectively respond to a pandemic outbreak. Such dissemination would require the speedy collection and sharing of data involving surveillance and scientific discovery. For example, comparing sequence data from each isolated case allows scientists to better understand and track the movement and evolution of the virus.[73] However, sharing information about H5N1 has been problematic. Scientists do not want to release their data until they have received published credit.[74] Similarly, many countries want to keep information confidential to protect national security and intellectual property (IP) interests. Therefore, international coordination is necessary to facilitate research. Such coordination should include exchanging study results to avoid duplication,[75] defining expectations and regulations to avoid conflicts in export and import, and supporting standardization to avoid quality divergence in industrialized and developing countries.[76] In an attempt to encourage collaboration, the WHO has maintained a restricted database, accessible by only a handful of laboratories.[77] Recently, this system has been criticized for being unnecessarily secretive.[78] Rather than allowing broad-based access to the data that would facilitate scientific research, the WHO has denied access to many groups.

It is equally important to share manufacturing and technical information. Potential patent disputes should be anticipated in advance because they have significant cost implications for commercial vaccines. The H5N1 virus is most effectively grown in fertilized chicken eggs with modification through reverse genetics.[79] However, this is a patented technology.[80]

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73. Martin Enserink, *As H5N1 Keeps Spreading, A Call to Release More Data*, 311 SCI. 1224, 1224 (2006).

74. *See id.* (quoting an Italian scientist who says, "[i]f publishing one more paper becomes more important, we have our priorities messed up").

75. Stöhr & Esveld, *supra* note 30, at 2196.

76. JULIE MILSTIEN ET AL., DIVERGENCE OF VACCINE PRODUCT LINES IN INDUSTRIALIZED AND DEVELOPING COUNTRIES, http://www.who.int/immunization_supply/divergence_vaccines.pdf (last visited Feb. 1, 2007).

77. *See Secret Avian Flu Archive*, N.Y. TIMES, Mar. 15, 2006, at A26 (noting that restrictions might encourage otherwise reluctant scientists to share their findings on a limited basis prior to publication).

78. *See id.* (mentioning an Italian scientist who has refused to reveal her data to the WHO's secret database that holds the genetic information of the virus).

79. Emily Singer, *Pandemic Fears Hatch New Methods in Flu Vaccine Industry*, 11 NATURE MED. 4, 4 (2005), *available at* http://www.nature.com/nm/journal/v11/n1/full/nm0105-4a.html.

Newer cell-based technologies, which promise more efficient mass production, are also subject to IP protection.[81] Although IP affords incentives for innovation, it can also impede rapid and large-scale vaccine production in a public health emergency.

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) allows countries to grant compulsory licenses to ensure access to essential medicines in a public health emergency.[82] Compulsory licenses, which afford the right to produce a product without the patent holder's authorization, are usually discussed in the context of life-saving medications for resource-poor countries; however, some have considered compulsory licenses to ensure adequate Tamiflu production.[83] Hoffmann-La Roche Inc., the patent-holder until 2016, stated that the global demand is well in excess of production capacity.[84] It will take ten years of constant production for the company to produce enough of the drug to treat twenty percent of the world's population. However, the company opposes compulsory licensing, citing the scarcity of raw materials, the complex manufacturing process, and the necessity of patent protection to create incentives.[85]

Whatever the merits of compulsory licensing, antivirals will have only limited utility in a pandemic. Gaining access to Tamiflu on time would entail visiting a physician or pharmacist. Because influenza is maximally infectious early in the course of the disease, doctor or pharmacy visits would seriously risk transmission to the public. Moreover, antiviral medications remain only partially effective against H5N1 and may not be effective against a human strain of the virus.[86] The potential for mass use and patient noncompliance within the five-day course of treatment pose a risk of drug resistance.[87] Consequently, reliance on stockpiling antivirals, although probably helpful in reducing hospitalizations, will not significantly impede a pandemic.

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80. Erika Check, *WHO Calls for Vaccine Boost to Prepare for Flu Pandemic*, 432 NATURE 261, 261 (2004).

81. *Id.* (noting that one company holding a patent on technology might accelerate the process of vaccine selection).

82. *Other Use Without Authorization of the Right Holder*, Part II, § 5, art. 31, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

83. Keith Bradsher, *Pressure Rises on Producer of a Flu Drug*, N.Y. TIMES, Oct. 11, 2005, at C1.

84. *See id.* (clarifying that Tamiflu would have to produce at its full capacity).

85. *Id*.

86. Frederick G. Hayden, *Perspectives on Antiviral Use During Pandemic Influenza*, 356 BIOLOGICAL SCI. 1877, 1877-81 (2001).

87. *See id.* at 1880 (explaining the possibility of a loss of the drugs' efficacy, even for those treated over shorter periods of time).

E. Liability and Compensation

Tort liability for the pharmaceutical industry and fair compensation for patients offers a sound dual approach to vaccine policies. The Public Readiness and Emergency Preparedness (PREP) Act, enacted in December 2005, makes manufacturers immune from liability under federal and state law with respect to all claims resulting from the use of medical countermeasures during a pandemic influenza.[88] The liability protections only apply to products administered or used during the effective period of the declaration of a public health emergency issued by the Secretary of HHS.[89]

The PREP Act also authorizes the Secretary to develop a compensation program for injured individuals. Such a system already exists in the national Vaccine Injury Compensation Program (VICP), but it needs reform. The VICP created a no-fault system that pays for injuries caused by specific immunizations[90] and Congress added influenza to VICP in 2005.[91] The Federal Claims Court adjudicates compensation based on a Vaccine Injury Table. To recover, claimants must show that a listed vaccine caused their injury. Compensation comes from a Compensation Trust Fund financed by a tax levied on each administered dose.[92]

Patients can opt-out of VICP, causing a sustained critique that legal liability represents a major disincentive for the industry. The President's influenza plan virtually bans all lawsuits except for willful misconduct and assigns liability determinations to a political figure—the HHS Secretary.[93] The political critique, however, overstates the negative influence of liability on vaccine production. Influenza vaccine litigation remains rare, with only ten reported cases during the past twenty years, most of which culminated in small-scale settlements.[94]

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88. *See* Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, 119 Stat. 2680, 2818 (2006); *see also* A POTENTIAL INFLUENZA PANDEMIC, *supra* note 26, at 12.

89. *Id.*

90. *See* HHS, HEALTH RES. AND SERVS. ADMINISTRATION, NATIONAL VACCINE INJURY COMPENSATION PROGRAM: FACT SHEET (2006), *available at* http://www.hrsa.gov/vaccinecompensation/fact_sheet.html.

91. *Id.*

92. 26 U.S.C. §§ 4131, 9510 (2000).

93. *See The HHS Pandemic Influenza Plan: Hearing Before the H. Comm. on Government Reform*, 109th Cong. 9 (2005) (statement of Michael Leavitt, Secretary, HHS) (setting out the guidelines for liability protections); *see also* HHS PANDEMIC INFLUENZA PLAN, *supra* note 1, at 33 (considering the effects of the protections on vaccine manufacturers, distributors, and healthcare providers).

94. *See* Michelle M. Mello & Troyan A. Brennan, *Legal Concerns and the Influenza Vaccine Shortage*, 294 J. AM. MED. ASS'N 1817, 1818-19 (2005) (charting the results of lawsuits against influenza vaccine manufacturers, most of which resulted in summary judgment in favor of the defendants).

Also, mass usage of an untried vaccine during a public health emergency could result in numerous adverse events. For instance, health care workers and patients might be less likely to volunteer without a fair compensation system, as the failed smallpox vaccination campaign demonstrated.[95] On the other hand, a no-fault system, like VICP, would provide relief for injured patients and greater certainty for industry. Experimental H5N1 vaccines currently are not covered under VICP, so the new vaccine would need to be added. Moreover, VICP has become adversarial, burdensome on claimants, and time consuming.[96] A reformed system must account for important issues, such as an overwhelmed program resulting in delays, insufficient money in the compensation trust fund, and injustices caused by excessive burdens placed on patients injured by a new vaccine. In return, the industry should be spared strict liability lawsuits, while remaining liable for recklessness or gross negligence.

F. Ethical Allocation of Scarce Resources

Considerable scientific uncertainty remains in predicting an influenza pandemic. Moreover, it is certain that there will be extreme scarcity of medical countermeasures in the short-term. Although H5N1 vaccines are in clinical trials,[97] companies cannot meet mass needs without dramatic improvements in production facilities and technologies (e.g., cell-based cultures and dose sparing).[98] Estimates suggest that the current combined global manufacturing capacity is only capable of making vaccines for 450 million people.[99] This is an optimistic estimate because it assumes low-dose vaccination, even though this dose might not be fully effective.[100] Given international trade law, which affords a single company exclusive manufacturing rights, along with complex production processes, the same scarcity might occur with antivirals. The United States, for example, has limited capacity, with only two domestic vaccine suppliers and no priority over purchasing orders for Tamiflu.[101]

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95. *See* INST. OF MED., THE SMALLPOX VACCINATION PROGRAM: PUBLIC HEALTH IN AN AGE OF TERRORISM 68 (Alina Baciu et al. eds., 2005).

96. *See* Myron Levin, *Vaccine Injury Claims Face Grueling Fight*, L.A. TIMES, Nov. 29, 2004, at A1 (noting that a young girl became mentally retarded, physically handicapped, and legally blind after a routine vaccination).

97. *See* NAT'L INSTS. OF ALLERGY AND INFECTIOUS DISEASE, NAT'L INSTS. OF HEALTH, QUESTIONS AND ANSWERS: H5N1 AVIAN FLU VACCINE TRIALS (2006), *available at* http://www3.niaid.nih.gov/news/QA/H5N1QandA.htm (stating that the National Institute of Allergy and Infectious Disease began their first clinical trial in April 2005).

98. Singer, *supra* note 79, at 4.

99. *See* David. S. Fedson, *Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development*, 26 J. PUB. HEALTH POL'Y 4, 12 (2005) (discussing the possibility that people will require two doses of the vaccine because most people will never have been infected with an influenza virus).

100. Meredith Wadman, *Race is On for Flu Vaccine*, 438 NATURE 23, 23 (2005).

101. Gardiner Harris, *U.S. Stockpiles Antiviral Drugs, but Democrats Call Pace Too*

The most challenging question facing bioethics is how to ration scarce, life-saving resources: "Who shall live when not all can live?"[102] "Blind justice" might dictate a random allocation of scarce interventions, such as a lottery or a first-come, first-served system. Yet, this procedure seems unsatisfying when life-saving countermeasures can be targeted more cost effectively. American society has accepted "need" as the singular principle for allocation of seasonal (interpandemic) influenza vaccine—e.g., the elderly and health care workers.[103] Given the devastating social, economic, and political ramifications of a serious pandemic, the following rationing criteria are worth consideration.

1. Prevention/Public Health

As the historic mission of public health is prevention, countermeasures to impede transmission should be a high priority. Thus, where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks. For example, ring vaccination of direct contacts in a family, congregate setting, or local community could be an effective intervention that would maximize lives saved.

2. Scientific/Medical Functioning

If the first political priority is public health, then it is essential to protect individuals who innovate and produce vaccines or antivirals, provide treatment, and protect the public's health. These are critical social missions necessary to save lives and provide care for the sick. Consequently, priority should be given to key personnel in developing countermeasures, delivering health care, and devising public health strategies.

3. Social Functioning/Critical Infrastructure

A large-scale pandemic could result in key sectors of society being unable to function. Many actors and elements are necessary for the public's health and safety: first-responders, security, essential product and

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Slow, N.Y. TIMES, Mar. 2, 2006, at A21.

102. John D. Arras, *Ethical Issues in the Distribution of Influenza Vaccines*, YALE J. BIOLOGY & MED. (forthcoming 2006).

103. HHS, HHS PANDEMIC INFLUENZA PLAN, APPENDIX D: NVAC/ACIP RECOMMENDATIONS FOR PRIORITIZATION OF PANDEMIC INFLUENZA VACCINE AND NVAC RECOMMENDATIONS ON PANDEMIC ANTIVIRAL DRUG USE, *available at* http://www.hhs.gov/pandemicflu/plan/appendixd.html (last visited Feb. 1, 2007); Anthony B. Iton, *Rationing Influenza Vaccine: Legal Strategies and Considerations for Local Health Officials*, 12 J. PUB. HEALTH MGMT. PRACTICE 349, 349 (2006); James G. Hodge, Jr. & Jessica P. O'Connell, *The Legal Environment Underlying Influenza Vaccine Allocation and Distribution Strategies*, 12 J. PUB. HEALTH MGMT. PRACTICE 340, 340-41 (2006).

services, critical infrastructure, and sanitation. Similarly, the continued functioning of governance structures, such as the executive, legislative, and judicial systems, is important.

4. Medical Need/Vulnerability

As mentioned, medical need is a widely accepted rationing principle. This criterion focuses on reducing serious illness and death among the most vulnerable individuals. It requires a scientific or epidemiologic judgment about at-risk groups that may vary. Seasonal influenza disproportionately burdens infants and the elderly, but highly pathogenic strains may affect young adults, as occurred with the Spanish flu.

5. Intergenerational Equity

The "medical need" criterion often favors the elderly because they are the most vulnerable to influenza complications. However, interventions may be less beneficial to the elderly than to younger, healthier populations. Vaccines, for example, may be less effective in older people because of poor immune system function.[104] All human lives have equal worth, but interventions targeted toward the young may save more years of life. Would a "fair innings" principle militate in favor of children, young adults, and pregnant women?

6. Social Justice/Equitable Access

What does justice tell us about how to ration scarce, life-saving resources? The foregoing criteria have a clear utility but focus on key personnel and sectors such as government, biomedical researchers, the pharmaceutical industry, health care professionals, and essential workers or first-responders. These apparently neutral categories mask injustice. In each case, individuals gain access to life-saving technologies based on their often high-status employment. This kind of health planning leaves out individuals who are either unemployed or employed in "non-essential" jobs—a proxy for the displaced and devalued members of society. Consequently, public health planning based on pure utility, while understandable, fails to have sufficient regard for the disenfranchised in society.[105]

Social justice demands more than "fair" distribution of resources in circumstances of extreme health emergency. The interests of vulnerable populations are undermined well beyond the detriments to their health. A

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104. Elizabeth M. Gardner et al., *Age-Related Changes in the Immune Response to Influenza Vaccination in a Racially Diverse, Healthy Elderly Population*, 24 VACCINE 1609, 1610 (2006).

105. *See generally* Lawrence Gostin & Madison Powers, *What Does Justice Require for the Public's Health*?, 25 HEALTH AFF. 1053 (2006).

failure to act expeditiously and with equal concern for all citizens, including the poor and less powerful, harms the whole community by eroding public trust and undermining social cohesion. It signals to those affected and to everyone else that the basic human needs of some matter less than those of others, and it thereby fails to show the respect owed to all members of the community.[106]

7. Global Justice

Justice is not bound by national borders but binds the human community around the globe. Scholars such as Martha Nussbaum[107] have drawn attention to the justice requirements of a shared humanity beyond citizenship. Realistically, however, resources will go to those countries where products are owned and manufactured. Major influenza vaccine producers operate and distribute almost exclusively in Europe, North America, Australia, and Japan.[108] This can have devastating consequences for resource-poor countries that cannot compete economically for expensive countermeasures. If all human life has equal value then there would be a strong moral justification for fair rationing from a global perspective. Even from a less altruistic perspective, there are reasons to invest in poor regions. Improved surveillance and response can help in early detection and containment of outbreaks, affording universal benefits.

8. Civic Engagement/Fair Processes

Public cooperation in a health emergency is more likely if citizens accept the fairness and legitimacy of allocation decisions. Advance discussion of ethical principles keeps the public informed and engages them in a participatory decisionmaking process. A pilot project on civic engagement found that stakeholders and citizens-at-large, at a high level of agreement, chose a functioning society and reducing deaths as priorities in vaccine allocation.[109] This altruistic consensus is comforting but may not reflect real behavior in a time of crisis, which could involve hoarding, stockpiling, and black marketeering. Citizens will agree to fair allocation if they believe the allocation process is fair. However, if they believe that others are jumping the queue through influence or money, they will be less likely to behave selflessly. This is all the more reason for transparent decisionmaking processes in advance of a pandemic.

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106. *Id.*

107. *See generally* Martha C. Nussbaum, *Patriotism and Cosmopolitanism*, *in* FOR LOVE OF COUNTRY? ix, 4 (Martha C. Nussbaum ed., 2002) (advocating for an allegiance to the worldwide community of human beings).

108. VACCINES FOR PANDEMIC INFLUENZA, *supra* note 51, at 4.

109. PUBLIC ENGAGEMENT PILOT PROJECT ON PANDEMIC INFLUENZA, CITIZEN VOICES ON PANDEMIC FLU CHOICES 7 (2005).

Planning for an influenza pandemic is vital to success. It requires scientific innovation, modern laws, and ethical action. Private markets cannot create stable supplies of life-saving countermeasures or assure fair allocations. Rather, constructive partnerships among government, industry, and the community can vastly improve survival and functioning in an impending crisis.

II. PUBLIC HEALTH STRATEGIES: ETHICAL AND HUMAN RIGHTS CONCERNS

A. The Importance of Public Health Interventions

The United States has placed a high value on medical countermeasures to prevent or contain a future influenza pandemic.[110] Given the limitations of medical countermeasures, however, public health interventions will be vital tools for slowing the spread of an emerging pandemic. Two recent IOM reports have also determined that the United States' emergency medical system is "at the breaking point."[111] In spite of these medical infrastructure concerns, Congress recently appropriated only $350 million to upgrade state and local capacity—about 9% of the $3.8 billion total allocation for pandemic influenza.[112] Furthermore, this limited funding will be significantly eroded by a recent $105 million cut in federal support for state public health[113] and an unfunded mandate for states to purchase antiviral drugs.[114]

This Part focuses on traditional public health interventions, drawing lessons from past influenza pandemics[115] and the outbreaks of Severe Acute Respiratory Syndrome (SARS).[116] Unfortunately, public health

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110. *See* Lawrence Gostin, *Public Health Strategies for Pandemic Influenza: Ethics and the Law*, 295 J. AM. MED. ASS'N 1700, 1700 (2006) (noting that 90% of spending on pandemic preparation is devoted to countermeasures) [hereinafter *Public Health Strategies for Pandemic Influenza*].

111. INST. OF MED., HOSPITAL-BASED EMERGENCY CARE: AT THE BREAKING POINT, *available at* http://www.iom.edu/CMS/3809/16107/35007.aspx (last visited Feb. 1, 2007); INST. OF MED., EMERGENCY MEDICAL SERVICES AT THE CROSSROADS, *available at* http://www.iom.edu/CMS/3809/16107/35010.aspx (last visited Feb. 1, 2007).

112. Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006, 42 U.S.C. § 247, Pub. L. No. 109-148, 119 Stat. 2680, 2786 (2005).

113. HHS, FY 2005 BUDGET IN BRIEF 105 (2005), *available at* http://www.hhs.gov/budget/05budget/fy2005bibfinal.pdf.

114. Jeffrey Levi et al., *Working Group on Pandemic Influenza Preparedness: Joint Statement in Response to Department of Health and Human Services Pandemic Influenza Plan*, 42 CLINICAL INFECTIOUS DISEASES 92, 93 (2006).

115. *See generally* BARRY, *supra* note 44, at 5 (expounding on the lessons learned in the great influenza pandemic of 1918, which the author describes as "the first great collision between nature and modern science").

116. Lawrence O. Gostin et al., *Ethical and Legal Challenges Posed by Severe Acute Respiratory Syndrome: Implications for the Control of Severe Infectious Disease Threats*,

strategies are difficult to evaluate. First, evidence of effectiveness is often historical or anecdotal, with few systematic studies.[117] Adequate resources for population-based research are urgently needed.[118] Second, an intervention's effectiveness depends on the transmission pattern, which cannot be fully understood in advance. Key issues in the transmission pattern include viral shedding (infectivity during pre- and post-symptomatic stages); mode and efficiency of transmission (large droplet, aerosol, contaminated hands and surfaces, etc.); incubation period (two days between infection to the start of symptoms); and serial interval between cases.[119] Third, an intervention's usefulness depends on the pandemic phase. In the pandemic alert period, surveillance, medical prophylaxis, and isolation are important tools. Yet, "[d]uring the pandemic period, the focus shifts to delaying spread . . . through population-based measures."[120] Thus, the key question is which measure, or combination of measures, works best at each stage of the pandemic? Multiple, targeted approaches are likely to be most effective, but they can have deep adverse consequences for the economy and civil liberties. Even using the most optimistic scenario, containing an emerging H5N1 pandemic at its source will only delay, not stop, mass transmission because of likely simultaneous introductions of the pathogen.[121]

The remainder of this Article will examine the ethical and legal issues associated with public health interventions. However, first it is necessary to identify the human rights and ethical principles that will guide this analysis.

B. Ethics and Human Rights

Pandemics can be deeply socially divisive, and the political response to these issues not only impacts public health preparedness, but also is important to a good and decent society. It is for this reason that it is particularly important to show respect for public health ethics and

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290 J. AM. MED. ASS'N 3229, 3229 (2003).

117. *But see* Neil M. Ferguson et al., *Strategies for Containing an Emerging Influenza Pandemic in Southeast Asia*, 437 NATURE 209, 209-10 (2005) (modeling systematically the pandemic spread of influenza in Southeast Asia and using studies done previously by the United States and Britain to show the downward trend of deaths that may be caused by an influenza pandemic).

118. INST. OF MED., THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY 17 (2003) [hereinafter THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY].

119. *See Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28, at 82-83.

120. *Id.* at 88 (noting that difficulties in influenza control include "peak infectivity" early in illness and short intervals between cases, among other factors).

121. Christina E. Mills et al., *Pandemic Influenza: Risk of Multiple Introductions and the Need to Prepare for Them*, 3 PUB. LIBR. SCI. MED. 1, 4 (2006), *available at* http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030135.

international law—particularly human rights law—when developing national policy for pandemic influenza. This Section sets out the relevant ethical principles that should be considered when planning to combat a highly pathogenic pandemic influenza outbreak.

1. International Human Rights

Basic human rights are inherent to all people because they are human; they are universal, so that people everywhere are "rights-holders;" and they create robust duties for the state.[122] State duties encompass the obligations to not interfere directly or indirectly with the enjoyment of human rights, to prevent private actors from interfering with human rights, and to take positive measures to enable and assist individuals and communities to enjoy their rights. Basic human rights are protected under international law so that a state can no longer assert that systematic maltreatment of its own nationals is exclusively a domestic concern.[123]

The main sources of human rights law are the Universal Declaration of Human Rights and two international covenants on human rights: the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR), as well as an optional protocol to ICCPR.[124] The United Nations has promulgated numerous treaties dealing with specific human rights violations including racial and gender discrimination, the rights of children, genocide, and torture.[125] Human rights are also protected under regional systems, including those in the Americas, Europe, and Africa.[126]

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122. Sofia Gruskin & Daniel Tarantola, *Health and Human Rights* (Francois-Xavier Bagnoud Center for Health and Human Rights, Working Paper Series, Working Paper No. 10, 2000), *available at* http://www.hsph.harvard.edu/fxbcenter/FXBC_WP10-Gruskin_and_Tarantola.pdf.

123. *See* LOUIS B. SOHN & THOMAS BUERGENTHAL, INTERNATIONAL PROTECTION OF HUMAN RIGHTS 5 (1973).

124. *See Universal Declaration of Human Rights*, G. A. Res. 217(III), U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948); International Covenant on Civil and Political Rights, Dec. 19, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR]; International Covenant on Economic, Social and Cultural Rights, Dec. 19, 1966, 993 U.N.T.S. 3 [hereinafter ICESCR].

125. *See generally* International Convention of All Forms of Racial Discrimination, Dec. 21, 1965, 660 U.N.T.S. 195; ICCPR, *supra* note 124; ICESCR, *supra* note 124; Convention on the Elimination of All Forms of Discrimination Against Women, Dec. 18, 1979, 1249 U.N.T.S. 13; Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Dec. 10, 1984, 1465 U.N.T.S. 85; International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families, G.A. Res. 45/158, U.N. GAOR, 45th Sess., Supp. No. 49, U.N. Doc. A/45/149 (Dec. 18, 1990).

126. *See* Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, 213 U.N.T.S. 222; African [Banjul] Charter on Human and Peoples' Rights, June 27, 1981, 21 I.L.M. 58; American Convention on Human Rights, Nov. 22, 1969, 1144 U.N.T.S. 123.

a. The Universal Declaration of Human Rights (UDHR)

The UDHR, adopted in 1948, identified specific rights and freedoms that deserve promotion and protection. The UDHR was the international community's first attempt to establish a common standard of achievement for all peoples and all nations to promote human rights. The UDHR represents a milestone in the struggle of humanity for freedom and human dignity, stating that human rights are self-evident and the highest aspiration of the common people. Article 1 proclaims that all human beings are born free and equal in dignity and rights.

The Universal Declaration is not a treaty, but a resolution with no explicit force of law. Nevertheless, its key provisions have so often been applied and accepted that they are now widely considered to have attained the status of customary international law.[127] The United Nations' General Assembly has declared that the principles embodied in the Universal Declaration "constitute basic principles of international law."[128] Moreover, it has "acquired a moral and political authority equal to that of the [United Nations] Charter."[129] In any event, the Declaration has inspired and influenced many international conventions and is reflected in national constitutions, legislation, and in the decisions of national and international tribunals.

Most relevant to the ethics of public health interventions, the UDHR provides that all people have the right to freedom from arbitrary arrest, detention, or exile; the right of movement and residence within and between the borders of each state, and the right to freedom from discrimination. While the UDHR served as the preliminary description of rights, two binding covenants, the ICCPR and ICESCR, followed.

b. International Covenant on Civil and Political Rights & International Covenant on Economic, Social and Cultural Rights

The ICCPR imposes an immediate obligation to respect and to ensure civil and political rights. A sister covenant, the ICESCR, requires state parties "to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its

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127. *See* RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (1987) (listing the following state practices as violating customary international law (CIL): genocide; slavery; murder or causing the disappearance of individuals; torture or other cruel, inhuman or degrading treatment or punishment; prolonged arbitrary detention; systematic racial discrimination; and consistent patterns of gross violations of internationally recognized human rights).

128. Creola Johnson, *Quarantining HIV-Infected Haitians: United States' Violations of International Law at Guantanamo Bay*, 37 HOW. L.J. 305, 314 (1994).

129. David W. Johnston, Comment, *Cuba's Quarantine of AIDS Victims: A Violation of Human Rights?*, 15 B.C. INT'L & COMP. L. REV. 189, 194 (1992).

available resources, with a view to achieving progressively the full realization of the rights recognized . . . by all appropriate means, including particularly the adoption of legislative measures."[130] The language of progressive realization and maximum resources may have been inserted because economic and social rights typically require greater funding and more complex solutions than civil and political rights. Still, the Committee on Economic, Social and Cultural Rights, established by the ICESCR, made clear that state parties have immediate obligations. Steps towards the goal of full realization must be taken within a reasonably short time. States parties have a minimum core obligation to ensure the satisfaction of each of the rights and should immediately implement legislation and judicial remedies to ensure non-discrimination in the exercise of economic and social rights.[131]

These covenants provide a number of rights that are relevant to the implementation of public health interventions including the right to freedom from cruel, inhumane, or degrading treatment or punishment; the right to freedom of movement and residence; the right to freedom from arbitrary detention; and most notably the right to health. The right to health encompasses the international obligation for all nations to promote and protect the health of its civilians, especially by facilitating access to basic health care services. The right to health, however, is not equivalent to a right to health care, nor is it an absolute right. It must be evaluated against both the means available to the state and the biological and socio-economical characteristics of the individual concerned.[132] Furthermore, the right to health cannot be seen in a vacuum; it depends on the realization of other human rights such as the right to life, the right to privacy and the right to non-discrimination. The right to health thus encompasses a broad spectrum of socio-economic factors and must be extrapolated to the underlying determinants of health such as hygiene, housing, environment, and clean drinking water.[133]

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130. ICESCR, *supra* note 124, at art. 2.

131. *See* Committee on Economic, Social and Cultural Rights, General Comment 3, The Nature of States Parties' Obligations, 5th Sess., 1990, ¶ 5, *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, U.N. Doc. HRI/GEN/1/Rev.7 (May 12, 2004).

132. *See* Committee on Economic, Social and Cultural Rights, General Comment 14, The Right to the Highest Attainable Standard of Health, 22d Sess., 2000, ¶ 4, *Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies*, U.N. Doc. HRI/GEN/1/Rev.7 (May 12, 2004).

133. *See id.* ¶¶ 8, 11.

c. Regional Conventions: The European Convention on Human Rights and Fundamental Freedoms and Its Protocols, and The American Convention on Human Rights

The European Convention on Human Rights and Fundamental Freedoms and its protocols (European Convention) and the American Convention on Human Rights (American Convention) identify many of the same rights and liberties as the Universal Declaration, including the right to privacy,[134] the right to be free from inhumane or degrading treatment,[135] the right to freedom of movement,[136] and the right to be free from discrimination—all of which public health measures could violate.[137]

2. Valid Limitations on Human Rights

Human rights have transcending value, but international law allows restrictions when necessary for the public good. The ICCPR's most fundamental guarantees are so essential as to be absolute and no state may derogate from them, even in a time of an emergency. The ICCPR, however, allows state parties to suspend most other civil and political rights in times of national crisis. The state must officially proclaim the public emergency and cannot engage in discrimination. The principal conditions for restraints on civil and political rights are that they must be prescribed by law; enacted within a democratic society; and necessary to achieve public order, public health, public morals, national security, public safety, or the rights and freedoms of others.[138] However, state parties may not impose restrictions aimed at the destruction of rights or their limitation to a greater extent than provided in the Covenant.[139]

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134. *See* Eur. Council, Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11, Nov. 1, 1998, Art. 8, *available at* http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/EnglishAnglais.pdf [hereinafter Fundamental Freedoms]; American Convention on Human Rights, Nov. 22, 1969, 1144 U.N.T.S. 123, art. 11.

135. *See* Fundamental Freedoms, *supra* note 134, art. 3.

136. *See* Eur. Council, Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms as amended by Protocol No. 11, Nov. 1, 1998, Europ. T.S. 46, Art. 2, *available at* http://www.echr.coe.int/NR/rdonlyres/D5CC24A7-DC13-4318-B457-5C9014916D7A/0/EnglishAnglais.pdf.

137. *See* Fundamental Freedoms, *supra* note 134, art. 14.

138. *See* ICCPR, *supra* note 124, art. 12 ¶ 3, art. 18 ¶ 3, art. 19 ¶ 3, art. 21, art. 22 ¶ 2 (permitting "limitations" or "restrictions" on the freedom of movement, religion, expression, assembly, and association).

139. *See The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, 7 HUM. RTS. Q. 3, 7 (1985) [hereinafter *Siracusa Principles*] (calling for all limitation clauses to be interpreted strictly and in favor of the human right at issue).

The Siracusa Principles, conceptualized at a meeting in Siracusa, Italy, are widely recognized as a legal standard for measuring the validity of limitations on human rights.[140] The Principles make clear that even when the state acts for a good reason, it must respect human dignity and freedom. Echoing the language of the ICCPR, the Siracusa Principles require that state limitations must be in accordance with the law; based on a legitimate objective; strictly necessary in a democratic society; the least restrictive and intrusive means available; and not arbitrary, unreasonable, or discriminatory.[141] International tribunals have relied on the Siracusa Principles to require states to use the least restrictive measure necessary to achieve the public health purpose.[142]

It is far more difficult to think about legitimate limitations on economic, social, and cultural rights. The ICESCR permits "such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society."[143] Because the ICESCR includes a right to health, it is best to conceptualize as valid "limitations" those measures necessary to attain health protection for the population. For example, the Covenant requires states to take steps aiming at "prevention, treatment and control epidemic, endemic, occupational and other diseases."[144] Thus, compulsory measures such as vaccination, treatment, or isolation would be permitted only if necessary to protect public health.

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140. *See* U.N. Econ. & Soc. Council (ECOSOC), *Status of the International Covenants on Human Rights*, U.N. Doc. E/CN.4/1985/4 (Sept. 28, 1984).

141. *Id.* ¶¶ 15-21.

142. *See* Enhorn v. Sweden, 2005 Eur. Ct. H.R. 1; Robyn Martin, *The Exercise of Public Health Powers in Cases of Infectious Disease: Human Rights Implications*, 14 MED. L. REV. 132, 134 (2006) (expounding on the European Court of Human Rights' use of the substantive requirements of Article 5 that the court consider all alternatives such that it is clear that less severe measures have been considered and that there is no arbitrariness in the deprivation of liberty in any and all circumstances (citing *Chahal v. U.K.*, 1996 Eur. Ct. H. R. 22414/93)).

143. The language of Article 4 suggests that cultural, economic, or social rights can be limited on grounds of the public's health. The Committee on Economic, Social and Cultural Rights, however, stresses that states have the burden of justifying each element of Article 4: powers must be in accordance with the law, including international human rights, in the interest of legitimate aims, and strictly necessary for the general welfare in a democratic society. Public health powers also must be the least restrictive, of limited duration, and subject to review. ECOSOC, Sub-Comm. on Econ., Soc. & Cultural Rights, *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14*, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000), *available at* http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument [hereinafter General Comment 14].

144. *Id.* art. 12(2)(c).

3. Public Health Ethics

These international human rights principles stress the importance of individual rights and freedoms, but make clear that freedoms can be restricted when the public health is threatened. Striking a balance between the individual and the collective can be a difficult task, especially under conditions of scientific uncertainty and crisis. Therefore, it is important to articulate the values of public health ethics that should influence pre-pandemic planning.

a. Public Health Necessity

Public health powers are exercised under the theory that they are necessary to prevent an avoidable harm. Early meanings of the term "necessity" are consistent with the exercise of police powers: to necessitate was to "force" or "compel" a person to do that which he would prefer not to do, and the "necessaries" were those things without which life could not be maintained.[145] Government, to justify the use of compulsion, therefore, must act only in the face of a demonstrable health threat. Public health officials must be able to prove that they had "a good faith belief, for which they can give supportable reasons, that a coercive approach is necessary."[146]

The standard of public health necessity requires, at a minimum, that the subject of the compulsory intervention must actually pose a threat to the community. In the context of infectious diseases, for example, public health authorities could not impose personal control measures (e.g., mandatory physical examination, treatment, or isolation) unless the person was actually contagious or, at least, there was reasonable suspicion of contagion. While this standard is obviously resistant to precise definition, it is important that countries clearly delineate what criteria for suspicion will be used and provide procedural safeguards.

b. Reasonable and Effective Means

Under the public health necessity standard, government may act only in response to a demonstrable threat to the community. The methods used, moreover, must be designed to prevent or ameliorate that threat. In other words, there must be a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective. Even though the objective of the legislature may be valid and beneficial, a public health intervention must be an effective means of combating the

145. THE CONCISE OXFORD DICTIONARY OF CURRENT ENGLISH 728 (6th ed. 1976).
146. James F. Childress et al., *Public Health Ethics: Mapping the Terrain*, 30 J.L. MED. & ETHICS 170, 173 (2002).

public health threat. A policy that entails personal burdens and economic costs is only justified if the government can demonstrate that there is a reasonable chance of protecting the public health.[147] Because it is extremely difficult to exactly define "reasonable chance" for all potential situations, the government has the burden of proof and has to engage in ongoing evaluation of the public health intervention and its effectiveness.

c. Proportionality

The public health objective may be valid in the sense that a risk to the public exists, and the means may be reasonably likely to achieve that goal—yet a public health regulation is unethical if the human burden imposed is wholly disproportionate to the expected benefit. Public health authorities have a responsibility not to overreach in ways that unnecessarily invade personal spheres of autonomy. This suggests a requirement for a reasonable balance between the public good to be achieved and the degree of personal invasion. If the intervention is gratuitously onerous or unfair, it may overstep ethical boundaries.

d. Distributive Justice

This ethical principle requires that the risks, benefits, and burdens of public health action be fairly distributed, thus precluding the unjustified targeting of already socially vulnerable populations. Tom Beauchamp and James Childress view distributive justice as the "fair, equitable, and appropriate distribution in society determined by justified norms that structure the terms of social cooperation."[148]

In the context of public health, this principle requires that officials act to limit the extent to which the burden of disease falls unfairly upon the least advantaged and to ensure that the burden of interventions themselves are distributed equitably.[149] Thus, in the exercise of compulsory powers, distributive justice requires a fair allocation so as not to burden unduly particularly vulnerable populations. Distributive justice has been viewed as so central to the mission of public health that it has been described as its core value. As Dan Beauchamp has said, "[t]he historic dream of public health . . . is a dream of social justice."[150]

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147. *Id.*

148. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 327 (4th ed. 1994).

149. *See* Council for International Organizations of Medical Sciences, *International Guidelines for Ethical Review of Epidemiological Studies*, 19 LAW, MED. & HEALTH CARE 247 (1991); Council for International Organizations of Medical Sciences, *Report of the Fifth CIOMS Core Group Meeting on the Revision of 1991 International Guidelines for Ethical Review of Epidemiological Studies* (2005).

150. Dan E. Beauchamp, *Public Health as Social Justice*, *in* NEW ETHICS FOR THE PUBLIC'S HEALTH 105 (Dan E. Beauchamp & Bonnie Steinbock eds., 1999).

Distributive justice does not merely require a fair allocation of risks and burdens. It also recognizes that public health often distributes benefits such as vaccines, treatment, or other services. Problems of fair benefits allocation arise under conditions of scarcity, where there is a competition for resources. This might occur, for example, with a scarcity of medical treatment in the midst of an influenza pandemic.

e. Trust and Transparency

Public health officials have the responsibility to involve the public in the process of formulating public health policies as well as to explain and justify any infringement on general moral considerations. Public health officials should honestly disclose relevant information to the public. Accordingly, citizens should have the right to request and receive information. Moreover, citizens' input should be solicited.[151]

The need for transparency stems in part from the government's ethical imperative to treat citizens with respect by offering reasons for policies that infringe on moral considerations.[152] Transparency also is essential to create and maintain public trust and accountability.[153] Openness and accountability are important to public health governance because of their intrinsic value and capacity to improve decisionmaking. Citizens gain a sense of satisfaction by participating in policymaking and having their voices heard. Even if the government decides that personal interests must yield to common needs, the individual feels acknowledged if she is listened to and her values are taken into account.

Transparency also has instrumental value because it provides a feedback mechanism—a way of informing public policy and arriving at more considered judgments. Open forms of governance engender and sustain public trust, which benefits the public health enterprise more generally. Without public support, and the voluntary cooperation of those at risk, coercive public health interventions would be difficult to achieve. The populace must be able to trust that its government is acting in its best interest.

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151. *See* Childress et al., *supra* note 146, at 174; PUBLIC HEALTH LEADERSHIP SOCIETY, PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH 3 (2002), *available at* http://www.apha.org/codeofethics/ethicsbrochure.pdf [hereinafter PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH].

152. PRINCIPLES OF THE ETHICAL PRACTICE OF PUBLIC HEALTH, *supra* note 151, at 4; Jayne Parry & John Wright, *Community Participation in Health Impact Assessments: Intuitively Appealing but Practically Difficult*, 6 BULLETIN OF THE WORLD HEALTH ORGANIZATION 388, 388 (2003), *available at* http://www.who.int/bulletin/volumes/81/6/parry.pdf.

153. *See* Parry & Wright, *supra* note 152, at 388 (citing the Gothenburg consensus paper, which "makes clear the need for participation to underpin the assessment process in order to maintain values of democracy, transparency and equity").

In the following Sections, we examine ethical issues raised by major public health interventions available for combating influenza. These interventions often present hard tradeoffs between population health on the one hand, and personal and economic interests on the other. Each Section describes a proposed public health intervention and explains the ethical problems connected with its implementation. An ethical solution to these problems will follow. Because of the incredible strains that pandemic-created crises put on even the best laid plans, in addition to the difficulty in asserting one set of ethical ideals, each Section will also discuss the mitigating factors that might make an ethical "ideal" impracticable. The accompanying recommendations are designed to promote the ultimate ethical ideal, but in a manner sensitive to the practical realities of a pandemic. However, before beginning the ethical analysis of specific public health interventions, it is useful to define these tools, as well as to articulate some of the general themes that run throughout this Article.

D. Public Health Interventions

Given the limitations of medical countermeasures, public health interventions will be vital for slowing the spread of an emerging pandemic.[154] The following Section will briefly identify and describe the various interventions. The Sections after that will explore general ethical concerns that permeate all influenza pandemic public health interventions. Subsequent sections will discuss each intervention in detail, focusing on ethical issues and drawing lessons from past influenza pandemics[155] and the outbreaks of SARS.[156]

E. General Ethical Themes in Public Health Responses to a Pandemic

1. Community Participation

The WHO's 1948 constitution states that "[i]nformed opinion and active co-operation on the part of the public are of the utmost importance in improving health."[157] Community participation in pandemic preparedness

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154. *See* Gostin et al., *supra* note 116, at 555 (emphasizing that "where feasible, rapid deployment of vaccines or prophylaxis to groups at risk of acquiring infection should be used to contain localized outbreaks"); Gostin, supra note 110, at 1700 (elaborating that during the pandemic alert phase of an outbreak important intervention measures include "surveillance, medical prophylaxis, and isolation").

155. *See generally* BARRY, *supra* note 44 (chronicling the developments in the 1918 influenza epidemic).

156. *See* Gostin et al., *supra* note 116, at 3229-36.

157. WHO CONST. pmbl., *available at* http://www.searo.who.int/LinkFiles/About_SEARO_const.pdf (last visited Feb. 1, 2007) (stating that "[i]nformed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people").

and response is critically important and ethically required. The ethical principles of trust and transparency require that the public be involved in decisions affecting their lives. During a pandemic, many actions taken will impose losses on members of society, both in terms of money and autonomy. Similarly, actions not taken will leave society at risk of disease. Public health policymakers must use education and input from the public to balance the risks of action versus inaction. This will help ensure that the policies ultimately adopted are well-suited to local circumstances and values.

At the national level, community participation will include advocacy, delivery of services, cost-sharing, and support to patients. Each person should have the opportunity to contribute to public discourse and thus must be adequately informed instead of being "managed" by the authorities. The government needs to identify its priorities, expectations, and financial capacity. Thus, an ethically appropriate policy in one country, or even one city, may be ethically inappropriate in another because of varying norms and differing benefits or losses caused by intervention.

Community participation has a positive impact on the success of project development and implementation and can reduce alienation of socially excluded groups.[158] Time and resource constraints may considerably complicate community outreach programs during a pandemic. Consequently, governments must gain the public's trust by providing it with adequate and accurate information well in advance. Of course, some issues will develop very quickly or unexpectedly during a pandemic, precluding advance information. In this case, governments should provide necessary information as quickly as possible, and community involvement in decisionmaking should be as great as allowed by the circumstances of a situation. When expediency does not allow full community involvement before policies are enacted, a post-enactment review process is particularly important to ensure transparency and accountability and should incorporate community involvement.

2. Expanded Research Agenda

The government must consider all possible strategies because it is difficult to predict and evaluate the effectiveness of any specific intervention. The key question is which measure, or combination of measures, works best at each stage of the pandemic. A number of considerations make this difficult to answer. First, evidence of effectiveness is often historical or anecdotal, with few systematic studies

158. *See* Parry & Wright, *supra* note 152 (noting that community participation also may "reorient power relationships with the professional decision-makers").

available.[159] Second, an intervention's effectiveness depends on the pandemic's transmission pattern, which is unpredictable.[160] Third, an intervention's usefulness depends on the stage of the pandemic. In the pandemic alert period, surveillance, medical prophylaxis, and isolation are important tools. Yet, during a pandemic, the focus shifts to delaying spread through non-pharmaceutical measures.[161] Evaluation of effectiveness is important not only from a public health perspective, but also from an ethical perspective. To the extent that interventions impose costs and burdens on individuals or the population, they are ethically warranted only to the extent that they are effective and proportionate in terms of benefits and burdens.

Multiple targeted approaches are likely to be most effective, but they can have significant adverse consequences for the economy and civil liberties. As such, governments should employ the least restrictive options possible. Given this principle and the uncertain utility associated with public health interventions, evidence of effectiveness is important and relevant to the ethical implications of public health interventions. Therefore, adequate resources for population-based research are urgently needed.[162]

3. Resource Allocation

Perhaps the greatest ethical issues of pandemic preparedness and response deal with the allocation of scarce resources. A pandemic will overtax the immediately available resources of even the richest countries on the planet while overwhelming less wealthy countries. For example, in 1918, influenza-related mortality was highest in the least developed parts of the world and lowest among the wealthiest countries.[163] Given the greater baseline levels of mortality, the higher prevalence of HIV/AIDS (and many other diseases such as malaria and tuberculosis), and reduced access to health care that is found in many developing countries, one can reasonably expect these countries to experience greater morbidity and mortality from influenza in a modern pandemic as well. At the same time, these countries will have the least resources available to protect their citizens and to slow the transmission of the disease.

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159. *But see* Neil M. Ferguson et al., *supra* note 117, at 213-14 (delineating various models and data sources used to predict the success of possible interventions).

160. *See Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28, at 92 (adding that because of this and other uncertainties, "WHO guidance is subject to revision based on additional information").

161. *See id.* at 88-93 (describing measures such as social distancing, procedures for those leaving or entering infected zones, and hygiene measures and personal protection).

162. THE FUTURE OF THE PUBLIC'S HEALTH IN THE 21ST CENTURY, *supra* note 118, at 6.

163. Niall P.A.S. Johnson & Juergen Mueller, *Updating the Accounts: Global Mortality of the 1918-1920 "Spanish" Influenza Pandemic*, 76 BULL. HIST. MED. 105, 105-15 (2002).

The demands of distributive justice require that resources be expended equitably, with attention paid to meeting the needs of those who are most vulnerable. In the context of pandemic influenza, this means that resources must be used in a fashion that can alleviate the greatest amount of human suffering and death. If the developing world is at the greatest peril from the disease, then wealthy countries have a duty to assist them to provide the greatest degree of protection that is feasible given the worldwide scarcity of resources. Furthermore, at least early in a pandemic, resource sharing will benefit both wealthy and developing countries. Models of influenza transmission indicate that a pandemic can be stopped early on if adequate resources are used,[164] but all available measures are expected only to slow transmission once a full-fledged pandemic is underway.[165] To the extent that a pandemic is likely to begin in a less developed country, effectiveness of the intervention demands that wealthy countries assist poorer countries to combat a nascent pandemic.

Additionally, in all countries, a fair system for allocating health-promoting resources must be developed, as the demand for medical care, hygienic measures, and other resources is likely to exceed the supply. This should be done with attention paid to obtaining the greatest degree of health promotion possible. To the extent possible, there should be transparency and broad participation in the rationing scheme.

4. International Cooperation and Coordination

The protection of the public health and national risk management is primarily the responsibility of national authorities. All countries therefore should develop a national influenza preparedness plan. In designing a justifiable containment strategy, each state needs to consider state-specific factors such as national political structures and principles, educational and cultural environment, the prevalence of the virus, and the strengths and weaknesses of the state's health care system. While different national approaches ordinarily are not a problem, considerable variation in response plans could prevent or delay an efficient response in a multi-country public health emergency.[166] Cooperation among national authorities and coordination by international bodies is therefore necessary.[167]

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164. Neil M. Ferguson et al., *Strategies for Mitigating an Influenza Pandemic*, 442 NATURE 448 (2006).

165. *Id.* at 210-12.

166. Lawrence O. Gostin et al., *The Model State Emergency Health Powers Act: Planning for and Response to Bioterrorism and Naturally Occurring Infectious Diseases*, 288 J. AM. MED. ASS'N 622, 624 (2002).

167. *Id.*

The WHO put particular emphasis on cooperation and coordination in its 2005 International Health Regulations (the Regulations), a revision of the 1969 text. The Regulations require countries to develop, strengthen, and maintain core public health capacities to detect, assess, and notify the WHO of events that may constitute a public health emergency of international concern via National IHR Focal Points in each State Party.[168] In June 2007, the Regulations will become legally binding on all WHO Member States, except those that have rejected them or submitted reservations. In light of the concern surrounding avian influenza, in May 2006, the 59th World Health Assembly adopted Resolution 59.2, which called upon WHO Member States to comply immediately and voluntarily with the provisions of the Regulations relevant to the pandemic influenza risk.

In addition to cooperation at the state level, there is a need for cooperation between international agencies. The response to a pandemic, especially in its early stages, will be borne by many international agencies, including the WHO, the Food and Agriculture Organization (FAO), and the World Organization for Animal Health (OIE). Additionally, national entities, such as the Centers for Disease Control and Prevention (CDC) in the United States, will be responsible for picking up international burdens during a pandemic. It will be important for knowledge gained by one entity to be disseminated quickly to other entities. Further, given the scarcity of resources that will be available to stem a pandemic, it will be important that work done by one agency not be unnecessarily duplicated by others—efforts spent unnecessarily will trade off with other, potentially life-saving efforts.

F. Public Health Surveillance

Surveillance is the backbone of public health, providing essential data to understand the epidemic threat and inform the public. Surveillance strategies include rapid diagnosis, screening, reporting, case management reporting, contact investigations, and monitoring trends. It is clear that surveillance will be necessary to quickly identify and respond to a pandemic influenza outbreak. The revised regulations require that, once a country identifies a signal suggesting human-to-human transmission, the country must immediately investigate and notify WHO of the event because any human influenza caused by a new subtype must be reported to

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168. David P. Fidler & Lawrence O. Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 33 J. LAW, MED. & ETHICS 85 (2006); WHO, *Revision of the International Health Regulations* (2005), *available at* http://www.who.int/csr/ihr/WHA58_3-en.pdf (last visited Feb. 1, 2007) [hereinafter *Revision of the International Health Regulations*].

WHO. The "triggering criteria" of early pandemic activity cannot be fully set out ahead of time. Public health officials should thus be vigilant and report all plausible signals that a pandemic virus may be emerging.

1. Global Responsibility to Develop Core Surveillance Capacities

Ideally, all countries would have the capacity to perform core surveillance functions. However, such a recommendation is impractical for many developing countries, which often lack the resources for animal or human surveillance and containment of outbreaks.[169] Specifically, in sub-Saharan Africa, the capacity for veterinary and human surveillance is limited or nonexistent.[170] In this and in other impoverished regions, allocating resources for the development or improvement of surveillance infrastructure may divert resources from a country's other, more immediate needs.[171] It can be difficult, for example, to convince the government of a developing country that has a high incidence of HIV or malaria to invest scarce resources towards the monitoring of a potential influenza threat.

Developed countries should be aware of this tradeoff and take measures to ensure that enhanced surveillance does not occur at the expense of managing the multitude of ongoing public health threats many developing countries face. Recognizing this imperative, many countries have pledged significant funds to meet the costs estimated by the World Bank to contain avian influenza.[172] These funds will only temporarily address the need for surveillance, however. The avian flu threat might not manifest itself for years, and future pandemics are almost certain to occur. Thus, it would be desirable to pursue the larger goal of creating sustainable public health systems across the globe. To this end, WHO's Commission on Macroeconomics and Health estimates that industrialized countries would have to spend $27 billion in 2007 to meet global needs for essential public health services.[173]

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169. *Public Health Strategies for Pandemic Influenza*, *supra* note 110.

170. Cathy A. Petti et al., *Laboratory Medicine in Africa: A Barrier to Effective Health Care*, 42 CLINICAL INFECTIOUS DISEASES 377 (2006).

171. *See id.* (contending, however, that failure to improve surveillance infrastructure ultimately costs more as "unreliable and inaccurate laboratory diagnostic testing leads to unnecessary expenditures").

172. *See* Beijing Declaration, International Pledging Conference on Avian and Human Pandemic Influenza, Jan. 18, 2006, *available at* http://siteresources.worldbank.org/PROJECTS/Resources/40940-1136754783560/beijingdeclaration.pdf; WORLD BANK, AVIAN AND HUMAN INFLUENZA: FINANCING NEEDS AND GAPS 8 (2005), *available at* http://siteresources.worldbank.org/PROJECTS/2015336-1135192689095/20766293/AHIFinancingGAPSFINAL12-21.pdf.

173. *See* COMM'N ON MACROECONOMICS AND HEALTH, WHO, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 11 (2001), *available at* http://www.emro.who.int/cbi/pdf/CMHReportHQ.pdf (adding that the funding required would increase over time, rising to $38 billion by 2015).

2. Mitigating Privacy and Autonomy Risks

Surveillance poses privacy risks as governments must collect sensitive medical information from patients, travelers, migrants, and other vulnerable populations.[174] Many countries have data protection statutes; however, these laws often make exceptions for surveillance in the context of a public health threat.[175] In a crisis situation, however, disclosure may be warranted when the immediate use of the information is necessary for an important public health purpose and disclosure is restricted to the confines of the public health system. Under these circumstances, the identity of the affected person should be protected as much as possible. The inclusion of any uniquely identifiable characteristics, such as a name, government identification number, fingerprint, or phone number should be avoided, particularly when the information is released outside of the public health system. Cases should stay anonymous or encrypted when reasonably feasible. Only the minimum amount of information necessary to achieve the goal should be released, and to as few people as possible.

Screening and testing also can pose serious threats to a person's privacy and bodily integrity. Ideally, public health officials should receive the individual's informed consent prior to performing any medical tests; however, in rare cases, mandatory testing might be necessary to advance the public good. A mandatory testing policy may be permissible when it is clearly necessary and effective in protecting the public health, it is performed by competent public health officials, and the least intrusive means are being used. At a minimum, compulsory testing should be limited to individuals known or at least suspected to be infected and should be done in a fair and non-discriminatory way. In addition, the individuals whose rights are being infringed should be informed of the reasons for the infringement.

Countries should enact public health information privacy laws to require justifiable criteria for data disclosure and to prohibit wrongful disclosures, for example, to employers, insurers, and immigration or criminal justice authorities.[176] Whenever a government authorizes or mandates the

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174. *See generally* Ronald Bayer & Amy Fairchild, *The Limits of Privacy: Surveillance and the Control of Disease*, 10 HEALTH CARE ANALYSIS 19 (2002) (discussing the "ethics of surveillance" through analysis of the history of surveillance and reporting in the context of HIV and other infectious diseases).

175. *See, e.g.*, Eur. Parl. and Council Directive 95/46, arts. 3, 13, 1995 O. J. (L 281) 35 (EC); Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. § 1320 (1996).

176. *See* Lawrence O. Gostin et al., *Informational Privacy and the Public's Health: The Model State Public Health Privacy Act*, 91 AM. J. PUB. HEALTH 1388 (2001).

disclosure of identifiable health data, it should make public the proposed use of the data, the reason for disclosure, and the extent to which third parties can have access to the data.

G. Limiting Animal/Human Pathogen Interchange

Close proximity between animals and humans poses serious risks as novel pathogens mutate and jump species.[177] Live bird markets, traveling poultry workers, fighting cocks, and migratory birds are vectors for spreading avian influenza.[178] Recently, Influenza (A) H5N1 also has spread to tigers,[179] leopards,[180] pigs,[181] domestic cats,[182] and stone martens.[183] Consequently, an early preventive strategy is critical to limiting animal/human interchange. Strategies to diminish the risk include separation of animal and human populations, health and safety in animal farming, and proper management of diseased or exposed animals.

1. Avoiding Proximity

Safe farming practices and the separation of animals and humans are critically important from a public health and economic perspective. Avoiding proximity between animals and humans can reduce the risk that the avian H5N1 virus will mutate and jump species.[184] The separation is hard to accomplish, however, given a culture of close contact between animals and humans in most countries. For example, the domestication of poultry is often necessary for family survival[185] and in many African and Asian countries, backyard chickens are kept not only for food but also as pets.[186] As one researcher reports, in Hong Kong, "thousands of residents are avid birdwatchers and Kowloon's famed Bird Garden is one of the world's largest marketplaces for exotic birds of all kinds."[187] Given these

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177. *See* William B. Karesh & Robert A. Cook, *The Human-Animal Link*, 84 FOREIGN AFF. 38, 38, 42 (2005).

178. *See Avian Influenza A (H5N1) Infection in Humans*, *supra* note 11, at 1374.

179. *See* Roongroje Thanawongnuwech et al., *Probable Tiger-to-Tiger Transmission of Avian Influenza H5N1*, 11 EMERGING INFECTIOUS DISEASES 975 (2005).

180. *See* Food and Agricultural Organization (FAO), Avian Influenza—Related Issues, http://www.fao.org/ag/AGAinfo/subjects/en/health/diseases-cards/avian_issues.html [hereinafter *FAO Report*] (last visited Feb. 1, 2007) (reporting that the avian flu has been detected in a leopard in Thailand).

181. *See id.* (noting that in Vietnam the avian flu virus has been discovered in a limited number of pigs).

182. *See* WHO, *H5N1 Avian Influenza in Domestic Cats* (Feb. 28, 2006), http://www.who.int/csr/don/2006_02_28a/en.

183. *See* WHO, *Avian Influenza—H5N1 Infection Found in a Stone Marten in Germany* (Mar. 9, 2006), http://www.who.int/csr/don/2006_03_09a/en.

184. *See Public Health Strategies for Pandemic Influenza*, *supra* note 110, at 1701.

185. *See Playing Chicken with Bird Flu*, N.Y. TIMES, Feb. 21, 2006, at A18.

186. *See id.*

187. MIKE DAVIS, THE MONSTER AT OUR DOOR: THE GLOBAL THREAT OF AVIAN FLU 45 (2005).

cultural norms, policies separating animal and human populations can cause not only economic hardship but also social unrest. Thus, governments and health care sectors should publicize clear rationales for such separation orders and should initiate and facilitate constructive public discussion about measures that can be taken to suppress the transmission of the virus.

2. Due Process and Compensation for Culling Decisions

Given that disease containment strategies can have a profound impact on the lives of individuals, it is ethically imperative that governments carefully construct their animal control policies. While mass slaughter of diseased and exposed animals seems to be the most logical way to achieve eradication of H5N1, it raises significant ethical concerns. A massive culling of birds can have a devastating economic toll on the poultry industries of the affected nations and the livelihoods of all classes of poultry owners, producers and their employees. Economic studies further indicate that those hardest hit by culling of flocks are individual farmers whose sole source of income generation is their poultry.[188] While culling has already played an important role in combating the current avian influenza strain, more convincing scientific evidence of its effectiveness in combating a pandemic influenza is needed for it to be ethically acceptable. Moreover, the appearance of H5N1 in wild birds and mammals has significantly diminished the possible advantages culling could bring.

For culling decisions to be justified, the public benefit should outweigh the personal and economic burdens placed on individuals. Judicial procedures are necessary to fairly balance societal interests and the interests of affected individuals. Governments should incorporate due process into their culling procedures by creating an a priori procedure for fair reviews of a decision to cull. Affected individuals should receive some notice of the proposed containment measure and be permitted to consult with counsel; if they cannot afford counsel, the government should provide one; a subsequent hearing should be held as soon as possible after the decision to cull; and the hearing should be held before an independent and accountable tribunal so as to allow farmers and families to protest erroneous or arbitrary decisions. Ideally, individuals should be allowed to appeal the tribunal's final order.

The extent to which procedures can be implemented depends, however, on the urgency of the emergency and the availability of resources. Public health officials might have to mitigate the ideal procedural standards in certain circumstances. Therefore, at the very least, to ensure non-

188. FAO Report, *supra* note 180.

discrimination and proportionality, public health officials need to publicly justify their decisions and the criteria applicable to the proposed measures. Moreover, the process by which decisions are made should be open to scrutiny, and the basis upon which decisions are made should be publicly accessible. Transparency and community participation in the decisionmaking process will enhance trust and acceptance. Post hoc review measures should be put in place to ensure that decisionmakers are accountable for their actions.

The economic impact of culling decisions, especially on small farmers, is significant. Consequently, the principles of distributive justice and reciprocity require adequate compensation as an ethical imperative.[189] This compensation could include providing alternate sources of food if culling involves depleting a family's source of nourishment. A recommendation of this nature will be useless, however, without financial aid from developed countries. In light of the economic consequences, when poultry export industries and the livelihood of farmers are at stake, it is uncertain that affected countries and individuals will be sincere about reporting the extent to which their flocks are infected.[190] Adequate compensation and open communication will, however, increase the incentive to report outbreaks. In addition, education programs should be directed to decreasing the stigma and social hostility toward infected people and countries. International cooperation and coordination will be essential.

3. Mitigating the Economic Impact of Trade Restrictions

Avian influenza causes severe financial and trade impacts. Recent H5N1 outbreaks have adversely affected industry profitability, employment, household livelihoods, and, potentially, food security, in many countries around the globe. Hundreds of millions of domesticated fowl have been culled or have died of infection, devastating domestic poultry production.[191] The overall impact of the current strain of avian influenza hurts all livestock sectors by increasing price volatility and generating uncertainties in markets. Research shows that "[t]he short-term costs to economies are considerable, and even short-term market impacts have long-term implications for trading patterns, policy formulation, longer-term investment in the sector, and overall industry and sector development."[192]

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189. Karesh & Cook, *supra* note 177.

190. *See* Lydia Polgreen, *Nigeria Tries TV Jingles, Anything to Chip Away at Ignorance of Spreading Bird Flu*, N.Y. TIMES, Feb. 26, 2006, at 17 ("The rapid spread of the disease to neighboring states, along with the near-impossibility of enforcing bans on moving birds around the country, has led veterinary experts to conclude that the virus will be nearly impossible to stamp out in Africa.").

191. Dennis Normile, *Are Wild Birds to Blame?*, 310 SCI. 426, 426 (2005).

192. TOBY MOORE & NANCY MORGAN, AVIAN INFLUENZA: TRADE ISSUES 6 (2006), *available at* http://www.cast-science.org/cast/news/aviantrade.pdf.

The detection of the avian influenza virus threatens not only to transform the eating habits of the population, but also to sharply curtail the export market. Many countries have introduced large-scale import controls and bans in response to outbreaks. For example, the United States and India ban the import of all birds from affected areas;[193] European authorities ban poultry and feathers from the Black Sea region;[194] Japan bans the import of all poultry products from France;[195] China, Japan, Malaysia, Singapore, and the Republic of Korea banned imports from the United States following a reported outbreak of a less virulent strain of avian influenza.[196] Some countries even prohibit the importation of birds from nations that vaccinate their flocks, arguing that the vaccines (although usually protective) mask symptoms in infected birds.[197] When considering a trade restriction, ethical considerations should balance the risk to the public's health against the harm that will be done by the restriction.

Nuisance bans on poultry imports because of small, localized outbreaks of the H5N1 virus in exporting countries should be avoided. In May 2005, the OIE advised governments to "allow trade to occur from certain zones or from compartments within a country even though avian influenza may be present in a completely separate zone or compartment in that country."[198] To that end, the regionalization of bans should be promoted. Timely dissemination of all relevant information about influenza outbreaks, interactions among animal and human health authorities, and rapid containment and eradication of the virus where it has emerged are necessary conditions for regional bans to be effective.

H. Community Hygiene and Hospital Infection Control

Hygienic measures to prevent the spread of respiratory infections are broadly accepted and have been widely used in previous influenza pandemics[199] and the SARS outbreaks, although with uncertain benefits.[200]

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193. CNTRS. FOR DISEASE CONTROL AND PREVENTION, EMBARGO OF BIRDS FROM SPECIFIED COUNTRIES (2005), *available at* http://www.cdc.gov/flu/avian/outbreaks/embargo.htm.

194. Commission Decision 2006/7/EC, art. 1, 2006 O. J. (L. 205) 1 (EC).

195. Andrew Jack et al., *Farmers Angry as 20 Countries Ban French Poultry Imports*, FIN. TIMES, Feb. 28, 2006, at 3.

196. FAO Report, *supra* note 180.

197. Elaine Sciolino, *The Discovery of Avian Flu on a Turkey Farm Sends French Poultry Industry Into a Tailspin*, N.Y. TIMES, Feb. 26, 2006, at 17.

198. MOORE & MORGAN, *supra* note 192, at 4.

199. *Influenza: A Report of the American Public Health Association*, 71 J. AM. MED. ASS'N 2068 (1918).

200. *See* WHO, HOSPITAL INFECTION CONTROL GUIDANCE FOR SEVERE ACUTE RESPIRATORY SYNDROME (SARS) (2003), *available at* http://www.who.int/csr/sars/infectioncontrol/en/ [hereinafter HOSPITAL INFECTION CONTROL GUIDANCE]; CENTERS FOR DISEASE CONTROL AND PREVENTION, PUBLIC HEALTH GUIDANCE FOR COMMUNITY-LEVEL PREPAREDNESS AND RESPONSE TO SEVERE ACUTE RESPIRATORY SYNDROME (SARS) (2005),

Infection control includes hand-washing, disinfection, respiratory hygiene, and personal protective equipment (PPE).[201] Evidence supports the use of hand hygiene and hospital infection control measures, but the effectiveness of disinfection, respiratory hygiene, and PPE in the community is unclear.[202] Research is needed to understand the appropriate role of community hygiene in a future pandemic. For example, mask use was common during the 1918 influenza pandemic and SARS outbreaks, but no controlled studies have evaluated its effectiveness.[203]

1. Encouraging Community Hygiene

Even if hygienic measures are effective, professionals and the public must use them properly and sustainably. Infection control is challenging (e.g., appropriately-fitted N95 respirators) and must be used reliably until the risk subsides. Studies demonstrate inconsistent infection control in hospitals, and the general public has not uniformly adopted even basic hygiene practices such as hand-washing.[204] During the SARS epidemic, people in affected areas used protective measures inconsistently.[205]

It is important to accurately inform the public of the need for hygienic measures, including the uncertainty of the measures' effectiveness. In past epidemics, misinformation has been rampant, leading to substantial public anxiety, reliance on word of mouth for knowledge, and purchase of ineffective and expensive products.[206] Issues of distributive justice arise because ineffective or inaccurate communications will impact the most marginalized members of society most heavily. Marginalized members of society are those without access to alternative, credible sources of information and those for whom wasting resources would have the greatest adverse effects. Finally, information should be provided to the public so individuals are able to make informed decisions about their health. The information disseminated through public education campaigns should be clear, uncomplicated, and not sensational or alarmist. Research indicates that panic is rare during civil emergencies, but that providing clear,

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available at http://www.cdc.gov/ncidod/sars/guidance/I/index.htm.

201. *See* HOSPITAL INFECTION CONTROL GUIDANCE, *supra* note 200.

202. *See generally Influenza: A Report of the American Public Health Association*, *supra* note 199; Bernard Lo & Mitchell H. Katz, *Clinical Decision Making During Public Health Emergencies: Ethical Considerations*, 143 ANN. INTERNAL MED. 493 (2005); CENTERS FOR DISEASE CONTROL AND PREVENTION, COMMUNITY CONTAINMENT MEASURES, INCLUDING NON-HOSPITAL ISOLATION AND QUARANTINE (2004), *available at* http://www.cdc.gov/ncidod/sars/guidance/D/index.htm.

203. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28.

204. *See, e.g.*, AMER. SOC. FOR MICROBIOLOGY, HAND WASHING SURVEY FACT SHEET, *available at* http://www.washup.org/assets/fact_sheet.pdf (last visited Feb. 1, 2007).

205. Janice Y.C. Lo et al., *Respiratory Infections During SARS Outbreak*, Hong Kong, 2003, 11 EMERGING INFECTIOUS DISEASES 1738 (2005).

206. Lesley Rosling & Mark Rosling, *Pneumonia Causes Panic in Guangdong Province*, 326 BRIT. MED. J. 416 (2003).

consistent, credible, and instructive information will assist the public in coping with fear.[207] It is important to avoid information that fails to treat members of the public as rational agents. The public should be treated as a partner, enhancing the principle of transparency.

Planning for community-level preparedness should account for variations in settlement patterns. Different types of settlements will present unique risks and challenges during a pandemic. Similarly, communities' unique cultural characteristics can interact with emergency preparedness endeavours. Public education campaigns are difficult when multiple languages are spoken in a community and when individuals have varying levels of literacy and access to media. Preparation plans must account for these geographic and cultural differences. They also must include diverse media sources, which can be achieved by encouraging community involvement in the planning and implementation process and by utilizing leaders from community subpopulations.

A lack of mass media infrastructure will impede broad dissemination of information in some areas. Resource constraints also prevent some populations from receiving messages that are distributed via costly media and a lack of governmental infrastructure may make dissemination of messages much more difficult. Furthermore, media may not be universally available to cater to particular subpopulations and insufficiently educated portions of the population.

However, countries should strive to reduce these problems by using existing communication networks. Health care workers and trusted community sources should be consulted and informed about hygiene measures in order to assist communication efforts by tailoring messages and making them accessible to target audiences. Messages should be posted in places such as markets, where the whole community is likely to see them.

2. Ensuring the Appropriate Use of Hospital Infection Control

Guidance exists to prevent the SARS-associated corona virus from spreading quickly in hospitals.[208] Disinfection, hand hygiene, PPE, and aerosol-generating procedures should be standard hospital practices.[209] Because of the historically high attack rate of influenza among health care workers,[210] the high degree of transmission from people not demonstrating

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207. Thomas A. Glass & Monica Schoch-Spana, *Bioterrorism and the People: How to Vaccinate a City Against Panic*, 34 CLINICAL INFECTIOUS DISEASES 217, 218-20 (2002).

208. *See, e.g.*, HOSPITAL INFECTION CONTROL GUIDANCE, *supra* note 200.

209. *Id.*

210. C. Beguin, B. Boland & J. Ninane, *Health Care Workers: Vectors of Influenza Virus? Low Vaccination Rates Among Hospital Health Care Workers*, 13 AM. J. MED. QUAL. 223, 223, 227 (1998).

clinical illness,[211] and the ease of transmission in crowded areas,[212] health practitioners who do not practice strict infection control may amplify disease transmission. It is vital to train health care workers and monitor the use of such measures. This could be done through legal oversight or licensing requirements.

There also are ethical concerns relating to hospital infection control and distributive justice. The level of resources that can be dedicated to infection control will vary substantially between and within countries. Recognizing this, a fair system of allocating scarce infection control resources should be developed. It is important to involve hospital staff in planning for the implementation of heightened infection controls and the creation of a fair system for determining who carries out high-risk tasks. Cultural sensitivity should be employed and control methods that require restricting valued personal and cultural behaviors (such as the shaving of beards to properly fit masks) should be carried out through consultation with affected people. Additionally, one should ensure that the implemented policies reflect the best available scientific research.

Nations should create training and monitoring programs to ensure that hospitals effectively use standard infection control procedures. Training programs are most effective when based on available science and provide practitioners with the information needed to minimize risks to them and their patients. Programs should be created with the involvement of practitioners, while implementation of these programs should be adapted to the specific features of health care institutions.

Limitations may impede countries' abilities to implement an ideal training and monitoring program. Some countries will lack the resources to purchase adequate PPE for a disease of long duration, while other countries may lack sufficient health care infrastructure to implement new programs on a speedy basis. Civil unrest may impede monitoring of programs. In such cases, legal infrastructure may have to be developed to enforce compliance with training and monitoring efforts.

Alternatives exist for countries facing substantial limitations. The strictness of infection control may have to be relaxed; for example, surgical masks may have to be substituted for N95 respirators. If areas do not have access to isolation rooms, segregating infectious patients into separate wards or hospitals or recommending home stay for mildly ill patients may be appropriate. Additionally, training without full oversight may be necessary should monitoring become infeasible.

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211. C. Fraser et al., *Factors that Make an Infectious Disease Outbreak Controllable*, 101 PROCS. OF THE NAT. ACAD. OF SCI. 6146, 6151 (2004).

212. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28.

Countries will also have to develop a method to ration scarce protective equipment. Governments will have to determine how to distribute masks and other PPE in a fair manner. Such plans should give serious consideration to questions of justice and seek to find a rationing scheme that maximizes health protection. Plans should be devised openly, with an opportunity for both experts and the public to be heard. It is important to enact a fair distribution process.

Additionally, policymakers will have to address the problem of critical shortages in infection control and patient care equipment (e.g., particulate respirators, surgical facemasks, hand sanitizers, disinfectants, ventilators, intensive care beds, and the like).[213] Given the potential duration and scope of a pandemic, even increased production of PPE will be overwhelmed by the demand, especially if use in hospitals and the community is widespread. International collaboration will be needed to address this problem. Further research is needed to develop reusable respirators[214] and to determine the effectiveness of alternatives to N95 respirators.[215] It is critical that research is conducted collaboratively and that results are shared in a fashion that fosters trust and transparency. Cooperation between companies, governments, and researchers will facilitate improved production and greater efficiency at meeting shortages of equipment.

I. Decreased Social Mixing/Increased Social Distance

Past experience shows that social separation and community restrictions form a significant response to pandemics.[216] There is limited evidence that school closure reduces seasonal influenza transmission,[217] and it is assumed that decreased social mixing slows the spread of respiratory disease.[218] Thus, societies have closed public places and cancelled public events in the face of pandemics. As fear rises, individuals may shun social gatherings. Predicting the effect of policies to increase social distance is difficult because infected persons and their contacts may be displaced into other settings, and individuals may voluntarily separate in response to perceived

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213. Donald G. McNeil, Jr., *States and Cities Lag in Readiness to Fight Bird Flu*, N.Y. Times, Feb. 6, 2006, at A1 (predicting that 67% of all intensive care beds would be filled with patients suffering from influenza).

214. INST. OF MED., REUSABILITY OF FACEMASKS DURING AN INFLUENZA PANDEMIC: FACING THE FLU 63 (2006), *available at* http://www.nap.edu/catalog/11637.html.

215. *Id.* at 68.

216. *See* AVIAN INFLUENZA: ASSESSING THE PANDEMIC THREAT, *supra* note 20, at 6. *See generally* Alexandra Minna Stern & Howard Markel, *International Efforts to Control Infectious Diseases, 1851 to the Present*, 292 J. AM. MED. ASS'N 1474 (2004).

217. Anthony Heymann et al., *Influence of School Closure on the Incidence of Viral Respiratory Diseases Among Children and on Health Care Utilization*, 23 PEDIATRIC INFECTIOUS DISEASE J. 675, 677 (2004).

218. *Nonpharmaceutical Interventions for Pandemic Influenza*, *supra* note 28, at 81.

risk.[219] For these reasons, additional research needs to be conducted on behavior during epidemics and the effects of social distancing on transmission.

Social separation, particularly for long durations, can cause loneliness and emotional detachment, disrupt social and economic life, and jeopardize individual rights. Community restrictions raise profound questions of faith (religious worship), family (funeral attendance), and protection of the vulnerable (food, water, clothing, medical care).

1. Government Authority and Accountability

Undoubtedly, most judicial systems would uphold reasonable community restrictions, but legal and logistical questions loom: Who has the power to order closure, under what criteria do they have such power, and for how long? What threshold of disease should trigger closure, and should thresholds be different for different entities? Under what circumstances should compensation for closures be paid? What should be the penalties for non-compliance? Enforcement and assurance of population safety remain critically important, but unanswered, questions in most countries.

One might fear that governments would restrict personal liberties unnecessarily. This could occur through implementing restrictions before they are needed, extending restrictions beyond a disease crisis, or enacting restrictions that do not decrease influenza transmission. In these situations, closures could encroach on the important values of necessity and proportionality. Furthermore, it is important to remember that restrictive policies will be borne most heavily by those with the fewest resources, so errant social distancing actions have distributive justice implications. Lastly, one might worry that governments would use social distancing in a discriminatory fashion, scapegoating ethnic or religious minorities, or using social distancing to pretextually crack down on dissidents who assemble to protest.

Ideally, questions of government authority and accountability would be answered by policy decisions made before a pandemic hit and created as part of an open and transparent process that encourages input from all portions of society. Governments should explicitly define who has the power to order social distancing strategies, and for what period of time. Governments should also clearly state the criteria under which such power is exercisable and clearly delineate the legitimate bases for any differential treatment. Penalties should be proportional to offenses and not based on irrational fears or discriminatory beliefs.

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219. Ferguson et al., *supra* note 117, at 211-12.

However, one must recognize that detailed pandemic influenza preparations are not the highest priorities for many countries dealing with important and immediate concerns. Furthermore, some countries lack the legal and governmental infrastructures to implement the ideal plan outlined above. At the very least, governments should dedicate themselves to non-discrimination and transparency before an influenza pandemic occurs. It is important that social distancing policies are implemented fairly and with broad planning involvement. This will not only help safeguard important ethical considerations, but also will improve the likelihood that the public will accept social distancing. Given that compliance with social distancing instructions will be difficult to enforce, public acceptance is critical to the measures' success.

2. Workplace Closings

Workplace and school closings present difficult ethical issues. Apart from the uncertainty of their effectiveness, the most important questions are those of distributive justice. Workplaces represent the livelihoods of both employees and entrepreneurs, so closing them can cause severe financial hardships. Lost profits caused by closures may force companies to go out of business, leading to job losses and other economic hardships. These problems may have a significant effect on anyone, but especially for those living at a subsistence level. Prior to an emergency, public health authorities should cooperate with industry and trades unions to establish mutually agreeable work closure procedures. However, for situations where workplaces should close but do not, employment protections are needed for workers who wish to comply with a social distancing order against the wishes of their employer. Similarly, one can imagine businesses closing in compliance with instructions, but workers seeking other work for need of income. Government needs mechanisms to encourage compliance with a social distancing order. Though governments should retain the legal power to enforce closures if absolutely necessary, it would be preferable to subsidize lost profits and incomes as necessary. The latter approach was used extensively in countries affected by SARS for people placed in quarantine.[220]

Practical constraints prevent some countries from being able to enact this solution. Many countries have more pressing needs than addressing a potential pandemic. Furthermore, some countries may be unable to provide compensation for closure. In 1918, each wave of the pandemic lasted for

220. MARK A. ROTHSTEIN ET AL., QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS 139 (2003), *available at* http://www.louisville.edu/medschool/ibhpl/images/pdf/SARS%20REPORT.pdf.

several months, and most locations were hit by multiple waves.[221] The amount of resources needed to compensate for lost income or profits for this amount of time may be well out of the reach of many of the world's governments.

In light of these constraints, governments should, at the very least, weigh seriously the risks to health and welfare from workplace closures and other social distancing measures against the preventive effects on disease transmission. For each country, the balance of risks may be resolved differently, depending on the country's resources and financial situation of the population. Countries should consider tactical closures if necessary. Perhaps only those entities that most facilitate transmission should be closed. Schools have been identified as a primary driver of seasonal influenza[222] and are also believed to be a substantial factor during pandemics. Countries might also consider using closures as a means to buy time for other preparations. Finally, closures could be implemented until the level of disease in a community exceeds a predetermined level and then relaxed, with the hope of slowing the initial spread of disease through the community.

3. Provision of Necessities

If people are instructed to avoid public places or if those places are required to close, there will be a need for people to procure food, medicine, and other necessities. Similarly, stoppage of mass transit may prevent people from being able to access facilities that remain open, and it may prevent some people from being able to seek medical care. There is a distributive justice concern relevant to all of these issues—namely, those with the least resources are least likely to be able to procure additional resources before closures occur. They are also the least likely to have private transportation available to seek medical care. Thus, they are both less likely to be able to receive care and more likely to have to remain in homes with infectious people.

Ideally, governments would set up networks for the distribution of necessary provisions to citizens' homes. Distribution would be conducted in a manner that takes into account ease of access in particular communities. It would be consistent and reliable and provide necessities such as food and medicine for the duration of social distancing measures. It should also be conducted in such a manner that minimizes interaction with potentially infectious people and infection control precautions should be employed to decrease the likelihood that supply distributors will vector disease. Transportation for medical care should be provided as needed by

221. Johnson & Mueller, *supra* note 163, at 107.
222. *See* Ferguson et al., *supra* note 117; Germann et al., *supra* note 30.

personnel who are apprised of the risks involved and provided with appropriate personal protective equipment. Similarly, a program should be put in place for the removal of bodies from homes in a safe and efficient manner.

Resource constraints and logistical difficulties are likely to impede such a program in many areas. Many governments may lack the resources to provide food, medicine, and other necessities to its citizens during a pandemic. Even if the resources are available, the workforce needed to conduct distribution may be absent, especially at the height of a pandemic. Furthermore, there may be a lack of people who want to interact closely with potentially infectious people to allow such a system to function. This may be especially true for medical transport and mortuary services.

At the least, governments should try to facilitate the provision of resources before areas are affected by disease. To the extent possible, governments should give advance warning of disease and make recommendations about how much food, medicine, and other supplies should be stockpiled. If possible, governments should provide these for people unable to afford their necessities. Governments should provide access to medical care to the greatest extent possible and assign public safety officers for this purpose. Governments also should provide a means by which people who have recovered from influenza (and are therefore immune), could assist others in the provision of necessities.

J. International Travel and Border Controls

Transnational public health law is increasingly important in global health, as evidenced by the WHO's International Health Regulations and national agencies' proposed communicable disease regulations.[223] These legal initiatives reflect recommendations for border controls by the WHO.[224] Transnational containment measures can include entry or exit screening, reporting, health alert notices, collection and dissemination of passenger information, travel advisories or restrictions, and physical examination or management of sick or exposed individuals. These kinds of powers were exercised in Asia and North America during the SARS outbreaks, although their effectiveness is not established.[225] The IHR also

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223. HHS., Quarantine, Inspection, Licensing Rule, 42 C.F.R. §§ 70-71 (2005).

224. WHO, WHO SARS RISK ASSESSMENT AND PREPAREDNESS FRAMEWORK (Oct. 2004), *available at* http://www.who.int/csr/resources/publications/CDS_CSR_ARO_2004_2.pdf; INST. OF MED., QUARANTINE STATIONS AT PORTS OF ENTRY: PROTECTING THE PUBLIC'S HEALTH (2005).

225. *See* David M. Bell & World Health Organization Working Group on Prevention of International and Community Transmission of SARS, *Public Health Interventions and SARS Spread, 2003*, 10 EMERGING INFECTIOUS DISEASES 1900 (2004); Ronald K. St. John et al., *Border Screening for SARS*, 11 EMERGING INFECTIOUS DISEASES 6 (2005).

authorizes sanitary measures at frontiers or on conveyances, such as inspection, fumigation, disinfection, pest extermination, and destruction of infected or contaminated animals or goods. [226]

1. Economic Impact of International Travel and Border Controls

Sovereign nations seek to safeguard their citizens' health from external threats, even in a global world where people, animals, and goods rapidly travel across state boundaries. Although border protection is legitimate, it can severely disrupt travel, trade, and tourism. The World Trade Organization (WTO) defends free commerce but permits science-based trade restrictions to protect the public's health.[227] As with trade restrictions, protection of the public's health needs to be balanced against the global economic impact of any travel restrictions or border control policies. Closure of borders will have an enormous global economic impact. World travel and tourism account for about 10% of global GDP and 8% of global jobs, generating more than $4 trillion in economic activity and over 200 million jobs in 2005.[228] During the SARS outbreaks, tourism in Asia dropped 30% to 80% for various countries in the region. After travel bans were put in place, almost half the planned international flights to Southeast Asia were cancelled. Even Australia saw a 20% decline in international arrivals. Even if countries will not officially close their borders during an influenza pandemic, voluntary social distancing would disrupt trade, transport, and travel.[229] In fact, studies suggest that European travel bookings have already diminished due to H5N1 fears.[230]

Given the sensitivity of economic disruptions of trade and travel during a pandemic, international coordination of border control policies is essential to avoid misunderstanding and promote cooperation. While the economic impact of a pandemic will be considerable for both developed and developing countries, the long-term consequences will be harder to overcome for the latter. Industrialized countries should be aware of this when making decisions with transnational impact. Governments should only take those measures that are necessary to address the actual risk to the community. Travel and border control measures should be implemented in a non-discriminatory fashion, and only when the harms caused by the intervention are proportionate to the benefits.

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226. *See Revision of the International Health Regulations*, *supra* note 168; *see also* 42 C.F.R. §§ 70-71.

227. *See, e.g.*, Appellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 172, WT/DS135/AB/R (Mar. 12, 2001).

228. *See* COOPER, *supra* note 25.

229. *See id.*

230. *See id.*

2. Governmental Transparency and Coordination

Given the transboundary nature of travel advisories as well as the economic impact they can have on affected countries, it should be left to the WHO to issue transparent and clearly justified travel recommendations in accordance with the revised IHR. Individual countries should communicate all relevant information on the emergence of a public health threat to the international community. Ultimately, it is the responsibility of the national government to use any policy instruments available to ensure compliance with the requirements of the new IHR. Reporting and surveillance responsibilities may be beyond the capacity of developing countries. The industrialized countries should show solidarity and be open in the way they carry out health protection responsibilities.

Fear of infection and uncertainty about the risk and virulence of the virus can have a negative impact on the global economy. Reactive and uncoordinated national actions to close borders or embargo trade could fuel unfounded fears in the early days of a pandemic, similar to the early stages of the SARS epidemic when public fears were amplified by concerns that some governments were withholding information about the disease. To avoid unwarranted travel disruptions and economic burdens governments have the responsibility to honestly disclose credible scientific information as early as possible.

3. Civil Liberties

International travel and border control also can infringe upon civil liberties. The freedom of movement is a basic right protected by national laws and international treaties, but it is subject to limits when necessary for the public's health.[231] In particular, these strategies can present serious privacy risks. For example, containment measures may require the travel industry to collect and disclose passenger data.[232] Privacy burdens are justified only if necessary to obtain high-quality surveillance data and in accordance with fair information practices. To avoid discrimination and to ensure proportionality, public health officials should inform the affected individuals about the reasons for the infringement, the intended use of the information and the extent of third parties access to the data.

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231. Shapiro v. Thompson, 394 U.S. 618 (1969); General Comment, Human Rights Comm., Continuity of Obligations Under the International Covenant on Civil and Political Rights, U.N. Doc. CCPR/C/21 (1999).

232. Ctrs. for Disease Control and Prevention, "Regulatory Impact Analysis of Proposed 42 C.F.R. Part 70 and 42 C.F.R. Part 71," *available at* http://www.cdc.gov/ncidod/dq/nprm/docs/draft_ria_final.pdf (last visited Feb. 1, 2007).

K. Isolation and Quarantine

The terms "quarantine" and "isolation" often are used interchangeably, but they are, in fact, distinct. The modern definition of quarantine is the restriction of the activities of asymptomatic persons who have been exposed to a communicable disease, during or immediately prior to the period of communicability, to prevent disease transmission.[233] In contrast, isolation is the separation, for the period of communicability, of known infected persons in such places and under such conditions as to prevent or limit the transmission of the infectious agent.[234] Quarantine and isolation can be accomplished by various means, including having the person stay in his or her home, restricting travel out of an affected area, or having the individual stay at a designated facility.[235] Whatever techniques are used, it is important to treat symptomatic, potentially exposed, and non-exposed populations differently. It would be inappropriate to place infected individuals in the same room as those who are only potentially exposed.

Isolation and quarantine were used widely in Asia and Canada during the SARS outbreaks in 2003.[236] In Toronto, between 13,000 people[237] and 30,000 people[238] were quarantined. In Beijing and Taiwan those numbers were even higher—specifically, 30,000 people in Beijing and 131,000 people in Taiwan were quarantined.[239] While quarantine and isolation played a major role in the containment of SARS, they will be less appropriate as containment measures during a pandemic influenza. Unlike SARS, influenza's transmission characteristics allow little time for isolation and quarantine.

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233. *See id.* at 541-43 (describing two forms of quarantine: absolute and modified); *see also* Daniel S. Reich, *Modernizing Local Responses to Public Health Emergencies: Bioterrorism, Epidemics, and the Model State Emergency Health Powers* Act, 19 J. CONTEMP. HEALTH L. & POL'Y 379, 406-07 (2002) [hereinafter *Modernizing Local Responses*]; *Revision of the International Health Regulations*, *supra* note 168 (defining quarantine as "the restriction of activities and/or separation from others of suspect persons who are not ill . . . in such a manner as to prevent the possible spread of infection or contamination").

234. *See* CONTROL OF COMMUNICABLE DISEASES MANUAL 539-40 (Abram S. Benenson ed., 16th ed. 1995) (describing six forms of isolation: strict, contact, respiratory, tuberculosis, enteric precautions, drainage/secretion precautions); *see also* Marguerite M. Jackson & Patricia Lynch, *Isolation Practices: A Historical Perspective*, 13 AM. J. INFECTION CONTROL 21 (1985).

235. U.S. Dep't of Homeland Sec., *Flu Pandemic Mitigation: Quarantine and Isolation*, *available at* http://www.globalsecurity.org/security/ops/hsc-scen-3_flu-pandemic-quarantine.htm. (last visited Feb. 1, 2007).

236. *See* Gostin et al., *supra* note 116.

237. Jane Speakman, *Quarantine in Severe Acute Respiratory Syndrome and Other Emerging Infectious Diseases*, 31 J.L. MED. & ETHICS 63 (2003).

238. *Id.* at 5.

239. *Id.*

Whatever their effectiveness, quarantine and isolation are the most complex, not to mention legally and ethically controversial, of the public health powers. Quarantine and isolation represent the tension between the interests of society in protecting and promoting the health of its citizens and the individual's rights of privacy, non-discrimination, freedom of movement, and freedom from arbitrary detention.[240] The legitimacy of such coercive public health powers rests on a careful balancing of these competing interests,[241] with the public benefit outweighing the burden quarantine may place on individual rights. Additionally, each country should comply with the internationally agreed upon Siracusa principles, which hold that restrictions of liberty should be legal, proportionate, necessary, and according to the least restrictive means that are reasonably available.[242]

1. Legal Authority

Clearly defined jurisdictional boundaries and limits on governmental power are necessary to create public accountability. Statutory criteria should incorporate rigorous scientific measures of risk and allow quarantine only when necessary for the public's health. Governments should use coercive health measures only when a disease is known through extensive scientific study to be contagious. Moreover, governments should limit application of the measures to those actually exposed to the disease.[243]

Occasionally, resource and time constraints will justify immediate government action without prior medical testing of each individual. In addition, the availability of accurate tests and competent medical staff can be limited. However, to ensure the legitimacy of such measures, public health authorities should fully and honestly disclose their reasons for action and allow community participation in such decisions. Transparency will enhance public trust and acceptance of the proposed containment measures.[244]

2. Due Process (Natural Justice)

In addition to substantive protections, judicial procedures—specified in terms of the process, rather than the outcome—are necessary to ensure the legitimate use of isolation and quarantine. Ideally, quarantine and isolation

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240. *Id.* at 3.
241. *Id.* at 4.
242. *See Siracusa Principles*, *supra* note 139.
243. *See Modernizing Local Responses*, *supra* note 233.
244. Daniel Markovitz, *Quarantines and Distributive Justice*, 33 J.L. MED. & ETHICS 323, 323 (2005); DAVID HEYMAN, CTR. FOR STRATEGIC AND INT'L STUD., MODEL OPERATIONAL GUIDELINES FOR DISEASE EXPOSURE CONTROL 16-17 (2005), *available at* http://www.csis.org/media/csis/pubs/051102_dec_guidelines.pdf.

would affect only those that are actually infected with H5N1. However, such infallibility is unlikely. Therefore, governments should design judicial procedures that reach toward the more feasible goal of protecting the public health while minimizing human rights violations and ethical concerns.

Of particular concern is the protection of groups of people—especially minority populations—from the inappropriate use of state power. Regardless of a country's judicial system and infrastructure, governments should avoid restrictions on individual movement that are arbitrary, unreasonable, or discriminatory. Isolation or quarantine orders should last no longer than scientific review justifies. Public health officials should publicly explain their decisions and re-evaluate any orders on a regular basis. Moreover, countries should have procedural mechanisms for groups to challenge the unjustified use of quarantine or isolation power.

As important as individual due process rights are, the urgency of a pandemic outbreak might preclude individual hearings. Many countries do not possess the judicial infrastructure to cope with the volume of hearings that would result from a mass quarantine, particularly since the high morbidity and mortality associated with a highly pathogenic influenza pandemic would strain the already existing infrastructure. However, developing countries with strong judicial infrastructures should maintain individualized due process to the extent feasible.

3. Monitoring and Enforcement: Voluntary or Least Intrusive Means

Quarantine and isolation should be voluntary whenever possible. When mandatory containment is necessary, governments should first apply the least restrictive measures followed, when necessary, by a graded application of more restrictive measures.[245] For example, while Canadians generally complied voluntarily with quarantine requests during the SARS outbreak,[246] public health officials elsewhere—including China, Hong Kong, and Singapore—had to use more coercive measures. In Hong Kong, barricades and tape were used to confine infected residents in a large housing complex.[247] In Singapore, three telephone calls were made per day

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245. WHO Pandemic Influenza Draft Protocol for Rapid Response and Containment, at 11-12 (Jan. 27, 2006), *available at* http://www.who.int/csr/disease/avian_influenza/guidelines/RapidResponse_27%2001.pdf.

246. UNIV. OF TORONTO JOINT CTR. FOR BIOETHICS, PANDEMIC INFLUENZA WORKING GROUP, STAND ON GUARD FOR THEE: ETHICAL CONSIDERATIONS IN PREPAREDNESS PLANNING FOR PANDEMIC INFLUENZA 13 (2005), *available at* http://www.utoronto.ca/jcb/home/documents/pandemic.pdf.

247. Nola M. Ries, *Public Health Law and Ethics: Lessons from SARS and Quarantine*, 13 HEALTH L. REV. 1, 3 (2001), *available at* http://www.law.ualberta.ca/centres/hli/pdfs/13-01/13-1-01_Ries.pdf.

to the home of each quarantined individual to confirm compliance.[248] Surveillance cameras were placed in homes where people were quarantined, and inhabitants were required to take their own temperatures on camera to avoid fraud.[249] Electronic wrist or ankle-bands also were used as enforcement measures.[250]

Different countries have different norms and needs, and one must view different enforcement measures in the context of what a given society considers to be reasonable. At a minimum, the monitoring and enforcement measures adopted should have a logical and proportionate relationship to the achievement of the public health objective and should be implemented in a fair and non-discriminatory manner. Finally, all measures taken should be culturally accepted and collectively approved by the populace.[251]

4. Ensuring Safe, Humane Implementation of Isolation or Quarantine

When quarantine and isolation are necessary, the principle of reciprocity obliges society to provide those affected with the necessities of life during the period of quarantine, including safe and humane housing, as well as high quality medical care and psychological support. Recent studies have confirmed that quarantine imposes serious financial and psychological hardships on affected individuals: about 30% of quarantined individuals suffer from post-traumatic stress disorder and depression.[252] All countries should be required to provide and pay for these basic needs. Furthermore, quarantine needs to be implemented in a humane manner that is sensitive to gender, religious, and ethnic issues.

Distributive justice requires that officials limit the extent to which the personal and economic burdens of a public health threat fall unfairly upon individual citizens. To this end, governments and national and international organizations should stockpile medical supplies and food in an effort to fairly and equitably address any lack of resources and amenities. A pandemic influenza will require solidarity among nations and collaborative approaches that set aside traditional values of self-interest and territoriality.

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248. ROTHESTEIN ET AL., *supra* note 220, at 25.
249. *See id.*; *see also* Ries, *supra* note 247, at 3.
250. *See* ROTHESTEIN ET AL., *supra* note 220, at 25.
251. *Id.*
252. *See, e.g.*, Laura Hawryluck et al., *SARS Control and Psychological Effects of Quarantine, Toronto, Canada*, 10 EMERGING INFECTIOUS DISEASES 7 (2004) (recording incidences of Post-Traumatic Stress Disorder (PTSD) among individuals quarantined during the Canadian SARS outbreak).

CONCLUSION

Preparing for an influenza pandemic presents difficult challenges, many of which transcend mere scientific effectiveness. Even when successful, coercive public health interventions can have deep, adverse consequences for economic and civil liberties. Therefore, it is vital that individual rights are sacrificed only when necessary to protect the public health. As such, laws must clearly establish the criteria for the exercise of such emergency powers and provide adequate due process to minimize infringements on individual rights.

The threat of an influenza pandemic is real and could affect millions of lives. If such a disaster occurs, we must not allow the widespread erosion of individual rights to compound the tragedy. We must form an immediate political and social response to the effect coercive public health measures will have on civil liberties. Only then are we equipped—ethically as well as scientifically—to deal with the impact of a global pandemic.

COMMENT

NOT GOOD ENOUGH FOR GOVERNMENT WORK: HOW OMB'S GOOD GUIDANCE PRACTICES MAY UNINTENTIONALLY COMPLICATE ADMINISTRATIVE LAW

CHRISTOPHER E. WILSON*

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* J.D. Candidate, May 2008, American University Washington College of Law; B.A., Public Policy Studies, Vanderbilt University, May 1997. Senior Staff, *Administrative Law Review*, 2006-2007. First, I wish to express my love and appreciation for Carla. Her love, support, and belief in me carries me throughout my endeavors. I would also like to thank my friends and family, including my father, Frank, my stepmother, Linda, and my siblings, Tom and Patricia, for their constant love and encouragement. I especially recognize my mother, Elizabeth, whose tireless and unconditional love and devotion provides me strength and comfort. Lastly, I want to acknowledge Professor Andrew Popper, Professor Anthony E. Varona, and the supremely talented staff of the *Administrative Law Review* for their insightful feedback and assistance on this Comment. You all exemplify why American University is such an enriching place to learn and study law.

INTRODUCTION

After receiving comments on its Proposed Bulletin for Good Guidance Practices issued on November 30, 2005, the Office of Management and Budget (OMB) published its Final Bulletin for Good Guidance Practices (Final Bulletin) on January 25, 2007.[1] OMB issued its Final Bulletin in response to the proliferation of guidance documents promulgated by federal agencies, and due to OMB's concern with their impact on private parties, a concern OMB has expressed since 2002.[2] At the same time that OMB issued its Final Bulletin, President Bush issued Executive Order 13,422, which amended Executive Order 12,866 on Regulatory Planning and Review, placing guidance documents under greater scrutiny by the White House.[3] Although the Final Bulletin and Executive Order 13,422 touch on some of the same issues, discussion of the Executive Order is beyond the scope of this Comment.

Some characterize agency use of guidance documents to bind private parties as a backdoor way of regulating without having to undertake the necessary procedures reserved for binding rules.[4] Indeed, agency treatment of guidance documents, especially guidance that is later determined to be "practically binding" on regulated entities, is subject to much criticism,[5] despite Congress—via the Administrative Procedure Act (APA)—

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1. *See* Final Bulletin for Agency Good Guidance Practices, 72 Fed. Reg. 3432 (Jan. 25, 2007) [hereinafter Final Bulletin] (acknowledging that guidance documents may be "poorly designed or improperly implemented" and therefore clear and consistent agency practices are needed); *see also* Proposed Bulletin for Good Guidance Practices, 70 Fed. Reg. 71,866 (Nov. 30, 2005) (indicating that the draft bulletin defines guidance, describes the legal effect of guidance documents, and establishes practices for developing guidance documents and receiving public input). Note that although a "bulletin" is a substantive rulemaking document, it is generally considered a "policy statement" in administrative law and should have no binding legal effect. Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like: Should Federal Agencies Use Them to Bind the Public?*, 41 DUKE L.J. 1311, 1315 (1992).

2. *See* Final Bulletin, 72 Fed. Reg. at 3432 (stating that "[a]s the impact of guidance documents on the public has grown, so too, has the need for good guidance practices").

3. *See* Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007) (addressing the potential need for interagency review of certain significant guidance documents by providing the Office of Management and Budget (OMB) authority to have advance notice of, and to review, agency guidance documents).

4. *See* H.R. REP. NO. 106-1009, at 1 (2000) (finding that "some guidance documents were intended to bypass the rulemaking process" and that "[s]uch 'backdoor' regulation is an abuse of power").

5. *See* Leslie M. MacRae & Kenneth E. Nicely, *Break the Rules and Run an Industry: Guidance Manuals More Destructive of the Rule of Law Than Bad Accounting*, 11 U. BALT. J. ENVTL. L. 1, 2 (2003) (noting that many agencies argue their policies bind regulated parties, but that these policies are adopted without following the Administrative Procedure Act's (APA) procedures for rulemaking); Anthony, *supra* note 1, at 1315 (suggesting that "[w]hile these nonlegislative rules by definition cannot *legally* bind, agencies often inappropriately issue them with the intent or effect of imposing a *practical* binding norm upon the regulated or benefited public").

differentiating a binding rule from a nonbinding issuance.[6] Though not defined in the APA, "guidance" is a broad term that could include an interpretive rule or a general policy statement.[7]

This Comment examines whether OMB's Final Bulletin mitigates the confusion regarding the legal status of guidance documents, both for private parties who are asked to adhere to the guidance, and for courts that must discern the legal efficacy of the guidance. Part I discusses the importance of guidance documents in administrative law and the resulting criticism and confusion surrounding their proliferation and misuse. Part II examines OMB's Final Bulletin in greater detail. Part III evaluates the Final Bulletin with regard to how it comports with pertinent case law and explores how the Final Bulletin may lead to unintended consequences, both with respect to the legal effect of guidance documents and the type of judicial deference afforded them. Finally, Part IV recognizes the need for certain good guidance practices, but recommends that OMB reconsider allowing notice and comment prior to the issuance of guidance documents to mitigate the potential for unintended consequences.

I. BACKGROUND

A. What is Guidance?

While the term "guidance" is not defined in the APA and generally is viewed as a legally insignificant term,[8] a guidance is a "substantive rulemaking document"[9] and can take the form of a wide-range of issuances from federal agencies—such as memoranda, manuals, and circulars—and

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6. *See* Administrative Procedure Act, 5 U.S.C. § 553(b), (c) (2000) (mandating that for a rule to be binding, a general notice of proposed rulemaking must be published in the Federal Register and that after such notice the agency must give interested persons an opportunity to submit written comments for agency consideration); *id*. § 553(b) (2000) (providing exemptions from the notice and comment procedures in certain situations, such as when an agency merely issues an interpretive rule or policy statement).

7. *See* Todd D. Rakoff, *The Choice Between Formal and Informal Modes of Administrative Regulation*, 52 ADMIN. L. REV. 159, 159 (2000) (recognizing that "guidance," as a distinct legal category, is a new concept in American administrative law); *see also* Anthony, *supra* note 1, at 1315 (distinguishing guidances as "policy statements" pursuant to APA terminology). While Professor Anthony is able to easily characterize guidance as a policy statement under the APA, agencies and courts have had a difficult time determining whether a guidance document constitutes an interpretive rule or a policy statement. *See* Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 93-94 (D.C. Cir. 1997) (suggesting that courts and litigants are prone to group interpretive rules and policy statements together in contrast to their treatment of substantive rules); RICHARD J. PIERCE, JR., 1 ADMINISTRATIVE LAW TREATISE § 7.10 (4th ed. 2002) (noting that characterizing a rule as exempt from notice and comment procedure is challenging because it is difficult to determine whether it is a statement of policy, an interpretative rule, or a rule of procedure).

8. *See* PIERCE, *supra* note 7, § 6.1 (explaining that labels such as "guidances," "compliance policies," "handbooks," and "manuals" have no legal significance).

9. Anthony, *supra* note 1, at 1315.

most likely meets the definition of a policy statement under the APA.[10] Guidance, therefore, plays an important role in federal administrative law.[11]

A guidance has several possible uses. It may supply additional detail unreasonable to expect from senior agency officials,[12] or it may simply allow an agency to inform the public.[13] Agency use of rulemaking is declining and, in its place, agencies increasingly are regulating through guidances and other nonlegislative rules.[14] Numerous reasons for the extensive promulgation of guidance documents exist, including an agency desire to avoid "enhanced political accountability for policy decisions,"[15] the "expensive and time-consuming procedures"[16] Congress has imposed on the rulemaking process, and the desire to withstand judicial review that requires a "detailed" and "encyclopedic" statement of basis and purpose.[17] Additionally, agencies often have little time to issue regulations.[18] This reality is especially problematic given that issuing a rule pursuant to the APA's notice and comment procedures consumes a great deal of an agency's time and resources.[19]

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10. *Id*.

11. *See* H.R. REP. NO. 106-1009, at 5 (2000) (discovering that the Occupational Health and Safety Administration (OSHA) issued 3,374 guidance documents between 1996 and 1999); RICHARD J. PIERCE, JR., 3 ADMINISTRATIVE LAW TREATISE § 17.3 (4th ed. 2002) (opining that a "quick inspection of the office of any senior agency employee or any private [regulatory] lawyer . . . will demonstrate that nonbinding agency instructions and policy statements dominate binding legislative rules" as sources of information for regulatory compliance); Peter L. Strauss, *The Rulemaking Continuum*, 41 DUKE L.J. 1463, 1468-69 (1992) (offering that "publication rules" such as technical guidance and staff manuals are produced often and in far greater number than more formal rules).

12. *See* Strauss, *supra* note 11, at 1478 (noting that publication rules, including guidances, can be seen as "filling in the details").

13. *See id*. at 1481 (stating that publication rulemaking has an informing character that allows important efficiencies to those who must deal with the government).

14. *See* PIERCE, *supra* note 7, § 7.11 (proffering that there is mounting evidence that agencies are using rulemaking less frequently).

15. *See id.* (explaining that the notice and comment requirement in advance of adoption gives Congress and the White House a good opportunity to deter an agency from adopting a policy that an agency prefers, but that the president or members of Congress oppose).

16. *See id.* (providing examples of bills that require an opportunity for limited oral testimony and cross-examination with respect to certain issues that are critical to the outcome of a rulemaking).

17. *See id.* (explaining that to avoid the risk of judicial reversal, an agency often must incorporate a statement of basis and purpose that is several hundred pages long); STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY 544 (6th ed. 2006) (acknowledging that courts have changed notice and comment rulemaking into a "more formal and time-consuming" process); Final Bulletin, 72 Fed. Reg. at 3432 (suggesting that agencies have an incentive to issue guidance documents instead of regulations because they involve fewer procedures).

18. *See* MacRae & Nicely, *supra* note 5, at 2 (recognizing that agencies are under time and political pressures to efficiently and effectively regulate industries subject to the statute).

19. *See* PIERCE, *supra* note 11, § 17.3 (stating that amending or promulgating a major legislative rule often takes at least five years).

Nonetheless, "guidance is a good thing."[20] Conceptually, the use of guidance allows agencies to better fulfill their responsibilities.[21] However, federal agencies' misuse of guidance documents has raised concern from Congress, corporations, and academics.[22] Regulated parties may attempt to get out from underneath an agency's thumb and contest agency guidance because the agency treats it as binding on private parties, even though it is not subjected to the APA's notice and comment procedures. Three relatively recent decisions from the United States Court of Appeals for the District of Columbia Circuit illustrate this trend.[23]

B. The Confusion

Legal scholars and federal courts struggle when attempting to determine whether an agency rule[24] should be subject to the APA's notice and comment requirements or is simply an interpretive rule or policy statement, and therefore exempt from these requirements.[25] Determining whether a

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20. Cindy Skrzycki, *Finding a Way to Better Guidance*, WASH. POST, Dec. 20, 2005, at D1 (quoting Professor Jeffrey Lubbers, who explains that guidance becomes problematic when agencies treat it as binding on the public without notice and comment).

21. *See generally* PIERCE, *supra* note 11, § 17.1 (indicating the necessity for agencies to have significant discretion to carry out their responsibilities effectively).

22. *See Is the Department of Labor Regulating the Public Through the Backdoor?: Hearing Before the Subcomm. on National Econ. Growth, Natural Res., and Regulatory Affairs of the H. Comm. on Govt. Reform*, 106th Cong. 342 (2000) (statement of LPA, Inc.) (highlighting the numerous abuses by the Department of Labor in issuing guidance documents); BREYER ET AL., *supra* note 17, at 544 (reporting that a review of the Federal Register for the first six months of 1987 shows that forty percent of rules published had been adopted without notice and comment by agencies invoking the exemptions in the APA); MacRae & Nicely, *supra* note 5, at 2 (noting that "arrogance is displayed towards the regulated and lawmakers by deliberately sidestepping rule making procedures").

23. *See* Gen. Elec. Co. v. EPA, 290 F.3d 377, 385 (D.C. Cir. 2002) (striking down polychlorinated biphenyls (PCB) risk assessment guidance as a legislative rule requiring notice and comment); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1023-24 (D.C. Cir. 2000) (overturning emissions monitoring guidance as a legislative rule requiring notice and comment); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 213 (D.C. Cir. 1999) (declaring an OSHA Directive a legislative rule requiring notice and comment).

24. It is important to note that the term "rule" is defined broadly in the APA, and guidance documents issued by agencies likely fall under the APA definition. *See* 5 U.S.C. § 551(4) (2000) (defining a rule as "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency . . . "); Att'y Gen.'s Manual on the APA (1947) at 13, *available at* http://www.oalj.dol.gov/PUBLIC/APA/REFERENCES/REFERENCE_WORKS/AG01.HTM (indicating that the definition of "rule" is not limited only to substantive rules, but embraces interpretive, organizational, and procedural rules as well, and that "rule" includes agency statements of general applicability and particular applicability). *But see* Pac. Gas & Elec. Co. v. Fed. Power Comm'n, 506 F.2d 33, 38 (D.C. Cir. 1974) (implying that a general statement of policy is not a rule under the APA, noting that it is not derived from either a rulemaking or an adjudication).

25. *See* GARY LAWSON, FEDERAL ADMINISTRATIVE LAW 302 (3d ed. 2004) (stipulating that determining whether a rule is substantive as opposed to an interpretive rule or general policy statement is a question that has "proven to be one of the most troublesome in all of administrative law").

rule is legislative, interpretive, or a policy statement is important because courts grant greater deference to a legislative rule than to an interpretive rule or policy statement.[26] As OMB noted, courts have not taken kindly to federal agencies attempting to bind regulated parties by way of guidance.[27] In *Community Nutrition Institute v. Young*,[28] the D.C. Circuit determined that Food and Drug Administration (FDA) "action levels," which are the allowable levels of unavoidable contaminants in food,[29] while supposedly nonbinding, nonetheless practically bound third parties and should have gone through the APA's notice and comment procedures required for legislative rules.[30] Subsequent cases before the D.C. Circuit indicate the court's lack of patience with agencies that issue what the agency considers nonbinding documents exempt from notice and comment but treat these documents in a way that practically binds parties.[31] Indeed, for years courts have considered whether an agency should issue a seemingly innocuous and nonbinding document in accordance with the APA's notice and comment principles.[32]

Recognizing that courts continue to find fault in agency use of guidance documents, OMB issued its Final Bulletin for Agency Good Guidance Practices as a way to provide greater clarity to the public with regard to such documents.[33] The foundation for the Final Bulletin is based on earlier recommendations and examples.[34]

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26. *See* Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984) (ruling that "legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute," or are reviewed for their reasonableness); *see also* Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944) (holding that courts do not treat rulings, interpretations, and opinions as controlling by reason of their authority, but that they are of value and may be relied upon by courts and litigants for guidance, and that their weight of authority is judged by their power to persuade).

27. *See* Final Bulletin, 72 Fed. Reg. at 3432 n.2 (indicating that courts are concerned with agency guidance practices).

28. 818 F.2d 943 (D.C. Cir. 1987).

29. *Id.* at 945.

30. *Id.* at 946 (finding that action levels are not policy statements).

31. *See* Gen. Elec. Co. v. EPA, 290 F.3d 377, 380 (D.C. Cir. 2002) (holding that the Environmental Protection Agency's (EPA) guidance document is a legislative rule because it purports to bind both the agency and applicants with the force of law); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1022-23 (D.C. Cir. 2000) (determining that whatever EPA may think of its guidance generally, the elements of the guidance strongly indicate a binding effect); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 211-12 (D.C. Cir. 1999) (finding that the Directive in question required more than adherence to existing law).

32. *See* Airport Comm'n v. Civil Aeronautics Bd., 300 F.2d 185, 188 (4th Cir. 1962) (deciding that a press release issued by the Civil Aeronautics Board was not an exercise of rulemaking power and need not be published in the Federal Register pursuant to the APA).

33. *See* Final Bulletin, 72 Fed. Reg. at 3433 (stating that the purpose of the Good Guidance Practices is to inject transparency, quality, and accessibility into the formulation of guidance documents, and to ensure guidance documents are properly reviewed and issued and not improperly treated as binding).

34. *See id.* (noting that the Food and Drug Modernization Act of 1997, FDA's Good Guidance Practices, and recommendations by the Administrative Conference of the United States (ACUS) informed the development of the Final Bulletin).

C. The Genesis of Good Guidance Practices

The idea of "good guidance practices," a colloquial term with no legal definition, has existed since at least 1976 when the Administrative Conference of the United States (ACUS)[35] recommended ways to improve the manner in which agencies issue interpretive rules of general applicability[36] and statements of general policy.[37] At that time, the ACUS focused its attention on interpretive rules of general applicability or statements of general policy likely to have a "substantial impact" on the public, and recommended that the agency use the procedures for notice and comment set forth in the APA.[38] The ACUS also suggested ways for an agency to improve the use of interpretive rules of general applicability or statements of general policy, even if the agency could not seek public comment prior to issuing the documents.[39]

In 1992, the ACUS made additional recommendations concerning agency policy statements.[40] Worried that regulated parties would not be able to effectively challenge binding agency policy statements, the ACUS recommended certain practices that allowed for interested parties to be heard.[41] Specifically, the ACUS suggested that agencies afford affected

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35. Congress formally established the ACUS in 1966 to, among other things, "promote more effective public participation and efficiency in the rulemaking process." Administrative Conference Act, 5 U.S.C. § 591 (2000). The ACUS no longer exists. *See* Treasury, Postal Service, and General Government Appropriations Act of 1996, Pub. L. No. 104-52, 109 Stat. 480 (ceasing funding for the ACUS and terminating its operations by February 1, 1996). Congress recently reauthorized the ACUS, but because it has not appropriated money for its operations, the ACUS remains dormant. *See* Federal Regulatory Improvement Act of 2004, Pub. L. No. 108-401, 118 Stat. 2255 (authorizing appropriations for the ACUS for fiscal years 2005, 2006, and 2007).

36. *See* Administrative Conference of the United States, Rec. 76-5, 1 C.F.R. § 305.76-5 (1976), *available at* http://www.law.fsu.edu/library/admin/acus/305765.html (determining that an interpretive rule of general applicability is a means by which an agency explains its view of the meaning of a statute or rule).

37. *See id.* (noting that a statement of general policy is an issuance from an agency describing how it will exercise its discretion).

38. *See id.* (stating that an opportunity to comment is meant to ensure greater confidence in and broader acceptance of ultimate agency judgments, and that an agency should publish the proposed interpretive rule or policy statement in the Federal Register, provide a concise statement of its basis and purpose, and invite interested persons to submit written comments, with or without opportunity for oral presentation).

39. *See id.* (suggesting that even if such a document is issued without prior publication or invitation for public comment, the document nonetheless should be published and include a statement of its basis and purpose and invite comment for a period of not less than thirty days from the date of issuance).

40. *See* Administrative Conference of the United States, Rec. 92-2, 1 C.F.R. § 305.92-2 (1992), *available at* http://www.law.fsu.edu/library/admin/acus/305922.html (proposing that agency policy statements make clear that they do not bind parties).

41. *See id.* (urging agencies to modify current informal and formal procedures to allow for an opportunity to challenge practically binding policy statements and that the particulars of such procedures should be left to an agency's discretion).

persons a "fair" opportunity, either at or before issuance, "to challenge the legality or wisdom of the document and to suggest alternative choices in an agency forum that assures adequate consideration by responsible agency officials."[42]

The FDA incorporated the ACUS's general recommendations into a document entitled "Good Guidance Practices" in 1997.[43] To ensure public awareness of guidance documents and thorough vetting of FDA-issued guidance documents, the FDA Good Guidance Practices categorizes guidance documents,[44] allows for public input in the development of certain guidance documents,[45] and allows the FDA to revise and reissue guidance,[46] among other things. While mirroring the ACUS recommendations, the FDA's Good Guidance Practices, in reality, formalized its past practice of allowing notice and comment for interpretive rules and policy statements.[47] Congress codified the FDA's Good Guidance Practices contemporaneously with the FDA's implementation of them.[48]

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42. *Id.* ACUS also recommended other means of improving the use of policy statements, including suggestions that notice and opportunity for comment on such policy statements be afforded, and that a notice of the policy statement's nonbinding nature be included with each document. *Id.*

43. *See* The Food and Drug Administration's Development, Issuance, and Use of Guidance Documents, 62 Fed. Reg. 8961 (Feb. 27, 1997).

44. *See* FDA Good Guidance Practices, 21 C.F.R. § 10.115(c)(1)-(2) (2005) (distinguishing between Level 1 and Level 2 guidance documents). Level I documents "(i) [s]et forth initial interpretations of statutory or regulatory requirements; (ii) [s]et forth changes in interpretation or policy that are of more than a minor nature; (iii) [i]nclude complex scientific issues; or (iv) [c]over highly controversial issues." *Id.* Level 2 guidance documents "set forth existing practices or minor changes in interpretation or policy." *Id.*

45. *See id.* § 10.115(g)(1)(i) (stipulating that the "FDA can seek or accept early input from individuals . . . outside the agency" in the preparation of a draft of a Level 1 guidance document "by participating in or holding public meetings or workshops").

46. *See id.* § 10.115(g)(1)(v) (granting the FDA the option of issuing another draft of the guidance document after providing an opportunity for comment).

47. Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113, 138-39 (1997) (explaining that the agency announces availability of a draft guideline, invites public input, and occasionally issues a subsequent notice to extend the comment period).

48. *See* 21 U.S.C. § 371(h) (2004) (providing that the FDA develop guidance documents with public participation and that such documents be publicized).

II. OMB'S GOOD GUIDANCE PRACTICES

A. Overview

The Final Bulletin provides a broad definition of guidance documents.[49] It further distinguishes and defines a "significant guidance document"[50] and an "economically significant guidance document."[51] The Final Bulletin explicitly excludes certain documents from the definition of "significant guidance document," including legal advisory opinions for internal executive branch use, editorials, press releases, and warning letters, among others.[52] Additional elements of the Final Bulletin include setting forth approval procedures that agencies should implement when issuing significant guidance documents to ensure their endorsement by appropriate senior agency officials,[53] and standardizing each significant guidance document's appearance, including a prohibition on the use of mandatory, binding language.[54]

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49. *See* Final Bulletin, 72 Fed. Reg. at 3439 (defining the term "guidance document" as "an agency statement of general applicability and future effect, other than a regulatory action (as defined in Executive Order 12,866, as further amended, § 3(g)), that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue").

50. *See id*. (providing four possible definitions for a "significant guidance document"). These include documents that may:

> reasonably be anticipated to (1) [l]ead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.

Id.

51. *See id*. (defining an "economically significant guidance document" as a document that may reasonably be anticipated to lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy or a sector of the economy, except that economically significant guidance documents do not include documents on Federal expenditures and receipts). While this definition closely resembles the definition of a "significant regulatory action" in Executive Order 12,866 regarding regulatory review, it differs in key respects. *See* Exec. Order No. 12,866, 58 Fed. Reg. 51,735, 51,738 (Sept. 30, 1993). *But see* Final Bulletin, 72 Fed. Reg. at 3435 (noting that the Final Bulletin includes the words "may reasonably lead to" and "lead to" an economically significant effect, while Executive Order 12,866 defined significant regulatory actions as having such an effect).

52. Final Bulletin, 72 Fed. Reg. at 3439.

53. *See id.* at 3440 (requiring each agency to develop or maintain written procedures for the approval of significant guidance documents and prohibiting agencies from circumventing the requirements of public notice for such documents).

54. *See id*. (dictating that each significant guidance document must involve the following standard elements: (1) include the term "guidance,"(2) identify the agency issuing the document, (3) identify the activity to which and the people to whom the document

Ensuring public access and feedback, the Final Bulletin declares that each agency must provide access to all of its significant guidance documents via the Internet and publicize on its website the method that the public may use to comment on such documents.[55] Agencies are not required by law to formally respond to comments submitted with regard to significant guidance documents.[56] However, for most economically significant guidance documents, the Final Bulletin imposes an affirmative duty on agencies to invite public comment and respond to the comments submitted,[57] although the Final Bulletin exempts an agency from publicizing and seeking comment on certain economically significant guidance documents.[58]

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applies, (4) include the date of issuance, (5) note if it is amending a previous guidance document, (6) provide a title of the guidance, and (7) not include mandatory language such as "shall," "must," "required," or "requirement" unless the agency uses these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties).

55. *See id*. (requiring each agency to post annually on its Web site a current list of its significant guidance documents in effect as well as to "clearly advertise on its website a means for the public to submit comments electronically on significant guidance documents, and to submit a request electronically for issuance, reconsideration, modification, or rescission of significant guidance documents"). It is important to note that the Final Bulletin does not require that significant guidance documents be published in the Federal Register. *See id*.

56. *See id*. (noting that public comments concerning significant guidance documents are solely for the agency's benefit and that an agency is not required to respond formally to comments). However, OMB does encourage agencies to consider following notice and comment procedures for "interpretive significant guidance documents that effectively would extend the scope of the jurisdiction the agency will exercise, alter the obligations or liabilities of private parties, or modify terms under which the agency will grant entitlements." *Id.* at 3437.

57. *See id*. at 3440 (mandating that when an agency prepares a draft of an economically significant guidance document, it publish a notice in the Federal Register, post it on the Internet in addition to making a hard copy available, invite public comment, and respond to such comments). The Federal Register notice is not required to include any specific information about the economically significant guidance document. Rather, such notice only announces that the draft guidance document is "available." *Id.* This "notice" seemingly requires less detail than is needed under full notice and comment rulemaking under the APA. *See* 5 U.S.C. § 553(b) (requiring notice to include a statement of time, place, and nature of the proceeding, reference to the legal authority relied upon, and the terms or substance of the proposal). Nonetheless, the Final Bulletin does mirror certain provisions of the APA by providing that agencies can invite oral presentations on economically significant guidance documents and can incorporate suggestions into the economically significant guidance documents. *Compare* Final Bulletin, 72 Fed. Reg. at 3438, *with* 5 U.S.C. § 553(c) (requiring agencies to give persons an opportunity to participate in the rulemaking, including via oral presentation if possible, and to incorporate in the rules a statement of basis and purpose after consideration of the comments submitted). Thus, the Final Bulletin's notice and comment requirements for economically significant guidance documents could be considered a hybrid of the APA's notice and comment requirements for rulemaking. OMB seems to concur in this assessment. *See* Final Bulletin, 72 Fed. Reg. at 3438 (acknowledging that these procedures are "similar" to APA notice and comment requirements).

58. Final Bulletin, 72 Fed. Reg. at 3440 (stating that agencies may at their discretion, but in consultation with the Administrator of the Office of Information and Regulatory

B. Commentary on OMB's Proposed Good Guidance Practices

To better understand OMB's reasoning behind the Final Bulletin, it is helpful to review the Proposed Bulletin and the comments submitted to OMB during the development of its good guidance practices. OMB received numerous comments on its Proposed Bulletin.[59] Generally speaking, commenters supported OMB's proposals regarding public access to significant guidance documents.[60] The bulk of the attention and criticism focused on OMB's definitions of significant guidance documents and economically significant guidance documents; some commenters found OMB's definitions too broad,[61] while others found them too narrow.[62] The

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Policy (OIRA), identify particular guidance documents or classes of guidance documents for which the notice and comment procedures are not feasible or appropriate).

59. Office of Mgmt. & Budget, Comments on Proposed Bulletin on Good Guidance Practices, *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-index.html (last visited Feb. 1, 2007) (providing a complete listing of the comments OMB received).

60. *See, e.g.*, Am. Bar Ass'n, Comments of the American Bar Association with Regard to OMB's Proposed Bulletin for Good Guidance Practices (2005), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-aba.pdf [hereinafter ABA Comments] (noting that the ABA supports OMB's efforts to make guidance documents available over the Internet); Citizens for Sensible Safeguards, Comments of Citizens for Sensible Safeguards with Regard to OMB's Proposed Bulletin for Good Guidance Practices 2 (2006), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-watch.pdf [hereinafter CSS Comments] (stating that while it believes that there could be better means to attain the goals of transparency and public participation, it has "no quarrel" with the substance of the public access portion of the Proposed Bulletin); Gen. Elec. Co., Comments of the General Electric Company with Regard to OMB's Proposed Bulletin for Good Guidance Practices 10 (2006), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-ge.pdf [hereinafter GE Comments] (recognizing that OMB's provision mandating the posting of significant guidance documents on the Internet is an important provision that furthers the goal of transparency).

61. *See* ABA Comments, *supra* note 60 (expressing concern that OMB, by defining significant guidance documents to include "initial interpretations of statutory or regulatory requirements, or changes in interpretation or policy," unnecessarily sweeps into the category of significant guidance documents all initial agency guidance no matter how routine or substantial). OMB seemed to agree with the ABA and did not include that particular definition in the Final Bulletin. *See* Final Bulletin, 72 Fed. Reg. at 3434 (recognizing that the "broad application" of the Final Bulletin and the "need for clarity" required changing the definition).

62. *See* GE Comments, *supra* note 60, at 6-7 (arguing that OMB should broaden the definition of "highly controversial issues" to include not just interagency concerns but all highly controversial issues that may arise, and should not limit "novel or complex issues" to include only those that are technical or scientific, but to include "precedent-setting" issues as well); *see also* U.S. Chamber of Commerce, Comments of the U.S. Chamber of Commerce with Regard to OMB's Proposed Bulletin for Good Guidance Practices 3-4 (2005), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-chamber.pdf [hereinafter Chamber Comments] (urging that the definition for "guidance documents" be clarified to state that any agency policy that is not a rule is guidance if it is used by the agency to "manage the regulatory process"). Although OMB did not clarify the definition per the Chamber of Commerce's suggestion, it did redefine the term "guidance document" in the Final Bulletin to exclude a regulatory action that is "an interpretation of a *statutory* or regulatory issue." Final Bulletin, 72 Fed. Reg. at 3439 (emphasis added). The Proposed Bulletin merely excluded from the definition "an interpretation of or a policy on a regulatory or technical issue." OMB, Proposed Bulletin for Good Guidance Practices 1, 9 (2005), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/good_guidance_preamble.pdf

American Bar Association expressed additional concerns regarding the exclusion of memoranda of understanding and contractor instructions from the definition of guidance,[63] the failure of the Proposed Bulletin to distinguish between guidance that binds an agency and guidance that binds subordinate employees of an agency,[64] and the absence in the Proposed Bulletin of any reminders for agencies to follow APA procedures when issuing guidance documents.[65]

Citizens for Sensible Safeguards (CSS) expressed the greatest criticism of the Proposed Bulletin, calling it "a solution in search of a problem."[66] CSS contended that if OMB implemented the Proposed Bulletin, further production of guidance materials would be hindered because the notice and comment requirements and agency approval processes would create "heavy burdens" and lead to less guidance.[67] Despite suggesting that the Proposed Bulletin was unnecessary, CSS nonetheless offered improvements to the document, including eliminating the provision requiring notice and comment for economically significant guidance documents.[68] Other parties balanced CSS's strong critique by arguing that the Proposed Bulletin would serve as a valuable and necessary tool for agencies to use when issuing guidance documents.[69]

[hereinafter Proposed Bulletin].

63. *See* ABA Comments, *supra* note 60 (noting that some memoranda of understanding and contractor instructions have regulatory impacts, and suggesting that consideration be given to include them in the definition of significant guidance documents).

64. *See id.* (reminding OMB that an agency can appropriately bind its subordinate employees without having to resort to notice and comment rulemaking).

65. *See id.* (proposing that OMB advise agencies to follow APA procedures when issuing guidance documents, such as the publication requirements of § 552). A review of the Final Bulletin indicates that OMB did not take the ABA up on its suggestion.

66. CSS Comments, *supra* note 60, at 3 (characterizing the Proposed Bulletin as "blind to the role of government in meeting the public's needs").

67. *Id.* at 13 (suggesting that heavy burdens will discourage agencies to produce guidance); *see also* Rebecca Adams, *Graham Leaves OIRA with a Full Job Jar*, CQ WKLY., Jan. 23, 2006, at 227 (reporting that agency officials worry that the proposed good guidance practices will deter agency interactions with the regulated public or will lead to more "covert" interactions).

68. CSS Comments, *supra* note 60, at 19 (criticizing the term "economically significant guidance" as misleading and incomprehensible, and arguing that making agencies subject such guidance to notice and comment would be "onerous and draining").

69. GE Comments, *supra* note 60, at 4 (noting that the Proposed Bulletin is modeled largely after the FDA's Good Guidance Practices and that the FDA has not been burdened in promulgating guidance since the inception of those practices); *see also* McKenna, Long & Aldridge LLP, Comments of McKenna, Long & Aldridge LLP with Regard to OMB's Proposed Bulletin for Good Guidance Practices 3 (2006), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-mckenna.pdf [hereinafter McKenna Comments] (suggesting that the Proposed Bulletin will lead to less judicial review of guidance documents and affords "administrative due process").

III. ANALYSIS

A. The "Practically Binding" Effect

Courts often must decide whether an agency-issued guidance document binds private parties, the agency, or both. In so doing, courts also must determine whether such a document constitutes a legislative rule that should have been subject to notice and comment.[70] Whether a rule is legislative, interpretive, or a general statement of policy continues to challenge courts and scholars.[71] OMB seemingly issued its Final Bulletin in an attempt to mitigate the confusion regarding the legal effect of guidance, as evidenced by OMB's concentration on the D.C. Circuit's opinions on the matter.[72]

In assessing whether OMB's good guidance practices will alleviate the confusion regarding the legal effect of guidance documents, it is important to review the reasoning of the D.C. Circuit in *Community Nutrition Institute v. Young*[73] and its offspring.[74] In *Community Nutrition*, the court examined whether the FDA's action level for flatoxins in corn violated the APA because it constituted a legislative rule issued without the requisite notice and comment procedures.[75] The FDA represented the action levels as a "nonbinding statement of agency enforcement policy."[76] The court looked at two criteria to distinguish between legislative and interpretive rules. First, the court analyzed whether the pronouncement acted prospectively because a statement of policy "may not have a present

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70. *See supra* note 31 and accompanying text (discussing the holdings of the U.S. Court of Appeals for the District of Columbia Circuit with regard to legislative rules masquerading as nonbinding guidance documents).

71. *See* Syncor Int'l Corp. v. Shalala, 127 F.3d 90, 93 (D.C. Cir. 1997) (acknowledging that the court has long recognized "that it is quite difficult to distinguish between substantive and interpretative rules"); LAWSON, *supra* note 25, at 302 (noting the "troublesome" nature of the distinction between substantive and interpretive rules); Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 383-84 (recognizing that although the theoretical difference between the legal effect of legislative and nonlegislative rules is clear, the practical difference is far less clear); ABA Comments, *supra* note 60 (stating that "the law concerning interpretive rules and policy statements may be among the most complex in administrative law").

72. *See* Final Bulletin, 72 Fed. Reg. at 3432 (quoting the D.C. Circuit's opinion in *Appalachian Power* extensively as justification for why the good guidance practices are necessary); Skrzycki, *supra* note 20, at D1 (quoting then-Administrator of the Office of Information and Regulatory Affairs (OIRA), John D. Graham, as stating that groups worried about good guidance practices burdening agencies should balance that concern against the time spent on court cases addressing "confusion about what is a rule and what is guidance").

73. 818 F.2d 943 (D.C. Cir. 1987).

74. *See generally* Gen. Elec. Co. v. EPA, 290 F.3d 377 (D.C. Cir. 2002); Appalachian Power v. EPA, 208 F.3d 1015 (D.C. Cir. 2000); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206 (D.C. Cir. 1999).

75. *Cmty. Nutrition Inst.*, 818 F.2d at 945.

76. *Id*. at 945-46.

effect."[77] Next, the court asked whether the purported policy statement allowed the agency any discretion in enforcement.[78] In applying those two criteria, the court held that the action level pronouncement was practically binding and therefore subject to notice and comment.[79] The court specifically attacked the action level statement's prominent use of the word "will" instead of the conditional "may," in requiring food producers to secure exceptions to the action levels.[80] In addition, the court objected to the FDA's statements indicating that the agency had no wiggle room to exercise discretion in determining whether the action levels could be breached without penalty.[81]

The court continued to use the criteria relied upon in *Community Nutrition* in subsequent cases, including the cases OMB references in its Final Bulletin.[82] Of particular note is the court's strident language in *Appalachian Power v. EPA*,[83] in which the court rejected a legal disclaimer at the end of an EPA guidance document expressing the agency's intention that the document not bind parties.[84] According to the court, the document resembled an authoritative decree.[85] The court also took no solace in the fact that a guidance document may provide private parties a safe harbor in which to act, and even considered that to be a factor evidencing the practical binding effect of the guidance document.[86]

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77. *Id.* at 946.
78. *Id*.
79. *Id.* at 947 (stating that the use of mandatory and definitive language was a dispositive factor suggesting that action levels are substantive rules).
80. *Id.* at 946-47.
81. *Id*. at 947-49.
82. *See* Gen. Elec. Co. v. EPA, 290 F.3d 377, 382 (D.C. Cir. 2002) (citing the two criteria expressed in *Community Nutrition* regarding how a court draws a line between a legislative rule and statements of policy); Appalachian Power Co. v. EPA, 208 F.3d 1015, 1021 (D.C. Cir. 2000) (recognizing that an agency's pronouncements can, as a practical matter, have a binding effect); Chamber of Commerce v. Dep't of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) (citing Am. Bus. Assoc. v. United States, 627 F.2d 525, 529-30 (1980)) (stating that the court determines if a rule is a policy statement by whether it has only a prospective effect and leaves the agency decisionmakers free to exercise informed discretion).
83. 208 F.3d 1015 (D.C. Cir. 2000).
84. *See id.* at 1022-23 (calling the EPA disclaimer "boilerplate"); *see also* Strauss, *supra* note 11, at 1485 (stating that the "best face one can put on such a notice is that it is a charade").
85. *See Appalachian Power*, 208 F.3d at 1023 (opining that the guidance document "reads like a ukase," an order with absolute authority).
86. *See id*. at 1021 (declaring that if an agency bases its enforcement decisions on the policies or interpretations proferred in the guidance document, then this demonstrates the practical "binding" nature of the document); *see also* Anthony, *supra* note 1, at 1329 (stating that if language in a document is such that private parties can rely on it as a safe harbor, it can be binding as a practical matter).

The practical binding effect test and criteria used by the court is not without criticism.[87] Nonetheless, the test must be juxtaposed with OMB's good guidance practices and the comments submitted in support of it to determine if, in fact, the Final Bulletin will ensure guidance documents are upheld as nonbinding. OMB prohibits guidance documents from using mandatory language such as "shall" and "must."[88] And while commenters agreed with that policy,[89] courts do not hold mandatory language determinative in assessing a document's practical binding effect.[90] Additionally, if private parties rely on the guidance issued via OMB's good guidance practices as a safe harbor, as some commenters suggested,[91] a court could find that the guidance document is binding.[92] This seemingly runs counter to OMB's intentions.[93] Finally, requests for a clear disclaimer indicating that the guidance document is not binding,[94] while possibly helpful in educating the public, likely will carry little weight with a court.[95]

In light of the case law, it seems that OMB's good guidance practices may serve the public well by allowing notice and comment.[96] However, they may not necessarily serve the agencies well. The Final Bulletin's procedures could lead to courts deeming more guidance documents

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87. *See, e.g.*, PIERCE, *supra* note 11, § 17.3 (opining that the holding in *Community Nutrition* and its progeny has the potential "to create an administrative state with characteristics that resemble Dante's Inferno").

88. Final Bulletin, 72 Fed. Reg. at 3440.

89. *See, e.g.*, GE Comments, *supra* note 60, at 8 (applauding OMB for "correctly" recognizing that guidance documents should not include mandatory language).

90. *See supra* notes 74-81 and accompanying text (discussing the various factors that courts analyze in assessing whether a guidance document is binding or not).

91. *See* McKenna Comments, *supra* note 69, at 10 (suggesting that it may be appropriate for agencies to create a safe harbor and that OMB should direct agencies to identify guidance documents that, if followed, would create a rebuttable presumption that the regulated entity complied with the regulatory requirements); *see also* GE Comments, *supra* note 60, at 9 (recommending that OMB direct agencies to refrain from alleging that activities consistent with the guidance violated the regulatory requirements that are the subject of the guidance).

92. *See supra* note 86 and accompanying text (discussing the ramifications of safe harbor provisions in assessing whether a document is binding). While OMB does not suggest in its Final Bulletin that guidance documents issued through the good guidance practices afford regulated entities a rebuttable presumption of compliance, it will be interesting to see how parties treat guidance issued by way of these OMB-mandated procedures, especially as agencies use the good guidance practices over time.

93. *See supra* note 72 and accompanying text (noting that OMB hopes that its Final Bulletin will end the confusion courts have with regard to guidance documents versus legislative rules).

94. *See* GE Comments, *supra* note 60, at 8-9 (stating that it is very important that agency guidance unequivocally state that the document is not legally binding).

95. *See supra* note 81 and accompanying text (recognizing that a court gives little deference to a boilerplate disclaimer in assessing the binding effect of a guidance document).

96. *See* Anthony, *supra* note 1, at 1373-75 (declaring that agencies, when issuing policy statements, ought to engage in an open-minded policy and allow for public participation in the development of the policy statements, which is consistent with APA principles of accountability and openness).

practically binding and susceptible to judicial challenge, or may have little effect on a court when it determines the legal efficacy of the guidance document.[97]

B. Judicial Deference

In addition to possibly exposing guidance documents to more legal challenges—contrary to one of OMB's primary motivations in issuing its Final Bulletin[98]—OMB's good guidance practices also may lead courts to afford greater deference to guidance documents than is otherwise justified.[99] A review of Supreme Court case law concerning judicial deference to administrative agency pronouncements indicates that courts apply varied levels of deference to agency issuances according to numerous factors. Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, certain agency issuances are granted substantial deference,[100] while under *Skidmore v. Swift & Co.*, others are entitled only to "respect" and are judged by their "power to persuade."[101] Various criteria influence whether a court should respect such issuances.[102] Additionally, the Court stated in *United States v. Mead Corp.*[103] that the measure of deference varied with

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97. *See* Strauss, *supra* note 11, at 1488-89 (reasoning that while public consultation in the promulgation of publication rules is desirable, cases undoubtedly will remain in which courts will conclude that legislative rule making is required for work that an agency characterizes as exempt).

98. *See* Final Bulletin, 72 Fed. Reg. at 3432 (highlighting the Final Bulletin's focus on D.C. Circuit case law).

99. *See* Professor William S. Jordan, III, Comments of Professor William S. Jordan, III, with Regard to OMB's Proposed Bulletin for Good Guidance Practices 3-4 (Feb. 23, 2006), *available at* http://www.whitehouse.gov/omb/inforeg/good_guid/c-wjordan.pdf [hereinafter Jordan Comments] (suggesting that various requirements of the Proposed Bulletin may have an unintended effect on judicial review because the procedural provisions and notice and comment requirement in the Proposed Bulletin may be enough to warrant *Chevron* deference). OMB, in its Final Bulletin, responded to this potential problem by suggesting that the good guidance practices "are not intended to, and should not, alter the deference that agency interpretations of laws and regulations should appropriately be given." Final Bulletin, 72 Fed. Reg. at 3439 n.31. OMB's opinion notwithstanding, whether guidance documents issued pursuant to the good guidance practices will receive greater judicial deference remains an open question.

100. *See* 467 U.S. 837, 843-45 (1984) (holding that a court reviews an agency construction of a statute that the court deems ambiguous, whether issued pursuant to an explicit delegation of Congress or an implicit delegation, based on whether it is a "permissible construction of the statute," that statutory constructions borne from an explicit congressional delegation of authority are upheld unless they are "arbitrary, capricious, or manifestly contrary to the statute," and statutory constructions evolving from an implicit congressional delegation of authority are upheld so long as they are a "reasonable interpretation").

101. 323 U.S. 134, 140 (1944).

102. *See id.* (indicating that the thoroughness of the agency's consideration of the issuance, the validity of the agency's reasoning, the agency's consistency with earlier and later pronouncements, and other persuasive factors will determine whether a court will respect an agency's decision, even though the decision does not have the power to control).

103. *See* 533 U.S. 218, 226-27 (2001) (holding that *Chevron* deference can be applied only to agency interpretations of a statute when it is evident that Congress delegated

the circumstances and that courts analyze how careful the agency was in issuing the interpretation, the agency's consistency, the formality used to issue the interpretation, relative expertise of the agency, and the agency's overall persuasiveness.[104]

Some scholars argue that the Court's decision in *Mead* has clouded when *Chevron* deference should be applied.[105] Soon after its ruling in *Mead*, the Court, in *Barnhart v. Walton*,[106] provided dicta that some scholars believe has created further "uncertainty" about the types of agency pronouncements that are due *Chevron* deference.[107] In particular, the Court noted that it may afford *Chevron* deference to an agency interpretation based on the interpretive method used.[108]

OMB's Final Bulletin provides formalized procedures for agencies to follow when issuing certain guidance documents.[109] These procedures may constitute enough consideration to justify *Chevron* deference, especially in light of the decision in *Mead* and the dicta in *Barnhart*.[110] Considering that the case law regarding judicial deference is a "mess,"[111] it is not

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authority to the agency to promulgate interpretations with the "force of law").

104. *Id.* at 228. The Court indicated that while notice and comment rulemaking is "significant" in determining if *Chevron* deference is required, it is not necessary. *Id.* at 230-31. That being said, the Court does take into consideration whether the agency rule was issued pursuant to notice and comment and whether the ruling is treated as binding on third parties. *Id.* at 233.

105. *See, e.g.*, Lisa Schultz Bressman, *How* Mead *Has Muddled Judicial Review of Agency Action*, 58 VAND. L. REV. 1443, 1447 (2005) (arguing that *Mead* has confused courts on whether *Chevron* deference applies to interpretations issued through informal procedures outside of full notice and comment rulemaking procedures). Of particular note is the Court's holding that *Chevron* deference can apply if the agency engages in activity evidencing a congressional delegation of authority, including notice and comment rulemaking, but also "some other indication of a comparable congressional intent." *Mead*, 533 U.S. at 226-27. Justice Scalia took particular umbrage with the holding. *See id.* at 239 (Scalia, J., dissenting) ("We will be sorting out the consequences of the *Mead* doctrine for years to come.").

106. 535 U.S. 212 (2002).

107. RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE § 3.5 (4th ed. Supp. 2006) (discussing the scope of Chevron and declaring that the "results to date are confusing and leave important questions unresolved").

108. *See Barnhart*, 535 U.S. at 222 (stating that the "interstitial nature of the legal question, the related expertise of the Agency, the importance of the question to administration of the statute, the complexity of that administration, and the careful consideration the Agency has given the question over a long period of time all indicate that *Chevron* [deference may be appropriate]").

109. *See* Final Bulletin, 72 Fed. Reg. at 3440 (providing that each agency shall develop or have written procedures for the approval of significant guidance documents, including ensuring that such guidance documents are approved by senior agency officials, and that economically significant guidance documents be published in the Federal Register and be subject to notice and comment).

110. *See* Jordan Comments, *supra* note 99, at 4 (suggesting that the OMB-imposed notice and comment processes may constitute enough fairness and input to warrant *Chevron* deference).

111. Bressman, *supra* note 105, at 1444-46 (arguing that Justice Scalia understated the effect of *Mead*); *see also* PIERCE, *supra* note 107, § 3.5 (claiming that circuit courts are struggling to apply the Supreme Court's decisions on the scope of *Chevron* to a variety of

unreasonable to think that guidance issued via these procedures may be entitled to *Chevron* deference. Such procedures lend more gravitas to the guidance and demonstrate the "careful consideration" the Court seeks if *Chevron* deference is to be afforded,[112] notwithstanding the fact that guidance documents have been held to lack the force of law.[113]

Even if courts do not apply *Chevron* deference to guidance documents issued via OMB's good guidance practices, the most likely scenario is that courts will always find such guidance persuasive enough to uphold it under *Skidmore* review.[114] Indeed, economically significant guidance documents issued via a notice and comment procedure pursuant to OMB's good guidance practices could more easily satisfy a court reviewing the issuance under the ever-present arbitrary and capricious test.[115]

CONCLUSION

OMB's Final Bulletin for Agency Good Guidance Practices offers some positive requirements for agencies to follow when issuing guidance. Notice of and access to guidance documents, especially with the growth of the Internet, is consistent with the principles of the APA and open government. However, OMB's decision to subject guidance documents to formal procedures, especially notice and comment procedures for economically significant guidance documents, is unwise and should be reconsidered. Based on the case law that OMB highlighted, it is not unreasonable to think that, at worst, courts could consider economically significant guidance documents as "practically binding" on third parties precisely because of the formalized procedures they must go through prior to issuance. At a minimum, OMB's good guidance practices will achieve little in clarifying for courts the differences in legal efficacy between guidance documents and legislative rules.

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agency pronouncements).

112. Barnhart, 535 U.S. at 222.

113. *See* Christensen v. Harris County, 529 U.S. 576, 587 (2000) (holding that interpretations contained in opinion letters, agency manuals, policy statements, and enforcement guidelines all "lack the force of law" and "do not warrant *Chevron*-style deference").

114. *See* United States v. Mead, 533 U.S. 218, 235 (recognizing that an agency ruling's "power to persuade" can be determined by its writer's "thoroughness, logic, and expertness, its fit with prior interpretations, and any other sources of weight").

115. *See* Motor Vehicle Mfrs.' Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (requiring that the agency examine relevant information and articulate a satisfactory explanation for its action with a "rational connection" to the facts and the choice made); Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416-17 (1971) (noting that under the arbitrary and capricious test, a court must consider whether the agency looked at the "relevant factors" and followed necessary procedural requirements).

Additionally, such good guidance practices may lead a court to apply *Chevron* deference to a guidance document, thereby giving it greater legal effect than either private parties or agencies need or desire. Alternatively, OMB's good guidance practices may buttress guidance documents subject to either a *Skidmore* review or judicial review under the arbitrary and capricious test—a result that regulated entities who challenge the legality of such documents would oppose. Thus, while imposing greater burdens on agencies when issuing certain guidance documents, OMB's good guidance practices could lead to the unintended consequence of making guidance documents more legally significant than they otherwise should be. In turn, this invites more litigation and further blurs the line between a binding rule and a nonbinding guidance document.

RECENT DEVELOPMENTS

HOW AGENCIES SHOULD GIVE MEANING TO THE STATUTES THEY ADMINISTER: A RESPONSE TO MASHAW AND STRAUSS

RICHARD J. PIERCE, JR.*

In an Article published in this Review in 2005,[1] Jerry Mashaw observed that "virtually no one has even asked, much less answered, some simple questions about agency statutory interpretation . . . ."[2] Mashaw referred to the Supreme Court's famous opinion in *Chevron*[3] and continued: "Surely, in a legal world where agencies are, by necessity, the primary official interpreters of federal statutes, and where that role has been judicially legitimated as presumptively controlling, attention to agencies' interpretive methodology seems more than warranted."[4] Mashaw cited a 1990 Article by Peter Strauss[5] as the only prior writing in which a scholar addressed the question of how agencies should interpret statutes.[6] Mashaw then proceeded to engage in what he characterized as a "preliminary inquiry into agency statutory interpretation."[7]

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1. Jerry L. Mashaw, *Norms, Practices, and the Paradox of Deference: A Preliminary Inquiry into Agency Statutory Interpretation*, 57 ADMIN. L. REV. 501, 503 (2005) (discussing the normative and positive dimensions of administrative agency interpretation of statutory language).

2. *Id.* at 501-02.

3. Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 865-66 (1984) (setting forth the doctrine of administrative deference).

4. Mashaw, *supra* note 1, at 502-03.

5. *See* Peter L. Strauss, *When the Judge Is Not the Primary Official with Responsibility to Read: Agency Interpretation and the Problem of Legislative History*, 66 CHI.-KENT L. REV. 321, 322 (1990) (discussing the use of legislative history in agency interpretation).

6. *See* Mashaw, *supra* note 1, at 502 n.2 (noting that while several articles on their face suggest a discussion of administrative statutory interpretation, only Strauss analyzes agency use of legislative history).

7. *Id.* at 501.

I have long regarded Jerry Mashaw and Peter Strauss as the most important administrative law scholars of their (and my) generation.[8] In this case, however, I think both have gone astray in their initial efforts to understand and to explain the roles of agencies in the process of applying the two-step test the Court announced in *Chevron*. Strauss argues that legislative history should play a more important role in agency efforts to interpret statutes than in judicial efforts to perform the same task.[9] Mashaw characterizes the process of describing and explaining the agency process of statutory interpretation as "vast."[10] He describes ten competing interpretive approaches and tools that agencies might use[11] and concludes that the agency interpretive process is so variable and complicated that "the proper roles of administrators and courts in molding the law cannot be cogently specified."[12] Mashaw also sees such a divergence between judicial and administrative methods of interpreting statutes that "[f]ully legitimate judicial interpretation will conflict with fully legitimate agency interpretation."[13]

I disagree with Strauss with respect to the relative importance of legislative history to agencies and courts,[14] and I disagree with most of Mashaw's characterizations of the process through which agencies give meaning to the statutes they administer. At least at the highest level of generality, the proper roles of courts and agencies can be cogently specified in relatively simple terms that do not create any conflict between the roles

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8. I took a course entitled Legislative and Administrative Law from Mashaw in 1969, my first year as a law student and his first year as a professor at University of Virginia. I was Strauss's colleague at Columbia for about a decade. I have learned more about administrative law from them and from their writings than from any other source.

9. *See* Strauss, *supra* note 5, at 322 (arguing that even though the use of legislative history generally is used at the judicial level, the agency, being more involved in politics, should make greater use of legislative history).

10. Mashaw, *supra* note 1, at 503.

11. *Id.* at 504-24.

12. *Id.* at 524.

13. *Id.* at 504.

14. I agree with many of Strauss's arguments in support of the use of legislative history as an interpretive tool that potentially is useful to any institution—agency or court—but I disagree with his argument that "legislative history has a centrality and importance for agency lawyers that might not readily be conceived by persons who are outside government . . . ." Strauss, *supra* note 5, at 329. Generally, agency lawyers care a lot about the views of those present members of the House and Senate who occupy positions in which they can help or hurt the agency, but they know little about the views of the typically past members who played major roles in enacting the statutes the agency implements. Similarly, the best compilations of legislative histories are not generally in agency libraries. Rather, they are usually in the possession of the major firms that practice before the agency. Firms use compilations of comprehensive legislative histories as one of the margins on which they compete, while most agencies lack the resources required to compile a comprehensive legislative history of a major statute. Mashaw found that "[l]egislative history is not as prominent [in agency decisionmaking] as one might expect." Mashaw, *supra* note 1, at 529. Moreover, any agency that relies on legislative history to a greater extent than a reviewing court is engaged in a self-defeating exercise in futility.

of courts and agencies. The roles of the two institutions differ only in ways that are complementary rather than conflicting.

Strauss and Mashaw go astray by taking their description of the agency decisionmaking process at issue too literally as "statutory interpretation." Scholars and judges often use that term as a convenient shorthand reference to the process through which agencies give meaning to ambiguous provisions in the statutes they implement, but the term is seriously misleading in that context if taken literally. "Interpret" means "to explain or tell the meaning of" something—such as a statutory text.[15] That definition accurately describes the decisionmaking process that the Supreme Court instructed reviewing courts to use in applying step one of *Chevron*, but it is not an accurate description of the process the Court expects agencies to use in making decisions that courts review through application of step two of *Chevron.*

The logical starting point in any attempt to understand and explain the roles of courts and agencies in implementing *Chevron* is the opinion itself, beginning with the two-step test the Supreme Court instructed courts to use when reviewing an agency decision to give an agency-administered statute a particular meaning:

> When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines that Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.[16]

The *Chevron* Court instructed reviewing courts to employ the "traditional tools of statutory construction" when applying step one, to decide whether Congress unambiguously resolved the question at issue.[17] In step one of *Chevron*, the Supreme Court instructed reviewing courts to engage in de novo review of agency interpretations, which is clearly an interpretative task.[18] However, in step two, the Court instructed reviewing

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15. MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 611 (10th ed. 2002).

16. Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).

17. *See id.* at 843 n.9 (concluding that when Congress has spoken unambiguously on the precise question at issue, the meaning given by Congress must stand).

18. *See id.* (asserting that the "judiciary is the final authority on issues of statutory construction" and that it must reject agency interpretations of statutes that are contrary to

courts to uphold the agency construction if it is "permissible."[19] In subsequent passages, the Court equated "permissible" with "reasonable,"[20] recognized repeatedly that an agency engages in policymaking when it gives meaning to ambiguous language in a statute,[21] and recognized that reviewing courts must uphold such decisions as "permissible" or "reasonable" unless they are "arbitrary, capricious, or manifestly contrary to the statute."[22]

Step two of *Chevron* does not instruct or authorize agencies to "interpret" statutes in any way that fits within the dictionary definition of "interpret."[23] Rather, it recognizes that institutions may choose among competing constructions of a statutory provision that is within the range of meanings that the statutory language can support through a process of "interpretation" of the statute's text.[24] An institution can make that choice only by engaging in a policymaking process. For example, the *Chevron* Court reviewed the EPA decision to adopt a plant-wide definition of "source" as a policy decision.[25] Thus, it referred to the EPA's use of policy-based normative reasoning with obvious approval in support of its decision.[26] The Court concluded that the "EPA has advanced a reasonable explanation for its conclusion that the regulations serve the environmental objectives [of the Clean Air Act]."[27] The Court accepted the EPA's choice of a particular definition of "source" as a "judgment as how to best carry out the Act,"[28] and it recognized that the EPA must consider "the wisdom of its policy on a continuing basis."[29] The Court further characterized the dispute, with respect to the meaning, to give the ambiguous statutory term "source" as "center[ed] on the wisdom of the agency's policy"[30] and stated

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congressional intent).

19. *See id.* at 843 (stating that if Congress was silent or ambiguous on the issue, the reviewing court must defer to an agency's construction, if it is "permissible").

20. *See id.* at 844-45, 863, 865-66 (holding that the Environmental Protection Agency's (EPA) construction of the statute was a "reasonable" construction and constituted a "permissible" construction of the statute).

21. *See id.* at 843-45, 862-65 (finding that when Congress leaves a gap in the law, it is proper and necessary for an agency to engage in policymaking).

22. *Id.* at 844.

23. *See* MERRIAM-WEBSTER, *supra* note 15 and accompanying text (defining "interpret" to mean "to explain or tell the meaning of. . .").

24. *See Chevron*, 467 U.S. at 864 (noting that different interpretations may be adopted by an agency in different contexts, and that it was the court, not Congress or the agency, that interpreted the statute in an inflexible manner).

25. *Id.* at 853.

26. *See id.* at 853-58 (reviewing the evolution of the EPA's statutory interpretation).

27. *Id.* at 863.

28. *Id.* at 858.

29. *Id.* at 863-64.

30. *Id.* at 866.

that "policy arguments" against the EPA's definitional decision "are more properly addressed to legislators or administrators, not to judges."[31]

In short, the *Chevron* Court recognized that step two of *Chevron* requires a court to review an agency policy decision that gives meaning to an ambiguous statutory provision by using the approach the Court announced in its prior term in *State Farm*.[32] The Court in *State Farm* stated that to avoid a judicial characterization of a policy decision as arbitrary and capricious, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'"[33] Conversely:

> [A]n agency [decision is] arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.[34]

Reviewing courts understand and apply *Chevron* in this manner. The D.C. Circuit's 2006 opinion in *Covad Communications v. FCC*[35] is one of many opinions that illustrates the judicial equation of *Chevron* step two and *State Farm*.[36] The question before the *Covad* court was the acceptability of the meaning the FCC gave to the statutory term "impair" in a rule. The court characterized its task as follows:

> Both the Supreme Court and our court have held that the 1996 Act's use of the term "impair" . . . is ambiguous and should be reviewed under *Chevron*'s second step . . . . Similarly, the Commission's reasonable interpretations of § 251(c) are entitled to deference . . . . Under the Administrative Procedure Act, we will uphold the Commission's policy choices unless they are arbitrary and capricious . . . . To survive review under this standard, the FCC "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[37]

The court went on to apply the *State Farm* test as its basis for upholding the FCC's "interpretation" of "impair" as reasonable.[38]

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31. *Id.* at 864.
32. Motor Vehicle Mfrs.' Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983).
33. *Id.* at 43.
34. *Id.*
35. 450 F.3d 528 (D.C. Cir. 2006).
36. For discussion of some of the other circuit court opinions that equate *Chevron* step two and *State Farm*, see 1 RICHARD J. PIERCE, JR., ADMINISTRATIVE LAW TREATISE 172-74 (4th ed. 2002) [hereinafter PIERCE, ADMINISTRATIVE LAW TREATISE]. For discussion of some of the Supreme Court opinions that equate *Chevron* step two and *State Farm*, see RICHARD J. PIERCE, JR., 2007 CUMULATIVE SUPPLEMENT TO ADMINISTRATIVE LAW TREATISE 147-58 (2006).
37. *Covad Commc'ns Co.*, 450 F.3d at 537.
38. *Id.* at 537-48.

The proper roles for agencies in conforming to *Chevron* follow logically and inevitably from the Court's instructions to reviewing courts in *Chevron*. Because a reviewing court will apply step one of *Chevron* first, a prudent agency must apply step one itself. To maximize the chances of having its action upheld, the agency must do its best to determine whether Congress resolved the question before the agency. Although this process definitely is interpretive, it is one in which the agency has no practical choice but to attempt to anticipate and replicate the interpretive process a reviewing court will use. Additionally, the agency should use the same "traditional tools of statutory construction" that it expects a reviewing court to use. If the agency uses a different method of interpretation—for example, if it relies on legislative history to a greater extent than a reviewing court as Strauss urges[39]—it increases significantly the risk of judicial reversal without good reason.[40]

Depending on the manner in which the agency uses legislative history, an agency that gives legislative history more significance than a reviewing court will be reversed either through judicial application of *Chevron* step one or through application of the principle the Court announced in *Chenery*—an agency decision can be upheld only on the basis stated by the agency.[41] Thus, for instance, an agency that relies on legislative history to resolve an ambiguity in the statute's text—and thereby supports an agency conclusion that the statute has an unambiguous meaning—will be reversed through application of *Chenery* if the reviewing court is not willing to use the legislative history for that purpose. Moreover, a court will reverse an agency decision even though it would uphold the same agency action if the agency had used the same interpretive approach as the court to support a conclusion that the statute is ambiguous and then had used policy-based reasoning to explain why it chose to give the ambiguous statute the meaning it preferred.[42] Conversely, an agency that relies on legislative

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39. Strauss, *supra* note 5, at 322.

40. It is possible that the court and the agency might adopt the same interpretation of the statute even though the agency uses different interpretive tools and techniques than the court uses. In that situation, however, the agency decision to use tools and techniques different from those used by the court is irrelevant—it has no effect on the outcome of the dispute.

41. SEC v. Chenery Corp., 318 U.S. 80, 87 (1943) ("The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based."). Therefore, an agency decision can be upheld only on the basis stated by the agency.

42. The Eleventh Circuit accurately explained the relationship between *Chevron* and *Chenery* in *Bank of America v. FDIC*. *See* 244 F.3d 1309, 1318-21 (11th Cir. 2001); *see also* PDK Labs. v. DEA, 362 F. 3d 786, 797-98 (D.C. Cir. 2004).

> In short, we do not agree that the meaning of §971(c)(1) is as plain as the DEA says it is. It may be that here, as in other cases, the strict dichotomy between clarity and ambiguity is artificial, that what we have is a continuum, a probability of meaning. In precisely those kinds of cases, it is incumbent upon the agency not to rest simply

history to create an ambiguity in an otherwise unambiguous statutory text will be reversed by a reviewing court through application of *Chevron* step one if the court is not willing to use legislative history for that purpose.[43] It follows that an agency must do its best to replicate the interpretive process courts use when attempting to anticipate judicial application of step one of *Chevron*.

Of course, an agency that attempts to anticipate and replicate the interpretive process a court will use in applying *Chevron* step one still runs a risk of reversal. The process of choosing the traditional tools of statutory interpretation to apply and further, applying those often conflicting tools in performing a particular interpretive task, is complicated and contentious.[44] Agencies will sometimes adopt interpretations that reviewing courts reject because the agency is unable to anticipate and replicate the interpretive process the reviewing court employs. Nonetheless, the agency's interpretive task is easy to describe. To the best of its ability, the agency should attempt to use exactly the same interpretive process a court would use—any intentional variation from that judicial interpretive process would be a self-defeating exercise in futility.

The agency's task in minimizing its risk of reversal through application of *Chevron* step two is totally different from its task in attempting to minimize its risk of reversal through application of step one. An agency's efforts to minimize the risk of judicial reversal through application of *Chevron* step two has little to do with statutory interpretation. Rather, the agency's task is to use a comprehensive and transparent policymaking process in which it identifies and explains each step in its decisionmaking process, relates each decision to the available data relevant to the decision, and explains why it rejected alternatives to, or criticisms of, the decisions it made.[45]

Depending on the context in which the agency makes the decision to give the ambiguous statutory term a particular meaning, the policymaking process that maximizes the likelihood of judicial approval through application of *Chevron* step two will require an agency to use tools made available by fields like economics, statistics, chemistry, toxicology,

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> on its parsing of the statutory language. It must bring its experience and expertise to bear in light of competing interests at stake. *See Chevron* . . . . When it does so it is entitled to deference, so long as its reading of the statute is reasonable. But it has not done so here and at this stage it is not for the court "to choose between competing meanings."

Id. (internal citation omitted).

43. 244 F.3d at 1319 ("It is the duty of the courts to interpret statutory language, and courts should decide whether there is ambiguity in a statute without regard to an agency's prior, or current, interpretation.").

44. For a discussion of this problem, see PIERCE, ADMINISTRATIVE LAW TREATISE, *supra* note 36, at 182-88.

45. For a discussion of this decisionmaking process, see *id.* at 441-63.

epidemiology, meteorology, etc. There is only one link between this policymaking process and the process of statutory interpretation. In the course of explaining why it made the decisions it made, the agency must refer to decisional factors that the underlying statute makes permissible.[46] For that purpose, the agency must engage in statutory interpretation to the extent necessary to explain why it believes that a decisional factor it applies is statutorily permissible. In other words, a court will—and should—reverse an agency action if the agency relies on a decisional factor that is logically relevant to its decision in the abstract but one that Congress has forbidden the agency to consider. Thus, for instance, an agency cannot reject an alternative to the action it takes based on its belief that the alternative will impose intolerably high costs on the economy if Congress has forbidden the agency from considering costs in its decisionmaking process.[47] Here again, however, the agency must do its best to anticipate and to replicate the interpretive process a reviewing court will use to minimize the agency's risk of judicial reversal of its action. A court will reverse an agency if the agency relies on a decisional factor the court determines to be impermissible.[48]

I disagree with Strauss and Mashaw at the most fundamental level. Unlike Strauss and Mashaw, I do not believe that agencies are "the primary official interpreters of federal statutes."[49] Rather, all agency statutory interpretations are subject to de novo review and potential rejection by a court through application of *Chevron* step one. Further, I do not believe that agencies should use methods of statutory interpretation that differ from the methods courts use.[50] Accordingly, I do not see the conflicts between legitimate agency interpretations and legitimate court interpretations that trouble Mashaw.[51] It is certainly true that agencies have the power to give meaning to ambiguous provisions in the statutes they administer, subject only to the deferential form of judicial review described in *Chevron* step

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46. *See* Motor Vehicle Mfrs.' Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983) (stating that "[n]ormally an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider . . .").

47. *See, e.g.*, Whitman v. Am. Trucking Ass'n, 531 U.S. 457, 464-65 (2001) ("[E]conomic considerations [may] play no part in the promulgation of ambient air quality standards under Section 109 of the CAA [Clean Air Act].") (internal quotation marks omitted).

48. *See, e.g.*, Pub. Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987) (rejecting an agency's determination that a *de minimis* exception applies to disputes governed by the Delaney Amendment based on court's determination that Congress did not authorize the agency to apply a *de minimis* exception).

49. *See* Mashaw, *supra* note 1, at 502-03; Strauss, *supra* note 5, at 333 (expressing the general acceptance of agency judgments about statutory meaning).

50. *See* Mashaw, *supra* note 1, at 504; Strauss, *supra* note 5, at 322.

51. *See* Mashaw, *supra* note 1, at 504 (voicing the author's concern over the possibility that legitimate judicial interpretation could conflict with legitimate agency interpretation).

two and *State Farm*.[52] When agencies undertake that important task, however, they are not involved in the process of statutory interpretation. Instead, they are engaged in a policymaking process, the end result of which is to choose which of several linguistically plausible meanings to give ambiguous language to further the purposes of the statute the agency is implementing.

52. *See supra* notes 19-38, 45-48 and accompanying text.

EXECUTIVE ORDER 12,866

Shortly before this issue of the Administrative Law Review *went to press, President George W. Bush issued Executive Order 13,422, which further amended Executive Order 12,866. .See Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 23, 2007). The amendments have the potential to dramatically impact the administrative law world. Accordingly, we have reproduced the text of amended Executive Order 12,866 below. Undoubtedly, future articles appearing in the* Administrative Law Review *will analyze the substance and effects of the changes to Executive Order 12,866.*

Executive Order 12866 of September 30, 1993, as amended by E.O. 13258 of February 26, 2002 and E.O. 13422 of January 18, 2007

REGULATORY PLANNING AND REVIEW

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal

agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Statement of Regulatory Philosophy and Principles.* (a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

(1) Each agency shall identify in writing the specific market failure (such as externalities, market power, lack of information) or other specific problem that it intends to address (including, where applicable, the failures of public institutions) that warrant new agency action, as well as assess the significance of that problem, to enable assessment of whether any new regulation is warranted.

(2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation or guidance document.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to

carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations and guidance documents that are inconsistent, incompatible, or duplicative with its other regulations and guidance documents or those of other Federal agencies.

(11) Each agency shall tailor its regulations and guidance documents to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations and guidance documents to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. *Organization.* An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) *The Agencies.* Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and guidance documents and assuring that the regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) *The Office of Management and Budget.* Coordinated review of agency rulemaking is necessary to ensure that regulations and guidance documents are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to

agencies and assist the President and regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations and guidance documents, as provided by this Executive order.

(c) *Assistance.* In fulfilling his responsibilities under this Executive order, the President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President may, from time to time, consult.

Sec. 3. *Definitions.* For purposes of this Executive order: (a) "Advisors" refers to such regulatory policy advisors to the President as the President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Director of the Office of Science and Technology Policy; (7) the Deputy Assistant to the President and Director for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Chairman of the Council on Environmental Quality and Director of the Office on Environmental Quality; (12) the Assistant to the President for Homeland Security; and (13) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

(1) Regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(2) Regulations that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(3) Regulations that are limited to agency organization, management, or personnel matters; or

(4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a regulation that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

(g) "Guidance document" means an agency statement of general applicability and future effect, other than a regulatory action, that sets forth a policy on a statutory, regulatory or technical issue or an interpretation of a statutory or regulatory issue

(h) "Significant guidance document" –

(1) means a guidance document disseminated to regulated entities or the general public that, for purposes of this order, may reasonably be anticipated to:

(A) lead to an annual effect of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(B) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(C) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights or obligations of recipients thereof; or

(D) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order; and

(2) does not include:

(A) Guidance documents on regulations issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;

(B) Guidance documents that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;

(C) Guidance documents on regulations that are limited to agency organization, management, or personnel matters; or

(D) Any other category of guidance documents exempted by the Administrator of OIRA.

Sec. 4. *Planning Mechanism.* In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law:

(a) *Agencies' Policy Meeting*. The Director may convene a meeting of agency heads and other government personnel as appropriate to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.

(b) *Unified Regulatory Agenda*. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) *The Regulatory Plan*. For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. Unless specifically authorized by the head of the agency, no rulemaking shall commence nor be included on the Plan without the approval of the agency's Regulatory Policy Officer, and the Plan shall contain at a minimum:

(A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;

(B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits of each rule as well as the agency's best estimate of the combined aggregate costs and benefits of all its regulations planned for that calendar year to assist with the identification of priorities;

(C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order, and specific citation to such statute, order, or other legal authority;

(D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;

(E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies and the Advisors.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency and the Advisors.

(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies and the Advisors.

(6) The Director may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) *Regulatory Working Group.* Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility and the Advisors. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Director on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) *Conferences*. The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. *Existing Regulations*. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program

more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Director, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. *Centralized Review of Regulations.* The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) *Agency Responsibilities.* (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. In consultation with OIRA, each agency may also consider whether to utilize formal rulemaking procedures under 5 U.S.C. 556 and 557 for the resolution of complex determinations. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate one of the agency's Presidential Appointees to be its Regulatory Policy Officer, advise OMB of such designation, and annually update OMB on the status of this designation. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

(i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and

(ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

(i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;

(ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and

(iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rulemaking proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

(i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);

(ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) *OIRA Responsibilities.* The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

(i) The status of all regulatory actions, including if (and if so, when and by whom) Presidential consideration was requested;

(ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and

(iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the **Federal Register** or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. *Resolution of Conflicts.* (a) To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, with the assistance of the Chief of Staff to the President ("Chief of Staff"), acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

(b) Resolution of such conflicts shall be informed by recommendations developed by the Chief of Staff, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

(c) During the Presidential review period, communications with any person not employed by the Federal Government relating to the substance

of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Chief of Staff shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

(d) At the end of this review process, the President, or the Chief of Staff acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. *Publication.* Except to the extent required by law, an agency shall not publish in the **Federal Register** or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a regulatory action, the head of that agency may request Presidential consideration through the Director, as provided under section 7 of this order. Upon receipt of this request, the Director shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. *Significant Guidance Documents*. Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with advance notification of any significant guidance documents. Each agency shall take such steps as are necessary for its Regulatory Policy Officer to ensure the agency's compliance with the requirements of this section. Upon the request of the Administrator, for each matter identified as, or determined by the Administrator to be, a significant guidance document, the issuing agency shall provide to OIRA the content of the draft guidance document, together with a brief explanation of the need for the guidance document and how it will meet that need. The OIRA Administrator shall notify the agency when additional consultation will be required before issuance of the significant guidance document.

Sec. 10. *Preservation of Agency Authority.* Nothing in this order shall be construed to impair or otherwise affect the authority vested by law in an agency or the head thereof, including the authority of the Attorney General relating to litigation.

Sec. 11. *Judicial Review.* Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 12. *Revocations.* Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.