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Some Observations About the Turn Toward Federal Rulemaking in Health Law

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SOME OBSERVATIONS ABOUT THE TURN TOWARD FEDERAL RULEMAKING IN HEALTH LAW

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The law respecting the provision and financing of health care and what we understand to be administrative law, as Professor Jost reminds us,[1] have long been intertwined. Moreover, given the many highly diverse activities involved in health care, Professor Jost is no doubt correct to point out that considerations of institutional competence go a good distance in explaining why much of health law has been administrative law.[2] One need only deliberate a bit about the problems raised by the screening of new drugs and medical devices for commercial distribution to appreciate the need for an agency like the FDA that can give continuous single-minded attention to safety and efficacy considerations, that has a professional staff which can develop and deploy scientific and technical expertise, and that is relatively independent of other institutions and so can make consistent and coordinated decisions.[3] Likewise, by calling to mind the complexities involved and the practical experience needed to accredit hospitals and other medical facilities or to oversee payment and underwriting practices of health insurers, it is not difficult to understand why the states have turned to specialized agencies as front-line decision makers. Moreover, while Professor Jost tells us that health law and administrative law are "intertwined," he also speaks of "the dominance of administrative law in health care," and he predicts that "administrative law may increase rather than decrease, as we continue to struggle to expand access to health care, reduce its cost, and improve its quality."[4] I want to emphasize and to expand on these latter, stronger sentiments. In particular, I want to suggest that the emergence of health law as a distinguishable, more or less coherent body of law is best seen through the lens of administrative law, and secondly, I want to call attention to some

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1. Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient,* 49 ST. LOUIS U. L.J. 1 (2004) (describing the roles administrative agencies play in overseeing the delivery and finance of health care).

2. *Id*. at 16.

3. *See generally,* Eric Claeys, *The Food And Drug Administration and the Command-and-Control Model of Regulation,* 49 ST. LOUIS U. L.J. 105 (2004).

4. Jost, *supra* note 1, at 33.

fundamental changes in administrative law over the past quarter century that are critical to understanding the shape and content of health law today.

I. THE TURN TOWARD FEDERAL RULEMAKING AND THE EMERGENCE OF HEALTH LAW

At the beginning of his paper, Professor Jost makes the important observation that it was not until the mid-1960s that health law began to emerge as a single body of law and policy.[5] The law dealing with health care until that time is best seen as a collection of more or less formal adjudicatory systems, many operating at the state level, and each meant to deal with a quite different kind of problem. Think of the several systems of common law adjudication, such as medical malpractice law's enquiries into responsibility for medical maloccurrences and contract law's adjudication of health insurance disputes. Think also of the various adjudicative systems operated by state administrative agencies, such as the boards charged with licensing and disciplining medical practitioners and with overseeing the rates and claims practices of health insurers. Consider the widespread reliance on the case-by-case hospital accreditation programs operated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[6] Finally, call to mind the case-by-case decision making of federal agencies, such as the FDA's screening of new drugs and medical devices, the NLRB's adjudication of unfair labor practice cases involving hospitals, the FTC's policing of fraud and other "unfair methods of competition," and the antitrust activities of the DOJ in the federal courts. Standing back a bit, one cannot help but notice two striking features about this pre-health law era. First, each of these systems operated by making case-by-case decisions that carried out a general though vague standard or directive. State medical malpractice law, for example, consisted of specialized rules and practices in accordance with which juries determined whether maloccurrences were caused by "medical negligence." Similarly, the FDA was directed to approve the marketing of a new drug or medical device only if it was determined to be "safe" and "effective."[7] Of equal importance, each of these various adjudicative systems operated almost wholly independent of the others. In medical malpractice cases, for example, evidence of a defendant's failure to be board-certified in a specialty was held to be inadmissible or merely some

5. *Id.* at 2.

6. For a general description of the JCAHO's status and activities, see BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 136–140 (3d ed. 1997).

7. Though operating through case-by-case decision making, each system exhibited a measure of coherence and accommodated development and change by elaborating its basic standard or directive in written opinions, issuing rules of practice and procedure, and developing analogical precedent.

evidence bearing on the question of whether he or she had been negligent.[8] As another example, the McCarran Ferguson Act of 1945 and the state action doctrine largely insulated state oversight of health insurance rates from perspectives and policies advanced by the FTC and by the Antitrust Division of the DOJ.[9] Looking back, it is entirely natural to understand this as a pre-health law era: Medical malpractice law was best seen as part of tort law, health insurance law as part of insurance law, physician licensure as part of state regulation of businesses and professions "impressed with the public interest," and the FDA screening process as part of food and drug law. There were many parts of law that had to do with the provision and financing of health care, but very little of it could be seen as tying these bits and pieces together.

Now, as Professor Jost emphasizes throughout his paper, the emergence and growth of health law as a coherent body of law and policy happens to coincide with the creation at the federal level of a whole series of statutory/regulatory structures that operate primarily through prospectively applicable rules.[10] He mentions the many statutes enacted since the 1960s that established rulemaking as the favored form of lawmaking by health and safety agencies.[11] The Medicare and Medicaid programs, created in 1965, augured in the change, giving rise to the promulgation of rules respecting, *inter alia*, coverage and payment, certification of facilities and providers, peer review, fraud and abuse, including false claims and kickback prohibitions.[12] Moreover, it was by way of the rulemaking process that Medicare was transformed in the 1980s from a cost-and-charge payment system into the administered system of DRG's for hospital reimbursement and the RBRVS-based physician payment program. Enactment of ERISA and of the National Health Resources Planning and Development Act in 1974 continued the trend that had begun a decade earlier by calling for the promulgation of a host of rules respecting employer-funded health insurance and state certification of need programs.[13] And appearing as a noteworthy countertrend in the era of deregulation, important new statutory/regulatory programs were initiated in the 1980s:

8. *See, e.g.*, Turek v. Saint Elizabeth Cmty. Health Ctr., 488 N.W.2d 567, 572 (Neb. 1992); Leahy v. Kenosha Mem'l Hosp., 348 N.W.2d 607, 613 (Wis. Ct. App. 1984); Fjerstad v. Knutson, 271 N.W.2d 8, 14 (S.D. 1978); Tittle v. Hurlbutt, 497 P.2d 1354, 1357 (Haw. 1972).

9. For a general discussion of the operation of the McCarran-Ferguson Act, see Charles D. Weller, *The McCarran-Ferguson Act's Antitrust Exemption for Insurance: Language, History and Policy*, 1978 DUKE L.J. 587 (1978).

10. *See* Jost, *supra* note 1.

11. *Id.*

12. For a general description of the Medicare and Medicaid programs, see FURROW ET AL., *supra* note 6, at 523–68.

13. Employee Retirement Investment Security Act, 29 U.S.C. § 1001 (2000).

- the enactment of the National Organ Transplant Act (NOTA)[14] in 1984, requiring the Department of Health and Human Services to promulgate rules establishing an Organ Procurement Transplant Network for the retrieval, distribution and transplantation of human organs;
- the passage of the Emergency Medical Treatment and Labor Act (EMTALA)[15] in 1986, giving rise to the promulgation of emergency room stabilization and active labor rules for Medicare providers;
- the passage of the Health Care Quality Improvement Act[16] in 1986, generating rules respecting hospitals' limited immunity for staff privilege decisions and governing the establishment and use of the National Practitioner Data Bank;
- the enactment in 1987 of the statutory predicate[17] for extensive federal regulation of nursing homes; and
- the passage of the Ethics in Patient Referrals Act (Stark I)[18] in 1989, requiring the promulgation of rules prohibiting physicians from making certain self-interested referrals of Medicare patients.[19]

Though the pace of statutory change was dealt a blow with the collapse of the Clinton health insurance initiative in 1994, Stark II,[20] enacted as part of the 1993 Omnibus Budget Reconciliation Act,[21] generated more rounds of detailed regulations implementing the statute's complex treatment of self-referrals.

14. Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified at 42 U.S.C. § 273 (2000)) (as amended by the Transplant Amendments Act of 1990, Pub. L. No. 101-616, 104 Stat. 3279, and by the Organ Donation and Recovery Improvement Act of 2004, Pub. L. No. 108-216, 118 Stat. 584).

15. Enacted as part of the Comprehensive Omnibus Budget Reconciliation Act (COBRA) of 1986, Pub. L. No. 99-272, 100 Stat. 164 (codified at 42 U.S.C. § 1395dd (2000)).

16. Pub. L. No. 99-660, 100 Stat. 3743 (codified at 42 U.S.C. §§ 11111–11115 (2000)).

17. Enacted as part of the Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 101 Stat. 1330 (codified at 42 U.S.C. § 1396r (2000)).

18. Enacted as part of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2236 (codified at 42 U.S.C. § 1395nn (2000)).

19. This is only a partial listing of the explosive increase in federal statutory/regulatory regimes created during the 1980s. Consider also that, as part of TERRA of 1980, HHS was required to promulgate rules permitting HMO's to provide services to Medicare beneficiaries on either a risk or capitation basis. And, as another example, the Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, 102 Stat. 3048, which includes the following titles: the National Institute on Deafness and Other Communication Disorders and Health Research Extension Act of 1988, Pub. L. No. 100-607, 102 Stat. 3048, the Organ Transplant Amendments Act of 1988, Pub. L. No. 100-607, 102 Stat. 3114, the Health Professions Reauthorization Act of 1988, Pub. L. No. 100-607, 102 Stat. 3122, and the Nursing Shortage Reduction and Education Extension Act of 1988, Pub. L. No. 100-607, 102 Stat. 3153.

20. Pub. L. No. 103-66, 107 Stat. 312, 596 (codified as amended at 42 U.S.C. § 1395nn).

21. 107 Stat. at 312.

Additionally, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)[22] has given rise to the promulgation of a host of rules dealing with, inter alia, pre-existing conditions limitations in health insurance plans, discrimination against individual participants and beneficiaries based on health status, small group insurance markets and small employer coverage, creation of insurance pools for high-risk individuals, medical savings accounts, tax incentives to encourage purchase of long-term care insurance, and a series of new federal health-care criminal offenses. And as recently as last year, Congress and the President enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[23] directing HHS to promulgate rules setting up complex temporary, and then permanent, programs through which Medicare beneficiaries can purchase prescription drugs at reduced prices and at public expense, and still more rules establishing a framework for creating medical savings accounts.

Additionally, it is important to keep in mind that alongside the creation of these new statutory/regulatory programs, many of the traditional legal structures in the health-care arena have been transformed by the addition of rulemaking powers or by the promulgation of federal rules that limit, condition, and circumscribe their operations. Professor Claeys describes the process by which statutory amendments to its enabling act in the 1960s and Peter Hutt's "legal entrepreneurship" in the 1970s shifted the FDA toward command-and-control style regulation.[24] In like fashion, the FTC asserted substantive rulemaking powers in the early 1970s[25] and was later statutorily authorized to promulgate rules that specified acts or practices as "unfair or deceptive."[26] Finally, and very importantly, Professor Jost mentions how the activities of "private entities" such as Medicare contractors, "qualified review organizations," and IRB's are directed and constrained by rules promulgated by federal administrative actors.[27]

Now, it seems to me that one cannot exaggerate the significance of this move toward rulemaking as the preferred mode for fashioning health law and policy.[28] It is widely thought, as Professor Jost notes, that rulemaking was

22. Pub. L. No. 104-191, 110 Stat. 1936.

23. Pub. L. No. 108-173, 117 Stat. 2066.

24. *See* Claeys, *supra* note 3.

25. Nat'l Petroleum Refiners Ass'n v. FTC, 482 F.2d 672, 698 (D.C. Cir. 1973) (ratifying FTC's substantive rule-making powers).

26. Federal Trade Commission Improvement (Magnuson-Moss) Act of 1974, 15 U.S.C. § 57a(a)(1)(A) (2000).

27. Jost, *supra* note 1, at 5.

28. Like Professor Jost, by "rulemaking," I refer not only to the "informal" notice-and-comment process of the Administrative Procedure Act (APA), 5 U.S.C. §§ 553–557 (2000), but also to what I sometimes call "informal, informal rulemaking," the process that yields the plethora of "interpretative rules, general statements of policy, or rules of agency organization, procedure or practice" that are excepted from notice-and-comment requirements by § 553(b)(A)

adopted in the 1960s and 1970s as an alternative to the formal trial-type processes of the New Deal and earlier "independent" agencies, which were seen to have been "captured" by regulated interests. It was not so much that agencies were thought to have been stuffed with ideologues of the right or of the left (which we might worry about today) or even that there was a "revolving door" between agencies and those they regulated (which we certainly worry about today). Rather, "capture" of the independent agencies by regulated interests was seen as a structural consequence of the formal trial-type processes themselves.[29] The adjudicative processes of the traditional agencies proceeded by way of expensive, time and resource intensive, case-by-case trials with relatively independent administrative law judges, designated parties, pleadings, examination and cross-examination of witnesses, formal records, burdens of proof, detailed findings of fact and precisely formulated decisions of law, intra-agency review, Article III judicial review, and stays pending review.[30] These features, given the vagaries of agency caseloads, made it very difficult for the agencies to develop consistent and coordinated policies, much less to alter their policies in response to changed circumstances or priorities. Moreover, because regulated interests were willing and able to use all manner of procedural devices to delay and frustrate the resolution of individual cases, the agencies tended to "compromise" with and to "accommodate" those whom they regulated as the price for getting anything done. Grudging and incremental change was the best that could be expected. "Capture"—a pattern of decisions protective of the existing regulated interests—was thought to be the more common outcome. And so the ICC was "captured" by the railroads and later also by the truckers; the FPC was "captured" by the gas producers and the pipelines, the FCC by the broadcasters and licensees, and the CAB by the airlines, with no failures and no new entrants for decades.

Given this picture of the adjudicative process, the empowering of agencies to engage in rulemaking was understood to be a much needed reform. With rulemaking, agencies could act on a wholesale basis, quickly and efficiently generating decisions that applied prospectively to large classes of cases. Rather than depending on the happenstance of litigation to raise important issues, agency heads and policy-makers could set their rulemaking agendas, fashion and coordinate the promulgation of inter-related rules to deal with

and the rules issued upon agency "good cause" findings that notice-and-comment procedures "are impracticable, unnecessary, or contrary to the public interest" under §553(b)(B). *See* 5 U.S.C. § 553(b) (2000).

29. *See generally* Thomas W. Merrill, *Capture Theory and the Courts: 1967–1983*, 72 CHI.-KENT L. REV. 1039 (1997); MARVER H. BERNSTEIN, REGULATING BUSINESS BY INDEPENDENT COMMISSION (1955). For the classic "capture" critique of independent agencies from the political left, see GABRIEL KOLKO, RAILROADS AND REGULATION 1877–1916 (1965).

30. For the federal APA's requirements for formal adjudication, see 5 U.S.C. §§ 554–557 (2000). For the procedures for formal rulemaking, see 5 U.S.C. §§ 553(c), 556–557 (2000).

complex problems, and modify and even reverse policies as conditions and priorities changed. And while the APA generally provided that any and all interested parties could get involved in the rulemaking process and that agencies must explain their decisions, participation was ordinarily by way of written comments only and, rather than setting out detailed findings of fact and conclusions of law, justification of rules commonly took the form of policy focused analyses of problems and information bearing upon them.[31] Moreover, the rulemaking process included few procedural devices with which to delay or frustrate agency actions. It lacked the many detailed subordinate decisions that might give rise to intra-agency and judicial review. In short, by the mid-1960s, it was widely thought that agencies' use of rulemaking could wrest the policy-making initiative from those whom they regulated.[32]

Also, as Professor Jost notes, a complimentary, decidedly positive theory of rulemaking had become ascendant by the mid-1960s. In the spirit of Kennedy era idealism and the ambition of Lyndon Johnson's "Great Society," there was widespread confidence that government could, and often did, act in ways that advanced "the public interest." Socio-economic life was taken to be complex, with a great many groups having interests that, while often diverging and clashing, were all nonetheless "legitimate" in some measure. The challenge and the task of government on matters of importance was to get all affected interests represented and to engage in decision-making processes that could be expected to "balance" or at least to effect compromises among the interests of the affected social and economic groups. Given this understanding, the privileged form of lawmaking was, of course, the statutory enactment. With identical language approved by a majority of each of two quite different representative bodies and by the President, who represented the broadest of all electorates, the statute was understood to literally embody the outcome of the "interest balancing" process.[33] Indeed, not the New Deal era, but the period from the mid-1960s through the late 1970s has been reckoned to have been the golden age of statutes.[34] Large and important areas of social and economic

31. For informal rulemaking, the APA merely requires agencies to give interested persons the opportunity to submit data, views, and arguments in writing and to "incorporate in the rules adopted a concise general statement of their basis and purpose," though it permits the agency at its discretion to provide for oral testimony. *See* 5 U.S.C. § 553(c) (2000).

32. *See, e.g.*, David L. Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921 (1965).

33. The privileging of statutory enactment during the 1960s and 1970s is put in relief by two other characteristics of this "legal process" era of legal thought: 1) its understanding of common law adjudication as an attempt to cognitively mimic the legislative process through a self-conscious "interest balancing" calculus and 2) the efforts to resolve "the counter-majoritarian difficulty" of constitutional review of statutes. *See generally* ALEXANDER M. BICKEL, THE LEAST DANGEROUS BRANCH: THE SUPREME COURT AT THE BAR OF POLITICS (1962).

34. *See generally* THEODORE J. LOWI, THE END OF LIBERALISM: THE SECOND REPUBLIC OF THE UNITED STATES (2d ed. 1979) (expressing strong dissatisfaction with the measure of

life—ranging from our treatment of air and water and wildlife resources to our imposition of health and safety risks on workers and consumers, from our responses to workplace discrimination and the difficulties of the handicapped to our treatment of the medical problems of the aged and the poor[35]—were brought under the influence, control, and structuring of government.

In contrast to most statutes of earlier periods, those enacted after the mid-1960s tended to be long and detailed.[36] In part, no doubt, this striking feature of modern statutes is a straightforward consequence of the attempt to describe and to fashion a single structure of interlocking goals and processes out of many diverging and often conflicting interests. For reasons both practical and theoretical, however, these long, detailed statutes ordinarily set out only the main features and skeletal shapes of their statutory/regulatory structures, delegating the powers and responsibilities of elaboration and implementation to administrative agencies. Indeed, the very complexity of design of these statutes and their linguistic richness multiply the uncertainties and ambiguities that call for clarification. And, as we have seen in the health-care area, modern statutes almost invariably call upon agencies to fill in the details through rulemaking. In the 1960s and 1970s, they did so in furtherance of the same "interest accommodating" objectives that inspired the passage of the enabling acts in the first place. The rulemaking contemplated by these statutes was informal, notice-and-comment rulemaking. It was expected that, upon notification of a proposed rule bearing upon matters of concern, interested parties would submit their views by way of written comments, thereby educating agency officials of the various interests and of how those interests related to one another. Agency officials, after giving "adequate consideration" to all affected interest, would attempt to fashion generally acceptable compromises, which would then be explained and justified in the course of the statements of "basis and purpose" required by the APA. Thus, notice-and-comment rulemaking was promoted not merely as a way for agencies to escape the incremental, piecemeal, often futile adjudicative processes of the "independent agencies," but also as a powerful vehicle by which they could elaborate and implement the new statutory/regulatory initiatives in an open, theoretically sound, and legitimate manner.[37]

discretion delegated to administrative actors and arguing for a resurrection of the non-delegation doctrine).

35. For a partial summary of statutory/regulatory systems established in the 1960s and 1970s, see *id*. at 55–56.

36. *See* Sidney A. Shapiro & Robert L. Glicksman, *Congress, the Supreme Court, and the Quiet Revolution in Administrative Law*, 1988 DUKE L.J. 819, 821–45 (detailing trend to greater statutory specificity through the 1970s).

37. For the classic articulation of this "interest representation" model of rulemaking, see Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669 (1975). Of course, mindful also of agency "capture," Stewart strongly endorsed the development

Now, plainly, in the course of the past quarter century, these historical bases for the turn toward rulemaking in the 1960s and 1970s have been thoroughly undermined. Kennedy era idealism has been displaced by the cynicism toward government advanced by the law and economics and public choice movements of the 1980s and 1990s. Sentiments behind Johnson's Great Society initiative have been recast as the ineluctable drive of big government to grow even bigger. Rather than waxing about "the public interest" and about the civic virtues of government officials, we are more likely to see special interests, self-protective bureaucrats, and the ideologically driven ambition of political appointees. We have become disparaging of the legislative process, alternating between consternation over its inability to get anything done and disgust over its use to pad the pockets of the connected, nurture moral hazard, and impose economic rents.[38] Indeed, one cannot have lived through the past two decades without becoming vividly aware that it is now the discipline of the market—and not the legislative process—that is taken as our privileged mode of regulation.

This fundamental shift in our paradigm of regulation is manifest in many ways. It can be seen, for example, in the continuous clamor to reduce taxes and to downsize government by starving it of resources. It can also be seen in the regulatory use of market mechanisms and in the deployment of cost-benefit analysis as an attempt to mimic the workings of markets.[39] But its most obvious manifestation has been the serial deregulation of industry after industry—railroads, trucking, airlines, natural gas production, package delivery, long distance and then local telecommunications, cable television, banking, etc.—beginning in the late 1970s and continuing through the 1990s. Indeed, as noted by Professor Jost[40] and described in more detail by Professor Gilhooley,[41] there has even been a modest deregulation in the health-care area.

It is important to note, however, that the industries that have been deregulated, with few exceptions, are those that had been put under the jurisdiction of the "independent agencies" of the New Deal era and earlier, e.g., the ICC, the CAB, the FCC, where the dominant mode of regulation had

of "hard look" review to enable courts to ensure that agencies give adequate consideration to all affected interests. *Id*. at 1758 n.426.

38. For a general discussion of this pessimism about government during what he calls "The Public Choice Era" after 1983, see Merrill, *supra* note 29, at 1053–55.

39. For an analysis of the "interest group maneuvering" undermining the EPA's "command and control" air pollution regulation with an argument for the adoption of economic incentives in its stead, see BRUCE A. ACKERMAN & WILLIAM T. HASSLER, CLEAN COAL/DIRTY AIR (1981). For an extended economic analysis of methods of regulation, see CASS R. SUNSTEIN, FREE MARKETS AND SOCIAL JUSTICE (1997).

40. *See* Jost, *supra* note 1, at 13 (noting repeal of the National Health Resources Planning and Development Act of 1974).

41. *See* Margaret Gilhooley, *FDA and the Adaptation of Regulatory Models*, 49 ST. LOUIS U. L.J. 131 (2004).

been formal and adjudicative in nature. Strikingly, those industries and activities subjected to regulation under the rulemaking regimes put in place during the 1960s and 1970s have generally not been deregulated. In fact, most statutes enacted during the 1980s and 1990s tend to increase the power of agencies to promulgate rules respecting such industries and activities.[42] This is especially the case with the regulation of health care. Not only have the statutory/regulatory structures put in place by the Medicare and Medicaid statutes and by ERISA not been dismantled, but new enactments during the 1980s (and later, as we have seen) have greatly increased the scope and reach of federal rulemaking. And that, in turn, raises several questions. What is there, we might ask, about the provision and financing of health care that distinguishes it from those industries and activities that have been deregulated? What is there about the regulation of health care that trumps our overall skepticism about government? And what connection is there between those considerations and our use of rulemaking as the dominant mode of regulating?

Professor Jost, I believe, has given us the answers to these questions. He tells us that the topic of our concern is "our largest industry, encompassing one-seventh of our economy, and intimately affecting each of our lives on a regular basis—occasionally literally in matters of life and death."[43] He also tells us that this topic of concern involves "the relationships among health-care providers, professionals, patients, and the government with respect to the organization, provision, and financing of health care."[44] These are matters of great importance, but even more obviously they are matters of great complexity. Indeed, in the course of his paper, Professor Jost mentions just a few of the tasks involved in the regulation of health care in contemporary America:

- licensing and certifying medical providers and medical facilities,
- making staff privilege decisions,
- protecting against medical malpractice,
- licensing the sale and use of new drugs and medical devices,
- overseeing research involving human subjects,
- safeguarding the privacy of medical information,
- overseeing nursing homes,
- subsidizing and overseeing employer-provided health benefit plans,

42. *See, e.g.*, the Clean Air Act Amendments of 1990, Pub. L. No. 101-549, §§ 808, 312, 104 Stat. 2399, 2690–92 (1990) (directing the EPA, *inter alia*, to promulgate rules creating an emission trading system for power plants).

43. *See* Jost, *supra* note 1, at 2.

44. *Id.*

- subsidizing and overseeing "charitable" medical institutions,
- spending hundreds of billions of dollars of Medicare and Medicaid funds,
- establishing coverage and payment practices rules for Medicare and Medicaid,
- policing against fraud and abuse,
- overseeing private insurance underwriting practices and coverage decisions,
- expanding access to insurance,
- ensuring emergency room screening and stabilization,
- providing some form of public insurance for the indigent,
- moving toward universal access.[45]

Now, one need but skim a list like this to see that what is being regulated is an industry in only the loosest sense of the term. In the first place, it is a whole sector of the economy that is regulated here, like the transportation sector or the agricultural sector, with no substitutes for accomplishing its ends. Secondly, because many components of the provision and financing of health care bear upon and are interrelated with one another, sometimes establishing background conditions for the operation of other components,[46] other times acting as functional substitutes for one another,[47] different parts of health law cannot easily be addressed, much less changed, in isolation and independently of others. Thirdly, with health-care providers and facilities and its financing cutting across the private, public, and not-for-profit sectors, its regulation necessarily has important ramifications on the domestic and global competitiveness of American businesses, on national and intergenerational income and wealth distribution, on federalism, and on our allocations of power among public and private actors. Finally, and most importantly, because health care is situated at the very center of our lives, literally from the cradle to the grave, it has come to be as critical to personal security as police protection, and the manner in which health care is distributed causes us to examine just what we are as human beings.

45. *Id.*

46. Consider, for example, the huge national network of hospitals that are financially dependent on Medicare functions as a background condition for the application of EMTALA obligations.

47. One obvious example is the pervasive use of drug therapy as a functional substitute for all manner of invasive interventions.

Given such complexity, Professor Jost is surely on solid ground to argue that regulation that relies only on stand-alone statutes, state courts, private ordering and markets, and the culture of professionalism is just not up to the job.[48] He concludes, almost by way of a process of elimination, that the union of health law with administrative law is here to stay.[49] But I think we must claim much more. It is not merely that various administrative law mechanisms match up well with some of the tasks given to health law, but, given the enormous importance of health care in contemporary life, the daunting challenges posed by its provision and financing, and the high stakes, we have had no choice, it seems to me, other than to deploy a particular form of administrative law, one that is dominated by federal rulemaking. It is only by way of statutory/regulatory structures elaborated and implemented through rulemaking that we have been able to regulate these various components of health care with sufficient information and at the level of detail necessary to address the trade-offs, the substitution effects, the inter-connectedness of different activities, the effects on wealth and income distributions, on competitiveness, on federalism, and so on, and to do this in a way that is sufficiently flexible to enable us to adapt our policies as underlying conditions and priorities change. Accordingly, I want to suggest that the rise of federal rulemaking and the emergence of health law as a distinguishable, more or less coherent body of law are not merely coincident. Indeed, I suggest that the connection between the two is causal, that it is largely by virtue of the operation of the administrative rulemaking process over the past quarter century that there exists a body of law that we know as health law.

II. THE CONCENTRATION OF RULEMAKING POWERS IN THE WHITE HOUSE

It is to administrative agencies and their top officials, of course, that the many statutes enacted since the mid-1960s delegate the task of promulgating rules. But an administrative agency does not operate in a legal vacuum. It always operates within a framework of actions and influences and powers that might be exercised by the White House, Congress, and the federal courts. Agency heads and their senior subordinates are appointed by the President with approval by the Senate, and most agency officials with rulemaking responsibilities can be dismissed by the President for any reason.[50] Agency budgets must be channeled through the White House, and the White House has

48. Jost, s*upra* note 1, at 30.

49. However, it seems to be an unhappy marriage, given his concluding recommendation for counseling. *See id.* at 33.

50. For the now classic trilogy of cases disabling Congress from limiting the President's power to dismiss officials charged with the performance of "executive functions" but restricting Presidential removal of those with "quasi-legislative" or "quasi-judicial" functions, see Myers v. United States, 272 U.S. 52 (1926); Humphrey's Ex'r v. United States, 295 U.S. 602 (1935); Wiener v. United States, 357 U.S. 349 (1958).

long exercised some influence over agencies' rules and rulemaking agendas. Congress, of course, conditions and qualifies agency rulemaking with all manner of statutory detail in an agency's enabling act. And it must always be kept in mind that Congress (together with the President) retains the power to amend an agency's enabling act and so is in a position to reject what the agency has set out to do or to mandate what it has refrained from doing. In addition to the Senate's role in the appointment of "high officers," Congress can in some measure influence an agency's rules and its rulemaking agenda by interjecting line item specifications in appropriations statutes and through the oversight and investigative hearings of its committees. Finally, it should be kept in mind that enabling acts setting out the terms and conditions for the exercise of agency rulemaking powers will ordinarily also provide for judicial review of the performance of those duties. And where the statute is silent, the APA's directives for judicial review are generally applicable.[51] Agencies promulgate their rules in reaction to, and often in anticipation of, decisions made by the reviewing courts. In light of this institutional complexity, the first lesson to be drawn from the study of administrative law is that agency lawmaking is always a matter of shared powers. This is as much the case with agency lawmaking through the fashioning and promulgating of rules as it is with agency lawmaking by adjudicating. But the next and more difficult lesson is that the relative measure of lawmaking powers exercised by the agencies, the White House, Congress, and the federal courts varies enormously from agency to agency, from context to context, and over time.

Indeed, during the first several decades of the rulemaking era, the lower federal courts and Congress developed and made extensive use of a variety of powerful ways to influence and control the rulemaking process. The judiciary exerted its influence primarily through what has become known as "hard look" review and by non-deferentially deploying traditional tools of statutory construction on many vague and ambiguous provisions of the statutes under which the agencies operated. "Hard look" review developed in the late 1960s and 1970s into an extraordinarily flexible technique by which a reviewing court could thoroughly scrutinize an agency action, yet deftly avoid displacing the agency from its position as front-line actor.[52] It typically played out in three stages: First, the reviewing court nondeferentially identified statutorily required factors and considerations that the agency must take into account and

51. With the removal of the amount in controversy requirement for suits against the government, the general federal question jurisdiction provision, 28 U.S.C. § 1331 (2000), nearly always empowers the district courts to entertain challenges to agency rules, and the APA, 5 U.S.C. § 701 (2000), provides that reviewing courts will take up any legal challenges to agency actions except where review is precluded by statute or the "action is committed to agency discretion by law."

52. *See generally* Peter L. Strauss, *Revisiting* Overton Park*: Political and Judicial Controls over Administrative Actions Affecting the Community*, 39 UCLA L. REV. 1251 (1992).

procedures that the agency must follow prior to taking action. Second, the reviewing court put a high burden of justification on the agency by taking "a hard look" at whether the agency in fact acted in ways that satisfied the specified statutory requirements. Finally, in the event that the agency was not able to convince the court that it had adequately taken those factors or considerations into account or that it had followed the required procedures, the reviewing court declared that it was unable to conclude that the action survived the "arbitrary, capricious, abuse of discretion" standard of review, and that it therefore had no option but to remand the matter back to the agency for another try.[53] Carrying the imprimatur of the Supreme Court after the *Overton Park*[54] decision in 1971, "hard look" review effectively transformed the "arbitrary, capricious, abuse of discretion" standard from an extraordinarily deferential test that was rarely used to prohibit an agency's exercise of discretion from reaching a specific outcome[55] into a procedurally focused method by which the lower courts could thoroughly involve themselves in the discretionary decisions of agencies while avoiding, thanks to the remand remedy, the ultimate responsibility for the outcomes of those decisions. The utility of "hard look" review was greatly increased with the Supreme Court's dramatic lowering of hurdles posed by traditional standing, ripeness, and reviewability doctrines,[56] and the method was available regardless of what process the agency used in coming to its decision.[57] But "hard look" review was especially powerful where the decision under review resulted from an agency's use of informal rulemaking procedures. For one thing, the notice-and-comment process enabled those objecting to an agency's proposed rule to submit data, studies, challenges to methodologies, additional factors,

53. In its essentials, "hard look" review was an elaboration of the older *Chenery* doctrine that a reviewing court will demand that the agency itself articulate the justifying basis for its decision. *See* SEC v. Chenery Corp., 318 U.S. 80 (1943).

54. Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402 (1971).

55. For an example of the deferential stance of the traditional "arbitrary, capricious, abuse of discretion" standard, see Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 290 (1974) (upholding a licensing decision of the ICC because "we can discern in the Commission's opinion a rational basis for its treatment of the evidence, and the 'arbitrary and capricious' test does not require more").

56. On the liberalization of the standing doctrine during this time, see, e.g., Ass'n of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150, 152–53 (1970) (replacing "legally protected interest" test with requirement that challengers of agency action show "injury in fact" and an interest "arguably within the zone of interests to be protected" by law); on liberalization of ripeness doctrine, see, e.g., Abbott Labs. v. Gardner, 387 U.S. 136 (1967) (authorizing pre-enforcement review of FDA rules respecting prescription drug labels and advertisements); on expansive reviewability, see *id.* at 140–141 (construing the APA to establish a presumption of reviewability of agency rules). For a sense of the period's general endorsement of active judicial review, see Kenneth Culp Davis, *The Liberalized Law of Standing*, 37 U. CHI. L. REV. 450 (1970).

57. *See* RICHARD J. PIERCE, JR. ET AL., ADMINISTRATIVE LAW AND PROCESS (1985).

countervailing considerations, and so on, thereby presenting the reviewing court with a large paper record that could structure and inform its "hard look." For another thing, its "concise general statement of basis and purpose" provision was judicially developed into a requirement that agencies include extended justificatory statements in the federal register notices of their final rules, and those decision documents could then be mined by challengers and reviewing courts alike in their search for indications that agencies failed to adequately consider all those factors and only those factors that the statute required them to consider or that they failed to follow the processes required by statute.[58]

As we have seen, "hard look" review commonly involved non-deferential statutory construction in its first step. But this should not be considered a departure from general judicial practices of the late 1960s and the 1970s. The detailed regulatory statutes of the rulemaking era supplied countless occasions for non-deferential judicial review, and the prevailing legal philosophy ensured that the judiciary was ready and willing to partake. As already mentioned, the legal process school understood lawmaking to be fundamentally a matter of compromising and coordinating among numerous interests, and it viewed the legislative process as the paradigmatic interest-balancing mechanism. Duly enacted statutes were understood to establish legislative ends—the goals and objectives of governmental action—and to outline at least some of the means for realizing those ends. Statutory ends, some of which might be specified in the statute's preamble and others known by implication, were almost always multiple. Some were understood to be primary, while others secondary and subordinate. Because novel and unexpected problems inevitably arose, these statutory means/ends structures were recurrently in need of elaboration and implementation. It is the agencies, of course, that were delegated front-line decision-making powers, and their actions were to be upheld so long as they performed their statutory duties, kept within statutory bounds, and were not otherwise unlawful. Indeed, as mentioned earlier, so long as agencies acted pursuant to their enabling acts, their use of notice-and-comment rulemaking was regarded as a functional substitute for the interest-balancing mechanics of the legislative process.

But there was reason to worry that agencies too often either failed to perform their statutory duties or acted beyond their statutory authorizations. Some of this suspicion was based on "capture" concerns, some on concern about undue influence from the White House and other "political" powers, and some on apprehension that an agency might be too single-mindedly focused on

58. *See, e.g.*, United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 248–51 (2d Cir. 1977) (remanding FDA safety regulations for smoked whitefish promulgated after notice and comment on grounds that FDA gave inadequate notice, failed to consider "all relevant factors," and published an inadequate "statement of . . . basis and purpose").

advancing some of its statutory goals at the expense of others.[59] Regardless of the basis for the worry, however, adherents to the legal process school were generally of the view that, unless provided otherwise by statute, it was central to the power and professional responsibility of federal judges to ensure that administrative actors performed their statutory duties and kept within the limits and bounds of their enabling acts.[60]

This general endorsement of non-deferential judicial review of agency interpretations of statutes was based on a particular understanding of what is involved in performing the task and on an assessment of the special competence of Article III judges—as much as it was based on worry about administrative over-reaching or non-performance of duty. Although I can only summarize here, it is based on an understanding that statutory interpretation is at bottom an elaboration of ends/means structures, the skeletal outlines of which are already established by the statutes involved.[61] Its proponents speak of "statutory construction," and they have in mind the image of someone continuing to build on a structure that already exists.[62]

Though not related physically, the parts of these structures are related functionally by way of means/ends connections. The task of statutory

59. *See* Merrill, *supra* note 29, at 1084–88.

60. Section 706 of the APA provides that "the reviewing court shall decide all relevant questions of law, interpret . . . statutory provisions, . . . [and] (2) hold unlawful and set aside agency action, findings, and conclusions found to be . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706 (2000). However, there have long been two lines of authority on the question of how much deference a reviewing court should give to an agency's interpretation of its enabling act. In the 1960s and 1970s, it was commonly said that the court should defer to reasonable agency interpretations when it was clear that Congress intended that the agency (rather than the reviewing court) make law on the issue, but that the court, as "the final authority on issues of statutory construction," should decide the matter without deference in all other instances. *See* 2 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 7:10, at 51–52 (2d ed. 1979) (distinguishing between "legislative rules" and "interpretative rules"). As a matter of practice, however, the non-deferential stance appears to have been on the increase throughout this time. Judge Leventhal expressed what seems to have been the prevailing sentiment when he wrote, "Congress has been willing to delegate its legislative powers broadly and courts have upheld such delegation because there is court review to assure that the agency exercises the delegated power within statutory limits." Ethyl Corp. v. EPA, 541 F.2d 1, 68 (D.C. Cir. 1976). Empirical data on the measure of deference reviewing courts give to agency views is virtually impossible to generate, if for no other reason than that instances where agency decisions are upheld on review are ambiguous as between whether the agency is affirmed (1) because the reviewing court has deferred to its views or (2) because the reviewing court, though not deferring, agreed with the position taken by the agency.

61. For a classic exposition, see BENJAMIN N. CARDOZO, THE NATURE OF THE JUDICIAL PROCESS (1949). *See also* Louis L. Jaffe, *Judicial Review: Question of Law*, 69 HARV. L. REV. 239 (1955) (espousing judicial oversight of agency interpretations using a "clear statutory purpose" test).

62. For a perspicuous account, see Lon L. Fuller, *Positivism and Fidelity to Law—A Reply to Professor Hart*, 71 HARV. L. REV. 630, 661–69 (1958).

construction is not merely to ensure that actions taken under statutory authority are consistent, but to specify those actions that best advance the arrangement of means/ends relations that the statutory/regulatory structure has already been given. The actor charged with interpreting a statute is understood to identify statutory ends or purposes, note their rank orders relative to one another, and elaborate the appropriate means for accomplishing those ends. It is seen as a piece of what Congress and the President did in enacting the statute in the first place.

What is more, the Article III judiciary was taken by adherents to this view to be especially suited to performing this task. Their general jurisdiction and long experience was thought to have them especially adept at identifying ends and purposes and at analyzing means/ends connections. Their life tenure and the sheer number of judges were thought to make it likely that the need for political independence could be met. Moreover, their obligation to explain decisions in writing was held to be a safeguard for ensuring that it was statutory purposes, and not other things, that were elaborated.

Any student of administrative law can identify many instances of federal judges non-deferentially rejecting important agency rules on statutory grounds in the late 1960s and the 1970s.[63] Indeed, given that non-deferential judicial review of agency interpretations of regulatory statutes was the background understanding of the day, it might be claimed that it was statutory/regulatory/judicially-fashioned structures that Congress and the President had in mind from the beginning. But it is of the highest importance to recognize that judicial decisions rejecting agency actions on statutory grounds are often not the last word. A judicial decision that prohibits an agency from doing what it wants to do or that requires it to do what it does not want to do can always be overturned by statutory amendment. Indeed, insofar as the actions of an agency represent the views and priorities of the President, judicial rejection of the agency's rule on statutory grounds should be seen as, at least in part, a structural decision, forcing the President to put the matter in controversy through the legislative process where the interests represented in both Houses of Congress, as well as those represented by the White House, can have their say. Moreover, by conditioning the agency's ability to accomplish White House objectives and policies on the consent of Congress, the courts will have conferred a measure of bargaining power on both Houses, enabling them to trade their approval of White House proposals for any number of compensating

63. W. Va. Div. of the Izaak Walton League of Am., Inc. v. Butz, 522 F.2d 945 (4th Cir. 1975) (construing the Forest Service's Organic Act of 1897 to prohibit large scale clear cutting in national forests); *see also* Wilderness Soc'y v. Morton, 479 F.2d 842 (D.C. Cir. 1973), *cert. denied*, 411 U.S. 917 (1973) (construing the right-of-way provisions of the Mineral Leasing Act of 1920 in a way that prevented the Department of Interior to authorize construction of the Alaska Pipeline).

favors.[64] Several obvious instances of just this kind of dynamic played a critical role in bringing about various rounds of statutory amendment in the 1970s.[65]

Additionally, it should not be overlooked that there was a much more prevalent and systematic way for Congress to exercise its influence and control over agency actions during the early decades of the rulemaking era. Virtually every regulatory statute enacted during the 1960s and 1970s conditioned its delegation of rulemaking powers with some form of legislative veto.[66] Depending on the statute in question, legislative veto provisions created a window of time during which each House of Congress or both Houses acting by concurrent resolution or even a particular Committee of the Congress was able to reject an agency's action. Though the legislative veto dates back to the New Deal and earlier, it appears that the device was actually used to reject agency actions fairly infrequently. But there is good reason to believe that its influence extended far beyond its actual use. By empowering Congress to reject agency actions after they were taken, the legislative veto created a strong incentive for agencies to consult and negotiate with Congress before they acted. Indeed, there is some evidence that a fair part of the agendas of many Congressional committee and subcommittee oversight hearings during the 1970s and early 1980s were set in the shadow of the legislative veto.[67]

Thus, while there was a fundamental turn toward rulemaking as the dominant form of federal administrative lawmaking in the late 1960s and 1970s, it is fair to say that this enterprise was performed jointly by the agencies (and thus the White House in some measure), the courts, and Congress. Statutes delegated the power to promulgate rules in the first instance to the

64. *See generally* William N. Eskridge, Jr., *Overriding Supreme Court Statutory Interpretation Decisions*, 101 YALE L.J. 331 (1991) (modeling statutory interpretation as part of a sequential political game and presenting the results of a study concluding that almost half of the Supreme Court's statutory interpretation decisions between 1975 and 1990 were made the specific focus of congressional override hearings).

65. For example, after the Supreme Court interpreted the Endangered Species Act of 1973 to prohibit the Tennessee Valley Authority from operating a $110 million dam in order to safeguard the protected snail darter, TVA v. Hill, 437 U.S. 153, 153 (1978), Congress amended the statute to establish an administrative mechanism (the "God Committee") to consider exemptions from the Act's prohibitions. *See* Endangered Species Act Amendments of 1978, Pub. L. No. 95-632, 92 Stat. 3751 (1978).

66. By the early 1980s, nearly 300 statutes contained a legislative veto feature. *See* INS v. Chadha, 462 U.S. 917, 944–45 (1983) (citing figures from James Abourezk, *The Congressional Veto: A Contemporary Response to Executive Encroachment on Legislative Prerogatives*, 52 IND. L. REV. 323, 324 (1977)).

67. *See generally* Harold H. Bruff & Ernest Gellhorn, *Congressional Control of Administrative Regulation: A Study of Legislative Vetoes*, 90 HARV. L. REV. 1369 (1977) (finding that although Congress rarely used the legislative veto, agencies commonly negotiated and compromised with congressional committees "in the shadow" of the veto).

agencies, but the exercise of that power was subject to the checks of "hard look" review and nondeferential review of agencies' statutory interpretations. Congress was kept in the loop through the amendment process when courts rejected agency rules on statutory grounds and more systematically when agencies consulted with Congressional actors about the prospect of legislative veto. The agencies had the first, and usually the dominant, say in determining just what came out of the rulemaking process, but the courts and Congress were far more than bit players. Though operating below the Constitutional level, administrative law was a genuine system of checks and balances.[68]

This period of shared governance, as it turned out, was short-lived. The reduction of judicial involvement began in the late 1970s with the *Simon* decision's interjection of strict causation and redressability elements into standing doctrine[69] and with *Vermont Yankee Nuclear* prohibiting lower courts from imposing extra-statutory procedural requirements as part of "hard look" review.[70] While doctrinal changes were important, those decisions were especially noteworthy for the stance they took on the supervisory role of the lower courts. The language of Justice Rehnquist in *Vermont Yankee Nuclear* expressed the new tone:

> The fundamental policy questions appropriately resolved in Congress and in the state legislatures are *not* subject to reexamination in the federal courts under the guise of judicial review of agency action. Time may prove wrong the decision to develop nuclear energy, but it is Congress or the States within their appropriate agencies which must eventually make that judgment. In the meantime courts should perform their appointed function.[71]

This new direction was taken further in the 1980s with a number of developments that weakened "hard look" review. The most important of these was the Reagan Administration's shift towards characterizing many more of its rules as "interpretative rules, statements of policy, or rules of agency organization, procedure, or practice" or as rules for which there was "good cause" to proceed without notice and comment,[72] and the concomitant

68. *See* Harold Leventhal, *Principled Fairness and Regulatory Urgency*, 25 CASE W. RES. L. REV. 66, 70 (1974) (describing the existing state of administrative law as acquiescing in broad delegations cabined by various controls on subsequent administrative actions).

69. Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26, 26, 44–46 (1976) (holding an organization representing indigents to be without standing to challenge IRS Revenue Ruling reducing indigent services requirements for hospitals to qualify for IRC §501(c)(3) status).

70. Vt. Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 544–45, 547–48 (1978).

71. *Id.* at 558.

72. *See* Juan J. Lavilla, *The Good Cause Exemption to Notice and Comment Rulemaking Requirements Under the Administrative Procedure Act*, 3 ADMIN. L.J. 317, 351 n.124 (1989) (finding that forty percent of the rules published during the first six months of 1987 in the *Federal Register* had been adopted without notice and comment).

readiness of the federal judiciary to acquiesce in that approach.[73] Though seemingly innocuous, this move greatly reduced the utility of "hard look" review by depriving opponents of agency action the opportunity to build a record and by starving reviewing courts of ammunition that might be used to support a remand. Other changes reinforced these developments. The traditional ripeness doctrine was turned on its head in the 1980s, as more and more rules were protected from enforcement-stage review.[74] Additionally, the development of negotiated rulemaking during this time effectively insulated such rules from serious challenge.[75] In summary, "hard look" review had lost its status as a generally used method of demanding non-statutory oversight of agency rulemaking and had become a kind of template within which a reviewing court might or might not closely scrutinize the basis and rationale of agency action.[76]

The most far-reaching change began in 1984, when along came *Chevron*.[77] The case arose out of a challenge to the Reagan Administration EPA's promulgation of an important air pollution control regulation. The rule, which replaced one that had been promulgated through notice-and-comment proceedings during the Carter administration, effectively exempted many existing sources of pollution in dirty air areas of the country from rigorous control requirements.[78] It was rejected by a panel of the D. C. Circuit Court of Appeals in an opinion that, giving little deference to the views of the Reagan

73. *See, e.g.*, Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037 (D.C. Cir. 1987) (agreeing with the Department of Health and Human Services that HHS rules concerning the organization of Peer Review Organizations, their activities, and their enforcement were either procedural in nature or policy statements and thereby exempt from APA § 553's notice-and-comment requirements). In the course of her opinion, Judge Wald explained how the courts had moved away from a "substantive impact" test to more relaxed standards when assessing agency choices of procedure. *Id*. at 1047–48.

74. For a summary of standards for enforcement stage review of rules that might have been reviewed immediately after promulgation, see NLRB Union v. FLRA, 834 F.2d 191, 195–97 (D.C. Cir. 1987).

75. In 1990, Congress amended the APA to authorize agencies to promulgate rules through negotiated rulemaking. *See* Negotiated Rulemaking Act of 1990, 5 U.S.C. §§ 561–570 (2000). For a skeptical review of experience with negotiated rulemaking, see Cary Coglianese, *Assessing Consensus: The Promise and Performance of Negotiated Rulemaking*, 46 DUKE L.J. 1255 (1997). For a defense of negotiated rulemaking, see Philip J. Harter, *Assessing the Assessors: The Actual Performance of Negotiated Rulemaking*, 9 N.Y.U. ENVTL. L.J. 32 (2000).

76. *See, e.g.*, Am. Dental Ass'n v. Martin, 984 F.2d 823 (7th Cir. 1993) (Posner, J.) (upholding OSHA's blood borne pathogens occupational exposure rule).

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

78. The rule, also issued after notice and comment, adopted what is known as "the bubble policy" for areas of the country that had been designated as not yet in attainment of the Clean Air Act's national ambient air quality standards. *See* Requirements for Preparation, Adoption and Submittal of Implementation Plans and Approval and Promulgation of Implementation Plans, 46 Fed. Reg. 50,766 (Oct. 14, 1981) (to be codified at 40 C.F.R. pts. 51, 52).

EPA, set out just how the agency's interpretation of ambiguous statutory language was incompatible with the ordering of purposes implicit in the structure of the 1977 Amendments to the Clean Air Act.[79]

In rejecting the decision of the Circuit Court, the Supreme Court transformed judicial review of agency interpretation of statutes from an examination of statutory means and ends ("purposes") into a search for the "meanings" of statutory words and phrases. Writing for a six member court,[80] Justice Stevens set out the now well-known two step process:

> 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 Congress has not directly addressed the precise questions 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.[81]

Now, given that agencies rarely act in ways that are expressly prohibited by statute, the *Chevron* approach, when taken literally, is extraordinarily deferential; step one is to reject only those agency interpretations which are logically inconsistent with statutory requirements. All other interpretations are to be upheld so long as they are "permissible."[82] Just as importantly, however, by reconceptualizing the problem from one of elaborating means-ends connections embedded in already existing statutory/regulatory structures into one of giving "meaning" to statutory language, *Chevron* establishes a systematically deferential stance to step one's look for clear congressional intent. Consider in this regard that nothing in *Chevron* explicitly bars the use of legislative history to determine whether Congress "directly addressed the precise questions at issue."[83] Nevertheless, most courts have refused to consider legislative history in step one of the analysis on the ground that resort to legislative history concedes that the statute is ambiguous and therefore

79. Natural Res. Def. Council v. Gorsuch, 685 F.2d 718, 726–28 (D.C. Cir. 1982).

80. Justices Marshall, Rehnquist, and O'Connor did not take part in the decision.

81. *Chevron*, 467 U.S. at 842–43.

82. The "permissible interpretation" standard of *Chevron*'s second step has been universally understood to be low. *See, e.g.*, Consumer Fed'n of Am. & Public Citizen v. Dep't of Health & Human Servs., 83 F.3d 1497, 1504–05 (D.C. Cir. 1996) (considering whether agency's policy choice is arbitrary); Republican Nat'l Comm. v. Fed. Election Comm'n 76 F.3d 400, 406–07 (D.C. Cir. 1996) (considering whether agency's interpretation of statute is reasonable).

83. *Chevron*, 467 U.S. at 842–43.

implicates step two's "permissible" interpretation inquiry.[84] Indeed, by posing the statutory construction problem as one that ordinarily demands that an actor fashion a precise "meaning" for a vague or ambiguous word or phrase, *Chevron* painted proponents of non-deferential judicial review into the uncomfortable corner of judicial activism.[85]

Although comparative data is extraordinarily difficult to generate, *Chevron* is reckoned to have generally reduced the federal judiciary's ability to limit and control agency action.[86] Its overall message to the courts cannot be better stated than it was by Justice Stevens in *Chevron* itself:

> The arguments over policy that are advanced in the parties' briefs create the impression that respondents are now waging in a judicial forum a specific policy battle which they ultimately lost in the agency . . . . Judges are not experts in the field, and are not part of either political branch of the Government. Courts must, in some cases, reconcile competing political interests, but not on the basis of the judges' personal policy preferences. In contrast, an agency to which Congress has delegated policy-making responsibilities may, within the limits of that delegation, properly rely upon the incumbent administration's views of wise policy to inform its judgments. While agencies are not directly accountable to the people, the Chief Executive is, and it is entirely appropriate for this political branch of the Government to make such policy choices—resolving the competing interests which Congress itself either inadvertently did not resolve, or intentionally left to be resolved by the agency charged with the administration of the statute in light of everyday realities.[87]

84. *See, e.g.*, Arco Oil & Gas Co. v. EPA, 14 F.3d 1431, 1435–36 (10th Cir. 1993). Justice Scalia has, of course, strongly criticized judicial use of legislative history, ANTONIN SCALIA, A MATTER OF INTERPRETATION: FEDERAL COURTS AND THE LAW 16–23 (Amy Gutmann ed., 1997), while Justice Breyer has encouraged its use, Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 847 (1992).

85. This conceptualization of statutory (and constitutional) construction/interpretation as a matter of giving "meanings" to words and phrases, with the corollary that the interpreter engages in unbridled lawmaking, is characteristic to twentieth century legal positivism. For the influential account of H.L.A. Hart, distinguishing between the clear "core" meaning of words and their indeterminate "penumbra" and the treatment of judicial interpretation in the "penumbral area" as an exercise of discretion, see H.L.A. Hart, *Positivism and the Separation of Law and Morals*, 71 HARV. L. REV. 593, 606–15 (1958). *See also* H.L.A. HART, THE CONCEPT OF LAW, 121–32 (1961).

86. One study examining nearly 2000 appellate decisions from 1984–85 and from 1988 reported finding "strong evidence" of changed outcomes due to *Chevron*. Peter H. Schuck & E. Donald Elliott, *To the Chevron Station: An Empirical Study of Federal Administrative Law*, 1990 DUKE L.J. 984, 1036 (1990).

87. *Chevron*, 467 U.S. at 864, 865–66.

Indeed, it is difficult to overestimate the influence of *Chevron*. Its reach extends to every corner of administrative law.[88] It has become the most cited Supreme Court decision of all time.[89] It has given rise to scores of law review articles. Insofar as legal change can be understood as a function of what it is that draws the attention of the "legal elites,"[90] one would be hard put to find a more influential topic in all of contemporary public law. It should be noted, however, that there is also a nondeferential version of *Chevron*, an understanding of the decision which invokes a footnote Justice Stevens appended to the first step of the new approach:

> The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent. . . . If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.[91]

Indeed, many cases, especially over the last ten years, have used this non-deferential gloss on step one to reject agency statutory interpretations. The best-known instance in the health law area is Justice O'Connor's *Brown & Williamson* opinion,[92] which used the classical statutory means/ends analysis to reject the FDA's child tobacco regulations as beyond the authority of the agency. Moreover, in recent years the Court has muddied *Chevron*'s waters by intimating that the non-deferential stance is particularly apt where agency interpretations are made in the course of "opinion letters" or are contained in "policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law."[93] What is more, the lower courts have recognized a

88. Supreme Court opinions in the health law area making use of *Chevron* deference to uphold agency interpretations include Young v. Cmty. Nutrition Inst., 476 U.S. 974, 980–84 (1986) (upholding HHS aflatoxin regulations on *Chevron* deference because statute was "ambiguous"); Rust v. Sullivan, 500 U.S. 173, 184–87 (1991) (upholding HHS regulations reversing long-standing contrary policy because the statute was ambiguous on whether abortion counseling and referrals were proscribed and *Chevron* deference therefore was appropriate); Good Samaritan Hosp. v. Shalala, 500 U.S. 402, 417 (1993) (upholding HHS Medicare reimbursement regulations because "where the agency's interpretation of a statute is at least as plausible as competing ones, there is little, if any, reason not to defer to its construction").

89. It has been reported that, as of December 2001, *Chevron* had been cited more than 7000 times in federal decisions, more often than *Brown v. Board of Education*, *Roe v. Wade*, and *Marbury v. Madison* combined. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY 289 (5th ed. 2002).

90. *See* Claeys, *supra* note 3, at 111.

91. *Chevron*, 467 U.S. at 843 n.9 (citations omitted) (citing numerous Supreme Court cases from the 1970s and earlier).

92. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 132–33 (2000).

93. *See* Christensen v. Harris County, 529 U.S. 576, 587 (2000); United States v. Mead Corp., 533 U.S. 218, 254 (2001).

number of "exceptions" to *Chevron*.[94] While these developments often give reviewing courts the doctrinal bases to interject their own policy preferences,[95] nondeferential approaches to statutory review seem to remain but a minor theme. And as illustrated best by some notoriously literalist opinions from Justice Scalia, nondeferential statutory review, when undertaken as a search for the "meaning" of statutory language, exposes the judge to charges of unbridled activism.[96]

Now, an enormously important, though largely unheralded, indirect effect of deferential *Chevron* has been on the power of Congress. Recall that in the *Chevron* case itself, the Court of Appeals struck down the Reagan Administration EPA's rule on statutory grounds. Had that been the end of the case, however, it is not at all clear that the White House would have been thwarted in its effort to reverse the Carter Administration's air pollution control policy. With policy change by rulemaking rejected, the White House would have been compelled to go to Congress for an amendment to the statute. Admittedly, with the House under Democratic control for all of the 1980s and the Senate for most of the decade, coming to an agreement on statutory changes might have been a formidable task. But it would not have been impossible. It is quite likely that the powers in the House and Senate would have been willing to give the Administration at least some of what it wanted in exchange for its agreeing to changes in other parts of the Clean Air Act or in some other area of policy that was important to the Democrats. Indeed, as we have seen, it is in just this way that the non-deferential, "purposive" mode of reviewing agency interpretations of their enabling acts tended to create a legislative agenda for the White House, thereby establishing an ongoing ability in Congress to exercise some bargaining power. But under deferential *Chevron*, this whole dynamic of give-and-take between the White House and the powers-that-be in Congress is short-circuited. Statutes are inveterately vague and ambiguous, and the range of "permissible" interpretations is wide. Thus, agencies in the Reagan/Bush era were able to reverse and greatly modify Carter Administration policies without going to Congress, Clinton Administration agencies were able to drastically change earlier policies through rulemaking, and the Administration of George W. Bush has been able

94. *See, e.g.*, Midland Coal Co. v. Office of Workers' Comp. Programs, 149 F.3d 558, 561 (7th Cir. 1998) (finding *Chevron* deference not appropriate to questions of agency's jurisdiction); Anderson v. Dep't of Health & Human Servs., 907 F.2d 936, 941–42 (10th Cir. 1990) (giving no deference to agency interpretation of statute it does not administer, such as Freedom of Information Act).

95. *See* Frank B. Cross & Emerson H. Tiller, *Judicial Partisanship and Obedience to Legal Doctrine: Whistleblowing on the Federal Courts of Appeals*, 107 YALE L.J. 2155 (1998).

96. *See, e.g.*, MCI Telecomm. Corp. v. Am. Tel. & Tel. Co., 512 U.S. 218, 225–29 (1994) (writing such that Justice Scalia finds himself adjudicating among various dictionaries' definitions of the word "modify").

to reject and modify many Clinton policies without seeking statutory changes.[97] Deferential *Chevron* obviously empowers the agencies. But just as plainly, it simultaneously disables Congress by depriving it of the bargaining power it would have possessed were the White House forced to seek statutory amendment as the price to be paid for at least some of what it wants.[98]

While deferential *Chevron* reduces the power of Congress by making it much easier for agencies to change policies without first obtaining amendments to their enabling acts, in its *Chadha* decision, issued a year before *Chevron*, the Supreme Court disabled Congress from using the legislative veto mechanism to control agency actions on a regulation-by-regulation basis.[99] In an opinion setting out an extraordinarily formal understanding of "separation of powers" doctrine, Chief Justice Burger, writing for a bare majority, struck all forms of legislative veto as incompatible with the "bicameralism" and "presentment" clauses of Article I.[100] As mentioned earlier, the utility of the legislative veto consisted not so much in the ex post rejection of agency decisions as in the bargaining power it gave to congressional committees and subcommittees to negotiate policies with federal agencies ex ante. However, after *Chadha*, this bargaining power was gone. With Congress disabled from rejecting particular administrative actions, agency officials have had little reason to consult or to negotiate with members of Congress in advance of their actions.

One might speculate a bit about the institutional consequences of the loss of congressional bargaining power at the statutory level in the wake of

97. *Compare* Medicare Program; Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care, 59 Fed. Reg. 32,086 (June 22, 1994) (to be codified at 42 C.F.R. pts. 405, 489) (Clinton Administration's regulation implementing EMTALA), *with* Medicare Program; Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care, 53 Fed. Reg. 22,513 (June 16, 1988) (to be codified at 42 C.F.R. pts. 405, 489, 1001, 1003) (less demanding Reagan Administration rule). *Compare* Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals With Emergency Medical Conditions, 68 Fed. Reg. 53,222 (Sept. 9, 2003) (to be codified at 42 C.F.R. pts. 413, 482, 489) (George W. Bush Administration regulation), *with* the Clinton rules, *supra*.

98. This second-order disabling effect on Congress is neglected by nearly all the commentators. *Cf.* Cynthia R. Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452 (1989) (criticizing *Chevron* for skewing the balance of power too far in the direction of the Executive Branch and arguing for placing interpretive power with the judiciary as a counterbalance but failing to note second-order effects on the power of Congress).

99. INS v. Chadha, 462 U.S. 919 (1983).

100. *Id.* at 946–59. For discussion and criticism of the Supreme Court's turn toward a formalist approach to "separation of powers" issues in the 1980s, see Peter L. Strauss, *Formal and Functional Approaches to Separation-of-Powers Questions—A Foolish Inconsistency?*, 72 CORNELL L. REV. 488 (1987).

Chevron and at the regulatory level with *Chadha*'s elimination of the legislative veto. It is clear, for example, that it has become much more difficult to amend existing enabling acts. Consider the long wait for the much needed 1990 amendments to the Clean Air Act or the seemingly intractable impediments to changing the Endangered Species Act.[101] Two decades of divided government, with one political party in the White House and the other in control of at least one House of Congress, has no doubt made it much more difficult to pass any legislation, but a background of divided government exacerbates the loss of congressional bargaining power that has been effected in the wake of deferential *Chevron*. The existing Administration can simply change policy by regulation and so has no incentive to deal with a Congress that is controlled by the other party.[102]

Of course, the one type of statute that cannot be avoided is the annual appropriations act that funds the various departments and other agencies of government, and here, it seems, we find the exception that proves the rule. With the President having no choice other than to deal, members of Congress not only routinely insert hundreds of riders having to do with narrow issues and problems that they cannot otherwise address, but Congress has come to use appropriations statutes to make major changes to existing enabling acts and even to establish entirely new statutory/regulatory regimes.

Interestingly, this manner of effecting statutory change has been especially common in the health law area.[103] Wrangling between Congress and the White House over the details of these appropriations statutes has been contentious and has often extended long into the oncoming fiscal year, yet in the end something is done, and the bargaining comes to some resolution. But the same cannot be said for the work of the congressional committees and subcommittees that have lost bargaining power, at least in part, as a consequence of *Chadha*. With the legislative veto risk removed, it appears that many agencies have found it unnecessary and not even worthwhile to consult (and certainly not to bargain) with congressional committees in control of the other political party prior to the issuance of rules. Indeed, it seems that changes in regulatory policy are routinely dressed in a "principled" garb of partisan rhetoric, frustrating the party in control of Congress and stoking the fires of ill will.[104] One might also ask whether these institutional changes have

101. *See* Endangered Species Act Amendments of 1888, Pub. L. No. 100-478, 102 Stat. 2306 (1988) (creating a recurrent focus of political conflict between the White House and the party that has controlled Congress for nearly a generation).

102. Again consider the expansion and then contraction of EMTALA obligations of hospitals with changes in administrations. *See supra* note 97 and accompanying text.

103. *See supra* notes 15, 17–18.

104. Consider once again the recurrent reversals of policy over funding of abortion counseling. Consider also the George W. Bush Administration NIH's withdrawal of Clinton Administration guidelines for research using stem cells derived from human embryos. *See*

had much to do with what seems to be an increasing use of investigative hearings in Congress and on the rise of what has become known as "the politics of personal destruction."[105]

There is another part of the *Chadha* saga that should be noted. As mentioned earlier, some 300 statutes contained legislative veto provisions by the time *Chadha* was decided. Every one of those statutes delegated lawmaking power to administrative agencies. In each instance, that lawmaking power was delegated with the understanding that its exercise would be subject to Congressional oversight by way of the veto mechanism. Indeed, it may well be that many legislators were willing to grant lawmaking powers to agencies on the assumption that Congress retained the ability to check the exercise of such powers through the veto mechanism.[106] Under *Chadha*, of course, all of the legislative veto provisions were voided. However, with very few exceptions the delegations that the veto mechanisms were understood to condition were retained. With a permissive gloss on the severability doctrine,[107] the courts have held that the legislative veto provisions alone were to be struck. The upshot of the whole scenario of course, is that the *Chadha* saga should be seen as the largest and most far-reaching delegation of lawmaking power to administrative agencies of the twentieth century.

These developments respecting judicial and congressional review of agency lawmaking over the past two decades have in substantial measure disabled the judiciary and Congress from exercising the kind of influence and control that they previously enjoyed. One might think that the upshot of all this would be that federal agencies have become more independent. And one might even argue that insulating federal agencies would enable them to engage in better rulemaking—integrating and coordinating important social and economic policies without the intermeddling of unelected federal judges or from politically motivated actors in Congress and the White House. But there has not been a change toward greater agency independence. In fact, during the time that agencies have been insulated from judicial and Congressional control,

National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107 (Nov. 14, 2001).

105. *See, e.g.*, Stephen Moore & Jeffrey Bell, *The Left's Nightmare*, WASH. TIMES, Oct. 28, 2004, at A21; Don Van Natta Jr., *Raising Funds: Impeachment is Powerful Tool*, N.Y. TIMES, July 20, 1999, at A1.

106. *See, e.g.*, Alaska Airlines, Inc. v. Donovan, 594 F. Supp. 92, 95 (D.D.C. 1984), *rev'd*, 766 F.2d 1550 (D.C. Cir. 1985), *judgment aff'd sub nom.* Alaska Airlines, Inc. v. Brock, 480 U.S. 678, 697 (1987) (concluding that Congress delegated certain powers to the CAB with the understanding firmly in mind that regulations issued by the Secretary would be subject to legislative veto).

107. *See Brock*, 480 U.S. at 685 (reversing the district court's decision after concluding that "the statute [would] function in a *manner* consistent with the intent of Congress" with the legislative veto provision alone excised).

there has been an enormous increase in influence and control from the White House.

Though modern White House influence on agency rulemaking had its beginnings with the Nixon, Carter, and Ford Administrations,[108] it was strengthened into what can only be called total White House control during the Reagan and Clinton years.[109] During his first month in office, President Reagan issued Executive Order 12,291, which directed all executive agencies to prepare and consider a "Regulatory Impact Analysis" (RIA) and to submit the RIA for review to what later became OMB's Office of Information and Regulatory Review (OIRA), before publishing the notice that it was proposing to promulgate a major rule.[110] The RIA was to include a description of the potential benefits and costs of the rule, a determination of the potential net benefits of the rule, and a description of any alternatives to achieving the regulatory goal at lower cost with an analysis of potential benefits and costs and an explanation of the legal reasons why such alternatives could not be adopted.[111] Additionally, the executive order directed agencies, "to the extent permitted by law," to regulate only if benefits exceeded costs and, even then, to choose the regulatory alternative that "involve[d] the least net cost to society."[112] The policy orientation of Reagan era regulatory review becomes clear in the guidance that David Stockman's OMB gave to the agencies, directing them to identify market failures that gave rise to the need for regulation and to explain how the regulation corrects them, to quantify all costs and benefits using willingness-to-pay methodologies when necessary, and to reduce all aggregate costs and benefits to present value using a discount rate as high as ten percent.[113] The deregulatory effect of the effort is obvious when

108. President Nixon created a "Quality of Life" office to review regulatory programs. President Ford required agencies to issue Inflation Impact Statements of their actions, with OMB oversight. President Carter imposed the first comprehensive regulatory analysis requirement and established a Regulatory Analysis Review Group in the White House to review agency rules having a significant economic impact. *See generally* Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245 (2001); Peter L. Strauss, *Presidential Rulemaking*, 72 CHI.-KENT L. REV. 965 (1997); Robert V. Percival, *Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency*, 54 LAW & COMTEMP. PROBS. 127 (1991); Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075 (1986).

109. It should be kept in mind throughout this brief summary that, while not expressly excluded from the APA § 551(1) definition of "agency," the President has been held not to be an agency under the APA and so not subject to its many procedural requirements and APA based judicial review. Franklin v. Massachusetts, 505 U.S. 788, 800–01 (1992). *See also* Jonathan R. Siegel, *Suing the President: Nonstatutory Review Revisited*, 97 COLUM. L. REV. 1612 (1997).

110. Exec. Order No. 12,291, 46 Fed. Reg. 13,193, 13,194 (Feb. 19, 1981).

111. *Id.*

112. *Id.* at 13,193–94.

113. *See* STEPHEN G. BREYER & RICHARD B. STEWART, ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES 114 (3d ed. 1992) (citing OMB,

one observes that government programs commonly involve readily quantifiable costs primarily at the front end (and so are only modestly discounted even with the high discount rate), whereas benefits are often diffuse and soft (and so are not easily quantified) and may extend far into the future (and so are reckoned with the ten percent per year discount rate at very low present values). Consider the implications of the analysis on, for example, government subsidized student loan programs, Medicaid benefits, or neo-natal care initiatives.[114]

Additionally, during his second term, President Reagan issued an executive order that established a formal mechanism for regulatory planning, again under the oversight of the OMB.[115] Each agency was required to annually submit to the OMB "a statement of its regulatory policies, goals and objectives for the coming year and information concerning all significant regulatory actions underway or planned."[116] The Director of OMB was to review the agency's program to ensure that all regulatory actions would be "consistent with the goals of the agency and of the Administration" and "to take such actions as may be necessary" to carry out the policies of the Administration "to the extent permitted by law."[117] Like the executive order establishing regulatory impact analysis and OMB review, this second directive declared that actions taken pursuant to its requirements were "intended only to improve the internal management of the Federal government," did not create any enforceable rights or benefits, and were not subject to judicial review.[118]

Early in his first term, President Clinton issued his own executive order,[119] replacing the two issued by Reagan, greatly modifying both the policy

REGULATORY PROGRAM OF THE UNITED STATES GOVERNMENT, April 1, 1988–March 31, 1989, at 32–37).

114. Summarizing the effect of the executive order during the Reagan years, one well informed observer notes:

> During Reagan's tenure, roughly eighty-five rules each year were either returned to the agencies for reconsideration or withdrawn by the agencies in the course of review. Although this figure amounted to less than four percent of all rules OMB reviewed, the rules that provoked OMB's displeasure tended to be among the most important. In 1986, responding to questions from Democrats in Congress, the OMB director could cite only six instances in which agencies had issued rules over OMB's objections: in four, the agencies had acted under judicial order, and in two, the agencies successfully had appealed their position to the White House.

Kagan, *supra* note 108, at 2278–79.

115. Exec. Order No. 12,498, 50 Fed. Reg. 1036, 1036 (Jan. 8, 1985).

116. *Id.* at 1036.

117. *Id*. at 1036, 1038.

118. *Id*. at 1038.

119. Exec. Order No. 12,866, 3 C.F.R. 638 (1994) *reprinted in* 5 U.S.C. 601 app. at 557–61 (formally rescinding Executive Orders 12,291 and 12,496).

orientation and structure of the earlier programs.[120] The Clinton Administration rejected the earlier single-minded emphasis on market failure, focusing more broadly on "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" as the predicate for regulation.[121] Though directing agencies to quantify costs and benefits "to the extent feasible,"[122] the Clinton order also required them to identify and consider "qualitative" costs and benefits, including "distributional impacts" and "equity," enhancement of health and safety, the protection of the natural environment, the reduction of discrimination and bias, and effects on state, local and tribal governmental programs and activities.[123] In contrast to Reagan era secrecy, the Clinton executive order required agencies to disclose RIA information after the issuance of their rules and to identify substantive changes between the drafts submitted for OIRA review and the decisions subsequently adopted.[124] Moreover, the Clinton order prohibited all oral communications between any person not employed in the executive branch and any OIRA employee other than its Administrator, and it established a system for disclosing written ex parte communications with OIRA.[125] As to the decision-making structure, the Clinton approach reoriented OIRA toward the performance of clearinghouse and coordination functions, created a new entity, the Regulatory Working Group (chaired by the Administrator of OIRA and consisting of representatives of agencies with significant regulatory responsibilities, the Vice President, and the President's domestic policy advisors) to perform the critical oversight tasks,[126] and gave the Vice President important responsibilities in resolving disagreements and conflicts between agencies or between OMB and an agency.[127] It should also be mentioned that the Clinton executive order required independent agencies, as well as traditional executive officials, to submit annual regulatory plans, and it created a substantial role for the Vice President in the planning process.[128]

Interestingly, the Clinton executive order limited its regulatory analysis requirements to rules "which the agency intends to have the force and effect of law," thereby exempting interpretive rules, policy statements, and rules of

120. President George H.W. Bush retained both Reagan executive orders, though he established a new body within the White House, the Council on Competitiveness, chaired by the Vice President, to oversee the work of OIRA.

121. Exec. Order No. 12,866, *supra* note 119, at 638–39.

122. *Id*. at 645.

123. *Id*. at 638.

124. *Id*. at 647.

125. *Id*.

126. Exec. Order No. 12,866, *supra* note 119, at 643.

127. *Id*. at 647.

128. *Id*. at 642–43.

agency procedure, organization and practice.[129] To some extent, this may have created another incentive for agencies to avoid the notice and comment process.[130] However, all significant agency actions were covered by the executive order's regulatory planning process, and the Clinton Administration developed several additional ways to influence and control agency actions. The most important was the use of formal directives, typically issued as memoranda to high officials, instructing them to issue a rule or to engage in some other type of agency action.[131] By issuing these directives, the Clinton White House was able to take the initiative in setting and implementing the Administration's regulatory agenda rather than merely reacting to actions proposed by the agencies. President Clinton made increasing use of these memoranda to direct and control agency action, not least on matters at the very center of health law.[132] Additionally, and famously, President Clinton developed the practice of personally and publicly presenting the work product and activities of agencies as accomplishments specifically of his

129. *Id*. at 641.

130. By the 1990s, notice-and-comment rulemaking was widely criticized as demanding, burdensome, and expensive. *See* Richard J. Pierce, Jr., *Seven Ways to Deossify Agency Rulemaking*, 47 ADMIN. L. REV. 59 (1995). More recently, however, the "ossification" thesis has been challenged. *See* William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393 (2000).

131. *See* Kagan, *supra* note 108, at 2294–95 (noting that Clinton issued 107 such directives during his eight years in office, compared to a total of nine during the Reagan years and four during the George H.W. Bush term).

132. *See* Kagan, *supra* note 108, at 2303-05. In 1998, Clinton issued a memorandum ordering agency officials with responsibility for health-care programs to report to him on the extent to which their actions complied with a model "patients' bill of rights" that one of his advisory commissions had developed. *Id.* at 2303. The memorandum also contained

> an order to the Secretary of Labor to propose regulations requiring health plans regulated under ERISA to meet strengthened standards regarding internal appeals of decisions to deny benefits; an order to the Administrator of the Office of Personnel Management, in her management of federal employees' health plans, to contract only with insurance carriers that agreed to comply with the model bill of rights and to propose regulations to ensure enforcement of one of the bill's provisions; and orders to the Secretaries of Health and Human Services (HHS), Veterans Affairs, and Defense to issue specified policy directives, notifications to relevant state officials, and other "appropriate administrative actions" to bring into compliance Medicare, Medicaid, and the veterans' and military health systems.

Id. at 2303–04. Kagan also mentions other directives on health care issued during President Clinton's second term, including one ordering HHS to revise the Medicare program to cover costs of clinical trials of new drugs and medical treatments, another directing various agencies to promote the enrollment of children in Medicaid and the Children's Health Insurance Program, and still another requiring agencies to develop ways to track medical errors and reduce errors associated with misuse of medications and medical devices. *Id.* at 2304–05.

Administration,[133] and this public "appropriation" of policy by the White House is said to have had "a substantive pull on administration decision making"[134] by inducing multifarious efforts to generate the kind of agency actions that the President could later tout.[135] Two striking illustrations of this "presidential appropriation" of policy in the health-care area are President Clinton's August 10, 1995, press conference announcement of the FDA's proposed regulations to reduce youth smoking and his May 23, 1999, announcement that he had directed the Secretary of Labor to issue a rule allowing States to offer paid leave to the parents of newborns through the unemployment insurance system.[136]

President George W. Bush has not revoked the Clinton Administration's regulatory review and planning executive order. However, in February 2002, he issued an executive order that amended the Clinton order primarily by replacing the Vice President with the Chief of Staff to the President in the formal regulation review structure and by routing conflict resolutions directly to the President. [137] Given the extraordinary secrecy of the Bush White House regarding internal decisions, especially after September 11, it is difficult to know the details of the actual process. [138] However, the Bush Administration appears to have made extensive use of the Clinton order's exemption of interpretive rules, policy statements, and rules of agency organization, procedure and practice from the OIRA process.[139] It also appears to have sidestepped the review process when it determines that a new rule decreases rather than increases regulatory burdens.[140] At the same time, the Bush White House seems to have increased the role of the President's domestic policy

133. *Id*. at 2299–302.

134. *Id*. at 2301.

135. *Id*. at 2299–302. *See also* Strauss, *supra* note 108, at 965–68.

136. Kagan, *supra* note 108, at 2282–83.

137. Exec. Order No. 13,258, 67 Fed. Reg. 9385, 9385–86 (Feb. 28, 2002).

138. This is highlighted by extended litigation between the Vice President and environmental groups over disclosure of membership in and activities of the National Energy Policy Development Group (NEPDG), culminating in Cheney v. United States Dist. Court, 124 S. Ct. 2576 (2004) (deciding that the Court of Appeals should have considered separation of powers arguments when considering whether to issue a writ of mandamus to the district court to exempt the Vice President and other members of NEPDG from procedural and disclosure requirements of Federal Advisory Committee Act).

139. *See, e.g.*, Erringer v. Thompson, 371 F.3d 625 (9th Cir. 2004) (holding HHS rules giving criteria to contractors for denial of payment for health services based on local coverage determinations to be "interpretive" rather than "substantive"); Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743 (6th Cir. 2004) (validating HHS "interpretive rule" allowing ALJ to grant summary judgment without an in-person hearing in proceeding against skilled nursing facility for failing to provide patient care).

140. *See, e.g.*, Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222 (Sept. 9, 2003) (the Bush EMTALA rule).

advisors and to have made extensive use of the innovations for control of agency action pioneered by President Clinton.[141] The present situation was perhaps best expressed during a speech by the General Counsel to HHS in March 2004, when he acknowledged that the Department could not get a word published in the Federal Register without White House approval.[142]

III. CONCLUSION

I have tried to make two basic observations about connections between health law and administrative law. First, I have noted that it is by virtue of the creation of statutory/regulatory structures where the operative law is fashioned primarily through rulemaking that health law has come into existence (and has changed and developed) as a distinguishable, reasonably coherent body of law and policy. Second, I have noted that over the past quarter century federal rulemaking has been substantially insulated from the influence and oversight of the federal judiciary and of Congress, while at the same time it has been increasingly put under the power and control of the White House. Now, each of these observations is interesting and noteworthy. But the really important development, in my view, has to do with the combination of the two, for if the content and form of health law is largely a function of federal rulemaking, and if federal rulemaking is largely in the control of the White House, then the present and future of health law and policy is situated right at the center of presidential politics.

There are many who applaud these developments. There is a school of constitutional law scholars who argue for strong presidential control of all agency lawmaking on originalist grounds and out of a strict separation-of-powers ideology.[143] Others endorse White House direction of agency rulemaking on accountability and efficiency considerations. They point out that many of the measures taken to increase White House control, such as the

141. For example, the Bush Administration NIH's withdrawal of the Clinton guidelines for research using stem cells derived from human embryos explains its actions as predicated on the President's decision to limit federal funding for research using only existing embryonic stem cell lines. National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 Fed. Reg. 57,107, 57,107 (Nov. 14, 2001). *See also* The White House, *Fact Sheet: Embryonic Stem Cell Research* (Aug. 9, 2001) (summarizing the President's directive on stem cell research), *at* http://www.whitehouse.gov/news/releases/2001/08/print/20010809-1.html.

142. Alex M. Azar II, Administrative Law Meets Health Law: Inextricable Pairing or Marriage of Convenience?, Keynote Address at the Saint Louis University Health Law Symposium (Mar. 26, 2004), *in* 49 ST. LOUIS U. L.J. 35 (2005).

143. For a sampling of the scholarship generated by the work of these so-called "unitarians," some of whom argue for the unconstitutionality of the "independent agencies," see Steven G. Calabresi & Saikrishna B. Prakash, *The President's Power to Execute the Laws*, 104 YALE L.J. 541 (1994); Martin S. Flaherty, *The Most Dangerous Branch*, 105 YALE L.J. 1725 (1996); Lawrence Lessig & Cass R. Sunstein, *The President and the Administration*, 94 COLUM. L. REV. 1 (1994).

use of RIA's and regulatory agendas and the President's readiness to take personal credit for regulatory initiatives, increase the transparency of rulemaking, enabling the public to better understand both issues and players. They then contend that, given the President's national electoral constituency, the White House is induced to tailor regulatory actions in ways that respond to whatever mandate might be inferred from the last election and that expand the President's base of public support for the next election. Moreover, proponents of presidential control extol the White House's ability to cost-effectively coordinate regulatory actions, to impose "a coherent regulatory philosophy across a range of fields to produce novel regulatory (or for that matter, deregulatory) policies," and to effect "a certain kind of dynamism or energy in administration" that overcomes bureaucratic inertia.[144] Indeed, some proponents of presidential control would reject judicial use of "hard look" review of rules,[145] which are shown to have been fashioned with active presidential influence, and they lament the development of doctrines that enable judges to refuse *Chevron* deference to rules issued with substantial White House involvement.[146]

Now, these arguments based on accountability and efficiency considerations are not without their weaknesses. Claims that the White House is accountable to the general electorate for its regulatory output might be dismissed as so much wishful thinking. Even proponents of presidential control acknowledge that connections between the substance of regulation and those who influence its adoption are as transparent as the occupants of the White House care to have them.[147] And given the generality and the opacity of the typical presidential election campaign, it is quite a reach to assert that the critical details of particular regulatory initiatives enjoy the endorsement of any past or future electorate. Moreover, the purported efficiency advantages of White House control of regulatory actions might just as easily be taken to be vices. In the first place, some activities—the operation of nuclear power plants, for example, or the development, manufacture and distribution of prescription medications—are best performed from within relatively stable rules of the game that are fashioned and implemented with a fairly single-minded focus rather than coordinated and integrated into a politicized and constantly changing regulatory agenda. Secondly, White House adherence to a "coherent regulatory philosophy" can take the form of a top-down imposition of a rigid and dangerous ideology that suppresses statutory goals as easily as it

144. Kagan, *supra* note 108, at 2339, 2341. For an extended argument endorsing White House control along these lines, see *id.* at 2331–46.

145. *Id*. at 2380–83.

146. *See id.* at 2372–80.

147. *See id.* at 2316 (contrasting Clinton and Reagan approaches, noting that the Clinton White House "in large part functioned in public view," while the Reagan administration operated "in private").

can constitute a rational setting of priorities among national problems. Lastly, the "bureaucratic inertia" overcome by the "dynamism" of White House control might manifest, not a lack of imagination or of energy or even of resolve, but the considered judgment of seasoned public servants who, at least as to some matters, have it right. There is, of course, an extremely cynical view of White House control. It sees the existing arrangement as designed for the powerful and the moneyed. On this view, big pharmaceutical and large public hospital corporations and ATLA and the AARP work their deals with the presidential candidates (or their staffs) and then get on with the selling of their candidate, manipulating the electorate in any way they can, and when their candidate wins, they win. But one might also advance a far more measured response to the concentration of regulatory power in the White House. It would acknowledge the importance of setting priorities and the need for policy coordination, and it would see the Presidency as playing the leading role. Yet it would also acknowledge the dangers and risks of exclusive White House control, regretting the past quarter century's loss of checks and balances.[148] And in this latter regard, it would press for institutional change, most concretely for ways to reintroduce the influence and responsibility of Congress, but more generally for a return to an understanding of statutory/regulatory structures as jointly fashioned means for advancing what are often complex social ends.

148. For such a criticism of the development of White House control, see Strauss, *supra* note 108.