Saint Louis University Law Journal

Volume 49
Number 1 *Administrative Law Meets Health Law: Inextricable Pairing or Marriage of Convenience? (Fall 2004)*

Article 7

12-1-2004

The Food and Drug Administration and the Command-and-Control Model of Regulation

Eric R. Claeys
Saint Louis University School of Law

THE FOOD AND DRUG ADMINISTRATION AND THE COMMAND-AND-CONTROL MODEL OF REGULATION

ERIC R. CLAEYS*

I. INTRODUCTION

This Article examines the overarching themes of this conference by studying major legal developments in the Food and Drug Administration (FDA) from roughly 1960 forward. There are several good reasons to conduct an in-depth study of the FDA. First, the FDA provides a concise way to compare developments in regulatory health law in relation to developments in federal administrative law generally. The FDA has been in existence almost as long as there has been federal "administrative law," and its organization and mandate have changed along with elite opinions about the proper objects of federal regulation. Congress established the Food and Drug Administration by statute in 1906,[1] changed its mission dramatically in 1938,[2] and has tinkered with its mandate in important ways since. Thus, while most of the other articles in this symposium cover statutes and regulatory structures created after 1960, the FDA's experience exemplifies how administrative law trends after 1960 affected an agency that already had a mission shaped by regulatory ideas from the Progressive Era and the New Deal.

Second, there are also advantages to studying the theme of this symposium by studying a single agency in depth. Professor Jost's keynote article will surely be more comprehensive than this Article, but when one goes for as much breadth as Jost does, one loses something in depth. In particular, the student of administrative law must pay attention not only when Congress changes the language of enabling statutes; he or she must also pay attention when courts change general doctrines of statutory interpretation and

* Assistant Professor of Law, Saint Louis University.

1. Pure Food and Drug Act of 1906, ch. 3915, 34 Stat. 768 (current version at 21 U.S.C. §§ 301–397 (2000)); PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW 4 (2d ed. 1991); *see also* Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 52–53 (1984); Wallace F. Janssen, *America's First Food and Drug Laws*, 30 FOOD DRUG COSM. L.J. 665, 665 (1975).

2. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301–397); *see* HUTT & MERRILL, *supra* note 1, at 10–13; *see also* CHARLES O. JACKSON, FOOD AND DRUG LEGISLATION IN THE NEW DEAL (1970).

administrative law judicial review. Most of all, the administrative lawyer must follow when the agency changes its policies and practices. The FDA illustrates several of these non-statutory developments.

In the period from 1960 to 1980, the FDA's mission and structure did not change at the wholesale level, but they did change at the retail level. Before 1960, the FDA acted primarily as an executive enforcement agency in its food docket, it acted as a watered- down licensing agency in its drug docket, and it had very limited powers to promulgate legislative rules. As of 1980, the FDA was still primarily an enforcement agency in relation to foods. It was still a licensing agency in relation to drugs, but Congress had strengthened its licensing powers and raised the standards for granting new drug applications. Congress invested the FDA with new licensing and rulemaking powers over medical devices. By 1980, the FDA had also asserted for itself the power to issue legislative rules over topics far wider than what was understood during the 1960s. Thus, the FDA retained the same overall structure and mission, but where Congress granted or the FDA asserted new powers, those powers tended to mirror theories of government and administrative law that prevailed among leading lawyers and academics in the period from 1960 to 1980.

These developments could support a few different conclusions, but I draw three here. First, to the extent that the FDA "grew" or developed toward the Great Society command-and-control model, one of the reasons was the administrative law version of peer pressure. From 1960 forward, administrative law specialists were increasingly dissatisfied with pre-existing models of regulation, and the Great Society command-and-control model was generally accepted as the common cure for the most common problems. Second, the FDA's structure tends to refute the idea that health agencies take on the structure they have to encourage the application of expertise. The FDA uses its experts in food, drug, and device safety in very different ways, and general ideas about expertise cannot explain these variations in FDA practice. Finally, the FDA's success in drug regulation helps explain at least in part why other health-related agencies needed, and still may need, to move toward the Great Society command-and-control model. The FDA's success in drug approval highlights the conditions in which a New Deal adjudicative or licensing-style approach can work. Many other federal health-related agencies do not meet the conditions that allow the FDA to succeed.

Before I begin, let me say one word about my method and the conclusions I will draw. This Article will concentrate heavily on the statutory law and key case law shaping the FDA's mission and structure. These sources are not far-ranging enough to provide a comprehensive description of the FDA's mission and institutional structure. To provide such a comprehensive description, one would need to describe what Richard Merrill has called the FDA's "architecture," and cover the FDA's internal organization, the important legislative and regulatory battles that have shaped the FDA's collective

experience, the institutional culture of different divisions, and other similar factors.[3] Nevertheless, the key statutes and cases should suffice to demonstrate the points I hope to prove.

Part II explains what makes the "Great Society," "rights revolution," or "command-and-control" model for regulation, used by many federal agencies, distinctive from other preceding regulatory models. Part III recounts how the FDA "grew" incompletely toward this model in the period from 1960 to 1980. Part IV interprets the lessons from the FDA's structure and changes to answer this conference's overarching questions about the relationship between health regulation and the Great Society command-and-control model.

II. THE EMERGENCE OF THE 1960S-1970S MODEL FOR COMMAND-AND-CONTROL REGULATION

In federal administrative law, the law depends heavily on history. Different agencies are structured differently and assume different substantive responsibilities depending on when they were enacted. That is because elites—the law professors; top-rank regulatory lawyers in private practice; and the leading public servants in Congress, the Department of Justice, and the agencies—have changed opinions about how best to run agencies. Of course, even when agencies are created in the same era, their enabling acts can differ due to differences in the topics they regulate, in the politics around those topics, or in the interest-group coalitions that pressure the public players in the field. Still, all administrative lawyers would agree that the structures of federal agencies are influenced to a significant degree by theories of law and government that prevailed when the agencies were created.

Cass Sunstein provides a representative and informative way of thinking about these shifts in elite opinion when he posits that there have been five "eras" or "waves" of thought about federal regulation since the nineteenth century.[4] First, during what is (loosely) called the Progressive Era, Congress

3. Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996). Even then, a social scientist might expect a comprehensive account to be more systematic and precise in assessing how different forces have shaped the FDA's policy making, as one can see by reading Theodore R. Marmor's critique of Merrill in *Commentary, Or the Notes and Asides of an FDA Amateur and Professional Political Scientist Specializing in Battles Over the Modern Welfare State*, 82 VA. L. REV. 1867 (1996).

4. CASS R. SUNSTEIN, AFTER THE RIGHTS REVOLUTION: RECONCEIVING THE REGULATORY STATE 18–31 (1990). For confirmation that Sunstein's approach is representative, it is worth noting that Gary Lawson presents a similar view in the opening chapter of his casebook FEDERAL ADMINISTRATIVE LAW 26–28 (3d ed. 2004). Lawson differs sharply from Sunstein in their opinions about the proper objects of federal regulation, on the proper objects of administrative law scholarship, and on what counts as "law" and "doctrine" worth teaching. *Id*. Even so, Lawson in this section presents the opinions of a Progressive, a New Dealer, and several post-1960s commentators to give a sample of the way in which contemporary legal opinions affect opinions about regulation. *Id*.

started creating what looked like modern administrative agencies, such as the Interstate Commerce Commission and the Federal Trade Commission.[5] Congress and courts developed statutory, due process, and interstitial judge-made doctrines to make sure that these new agencies guaranteed trial-type procedures and provided for judicial review.[6] The New Deal then effected a wholesale change both of the objects of and the institutions of government. The New Deal was organized not around private freedoms of property and contract but around public rights of the sort that President Roosevelt listed in his second Bill of Rights—"[t]he right to a useful and remunerative job . . . [t]he right of every businessman, large and small, to trade in an atmosphere of freedom from unfair competition" and so forth.[7] As Cass Sunstein recognizes, "[p]rotection of rights of this sort of course extended the reach of the government in altogether different directions from those marked out by the original property and contract interests."[8] Of course, government could not secure these "affirmative" public rights without a massive structural transformation—in Sunstein's description, "a transfer of power from the states to the federal government, a massive growth in the national bureaucracy, a weakening of the judiciary and of legal controls on politics and administration."[9]

After an intermediate third period, in which the growth of administration subsided and Congress passed the Administrative Procedure Act,[10] administration grew dramatically again in the period of the Great Society and the Nixon presidency. Cass Sunstein calls this period the "rights revolution."[11] The rights revolution built on the basic institutional and substantive commitments of the New Deal, but with important modifications.[12] First, substantively, national elites extended the logic of the "affirmative rights" touted during the New Deal to new categories of rights.[13] The New Deal had applied affirmative rights logic to economic interests, such as the worker's

5. SUNSTEIN, *supra* note 4, at 19.

6. *See* STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY 19–35 (5th ed. 2002).

7. Franklin D. Roosevelt, Message to the Congress on the State of the Union (Jan. 11, 1944), *reprinted in* 13 THE PUBLIC PAPERS AND ADDRESSES OF FRANKLIN D. ROOSEVELT, at 32, 41 (1969). Sunstein has written on the symbolic importance of Roosevelt's Second Bill of Rights. *See* CASS R. SUNSTEIN, THE SECOND BILL OF RIGHTS: FDR'S UNFINISHED REVOLUTION AND WHY WE NEED IT MORE THAN EVER (2004).

8. SUNSTEIN, *supra* note 4, at 22.

9. *Id.* at 23.

10. Administrative Procedure Act, ch. 324, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. §§ 551–559, 701–706 (2000)). For discussion of the phase Breyer calls "the Maturation of the Traditional Model of Administrative Law," *see* BREYER ET AL., *supra* note 6, at 24–26.

11. SUNSTEIN, *supra* note 4, at 24.

12. *Id*. at 24–29.

13. *Id*. at 24.

right to a job, a fair wage, and collective bargaining, and the business's right to a level playing field in competition.[14] By the 1960s, as Sunstein recounts, "Congress and the President [were] invok[ing] the rhetorical power of the civil rights movement on behalf of causes involving not only discrimination on various grounds, but also the environment, workers, the poor, and even consumers."[15] Congress passed laws setting out to accomplish "bold regulatory initiatives in a number of new areas, most prominently involving air and water pollution, discrimination, and management of social risks in general."[16] This demand for new rights encouraged the creation of many of the health-related agencies and initiatives that Professor Jost recounts in his keynote address.

Separately, Congress also tinkered with the New Deal blueprint for administrative government during the "rights revolution" period. While the rights revolution marked "an outburst of enthusiasm for regulatory solutions to public problems," Sunstein recognizes, this outburst occurred as "[t]he work of administrative agencies came under increasingly sharp attack on several fronts."[17] One common theme was "capture," the concern that agencies were becoming what Gary Lawson calls "pawns of the regulated industries."[18] Another was that agencies proceeded unfairly because they decided similar adjudications differently.[19]

Third, and most important, New Deal agencies, which relied heavily on adjudications to make new law, were not making new law quickly enough to secure the many affirmative rights Congress expected them to secure. To appreciate elite frustration, consider the case of James Landis. Landis's 1938 book *The Administrative Process*[20] is still regarded as an excellent and representative justification of the New Deal independent commission. In 1960, however, in response to a request by President-elect Kennedy, Landis wrote a report despairing of the effectiveness of administrative agencies. "A prime criticism of the regulatory agencies is their failure to develop broad policies in the areas subject to their jurisdiction."[21] Landis attributed this problem to an "inability to fashion viable patterns through the process of adjudication."[22] He

14. *Id*. at 21–22.

15. *Id*. at 24–25.

16. SUNSTEIN, supra note 4, at 25–26.

17. BREYER ET AL., *supra* note 6, at 26.

18. LAWSON, *supra* note 4, at 10; *see, e.g.*, ROGER G. NOLL, REFORMING REGULATION 40–43 (1971); Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 CHI.-KENT L. REV. 1039, 1050–52 (1997).

19. *See, e.g.*, KENNETH CULP DAVIS, DISCRETIONARY JUSTICE 66 (1971).

20. JAMES M. LANDIS, THE ADMINISTRATIVE PROCESS (1938).

21. STAFF OF SENATE SUBCOMM. ON ADMIN. PRACTICE & PROCEDURE TO THE SENATE COMM. ON THE JUDICIARY, 86TH CONG., REPORT ON REGULATORY AGENCIES TO THE PRESIDENT-ELECT 22 (Comm. Print 1960) (written by James M. Landis).

22. *Id*.

called for "other methods of policy planning,"[23] especially rulemaking, because "[p]olicy also emanates from rule-making where forward-planning is more possible."[24]

As a result, Great Society-vintage agencies and enabling statutes followed a slightly different model from New Deal-vintage agencies and statutes. Unlike the New Deal model, the Great Society model extended collective securities to a wider range of conduct. In addition, "rights revolution" enabling statutes tried to conquer social problems on a wide range of fronts. The statutes were often ambitious in scope. The statutory preambles declared problems like clean air, clean water, workplace safety, and traffic safety to be national menaces; the operative language gave the agencies broad enforcement powers to reduce or eliminate these problems.[25] Separately, to avoid many of the capture problems associated with the New Deal model, it abandoned the multi-member independent commission and embraced the single-headed executive agency model.

Finally, because Landis and other elites were so frustrated with "one case at a time" administrative adjudication, Great Society-vintage agencies acquired much more sweeping rulemaking powers. The NLRB, created in the New Deal, makes a great deal of law in unfair-labor-practice adjudications; the FCC, created in the 1920s, had a long tradition of making law through licensing proceedings. Agencies created after 1960, by contrast, were expected to make law by promulgating binding performance standards and other binding, general, and forward-looking rules of conduct.

The Food and Drug Administration makes an extremely interesting case study because it is a hybrid of these different periods. Different divisions of the FDA reflect different eras of thought about federal administration. Structurally, the FDA looks more like a Great Society-vintage single-headed agency than a New Deal multi-member independent commission. In reality, however, it follows the single-headed model because it was organized in the late nineteenth and early twentieth centuries, during the Progressive Era, when the independent commission model was of doubtful constitutionality.[26]

More important, in terms of its functions, the FDA was, as of 1955, in part a Progressive Era enforcement agency and in part a New Deal licensing agency. In its food and cosmetic dockets, the FDA acted then, and to a large extent still acts now, as a specialized enforcement agency—as a specialized adjunct to federal prosecutors in the Department of Justice. While the FDA issues guidelines and tries to set enforcement policies relating to foods and cosmetics, it does not oversee the marketing of foods and cosmetics in any

23. *Id*.
24. *Id*. at 18.
25. SUNSTEIN, *supra* note 4, at 29.
26. *See* LAWSON, *supra* note 4, at 9.

centralized way. Instead, it identifies food and cosmetics on the market that might be adulterated or misbranded and then cooperates with U.S. Attorneys and Justice Department officials to control these articles with traditional law-enforcement techniques. In its drug docket, by contrast, the FDA acted more like a New Deal licensing agency. Drug companies were required to notify the FDA before they brought new drugs to market, and the FDA had the opportunity to review these drugs for their safety. While the FDA concentrated on prosecution and the review of drug safety, it was given exceedingly narrow powers to promulgate "substantive" or "legislative rules"—food, drug, and other standards as binding and enforceable as provisions of the Food, Drug, and Cosmetic Act. Each of these features of the FDA's structure and powers, however, changed significantly starting in the late 1950s.

III. DEVELOPMENTS IN FOOD AND DRUG LAW

The FDA changed along with the times during the 1960s and 1970s. The FDA, one should note, did *not* undergo any wholesale overhaul in its mission or structure. Agencies tend to retain their basic structure and mission once created. Absent unusual circumstances, factors including inertia, reliance interests, and interest-group politics deter Congress from drastically restructuring the agencies it supervises. Congress occasionally reorganizes agencies in response to crises such as 9/11, but 9/11 shows how exceptional circumstances must be to break from the general rules. Even so, when Congress updated the Food, Drug, and Cosmetic Act, some of the changes carried the spirit of the Great Society with them. More interesting, the FDA's mandate changed as legal elites outside Congress—FDA lawyers and the courts—cited general administrative law principles that were *au courant* at the time to read the Food, Drug, and Cosmetic Act very differently from how it had been read during the New Deal.

A. The Additive Amendments and the Delaney Clause

Congress gave a hint at what would become the "rights revolution" when it enacted several major amendments to the Food, Drug, and Cosmetic Act in the early 1960s. Generally, the FDA regulates the sale of food more leniently than many other articles in its jurisdiction. Again, "food" regulation follows the pre-New Deal, "enforcement" blueprint. Unlike devices and drugs, the FDA does not require pre-approval to sell foods. In addition, unlike drugs and medical devices, food is presumed safe until the FDA specifically proves it to be dangerous, not the other way around. To prove food is adulterated, the FDA must prove either that it contains an added poisonous or deleterious substance that creates a possibility that the food may be injurious to health or that it contains an unadded substance that ordinarily renders it injurious to

health.[27] As interpreted, the FDA presumes food is safe but goes after added substances if they create any possibility of threat to the health of any consumer.[28]

In 1958 and 1960, Congress tightened the safety standards for food additives and color additives, respectively. The concerns expressed in congressional debates reflected the kinds of health and consumer concerns that would become popular arguments in the 1960s. In the legislative record for the Food Additives Amendment of 1958, Senators complained that the FDA needed two or more years of proof to document a threat to health.[29] As one Senate report complained, "[y]et, until that proof is forthcoming, an unscrupulous processor of foodstuffs is perfectly free to purvey to millions of our people foodstuffs containing additives which may or may not be capable of producing illness, debility, or death."[30]

The 1958 Amendments provided a solution. For additives not already in common use or generally recognized by experts as safe,[31] the law switched from a presumption that the product is safe to a presumption it is not, and put the burden on the manufacturer to prove otherwise.[32] The same Senate report explained: "[T]he processor who wants to add a new and unproven additive [should be required] to accept the responsibility now voluntarily borne by all responsible food processors of first proving it to be safe for ingestion by human beings."[33] Congress followed a similar approach with respect to color additives in the Color Additive Amendments of 1960.[34]

These additive amendments created even less tolerance for additives containing cancer-causing substances. The Food and Cosmetics Additive Amendments also contained language popularly known as the "Delaney Clause." These clauses instruct the FDA "[t]hat no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal."[35] This language comes from section 409 of the Act, relating to food additives, but the Act contains similar language for color additives, courtesy of the Color Additive

27. *See* 21 U.S.C. § 342(a)(1) (2000); United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 406 (1914).

28. *See Lexington*, 232 U.S. at 411.

29. S. REP. NO. 85-2422, at 1 (1958).

30. *Id.*

31. Food Additives Amendment of 1958, Pub. L. No. 85-929, § 2, 72 Stat. 1784, 1784 (codified at 21 U.S.C. § 321(s) (2000)).

32. 21 U.S.C. §§ 348(a), (b)(1), (c)(3)(A) (2000)). This statute also allows the FDA to set tolerance limits for additives on specified conditions. 21 U.S.C. § 348(c)(4) (2000).

33. S. REP. NO. 85-2422, at 2.

34. Color Additive Amendments of 1960, Pub. L. No. 86-618, § 706(a), 74 Stat. 397, 399 (codified at 21 U.S.C. § 379e(a) (2000)).

35. 21 U.S.C. § 348(c)(3)(A).

Amendments of 1960.[36] Among scholars and lawyers who work with risk management, the Delaney Clauses serve as a metaphor for overzealous regulation.[37]

Even with these changes, food regulation is more interesting conceptually than practically. The regulation of food illustrates nicely the relatively *laissez-faire* approach to public regulation in the early twentieth century. The regulation of additives, especially cancer-causing additives, foreshadows and illustrates the penchant for "zero tolerance" typical of some Great Society-vintage statutes. Yet even with the additive amendments, the FDA's basic approach to food regulation remained in the "enforcement" model.

B. Drugs: Pre-approval and Clinical Trials

By contrast, in 1962 Congress also passed far-reaching amendments to the FDA's drug provisions. These amendments completed the FDA's move toward a "licensing" model for drug regulation. The 1938 Act required manufacturers to notify the FDA of their intentions to market "new drugs" and to allow FDA staff time to assess the safety of those drugs,[38] but it did not bar manufacturers from marketing and selling drugs without FDA pre-market approval.[39] In response to a tragedy involving the drug thalidomide,[40] Congress also amended the Act in 1962 in several respects. First, and most important, Congress converted, in Richard Merrill's words, "what had been a pre-market *notification* system . . . into a pre-market *approval* system."[41] The

36. Color Additive Amendments of 1960, Pub. L. No. 86-618 § 706(b)(5)(B), 74 Stat. 397, 400 (codified at 21 U.S.C. § 379e(b)(5)(B) (2000)).

> A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal . . . .

Id.

37. *See, e.g.*, FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 179 (2000) (Breyer, J., dissenting) (citing the Delaney amendments to illustrate why "experience counsels against an overly rigid interpretation of the FDCA that is divorced from the statute's overall health-protecting purposes"); Margaret Gilhooley, *Plain Meaning, Absurd Results and the Legislative Purpose: The Interpretation of the Delaney Clause*, 40 ADMIN. L. REV. 267 (1988).

38. Food, Drug, and Cosmetic Act, ch. 675, § 505, 52 Stat. 1040, 1052–53 (1938) (codified at 21 U.S.C. § 355 (2000)).

39. *See* Merrill, *supra* note 3, at 1762–64 (discussing problems with the 1938 enforcement scheme).

40. *See* THE INSIGHT TEAM OF THE *SUNDAY TIMES* OF LONDON, SUFFER THE CHILDREN: THE STORY OF THALIDOMIDE (1979).

41. Merrill, *supra* note 3, at 1764–65 (emphasis added).

amendments changed the law to deem adulterated any new drug for which the FDA had not yet approved a new drug application.[42]

Second, Congress changed the substantive standards for determining whether a new drug is adulterated. It added a new criterion beyond safety—effectiveness for the drug's intended use under prescribed conditions.[43] Congress also substantially increased the standard of proof to show a drug is not adulterated. The amendments required the company to prove both safety and effectiveness by "substantial evidence," which section 505(d) of the Act defines to mean "evidence consisting of adequate and well-controlled investigations"—which means more than one investigation—"including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."[44]

No doubt, these amendments were passed in part in response to a public backlash against the thalidomide scare. At the same time, they also reflect in part the "no tolerance" mentality that would become characteristic of later Great Society regulatory programs. As Richard Merrill explains, "Citizens may complain when local police fail to curtail unlawful or violent activity, but few believe that even the best-functioning police force can solve, much less prevent all crimes."[45] Courtesy of the 1962 amendments, however, the "FDA is believed to have a different role, a responsibility to prevent harm before it occurs. . . . [I]n some sense, the agency becomes a warrantor of manufacturer compliance with the rules that govern drug development and marketing."[46]

C. The Medical Device Amendments

With respect to medical devices, however, Congress took a different route. The 1976 Medical Device Amendments show how general theories of government can run into serious limits when applied to particulars. In the late 1960s and early 1970s, federal appeals courts issued decisions upholding FDA attempts to regulate as FDA "drugs" articles that were "devices" by ordinary, common-sense understandings of the difference between "devices" and "drugs."[47] These developments prompted Congress and device manufacturers

42. Drug Amendments of 1962, Pub. L. No. 87-781, §104(a), 76 Stat. 780, 784 (codified at 21 U.S.C. § 355(a)).

43. 21 U.S.C. § 355(d)(5).

44. 21 U.S.C. § 355(d).

45. Merrill, *supra* note 3, at 1768.

46. *Id.*

47. *See, e.g.*, United States v. An Article of Drug . . . Bacto-Unidisk . . . , 394 U.S. 784 (1969) (holding an antibiotic sensitivity disk to be a "drug"); AMP Inc. v. Gardner, 389 F.2d 825 (2d Cir. 1968) (holding a ligature product to be a "drug").

to consider amending the FDCA to provide medical devices with a regulatory track different from the pre-approval track for drugs.[48]

If "rights-revolution" ideas were the only factor influencing the FDA and Congress, Congress could have chosen to do very little—to sit back and encourage the FDA to classify more device-seeming articles as "drugs." Legally, since the FDA may classify as a drug any "articles (other than food) intended to affect the structure or any function of the body" or any article intended to have a therapeutic effect, the statutory definitions for drugs gave the FDA great authority to classify medical devices as FDA drugs.[49] Politically, medical devices create the same sorts of incentives regulators face with drugs—to err on the side of caution. FDA regulators typically get little blame for stifling innovation when they take a long time to pre-approve a medical device; they get a great deal of blame when a device or drug causes harm to a substantial group of consumers. To illustrate, in the early 1970s, the Dalkon Shield generated unwanted pregnancies, infections, and deaths.[50] In the late 1970s and 1980s, the FDA was criticized heavily for failing to do more to regulate silicone breast implants.[51] These criticisms were similar to the criticisms it experienced in the early 1960s after the thalidomide scare.[52] Thus, elite opinions about administration and popular political opinion about health risks gave Congress strong incentives to continue to allow the FDA to extend the post-1962 new-drug model to devices.

Yet this was not the approach Congress and the FDA chose to take.[53] In 1969, the Association for the Advancement of Medical Instrumentation sponsored and the National Institutes of Health funded a short conference about the proper scope of medical-device regulation. The conferees recommended that devices be regulated differently from drugs for five reasons: (1) Medical devices are subject to frequent innovations; (2) relatively speaking, professionals tend to use devices on patients, while patients tend to use drugs on themselves; (3) relatively speaking, physicians develop devices, while pharmaceutical companies develop drugs; (4) device-making companies are usually less fully capitalized than drug companies; and (5) devices usually

48. *See* Peter Barton Hutt et al., *The Standard of Evidence Required for Pre-market Approval Under the Medical Device Amendments of 1976*, 47 FOOD & DRUG L.J. 605, 612 (1992).

49. *See* 21 U.S.C. § 321(g)(1) (2000).

50. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996).

51. Merrill, *supra* note 3, at 1814.

52. *See* FDA Seeks Panel's Advice on Silicone Breast Implants, FDA Talk Paper No. T88-81 (Nov. 3, 1988); *see also* Merrill, *supra* note 3, at 1814.

53. The following discussion relies on the comprehensive discussion of the legislative history of the Medical Device Amendments of 1976 written by Peter Barton Hutt, Jr., Richard A. Merrill, and Alan N. Kirschenbaum, *supra* note 48, at 610–26.

generate less revenue than drugs.[54] Later, 1973 and 1975 congressional hearings developed these differences. As Peter Hutt, Richard Merrill, and Alan Kirschenbaum recount, at these hearings, "[i]ndustry representatives agreed that, because devices, unlike drugs, are not metabolized, their results are observed more readily and predicted without the necessity of elaborate clinical trials. FDA representatives acknowledged that extensive clinical testing was unnecessary for many [device] products."[55] Meanwhile, doctors testified that it was difficult or impossible to test devices by the same controlled, double-blind tests as drugs because devices operate on and outside the body. They also testified that the development protocols for devices built in more testing, consistent with medical norms, than corresponding protocols for new drugs.[56]

When Congress passed the Medical Device Amendments of 1976, it considered these differences between drugs and devices—in the economics of the firms and markets, in the ability to test the product, and, above all, in the need for extensive pre-market testing and licensure for the product. First, the 1976 Amendments grandfather devices on the market before 1976 unless and until the FDA initiates regulatory action to re-classify them.[57] Second, a device maker need not seek pre-market approval for any device substantially equivalent to a pre-1976 grandfathered device[58]—the manufacturer need only provide the FDA ninety days advance notice of its intent to market and of the substantial-equivalence claim.[59] These two exceptions exempt many devices from FDA pre-approval. One 1990 U.S. House of Representatives study claimed that more than 80% of the devices marketed since 1976 have been treated as substantially equivalent to grandfathered devices; a Senate study claimed the number was 95%.[60] By contrast, given how the FDA and the

54. *See Report of the National Conference on Medical Devices*, 3 JAAMI 647 (1969).

55. Hutt et al., *supra* note 48, at 618 (footnote omitted); *see also Medical Devices: Hearings Before the Subcomm. on Pub. Health and Env't of the House Comm. on Interstate and Foreign Commerce*, 93d Cong. (1973); *Medical Device Amendments, 1973: Hearings Before the Subcomm. on Health of the Senate Comm. on Labor and Pub. Welfare*, 93d Cong. (1973); *Medical Device Amendments of 1975: Hearings Before the Subcomm. on Health and the Env't of the House Comm. on Interstate and Foreign Commerce*, 94th Cong. (1975).

56. *See* Hutt et al., *supra* note 48, at 619.

57. *See* 21 U.S.C. § 360e(b)(1)(A) (2000).

58. *See* 21 U.S.C. §§ 360c(f)(1), 360e(b)(1)(B). For the statutory definition of "substantially equivalent," see 21 U.S.C. § 360c(i)(1)(A).

59. *See* 21 U.S.C. § 360(k) (requiring device makers to notify the FDA ninety days before introducing a device into interstate commerce); *see also* Medtronic, Inc. v. Lohr, 518 U.S. 470, 478 (1996).

60. *See* S. REP. NO. 101-513, at 15 (1990); *see also Medtronic*, 518 U.S. at 479–80; LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, & MEDICAL TECHNOLOGY 246 (2002); Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Pre-market Review of*

Supreme Court construe the "drug" provisions of the Act, it is legally impossible for a drug manufacturer to bring a drug to market without obtaining pre-market approval under section 505 of the Act.[61]

Separately, even when device makers may not use the pre-market notification route, the pre-market-approval process is more lenient for device makers than the new drug approval process. Even for the most rigorously scrutinized category of devices, Class III devices, the manufacturer need not show safety and effectiveness with proof from multiple well-controlled clinical trials; it need only show a "reasonable assurance" of safety and effectiveness under the prescribed conditions.[62] Thus, Congress and the FDA both broke from the general blueprint for rights-revolution regulation to design a system of regulation more likely to reflect the economic, physical, safety, and use differences between drugs and devices.

D. Entrepreneurship at the Agency: The FDA's Rulemaking Powers

But Congress was not the only entity active in changing the FDA's mandate. FDA officials also took a proactive part in reshaping their own powers to conform to the "rights-revolution" model for agencies. In particular, through a pattern of enforcement and test-case litigation, enterprising FDA lawyers managed to convince prominent federal courts to recognize in the FDA rulemaking powers considerably broader than those originally envisioned. Because Thomas Merrill and Kathryn Tongue Watts have recounted this story in detail, I will simply summarize the relevant points of their discussion and add a few details extraneous to their argument but relevant to mine.[63]

The 1938 Federal Food, Drug, and Cosmetic Act vested in the FDA two new classes of regulatory powers. The 1906 Act had given the FDA power to promulgate advisory regulations, but not legislative rules with the force of law, to provide definitions and standards of identity for foods.[64] The 1938 Act increased the FDA's rulemaking powers by vesting in the FDA power to issue

Medical Devices, 56 FOOD & DRUG L.J. 317 (2001); David A. Kessler et al., *The Federal Regulation of Medical Devices*, 317 NEW ENG. J. MED. 357, 359 (1987).

61. *See* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 629–30 (1973) (approving FDA regulations construing the phrase "generally recognized as safe and effective" within the definition of a "new drug" under 21 U.S.C. § 321(p) to require the same proof of safety and effectiveness as a new drug application under 21 U.S.C. § 355); United States v. 50 Boxes More or Less etc., 909 F.2d 24 (1st Cir. 1990).

62. 21 U.S.C. §§ 360e(d)(2)(A), (B).

63. Thomas W. Merrill & Kathryn Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002).

64. *See* Wesley E. Forte, *The GMP Regulations and the Proper Scope of FDA Rulemaking Authority*, 56 GEO. L.J. 688, 692 (1968); C. W. Crawford, *Ten Years of Food Standardization*, 3 FOOD DRUG COSM. L.Q. 243, 244–45 (1948).

legislative rules with the force of law for definitions and identity standards for food, dietary-use claims on food labeling, regulations setting precautionary standards deteriorative drugs, and three other specific topics relating to the identity, adulteration, or misbranding of food and drugs.[65] At the same time, by contemporary standards, this rulemaking grant was quite narrow and restricted. Because section 701(e) of the 1938 Act required the FDA to provide a "hearing" and base its decision "only on substantial evidence of record," the FDA was required to follow in these new legislative rulemakings the cumbersome procedural requirement that later came to be known as "formal" rulemaking requirements.[66] More important, because it expressly vested legislative-rulemaking power in the FDA only for the six topics expressly enumerated in section 701(e), the 1938 Act tacitly withheld the power to make legislative rules on virtually every other substance in the FDA's jurisdiction.

Section 701(a) of the 1938 Act, however, gave the FDA "authority to promulgate regulations for the efficient enforcement of this Act."[67] Based on the conventions of the time, section 701(a) only authorized the FDA to promulgate interpretive regulations, not legislative regulations with the force of law. As Merrill and Watts explain after a close review of the 1938 Act, "nothing in the Act indicated that a regulation issued under the authority of section 701(a) would subject the violator to any sanction."[68] The differences between sections 701(a) and 701(e) reinforced this conclusion. Section 701(a) did not then and does not now establish any requirements for a closed record of evidence and a trial-type hearing.[69] It would have been incongruous if the FDA had needed to follow elaborate evidence and hearing requirements for about half a dozen rulemakings, but no similar requirements for rulemakings on much more important issues in its food and drug dockets. In other words, the FDA's narrow rulemaking powers confirmed what was apparent from the rest of the 1938 Act. Except where 701(e) gave the FDA rulemaking powers to the contrary, the FDA was primarily an enforcement agency for its food and cosmetics dockets, and primarily a licensing agency for its drug docket.

Congress confirmed this understanding of section 701(a) over the years by amending the Act to insert sections granting the FDA more legislative-rulemaking powers over targeted subjects. For instance, in the 1976 Medical Device Amendments, in what is now section 513 of the Act, Congress vested in the FDA power to classify medical devices into one of the three statutory

65. Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1055 (1938) (codified as amended at 21 U.S.C. § 371 (2000)).

66. *Id*. For the most famous judicial discussion of "formal" rulemaking, see United States v. Fla. E. Coast Ry. Co., 410 U.S. 224, 238–45 (1973).

67. Ch. 675, 52 Stat. at 1055.

68. Merrill & Watts, *supra* note 63, at 515.

69. *See* 21 U.S.C. § 371.

categories.[70] Amended section 514 of the Act vested in the FDA power to set performance standards for medical devices.[71] Amended section 515 vested in the FDA power to promulgate regulations for medical device manufacturers to follow in order to gain approval of Class III medical devices, the most dangerous and closely regulated class of medical devices.[72] Amended section 516 vested in the FDA power to promulgate regulations banning devices it proved to be substantially deceptive or unreasonably dangerous.[73] All of these enabling statutes contemplate that the FDA will promulgate legislative rules with the force of law and subject to FDA enforcement for their violation.[74] Consistent with trends throughout administrative law in the 1960s and 1970s, all of these rulemaking statutes made it easier than section 701(e) for the FDA to make legislative rules. None required the FDA to provide a formal, trial-type hearing on a closed record; all allowed the FDA to proceed by informal, "notice and comment" rulemaking requirements consistent with section 553 of the Administrative Procedure Act.[75] Congress thus "ratified" the narrow understanding of section 701(a): If Section 701(a) authorized the FDA to promulgate legislative rules with informal notice-and-comment procedures, all of these medical-device rulemaking powers would have been unnecessary.[76]

At roughly the same time as Congress was giving the FDA new statutory rulemaking powers, however, the FDA made what one treatise called a "belated discovery" that section 701(a) of the Act had given the FDA

70. *See* 21 U.S.C. § 360c(d).

71. *See* 21 U.S.C. § 360d(b).

72. *See* 21 U.S.C. § 360e(b).

73. *See* 21 U.S.C. § 360f(a).

74. *See* 21 U.S.C. §§ 352(f), (g) (2000) (defining medical devices as adulterated if they violate specified regulations); *see also* 21 U.S.C. §§ 331(b), (c) (making it a federal offense to sell or receive an adulterated medical device in interstate commerce, or to adulterate a device while it is in interstate commerce).

75. *See* 5 U.S.C. § 553(b); Conn. Light & Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525 (D.C. Cir. 1982). Section 516 gives the FDA power to make medical-device bans effective immediately upon publication as long as it provides notice and opportunity for comment as expeditiously as possible. *See* 21 U.S.C. § 360f(b). This provision is not necessarily inconsistent with section 553 of the APA, however, because section 553 allows agencies to suspend notice-and-comment procedures when they have good cause. 5 U.S.C. § 553(b)(3)(B); *see also* Tenn. Gas Pipeline Co. v. Fed. Energy Regulatory Comm'n, 969 F.2d 1141 (D.C. Cir. 1992).

76. For a recent illustration of this "ratification" principle at work in statutory interpretation, see FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000) (holding that the FDA was barred from treating nicotine as a "drug" and cigarettes as "combination" drug-device products, both within the jurisdiction of the Act, because Congress had "ratified" the FDA's position that these articles were not within FDA jurisdiction by passing several statutes regulating nicotine and cigarettes inconsistently with the Federal Food, Drug, and Cosmetic Act).

legislative-rulemaking powers all along.[77] Peter Barton Hutt served as the FDA's chief counsel from 1971 to 1975.[78] During his tenure, he advocated reading the Act as a "constitution."[79] He read section 701(a) to provide "ample legal authority" for the FDA to issue legislative rules.[80]

As a legal argument, Hutt's reading of section 701(a) may have run contrary to long-standing practice, but it was quite plausible in the context of the 1970s. Read in isolation, section 701(a) seems to confer a generous grant of rulemaking power. Again, it gives the FDA power to "promulgate regulations for the efficient enforcement" of the Act.[81] To read section 701(a) narrowly, one must remember to read it *in pari materia* with the more cumbersome formal-rulemaking provisions set forth in section 701(e), and in the context of 1938, when administrative enabling statutes tended to be much more grudging in their grants of general rulemaking authority. In the context of the "rights revolution" around 1975, however, these background assumptions for reading enabling language no longer made any sense. Little wonder, then, if the Second Circuit validated the FDA's exercise of legislative-rulemaking powers in two decisions in 1978 and 1981.[82] In the 1981 case, administrative-law expert Judge Henry Friendly read section 701(a) "with the eyes of 1980" and concluded it gave the FDA power to promulgate both "substantive as well as procedural" regulations.[83]

Hutt's entrepreneurship and the Second Circuit's statutory construction gave the FDA the power to make legislative rules on a par with the EPA, OSHA, and other agencies created during the Great Society and the Nixon years. The shift should not be overstated. To a degree unusual for most agencies, the FDA still sets policy by generating guidelines and interpretive rules. The FDA has considerable freedom to generate "shadow law." This freedom is especially wide in drug regulation because the new drug approval

77. 1 JAMES T. O'REILLY, FOOD AND DRUG ADMINISTRATION § 4.02, at 4-10 (1979). *Compare* Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973), *with* Pharmaceutical Mfrs. Ass'n v. Finch, 307 F. Supp. 858 (D. Del. 1970) (indicating that section 701(a) can trigger legislative or substantive regulations without so holding).

78. HUTT & MERRILL, *supra* note 1, at xiii.

79. Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 178 (1973).

80. *Id.* at 185. *See also* Merrill & Watts, *supra* note 63, at 558–60.

81. 21 U.S.C. § 371(a) (2000).

82. *See* Nat'l Ass'n of Pharmaceutical Mfrs. v. FDA, 637 F.2d 877 (2d Cir. 1981); Nat'l Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688 (2d Cir. 1975).

83. *Nat'l Ass'n of Pharmaceutical Mfrs.*, 637 F.2d at 879. *See also id.* at 880 ("In the interest of historical accuracy, it should be noted that at one time it was widely understood that generalized grants of rulemaking authority conferred power only to make rules of a procedural or an interpretative nature, and not binding substantive regulations, for which a specific delegation was thought necessary."). For an insightful discussion of Friendly's opinion, see Merrill & Watts, *supra* note 63, at 562–65.

process and the economic pressures to rush new drugs to market make it suicidal for manufacturers to challenge the FDA's constructions of its statutes.[84] Even so, as one leading treatise observed at the time, "[t]he Food and Drug Administration grew during the late 1960s and the 1970s from a law enforcement agency which brought deterrent actions against violators, into a more paper-bound generator of rules and regulations."[85]

E. Changes in the Courts: The Rise of Purposivism

As the Second Circuit's active participation in expanding the FDA's rulemaking powers shows, courts were not passive bystanders in the expansion of administrative power during the 1960s and 1970s. Courts changed generally applicable canons of construction to accommodate the rise of the Great Society regulatory agency. For instance, one 1956 case construed the Food, Drug, and Cosmetic Act not to allow the FDA to seek restitution relief, in large part because "[t]he use of the extraordinary remedies of equity in governmental litigation should never be permitted by the courts unless clearly authorized by the statute in express terms."[86] After several decades of Supreme Court precedent attacking this presumption, a 1999 appellate court could confidently reverse the presumption: "Absent a clear command by Congress that a statute providing for equitable relief excludes certain forms of such relief, this court will presume the full scope of equitable powers may be exercised."[87]

The most important contribution by courts related to how they construed agency organic statutes. The 1960s and 1970s witnessed the rise of a style of public-law statutory interpretation known as "purposivism."

The U.S. Supreme Court encouraged the use of purposivism in several FDA cases in the late 1960s and early 1970s. In *United States v. An Article of Drug Bacto-Unidisk*, for instance, the Supreme Court considered a challenge by the maker of a bacteria sensitivity disk to the FDA's decision to classify the disk as a "drug" and not as a (pre-1976 Amendment) "device."[88] The disk maker's argument was probably weak in any event, because the Act's definition of "drug" is quite broad. Even on the most "plain-meaning" reading of "drug," a diagnostic bacteria sensitivity disk counts as an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in

84. *See* NOAH & NOAH, *supra* note 60, at 104–05; Lars Noah, *The FDA's New Policy on Guidelines: Having Your Cake and Eating It Too*, 47 CATH. U. L. REV. 113 (1997); Lars Noah, *Administrative Arm-Twisting in the Shadow of Congressional Delegations of Authority*, 1997 WIS. L. REV. 873 (1997).

85. O'REILLY, *supra* note 77, at 4-7.

86. United States v. Parkinson, 240 F.2d 918, 922 (9th Cir. 1956).

87. United States v. Universal Mgmt. Servs., Inc., 191 F.3d 750, 761 (6th Cir. 1999).

88. 394 U.S. 784 (1969).

man."[89] The Supreme Court noted this plain-meaning argument but went on to add that "we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health."[90]

Similarly, in *Weinberger v. Hynson, Westcott & Dunning*, the Court considered the legality of the FDA's decision to classify generic drugs as "new drugs," bound by the same pre-approval and withdrawal rules as drugs manufactured by mainline pharmaceutical companies.[91] Because this issue arose before Congress passed a comprehensive set of rules for generic drugs in the 1984 Hatch-Waxman Amendments, it had great practical importance.[92] The Court upheld the FDA's interpretations of the relevant statutes. It rejected the argument that the generic drug manufacturers were entitled to individual adjudicative hearings before the FDA suspended their rights to sell their drugs. "To require separate judicial proceedings to be brought against each, as if each were the owner of a Black Acre being condemned, would be to create delay where in the interests of public health there should be prompt action."[93] On that basis, the Court "interpret[ed] separate provisions of a single Act . . . to give the Act 'the most harmonious, comprehensive meaning possible' in light of the legislative policy and purpose."[94]

Purposivism gave the FDA an argument for reading the Food, Drug, and Cosmetic Act more expansively at the margins of its jurisdiction and its powers. One must be careful not to attribute too much importance to purposivism, because the definitional statutes of the FDCA and many of the FDA's powers over adulteration and misbranding are quite broad even on a fairly narrow reading. Even so, purposivism encouraged the FDA to approach its jurisdiction differently. As the Act is written, jurisdictional issues are separate from safety issues. If the FDA means to regulate a substance as a drug, it must prove first that the article is intended to have a therapeutic effect or to affect the structure or any function of the body.[95] Only when the product is a drug may the FDA apply the safety standards written into section 505(d) and other adulteration and misbranding rules in the Act's drug provisions. Purposivism encouraged the FDA to use evidence of safety problems to establish that articles were drugs in the first place. If the overriding purpose of the Act is to protect the safety of the American public, the FDA reasoned, in close definitional cases better to err on the side of reading the Act to treat

89. *See* 21 U.S.C. § 321(g) (2000).
90. *An Article of Drug Bacto-Unidisk*, 394 U.S. at 798.
91. 412 U.S. 609 (1973).
92. *See* 21 U.S.C. § 355(j) (2000).
93. *Hynson, Westcott, & Dunning*, 412 U.S. at 625.
94. *Id.* at 631–32.
95. 21 U.S.C. § 321(g) (2000).

particular articles as "drugs" to gain the safety benefits provided by drug regulations. For instance, in an (unsuccessful) attempt to classify high dosages of vitamins A and D as drugs, the FDA Commissioner relied on the "potential for toxicity for the ingestion of large doses of these vitamins" as a ground for satisfying the definition of a drug.[96]

IV. THE RELATION BETWEEN ADMINISTRATIVE STRUCTURE AND FDA MISSION

A. The Influence of the Rights Revolution Model on the FDA

A few lessons emerge from these developments. First, general attitudes about regulation were one of several factors influencing how Congress, the FDA, and the courts all changed the FDA's legal mandate. These attitudes probably influenced the drafting of the Delaney Clauses, the FDA's powers over food and color additives, and its new powers over drugs. Justice Jackson anticipated the preference for low-tolerance safety standards in a 1953 dissent, when he claimed that in a world dominated not by "natural or simple products but [by] complex ones whose composition and qualities are often secret. . . . a dependent society must exact greater care than in more simple days and must require from manufacturers or producers increased integrity and caution as the only protection of its safety and well-being."[97]

To be sure, elite attitudes about safety regulation were not the only factors. These attitudes went hand in hand with or capitalized on popular fears, arising from generalized fears, like the public's growing concern about cancer after World War II, and public reactions against tragedies such as those involving thalidomide, the Dalkon shield, and breast implants. The Medical Device Amendments of 1976 show that practical concerns and interest-group politics could counteract elite and popular demands for lower-tolerance safety regulation. Even so, elite opinions about safety regulation were one part of the mix.

General elite despondency about New Deal-style regulation played a powerful role when the FDA made the move to expand its rulemaking powers. One can see the influence in a speech published by Peter Barton Hutt, then Assistant General Counsel for Food and Drugs, in 1973. Hutt agreed with Justice Jackson in that "[t]he extraordinary variety and complexity of products available in the marketplace today" created a demand for more sweeping public-law regulation and in fact created a stronger need than when Jackson spoke in 1954.[98] He concluded that the FDA needed to exercise "initiative and leadership in the public interest," and was "obligated to develop whatever

96. Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977).

97. Dalehite v. United States, 346 U.S. 15, 51 (1953) (Jackson, J., dissenting).

98. Hutt, *supra* note 79, at 177.

innovative and creative regulatory programs are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress."[99]

Most important, in defending the FDA's stance on rulemaking, Hutt appealed to the same sentiments that had led observers such as James Landis to call for more forward-looking rule- and policy-making more than a decade earlier:

> In the past 20 years there has been a gradual realization both that the government has a duty to inform those it regulates of the precise requirements that they are expected to fulfill under the law, and that promulgation of regulations specifying in detail these legal requirements is the most effective and efficient means by which industry-wide regulation can be achieved. Standing alone, institution of legal enforcement action, resulting in costly and time-consuming litigation on a case-by-case basis, is an inadequate method of regulation. It fails to inform the regulated industry of its obligations, it involves years of delay, and the end results are often uncertain. Worst of all, it inevitably results in invidious selective enforcement, whereby one or two individuals or companies must be singled out as the test cases while the rest of the industry is left alone. By contrast, the promulgation of regulations informs an entire industry of all applicable requirements and has proved to be far more likely to induce widespread compliance.[100]

Here, Hutt displays Landis's same optimism about rulemaking and pessimism about law-enforcement policing and administrative adjudication. Hutt says nothing in this passage that is particular to the experience of the FDA; to the contrary, he is appealing to food and drug lawyers to let the FDA learn from the experiences from other agencies to discharge its responsibilities better.

If the FDA is a reliable guide to the rest of the health law field, one of the reasons that many health-related agencies follow the Great Society model is that "everyone else was doing it." In the period from 1960 to 1980, members of Congress, their staff, leading government lawyers, and courts heavily involved in administrative law tended to agree that law-enforcement policing and administrative adjudication did not let government make policy well enough or fast enough to meet its obligations. This is not to say that other factors, like democratic pressures, interest-group politics, and practical considerations, did not play a role. Rather, in the climate of the 1960s, when policy-makers saw a health problem, their first response was to call for a Great Society-style agency and then adjust that blueprint as necessary to account for the political and policy problems that made the problem distinctive.

99. *Id.* at 179.
100. *Id.* at 183.

B. Expertise

Separately, in my judgment, the FDA's structure and track record tend to call into question another explanation typically given to explain why health agencies are structured the way they are. That justification is expertise. Expertise proves too little as a theory for running a government. Whatever value expertise brings to regulation, it does not require any single agency mission or organizing structure. To illustrate with an extreme case, it would be possible to fold expert officials into a very strict understanding of separation of powers. For any complicated topic of regulation, one could deputize a group of experts as staff to the House and Senate authorizing committees and then create a separate division of the Department of Justice, like its environmental or antitrust divisions, staffed with experienced prosecutors and non-lawyer support specialists to prosecute public-law violations of the rules those committees persuade Congress to pass. One then could create a separate set of specialized Article III courts, like the Court of Claims or the Court of Appeals for the Federal Circuit, aided by expert special masters, to hear cases arising out of those specialized prosecutions.[101]

Indeed, the FDA's organization illustrates some of the different possibilities. The FDA certainly has substantial expertise in the safety of food, devices, and drugs, but the FDA's experts make and enforce the law differently in different subject areas. All of the FDA's centers engage in some rulemaking and issue guidelines and other advisory materials. The Center for Food Safety and Applied Nutrition, however, devotes a considerable amount of effort to "traditional" executive investigatory and enforcement work—conducting inspections and assisting U.S. Attorneys and Department of Justice staff when they prosecute violations of the food adulteration and misbranding laws.[102] Meanwhile, on the drug side, the Center for Drug Evaluation and Research tends to concentrate on "adjudicative" work—reviewing new drug applications. Both approaches take advantage of subject-matter expertise, but each does so within a different organizational chart.

101. The only limitation in a really strict system of separation of powers might be that the Seventh Amendment would force juries to consider factual issues that a policy-maker might prefer be left to expert finders of fact. Even so, many issues of "fact" in technical proceedings are actually settled by legislative policy judgments.

102. *See* CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMIN., *at* http://www.cfsan.fda.gov/~lrd/cfsan4.html (last modified Aug. 15, 2001) (discussing CFSAN's self-identified functions, including inspections, sample collections, and research); CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMIN., CFSAN 2003 PROGRAM PRIORITIES, *at* http://www.cfsan.fda.gov/~dms/cfsan303.html (last modified Mar. 13, 2003); Charles R. McConachie, *The Role of the Department of Justice in Enforcing the Federal Food, Drug and Cosmetic Act*, 31 FOOD DRUG COSM. L.J. 333 (1976).

C. The Relation between Great Society Positive Rights and the Need for Control

Finally, the FDA's story hints at one last explanation, the relation of administrative powers and structure to substantive priorities. Even after the FDA started issuing legislative rules under section 701(a), it still remained in many respects an enforcement and licensing agency. The FDA *can* remain an enforcement and licensing agency because its goals are relatively focused and only in a few cases do those goals set extremely low tolerances for safety problems. While I cannot demonstrate as much here, I suspect these factors distinguish the FDA from federal health agencies created after 1960.

Cass Sunstein's account of the "rights revolution" approach to regulation, recounted in part I, is instructive because Sunstein appreciates how substantive objectives influence the coercive apparatus the law needs to achieve the substantive goals. Richard Epstein appreciates this point too. Whether or not one agrees with his prescriptions for health law, he has an advantage in that he sees the conventional wisdom among health lawyers as an outsider looking in. In his view, "[t]he protagonists of the [health] debate all start from one grand working assumption . . . that health care is a 'right' that should be made available to all Americans."[103] In Epstein's distinction, in health law generally, health policy-makers generally prefer a positive, or "rights to" understanding of legal rights, associated with the welfare state, as opposed to a negative, "freedom from" conception of rights, associated with the common-law tradition.[104] Now, one can disagree with Epstein about which of the two conceptions of rights is preferable in health law.[105] Even so, I think the FDA experience, especially with drug and device regulation, confirms Epstein's point at a descriptive level: The choice of government structure is heavily influenced by a positive, entitlement conception of the right the federal government has committed to providing.

Let me illustrate by using the FDA as a contrast against the rest of health regulation. The following impression is just an impression because I know more about (and am probably more sympathetic to) the aims and practicability of food and drug law than the law and regulation for other federal areas of health law. With those reservations, the FDA has a reputation as an agency that "works" better than many. Several factors have contributed to this reputation. It has a stable culture because it is a long-established agency and it has broad political support. Even if the FDA suffers the occasional fiasco like

103. RICHARD A. EPSTEIN, MORTAL PERIL 1 (1997).

104. *See id.* at 3.

105. *See, e.g.*, Lawrence O. Gostin & M. Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46 PERSPS. IN BIOLOGY AND MED. S160 (2003).

its attempt to regulate tobacco,[106] and even if political forces occasionally pressure the FDA to help make drug prices more affordable, by and large, the FDA is apolitical, and it does not get pulled very often into high-profile political regulatory disputes.

But the FDA also seems to indicate indirectly why command-and-control regulation might be necessary in health law. The move to Great Society, "rights revolution"-style lawmaking was prompted in large part by a collective belief among legislators, regulators, and lawyers around 1960 that earlier models for regulation were not making the right kinds of regulations as fast as they needed to be made. By some combination of luck and good design, the FDA's overall structure illustrates when the regulatory models that preceded the "rights revolution" model are most likely to succeed. Because a great deal of health-care regulation operates outside of the FDA's political and administrative parameters, perhaps that regulation depends more heavily on the command-and-control model than FDA law does.

Among the various parts of the FDA's docket, the FDA seems to follow the regulatory equivalent of the "police patrol" and "fire alarm" models, each when appropriate.[107] The FDA's food docket shows the advantages of the pre-New Deal, enforcement-based regulatory model. The FDA conducts food inspections and initiates prosecutions and seizure proceedings. It issues legislative food identity and labeling standards, but it relies heavily on industry compliance with those standards. With respect to food, the FDA relies heavily on the fire-alarm model, "less centralized and involv[ing] less active . . . oversight."[108] Now, because this approach relies heavily on industry compliance and after-the-fact discovery and prosecution, relatively speaking it does not allow the FDA to change food manufacturers' incentives or set exacting standards. On the other hand, the FDA probably has no other choice. FDA lawyers and officials are fond of saying that consumers spend twenty-five cents of every dollar on products within the FDA's jurisdiction; of those twenty-five cents, consumers spend nineteen on foods.[109] Practically, it is extremely unlikely that the FDA would ever try to guarantee the safety of food

106. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000); DAVID KESSLER, A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY (2001); Margaret Gilhooley, *Tobacco Unregulated: Why the FDA Failed, and What to Do Now*, 111 YALE L.J. 1179 (2002) (reviewing KESSLER, *supra*).

107. Mathew D. McCubbins and Thomas Schwartz developed this distinction to explain Congress's behavior while overseeing agencies in *Congressional Oversight Overlooked: Police Patrols versus Fire Alarms*, 28 AM. J. POL. SCI. 165 (1984). However, the analogies apply to regulatory enforcement efforts over private parties, too.

108. *Id.* at 166.

109. CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMIN., *at* http://www.cfsan.fda.gov/~lrd/cfsan4.html (last modified Aug. 15, 2001).

before the fact, and it would be extremely difficult for the FDA to regulate food on any standard higher than its potential to cause illness or injury.

With respect to devices, the FDA takes something of an intermediate position between the pre-New Deal enforcement model and the New Deal licensing model. The medical-device provisions of the Act give the FDA power to conduct drug-like pre-approval over Class III drugs, the most dangerous class of devices. But again, in part because the device market is more diffuse, the FDA allows most devices to go to market without pre-market approval, only with pre-market notification, on the ground that they are substantially equivalent to devices grandfathered or already approved. And the substantive standard is a less stringent standard: The FDA need only be satisfied with a reasonable assurance of safety and efficacy for the devices' intended use.

At the other extreme, when it comes to drugs, the FDA approaches most closely to the New Deal licensing, a police-patrol model—"comparatively centralized, active, and direct."[110] Here, the FDA is required to approve the manufacturer's showing that an applied-for drug is safe and effective according to clinical methodology considered adequate for the field. This is an ambitious responsibility. To the extent the FDA manages to discharge it in a timely manner,[111] one of the factors is that it does not need to consider many applications. In 2002, the FDA received eighty-seven new new-drug applications, granted seventy-eight pending new-drug applications, and granted 321 generic applications.[112] Pharmaceutical research and development are prohibitively expensive (in no small part because of the NDA process itself). Thus, the FDA can afford to be what Richard Merrill called a sort of "warrantor of manufacturer compliance with the rules that govern drug development and marketing," because it needs to consider relatively few new

110. McCubbins & Schwartz, *supra* note 107, at 166.

111. The FDA has long come under criticism for taking too long to rule on new-drug applications. *See, e.g.*, GENERAL ACCOUNTING OFFICE, FDA DRUG APPROVAL: REVIEW TIME HAS DECREASED IN RECENT YEARS (1995); Richard Dorsey, *The Case for Deregulating Drug Efficacy*, 242 JAMA 1755 (1979); Mary K. Olson, *Regulatory Agency Discretion among Competing Industries: Inside the FDA*, 11 J.L. ECON. & ORG. 379 (1995). Congress responded to the complaints by establishing a system of user fees with which the FDA could hire more review staff. *See* 21 U.S.C. §§ 379g-h (2000); U.S. FOOD AND DRUG ADMIN., USER FEES, *at* www.fda.gov/oc/oms/ofm/userfees/userfees.htm (last visited Sept. 8, 2004). For discussions about whether the User Fee Amendments have accelerated the FDA's review process, see Mary K. Olson, *Regulatory Reform and Bureaucratic Responsiveness to Firms: The Impact of User Fees in the FDA*, 9 J. ECON. & MGMT. STRATEGY 363 (2000); Chris Adams & Scott Hensley, *Drug Makers Want FDA to Move Quicker*, WALL ST. J., Jan. 29, 2002, at B12.

112. CTR. FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMIN., 2002 REPORT TO THE NATION: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 3, 12 (2003) *at* http://www.fda.gov/cder/reports/rtn/2002/rtn2002.pdf (May 5, 2003).

drug applications.[113] It can demand that drug manufacturers follow a centralized *ex ante* licensing system at least in part because it is not besieged by drug applications.

The FDA stands in contrast with much health-care regulation because it can indulge in the enforcement and licensing models where other health agencies cannot. The FDA's overriding mission relates to the quality of the products it regulates—that they be safe, effective, and not misleading or deceptive. By contrast, other federal health agencies are required to discharge broader and conflicting sets of goals—involving issues such as access to health care, at adequate quality, and for affordable prices. Furthermore, in those areas where the FDA is required to take the most centralized, *ex ante*, labor-intensive approach, relatively speaking, the FDA does not have many items on its agenda. By contrast, I suspect that health-care finance and access issues create many problems. Thus, the structures chosen in regulatory health law may be a product of the statutory goals health agencies are required to meet, the hard policy choices they must make between conflicting goals, and the broad interests they must control or accommodate in pursuing those goals.

Thus, the FDA can afford to monitor food primarily by enforcement because it is only regulating food for one main criterion—safety. And it can centralize drug and to a lesser extent device regulation because it again has a discrete regulatory objective and because there are not many applications to consider. To the extent that these conditions break down in health-care regulation, there is a much greater need for sweeping rulemaking and stronger enforcement powers to meet the various goals of health care.

113. Merrill, *supra* note 3, at 1768.