Saint Louis University Law Journal

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

Article 8

12-1-2004

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FDA AND THE ADAPTATION OF REGULATORY MODELS

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Food and drug law has been a niche part of the academic curriculum, perhaps seen as too esoteric for those without a medical or technical background. The increased recognition of the importance of the diet to health and the significance of drugs to health and health costs may increase interest in the course itself. In administrative law, developments at the Food and Drug Administration (FDA) do not get the analysis topics such as environmental regulation get, even though the FDA has contributed its share of notable cases found in casebooks.[1] Professor Eric Claeys's paper[2] makes a very useful contribution by putting FDA regulation into the framework of the larger administrative law themes about government regulation. He examines the FDA in light of the eras of regulation identified by Cass Sunstein and the changes brought about by the views among scholars and other "elites" about how best to run agencies.[3] Professor Claeys has also gone back to key sources such as Richard Merrill's analysis of the FDA and James Landis's study of the administrative agencies in the New Deal and the Kennedy Administration.

As Claeys's paper notes, the FDA has layers of different models of regulation, with the Progressive era model still predominant for foods and the Great Society command and control licensing model key in the drug field. His paper also makes a useful analogy that some health protection statutes simply give the agency a fire alarm role, while others give it a wider police patrol or preventive management role.[4] The FDA has also been described as "proactive" and "entrepreneurial" in administering statutes.[5]

In looking for lessons and models from the FDA experience, I will comment briefly on a few points: the importance of an agency's adaptive role

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1. *See* Heckler v. Chaney, 470 U.S. 821 (1985) (presumption of non-review of enforcement discretion); Abbott Labs. v. Gardner, 387 U.S. 136 (1967) (presumption of reviewability and test for ripeness); United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240 (2d Cir. 1977) (discussing tests for review of legislative rules).

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

3. *Id.*

4. *Id.*

5. *Id.*

and judicial review under that model, the significance of legislative rulemaking, the impact of the recent statutory and constitutional deregulation of food and drug law, and the uncharted impact on drug regulation of the new efforts to limit drug costs. The overall lesson for health law is the need for, and the appropriateness of, agencies taking the initiative to adapt the law to deal with new problems.

I. THE RANGE OF THE AGENCY'S ADAPTIVE ROLE AND JUDICIAL REVIEW

The FDA's adaptive role is most dramatically seen against the background of the strict command and control licensing schemes adopted by Congress. Particularly notable is the pre-market approval requirement enacted in 1958 for food additives not generally recognized by experts as safe (GRAS) and the prohibition on the addition of any carcinogenic additive to foods.[6] In 1962, in landmark legislation of the Kennedy Administration, new drugs had to be approved in advance for efficacy based on adequate and well-controlled studies.[7] Meeting the drug testing requirements takes years and can cost up to $800 million according to an estimate that has engendered debate.[8] In the 1970s, Congress adopted a less rigorous statutory scheme for medical devices with the agency's support. That scheme was less strict because of the "economic, physical, safety, and use differences between drugs and devices."[9]

Peter Hutt, chief counsel for the FDA in the early 1970s, articulated a "regulatory philosophy" that the statute should be regarded as a constitution and that the agency should seek to achieve the general objectives of the law in creative ways that do not violate statutory restrictions.[10] This philosophy reflects an expansive view of the mission that Congress has delegated to agencies. It assumes with confidence that the agency can and should adapt the law to new circumstances. It also echoes the problem-solving role that New Deal theorists saw for administrative agencies, a role not fully captured by reference to agency expertise, as if the role related only to technical matters.[11]

6. 21 U.S.C. § 321 (2000); 21 U.S.C. § 348 (2000) (barring any carcinogenic additive).

7. *See* 21 U.S.C. § 355 (2000).

8. S*ee* Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003) (estimating the costs associated with drug testing requirements). *See, e.g.*, MERRILL GOOZNER, THE $800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 238–39 (2004) (debating DiMasi's estimation).

9. Claeys, *supra* note 2.

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

11. *See* Louis L. Jaffe, *The Effective Limits of the Administrative Process: A Reevaluation*, 67 HARV. L. REV. 1105, 1133 (1954). He describes the role of the staff:

> Where regulation is enacted there is conflict. Large forces find themselves in opposition, each seeking solutions which threaten social unity . . . . [J]ust at these points administration has a legitimate role in creating solutions. The agencies, specialized and

The use of the adaptive approach can lead to an expansion of the agency's authority, as shown by the FDA's rule that food products bear codes to facilitate recalls, an expansion upheld by the courts even though the authority was not explicit.[12] On the other hand, the adaptive approach can also lead to deregulation. For example, the agency's authority to set food standards discouraged changes in food products. The FDA reinterpreted the law in a way that permitted non-standardized foods to be sold with new, non-misleading names—a change the courts accepted.[13]

In recent years, the agency has lessened the rigors of the drug efficacy requirements. Notably, at the time the AIDS crisis emerged, the agency came to accept that requiring full testing in advance was detrimental when promising drugs could save lives.[14] The agency adopted a policy and issued rules to allow drugs for life-saving and debilitating conditions to be approved based on preliminary tests on the condition that full testing be completed after the drug went on the market.[15] The agency's position was never legally challenged. Indeed, Congress enacted it into law.[16] While the adaptation of food and drug regulation does not involve market incentives like the ones in the environmental field that were upheld in *Chevron*, this "fast track" provision illustrates the form in which alternative schemes of regulation can play a role in the FDA.[17]

> experienced each in its way, are in a position to offer solutions that do not depart so far from the given technical base as to be unacceptable or unworkable.

Id.; see also JAMES M. LANDIS, THE ADMINISTRATIVE PROCESS 33 (1938) ("[T]here are certain fields where the making of law springs . . . from a 'practical' judgment which is based upon all the available considerations and which has in mind the most desirable and pragmatic method of solving that particular problem.").

12. Nat'l Confectioners Ass'n v. Califano, 569 F.2d 690, 694–95 (D.C. Cir. 1978) (upholding a rule requiring codes on foods to facilitate recalls). "A regulation that is self-evidently rational is not less legitimate than a regulation whose rationality must depend on elaborate statistical, expert, or other evidence." *Id.*

13. The agency, for example, issued rules for naming foods by giving the percentage of important ingredients such as the amount of shrimp in bottles of shrimp cocktail. That approach replaced the issuance of food standards that would have mandated a minimum requirement for the amount to set the minimum content of ingredients such as shrimp. Am. Frozen Food Inst. v. Mathews, 413 F. Supp. 548, 554 (D. D.C. 1976).

14. Investigational New Drug, Antibiotic, and Biological Drug Product Regulations; Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses; Interim Rule, 53 Fed. Reg. 41,516 (Oct. 21, 1988) (to be codified at 21 C.F.R. § 312.80).

15. *Id.*

16. 21 U.S.C. § 356 (2000).

17. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984). In the drug field, direct financial incentives come from Congress. For example, Congress gives drug companies added periods of market exclusivity for doing pediatric studies. 21 U.S.C. § 355(c)(3) (2000). This extended period can be very valuable, as illustrated by the exclusivity for the pediatric testing of Claritin that was worth nearly one billion dollars. *See* LARS NOAH & BARBARA A. NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY 824 (2002) (citing Rachel

Important changes have also been made to the food additive provisions that set a zero-tolerance approach to carcinogens, and the courts played their own adaptive role. Judge Leventhal recognized that Congress had not mandated a rigid, no-risk policy in dealing with trifling risks in food, even for carcinogens, when methods to detect or predict the presence of additives became vastly more sensitive.[18] Although the decision related to detection methods, it made the agency more willing to develop policies that had at their core a de minimis standard for carcinogens. The agency prevailed in that interpretation in dealing with a similar issue for color additives but only when there was a textual basis for allowing low-levels of carcinogens that were constituents in other ingredients, and not when the issue concerned directly added substances.[19] Congress has since adopted a notification approach for indirect food additives that accommodates the use of a constituent and a de minimis standard.[20]

The most striking recent example of an adaptive approach to the rigors of the food additive provisions involved a statement of policy in which the FDA recognized that genetically modified foods do not ordinarily need prior approval of the added gene. Instead, the genes are presumptively GRAS based on their resemblance to traditional plant breeding.[21] That policy has been judicially upheld as one within the agency's discretion,[22] but the extension of the GRAS determination to include substantially equivalent products has had its critics.[23]

The FDA also makes use of adaptive regulatory techniques involving the use of management techniques, as exemplified by its effort to establish good manufacturing practices (GMPs) for cooking times to prevent botulism in

Zimmerman, *Pharmaceutical Firms Win Big on Plan to Test Adult Drugs on Kids*, WALL ST. J., Feb. 5, 2001, at A1).

18. Monsanto Co. v. Kennedy, 613 F.2d 947, 955 (D.C. Cir. 1979). While the *Monsanto* case does not state that it dealt with a carcinogen, those who worked on the matter know that at the time of the administrative decision, an ongoing test made it a suspected carcinogen, and that by the time of the court litigation, the test had shown it was an animal carcinogen.

19. Scott v. FDA, 728 F.2d 322, 325 (6th Cir. 1984) (upholding the constituent theory for color additives). Zero tolerance was found necessary, though, for *de minimis* carcinogens in color additives that were not constituents. *See* Public Citizen v. Young, 831 F.2d 1108, 1122 (D.C. Cir. 1987).

20. 21 U.S.C. § 348(h) (2000).

21. Statement of Policy: Foods Derived From New Plant Varieties, Notice, 57 Fed. Reg. 22,984 (May 29, 1992).

22. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp.2d 166 (D.D.C. 2000).

23. *See, e.g.*, Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403 (2002); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167 (2004) (analyzing regulatory approaches needed for the next-generation developments in biotechnology).

whitefish. The agency won on its authority to establish GMPs, notwithstanding the logic of the textual argument, based on the public health purpose of the statute, but the court found the agency insufficiently articulate in acknowledging the implications of its no-risk approach.[24] The Department of Agriculture, though, was unsuccessful in establishing that it had the authority under a similar provision to establish preventative standards in plants to guard against the risk of salmonella from incoming meat supplies.[25] The FDA's ability to establish GMPs for foods also shows that the agency is not limited to a fire alarm model in dealing with risks from foods.

The fate of agency policies on judicial review is not always as predictable as this survey illustrates. The courts, particularly at earlier times, used a purposive approach to statutory interpretation, an approach that can lead to upholding adaptive policies but does not always do so.[26] Now, under *Chevron*, as the first step, the courts look not at Congress' purpose, but whether Congress has addressed the issue; as the second step, they defer to reasonable agency interpretations.[27] The Supreme Court's decision on tobacco restates the first step as involving an examination of the text, the statutory context, and common sense, but not the statutory purpose.[28] That formula still leaves much to judicial judgment, and the textual approach can accommodate some changes that reflect policy views about the need to deal with new circumstances.[29] Even if the statutory purpose were acknowledged as playing an appropriate role, as I believe it should, the determination of Congress' intent would not be easy or always favorable to the agency.

Some unpredictability should not be surprising when agencies are adapting statutes that embody major political compromise in order to deal with new circumstances with widespread consequences for different segments of the industry and the public. Agencies should not, though, give up the adaptive role. The agency gets the first crack at working out emerging problems and trying to find a solution that will become accepted. If it can reformulate Congress's primary concern and reconcile that concern with the merits and drawbacks of continuing to apply past practices, without going "too far," it has a good chance to prevail in the courts. That may not be much guidance, but I am skeptical that there is a litmus test for finding the legal limits to the scope

24. *See* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 253 (2d Cir. 1977) (discussing FDA procedure for balancing commercial infeasibility against public interest).

25. Supreme Beef Processors v. U.S. Dep't of Agric., 275 F.3d 432 (5th Cir. 2001).

26. *Compare id.* (agency prevails on authority based on purpose), *with* Monsanto Co. v. Kennedy, 613 F.2d 947, 955 (D.C. Cir. 1979) (agency interpretation inconsistent with a presumption about Congressional intent).

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

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

29. Scott v. FDA, 728 F.2d 322, 325 (6th Cir. 1984).

of the agency's authority to adapt its mission to new circumstances and the changed views about public needs.[30]

II. IMPORTANCE OF LEGISLATIVE RULEMAKING

The use of rulemaking was an important way in which the FDA developed and implemented its adaptive role. Professor Claeys recounts that the FDA made the "belated discovery" that it could issue legislative rules and that this discovery goes beyond the original convention.[31] But it really was Justice Harlan in *Abbott Laboratories* who made this discovery, and the agency acted on its implications.[32] Professor Claeys also points out that the ratification theory in *Brown and Williamson Tobacco* could be used to undercut the FDA's legislative rulemaking authority, irrespective of the support that the *Abbott* case provided.

I think this would be unfortunate, as the agency would be left with having to rely even more on guidance documents,[33] and some matters cannot be handled through guidance. Legislative rules are needed to establish broad, definitive and innovative standards such as the GMP that required recall codes for food and the systematic review program for over-the-counter (OTC) drugs.[34]

III. IMPOSED DEREGULATION: THE '90S AND BEYOND

A. Dietary Supplements

I have been discussing the adaptive approach to the law undertaken by the FDA. While some of these changes were deregulatory, it was deregulation that the agency supported. However, in the 1990s deregulation was imposed from outside the agency. Notably, Congress deregulated dietary supplements from

30. *See* Margaret Gilhooley, *Tobacco Unregulated: Why the FDA Failed, and What To Do Now*, 111 YALE L.J. 1179, 1191–1203 (2002) (elaborating on the factors that can influence the determination of the agency's delegated authority).

31. Claeys, *supra* note 2 (citing Thomas Merrill & Kathleen Tongue Watts, *Agency Rules with the Force of Law: The Original Convention*, 116 HARV. L. REV. 467 (2002)).

32. Abbott Labs. v. Gardner, 387 U.S. 136, 151–52 (1967) (stating that the agency's definitive policy would, if within the agency's authority, "have the status of law").

33. *See* Claeys, *supra* note 2 (criticizing the use of guidance documents). I see a need for agency flexibility about the use of this form of advice, but I am troubled by the idea that the agency can state advice that really is firm yet elude judicial review. In an earlier article, I identified a possible approach to alleviate this by having private parties request advice on specific situations, with the agency providing a timely response, that would ordinarily be sufficiently ripe for review. *See* Margaret Gilhooley, *Constitutionalizing Food and Drug Law: When Avoidance is Right*, 38 HOUS. L. REV. 1383, 1390–93 (2002).

34. *See* United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 253 (2d Cir. 1977); *see also* PETER BARTON HUTT & RICHARD A. MERRILL, FOOD AND DRUG LAW: CASES AND MATERIALS 588–99 (2d ed. 1991).

the drug command and control model. As a result, the agency now largely has a fire-alarm role to deal with problems revealed by the experience of the public.[35] This enactment illustrates the tensions involved in reconciling consumer choice with the paternalism inherent in regulatory schemes that limit access to products in order to protect the user.

B. Commercial Speech

More recently, deregulation has come from the courts based on the constitutional protections for commercial speech. The Supreme Court found in *Thompson v. Western States Medical Center* that Congress cannot prohibit advertisements for variations of a new drug compounded by a pharmacist to meet individual needs if other alternatives were adequate to prevent deception—including a warning that the product has not been approved by the FDA.[36] This principle could weaken the rigor of the drug efficacy amendments because it may allow drug companies to distribute medical articles about new uses of approved drugs with a disclaimer that the FDA has not approved the new use.[37] These developments may also have some implications for the efforts to limit drug costs as noted below.

IV. IMPLICATIONS OF FDA REGULATION FOR HEALTH AND DRUG FINANCING

FDA regulation may seem to be a settled field—placid compared to the responsibilities of agencies that have to deal with conflicting goals such as those "involving access to health care, at adequate quality and for affordable prices."[38] The FDA field has not been all that placid—as the litigation over tobacco and commercial speech illustrate. There also is an intense resistance to changing the core of the command and control model for drugs. But I agree that health-care financing is especially thorny, and, if anything, it will become even more difficult because of the new Medicare prescription drug coverage program.

Government has a more accepted and easier role if it adopts the more conservative approach of trying to prevent harm than if it goes further to

35. *See* Margaret Gilhooley, *Deregulation and the Administrative Role: Looking at Dietary Supplements*, 62 MONT. L. REV. 85, 118–27 (2001) (exploring whether a safety substantiation model could be an adequate alternative if Congress were ever ready to toughen the regulation of supplements but did not want to reinstitute the command and control model). As a political institution, Congress is prone to move by compromise and to take intermediate positions.

36. 535 U.S. 357 (2002) [hereinafter *Western States*]. The D.C. Circuit found that supplements could use disclaimers about the lack of FDA approval in lieu of meeting the statutory testing requirements. Pearson v. Shalala, 164 F.3d. 650 (D.C. Cir. 1999).

37. *See* Margaret Gilhooley, *Drug Regulation and the Constitution after Western States*, 37 U. RICH. L. REV. 901, 921–30 (2002) [hereinafter *Drug Regulation*].

38. Claeys, *supra* note 2.

require that the good be done or that benefits be provided to large numbers.[39] The American public may perceive the new Medicare law as providing seniors a "right" to affordable prescription drugs, encompassed in some sort of donut—a perception that resembles the rights revolution of the 1960s. But President Bush has adopted a new model for providing that benefit, one that uses competition among health insurers to control costs. Making that model "work" or work "well enough" will be a challenge. How much affordability is needed and for what drugs? Will competition and formularies and co-pays be enough?

In connection with health financing, Professor Tim Jost raises the need to consider alternative models such as the direct provision of government services to the poor or corporativist models that negotiate budgets between insurers and providers.[40] In some way, the FDA may be drawn into having to think out new ways to deal with the challenges presented by the prescription drug benefit. Until recently, for example, the FDA viewed its responsibility for the Hatch-Waxman generic drug provisions as ministerial, but it undertook last year to correct "abuses." That effort found its way into the new statute.[41] The agency may be called upon yet again to deal with other aspects of the interface between the scientific support for drugs and their cost. We as a nation are launched on a difficult venture to provide affordable drug benefits and health benefits to seniors in a way that does not bust the federal budget. I am unsure about how it will be done, or how fully it can be done. We will need all the

39. The issue is like that in torts with respect to whether the law should impose liability on Good Samaritans who fail to rescue those whom they have not harmed or should leave the choice to do good as a voluntary and moral obligation.

40. Timothy Stoltzfus Jost, *Health Law and Administrative Law: A Marriage Most Convenient*, 49 ST. LOUIS U. L.J. 1 (2004).

41. *See* Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patient Claiming a Drug is Invalid or Will Not be Infringed; Final Rule, 68 Fed. Reg. 36,676 (June 18, 2003) (codified at 21 C.F.R. pt. 314); *see also* Application of 30-Month Stays on Approval of Abbreviated New Drug Applications and Certain New Drug Applications Containing a Certification That a Patent Claiming the Drug Is Invalid or Will Not Be Infringed; Technical Amendment, 69 Fed. Reg. 11,309 (Mar. 10, 2004) (revoking notice-related provisions of Final Rule to take account of changes in Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 177 Stat. 2066, made to sections of the Federal Food Drug and Cosmetic Act, 21 U.S.C.A. §§ 505 (a), (b), (j) (West 2004)); *see* CTR. FOR DRUG EVALUATION AND RESEARCH, U.S. FOOD AND DRUG ADMIN., Guidance for Industry Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Questions and Answers (Oct. 2004), *available at* http://www.fda.gov/cder/guidance/6174dft.htm; *see also* Erika King Lietzan, *A Brief History of 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act*, 59 FOOD DRUG L.J. 287 (2004) (finding the new law to be "intricate" and "undoubtedly will give rise to new interpretative questions").

creative thinking and adaptive regulation that administrative agencies can come up with.

But we will also need all the strategies that Congress can devise. For this reason, the commercial speech doctrine is deeply troubling in placing restraints on Congress' ability to deal with health and safety regulation. To give an illustration, there are some who believe that the direct-to-consumer advertising of prescription drugs drives up drug costs.[42] Congress' ability to preclude these ads is in doubt given the rigors of the *Central Hudson* test. If Congress had greater authority, I doubt it would impose a complete ban on the ads, but it might consider restraining some types of ads in some ways that are now more open to challenge. Congress needs adequate tools and levers and power to use in reaching compromises on measures to restrain prescription drug costs. Thus, I think Justice Breyer was right about the cautions he expressed in the dissent in *Western States* about making commercial speech doctrine overly rigid.[43]

In conclusion, I will say that this conference has chosen an important time to provide perspective on the kinds of strategies that can be used for regulation in the health field to meet the present challenges and the hard ones ahead.

42. *See Drug Regulation*, *supra* note 37, at 918–19.

43. Thompson v. W. States Med. Ctr., 535 U.S. 357, 389 (2002) (Breyer, J., dissenting). Justice Breyer stated:

> [A]n overly rigid "commercial speech" doctrine will transform what ought to be a legislative or regulatory decision about the best way to protect the health and safety of the American public into a constitutional decision prohibiting the legislature from enacting necessary protections. As history in respect to the Due Process Clause shows, any such transformation would involve a tragic constitutional misunderstanding.

Id.