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Framing Regulatory Standards to Avoid Formal Adjudication: The FDA As a Case Study

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Recently the Food and Drug Administration has taken aggressive action to reduce the burden of prolonged administrative hearings by initiating the use of summary judgment, by allocating the burden of proof to the drug manufacturers in drug efficacy hearings, and by using its rulemaking authority to its full extent so as to avoid questions of fact in both agency adjudication and judicial enforcement proceedings. This Article undertakes a careful examination of these procedures and of the case law upholding their validity and suggests that such procedures might be adapted by other agencies faced with increasing demands for administrative adjudication.

Formal agency adjudication is nearly always slow and cumbersome¹ and often futile as well.² The presentation, cross-examination,

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1. See, e.g., REPORT OF THE ABA COMMISSION TO STUDY THE FEDERAL TRADE COMMISSION 28-32, 34 (1969); see J. LANDIS, REPORT ON REGULATORY AGENCIES TO THE PRESIDENT-ELECT 5 (submitted by the Chairman of the Subcommittee on Administrative Practice and Procedure to the Senate Committee on the Judiciary), 86th Cong., 2d Sess. (Comm. Print 1960) [hereinafter cited as LANDIS REPORT]; Friendly, *A Look at the Federal Administrative Agencies*, 60 COLUM. L. REV. 429, 432-34 (1960); Goldnan, *Administrative Delay and Judicial Relief*, 66 MICH. L. REV. 1423 (1968).

2. See Friendly, *supra* note 1, at 435; Reich, *The Law of the Planned Society*, 75 YALE L.J. 1227, 1242-43 (1966); Westwood, *Administrative Proceedings: Techniques of Presiding*, 50 A.B.A.J. 659, 660 (1960).

and rebuttal of oral testimony may promote completeness and accuracy of material evidence in many settings,³ but in others it only engenders obscurity and protracts agency proceedings, diverting resources from the design and implementation of regulatory policies.⁴ All too often testimony in formal adjudication ranges aimlessly into topics of law and policy, or covers areas rendered immaterial by the rules that ultimately govern the proceedings. While scholars have explored various methods of reducing agency reliance on formal adjudication consistent with statutory and constitutional requirements,⁵ administrative agencies have shown continued attachment to trial-type procedures, perhaps fearing reversal by less enlightened courts.⁶ It is therefore encouraging to find an agency that has, on its own initiative, developed legitimate ways of avoiding formal adjudication.

The Food and Drug Administration is perhaps uniquely qualified as a source of administrative innovation. The specialized nature of its jurisdiction, the volume of products with which it deals, and the severe consequences of regulatory miscalculation combine to give the FDA unusually broad authority.⁷ Thomas Austern, a seasoned food and drug law practitioner, has expressed it vividly:

3. MCCORMICK'S HANDBOOK OF THE LAW OF EVIDENCE § 19 (2d ed. 1972).

4. See Reich, *supra* note 2, at 1240-43.

5. See Boyer, *Alternatives to Administrative Trial-Type Hearings for Resolving Complex Scientific, Economic, and Social Issues*, 71 MICH. L. REV. 111 (1972) [hereinafter cited as Boyer]; Freedman, *Review Boards in the Administrative Process*, 117 U. PA. L. REV. 546 (1969); Gellhorn & Robinson, *Summary Judgment in Administrative Adjudication*, 84 HARV. L. REV. 612 (1971) [hereinafter cited as *Administrative Summary Judgment*]; Mashaw, *The Management Side of Due Process: Some Theoretical and Litigation Notes on the Assurance of Accuracy, Fairness, and Timeliness in the Adjudication of Social Welfare Claims*, 59 CORNELL L. REV. 772 (1974) [hereinafter cited as Mashaw]; Note, *The Requirement of Formal Adjudication Under Section 5 of the Administrative Procedure Act*, 12 HARV. J. LEG. 194 (1975) [hereinafter cited as *APA § 5 Adjudication*]; Note, *The Use of Agency Rulemaking to Deny Adjudications Apparently Required by Statute*, 54 IOWA L. REV. 1086 (1969) [hereinafter cited as *Rulemaking to Deny Adjudications*]. Cf. Robinson, *The Making of Administrative Policy: Another Look at Rulemaking and Adjudication and Administrative Procedure Reform*, 118 U. PA. L. REV. 485 (1970) [hereinafter cited as Robinson]; Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 HARV. L. REV. 921 (1965) [hereinafter cited as Shapiro].

6. Cf. Wright, *The Courts and the Rulemaking Process: The Limits of Judicial Review*, 59 CORNELL L. REV. 375, 387-88 (1974) [hereinafter cited as Wright].

7. See *Dalehite v. United States*, 346 U.S. 15, 51-52 (1953) (Jackson, J., dissenting); Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSM. L.J. 177, 179 (1973) [hereinafter cited as Hutt].

[T]he fact that Congress simply has not considered or spoken on a particular issue certainly is no bar to the Food and Drug Administration exerting initiative and leadership in the public interest. Except where expressly prohibited, I believe the Food and Drug Administration is obligated to develop whatever innovative and creative regulatory programs are reasonable and are most appropriate to achieve the fundamental objectives laid down by Congress. And in spite of the diversity of the Agency's new programs, I am not at all certain

[E]very experienced food and drug lawyer will tell you that in 999 out of 1,000 cases, even the most sanguine counsel knows that he hasn't a prayer of persuading an appellate court to second guess the FDA.

Every finding is dressed up as a scientific determination. . . . Colorful phrases of remote bearing—such as “poisoning the public,” “prevention of cancer,” “deleterious food injuring the public”—are regularly trotted out.

It is indeed a sturdy appellate judge who is not tempted to clutch his stomach, to recall every episode of family illness, and to react in favor of those who march under the banner of protecting the aged, lactating mothers, and infant children.⁸

But the FDA's advantage in the courts is more pronounced in substantive than in procedural areas,⁹ and the techniques it has developed for avoiding hearings should not be dismissed as the privilege of a uniquely burdened agency. Indeed, analysis suggests that the FDA innovations rest on broadly applicable principles of administrative law.

Working from the basic premise that determination of contested adjudicative facts requires trial-type procedure,¹⁰ the FDA has developed two principal techniques for confining factual dispute. To avoid formal hearings before the agency, the FDA has made aggressive use of summary judgment against a background of stringent regulatory standards of both general and particular applicability. To avoid judicial enforcement proceedings, the FDA has promulgated comprehensive regulations to guide court action. Both techniques test the limits of agency authority to frame regulatory standards for adjudication. This Article will consider each technique in turn, first setting forth the FDA procedure in context, and then analyzing it with a view towards its availability—in whole or in part—to other agencies.

I

SUMMARY JUDGMENT TO AVOID FORMAL HEARINGS

In 1958 Professor Davis suggested that administrative agencies “take a leaf” from the Federal Rules of Civil Procedure and use summary

that the Food and Drug Administration has yet begun to explore the full reaches of existing statutory authority.

Id. at 179.

8. Austern, *Sanctions in Silhouette: An Inquiry into the Enforcement of the Federal Food, Drug and Cosmetic Act*, 51 CALIF. L. REV. 38, 45 (1963) [hereinafter cited as Austern, *Sanctions in Silhouette*], quoted in, J. MASHAW & R. MERRILL, *INTRODUCTION TO THE AMERICAN PUBLIC LAW SYSTEM* 466 (1975) [hereinafter cited as J. MASHAW & R. MERRILL].

9. See, e.g., *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974); *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F.2d 455 (D.C. Cir. 1972).

10. 1 K. DAVIS, *ADMINISTRATIVE LAW TREATISE* § 7.02 (1958) [hereinafter cited as DAVIS TREATISE]; *APA* § 5 *Adjudication*, *supra* note 5.

ry judgment in adjudication "when no issue of fact is presented."¹¹ With a recent boost from the Administrative Conference,¹² Professor Davis's idea has taken hold. Seeking to avoid lengthy proceedings in the absence of factual issues requiring trial, several federal administrative agencies now provide for summary judgment in their regulations.¹³ Like Rule 56 of the Federal Rules of Civil Procedure, the new regulations typically place the burden on the party seeking summary decision to show that there is "no genuine issue as to any material fact,"¹⁴ and thus no need for trial procedures.

Since 1969, the FDA has relied extensively on summary judgment as a means of fulfilling its mandate to adjudicate the efficacy of each of more than 1,000 prescription drugs.¹⁵ Yet, unlike the other agencies that have turned to summary judgment, the FDA has not simply emulated the judicial model. Instead, by shifting the burden to the drug manufacturer to show the need for a hearing, and by interpreting the efficacy standard so as to make that burden difficult to meet, the FDA has transformed summary judgment into an active instrument of regulatory policy.

A. Summary Judgment at the FDA

1. The Regulatory Framework

The FDA's use of summary judgment has played a central role in the implementation of the 1962 Drug Amendments¹⁶ to the Federal Food, Drug and Cosmetic Act of 1938.¹⁷ Where the 1938 Act had provided for premarketing FDA evaluation of all "new drugs"¹⁸ to

11. 1 DAVIS TREATISE, *supra* note 10, § 8.13, at 578.

12. See Administrative Conference of the United States, Recommendation No. 20: Summary Decision in Agency Adjudication (adopted June 30, 1970). For commentary on this recommendation, see *Administrative Summary Judgment*, *supra* note 5.

13. *E.g.*, 16 C.F.R. § 3.24 (FTC 1974); 46 C.F.R. §§ 201.91-93 (Maritime Administration 1974); 47 C.F.R. § 1.251 (FCC 1974); see 18 C.F.R. §§ 1.6(d), 1.9(c) (FPC 1974); 49 C.F.R. §§ 1100.45, .49, .50, .53 (ICC 1974). See generally *Administrative Summary Judgment*, *supra* note 5, at 622-31.

14. *E.g.*, 16 C.F.R. § 3.24 (FTC 1975).

15. See text accompanying notes 44-63 *infra*.

16. 21 U.S.C. §§ 301-92 (1970), amending 21 U.S.C. §§ 301-92 (1958). For a collection of materials and a detailed discussion of the 1962 Amendments and their implementation by the FDA, see J. MASHAW & R. MERRILL, *supra* note 8, at 459-537; Note, *Drug Efficacy and the 1962 Drug Amendments*, 60 GEO. L.J. 185 (1971) [hereinafter cited as *Drug Efficacy*]. For a layman's conspiratorial view of the legislative history, see R. HARRIS, *THE REAL VOICE* (1964).

17. 21 U.S.C. §§ 301-92 (1970). For an account of the operation of the Act before 1962, see *Developments in the Law: The Federal Food, Drug and Cosmetic Act*, 67 HARV. L. REV. 632 (1954).

18. A "new" drug is one "not generally recognized, among experts . . . , as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof" 21 U.S.C. § 321(p) (1970).

ensure safety,¹⁹ the 1962 Amendments extended premarketing review to drug efficacy. The Amendments required the FDA to prohibit the marketing of any new drug in the absence of "substantial evidence"²⁰ of its effectiveness.²¹ This mandate applied not only to the nearly 100 medicines marketed each year for the first time, but also to the approximately 4,000 drugs still on the market for which new drug applications (NDAs)²² had become effective between 1938 and 1962.²³ In 1966 the FDA engaged the National Academy of Sciences/National Research Council (NAS-NRC) to review the efficacy of the "pre-1962" drugs in an advisory capacity.²⁴ Working through panels of experts in some 30 therapeutic classes, the NAS-NRC was able to complete its work within a 2-year period. The results were disheartening: over 70 percent of the 16,573 claims reviewed were found unwarranted,²⁵ and only 434 drugs

19. *Id.* §§ 355(d), (e).

20. The Act defines "substantial evidence" as:

evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 355(d) (1970).

21. 21 U.S.C. § 355(d) (1970) provides for disapproval of an initial application: If the Secretary finds . . . that . . . (5) evaluated on the basis of the information submitted to him as part of the application and any other information available before him with respect to such drug, there is lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof . . . he shall issue an order refusing to approve the application.

21 U.S.C. § 355(e) (1970) provides for withdrawal of approval previously granted:

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds . . . (3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof. . . .

22. An NDA is an application for FDA clearance to market a new drug. The NDA becomes "effective" upon FDA approval. 21 U.S.C. § 355(a) (1970). The requirements for an NDA are set forth in 21 U.S.C. § 355(b) (1970); 35 Fed. Reg. 7250 (1970), *amending* 21 C.F.R. 130.12(a)(5) (1974).

23. *Drug Efficacy*, *supra* note 16, at 207 nn.140 & 141.

24. The review panel was a select group:

[T]he panelists selected for the study were predominately physicians affiliated with academic institutions. . . . Commissioner Ley of the FDA remarked that "[n]o other organization could have brought greater objectivity, expertise, or authority to this landmark study." . . . [T]he prestige of the NAS-NRC made it difficult for the drug industry to challenge its findings.

Id. at 208 (footnotes omitted).

25. The NAS-NRC panels rated the 16,573 claims made for the various drugs as follows:

were found effective for all claimed uses.²⁶

The task of enforcement facing the agency was complicated by the procedural provisions of the Act. Under the statutory scheme, the burden of producing substantial evidence of efficacy rested on the drug manufacturer—even where the FDA moved to withdraw approval of a drug already on the market.²⁷ Significantly, however, the FDA was required to give the manufacturer notice and “opportunity for hearing” before either disapproving an NDA initially or withdrawing approval previously granted.²⁸ The “hearing” envisioned, as the FDA has conceded,²⁹ was the formal, trial-type proceeding described in sections 554, 556, and 557 of the Administrative Procedure Act.³⁰

<u>Rating</u>	<u>No. of claims</u>	<u>% of claims</u>
Ineffective	2,442	14.7
Possibly effective	5,778	34.9
Probably effective	1,204	7.3
Effective, but	3,990	24.0
Effective	3,159	19.1
Total	16,573	100.0%

Id. at 210 n.160. The less than effective categories were defined as follows: (1) Ineffective: No acceptable evidence to support claim of effectiveness. (2) Possibly effective: Little evidence of effectiveness, but possibility of additional evidence should not be ruled out. (3) Probably effective: Additional evidence required to consider effective. Remedy could be additional research of modification of claims or both. (4) Effective, but: Effective for claimed indication but not approved form of treatment because better, safer or more conveniently administered drugs available. *Id.* at 209 n.153.

26. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621 (1973). The FDA's former General Counsel, Peter Barton Hutt, estimated that the agency “did not accept roughly 20 percent of the National Academy of Science's recommendations with respect to its review of drug effectiveness.” *Hearings on the Use of Advisory Committees by the FDA Before the Intergovernmental Subcomm. of the Comm. on Government Operations*, 93d Cong., 2d Sess. 80 (1974) [hereinafter cited as *Hearings on Advisory Committees*]; see *id.* at 98.

The FDA currently uses advisory committees to help evaluate NDA's which pose delicate scientific questions. *Id.* at 46-53.

27. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 22 (1973); *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772, 774 (1974); *Ubiotica Corp. v. FDA*, 427 F.2d 376, 378 (6th Cir. 1970); *Upjohn Co. v. Finch*, 422 F.2d 944, 955 (6th Cir. 1970); see *Agri-Tech, Inc. v. Richardson*, 482 F.2d 1148, 1154 (8th Cir. 1973); *contra Bell v. Goddard*, 366 F.2d 177, 181 (7th Cir. 1966).

With respect to pre-1962 drugs marketed without a determination of efficacy, these courts have construed the “new information” requirement to require only a reexamination of old data in light of new legal requirements and to impose no burden of producing evidence on the FDA. Whether the same construction will obtain with respect to drugs once approved as effective is uncertain. *Cf. Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975, 992 (D.C. Cir. 1974) (imposing the initial burden of adducing “new evidence” on the FDA under the safety clause of the new animal drug provisions).

28. 21 U.S.C. §§ 355(c)-(e) (1970).

29. 40 Fed. Reg. 22958, 22993 (1975); *cf. Wong Yang Sung v. McGrath*, 339 U.S. 33 (1950); 5 U.S.C. § 554(a) (1970); *APA § 5 Adjudication*, *supra* note 5.

30. 5 U.S.C. §§ 554, 556, 557 (1970). These provisions of the Administrative Procedure Act require an impartial tribunal, opportunity for introduction of oral testimony and cross-examination of adverse witnesses, and decision based on the record of the proceeding. 5 U.S.C. §§ 556(b),(d),(e) (1970). If the agency does not preside, the

The FDA's initial plan was to act on hearing requests only after withdrawal, when delay would no longer be in the manufacturer's interest.³¹ In 1969, however, two district courts insisted that the opportunity for hearing precede withdrawal.³² To an agency with only two hearing examiners,³³ one of whom was already engaged in a protracted formal rulemaking proceeding,³⁴ these decisions represented a serious setback. Pre-withdrawal hearings would have meant enormous delay in implementation of the 1962 Drug Amendments, a process the FDA was under increasing congressional pressure to expedite.³⁵ A reappraisal by the agency resulted in its adoption of summary judgment as a major regulatory procedure designed to aid the implementation of the 1962 Amendments.

2. *The FDA Procedures*

Two approaches have characterized the FDA's use of summary judgment. Essential to both is the agency's interpretation of the "substantial evidence" standard. Under the first approach, the FDA forecloses factual debate by referring to generally-applicable agency regulations refining the statutory standard. Under the second, the FDA seeks to achieve the same result by particularizing the standard in the same case in which it invokes summary judgment.

a. *The "Substantial Evidence" Regulations*

Section 701(a) of the Federal Food, Drug and Cosmetic Act

provisions require agency review of the initial decision, with opportunity for additional submissions, and a final decision based on formal findings. *Id.* §§ 557(b), (c). For the FDA regulations governing formal adjudicatory procedure, see 40 Fed. Reg. 23000-10 (1975), amending 21 C.F.R. §§ 2.100-191 (1974).

31. See *American Home Products Corp. v. Finch*, 303 F. Supp. 448, 451-52 (D. Del. 1969); *Upjohn Co. v. Finch*, 303 F. Supp. 241, 244-45 (W.D. Mich. 1969). In the *Upjohn* case, the FDA briefly considered providing a pre-withdrawal hearing. *Id.* at 244; *Hearings on Drug Efficacy Before the Intergovernmental Relations Subcomm. of the House Comm. on Governmental Operations*, 91st Cong., 1st Sess., pt. 2, at 189-90 (1969) [hereinafter cited as *Hearings on Drug Efficacy*].

32. *American Home Products Corp. v. Finch*, 303 F. Supp. 448 (D. Del. 1969); *Upjohn Co. v. Finch*, 303 F. Supp. 241 (W.D. Mich. 1969). Both cases involved the effectiveness claims of fixed combination antibiotic drugs subject to section 507 of Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 357 (1970). Unlike section 505 of the Act, (21 U.S.C. § 355 (1970)) section 507 specifically requires the party requesting a hearing to state "reasonable grounds therefor." 21 U.S.C. § 357(f) (1970). The courts have not found the difference in language significant. Compare *Pfizer, Inc. v. Richardson*, 434 F.2d 536, 542-43 (2d Cir. 1970), with *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466, 468 (2d Cir. 1971).

33. *Hearings on Drug Efficacy*, *supra* note 31, pt. 2, at 198.

34. See J. MASHAW & R. MERRILL, *supra* note 8, at 470.

35. See, e.g., *Hearings on Drug Efficacy*, *supra* note 31, pt. 2, at 173-75. Later, the courts exerted similar pressure. *American Public Health Ass'n v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972).

empowers the FDA "to promulgate regulations for the efficient enforcement of this Act."³⁶ In September, 1969, the FDA invoked 701(a) as authority to issue regulations particularizing the "substantial evidence" standard³⁷ for proof of drug efficacy. Characterizing these regulations as "procedural and interpretative," the FDA initially promulgated them without prior notice or opportunity for submission of comments by interested persons.³⁸ Later, however, in response to a district court decision³⁹ invalidating the regulations for failure to follow the notice-and-comment procedures required by section 553 of the Administrative Procedure Act,⁴⁰ the FDA initiated rulemaking proceedings⁴¹ and in May, 1970, repromulgated the regulations without significant change.⁴²

In substance, the regulations impose stringent standards for conducting clinical studies of drugs. To merit FDA consideration, a test submitted to show effectiveness must include: (1) a clear summary of objectives; (2) methods of selection and assignment to test groups of subjects designed to assure suitability for study, minimal bias, and comparability in test and control groups; (3) methods of observation and recording designed to minimize bias on the part of the subject and observer; (4) comparison with a precisely described control susceptible of qualitative evaluation; and (5) a summary of methods of analysis and an evaluation of data, including appropriate statistical methods.⁴³ Although the FDA properly characterizes these requirements as principles "recognized by the scientific community as the essentials of adequate and well-controlled clinical investigations,"⁴⁴ it is nonetheless clear that in crystallizing the statutory language the regulations "effect a material narrowing of the range of evidence"⁴⁵ that might otherwise be relevant to the issue of drug efficacy.⁴⁶ The regulations give the FDA power, for

36. 21 U.S.C. § 371(a) (1970).

37. See note 20 *supra*.

38. 34 Fed. Reg. 14598 (1969). Administrative Procedure Act § 4, 5 U.S.C. § 553 (1970), exempts from the general notice and comment requirement "interpretative rules, general statements of policy, or rules of agency organization, procedure or practice." *Id.* § 553(b)(A).

39. Pharmaceutical Mfrs. Ass'n v. Fitch, 307 F. Supp. 858 (D. Del. 1970).

40. 5 U.S.C. § 553 (1970).

41. 35 Fed. Reg. 3073 (1970).

42. 35 Fed. Reg. 7251 (1970), *codified in* 21 C.F.R. § 314.111 (1975). The same court that had invalidated the September regulations on procedural grounds subsequently upheld the May regulations against substantive attack. Pharmaceutical Mfrs. Ass'n v. Richardson, 318 F. Supp. 301 (D. Del. 1970).

43. 21 C.F.R. § 314.111(a)(5)(ii)(a) (1970).

44. *Id.* § 130.14(a)(5)(ii).

45. Pharmaceutical Mfrs. Ass'n v. Finch, 307 F. Supp. 858, 865 (D. Del. 1970).

46. The Director of the Bureau of Drugs, Dr. J. Richard Crout, testified recently that "[t]he data we are seeing today, in 1974, on new drug applications that have been worked up in the last few years, is much better than it used to be." *Hearings on Advisory Committees*, *supra* note 26, at 97. Dr. Crout pointed specifically to the FDA's 1970

example, to disregard a consensus of practicing physicians that a drug is effective.⁴⁷

To capitalize on these stringent requirements for evidence of drug efficacy, the 1970 regulations included provisions for summary judgment. As amended in 1974,⁴⁸ these provisions authorize a two-stage procedure. In the case of pre-1962 drugs, the products for which the substantial evidence regulations were designed, the FDA notifies the manufacturer that an NAS-NRC panel has found the drug ineffective, that the Bureau of Drugs agrees that the material submitted for NAS-NRC review fails to constitute the adequate and well-controlled investigations required by the regulations, that the Bureau proposes to with-

substantial evidence regulations "as terribly important in upgrading the whole field." *Id.* Dr. Crout continued:

I think during the 1960's there was no doubt that there was enormous confusion, bitterness, debates between the industry and investigators and the Food and Drug Administration and so on, on what was required. But that got clarified in 1970 and the people began to measure up, and we are seeing applications of much higher quality than were produced in the late 1960's.

Id.

47. Evidence of such a consensus, even if derived from scientifically sound polling techniques, would not satisfy the legal standard of "adequate and well-controlled" investigation. "The law provides that a consensus of medical opinion is not sufficient to establish the effectiveness of a drug or to justify a hearing." 39 Fed. Reg. at 9756 (1974). The Supreme Court has upheld the exclusion of "anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug" as "amply justified by the legislative history" of the 1962 amendments. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973); *accord* *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970). *But cf.* Justice Powell's opinion in *Hynson*, concurring in part and concurring in the result in part:

Were we required to reach these issues, there might well be serious doubt whether the Commissioner's rigorous threshold specifications as to proof of "adequate and well controlled investigations," coupled with his restrictive summary judgment regulation, *go beyond the statutory requirements* and in effect frustrate the congressional mandate for a prewithdrawal "opportunity for hearing." 21 U.S.C. § 355(e). There is also a genuine issue of procedural due process where, as in this case, the Commissioner construes his regulations to deny a hearing as to the efficacy of a drug *established and used by the medical profession for two decades*, and where its effectiveness is supported by a significant volume of clinical data and the *informed opinions of experts* whose qualifications are not questioned.

412 U.S. at 638-39 (footnote omitted and emphasis added).

Only if the drug manufacturer submits at least one study satisfying the regulations must the FDA grant a hearing before withdrawal. And in such a case, nothing prevents the FDA from accepting the test results and leaving the drug on the market rather than forcing a hearing to dispute the manufacturer's claim:

If review of the data, information, and analyses submitted warrants the conclusion . . . that substantial evidence of effectiveness exists, the Commissioner shall deny the hearing, enter summary judgment for the person(s) requesting the hearing, and rescind the notice of opportunity for hearing.

21 C.F.R. § 314.200(g)(4) (1975). For an argument that the FDA's "threshold" requirements are no different from the ultimate standard, see Kleinfeld, *Reasonable Grounds, Substantial Evidence, and Law and Order*, 25 FOOD DRUG COSM. L.J. 210, 216 (1970).

48. 39 Fed. Reg. 9761-64 (1974); see notes 87, 94 and accompanying text *infra*.

draw the drug's NDA, and that the manufacturer may request a hearing.⁴⁹ Unless the manufacturer makes such a request within 30 days and submits studies that satisfy the regulations within 60 days,⁵⁰ the FDA withdraws the NDA without a hearing.⁵¹ In the case of drugs submitted for initial marketing approval, the FDA purports to follow the same procedure to disapprove the NDA, referring in this context to the evidence submitted as part of the application.⁵² In practice, the procedure for initial NDA approval is highly informal, since most manufacturers would rather retest newly developed formulations than insist on the right to a hearing which, at worst, may yield an unfavorable decision, and at best will delay marketing.

In 1973 the Supreme Court upheld the FDA's two-stage procedure in *Weinberger v. Hynson, Westcott & Dunning, Inc.*⁵³ The Court approved not only the agency's substantial evidence regulations but also the invocation of summary judgment "where it is apparent at the threshold that the applicant has not tendered *any* evidence which *on its face* meets the statutory standards as particularized by the regulations."⁵⁴ In a footnote, however, the Court added that its approval of the summary judgment procedure extended "only to those regulations that are precise."⁵⁵ The Court stated that "it might not be proper to deny a hearing" on the ground of failure to comply with regulations that "call for the exercise of discretion or subjective judgment in determining whether a study is adequate and well controlled."⁵⁶

In procedural regulations adopted in March 1974, the FDA has accepted with some elaboration the Supreme Court's insistence on precision. It will not invoke summary judgment "solely because of failure to comply with the judgmental elements" of the regulations *unless* it finds "total failure of a study even to attempt to comply."⁵⁷ As an example, the FDA states that failure to provide "adequate" assurance of suitable subject selection will not be sufficient for summary judgment, but that failure to include any such assurance will.⁵⁸ The District of Columbia

49. 21 C.F.R. §§ 314.200(a)(2), (g)(1) (1975).

50. *Id.* § 314.200. If the regulations fail conclusively to disqualify any of the studies submitted at this point, the manufacturer avoids immediate summary judgment. For the possibility that the FDA may nevertheless press for summary judgment after issuing additional notice see text accompanying note 91 *infra*.

51. 21 C.F.R. § 314.200(g)(1) (1975).

52. *Id.* § 314.200.

53. 412 U.S. 609 (1973). Although the Court upheld the FDA's summary judgment procedure, it found Hynson's submission sufficient to warrant a hearing in the particular case. *Id.* at 623.

54. *Id.* at 620 (emphasis added).

55. *Id.* at 621 n.17.

56. *Id.*

57. 39 Fed. Reg. at 9757 (1974).

58. *Id.*

Circuit Court of Appeals has recently approved this interpretation of *Hynson*.⁵⁹

To date the FDA has not attempted to take advantage of *Hynson* by making more precise its "substantial evidence" regulations; the limits of such further rulemaking remain to be explored. Thus, the agency has taken action under the regulations only against the most vulnerable pre-1962 drugs, while giving manufacturers of those drugs declared "probably" or "possibly" effective in the NAS-NRC review a grace period to allow retesting.⁶⁰ The FDA has not, however, been content to leave summary judgment in the posture approved by *Hynson*. Instead, it has begun to develop a second approach to summary judgment that complements the first.

b. The Case-by-Case Approach

This second approach has origins predating the first. As early as 1959, the FDA denied a hearing requested by a food coloring manufacturer whose contentions it deemed "legally insufficient" in light of a Supreme Court case decided after the contentions were made. The Food, Drug and Cosmetic Act provided at the time for "batch certification" of coal-tar colors to assure harmlessness, and gave any person adversely affected by failure to certify the right to a hearing.⁶¹ A manufacturer of colorings used in butter and margarine claimed that its products, although toxic when ingested alone, were "harmless" when added in small amounts to edible fat products. Before any FDA ruling on the manufacturer's hearing request, the Supreme Court decided in another case that a coal-tar color that itself was toxic could not be certified as harmless.⁶² On this basis, the FDA refused to provide a hearing.⁶³

According to Professor Davis, the decision upholding the FDA action, *Dyestuffs & Chemicals, Inc. v. Flemming*,⁶⁴ "probably stands as authority approving the denial of a hearing, even when a hearing is required by statute, on objections an administrator deems legally insuffi-

59. *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974): The court noted that "[A] regulatory provision which seems vague in the abstract may nonetheless be conclusively at odds with a peculiarly deficient item of evidence." *Id.* at 780.

60. The FDA's authority to provide such grace periods was narrowly circumscribed by the decision in *American Public Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1315-16 (D.D.C. 1972).

61. Federal Food, Drug, and Cosmetic Act, 52 Stat. 1049, 1055, *as amended*, 21 U.S.C. §§ 376, 371 (1970).

62. *Flemming v. Florida Citrus Exch.*, 358 U.S. 153 (1958).

63. 24 Fed. Reg. 883 (1959).

64. 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).

cient, even when the issues of legal sufficiency are live and difficult.”⁶⁵ But if the power existed in 1959 to deny a hearing on the basis of contemporaneous interpretation of the statute, it was a power the FDA largely ignored until recently.⁶⁶ Only after *Hynson* did the utility of such a power, complementing its reliance on “precise” regulations, become clear. The inspiration for revival of the *Dyestuffs* approach has come from two 1974 decisions of the District of Columbia Circuit,⁶⁷ and in particular from the opinions—the first for the court, the second in dissent—of Judge Leventhal. Both opinions, while critical of FDA hearing denials, offer potentially far-reaching suggestions for procedural innovation.

In *Hess & Clark, Division of Rhodia, Inc. v. FDA*,⁶⁸ the FDA had attempted in summary proceedings to withdraw approval of the new animal drug application (NADA) for diethylstilbestrol (DES), a synthetic estrogen fed to, or implanted in, beef cattle to increase feed efficiency and to speed growth.⁶⁹ One of the justifications given by the

65. 1 DAVIS TREATISE, *supra* note 10, § 6.05 (1970 Supp.).

66. For examples of instances where the FDA has denied hearings pursuant to the *Dyestuffs and Chemicals* case, see Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEX. L. REV. 1132, 1185-89 (1972).

67. *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974); *Hess & Clark, Division of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974).

68. 495 F.2d 975 (D.C. Cir. 1974).

69. The problem with DES was not its efficacy, but its safety. Broadly recognized as a carcinogen, DES would have been banned from the market by the original Delaney Clause of the new animal drug provisions, 21 U.S.C. § 360b (1970), a clause which automatically prohibited approval of cancer-causing animal drugs. But because of the commercial importance of DES and the belief that its residues did not remain in slaughtered cattle, Congress in 1962 framed an exception to the Delaney Clause with DES specifically in mind. As amended, the clause still provides for automatic disapproval, or withdrawal of approval, of a carcinogen intended for use in animals, but only if residues can be detected in edible portion of the animals by a test approved for that purpose by FDA regulations. This section provides for disapproval of an NDA if

such drug . . . after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice . . . (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations . . .), in any edible portion of such animals after slaughter or in any food yielded by or derived from living animals. . . .

Id. § 360b(d)(1)(H). Consequently, DES was approved and became widely used.

In 1973, however, after a period of experimentation with increasingly sensitive testing techniques, the United States Department of Agriculture developed a radioactive tracer study establishing the presence of DES residues in beef livers. Reacting earlier to less conclusive USDA test results, the FDA had issued a notice in effect inviting a hearing “to develop on the public record the information necessary for a conclusion as to the proper handling of this matter.” 37 Fed. Reg. 12251, 12252 (1972). But now, under heavy public pressure to act expeditiously, the FDA reversed itself, denying the hearing despite the manufacturers’ request and issuing instead a final order summarily withdrawing approval of DES. 38 Fed. Reg. 10,485-88 (1973). For a general discussion of the

FDA for invoking summary judgment was the Delaney Clause.⁷⁰ Although the new animal drug provisions require an "opportunity for hearing" before disapproval of a drug, the Delaney Clause must have seemed after *Hynson* to lend itself to summary judgment procedures. For an acknowledged carcinogen like DES, Congress itself had narrowed the relevant factual issues to the question whether an approved test had detected residues of the drug in edible tissue. But in acting precipitously, the FDA had failed to trigger the clause by adopting regulations "approving" the radioactive-tracer testing method on which it had relied. Consequently, in defending its order before the District of Columbia Circuit Court of Appeals, the FDA had to fall back on the general safety clause,⁷¹ which requires withdrawal of approval from a new animal drug if new evidence "shows that such drug is not shown to be safe."⁷²

On this theory the FDA was in a comparatively weaker position to justify invoking summary judgment. In attacking the FDA order Hess & Clark submitted evidence attacking the radioactive-tracer tests. The manufacturer disputed the FDA's factual contention that the residues detected in beef livers by the tests were DES residues, and claimed that even if the residues were DES, the FDA had failed to demonstrate that, in the quantities detected DES was no longer "shown to be safe."⁷³ In the absence of any regulations, either prescribing the method of detecting DES residues under the Delaney Clause or elaborating the general safety standard, the FDA was in a poor position to demonstrate the absence of genuine and substantial issues of fact. Furthermore, since the FDA had failed to notify Hess & Clark of the new tests before withdrawing DES without a hearing,⁷⁴ the manufacturer could claim that it had been provided no fair opportunity to raise issues of fact before the agency.

The court found the notice contention dispositive. The FDA's only notice had failed, in the court's view, "to serve as an alert that manufacturers were required to analyze characteristics of a potential, as yet undisclosed, testing method, under pain of forfeiting their statutory opportunity for hearing."⁷⁵ This error was enough to require reversal of the summary judgment order.

Delaney Clause see Blank, *The Delaney Clause: Technical Naïveté and Scientific Advocacy in The Formulation of Public Health Policies*, 62 CALIF. L. REV. 1084 (1974).

70. 38 Fed. Reg. 10,487 (1973). See note 69 *supra*.

71. 495 F.2d at 988. This "change of theory," as the court labeled it, underscored the inadequacy of the agency's notice of proposed summary judgment. See *Sterling Drug, Inc. v. Weinberger*, 503 F.2d 675 (2d Cir. 1974); *L&M Industries, Inc. v. Kenter*, 458 F.2d 968 (2d Cir. 1972).

72. 21 U.S.C. § 360b(e)(1)(B) (1971).

73. 495 F.2d at 992-94.

74. *Id.* at 985-86.

75. *Id.* at 986.

Significantly, however, Judge Leventhal chose not to stop there. Instead, he accepted the agency's invitation to examine the summary judgment order "as if that were the agency's *prima facie* case"⁷⁶ and undertook "to explore how the case would stand . . . if the Commissioner had followed the proper procedures."⁷⁷ While the court refused to condone summary disposition of the case at hand, which involved "a substantial and complex problem consisting of issues of both fact and policy," requiring resolution "through the hearing mechanism,"⁷⁸ Judge Leventhal's discussion did suggest that in a proper case, with proper notice, the agency might act without a hearing under the safety standard—even in the absence of particularized regulations. Analogizing to the judicial model of summary judgment, Judge Leventhal stressed the importance of the notice in framing the parameters of factual dispute. Like a motion under Rule 56 of the Federal Rules of Civil Procedure, the FDA notice must set forth "the uncontested facts that warrant summary judgment."⁷⁹ These facts must constitute "at a minimum, presentation of the *prima facie* case . . . for withholding"⁸⁰ a hearing. Such presentation is necessary to allow "meaningful opportunity to controvert the alleged facts and present a material issue for hearing."⁸¹

By clear implication, the proposed notice might present not only the FDA's version of the facts, but also its version of which factual issues were "material" under the Act. Thus, the notice would serve the same function as the substantial evidence regulations approved in *Hynson*,⁸² achieving a similar narrowing of material issues in a single, factually-based notice of proposed agency action. In short, it would

76. *Id.* at 988.

77. *Id.* at 989.

78. *Id.* at 994.

79. *Id.* at 984.

80. *Id.*

81. *Id.*

82. Before *Hynson*, in *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F.2d 455 (D.C. Cir. 1972), the District of Columbia Circuit had overturned the FDA's reliance on those regulations in a summary NDA withdrawal proceeding, partly for failing to give adequate notice of the agency's *prima facie* case. *Id.* at 461. Now Judge Leventhal attempted to square *USV* with *Hynson*:

Hynson in effect reaffirms the propriety of administrative summary judgment, if taken in a context where the pleadings on their face "conclusively" show that the hearing can serve no useful purpose. It did not overturn *USV*'s requirement that the agency make some showing as a predicate for summary adjudication. It rather found that such a showing and predicate was supplied by particularized regulations setting forth precisely what the manufacturer was required to supply and by findings that the study adduced was conclusively deficient.

495 F.2d 975, 987 (D.C. Cir. 1974). The notice approved in *Hynson* set forth no facts or evidence; its reference to the regulations served simply to demonstrate what contentions it would consider legally material.

permit the agency to amplify the requirements of the Act, for purposes of summary judgment, by adjudication as well as by rulemaking.

Cooper Laboratories, Inc. v. Commissioner, FDA,⁸³ a decision handed down three months later, gave the District of Columbia Circuit its first opportunity after *Hynson* to examine the FDA's invocation of its substantial evidence regulations to deny a hearing on a drug found ineffective. The majority, in an opinion by Judge Wright, upheld an FDA order that had summarily withdrawn approval of Protamide, an injectible enzyme for symptomatic treatment of herpes zooster and related conditions. After "a searching examination" of the evidence submitted by the manufacturer, the FDA's response, and the agency's regulations, the majority concluded that the FDA "has located for each item of evidence at least one deficiency (and usually many such) which conclusively disqualifies the item 'in light of the pertinent regulations.'"⁸⁴

Judge Leventhal disagreed. In his view the regulations were not sufficiently precise on their face to dispose of Cooper's submissions without further elaboration. Instead, he contended, the FDA—like the court majority—was particularizing the regulations in the case at hand:

A central difficulty is that FDA is engaged in fleshing out general regulations with concrete applications. This is fair enough. What may not be fair is a system of particularization without hearings, letting applicants know after the fact that they were in default all along for failure to observe a requirement that had not yet been spelled out. And when FDA is administering regulations that are in some measure "imprecise," "subjective," or lacking in "clear-cut definition," these are elements that militate against disposition without a hearing.⁸⁵

The problem for Judge Leventhal was similar to that involved in the FDA's attempt in *Hess & Clark* to "flesh out" the safety standard in specific proceedings against DES. In both cases the FDA had informed the manufacturer which contentions would be considered material only after the contentions were made. In *Cooper Laboratories*, however, Judge Leventhal went further in recommending a solution:

The first move toward untying the tangle could be taken if the FDA allowed the petitioners an opportunity for at least a written response to the determination that is now issued as the FDA's final order, but which, under a change of procedure to cope with the problem, would become a proposed disposition. At that time, NDA holders would, for the first time, have the FDA's declared approach for

83. 501 F.2d 772 (D.C. Cir. 1974).

84. *Id.* at 781, citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973).

85. 501 F.2d 772, 792 (D.C. Cir. 1974).

rejection of the study, and have a genuine opportunity to respond to that approach. Such a procedure would open up the process toward a reasoned decision based on fair opportunity for input. Perhaps petitioners could supplement the studies. . . . Or perhaps they could point out flaws in the FDA's approach.⁸⁶

The manufacturer's response might well lead to a hearing. On the other hand, it might be "so palpably shallow" as to permit summary judgment, subject to judicial review on "a more focused record."⁸⁷ In such a case, summary disposition would be appropriate despite the absence of a definitive standard in the statute or in FDA regulations.

On March 13, 1974, shortly before the *Cooper Laboratories* decision, but too late to influence the opinions in that case, the FDA promulgated revised procedural regulations for handling NDA withdrawals,⁸⁸ designed in part to reflect the *Hess & Clark* decision. The agency's preamble recognized two possible summary judgment procedures, in addition to the reference to precise regulations approved in *Hynson*. First, the agency might proceed immediately on the basis of new information to serve notice of opportunity for hearing and proposed summary judgment, containing "a detailed description and analysis of all of the facts which have led to the proposed action."⁸⁹ This was the sort of notice Judge Leventhal had found lacking in *Hess & Clark*. Alternatively, the agency might first provide only a general notice of opportunity for hearing "comparable to a general complaint filed in a court."⁹⁰ Then, if the request for a hearing seemed inadequate, a "proposed denial of the hearing would be required to be furnished to the person requesting the hearing,"⁹¹ with further opportunity for response. This was essentially the procedure Judge Leventhal would soon recommend in his *Cooper Laboratories* dissent.⁹²

Whichever notice the FDA might provide, the manufacturer would have 60 days to respond with evidence raising a "genuine and substantial issue of fact that requires a hearing."⁹³ The preamble explained that *Hynson*-type summary judgment would be reserved for situations where the substantial evidence regulations were clearly dispositive.⁹⁴ The other

86. *Id.*

87. *Id.* at 793.

88. 39 Fed. Reg. 9750-66 (1974), amending 21 C.F.R. 130, 146 (1973).

89. 39 Fed. Reg. 9750 (1974); see *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 983 (D.C. Cir. 1974). See also *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772, 793 (D.C. Cir. 1974) (statement of Leventhal, J., as to why he voted to deny rehearing).

90. 39 Fed. Reg. 9750 (1974).

91. *Id.*

92. See text accompanying note 86 *supra*.

93. 21 C.F.R. § 314.200(g).

94. 39 Fed. Reg. 9753, 9755 (1974).

procedures would be invoked either where the FDA had not promulgated a regulation elucidating a statutory standard, as in the case of safety issues, or where existing regulations were not sufficiently clear in a particular case.⁹⁵

The March 1974 regulations have not been in effect long enough to reveal how the FDA will employ its new summary judgment procedures. For example, the FDA has yet to respond to a request for hearing with a proposed denial. Nevertheless, as manufacturers become more familiar with the substantial evidence regulations, and as the agency begins to move against the pre-1962 drugs that the NAS-NRC panels found "probably" and "possibly" effective, the number of drug efficacy cases requiring the new procedures is likely to increase. And in the less common cases questioning drug safety, for which no particularizing regulations have been promulgated, the new procedures will continue to be essential mechanisms for summary disposition.⁹⁶

B. *Summary Judgment as a Hearing-Avoidance Technique*

In its use of summary judgment the FDA has succeeded in eliminating dispute over the legal import of all but the most unusual factual contentions. In the years 1969-1975 the FDA forced the withdrawal of dozens of ineffective drugs from the market and the modification of hundreds of efficacy claims. Yet in those years, the agency held only two formal adjudicatory hearings, involving the drugs Lutrexin and Serc.⁹⁷

This record of successful hearing avoidance raises important questions: Does the FDA's use of summary judgment comport with the requirements of the Food, Drug and Cosmetic Act, the Administrative Procedure Act, and the Due Process Clause? If it does, to what extent is its legality tied to the peculiarities of the Food, Drug and Cosmetic Act's drug licensing scheme—that is, to what extent may other agencies successfully emulate the FDA innovation? To explore these questions it

95. *Id.*

96. See, e.g., *E. R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382, 1386 (3d Cir. 1973) (remanding to the agency on the issue of safety "because the standard . . . has not been made clear by the FDA").

97. The Lutrexin hearing took place after the Supreme Court reversed an FDA order of summary judgment in *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973), and resulted in a tentative order by the Administrative Law Judge withdrawing approval of Lutrexin's NDA. See 40 Fed. Reg. 52426 (1975). The Serc hearing took place on FDA initiative and also resulted in withdrawal of agency approval. See text accompanying notes 180-89 *infra*.

The FDA was recently ordered to hold a hearing on the drug Cothyrobal in *Edison Pharmaceutical Co. v. FDA*, 513 F.2d 1063, rehearing *en banc* denied, 517 F.2d 164 (D.C. Cir. 1975). In voting to deny rehearing, four members of the court characterized the case as "a decision to rein in, not to be given its head to run away with the law." *Id.* at 166.

is necessary to focus first on the theory of summary judgment and then on the scope of agency authority to particularize statutory standards.

1. *The Invocation of Summary Judgment: Allocating the Burden of Proof*

Although the FDA claims to have modeled its summary judgment rules after Rule 56 of the Federal Rules of Civil Procedure,⁹⁸ its procedures depart from Rule 56 by requiring the manufacturer who requests a hearing to demonstrate the need for it. This departure has enabled the FDA to invoke summary judgment under the substantial evidence regulations without having to identify in its notice of proposed summary judgment any specific deficiencies in the manufacturer's submissions. In view of the number of drug products with doubtful efficacy claims, the voluminous data on each product, and limitations in the FDA's resources, avoidance of such a factual presentation in each case is essential to extensive use of the summary judgment technique.

Rule 56 authorizes a federal court to grant summary judgment on the motion of a party if the submissions before the court "show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law."⁹⁹ The rule places the burden of demonstrating the absence of genuine issues on the moving party.¹⁰⁰ He can satisfy that burden for each issue raised by his opponent's pleading only by demonstrating (1) that the issue is not genuine because the opponent's allegations are unsupported by adequate evidence,¹⁰¹ or (2) that it is not material because its resolution cannot affect the court's judgment,¹⁰² or (3) that it is not an issue of fact but one of law, which may be resolved by the court without trial.¹⁰³ In deciding whether genuine issues of material fact exist, the court resolves all doubts against the moving party.¹⁰⁴ If the court finds such issues, the moving party must go to trial to win; if, on the other hand, the court finds an absence

98. For more detailed analyses of Rule 56, see F. JAMES, *CIVIL PROCEDURE* § 6.18 (1965); 6 J. MOORE, *FEDERAL PRACTICE* § 56 (2d ed. 1974) [hereinafter cited as J. MOORE]; C. WRIGHT & A. MILLER, §§ 2711-42 (1973) [hereinafter cited as C. WRIGHT & A. MILLER].

99. FED. R. CIV. P. 56(c).

100. 6 J. MOORE, *supra* note 98, § 56.15[3], at 2336-43; C. WRIGHT & A. MILLER, *supra* note 98, § 2725, at 519. For a proposal to relax the severity of the Rule 56 burden of proof in certain circumstances, see Louis, *Federal Summary Judgment Doctrine: A Critical Analysis*, 83 YALE L.J. 745 (1974) [hereinafter cited as Louis].

101. 6 J. MOORE, *supra* note 98, § 56.04[1], at 2057-60; 10 C. WRIGHT & A. MILLER, *supra* note 98, § 2725, at 507-12.

102. See 10 C. WRIGHT & A. MILLER, *supra* note 98, § 2725, at 506-07.

103. *Id.* § 2725, at 499-500. The court may, in its discretion, decline to grant summary judgment where the legal issues are novel or complex.

104. *Id.* § 2727, at 526.

of such issues, it must still decide whether to grant the moving party judgment as a matter of law.¹⁰⁵

The FDA's adoption of a test equivalent¹⁰⁶ to that of Rule 56 for identifying issues not meriting trial finds ample support in the cases.¹⁰⁷ The "mission" of Rule 56 "is to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial."¹⁰⁸ Rule 56 attempts to define the kind of issues for which the constitutional assurances of due process and trial by jury require a full-scale trial. Because the right of jury trial does not apply to administrative adjudication,¹⁰⁹ adoption by an administrative agency of a formulation equivalent to Rule 56 should *a fortiori* satisfy the constitutional requirements.¹¹⁰ As for the statutory requirement of "opportunity for hearing," the courts have refused to find congressional intent to require an administrative trial in circumstances where a judicial trial would be unnecessary.¹¹¹ In such circumstances, an administrative trial would be "a useless and wasteful ritual."¹¹²

105. The uncontested facts may be insufficient to establish the moving party's case and the court may decline to grant judgment without the benefit of a more complete record. *See Arenas v. United States*, 322 U.S. 419 (1944); 6 J. MOORE, *supra* note 98, § 56.15[8], at 2435.

106. 39 Fed. Reg. 9763 (1974), amending 21 C.F.R. § 314.200(g) (1975). The phrase "genuine and substantial" has been used in connection with the Rule 56 standard. *Richard v. Credit Suisse*, 242 N.Y. 346, 152 N.E. 110 (1926) (Cardozo, J.). The word "substantial" may nonetheless take on added meaning in administrative summary judgment where an agency may safely ignore evidence that is insubstantial without fear of usurping a jury's role. See text accompanying at note 124 *infra*. For the practical difficulties of defining "substantiality" in this sense, see *Hearings on Advisory Committees*, *supra* note 26, at 232-33.

107. *See Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 621 (1973); *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 202-05 (1956); *Bank America Corp. v. Fed. Reserve Bd.*, 491 F.2d 985 (9th Cir. 1974); *Pennsylvania Gas & Water Co. v. FPC*, 463 F.2d 1242 (D.C. Cir. 1972); *United States v. Consolidated Mines & Smelting Co.*, 455 F.2d 432, 453 (9th Cir. 1971); *Citizens for Allegan County, Inc. v. FPC*, 414 F.2d 1125, 1128-29 (D.C. Cir. 1969); *Producers Livestock Marketing Ass'n v. United States*, 241 F.2d 192, 196 (10th Cir. 1957), *aff'd sub nom. Denver Union Stockyard Co. v. Producers Livestock Marketing Ass'n*, 356 U.S. 282 (1958). *See generally Administrative Summary Judgment*, *supra* note 5.

108. Advisory Committee Note to the 1963 amendment of FED. R. CIV. P. 56(e); see note 101 *supra*.

109. *See, e.g., NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 48-49 (1937); *Wickwire v. Reinecke*, 275 U.S. 101, 105-06 (1927); *Guthrie Nat. Bank v. Guthrie*, 173 U.S. 528 (1899).

110. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973). *See Pennsylvania Gas & Water Co. v. FPC*, 463 F.2d 1242 (D.C. Cir. 1972); *cf. FCC v. WJR, the Goodwill Station, Inc.*, 377 U.S. 265 (1949); *Sun Oil Co. v. FPC*, 256 F.2d 233, 240-41 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).

111. *E.g., United States v. Consolidated Mines & Smelting Co.*, 455 F.2d 432, 453 (9th Cir. 1971).

112. *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466, 468 (2d Cir. 1971) (Friendly, J.).

On the other hand, the FDA's reversal of Rule 56's burden of coming forward has been the subject of extended judicial controversy.¹¹³ The District of Columbia Circuit held in *USV Pharmaceutical Corp. v. Secretary of HEW*,¹¹⁴ for example, that the FDA would have to approximate Rule 56 practice more closely in implementing the 1962 amendments. Specifically, the agency's notice of proposed agency action would have to "state facts and reasons showing at least prima facie that the evidence before [the agency] raised no material issue of fact which would justify a hearing."¹¹⁵ The Supreme Court later upheld the notice procedures disapproved in *USV* without mentioning any such requirement.¹¹⁶ Nonetheless, the D.C. Circuit continues to insist that, in the absence of regulations "setting forth precisely what the manufacturer was required to supply,"¹¹⁷ the FDA include in its notice a prima facie case for summary withdrawal. Other courts of appeals, reading *Hynson* more broadly, have seemed disinclined to impose such a sweeping requirement on the agency.¹¹⁸

At the outset it is important to note that Congress has not spoken to the propriety of summary judgment at the FDA—or at any other agency—much less to the allocation of the burden with regard to summary judgment. In disputes over drug efficacy, the Food, Drug and Cosmetic Act allocates the burden of proof to the manufacturer only on the ultimate issue. By placing the same burden on plaintiffs and defendants, Rule 56 makes it clear that the burden at trial need bear no relation to the burden of identifying issues of fact. Of course, one regulatory scheme may be more consistent with a particular manner of allocating the burden than another. Nonetheless, the absence of explicit congressional direction makes it possible to consider the regulatory scheme within the context of a more broadly applicable analysis.¹¹⁹

113. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974); *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975 (D.C. Cir. 1974); *E.R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382 (3d Cir. 1973); *Agri-Tech, Inc. v. Richardson*, 482 F.2d 1148 (8th Cir. 1973); *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F.2d 455 (D.C. Cir. 1972); *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466 (2d Cir. 1971); *Pharmaceutical Mfrs. Ass'n v. Richardson*, 318 F. Supp. 301 (D. Del. 1970).

114. *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F.2d 455 (D.C. Cir. 1972).

115. *Id.* at 461; see note 82 *supra*.

116. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

117. *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 985 (D.C. Cir. 1974).

118. See note 141 and accompanying text *infra*.

119. See Cleary, *Presuming and Pleading: An Essay on Juristic Immaturity*, 12 STAN. L. REV. 5, 10 (1969) [hereinafter cited as Cleary]:

Actually the reported decisions involving problems of allocation rarely contain any satisfying disclosure of the *ratio decidendi*. Implicit, however, seem to be considerations of policy, fairness, and probability. None affords a complete

a. Policy

The first consideration is policy. Allocation of the burden of producing evidence on an issue is in effect an allocation of the risk of erroneous resolution of that issue. A party with the burden of production runs the risk that the evidence will be inadequate or unpersuasive even where his claim is in fact valid.¹²⁰ Allocation of burden thus requires choosing the side of an issue on which the risk of a failure of proof is more palatable.¹²¹ In the context of summary judgment the choice is between the denial of hearings where factual issues deserve trial and the provision of hearings where no worthy factual issues exist.¹²² If it is assumed that trials promote accurate determinations and maximize opportunities for participation at the cost of efficiency,¹²³ then the choice is between a reduction in accuracy and participation on the one hand and a reduction in efficiency on the other.

Good reasons exist for resolving this policy choice differently for administrative agencies than for courts. Perhaps most important, the seventh amendment right to jury trial applies to courts but not to administrative agencies.¹²⁴ Courts are constrained in granting summary judgment by the constitutional reservation of factual questions for decision by an independent jury. Agencies, by contrast, are empowered to decide factual as well as legal issues. While summary judgment may foreclose extensive agency exploration and deliberation of the facts, it

working rule. Much overlap is apparent, as sound policy implies not too great a departure from fairness, and probability may constitute an aspect of both policy and fairness. But despite the vagueness of their generality, it is possible to pour enough content into these concepts to give them some real meaning.

See also MCCORMICK'S HANDBOOK OF THE LAW OF EVIDENCE § 337 (1972); 9 WIGMORE, EVIDENCE § 2486 (3d ed. 1940); Chambers, *Burden of Proof in Labor Arbitrations*, 3 DUKE L.J. 127 (1954); James, *Burdens of Proof*, 47 VA. L. REV. 51 (1964).

120. Cf. C. CLARK, CODE PLEADING § 96, at 609 (2d ed. 1947): "One who must bear the risk of getting the matter properly set before the court, if it is to be considered at all, has to that extent the dice loaded against him." Quoted in Cleary, *supra* note 119, at 11.

121. In suppression hearings in criminal cases, for example, the government bears the burden of proof in part because it is thought preferable to err on the side of protecting fourth and fifth amendment rights. See *Lego v. Twomey*, 404 U.S. 477 (1972).

122. Louis, *supra* note 100, at 753 (characterizing the question raised by the author's proposal to modify the severity of the Rule 56 burden as "the fundamental question of whether a few wrongful dismissals constitute a greater evil than many unnecessary trials").

123. See, e.g., *Goss v. Lopez*, 419 U.S. 565 (1975); *Goldberg v. Kelly*, 397 U.S. 254 (1970).

124. "If this were a case involving trial by jury as provided in the Seventh Amendment, there would be sharper limitations on the use of summary judgment" *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973); *id.* at 622 n.18.

will not reassign the power to decide.¹²⁵ Agencies should be free to balance the value of extended deliberation against the need for efficiency, a value more central to the administrative than to the judicial role. Judge Learned Hand once cautioned against excessive judicial reliance on Rule 56:

It is an easy way for a court with crowded dockets to dispose of them, and the habit of recourse to it readily becomes a denial of that thorough though dilatory, examination of the facts, on which justice depends even more than upon a studious examination of the law Speed and hurry ought to be the antipodes of judicial behavior.¹²⁶

But "speed and hurry" are among the reasons why Congress has established administrative agencies.¹²⁷ "If it cannot be considered an ultimate concern of administrative law that tasks be accomplished with the minimum expenditure of time and resources it is nevertheless a matter of large importance."¹²⁸ In the absence of the jury right, administrative efficiency may be sufficiently important to justify the possibility of occasional deprivations of trial safeguards.

Further generalization of the policy choice is hazardous, because the relative value of efficiency as compared with accuracy and participation will ultimately depend upon the regulatory context. An agency's caseload and the nature of the issues ordinarily in controversy will affect the degree to which trial procedures can enhance accuracy and participation on the one hand or impede efficiency on the other.¹²⁹ Cross-examination, in particular, will be most useful where the issues involve specific facts capable of perception from different viewpoints and with divergent biases—for example, whether an employee struck or was struck by his employer.¹³⁰ It will be most cumbersome when the issues are complex and "polycentric,"¹³¹ and the parties or cases are numerous.¹³² Beyond that, the balance may turn on the relative importance

125. See *Administrative Summary Judgment*, *supra* note 5, at 630.

126. *California Apparel Creators v. Weider of California*, 162 F.2d 893, 902 (2d Cir.) (dissenting opinion), *cert. denied*, 332 U.S. 816 (1947); *accord*, *Doehler Metal Furniture Co. v. United States*, 149 F.2d 730 (2d Cir. 1945).

127. 1 DAVIS TREATISE, *supra* note 10, § 1.05, at 39; Austern, *Sanctions in Silhouette*, *supra* note 8, at 40.

128. Robinson, *supra* note 5, at 516.

129. See generally Boyer, *supra* note 5; Mashaw, *supra* note 5.

130. Cf. *Upjohn Co. v. Finch*, 422 F.2d 944, 955 (6th Cir. 1970): "We agree with the Commissioner that: 'No amount of examination and cross-examination can change the scientific studies and the data reported into something they are not.'"

131. See Fuller, *The Forms and Limits of Adjudication* 36 (1959) (unpublished article prepared for the Roundtable on Jurisprudence, Association of American Law Schools), *quoted in* Boyer, *supra* note 5, at 116-17 & n.23.

132. Cf. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973):

If FDA were required automatically to hold a hearing for each product whose efficacy was questioned by the NAS-NRC study, even though many hearings would be an exercise in futility, we have no doubt that it could not fulfill its

Congress attributes to the individual and public interests at stake in the ultimate decision. Because its assessment of those interests directly affects the way Congress allocates the trial burden,¹³³ the burden of showing a genuine need for trial and the burden of presenting evidence at trial may well fall on the same party.

The 1962 Drug Amendments impose the ultimate burden of proving efficacy on the drug manufacturer even in proceedings to withdraw approval,¹³⁴ thereby departing from the usual requirement that the government must come forward with evidence of disqualification when it attempts to revoke an outstanding license.¹³⁵ The usual pattern reflects a policy favoring retention of vested interests;¹³⁶ its reversal in the 1962 Drug Amendments reflects in part a countervailing policy favoring expeditious action in a field of great public importance. As Justice Douglas wrote in *Hynson*:

Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labelled in mysterious scientific dress.¹³⁷

Some of the reasons that justify allocating the risk of error in the ultimate determination of drug efficacy to the manufacturer also justify assigning the burden to the manufacturer at summary judgment. If the need for consumer protection demands that the manufacturer bear the risk of error in the determination of efficacy, it may also demand that he bear the risk of error in procedures designed to ensure a fair and accurate substantive decision. However, this is not to say that allocation of the trial burden should always control the burden at summary judgment. On the one hand, the prevalence of complex, scientific issues may justify requiring a party to show the need for a trial even where the government bears the ultimate trial burden; on the other, the importance of trial procedure in preventing arbitrary agency action may justify imposing the summary judgment burden on the government even where the public's substantive interests carry a higher value.

statutory mandate to remove from the market all those drugs which do not meet the effectiveness requirements of the Act.

Id. at 621.

133. See note 120 *supra*.

134. See notes 21, 27 *supra*.

135. Administrative Procedure Act § 386(d) provides that "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d) (1970); see *id.* § 558(c). But see *Clifford v. Schoultz*, 413 F.2d 868 (9th Cir.), *cert. denied*, 396 U.S. 962 (1969) (burden on government employee to show continuing eligibility for security clearance).

136. Cf. *Bell v. Burson*, 402 U.S. 535 (1971): "Once licenses are issued . . . their continued possession may become essential in the pursuit of a livelihood." *Id.* at 539.

137. 412 U.S. at 622.

b. *Fairness*

Another consideration in allocating burdens of proof is the fairness of the burdens imposed. Due process requires that the party opposing summary judgment be apprised of the factual showing he must make to preserve his right to trial.¹³⁸ Rule 56 satisfies this notice requirement by forcing the moving party to present the facts that entitle him to judgment as a matter of law. Reversal of Rule 56's allocation rule raises the problem of finding alternative means of providing adequate notice.

In *Hynson* the Supreme Court recognized that detailed and precise regulations governing the sufficiency of a request for hearing would constitute adequate notice, at least in some circumstances.¹³⁹ In *Hess & Clark*, the District of Columbia Circuit recognized a second option: an initial presentation of the agency's prima facie case, which provides a "meaningful opportunity to controvert the alleged facts."¹⁴⁰ Although Judge Leventhal apparently considered these to be the only alternatives, a third option, dependent neither on precise regulations nor on a factual presentation, has been recognized: a precise specification, in the form of an individual ruling applicable to the immediate case, of the issues the agency will consider material and the kind of evidence it will consider genuine.¹⁴¹

These options may not always be interchangeable. Fairness may require notice of facts upon which an agency proposes to act, particularly if the private party is unaware of their existence.¹⁴² In *Hynson*, the

138. In *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975 (1974), the Court stated:

Of course, administrative agencies are not bound by the same details of procedure as the courts. But the agencies are governed by the same basic requirements of fairness and notice, and these include specificity of notice and opportunity to respond if what is instituted is intended to be a procedure for summary disposition without hearing.

Id. at 984; *see Sterling Drug Inc. v. Weinberger*, 503 F.2d 675 (2d Cir. 1974).

139. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 622 (1973): "The drug manufacturers have full and precise notice of the evidence they must present to sustain their NDA's, and under these circumstances we find FDA hearing regulations unexceptionable on any statutory or constitutional ground."

140. 495 F.2d at 984. Administrative Procedure Act § 358(c)(1) requires "notice by the agency in writing of the facts or conduct which may warrant" a license revocation. The requirement is inapplicable, however, where the "public health, interest, or safety requires otherwise." 5 U.S.C. § 558(c) (1970).

141. *See E. R. Squibb & Sons, Inc. v. Weinberger*, 483 F.2d 1382, 1386 & n.20 (3d Cir. 1973) (remanding for amplification of findings in an FDA order of summary judgment on the issue of safety, for which the FDA has no particularized regulations); *cf. Sterling Drug, Inc. v. Weinberger*, 503 F.2d 675 (2d Cir. 1974). "The petitioners were not required to indulge in . . . guesswork. They were entitled to notice of the specific grounds on which the FDA proposed to withdraw approval of [their] NDA's" *Id.* at 682.

142. "The nature of a particular element may indicate that evidence relating to it lies more within the control of one party, which suggests the fairness of allocating that element to him." Cleary, *supra* note 119, at 12.

FDA was dependent upon the manufacturer for virtually all of the data relevant to its decision. In this circumstance, which is common in public regulation,¹⁴³ it is not unfair to require the manufacturer to sift through its own files to find evidence satisfying the standards of which it has received notice. The manufacturer is certainly better situated to undertake such screening than the agency.¹⁴⁴ In *Hess & Clark*, on the other hand, the FDA acted on the basis of "new evidence" that it had obtained independently.¹⁴⁵ Here, fairness would seem to require notice of both those new facts and the agency's legal theory.¹⁴⁶

c. Probability

A third—and less important—consideration in allocating the burden of proof, is probability.¹⁴⁷ To avoid the time and expense involved

143. One author has described agency dependence upon data supplied by manufacturers as follows:

[A]gency determinations of "fact" are bound to be based on evidence supplied by the represented special interests. Most of the information flowing to the agency will come from the regulated, who can afford to use much better resources in regulatory cases than will be employed to represent the interests of the general public.

R. NOLL, *REFORMING REGULATION* 41 (1971).

144. This was the position taken by the FDA in *Hynson*:

Since the NAS-NRC panels concluded that more than 13,000 of the claims they reviewed were not supported by substantial evidence, . . . FDA would be faced with a truly monumental task if it had to prepare a detailed substantiation of each of these conclusions before it could move against the drug. By placing the burden of coming forward on the manufacturer, the process of weeding out wholly unsubstantial drug efficacy claims is rendered at least partially manageable.

Consolidated Reply Brief for the Federal Parties at 26 n.30, *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973).

145. See note 69 *supra*.

146. In civil cases an additional fairness concern is the possible use of the summary judgment motion as a device for harassment. Conditioning summary judgment on production by the moving party of the uncontested facts that entitle him to judgment minimizes the risk that the motion will be used merely to delay or to gain a preview of an opponent's legal theories. See *Louis*, *supra* note 100, at 753-58. This concern has less force where the moving party is a branch of the agency deciding the case. An agency has less reason than a civil litigant to delay or to impose costs in hope of forcing settlement; indeed, an agency has good reason to discover the private party's case for purposes of preventing delay. Compare *Ciba-Geigy Corp. v. Richardson*, 446 F.2d 466, 468 (2d Cir. 1971) (where the court analogized the FDA's authority to the judicial power under Fed. R. Civ. P. 37(d) to dismiss a civil suit without trial "for failure to furnish facts essential to narrow the issues" in upholding the FDA procedures), with *USV Pharmaceutical Corp. v. Secretary of HEW*, 466 F.2d 455, 461 (1972) (where the court found the FDA's dual role as moving party and arbiter of the motion "a vital distinction" requiring the FDA as moving party to assume the burden of proof).

Responding to *USV*, the FDA has instituted a separation of functions between the Bureau of Drugs, as movant, and the Commissioner, as decider. 39 Fed. Reg. 9763 (1974). But cf. Friendly, *A Look at the Federal Administrative Agencies*, 60 COLUM. L. REV. 429, 438 (1960) (questioning the efficacy of such formal separations) [hereinafter cited as Friendly].

147. Cf. Ball, *The Moment of Truth: Probability Theory and Standards of Proof*,

in pleading and proving uncontested facts, courts will often consider an issue only if the party asserting the less probable version of events produces evidence.¹⁴⁸ For example, it is partly because plaintiffs are unlikely to bring an action on bills that have already been paid that payment is an affirmative defense to a complaint alleging the non-satisfaction of a monetary claim.¹⁴⁹ In the context of summary judgment, the problem is to determine the likelihood of genuine dispute over particular issues of fact.

The probability of factual dispute relates closely to the precision of legal standards. Precise standards narrow the range of relevant factual contentions and thus reduce the probability of genuine and material factual disputes. A charge of driving at a "dangerous" speed is more readily contested than a charge of driving over a 50 mile-per-hour speed limit. And if the law specifies an "approved" radar test of speed, factual contest may be rare indeed. Moreover, in classes of adjudication where only one source of factual information exists, dispute is less likely than where there are alternative versions of the facts. Both precise standards of proof and the absence of competing sources of data have characterized the FDA's implementation of the drug efficacy requirement of the 1962 Amendments. Indeed, in this sense the FDA's success in invoking summary judgment¹⁵⁰ may be viewed as vindicating its allocation of the burden of demonstrating the need for hearings.

2. *The Framework for Summary Judgment: The Definition of Material Issues*

The key to the FDA's ability to avoid hearings has been its "substantial evidence" regulations governing clinical studies of drug effectiveness. The FDA has invoked these regulations with great success to exclude efficacy studies that were in circulation before the regulations were drafted, and has used the regulations with still greater success to exclude studies made before proof of efficacy became a requirement of the law.¹⁵¹ In accordance with *Hynson*,¹⁵² the regulations have "conclusively" disqualified nearly all of these early studies.

14 VAND. L. REV. 807, 817-18 (1961) (questioning reliance on probability as unfair in a jury case where it already influences jury expectations).

148. See Morgan, *How to Approach Burden of Proof and Presumptions*, 25 ROCKY MT. L. REV. 34 (1953). See text accompanying notes 127-28 *supra*.

149. Cleary, *supra* note 119, at 13; see FED. R. CIV. P. 8(c).

150. See note 97 and accompanying text *supra*.

151. See, e.g., *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974) (upholding disqualification of eight studies published between 1947 and 1960 and one study published in 1968).

152. *Hynson* directed reviewing courts to "determine whether the Commissioner's findings accurately reflect the study in question, and if they do, whether the deficiency he finds conclusively render the study inadequate or uncontrolled in light of the pertinent regulations." 412 U.S. at 622.

Like all legal guidelines, however, the FDA regulations are less likely to be dispositive in their prospective application. As manufacturers seek to comply, and as new testing methodologies are devised and new problems arise, the questions whether a particular study conforms to the regulations and whether it should be accepted even if it fails to conform are likely to grow more difficult. In turn, the continuing feasibility of summary judgment will depend on the agency's inclination and authority to update its elaboration of the statutory standards to accommodate new developments.¹⁵³ The power to further particularize the statutory standard through rulemaking is well defined. What is less clear is the extent to which an agency like the FDA can or should supplement its regulations by further elaborating threshold standards in the early stages of adjudicatory proceedings.

a. Substantive Authority

The FDA's lawmaking power in the field of drug regulation consists of a combination of express rulemaking authority "for the efficient enforcement of this Act"¹⁵⁴ and implicit authority to interpret statutory licensing standards in evaluating the qualifications of particular NDAs.¹⁵⁵ This power to make law is subject to two related substantive constraints: the agency must adopt an interpretation consistent with the statute,¹⁵⁶ and it must not act in an "arbitrary or capricious" manner.¹⁵⁷ The "arbitrary and capricious" standard, which requires that the adopted rule have some rational foundation in fact, has become the vehicle for rising judicial willingness to scrutinize the empirical justifications for

153. Cf. Shapiro, *supra* note 5, at 932-33 (suggesting that agencies with the power to initiate as well as decide cases may exercise "virtually the same degree of planning in commencement of adjudicatory proceedings as they can in rulemaking"). But cf. LANDIS REPORT, *supra* note 1, at 18 ("Decision making . . . throws up issues . . . most frequently as a result of the incidence or accident of cases or controversies.").

154. Federal Food, Drug, and Cosmetic Act § 701(a), 21 U.S.C. § 371(a) (1970) authorizes the promulgation of regulations "for the efficient enforcement of [the] Act." This language is sufficient to support issuance of binding substantive rules. National Nutritional Foods Ass'n v. Weinberger, 504 F.2d 761 (2d Cir.), *cert. denied*, 419 U.S. 874 (1975). Regarding other regulatory agencies, see *Mourning v. Family Publications Serv., Inc.*, 411 U.S. 356 (1973); *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir.), *cert. denied*, 415 U.S. 951 (1974).

155. "If the courts may and do make rules in the course of adjudicating, a fortiori the Commission may—and indeed is under a positive obligation to—engage in substantive rulemaking in its adjudications." Statement of Basis and Purpose of Trade Regulation Rule, 29 Fed. Reg. 8325, 8366 (1964).

156. The Administrative Procedure Act requires reviewing courts to set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right . . ." 5 U.S.C. § 706(2)(C) (1970).

157. The Administrative Procedure Act requires reviewing courts to set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . ." 5 U.S.C. § 706(2)(A) (1970).

agency action.¹⁵⁸ Yet the more pertinent constraint for purposes of this discussion is that of consistency.¹⁵⁹

Because the "substantial evidence" standard of drug efficacy is phrased in evidentiary terms, it is tempting to conclude that the FDA's success in adopting summary judgment procedures is *sui generis*. After all, the Supreme Court had to hold in *Hynson* only that the FDA's threshold standards for evidence of efficacy were consistent with a statutory standard which itself explicitly sought to limit the kind of submissions that could govern the licensing decision. But insofar as consistency with statutory standards measures the legitimacy of agency regulations, inclusion of evidentiary criteria in the statute should not be essential. Substantive criteria are equally appropriate subjects for agency particularization—and to the extent that the resulting substantive guidelines are precise, they will become effective evidentiary standards.¹⁶⁰

Nor is the constraint of consistency likely to prevent statutory elaboration of a kind that will permit extensive reliance on summary judgment.¹⁶¹ In *United States v. Storer Broadcasting Co.*,¹⁶² the Supreme Court sustained an FCC regulation that elaborated the "public interest" standard of the Communications Act by limiting to five the number of VHF television stations one licensee could own. And in *FPC v. Texaco, Inc.*,¹⁶³ the Court upheld regulations elaborating the "public convenience and necessity" standard of the National Gas Act by proscribing all but certain "permissible" price change provisions in contracts filed as rate schedules. Although both statutes required hearings, in both cases the regulations served to bar at the threshold private parties whose submissions on their face showed they did not comply. In both cases the agencies reduced broad substantive standards commonly found in regulatory legislation to precise guidelines by which to determine the need for a hearing.¹⁶⁴

158. See, e.g., *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402 (1971); cf. Wright, *supra* note 6, at 388-95.

159. "Lower courts have upheld the validity of these regulations, and it is not disputed here that they express well-established principles of scientific investigation." *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 618-19 (1973).

160. See, e.g., *FPC v. Texaco, Inc.*, 377 U.S. 33, 39 (1964); *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 202-05 (1956); *American Airlines, Inc. v. CAB*, 359 F.2d 624, 628-29 (D.C. Cir.), *cert. denied*, 385 U.S. 843 (1966). See generally *Rulemaking to Deny Adjudications*, *supra* note 5.

161. 1 DAVIS TREATISE, *supra* note 10, § 2.05, at 98-99 (1958), 46-50 (Supp. 1970); Hutt, *supra* note 7, at 179-80; cf. Jaffe, *The Illusion of the Ideal Administration*, 86 HARV. L. REV. 1183 (1973).

162. 351 U.S. 192 (1956).

163. 377 U.S. 33 (1964).

164. Regarding other agencies, see *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974); *WBEN v. United States*, 396 F.2d 601 (2d Cir.), *cert. denied*, 393 U.S. 914 (1968); *American Airlines, Inc. v.*

b. *Procedural Limitations*

After *Hynson* the FDA's authority to promulgate regulations elaborating the "substantial evidence" standard through notice-and-comment rulemaking is no longer in doubt. But the present FDA regulations contemplate the possibility that legal rulings in the early stages of adjudication can serve the same function as the regulations upheld in *Hynson*. Significantly, the FDA regulations suggest that the FDA can frame a new legal rule and invoke it in the course of a single summary adjudication. As discussed above, such a procedure is subject to the requirement that the agency give notice of the factual showing necessary to preserve the right to a hearing.¹⁶⁵ Ordinarily, notice satisfying this requirement will afford ample opportunity within the confines of summary proceedings to challenge the new rule as well as to comply with its terms. Occasionally, however, a hearing may be needed to ventilate the "legislative facts" underlying opposing legal contentions.¹⁶⁶

In the federal courts summary judgment is generally considered inappropriate in cases involving novel and complex legal issues, where the submissions of the parties may be inadequate to assure an accurate foundation for the legal conclusions sought by the moving party.¹⁶⁷ The same principle should govern administrative procedure.¹⁶⁸ An agency seeking to articulate a new statutory interpretation in summary proceedings should provide a genuine opportunity to point out flaws in the new approach.¹⁶⁹ Where the proposed interpretation raises complex questions of regulatory policy, documentary submissions may be insufficient, and a hearing—possibly including cross-examination—may be necessary to assure a "reasoned decision" and to provide a basis for judicial review.¹⁷⁰

CAB, 359 F.2d 624 (D.C. Cir.), *cert. denied*, 385 U.S. 843 (1966); *Air Line Pilots Ass'n Int'l v. Quesada*, 276 F.2d 892 (2d Cir. 1960).

165. See text accompanying notes 138-46 *supra*.

166. For the definitions of "legislative" and "adjudicative" facts, see text accompanying note 273 *infra*.

167. 6 J. MOORE, *supra* note 98, § 56.16; 10 WRIGHT & MILLER § 2732. "While the existence of an important, difficult, or complicated question of law is not a bar to a summary judgment, the record must be adequate for decision of the legal question presented by the motion for summary judgment." 6 J. MOORE § 56.15[7]. In *White Motor Co. v. United States*, 372 U.S. 253 (1963), for example, the Supreme Court declined to resolve difficult antitrust issues of first impression on the ground that it was inappropriate "to reach a conclusion on the bare bones of the documentary evidence." *Id.* at 261; *accord*, *Kennedy v. Silas Mason Co.*, 334 U.S. 249, 256-57 (1948).

168. See *Administrative Summary Judgment*, *supra* note 5, at 618.

169. See text accompanying note 86 *supra*.

170. See *Municipal Light Bds. v. FPC*, 450 F.2d 1341, 1345 (D.C. Cir. 1971), *cert. denied*, 405 U.S. 989 (1972); *Citizens for Alleghen County, Inc. v. FPC*, 414 F.2d 1125, 1129 (D.C. Cir. 1969); *cf.* *Walter Holm & Co. v. Hardin*, 449 F.2d 1009, 1016 (D.C. Cir. 1971) (requiring oral argument for "novel or crucial matters" involved in rulemaking); Austern, *Food Standards: The Balance Between Certainty and Innovation*, 24

Indeed, it has been argued that agencies must go well beyond the courts in one respect: when departing from established policy they must provide notice and opportunity to be heard not just to the parties in a particular adjudication, but to the public as well, as the Administrative Procedure Act requires for rulemaking.¹⁷¹ The Supreme Court has rejected this argument in a case involving an attempt by the National Labor Relations Board to develop new principles in formal adjudication. In *Bell Aerospace Co., Division of Textron, Inc. v. NLRB*,¹⁷² the Court held that the Board "has discretion to decide that the adjudicative procedures in this case may also produce the relevant information necessary to mature and fair consideration of the issues. Those most immediately affected are accorded a full opportunity to be heard before the Board makes its determination."¹⁷³ Nothing in the opinion suggests that the argument would fare any better in the context of a summary judgment proceeding. Of course, *Bell Aerospace* dealt with the question of union participation by "managerial employees" under the National Labor Relations Act; no interests comparable to those at stake in FDA withdrawal of approval of an NDA were involved.¹⁷⁴ Nevertheless, the Court's articulated requirement that "those most immediately affected [be] accorded an opportunity to be heard" in order to "produce the relevant information," merely restates the procedural limitations on development of new principles in summary adjudication.¹⁷⁵

c. Particularization: Rulemaking versus Summary Adjudication

The *Bell Aerospace* decision reiterates the principle that "the choice between rulemaking and adjudication lies in the first instance within [agency] discretion."¹⁷⁶ Often this choice is influenced by the

FOOD DRUG COSM. L.J. 440, 451 (1969); "[H]e who regulates ought to appear publicly if there is a challenge, and put on the table, subject to cross-examination the facts on which he grounds his proposal." See also text accompanying notes 298-316 *infra*.

171. 5 U.S.C. § 553 (1970); see *Bell Aerospace Co. v. NLRB*, 475 F.2d 485 (2d Cir. 1973) (Friendly, J.), *aff'd in part, rev'd in part*, 416 U.S. 267 (1974).

172. 416 U.S. 267 (1974).

173. *Id.* at 295. "Regardless of whether sufficient notice of the regulation . . . was given to other members of the Pharmaceutical Manufacturers Association, the record demonstrates that adequate notice was given to Upjohn." *Upjohn Co. v. Finch*, 422 F.2d 944, 956 (6th Cir. 1970).

174. The Court stated:

[T]his is not a case in which some new liability is sought to be imposed on individuals for past actions which were taken in good faith reliance on Board pronouncements. Nor are fines and damages involved here. In any event, concern about such consequences is largely speculative, for the Board has not yet determined whether these buyers are "managerial."

416 U.S. at 295. It is interesting to note that Justice Powell, author of the majority opinion in *Bell Aerospace*, in effect dissented in *Hynson*, noting substantial problems with this issue. See note 47 *supra*.

175. See text accompanying notes 138-46, 165-70 *supra*.

176. 416 U.S. 267, 294 (1974). See *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759

disproportionate burden of trial-type hearings on the adjudication side of the scales.¹⁷⁷ But if summary judgment is appropriate, that burden shrinks to the more manageable obligation to articulate the applicable legal standards and to make a reasoned decision. Differences in efficiency are thus less crucial, and the choice is more clearly between particularizing the statute in generally applicable rules and particularizing it in individual rulings. This is not an "either-or" choice, but a question of what combination of procedures best accomplishes fair and effective enforcement of the statutory mandate.¹⁷⁸

The need for administrative flexibility is likely to restrain the promulgation of uniform regulations designed to serve as a framework for summary judgment.¹⁷⁹ The FDA's experience with Serc, a drug

(1969); *SEC v. Chenery Corp.*, 332 U.S. 194 (1947). See generally Fuchs, *Agency Development of Policy Through Rule-Making*, 59 Nw. U.L. Rev. 781 (1965); Robinson, *supra* note 5; Shapiro, *supra* note 5.

177. See, e.g., FTC, Statement of Basis and Purpose of Trade Regulation Rule, 29 Fed. Reg. 8325, 8368 (1964) (referring to adjudication as "prohibitively time consuming, costly, and inefficient").

178. Cf. Robinson, *supra* note 5, at 536-37: "Future efforts in the direction of administrative procedure reform should steer away from prescription of uniform procedures for the entire administrative system and focus instead on specific procedures tailored to the distinctive functions of each individual agency."

179. Cf. *SEC v. Chenery Corp.*, 332 U.S. 194 (1947):

Not every principle essential to the effective administration of a statute can or should be cast immediately into the mold of a general rule. Some principles must await their own development, while others must be adjusted to meet particular, unforeseeable situations

In other words, problems may arise in a case which the administrative agency could not foresee, problems which must be solved despite the absence of a relevant general rule. Or the agency may not have had sufficient experience with a particular problem to warrant rigidifying its tentative judgment into a hard and fast rule. Or the problem may be so specialized and varying in nature as to be impossible of capture within the boundaries of a general rule. In those situations, the agency must retain power to deal with the problems on a case-to-case basis if the administrative process is to be effective.

Id. at 202-03.

Those principles are especially pertinent in the field of drug regulation. "The history of medicine is littered with once favored but not discarded remedies." *Upjohn Co. v. Finch*, 422 F.2d 944, 951 (6th Cir. 1970). Present notions of what qualifies as an "adequate and well controlled" study are not likely to endure. Yet rigid, uniform regulation of such methods may artificially prolong the use of outmoded techniques. See S. PELTZMAN, *REGULATION OF PHARMACEUTICAL INNOVATION* (1974). Moreover, the FDA deals with diverse chemical formulations designed to alleviate unique human ailments. Deciding whether to allow a drug to be marketed requires an individualized inquiry into the effects—both salutary and harmful—that the particular drug may cause. This means focusing not simply on efficacy or safety, but also "calculating whether the benefits which the drug produces outweigh the costs of its restricted use." *Hess & Clark, Div. of Rhodia, Inc. v. FDA*, 495 F.2d 975, 993-94 (D.C. Cir. 1974), citing *Merrill, Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 9-11 (1973). Because the Administrative Procedure Act treats safety and efficacy as discrete criteria, the FDA can omit from its efficacy regulations any mention of safety affronting the statute. See note 156 *supra*. But if the FDA were to give its efficacy regulations greater precision and to

intended to relieve vertigo in the victims of Meniere's Syndrome,¹⁸⁰ is instructive. Skeptical of the adequacy of the evidence submitted to demonstrate efficacy, the FDA initiated proceedings to withdraw Serc's NDA.¹⁸¹ An evidentiary hearing in 1969—a rare occasion at the FDA—resulted in a formal finding that the studies submitted on behalf of Serc did not constitute substantial evidence of effectiveness.¹⁸² Nevertheless, the agency stayed its order withdrawing Serc's NDA to allow court review¹⁸³ and, more surprisingly, continued the stay¹⁸⁴ even after its ruling was upheld by the District of Columbia Circuit on February 7, 1972.¹⁸⁵ Only after considerable public prodding, including congressional hearings¹⁸⁶ and the announcement of a lawsuit to force the FDA to act,¹⁸⁷ did the FDA notify Serc's manufacturer (on December 21, 1972) that the order would finally become effective.¹⁸⁸

Three factors appear to have influenced the FDA's refusal to implement its own negative appraisal of Serc's effectiveness. First, in its prescribed use by victims of Meniere's Syndrome, Serc had been proved safe to the agency's satisfaction. Second, there was no known alternative therapy for vertigo in persons suffering from the disease. Finally, although the submissions on behalf of Serc had been inadequate, it still seemed possible that the manufacturer could prove effectiveness. But the necessary clinical studies would be financially feasible for the manufacturer, the FDA believed, only if Serc remained

apply them woodenly, it might foreclose the most sensible approach to drug regulation. Cf. *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974):

The natural question that occurs to me . . . is why a study is plainly not "adequate," is too unsubstantial for serious consideration, merely because the "control" used is a preparation that may be generally productive of well being, even though it is neither an inert placebo nor an "effective regimen of therapy"

. . . .

I see particular problems for the FDA, in any rigidity concerning the requirement for an inert control substance, when the drug being tested is designed to relieve pain . . . in view of striking analgesic effect assigned by authoritative medical research to placebos.

Id. at 791 (Leventhal, J., dissenting).

180. See generally *Hearings on FDA Regulation of the New Drug "Serc" Before the Intergovernmental Subcomm. of the House Comm. on Governmental Operations*, 92d Cong., 2d Sess. (1972) [hereinafter cited as *Hearings on Serc*].

181. 33 Fed. Reg. 10228 (1968).

182. 35 Fed. Reg. 17563 (1970); see note 97 *supra*.

183. 35 Fed. Reg. 18411 (1970).

184. Letter from R. Joel Slomoff, Special Ass't to the Assoc. Comm'r for Compliance, to Mr. Donald J. Cronin, Counsel for Unimed, Inc., February 28, 1972, in *Hearings on Serc*, *supra* note 180, at 24.

185. *Unimed, Inc. v. Richardson*, 458 F.2d 787 (D.C. Cir. 1972).

186. *Hearings on Serc*, *supra* note 180.

187. *Consumers Union of America, Inc. v. Richardson*, Civil No. 2498-72 (D.D.C., filed Dec. 15, 1972).

188. Letter from Dr. Henry E. Simmons, Director, Bureau of Drugs, to Unimed, Inc., Dec. 21, 1972.

on the market. Together, these factors added up to a low risk and a potentially high, if essentially unknown, benefit in continuing marketing of the drug.¹⁸⁹

The Serc episode is illustrative of the FDA's understanding of its mandate. In the ultimate decision whether to take the drastic step of removing the drug from the market, the FDA chose not to limit itself to considering the adequacy—under its own regulations—of the evidence of Serc's efficacy. It chose to rely on factors peculiar to Serc: the assurance of safety, the absence of alternative therapy, the possibility that efficacy might yet be shown if marketing continued. The importance of such factors demonstrates the impracticality of carrying uniform particularization of statutory standards too far. The efficacy standard the FDA must enforce ultimately requires an individualized inquiry, and an attempt to push uniformity too far may simply invite the agency—as in the Serc episode—to ignore its rules in hard cases.

An agency can achieve desired flexibility without foregoing the opportunity for summary disposition in two ways: it can create uniform regulations elaborating a statutory standard but consider waiving the regulations when their application to a particular case seems unwise; or it can maintain a general standard and wait until particular problems arise before announcing what the standard means in the course of adjudication. An agency's rules establish the baseline for the performance of persons subject to its control. By waiving the rules, the agency can permit some conduct to fall short of the line, and by articulating new standards in adjudication it can require other conduct to surpass the established baseline.

The reliance an agency places on one or the other of these techniques for achieving flexibility will depend upon the extent to which its regulations embody the standards it will require in practice. If an agency's regulations go further than it is willing to go in all individual enforcement proceedings, as the FDA's substantial evidence regulations did in 1969, it will have to make adjustments by waiver; if its regulations fall short of its enforcement objectives, it will have to articulate new standards in adjudication. And where the field of regulation requires individualized as well as uniform standards, efficiency may require combining innovation through adjudication with a set of uniform regulations. In the past the FDA has relied extensively on a combination of stringent regulations and functional "waivers" in the form of delayed enforcement. Unlike its awkward handling of Serc—where it took legal action against the drug first and only later considered the conse-

189. Cf. *Hearings on Serc*, *supra* note 180, at 6 (testimony of Dr. Henry E. Simmons, Director, Bureau of Drugs). See note 179 *supra*.

quences of withdrawal¹⁹⁰—the more typical FDA approach to pre-1962 drugs whose efficacy is possible but unproved has been to delay institution of legal proceedings, affording the manufacturer time to conduct “adequate and well controlled studies.”¹⁹¹ Only after submission of the requisite studies does the agency conduct an individual inquiry into the costs and benefits of the drug. In the future, as general compliance with the present regulations becomes feasible, the FDA will turn increasingly to case-by-case particularization. If, for example, scientific advances reveal that a large control group is indispensable for reliable testing of pain-relieving drugs, the agency might choose to leave untouched the general requirement of an “adequate” control group and wait for individual proceedings involving pain-relievers to articulate more specific requirements.

The question remains whether an agency should err on the side of stringency or laxity when it adopts general rules. The Supreme Court seems to have sanctioned deliberate over-regulation. In cases upholding uniform regulations particularizing broad statutory standards, the Court has emphasized the possibility of waiver in circumstances where application of the regulations would be inappropriate.¹⁹² In *United States v. Storer Broadcasting Co.*,¹⁹³ for example, the Court spoke of the “necessity for flexibility” under the rules:

That flexibility is here. . . . We read the Act and Regulations as providing a “full hearing” for applicants who have reached the existing limit of stations, upon their presentation of applications . . . that set out adequate reasons why the Rules should be waived or amended.¹⁹⁴

In a sense, the Court conditioned its present approval of the regulations on the agency’s future exercise of the waiver power in appropriate cases.¹⁹⁵

Paradoxically, however, agency decisions on requests for waiver in particular cases have been largely immune from substantive scrutiny by

190. “What we did was to choose the legal route that would cut down the amount of time to the bare minimum necessary so we would be in a strong legal position to take whatever action was warranted by the facts.” *Id.* at 20.

191. *American Public Health Ass’n v. Veneman*, 349 F. Supp. 1311 (D.D.C. 1972).

192. See *FPC v. Texaco*, 377 U.S. 33, 40-41 (1964); *United States v. Storer Broadcasting Co.*, 351 U.S. 192, 202-05 (1956); *National Broadcasting Co. v. United States*, 319 U.S. 190, 225 (1943). *But cf.* *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973) (failing to mention the possibility of FDA waiver of the “substantial evidence” regulations).

193. 351 U.S. 192 (1956).

194. *Id.* at 205.

195. The Court earlier had made this explicit in *National Broadcasting Co. v. United States*, 319 U.S. 190, 225 (1956): “If time and changing circumstances reveal that the ‘public interest’ is not served by application of the regulations, it must be assumed that the Commission will act in accordance with its statutory obligations.”

the courts. In only one reported case has a reviewing court failed to approve an agency's reliance on its regulations in the face of a waiver request. There, the court demanded only that the agency give the request "a hard look" on remand.¹⁹⁶ And when the agency provided the ordered "hard look" and denied the request for a second time, its action was sustained.¹⁹⁷ This approach may have the effect of encouraging agencies to frame regulations more demanding than their expectations, for the "hard look" required for a waiver request will be far less burdensome than even a summary adjudication.

It may also be argued that the *Storer* doctrine provides a means of achieving flexibility without the unfairness of retroactive application of new legal requirements. The rules prepare members of the industry for the worst; the manufacturer who has the opportunity to participate in agency rulemaking proceedings is in a poor position to protest eventual application of the rules to him, especially if the rules have been upheld in court. If occasion demands, on the other hand, the agency may waive the rules on grounds that their application to a particular case is unwise. Yet the argument is only convincing where an agency waives its rules on rare occasions. If waiver becomes routine for special classes of cases, the manufacturer who can claim that his case falls within the class can also claim that he had no reason to expect the regulations to apply. Application of the regulation to him may be as unexpected as "retroactive" application of a legal standard formulated with his peculiar circumstance in mind. Moreover, extensive exercise of the waiver power will vitiate the policies favoring promulgation of regulations. Uniformity of treatment, notice of statutory requirements, and predictability are all undercut when rules cease to apply generally.

Where uniformity is impractical because individual characteristics predominate, the wiser course for an agency is to rely on individual adjudication. Of course, even if many cases can be disposed of summarily, adjudication is likely to be a time-consuming process because of the need to articulate standards and prepare detailed findings. But by relying on rulemaking to resolve issues capable of general solution, and by insisting on summary judgment where it is appropriate, an agency can reduce the burden of the individual proceedings that diversity requires.

The FDA approach to regulation embodies these principles. With the exception of its delay in acting against the drugs rated "probably" or "possibly" effective by the NAS-NRC panels, the FDA has eschewed

196. *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969); *cf. International Harvester Co. v. Ruckelshaus*, 478 F.2d 615, 641 (D.C. Cir. 1973).

197. *WAIT Radio v. FCC*, 459 F.2d 1203 (D.C. Cir.), *cert. denied*, 409 U.S. 1027 (1972). *See also* *Port Angeles Telecable, Inc. v. FCC*, 416 F.2d 243 (9th Cir. 1961).

extensive reliance on its waiver power.¹⁹⁸ Instead, it has tried to maintain a clear line between the aspects of the efficacy standard suitable for uniform rules and those aspects requiring particularized application. For the most part it has promulgated only such regulations as it believed it could apply across the board, leaving to particular proceedings specification of legal requirements in areas where flexibility seems necessary. As long as it pursues its statutory mandate, and as long as the procedures it observes are fair, the agency should not only be upheld, but should be encouraged in this enforcement approach.

II

QUASI-FORMAL RULEMAKING TO AVOID JUDICIAL ENFORCEMENT

The Food and Drug Administration has attempted to frame regulatory standards not only for adjudications before the agency, but also for judicial enforcement proceedings in which the agency's role is limited to prosecuting charges against manufacturers. The FDA monographs for over-the-counter (OTC) drugs represent a unique agency effort to set comprehensive guidelines for judicial proceedings. This second FDA technique for avoiding formal adjudication—the creation of monographs for prosecutorial use—will not be as widely available to other agencies as the FDA's summary judgment procedures, for other agencies are rarely cast in the FDA's prosecutorial role.¹⁹⁹ In its component parts, however, the FDA's use of rulemaking to guide judicial enforcement may be of far-reaching significance. In one aspect, the FDA monographs represent a novel assertion of primary jurisdiction. Rather than waiting to have primary jurisdiction thrust upon it by the courts,²⁰⁰ the FDA has reached out to seize a decisionmaking role in adjudications which, as a litigant, it cannot control. In another aspect, the FDA monographs represent an imaginative assertion of rulemaking authority. So comprehensive are the monographs that for hundreds of over-the-counter remedies acceptance of the appropriate monograph will leave no contestable factual issues to adjudicate. Because the net result is

198. The waiver provision is at 21 C.F.R. § 314.111(a)(5)(ii)(a) (1975). The FDA's former General Counsel has stated that the purpose of the provision is to deal with those circumstances where the regulations are "either impossible of achievement or would result in unethical conduct." *Hearings on Advisory Committees, supra* note 37, at 226; cf. *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772, 778 (D.C. Cir. 1974) (rejecting a waiver request on the ground that it went to the basic requirements of the 1962 Amendments).

199. There may be a direct application of these techniques to the FTC. See note 256 *infra*.

200. See, e.g., *United States v. Western Pacific R.R. Co.*, 352 U.S. 59 (1956); *Texas & Pacific Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1967).

to reduce the availability of formal adjudicatory safeguards, the FDA has taken the initiative to adopt a quasi-formal rulemaking process that assures empirical accuracy and heightens opportunities for participation.²⁰¹

A. *Quasi-Formal Rulemaking at the FDA*

1. *The Regulatory Framework*

By 1971 the FDA's program for enforcing the 1962 Amendments against prescription drugs was well under way, but the agency lacked a strategy for extending to OTC drugs the congressional mandate that drug products be shown to be effective.²⁰² The OTC drugs requiring evaluation far outnumbered the prescription drugs studied by the NAS-NRC panels, and included a higher percentage of products that ultimately might have had to come off the market. An inventory conducted by the agency in 1974 indicated that about 400,000 OTC drugs were being marketed in the United States.²⁰³ Of these, the FDA had reason to fear that the large majority would be found ineffective for at least one claimed use.²⁰⁴ To proceed against the drugs individually was clearly impractical.

But not all OTC products were subject to the proof-of-efficacy requirement. Congress had exempted those drugs which, on the day before the amendments were enacted, were: (1) sold in the United States; (2) generally recognized as safe; (3) not covered by effective NDAs; and (4) "intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."²⁰⁵ This "grandfather clause" had the effect of exempting pre-1962 drugs whose labeling had remained unchanged, if in 1962 they were generally recognized as safe and lacked effective

201. The term "quasi-formal" is used here because it suggests procedures approaching those used at trials. Other commentators have used the term "hybrid" rulemaking. See, e.g., Verkuil, *Judicial Review of Informal Rulemaking*, 60 VA. L. REV. 185 (1974); Wright, *supra* note 6.

202. The FDA dealt with prescription drugs first because of the greater risks believed to be associated with such products, and because the number of products involved was of a much more manageable size. 37 Fed. Reg. 85 (1972). Future FDA projects may include a review of OTC veterinary medications. See 37 Fed. Reg. 9464 (1972).

203. See *Weimberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 649-50 (1973).

204. *Hearings Before the Senate Subcom. on Monopoly of the Select Comm. on Small Business on Advertising of Proprietary Medicines*, 92d Cong., 1st Sess., at 8-10 (1971) [hereinafter *Hearings on Proprietary Medicine Advertising*].

Later the FDA was willing to concede that some products were termed "possibly" or "probably" effective, or "effective but." Even then 75 percent of the claims were not considered substantiated by substantial evidence. 37 Fed. Reg. 9464-62 (1972).

205. 21 U.S.C. § 321 note (1970); Act of Oct. 10, 1962, Pub. L. No. 87-781 § 107(c)(4), 76 Stat. 788.

NDAs. In addition, the clause automatically exempted pre-1938 drugs retaining pre-1938 labeling.²⁰⁶

This statutory loophole posed a dilemma for the FDA. Of the OTC drug products on the market in 1962, fewer than one percent were covered by effective NDAs, and many pre-dated the 1938 Act.²⁰⁷ Not only would classification of these products as grandfathered or non-grandfathered be a burdensome task, but more importantly the resulting pattern of regulation would be inequitable. An antacid covered by an effective NDA in 1962 might be withdrawn as an ineffective new drug, while a competing product with a different formulation not covered by an NDA in 1962 could stay on the market despite equal ineffectiveness.²⁰⁸ Enforcement of the 1962 Amendments against the OTC drugs would be justifiable, the FDA believed, only if all products making equivalent claims could be similarly treated.²⁰⁹

The problem was to find a way to regulate all OTC drugs. A solution was suggested by the Food, Drug and Cosmetic Act treatment of drug labeling. Under the new provisions both safety and efficacy are measured in terms of the claims in a drug's labeling. Similarly, a drug's grandfathered status turns on whether the labeling claims made for it remain unchanged. This emphasis on labeling has a counterpart in the "misbranding" provisions of the Act. Section 301(a) prohibits the marketing of any drug or other product that is "misbranded,"²¹⁰ and section 502(a) defines as misbranded a product whose "labeling is false or misleading in any particular."²¹¹ Neither section exempts grandfathered drugs.

In combination with the 1962 Amendments, the misbranding provisions provided a vehicle for uniform OTC drug review. A product with labeling that contained false claims of effectiveness would be misbranded, whether grandfathered or not; yet any change in labeling claims designed to avoid a misbranding violation would forfeit a product's grandfather protection and necessitate its approval under the 1962 Amendments in the absence of general recognition of safety and

206. Pre-1938 drugs were "grandfathered" under an exemption contained in the 1938 Act itself. 21 U.S.C. § 321(p)(1) (1970). The grandfather clause in the 1962 Amendments specifically recognized the continued vitality of that exemption. 21 U.S.C. § 321 note (1970).

207. J. MASHAW & R. MERRILL, *supra* note 8, at 537.

208. The Supreme Court held in *Hynson* that if a "pioneer" drug were not grandfathered, no "me too" drugs having the same formulation as the pioneer could claim grandfather protection. *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 625-26 (1973).

209. See generally Hutt, *supra* note 7.

210. 21 U.S.C. § 331(a) (1970).

211. 21 U.S.C. § 352(a) (1970).

effectiveness.²¹² But the misbranding provisions, unlike the efficacy provisions, contemplate FDA action against misbranded drugs only through *judicial* enforcement proceedings.²¹³ If the agency wished to play a role beyond that of prosecutor in implementing the misbranding standard, it would have to rely on its authority, under section 701(a) to promulgate regulations for the efficient enforcement of the Act.²¹⁴ The extent to which this general authority permitted elaboration of the misbranding standard to guide judicial enforcement was unclear.

2. *The Over-the-Counter Regulations*

On May 11, 1972, the FDA issued regulations setting forth its plan to review OTC drugs for safety and effectiveness.²¹⁵ Under the announced procedures, the FDA would form expert advisory review panels to evaluate the safety and effectiveness of OTC drugs and review their labeling.²¹⁶ Each panel would study a specific class of drugs, such as antacids, laxatives, or dandruff agents,²¹⁷ and would recommend a proposed "monograph" defining the claimed uses for which products in the class were generally recognized as safe and effective and not mis-

212. NDA approval under the 1962 Amendments is required only for "new drugs," i.e., drugs not generally recognized as safe and effective for their claimed uses. See note 18 *supra*.

213. Any drug which is "misbranded . . . shall be liable to be proceeded against . . . in any district court. . . ." 21 U.S.C. § 334(a) (1970). Individual violators may receive criminal punishment of up to 1 year in prison and a fine of \$1,000. *Id.* § 333(a). The provisions say nothing about administrative enforcement.

214. 21 U.S.C. § 371(a) (1970).

215. 37 Fed. Reg. 9464 (May 11, 1972). The lengthy preamble runs for almost ten pages, with the actual order beginning at 37 Fed. Reg. 9473 (May 11, 1972). Later the regulations were amended, 39 Fed. Reg. 11741 (March 29, 1974), and 39 Fed. Reg. 19878 (June 4, 1974). They are codified at 21 C.F.R. § 330.10 (1975).

216. The FDA has had much experience with the use of advisory committees. Between 1972 and 1973 the number of such panels has increased from 24 to 45, and the number of meetings has increased from 55 to 167. Presently the FDA is using about 66 advisory committees, but the number varies with need. See *Hearings on Advisory Committees*, *supra* note 26, at 3. See generally 1 DAVIS TREATISE, *supra* note 10, at § 6.03.

217. The categories were as follows: (1) antacids; (2) laxatives; (3) antidiarrheal products; (4) emetics; (5) antiemetics; (6) antiperspirants; (7) sunburn prevention and treatment products; (8) vitamin-mineral products; (9) antimicrobials; (10) dandruff agents; (11) oral hygiene aids; (12) hemorrhoidal products; (13) hematinics; (14) bronchodilators and antiasthmatics; (15) analgesics; (16) sedatives and sleep aids; (17) stimulants; (18) antitussives; (19) allergy treatments; (20) cold remedies; (21) anti-rheumatics; (22) ophthalmic products; (23) contraceptives; (24) miscellaneous dermatologic products; (25) dentifrices and dental products; (26) all others. These categories are now codified at 21 C.F.R. § 330.5 (1975). Originally there were to be 26 review panels, one for each category of drugs. But because many combination products overlapped into several categories, the number of panels was reduced to 18, with some panels evaluating drugs in more than one class. For example, one panel studied cough, cold, allergy, bronchodilator, and antiasthmatic products. Yingling, *The OTC Drug Review*, 28 FOOD, DRUG & COSM. L.J. 273 (1973).

branded. The Commissioner would use the panel's recommendation as the basis for a proposed rule establishing a final monograph. Upon promulgation of the final monograph any product deviating from the monograph would become "subject to regulatory action,"²¹⁸ either as an unapproved new drug or as misbranded. A drug which was claimed to be effective as an antacid, for example, but which lacked one of the prescribed antacid formulations, would not be recognized as an effective antacid and thus would ordinarily be a new drug requiring NDA approval—based on "adequate and well controlled clinical studies"—for further marketing. But even if the drug were grandfathered, and thus exempt from regulation as a new drug, its claim to be effective as an antacid would constitute misbranding, subjecting its manufacturer to possible criminal punishment. If, to avoid punishment, the manufacturer modified or abandoned its antacid claim, the drug would automatically lose its grandfathered status and become subject to NDA approval unless the new claim complied with another monograph.

The FDA plan thus circumvented the grandfather clause and regulated OTC drug products regardless of their marketing history. Of equal significance, the FDA plan largely obviated the need for formal adjudication—both within the agency and before the courts. A deviating OTC product lacking grandfather protection and thus requiring NDA approval would be subject to the same summary judgment procedures that the agency had developed for prescription drugs. Alternatively, if a manufacturer forced a misbranding action by retaining its deviating claim, the FDA could be confident of summary judicial enforcement—assuming the court recognized the validity of the monograph—since the only relevant factual issue would be whether the particular product deviated from the monograph, an empirical question unlikely to be contested.

The crucial question was whether the courts would accept the validity of the monographs. Anticipating a possible legal attack, the FDA buttressed its case by providing procedures for promulgating the

218. 21 C.F.R. § 330.10(a)(12), *as amended* 21 C.F.R. § 330.10(b).

The proposed regulations had indicated that they would be "binding" authority in court. 37 Fed. Reg. 84, 88 (1972). This language was deleted from the final regulations, however, on the ground that it was superfluous. The FDA noted that "there is no comparable statement of legal enforcement position in similar agency regulations" 37 Fed. Reg. 9472 (1972). Other language clearly indicates the agency's intent to substitute its procedures for "case-by-case adjudication" in court. *See* 37 Fed. Reg. 9471-72 (1972). Nevertheless, drug industry lawyers have expressed confusion concerning the intended effect of the monographs. *See, e.g., Whyte, FDA's OTC Drug Review*, 28 *Food, Drug & Cosm. L.J.* 381, 382-85 (1973). In a display of cynicism, Whyte concludes that the FDA intentionally created the confusion to avoid legal challenge. *Id.* at 385. *See also* O'Keefe, *The Over-the-Counter Drug Review*, 29 *Food, Drug & Cosm. L.J.* 262, 268-69 (1974).

monographs that went well beyond the notice and comment procedures described in section 503 of the Administrative Procedure Act. The regulations invited and encouraged interested persons to present data, both in writing and orally, to the advisory review panels.²¹⁹ In addition, during the rulemaking proceeding on the final monograph, interested persons could file initial and rebuttal comments with the Commissioner and, in appropriate cases, make oral argument.²²⁰ The agency did not, however, provide the right of formal cross-examination at any stage in the proceedings.

Although the FDA has now promulgated final monographs for both antacids and laxatives, its OTC review procedures have not yet been directly challenged in court. But this has not prevented the FDA from seeking judicial support for its scheme. *Hynson* and a companion case, *Weinberger v. Bentex Pharmaceuticals, Inc.*,²²¹ both involved the question whether the FDA had primary jurisdiction to decide that a drug lacks general recognition of safety and effectiveness and is therefore subject to regulation as a "new drug." Since this question was also at stake in the OTC review, the Government's brief thrust the OTC regulations forward for consideration.²²² The Proprietary Association responded by filing an amicus brief attacking the OTC procedures and the resulting rules.²²³ With the issue thus drawn, the Court reached out to decide it in *Bentex*. To demonstrate the central role played by primary jurisdiction in the FDA's overall enforcement scheme, the Court began by outlining the OTC procedures.²²⁴ It then upheld the FDA's primary jurisdiction to determine new drug status in language that seemed also to approve the OTC review:

We think that it is implicit in the regulatory scheme, not spelled out *in haec verba*, that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the "new drug" status of individual drugs or classes of drugs. The deluge of litigation that would follow if "me-too" drugs and OTC drugs had to receive *de novo* hearings in the courts would inure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect by the 1962 amendments as well as OTC drugs and drugs covered by the 1972 [Drug Listing] Act.²²⁵

219. 37 Fed. Reg. 9472 (1972).

220. *Id.*

221. 412 U.S. 645 (1973).

222. Brief for Petitioners at 24-25, *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973).

223. Brief for Proprietary Ass'n as Amicus Curiae at 34-49, *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1963).

224. 412 U.S. at 650.

225. *Id.* at 653 (emphasis added).

On the basis of this paragraph, with its awkwardly phrased final reference to OTC drugs, lower courts have read *Bentex* as establishing the validity of the OTC drug review regulations.²²⁶

The *Bentex* opinion undoubtedly strengthens the FDA's claim of authority, as does the Proprietary Association's failure to launch a direct challenge to the FDA regulations soon after their promulgation. But the most difficult issues of primary jurisdiction and rulemaking authority retain their vitality and interest.

B. *Quasi-Formal Rulemaking as a Technique for Avoiding Judicial Enforcement*

The FDA monographs raise two issues: First, to what extent can an agency claim primary jurisdiction to decide in advance the issues raised by a class of cases subject to court adjudication, but over which the agency lacks adjudicatory power? Second, to what extent must an agency that seeks through rulemaking to foreclose full exploration of issues in individual trials accord opportunities for participation beyond those ordinarily required by the Administrative Procedure Act?

1. *Primary Jurisdiction*

The doctrine of primary jurisdiction requires that a court refrain from deciding complex questions of fact and law in an area in which an administrative agency has special responsibilities and expertise.²²⁷ Courts have recognized primary jurisdiction most often in the agencies charged with policing the regulated industries.²²⁸ For example, the Interstate Commerce Commission, responsible for implementing a per-

226. See, e.g., *National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672, 680 n.12 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 951 (1974).

This conclusion fails to note, however, that the OTC review involves issues that go beyond the precise issue involved in *Bentex*. Jurisdiction to decide "new drug" status is in the nature of jurisdiction to determine jurisdiction. Cf. *United States v. United Mine Workers*, 330 U.S. 258 (1947). The FDA has unquestioned authority to regulate new drugs once that status is established. But as the regulations implicitly concede, many OTC drugs will be grandfathered and thus not subject to review for safety and effectiveness. Authority over these grandfathered drugs rests entirely on the misbranding standard—a standard whose enforcement Congress left to the courts. In framing a monograph that prescribes the formulations for which specified claims can be made without misbranding, the FDA is asserting not the threshold jurisdiction expressly approved in *Bentex*, but jurisdiction to guide judicial decisions on an issue over which it has no explicit control.

227. See generally 3 DAVIS TREATISE, *supra* note 10, § 19.01 (1958); L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION 121-51 (1965) [hereinafter cited as JAFFE]. "[F]ew aspects of administrative law have been so systematically and satisfactorily developed [as has the doctrine of primary jurisdiction]." 3 DAVIS TREATISE, *supra* note 10, § 19.01 at 6 (1958).

228. See JAFFE, *supra* note 227, at 124.

vasive regulatory and rate setting scheme, has primary jurisdiction to decide whether rates are reasonable.²²⁹ Outside the regulated industries, however, courts have not deferred as readily to their administrative counterparts. For example, while the Federal Trade Commission is empowered to regulate a variety of trade practices, it has not been held to possess primary jurisdiction over similar claims raised in private suits brought either at common law or under the Clayton Act.²³⁰

In the OTC review the FDA is attempting to supplant court jurisdiction with an integrated regulatory scheme for determining which OTC products are new drugs and which are misbranded. Yet on what basis can the FDA claim primary jurisdiction where Congress has specifically provided for judicial enforcement without providing for concurrent agency jurisdiction? And what justifications exist for deference to the FDA monographs by a court that refuses to regard the monographs as binding authority?

a. Nonexclusivity of Judicial Enforcement Authority

The doctrine of primary jurisdiction usually determines which of two tribunals will make the initial decision in a controversy where both have jurisdiction.²³¹ In cases of concurrent agency and court jurisdiction, courts customarily defer to the "specialized administrative tribunal" on questions within its expertise.²³² According "primary" jurisdiction to one forum or the other is essential to assure uniformity, and the agency's special expertise and its ability as a single forum to develop consistent rulings make it the preferable choice. However, even where a regulatory statute fails to provide an administrative remedy, the courts may recognize primary jurisdiction in an agency.²³³ The Supreme Court has repeatedly held, for example, that the Federal Maritime Board has primary jurisdiction under the 1916 Shipping Act to hear challenges to the rate systems of common carriers by water, even though the Board lacks power to approve or disapprove the rates involved.²³⁴ The doctrine

229. See *Texas & Pacific Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907).

230. JAFFE, *supra* note 227, at 133.

231. 3 DAVIS TREATISE, *supra* note 10, § 19.01 (1958).

232. JAFFE, *supra* note 227, at 124.

233. *Id.* at 141.

234. *Federal Maritime Board v. Isbrandtsen Co.*, 356 U.S. 481 (1958); *Far East Conference v. United States*, 342 U.S. 570 (1952); *United States Navigation Co. v. Cunard S.S. Co.*, 284 U.S. 474 (1932). In *Far East Conference v. United States*, the Court set out what it considered to be a "firmly established rule":

[I]n cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over. This is so even though the facts after they have been appraised by specialized competence serve as a premise for legal consequences to be judicially imposed.

342 U.S. at 574. Six years later, in *Federal Maritime Board v. Isbrandtsen Co.*, the Court stated that in some cases "precise findings by the Board . . . would become

of primary jurisdiction is thus not anchored to a requirement of final adjudicatory authority in the agency. Instead, the focus is on whether the agency was "created by Congress for regulating the subject matter."²³⁵

Courts have not yet passed upon the FDA's authority to issue regulations specifying what OTC drug claims will constitute misbranding, but in *National Nutritional Foods Ass'n v. Weinberger*,²³⁶ the Second Circuit upheld a closely analogous exercise of authority under the "prescription drug" sections of the Food, Drug and Cosmetic Act. Section 503 of the Act provides that sale of a prescription drug without prescription specifically violates the misbranding prohibition,²³⁷ and cites "toxicity or other harmful effect" as one basis for classifying a product as a prescription drug.²³⁸ By notice-and-comment rulemaking the FDA had issued regulations classifying as prescription drugs preparations containing vitamins A and B in amounts exceeding specified limits. The National Nutritional Foods Association brought suit, challenging the agency's authority under section 701(a) to particularize a standard beyond its authority to enforce. The Second Circuit upheld the FDA regulations as binding interpretations of the toxicity standard. Although the court found only meager support for the agency's position in the legislative history, it concluded that Congress intended to allow the agency to promulgate authoritative interpretations of the standards in the Act "rather than leave the decisions to the courts, which lack the medical and scientific knowledge essential to such decisions."²³⁹ And despite the distinction urged between standards enforced administratively and those enforced judicially, the court reasoned that "an agency which possesses the power to determine administratively what products are 'new drugs' has the authority to decide what products are 'prescription drugs.'"²⁴⁰

Although the toxicity standard for prescription drugs is more specific and more obviously scientific than the general misbranding definition, the similarity of exclusive judicial enforcement authority overshadows any distinction between the two provisions. Thus, the *Nutritional Foods* decision is strong authority for the proposition that the OTC monographs, if promulgated by proper procedure, are also valid and binding in judicial proceedings.

essential to a judicial determination of the [rate] system's validity under the statute." 356 U.S. at 499 (emphasis added).

235. See note 234 *supra*.

236. 512 F.2d 688 (2d Cir. 1975).

237. 21 U.S.C. § 353(b)(2) (1970).

238. *Id.* § 353(b)(1)(B).

239. 512 F.2d at 699.

240. *Id.*

Even assuming *Nutritional Foods* is not followed, however, the monographs may still be worthy of judicial deference as "interpretative regulations." Interpretative regulations

constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking the power to control.²⁴¹

While a court theoretically has the power to substitute its judgment for an agency's interpretative regulation, a pattern of judicial restraint has developed which effectively gives such regulations the force of law when they embody expert understanding more commonly found in an agency than in a court.²⁴² Thus, even if the FDA lacks substantive power to interpret the misbranding provisions, its regulations may still command judicial deference.

b. Factors Counseling Primary Agency Jurisdiction

In the customary operation of the primary jurisdiction doctrine, where a court obtains power over a case prior to any agency action, three factors appear to influence judicial deference to agency authority: (1) deference to administrative expertise; (2) the need for uniform interpretation of legal standards; and (3) the need for efficient enforcement of a congressional mandate. The same factors favor judicial adherence to the FDA monographs—even by courts that question whether the monographs have binding effect.

Deference to agency expertise is perhaps the most common basis for placing primary jurisdiction in an administrative body.²⁴³ In upholding FDA primary jurisdiction to decide new drug status in *Bentex*, the Supreme Court stressed the agency's special competence in the field of drug regulation.²⁴⁴ The agency's claim of expertise in resolving misbranding issues rests ultimately on the same footing. Although courts are accustomed to deciding questions of misrepresentation, determining the truth claimed to be misrepresented in a misbranding case requires

241. *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944). See also 1 DAVIS TREATISE, *supra* note 10, §§ 5.03-07.

242. 1 DAVIS TREATISE, *supra* note 10, § 5.05, at 315 (1958).

243. For example, in *United States v. Western Pacific R.R. Co.*, 352 U.S. 59 (1956), the Supreme Court held that the ICC should first decide the meaning of "incendiary bomb" in a tariff. The question turned on problems of cost-allocation, requiring examination of "voluminous and conflicting evidence" and acquaintance with intricate facts normally found only in a "body of experts." *Id.* at 66.

244. 412 U.S. 645, 652 (1973).

resolution of the same questions of efficacy (or possibly safety) on which the agency's superior familiarity is acknowledged.²⁴⁵ As the FDA has noted:

The task of establishing the parameters of misbranding is fundamentally the same as the task of establishing the parameters of general recognition of safety and effectiveness, and indeed it would be a gross waste of resources to attempt to separate these two aspects of what must be essentially one review of the scientific and medical basis for OTC drug products.²⁴⁶

The FDA's reliance on advisory review panels composed of experts undoubtedly strengthens the agency's claim of specialized competence.²⁴⁷ No court possesses comparable ability to deal with the "voluminous and conflicting evidence" upon which findings of safety and effectiveness are based. Even a special master would be unlikely to be more qualified than an individual panel member, and would lack comparable assistance from other panel members and from agency staff. The flexible procedures available in an administrative proceeding also favor reliance on the agency, since judicial rules governing the use of expert witnesses limit scientific inquiry.²⁴⁸ Finally, the use of outside experts may blunt the charge that the agency cannot judiciously resolve issues that it may subsequently have to litigate as a party.

That the monographs are designed to serve as legal standards for future judicial proceedings should not diminish the agency's claim of expertise. It is true that Justice Brandeis, speaking for the Court in *Great Northern Ry. v. Merchants Elevator Co.*,²⁴⁹ once contended that primary jurisdiction did not require judicial deference on matters "solely of law." But *Great Northern* involved construction of language in an interstate carrier's tariff intended to be read according to "ordinary meaning"; the question was not "in its nature administrative in contradistinction to judicial."²⁵⁰ Even if the determinations involved in

245. The OTC regulations give the flavor of the determinations involved. They define general recognition of effectiveness as "a reasonable expectation that, in a significant proportion of the target population" the product will provide "clinically significant relief of the type claimed." 21 C.F.R. § 330.10(a)(4)(ii) (1970). Proof of effectiveness must be based on controlled clinical investigations as defined by the "adequate and well-controlled clinical studies" regulations. See text accompanying notes 43-47 *supra*. Proof of general recognition of safety "shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data." 21 C.F.R. § 330.10(a)(4)(ii) (1970) (emphasis added). The flexibility in "ordinarily" requiring published studies was seen as necessary to allow panels the opportunity to rely on the "best scientific evidence available." 37 Fed. Reg. 9469 (May 11, 1972).

246. 37 Fed. Reg. 9472 (May 11, 1972).

247. See generally 1 DAVIS TREATISE, *supra* note 10, 366-70 (1958).

248. See Boyer, *Alternatives to Administrative Trial-Type Hearings for Resolving Complex Scientific, Economic, and Social Issues*, 71 MICH. L. REV. 111, 125-30 (1972).

249. 259 U.S. 285 (1922).

250. *Id.* at 291.

the OTC monographs can be characterized as matters "solely of law," which is doubtful, they are surely more "administrative" than "judicial" in nature. In any event, the Court has since abandoned Justice Brandeis' reliance on the law-fact distinction as a limitation on primary jurisdiction. In *United States v. Western Pacific R.R.*²⁵¹ Justice Harlan insisted that federal agencies have "exclusive primary jurisdiction" to make findings of fact and to interpret, define, and apply legal standards where to do so requires specialized competence residing in the agency.²⁵²

The need for uniformity, and the parallel concern that parties similarly situated be similarly treated, also influences the decision to accord an agency primary jurisdiction. In *Texas & Pacific Ry. v. Abilene Cotton Oil Co.*²⁵³ the Court stressed that failure to acknowledge primary jurisdiction in the ICC to determine the reasonableness of common carrier rates would make the congressional mandate for a uniform and nondiscriminatory standard for rates impossible to achieve "unless all courts reached an identical conclusion."²⁵⁴ Much later, in *Bentex*, the Court responded favorably to the argument that administrative primary jurisdiction to determine new drug status would promote uniform, and therefore fair, treatment of drug products under the Food, Drug and Cosmetic Act.²⁵⁵

By acting through rulemaking the FDA has responded directly to the need for uniformity. Since the FDA's findings are expressed in its monographs, courts facing misbranding cases know the agency's interpretation in advance. And since all related claims are handled at once in a single rulemaking proceeding, no party is subject to nonconforming, disparate treatment.²⁵⁶

251. 352 U.S. 59 (1966).

252. *Id.* at 65-66.

253. 204 U.S. 426 (1907).

254. 204 U.S. at 440. *See also* National Nutritional Foods Ass'n v. Weinberger, 376 F. Supp. 142, 147-48 (S.D.N.Y. 1974), *aff'd*, 512 F.2d 688 (2d Cir. 1975).

255. 412 U.S. at 645.

256. This technique may also be available to the Federal Trade Commission. The FTC's jurisdiction over deceptive practices shares two interfaces with the judiciary. First, the FTC must enforce violations of cease and desist orders in federal court. After *United States v. J. B. Williams Co.*, 498 F.2d 414 (2d Cir. 1974), it appears that where the Commissioner seeks a civil penalty for such a violation the defendant is entitled to a jury trial on disputed issues of fact, including whether a defendant's actions came within the scope of a cease and desist order. Application of a cease and desist order to a particular defendant is a difficult process. Use of rulemaking to particularize the standards for judging when an action is sufficiently "different" to fall outside a cease and desist order could be a useful extension of the Commission's regulatory power. While such standards could probably not be set out with such particularity as to resolve all questions of fact at the summary judgment level, they could be useful in many cases, and would in any event guide jury instruction. As is the case with the FDA's particularization of the misbranding provisions, such an effort by the FTC would not so much supplant the authority vested in the district courts by Congress, turning them into a "rubber stamp"

Finally, the need to assure efficient implementation of congressional purpose may provide a further justification for primary jurisdiction. In *Bentex* Justice Douglas emphasized that the FDA's limited time and budget made determination of new drug status through individual judicial proceedings unworkable.²⁵⁷ Similarly, judicial deference to the FDA monographs may be the only practical way of implementing the broad congressional mandate that new drugs be subject to premarketing review for both safety and effectiveness.

2. *Procedural Limitations on the Use of Rulemaking*

Like the substantial evidence regulations governing NDA approvals, the OTC monographs particularize a standard of the Food, Drug and Cosmetic Act so that subsequent adjudications of noncompliance, if they arise,²⁵⁸ will be disposed of summarily. Unlike the substantial evidence regulations, however, the monographs do not provide a single standard for all drugs subject to their control; instead, they prescribe a different standard for each category of OTC drugs. These standards have, in practice, specific applicability to particular drug formulations and products. As a result, the OTC monographs raise troublesome procedural issues.

Accordingly, in its OTC regulations the FDA provides more than the notice-and-comment procedures it used in issuing the substantial evidence regulations. Besides inviting comments on a proposed monograph, the agency permits interested parties to participate—orally as well as in writing—before its advisory panels, to submit data to the agency, and to file briefs and make oral argument before promulgation of the final monograph. The question is whether these additional procedures are sufficient to satisfy the applicable requirements of the Administra-

for the Commission (*see Note, Jury Trial in Penalty Action for Deceptive Advertising*, 49 *ST. JOHN'S L. REV.* 239, 242-47 (1975)), as it would enhance the consistency of judicial enforcement.

The second interface shared by the FTC and the judiciary is concurrent jurisdiction to enforce several statutes, primarily the Clayton Act. Here the FTC does not take its cases before the courts since it has adjudicatory powers of its own under Section 5 of the FTC Act, 15 U.S.C. §§ 41-77 (1970). Yet there is the potential for conflict between the legal theories used by the Commission in its own cases and the judge-made law of deception created in private actions. The FTC can use its substantive rulemaking powers to define greater numbers of practices it finds to be deceptive. *See, e.g., National Petroleum Refiners Ass'n v. FTC*, 482 F.2d 672 (D.C. Cir. 1973), *cert. denied*, 415 U.S. 95 (1974). Were the FTC to develop a list of practices found to be deceptive after a substantial inquiry by experts in business, economics, and consumer habits, courts might more readily look to it for aid in deciding private actions.

257. 412 U.S. 645, 653 (1973).

258. The comments filed with the FDA following the notice of proposed rulemaking indicated that "the regulations will be substantially followed by industry." 37 *Fed. Reg.* 9472 (1972).

tive Procedure Act, the Constitution, and the Food, Drug and Cosmetic Act.

a. The Administrative Procedure Act: Rules versus Orders

The Administrative Procedure Act makes two distinctions between types of administrative action relevant to determining the procedures an agency must follow. First, it distinguishes between "orders" and "rules." The prospective effect of a rule, defined as "an agency statement of general or particular applicability and *future effect* designed to implement, interpret, or prescribe law or policy. . .,"²⁵⁹ distinguishes it from an order, which is defined as a "final disposition . . . in a matter other than rulemaking."²⁶⁰ Thus, unlike an order, a rule is not "final"; it requires a subsequent "adjudication"—the process leading to formulation of an order²⁶¹—in order to be enforced against a particular party or product. The Administrative Procedure Act also distinguishes between rules that must be "made on the record after opportunity for an agency hearing" and other rules.²⁶² Formal rulemaking procedures, including opportunity for a trial-type hearing under sections 556 and 557 of the Administrative Procedure Act, are required for rules only if the agency's statute explicitly prescribes a hearing "on the record";²⁶³ otherwise notice-and-comment procedures pursuant to section 553 will suffice.²⁶⁴

The OTC monographs are clearly rules within the meaning of the Administrative Procedure Act. The FDA can take no action against a particular product that deviates from a monograph until after a court trial or an adjudication by the agency in a NDA approval proceeding. Moreover, no language in the Food, Drug and Cosmetic Act triggers the formal rulemaking procedures of the Administrative Procedure Act. Consequently the Act requires only notice-and-comment procedures, or less than what the FDA provides.

259. 5 U.S.C. § 551(4) (1970) (emphasis added).

260. *Id.* § 551(6) (1970).

261. *Id.* § 551(7) (1970).

262. *Id.* § 554(a) (1970).

263. See *United States v. Florida East Coast Ry.*, 410 U.S. 224 (1973); *United States v. Allegheny-Ludlum Steel Corp.*, 406 U.S. 742 (1972). After *Florida East Coast*, language requiring that a hearing be held "on the record" in an agency's statute is virtually "a touchstone test of when section 556 and section 557 proceedings are required." *Mobil Oil Corp. v. FPC*, 483 F.2d 1238, 1250 (D.C. Cir. 1973). See generally Verkuil, *Judicial Review of Informal Rulemaking*, 60 VA. L. REV. 185 (1974); Note, *The Judicial Role in Defining Procedural Requirements for Agency Rulemaking*, 87 HARV. L. REV. 782, 790-96 (1974).

264. Section 553(a)(2) of the Administrative Procedure Act, 5 U.S.C. §§ 551-76, 701-06, 3105 (1970), allows agencies to waive even notice-and-comment procedures in certain specified circumstances. This exception has caused concern among those who strongly support public participation in agency decisionmaking. See Comment, *Due Process Rights of Participation in Administrative Rulemaking*, 63 CALIF. L. REV. 886, 901-07 (1975).

b. *The Constitution: Due Process and General Applicability*

The Constitution may at times require a trial-type hearing for rulemaking even where the Administrative Procedure Act does not. In *United States v. Allegheny-Ludlum Steel Corp.*,²⁶⁵ and *United States v. Florida East Coast Railway*,²⁶⁶ cases giving a narrow construction to the Administrative Procedure Act's requirement of formal rulemaking, the Supreme Court recognized that procedural limitations may derive from other sources. Thus in *Florida East Coast* the Court noted that the APA did not "limit or repeal additional requirements imposed by statute or otherwise required by law."²⁶⁷ These other sources of law include the Constitution.

While the Administrative Procedure Act permits notice-and-comment procedures for rules of "general or particular applicability," the Constitution may require additional protections for parties singled out for regulation. In *Florida East Coast*, which upheld industry-wide rates for the use of freight cars, the Court found the ICC's use of notice-and-comment procedures appropriate because the rates applied prospectively and were generally applicable, giving no special consideration to any one party based on "its own peculiar circumstances."²⁶⁸ Significantly, the Court recognized that where "a small number of persons 'were exceptionally affected, in each case upon individual grounds,'" the Constitution might require a trial.²⁶⁹

Florida East Coast revives a distinction first suggested in *Londoner v. Denver*²⁷⁰ and *Bi-Metallic Investment Co. v. State Board of Equalization*,²⁷¹ both decided prior to 1920. Those cases established the principle that government action requires a trial when it sufficiently affects individual interests and is "based on individual grounds." Professor Davis has explained²⁷² this principle in terms of "legislative" and "adjudicative" facts:

Adjudicative facts are the facts about the parties and their activities, businesses, and properties. Adjudicative facts usually answer the questions of who did what, where, when, how, why, with what motive or intent; adjudicative facts are roughly the kind of facts that go to a jury in a jury case. Legislative facts do not usually concern the im-

265. 406 U.S. 742 (1972).

266. 410 U.S. 224 (1973).

267. *Id.* at 235, citing 5 U.S.C. § 559 (1970).

268. *Id.* at 244-46.

269. *Id.* at 245.

270. 210 U.S. 373 (1908).

271. 239 U.S. 441 (1915).

272. 1 DAVIS TREATISE, *supra* note 10, § 7.04, at 420-21 (1958). See also Boyer, *supra* note 5, at 115.

mediate parties but are generally facts which help the tribunal decide questions of law and policy and discretion.²⁷³

According to Professor Davis due process requires a hearing for the resolution of adjudicative but not legislative facts.²⁷⁴

The FDA's monographs for OTC drugs are difficult to classify in these terms. On the one hand, because the rules are designed with specific drug formulations in mind, and because many drug formulations are identified with particular manufacturers, the monographs appear in part to be resolving adjudicative facts.²⁷⁵ The agency's treatment of Alka-Seltzer provides an apt illustration.

Alka-Seltzer is a combination of antacid ingredients and aspirin, and as a combination product must meet special requirements.²⁷⁶ The advisory panel reviewing antacids balked at recommending the inclusion of the Alka-Seltzer formulation in the antacid monograph. Some clinical studies had indicated that aspirin upset the stomach, thereby making the antacid ingredients less effective and potentially unsafe; the panel believed the presence of the two active ingredients in combination might decrease the safety or effectiveness of the individual active ingredients. The agency, however, could not ignore the millions of people who regularly used Alka-Seltzer and who would be offended if the drug was no longer available; it was generally acknowledged that the symptoms treated by aspirin—headache and other pain—often accompanied the symptoms treated by antacid products. At the FDA's urging, the panel included the Alka-Seltzer formulation in its proposed monograph.²⁷⁷ The FDA then held a rulemaking proceeding on the pro-

273. 1 DAVIS TREATISE, *supra* note 10, § 7.02, at 413 (1958).

274. *Id.* at 413-14. See *Powellton Civic Homeowners Ass'n v. HUD*, 284 F. Supp. 809 (E.D. Pa. 1968).

275. Consider the following attack on the OTC review procedures:

The ultimate question, as I see it, is whether this proceeding to adopt binding monographs is legislative or adjudicatory in nature. Are the factual determinations which FDA will make as to GRAS and GRAE and misbranding legislative facts or adjudicative facts? . . . FDA proposes to determine whether a particular drug product is GRAS, GRAE, and whether its labeling misbrands it. I believe these are "facts about the parties and their activities, businesses, and properties." While they are described by FDA as rulemaking, general in scope, these determinations in substance and effect are individual in impact.

Whyte, *supra* note 218, at 388-89.

276. The regulations provide:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

21 C.F.R. § 330.10(a)(4)(iv) (1975).

277. Mintz, *Pressure by FDA is Alleged on Experts' Antacids Guides*, The Washington Post, May 13, 1975, at A8, col. 4-6.

posal.²⁷⁸ When the final monograph for antacids was promulgated, Alka-Seltzer's formulation was approved and a specific section on combination products spoke directly to its case.²⁷⁹

The process by which Alka-Seltzer was approved and the identification of its formulation with the Miles product are suggestive of a determination of adjudicative facts focusing on the immediate parties. On the other hand, the final monograph applies not just to Alka-Seltzer, but to all similar antacid-aspirin combinations marketed now or in the future. In this respect the determination was legislative.

A case recently decided by the Third Circuit lends support to the contention that the OTC monographs resolve only legislative facts. In *Hoffman-La Roche v. Kleindienst*²⁸⁰ the court was asked to review an order by the Director of the Bureau of Narcotics and Dangerous Drugs finding that Librium (chlordiazepoxide) and Valium (diazepam) were depressant drugs having a potential for abuse and requiring control. Hoffman-La Roche, the manufacturer of Librium and Valium, challenged the proceeding on the ground that although it was an adjudication the government had not observed the separation-of-functions requirement. The court rejected the argument, holding that the action was properly characterized as legislative.

Here the final order will apply across the board to all producers, wholesalers, and distributors of Librium and Valium, as well as to pharmacies and physicians. Hoffman was not singled out for special consideration based on its own peculiar circumstances. The fact that Hoffman may be one of those adversely affected explains the highly adversary character of the proceeding but does not change the generalized nature of the order. Although the proceeding involved a concrete factual situation from which factual inferences provided the basis for the Director's order, the facts and inferences therefrom were used to formulate a basically legislative-type judgment of entirely prospective application.²⁸¹

This language could apply as well to the FDA's treatment of Alka-Seltzer.²⁸²

Because the OTC monographs combine aspects of both legislation and adjudication, it is necessary to examine directly the principles

278. The oral argument allowed in this proceeding attracted much attention. See O'Keefe, *A Fine New Twist—A Brief Commentary on the Commissioner of Food and Drugs' First Oral Hearing*, 29 FOOD, DRUG, & COSM. L.J. 116 (1974).

279. 21 C.F.R. § 331.15 (1975). Perhaps in response to the panel's early concerns, Miles Laboratories is now marketing an antacid without aspirin: Alka-Seltzer "Gold."

280. 478 F.2d 1 (3d Cir. 1973).

281. *Id.* at 13.

282. The court might have taken another view of the case had the procedural right at stake been the opportunity to cross-examine rather than the separation of functions. See Friendly, *supra* note 146, at 438. But see text following note 334 *infra*.

underlying the dichotomy between legislative and adjudicative facts. To determine what process should attend a particular governmental deprivation, courts customarily weigh the benefits of formal procedure—measured both by the importance of the individual interest and by the extent to which formality will protect against arbitrary government action—against the cost to the government in terms of less efficient implementation of programs.²⁸³ The legislative-adjudicative fact dichotomy is perhaps best viewed as a shorthand expression of this analysis: where an agency determination affects a large number of parties and issues of law and policy predominate, formal process is costly and of limited utility; on the other hand, where the determination involves a limited number of parties and a prevalence of factual issues about which the parties have the best available knowledge, trial safeguards are properly insisted upon. Thus, where a determination is difficult to classify, as are those involved in the OTC monographs, the most useful approach may be to focus directly on the costs and benefits of trial-type procedure.

The notion that administrative practicability is a proper consideration in the decision whether to impose trial-type procedure as a constitutional requirement finds support in a line of cases examining the Federal Power Commission's independent pipeline rates. As a result of *Phillips Petroleum Co. v. Wisconsin*²⁸⁴ the FPC found itself charged with responsibility for setting pipeline rates for several thousand independent producers it previously believed were outside its jurisdiction.²⁸⁵ To respond to this staggering increase in its workload, the FPC turned to area ratemaking procedures, thereby reducing from several thousand to seven the number of proceedings it had to conduct. In *Permian Basin Area Rate Cases*²⁸⁶ the Supreme Court approved the class proceedings, concluding that "administrative authorities must be permitted, consistently with the obligations of due process, to adapt their rules and policies to the demands of changing circumstances."²⁸⁷

The reach of this holding was at first unclear. The procedures the Court approved, while areawide rather than individual, had included a trial-type hearing. In fact, the first area rate proceeding lasted five years.²⁸⁸ Yet the lower courts read *Permian Basin* expansively: "[T]he

283. See, e.g., *Goss v. Lopez*, 419 U.S. 565 (1975); *Goldberg v. Kelly*, 397 U.S. 254 (1970); *Hahn v. Gottlieb*, 430 F.2d 1243 (1st Cir. 1970); *Powellton Civic Homeowners Ass'n v. HUD*, 284 F. Supp. 809, 829-30 (E.D. Pa. 1968).

284. 347 U.S. 672 (1954).

285. See Note, *FPC Ratemaking and Judicial Control of Administrative Procedural Flexibility*, 1974 DUKE L.J. 326.

286. 390 U.S. 747 (1968).

287. *Id.* at 784.

288. Note, *supra* note 323, at 328.

thrust of *Permian* is that the FPC is free to make an administrative determination which it believes will foster the most efficient and thorough regulation of natural gas rates.”²⁸⁹ The Tenth Circuit has gone farther than other post-*Permian* courts; in *Phillips Petroleum Co. v. FPC*,²⁹⁰ decided in 1974, it approved informal ratemaking procedures, not held “on the record,” and not providing opportunity for cross-examination.²⁹¹

Similarly, in *Hynson* the Supreme Court focused on the cost to the public of providing a separate trial-type hearing for each of a number of similar drug formulations. The FDA had maintained that the withdrawal of approval of an NDA also covered all “me-too” drugs—those similar or identical drugs marketed without FDA approval in reliance on the “pioneer” drug’s reputation for safety and effectiveness.²⁹² While noting that regulatory agencies have usually proceeded on a case-by-case basis, Justice Douglas emphasized there was not always a “constitutional reason” why this must be done.

The comprehensive, rather than the individual, treatment may indeed be necessary for quick effective relief [citing *Permian Basin*] A generic drug—which is found to be unsafe and/or lacking in efficacy—may be manufactured by several persons or manufacturers. 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. A single administrative proceeding in which each manufacturer may be heard is constitutionally permissible measured by the requirements of procedural due process.²⁹³

Justice Douglas’s inclusion of the requirement that each manufacturer be given an opportunity to be “heard” in a group proceeding limits the applicability of the case. For although the opinion fails to define explicitly what kind of hearing was sufficient, the Court nevertheless remanded the action to the agency for the full trial-type hearing that FDA regulations prescribe for resolution of genuine issues of material fact.

Although *Permian* and *Hynson* do not specifically validate the use

289. *Placid Oil Co. v. FPC*, 483 F.2d 880, 912 (5th Cir. 1973), *affirmed*, 417 U.S. 283 (1974).

290. 475 F.2d 842 (10th Cir. 1973), *cert. denied*, 414 U.S. 1146 (1974).

291. *But see Mobil Oil Corp. v. FPC*, 483 F.2d 1238 (D.C. Cir. 1973).

292. 412 U.S. at 625.

293. *Id.* at 624-25. The reasons underlying the Court’s holding included efficiency, the need for quick action to protect the public, and the need to treat similarly situated drug products similarly. This last point has received much attention in the OTC drug review. In the May regulations, the FDA explained its failure to take immediate action against the 420 OTC drugs studied in the NAS-NRC review in part on the grounds that “it would be highly unfair and anticompetitive to move against the 420 drugs reviewed by the NAS-NRC” when others which were “no safer or no more effective” remained on the market. 37 Fed. Reg. 9465 (1972).

of informal procedures, they do invite consideration of efficiency in determining the constitutionality of informal procedures in other contexts. And, given the number of products and the complexity of the drug efficacy issues, the need for informal procedure in the OTC drug review is compelling. The question remains whether the cost of trial-type procedure in reducing efficiency is justified by some overriding benefit. Here, the primary consideration should be the extent to which trial-type procedures will add to the accuracy or fairness of agency decisions. As Professor Davis has observed, formal procedure will be most useful where "the parties know more about facts concerning themselves and their activities than anyone else is likely to know" ²⁹⁴ In the FDA review of OTC drugs, manufacturers can clearly make a significant contribution to the resolution of the pertinent issues. But it seems doubtful that a trial is the only way, or even the best way, for the parties to contribute in this context.

The Second Circuit's decision in *National Nutritional Foods Association v. Weinberger* ²⁹⁵ is instructive. The court held not only that the FDA need not conduct a formal, trial-type hearing before deciding prescription drug status, but also that mere notice-and-comment proceedings would suffice. Such proceedings would be adequate "for the purpose of airing issues, evidence, and relevant factors to be considered by an agency in determining whether a rule is to be promulgated and, if so, its terms." ²⁹⁶

Since the decision [classifying high dosages of vitamins A and D as prescription drugs] did not turn on precise factual issues or on the credibility of witnesses but represented a judgment based upon consideration of relevant medical and scientific data, we doubt that a trial-type adversary hearing would have shed any further light on the question. . . . The question was one to be resolved on the basis of a general appraisal of the risk of toxicity. ²⁹⁷

The OTC regulations prescribe not only notice-and-comment procedures, but also written and oral participation with the appropriate review panel, submission of data with the FDA, and briefs and oral argument before final agency decision. The provision of additional formalities, and particularly the opportunity to cross-examine witnesses in adversary proceedings would unduly burden the agency's plan for fair and efficient regulation of OTC drugs without generating any proportionate increase in fair and accurate determinations of which drugs are

294. 1 DAVIS TREATISE, *supra* note 10, §§ 7.01-.02.

295. 512 F.2d 688 (2d Cir. 1975). See text accompanying notes 236-40 *supra*.

296. 512 F.2d at 700.

297. *Id.* Similarly, see *Burr v. New Rochelle Municipal Housing Authority*, 479 F.2d 1165, 1169 (2d Cir. 1973) (decision to increase rents based on complex financial data about which tenants would have no special knowledge).

new and which are misbranded. Thus, even if a court is reluctant to go as far as *Nutritional Foods* in approving informal procedures, it should at least find the FDA's quasi-formal procedures sufficient to satisfy due process.

c. *The Authorizing Statute: Implied Limitations and Judicial Review*

Congress can impose procedural requirements on agency rulemaking in addition to those made mandatory by the Administrative Procedure Act and the Constitution. It may do so explicitly, as it has done in imposing trial-type procedures on some FDA rulemaking activities, most notably in the area of food standardization.²⁹⁸ Or it may impose the additional procedures by implication, either by specifying a heightened standard of judicial review,²⁹⁹ or by designing a pattern of regulation in which the agency bears an unusual burden of justifying its actions.³⁰⁰ Because the Food, Drug and Cosmetic Act does not prescribe formal—or any other—procedures for rulemaking under the misbranding sections, the question is whether any congressional intent to impose trial-type procedures in this context can be implied from the Act.

Under the Administrative Procedure Act, an agency is obliged to base its rules on a rational factual foundation,³⁰¹ and notice-and-comment procedures suffice to enable the courts to determine whether that foundation exists.³⁰² In an authorizing statute, however, Congress may impose a burden of factual justification exceeding mere rationality; and to ensure effective review of the agency's efforts to satisfy that burden, courts may read into the statute a corresponding requirement of more than notice-and-comment procedures.

For example, in *Mobil Oil Corp. v. FPC*,³⁰³ the District of Columbia Circuit found that "adversary procedural devices" beyond notice-and-comment participation were necessary to assure FPC satisfaction of the "substantial evidence" standard in the Natural Gas Act. The petitioners had sought review of an FPC order setting mandatory minimum rates for the transportation of liquefiable hydrocarbons by natural gas

298. 21 U.S.C. § 371(e); Merrill & Collier, "Like Mother Used to Make." *An Analysis of FDA Standards of Identity*, 74 COLUM. L. REV. 561 (1974). See also Hamilton, *Rulemaking on a Record by the Food and Drug Administration*, 50 TEXAS L. REV. 1132 (1972).

299. See, e.g., *Mobil Oil Corp. v. FPC*, 483 F.2d 1238 (D.C. Cir. 1973) (requiring a limited adversary proceeding to assure satisfaction of a "substantial evidence" standard for agency findings), discussed at notes 303-07 *infra*.

300. See, e.g., *International Harvester Co. v. Ruckelshaus*, 478 F.2d 615 (D.C. Cir. 1973) (inferring an unusual burden of justification from the importance of the substantive interests at stake in a rulemaking proceeding), discussed at notes 308-16 *infra*.

301. See note 157 *supra*.

302. *United States v. Florida East Coast Ry.*, 410 U.S. 224 (1973).

303. 483 F.2d 1238 (D.C. Cir. 1973).

pipelines. Area ratemaking proceedings had been approved in *Permian Basin Rate Cases* but in *Mobil Oil* the FPC had taken the further step of abandoning all formal procedures. Although the FPC purported to act pursuant to its general rulemaking authority under Section 16 of the Natural Gas Act,³⁰⁴ Judge Wilkey thought the agency had gone too far: "Section 16, which uses a broad generality of 'necessary or appropriate' that is not rooted in a function, cannot enlarge the choice of permissible procedures beyond those that may fairly be implied from the substantive sections and the functions there defined."³⁰⁵ Judge Wilkey found "highly significant" the Natural Gas Act requirement that agency findings of fact, even in ratemaking proceedings, be supported by substantial evidence.³⁰⁶ This requirement indicated that Congress was "particularly concerned with the degree of certainty required in establishing factual predicates in ratemaking."³⁰⁷ Because the court could not determine from the record of informal rulemaking whether the FPC's factual determinations were supported by substantial evidence, it remanded the cause for further proceedings incorporating some sort of adversary, fact-finding procedures, though not necessarily the full panoply of trial procedures provided by sections 556 and 557 of the Administrative Procedure Act.

Unlike the National Gas Act, the Food, Drug and Cosmetic Act has no "substantial evidence" standard applicable to the misbranding provisions. But the principle of *Mobil Oil*—that congressional imposition of a heightened burden of justification implies corresponding procedural requirements—may still apply. The congressional plan for judicial enforcement casts the FDA in the role of prosecutor. And as prosecutor in a criminal misbranding case, the agency bears the burden of proving the relevant facts beyond a reasonable doubt. On this basis courts might find an implied congressional requirement that any FDA rulemaking designed to foreclose individual misbranding proceedings be based on a more substantial footing than mere rationality. While the agency's burden would probably not approach the reasonable doubt standard for court enforcement, it could exceed or at least match the substantial

304. Section 16, 15 U.S.C. § 717(o) (1970), allows the FPC to perform "any and all acts," including making rules, that are "necessary or appropriate to carry out [the Act]."

305. 483 F.2d at 1257. *But see* Phillips Petroleum Co. v. FPC, 475 F.2d 842 (10th Cir. 1973), *cert. denied*, 414 U.S. 1146 (1974), where the court held that informal procedures were adequate for ratemaking. The dissent in *Phillips* took essentially the same approach as that taken later in *Mobil Oil*. *Id.* at 857.

306. Section 19(b), 15 U.S.C. § 717(b) (1970). Since ratemaking "necessarily involves finding facts," the requirement applied. 483 F.2d at 1258 n.69. Other FPC rulemaking not based on fact-finding may not be subject to substantial evidence review. *Id.* at 1258.

307. *Id.* at 1258 n.68.

evidence standard considered in *Mobil Oil*. Were some such intermediate burden of justification to be imposed, the quasi-formal procedures the FDA provides would take on added significance.

The possibility that a court might demand even more formal procedure than the FDA provides is suggested by *International Harvester Co. v. Ruckelshaus*.³⁰⁸ In *International Harvester* the District of Columbia Circuit, speaking through Judge Leventhal, held that the Environmental Protection Agency had to give auto manufacturers opportunity for limited cross-examination on certain factual issues, such as the adequacy of the EPA's test methodology, before the Agency could deny their request for a 1-year suspension of the 1975 emissions standards established by the Clean Air Act. Although there was "neither express wording nor legislative history on the precise issue,"³⁰⁹ Judge Leventhal found a requirement for specific evidentiary support of the EPA's refusal implicit in the Clean Air Act and in its legislative history. Weighing the risk of an erroneous denial of suspension against the risk of an erroneous grant, Judge Leventhal concluded that Congress considered the potential harm of an erroneous failure to suspend the standards to be the greater of the two.³¹⁰ He therefore held that the "burden of proof" rested with the EPA to show that suspension was not required,³¹¹ and remanded the case with directions that the Agency provide more formal procedures—including cross-examination—to assure satisfaction of the substantive standard.

But if *International Harvester* thus illustrates how courts might impose full trial-type procedure to assure the substantive validity of the FDA monographs, the decision is best viewed as a narrow precedent. For one thing, Judge Leventhal was able to rely in part on an explicit "public hearing" requirement³¹² in the Clean Air Act as well as on the EPA's implied burden of proof. For another, he was moved to intervene by the auto manufacturers' showing, supported by the National Academy of Sciences,³¹³ that technology was not available to meet the stan-

308. 478 F.2d 615 (1973); see Verkuil, *Judicial Review of Informal Rulemaking*, 60 VA. L. REV. 185 (1974). See also Wright, *supra* note 6. Note, *Judicial Role in Defining Procedural Requirements for Agency Rulemaking*, 87 HARV. L. REV. 782 (1974).

309. 478 F.2d at 648.

310. *Id.* at 641, 648.

311. "Burden of proof" was not used by the court in the "conventional sense of civil trials," but instead connoted the burden to adduce a reasoned presentation in support of agency actions. *Id.*

312. 42 U.S.C. § 1857f-1(b)(5)(D) (1970). This reliance was limited by the fact that adjudicatory hearings were specifically prescribed elsewhere in the statute. See, e.g., 42 U.S.C. § 1857c-5(f)(2) (1970) (hearing on 1-year postponement of plan requirement at request of state governor); 42 U.S.C. § 1857f-5(b)(2)(B) (1970) (hearing on suspension or revocation of motor vehicle certifications). Both determinations were required to be "on the record."

313. The NAS was required by Congress to carry out its own study of auto emission control technology.

dards. In light of this evidence in the record it was not unreasonable to require the EPA to permit more vigorous exploration of the facts underlying its decision.³¹⁴

Moreover, the procedures Judge Leventhal imposed proved to be ill-considered.³¹⁵ Although the limited right of cross-examination expressly granted to the auto manufacturers was thought to be a significant concession, in the subsequent proceedings before the EPA no party took advantage of the court's order.³¹⁶ Instead the factual issues were discussed and developed at conference-type meetings. Thus, even if a better developed record is necessary to satisfy implicit substantive concerns, requiring formal procedures may not be sensible.

Courts should be particularly hesitant to impose formal procedures on the FDA in its promulgation of the OTC monographs. The FDA has not only developed procedures attuned to its own needs, but in the OTC review has demonstrated a sensitivity to the concerns of fairness and accuracy that are the ultimate object of trial-type hearings. The procedures it has adopted for promulgating the monographs provide a broad range of participatory rights, omitting only the right of cross-examination. Judicial imposition of that right would be unlikely to improve the quality of the administrative record, and would certainly protract the proceedings to the detriment of efficient implementation of the congressional mandate. In short, the FDA's quasi-formal rulemaking appropriately reconciles enforcement goals with procedural restraints and thus deserves judicial approval.

CONCLUSION

It is perhaps tempting to dismiss the FDA's success in avoiding formal adjudication as the unique prerogative of an agency faced with a staggering caseload and equipped with many standards that only scientists can fully comprehend. But if it is true that the FDA owes much of its success in the courts to its unique caseload and expertise, it is also true that the agency's procedural innovations are justifiable, as the courts have recognized, on a broader principle: Agencies can and should consider the efficiency of available modes of enforcement in framing substantive regulatory standards. The statutory and constitutional limits of this principle will of course vary from agency to agency. The focus in this Article has been on the constraints applicable to the FDA.

314. See Wright, *supra* note 6.

315. Significantly, in no other case of this type has the D.C. Circuit made cross-examination mandatory.

316. Williams, *Hybrid Rulemaking: The Evolution of Notice-and-Comment Procedures Under Section 553 of the Administrative Procedure Act* (unpublished article prepared for the Administrative Conference) at 43.

But the authors believe that many agencies—among them the FCC, FTC, and FPC—could pay far more attention to the interplay of substance, procedure, and efficiency, and could benefit from a close look at what the FDA has done.