UIC Law Review

Volume 9 | Issue 3 Article 7

Spring 1976

# Declaratory and Injunctive Relief as a Preenforcement Remedy against Invalid FDA Regulations, 9 J. Marshall J. Prac. & Proc. 819 (1976)

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# DECLARATORY AND INJUNCTIVE RELIEF AS A PREENFORCEMENT REMEDY AGAINST INVALID FDA REGULATIONS

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A food, drug, or cosmetics manufacturer subject to an administrative regulation which it honestly considers to be invalid traditionally has been confronted with a cruel dilemma. It could either comply with the regulation despite the fact that it was believed to be invalid, or disobey it deliberately and attempt to set up the invalidity of the regulation as a defense to any threatened civil or criminal enforcement action. If the latter course was chosen and the court disagreed with the manufacturer's judgment, it was likely that the manufacturer would find itself in the uncomfortable position of having incurred civil or criminal liability. A third alternative, preenforcement declaratory and injunctive relief, has been used effectively in a variety of situations, but until recently has been considered to be inapplicable[1] with respect to regulations promulgated pursuant to the Food, Drug, and Cosmetic Act.[2]

Beginning with *Abbott Laboratories v. Gardner*,[3] however, a handful of decisions have granted preenforcement declaratory and injunctive relief against FDA actions. In departing from an earlier belief that declaratory and injunctive relief was available only in the rare case,[4] two major factors have emerged.

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1. *E.g.*, Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950).

2. 21 U.S.C. §§ 301 *et seq.* Perhaps a preliminary word is necessary at the commencement of this study dealing principally with the FDA's attempt to put into force various amendments which were added to the Food and Drug Act in 1962. While some may view the outcome of these attempts as a triumph for the FDA, the coherence of the agency's methods in effectuating the amendments' policies is suspect. Numerous determinations, regulations, and other administrative actions taken in pursuance of those amendments were on an ad hoc basis, were directed toward immediate problems confronting the FDA in administering the Drug Act, and were certainly not designed to be sensitive to long range problems of policy development. The unfolding tale which emanated was one of administrators' attempting to implement legislative directives with inadequate regulatory tools while numerous pressures, not the least of which has been by the drug industry, have disrupted the overall FDA environment.

3. 387 U.S. 136 (1967).

4. *E.g.*, Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950) (court would not interfere with FDA's summary seizure of petitioner's goods which were potentially hazardous to human health, especially in view of the fact that the process by which seizure was effected was only a preliminary step in the administrative procedure).

The first is procedural in nature, and relates to questions of justiciability of preenforcement judicial review. Here there has been a marked change in favor of a pragmatic view of justiciability, utilizing a balance of harms approach. The second factor is substantive in nature and relates to major revisions in the *FDC* Act itself. Specifically, the Act was amended in 1962 to incorporate, *inter alia*, a specific standard of review—the substantive evidence rule.

This article will explore the facts ordinarily found necessary to obtain declaratory and injunctive relief as a preenforcement remedy within the purview of these developments. In any suit brought for preenforcement judicial review, recurring facts have been critical in determining the availability of any preenforcement remedy: (1) the sensitivity of the subject matter,[5] both in terms of the inherently harmful effect of unsafe foods and drugs as well as the indirect consequences of adverse public reaction to food and drug manufacturers;[6] (2) economic harm to the manufacturer;[7] (3) the need for drugs which are effective as well as available;[8] (4) the need to have the agency develop its own guidelines without judicial interference;[9] (5) the adequacy of alternative remedies, if any, for manufacturers;[10] (6) the nature of the question presented for judicial review—one of law or fact.[11]

## Elements of Justiciability

Before a discusssion of the merits of any given action can be reached, a series of jurisdictional hurdles must be met. These are the traditional elements of justiciability as adapted to preenforcement judicial review of FDA actions.

### *Availability of a Remedy*

Much of the inquiry in this area has been made academic by §§ 701, 702, and 704 of the Administrative Procedure Act (*APA*).[12] The Food, Drug, and Cosmetic Act (*FDC* Act) con-

5. Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609 (1973) (prescription drugs); Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167 (1967) (same); Toilet Goods Ass'n, Inc. v. Gardner, 387 U.S. 158 (1967) (same); Abbott Labs. v. Gardner, 387 U.S. 136 (1967) (same); Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950) (misbranded vitamins); Upjohn Co. v. Finch, 303 F. Supp. 241 (W.D. Mich. 1969) (prescription drugs), *aff'd*, 422 F.2d 944 (6th Cir. 1970).
6. *See* cases cited at note 5 *supra*.
7. *Id.*
8. *Id.*
9. *Id.*
10. *Id.*
11. *Id.*
12. 5 U.S.C. §§ 500 *et seq.*

tains specific remedial provisions for administrative hearings and for review in the courts of appeals. These remedies correlate with regulations issued under certain enumerated provisions of the *APA*.[13] The traditional view has been that where an act specifies a remedy, all other remedies, including preenforcement judicial review, are normally excluded.[14]

In the case of *Abbott Laboratories v. Gardner*,[15] the Supreme Court overruled the traditional view. The true inquiry, the Court said,

> is whether Congress by the Federal Food, Drug, and Cosmetic Act intended to forbid preenforcement review of . . . regulation[s] promulgated by the Commissioner. The question is framed in terms of prohibition rather than authorization because . . . judicial review of a final agency action . . . will not be cut off unless there is a persuasive reason to believe that such was the purpose of Congress.[16]

The court pointed out further that § 702 of the *APA*

> embodies the basic presumption of judicial review to one 'suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute [here the *FDC* Act],' 5 U.S.C. § 702, so long as no statute [again the *FDC* Act] precludes such relief or the action is not one committed by law [under the *FDC* Act] to agency discretion, 5 U.S.C. § 701(a). The Administrative Procedure Act provides specifically not only for review of '[a]gency action made reviewable by statute' but also for review of 'final agency action for which there is no adequate remedy in a court,' 5 U.S.C. § 704.[17]

The Court reviewed the legislative history of the *APA* and concluded that "only upon a showing of '*clear and convincing evidence*' of a contrary legislative intent should the courts restrict access to judicial review."[18]

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13. 5 U.S.C. §§ 701 *et seq.*

14. Switchman's Union v. Nat'l Mediation Bd., 320 U.S. 297 (1943); Myers v. Bethlehem Shipbuilding Corp., 303 U.S. 41 (1938). In Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950), plaintiff sought an injunction against the FDA to prevent it from proceeding with multiple seizures of plaintiff's products on the grounds that the manufacturer had not been given the opportunity to present evidence on the question of whether there was probable cause for issuance of seizure process. In denying the relief sought, the Court stated that the

> highly selective manner in which Congress has provided for judicial review reinforces the inference that the only review of the issue of probable cause which Congress granted was the one provided in the libel suit [to the effect that no administrative hearing at the preliminary stage is required by due process as long as one is held before a "final" administrative order became final].

*Id.* at 600-01.

15. 387 U.S. 136 (1967).

16. *Id.* at 139-40 (*citing* Rusk v. Cort, 369 U.S. 367 (1962); Brownell v. Tom We Shung, 352 U.S. 180 (1956); and Board of Governors v. Agnew, 329 U.S. 441 (1947)).

17. 387 U.S. 136, 140 (1967).

18. *Id.* at 141 (emphasis added).

The Court next turned its attention to the remedial provisions of the *FDC* Act to apply the *APA* exclusion of review test outlined above. It pointed out that the *FDC* Act nowhere prohibited remedies other than those enumerated and, in fact, § 701(f)(6) states, "[t]he remedies provided in this subsection shall be in addition to and not in substitution for any other remedies provided by law."[19] The Court rejected the government's argument that the inclusion of a specific procedure for review of certain enumerated kinds of regulations[20] precluded other types of preenforcement review on the basis of an examination of the legislative history of these sections, pointing out that

> [a]t the time the Food, Drug, and Cosmetic Act was under consideration, in the late 1930's, the Administrative Procedure Act had not yet been enacted, the Declaratory Judgment Act was in its infancy, and the scope of judicial review of administrative decisions under the equity power was unclear.[21]

The provisions of § 701(f) quoted above were added to the *FDC* Act by "those who feared the life-and-death power given . . . to the executive officials . . . ."[22]

The Court distinguished the *Abbott* decision from the early case of *Ewing v. Mytinger & Casselberry, Inc.*,[23] on the grounds that the injunction sought in *Ewing* was based upon the theory that a hearing had not been held to establish probable cause for the seizure action therein. The *Abbott* Court compared the Administrator's finding of probable cause to the determination by a grand jury: "[I]t is a finding which only has vitality once a proceeding is commenced, at which time appropriate challenges can be made."[24] This, the *Abbott* Court concluded, is substantially different from a case challenging final agency action.[25]

In *Upjohn Co. v. Finch*,[26] the district court opinion found the *Abbott* conclusion—that neither the *APA* nor the *FDC* Act precluded preenforcement judicial relief[27]—equally applicable where the question was one of the Administrator's jurisdiction to promulgate a certain order:

> The controversy in this case is not unlike that considered by the United States Supreme Court in *Abbott*. As in *Abbott* the drug manufacturer (Upjohn) is faced with enforcement of an agency order before it has an effective opportunity to seek to have the order reviewed pursuant to the provisions of the

19. 21 U.S.C. § 371(f)(6).
20. 21 U.S.C. § 371(e).
21. 387 U.S. 136, 142 (1967).
22. *Id.*
23. 339 U.S. 594 (1950).
24. 387 U.S. 136, 147 (1967).
25. *Id.* at 148.
26. 303 F. Supp. 241, 249-50 (W.D. Mich. 1969).
27. 387 U.S. 136, 148 (1967).

> [*FDC*] Act. As in *Abbott* there is here a serious question as to whether the defendants are attempting to exceed the powers granted by Congress to the substantial detriment of the plaintiff.
> . . .
> . . . [T]he instant action is a proper case for judicial review in its present posture.[28]

The Supreme Court's decision in *Abbott* has obviously done much to clarify the question of the availability of an injunctive remedy in those cases where the FDA administrative regulations are involved. The ease with which the *Abbott* doctrine was applied to the facts in *Upjohn* indicates that the availability issue, a major problem prior to *Abbott*, is unlikely to be of significant concern in the future. Nevertheless, applicable statutory provisions must be scrutinized to make certain that review of specific action taken has not been precluded by and through the above *APA* sections, or by and through a comprehensive reading of the *FDC* Act and its legislative history.

### *Ripeness—Finality*

One of the decided departures taken in recent cases dealing with preenforcement judicial review relates directly to the dual question of whether the matter presented for review is and was final agency action within the meaning of the *FDC* Act,[29] and is otherwise ripe for review. Ripeness denotes primarily the status of a controversy which has reached the stage which makes it appropriate for judicial recognition. The Supreme Court has substantially clarified its criteria for determining whether a case involving the availability of injunctive relief as a preenforcement remedy against administrative regulations is ripe for review. The Court has stated that two criteria must be met: first, the issue tendered must be appropriate,[30] and, second, the hardship

28. 303 F. Supp. 241, 249-50 (1969).

29. Although the *FDC* Act itself contains no definition of final agency action or agency action, the *APA*, 5 U.S.C. § 551(13) defines agency action to include "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." Cases under the *FDC* Act refer to this definition when the term agency action arises. *See generally* note 90 *infra*.

30. Injunctive relief was granted in Columbia Broadcasting System, Inc. v. United States, 316 U.S. 407 (1942). The FCC issued regulations expressing "the general policy we will follow in exercising our licensing power" and stated that "no license shall be granted" to any station entering into certain specified types of contracts. Many of the contracts which Columbia had with stations in its network chain were among the types proscribed by the regulations. In the opinion, the Court stated that

> it is evident that application by the Commission of its regulations in accordance with their terms would disrupt appellant's broadcasting system and seriously disorganize its business.

*Id.* at 414. The Court stated that where regulations affect a petitioner's rights as such, they "have the force of law . . . ." *Id.* at 418-19. *See also* text accompanying note 37 *infra*.

Similarly, in Abbott Labs. v. Gardner, 387 U.S. 136, 137-38 (1967),

to the parties if judicial relief is denied must be substantial.[31]

Obviously, the criterion of appropriateness for judicial relief, standing by itself, does not provide a great deal of guidance; however, by providing a description of the specific factors which it will consider to determine appropriateness, the Court has substantially clarified this question. These factors are three: the regulation or order in question must be a final agency action within the meaning of § 10 of the *APA*;[32] the issue, as it is framed by the case, must present a purely legal question; and the regulation or order must be phrased in such a manner that it immediately affects the day-to-day conduct of the manufacturer.

In addition, courts have found themselves uniquely competent in dealing with cases in which the issue presented for preenforcement review is in the nature of a question of law. One such question of law often raised is whether the agency has acted within its jurisdiction, for courts have been reluctant, except in

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the Supreme Court found the controversy to be "ripe" within the following context:

> In 1962 Congress amended the Federal Food, Drug, and Cosmetic Act . . . to require manufacturers of prescription drugs to print the 'established name' of the drug 'predominantly and in type at least half as large as that used thereon for any proprietary name or designation for such drug,' on labels and other printed material . . . . The 'established name' is one designated by the Secretary of Health, Education, and Welfare pursuant to § 502(e)(2) of the Act, 21 U.S.C. § 352 (e)(2); the 'proprietary name' is usually a trade name under which a particular drug is marketed. The underlying purpose of the 1962 amendment was to bring to the attention of doctors and patients the fact that many of the drugs sold under familiar trade names are actually identical to drugs sold under their 'established' or less familiar trade names at significantly lower prices. The Commissioner of Food and Drugs, exercising authority delegated to him by the Secretary, 22 Fed. Reg. 1051, 25 Fed. Reg. 8625, published proposed regulations designed to implement the statute, 28 Fed. Reg. 1448. After inviting and considering comments submitted by interested parties the Commissioner promulgated the following regulation for the 'efficient enforcement' of the Act, § 701 (a), 21 U.S.C. § 371 (a): 'If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany *each appearance* of such proprietary name or designation.' 21 CFR § 1.104(g)(1).

(emphasis added).

31. In *Abbott* the harm alleged was both economic, in terms of the fact that the costs to relabel all of petitioner's drugs affected by the regulation outlined in note 30 *supra* would have been enormous, and intangible, due to the tremendous loss of goodwill which the pharmaceutical firm would incur should it have been found to have been mislabeling its prescription and other drugs. Since the *Abbott* case, therefore, the loss of goodwill has been clearly recognized as a factor going to the question of hardship as it relates to the overall consideration of ripeness. *See, e.g.*, Upjohn Co. v. Finch, 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970) (if preenforcement review was denied, plaintiff would have had to discontinue sale of many of its drug products or, by acting in defiance of FDA rulings, risk summary seizure of its drugs and prosecution).

32. 5 U.S.C. § 704.

the case of discretion lodged by statute in the administrator, to allow the agency to determine its own parameters of action.[33] Another legal question exists where the agency has interpreted a broad statutory term which fails to follow the exact intention manifested by Congress by a reading of legislative history.[34] Thus, where an agency has taken a generic term and interpreted it within the purview of the goals it views as being effected by the statute, a court may find concreteness in terms of whether the interpretation is unwarranted.[35]

In *Columbia Broadcasting System v. United States*,[36] plaintiff sought review of an FCC regulation which stated that the Commission would refuse to issue or renew licenses of stations which entered into certain types of proscribed contracts. At the time suit was brought for preenforcement relief against the regulation, no licenses had been denied or revoked and the regulation properly could have been classified as merely a statement of the Commission's intentions. A preenforcement challenge, however, was allowed:

> Such regulations have the force of law before their sanctions are invoked as well as after. When, as here, they are promulgated by order of the Commission and the expected conformity to them causes injury cognizable by a court of equity, they are appropriately the subject of attack . . . .[37]

Similarly, in *Abbott*, the Court considered the ripeness of a suit to enjoin enforcement of an FDA regulation requiring the use of the generic name[38] of a prescription drug *every time* the brand name appeared on the product's label. The industry practice had involved the use of the generic name with the most

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33. It is essential for the agency itself to develop its own guidelines without judicial interference. The issues presented in Upjohn Co. v. Finch, 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970), presents the type of situation where a court will not defer to an initial agency determination. The sole questions presented for preenforcement judicial review in *Upjohn* were whether the FDA had acted in excess of its statutory authority and without observance of the procedures required by law in ordering certain of the petitioner's drugs off the market. These questions primarily concern problems of statutory construction and, as will be developed later, unless policy determinations in the form of statutory interpretation are placed within the exclusive province of an administrator, are the types of questions which courts traditionally have been competent in dealing with.

34. *E.g.*, NLRB v. Hearst Pubs., Inc., 322 U.S. 111 (1944).

35. The generic name of a drug is its common or recognized pharmacological name (such as "Meprobamate"), while the brand name is the manufacturer's trade or proprietary name (such as "Miltown"). The FDA regulation in *Abbott* would have required the manufacturer to indicate the generic name *every time* the proprietary name was used on certain drugs' labels; whether this regulation was warranted by a reading of the enabling legislation became the sole question on a review of the merits of the controversy in the Supreme Court.

36. 316 U.S. 407 (1942).

37. *Id.* at 418-19.

38. *See* notes 30 and 35 *supra*.

prominent appearance of the brand name only. Compliance with the regulation would have required extensive labeling changes throughout the industry. The Court found the controversy to be "ripe" for judicial resolution.

First, the regulation in question was found to be a "final agency action."[39] Relying upon *Columbia Broadcasting*,[40] *Frozen Food Express v. United States*,[41] and *United States v. Storer Broadcasting Co.*,[42] the Court found the element of "finality" to be satisfied.

> The regulation challenged here, promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties is quite clearly definitive. There is no hint that this regulation is informal . . ., or only the ruling of a subordinate official . . ., or tentative. It was made effective upon publication, and . . . compliance was expected.[43]

Second, the issue presented by the case was found by the Court to be a purely legal one:

> [W]hether the [*FDC*] statute was properly construed by the Commissioner to require the established name of the drug to be used *every time* the proprietary name is employed.[44]

Since both sides had approached the case as one of congressional intent, and the Government had made no effort to justify the regulation in factual terms, the parties themselves had restricted the case to this legal question.

With regard to the third criterion, the Court found that "the impact of the regulations upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review . . . ."[45] The regulations in question were clear-cut and were effective immediately upon publication. If denied judicial relief at this stage, the plaintiff either would have had to expend vast sums of money to alter its labeling, or risk both seizure of its products and subsequent prosecution. Finally, for the same reason, the context in which the regulation faced by the manufacturer was issued should be considered. The Court found it

> relevant . . . to recognize that petitioners deal in a sensitive industry, in which public confidence in their drug products is especially important. To require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily.[46]

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39. 387 U.S. 136, 149 (1967).
40. 316 U.S. 407 (1942).
41. 351 U.S. 40 (1956).
42. 351 U.S. 192 (1956).
43. 387 U.S. 136, 151 (1967).
44. *Id.* at 149.
45. *Id.* at 152.
46. *Id.* at 153.

Further, in *Abbott*, the Court stated that the injunctive and declaratory judgment remedies were discretionary, and that courts traditionally had been reluctant to apply them to administrative decisions unless it could be proved that they had arisen in a controversy ripe for judicial resolution.[47] The Court stated that the primary reason for this procedure was to prevent the courts from excessive entanglements in various abstract arguments over administrative policies, to avoid premature adjudications, and to protect the agencies from interference from the judiciary until the results of the administrative decision could have an effect upon the manufacturers' day-to-day activities. Justice Harlan stated quite clearly in his opinion:

> [W]e believe the issues presented are appropriate for judicial resolution at this time. First, all parties agree that the issue tendered is a purely legal one; whether the statute was properly construed by the Commissioner to require the established name of the drug to be used *every time* the proprietary name is employed. Both sides moved for summary judgment in the District Court, and no claim is made here that further administrative proceedings are contemplated.[48]

The Court also stated that the regulations in question were found to be final agency action within the meaning of § 10 of the *APA*,[49] as construed in judicial decisions. It should be noted that in *Gardner v. Toilet Goods Ass'n, Inc.*,[50] similar considerations impelled the conclusion that the manufacturer's dilemma with respect to three color additive regulations there in question was ripe for judicial review.

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47. *Id.*
48. *Id.* at 149.
49. 5 U.S.C. § 704. *See also* for a definition of "agency action" within the purview of the *APA*, note 29 *supra*. Both Frozen Food Express v. United States, 351 U.S. 40 (1956), and United States v. Storer Broadcasting Co., 351 U.S. 192 (1956), took a similarly flexible view of finality. At issue in *Frozen Food Express* was an ICC order specifying commodities that were deemed to fall within the statutory class of "agricultural commodities." Vehicles carrying such commodities were exempt from ICC supervision. An action was brought by a carrier that claimed to be transporting exempt commodities, but which commodities the ICC order had not included in its terms. Although the dissenting opinion noted that this order only had authority to give notice of how the Commission interpreted the Interstate Commerce Act and would have had effect only if and when a particular action was brought against a particular carrier, and argued further that "judicial intervention [*should*] be withheld until administrative action has reached its complete development," 351 U.S. 40, 45 (1956), the majority of the Court held the order reviewable without particular application. Also, in *Storer Broadcasting*, the Court held to be a final agency action within the *APA* an FCC regulation announcing a Commission policy that no television operating license would be issued to any applicant already holding five such licenses, even though no specific application of the policy announcement was before the Commisison. The Court stated: "The process of rulemaking [by which Storer claimed to be aggrieved] was complete." 351 U.S. 192, 198 (1956).
50. 387 U.S. 167 (1967).

Thus, modern cases following *Abbott* have taken the position that finality, as it relates to ripeness within the context of an FDA action, ought to be decided upon a pragmatic basis. Where no more action is required to force some sort of compliance by a manufacturer and has immediate effects upon the manufacturer, the action should be deemed final.[51] As such, the same considerations which impelled a finding of ripeness in both *Columbia Broadcasting* and *Abbott* surfaced in *Upjohn Co. v. Finch*.[52]

In *Upjohn*, the FDA promulgated an order which, thirty days after publication in the *Federal Register*, would have automatically revoked prior certification of existing batches of plaintiff's otherwise widely accepted drug. No stay of the order pending any administrative hearing was provided for in the order itself. In addition, it was obvious that no new batches of plaintiff's drug could be certified, in view of that order. The administration clearly expected compliance; the thirty day delay, it was argued, was included merely "to allow time for a recall [of plaintiff's drug] to be completed."[53] The impact of this order upon the plaintiff was immediate and substantial. Not only would it suffer loss of revenue during the period the drug was off the market, but even if it should ultimately prevail in subsequent administrative hearings or judicial proceedings, the damages resulting from adverse publicity and loss of physicians' confidence would be immeasurable. As defined in *Columbia Broadcasting*,[54] the *Upjohn* order was clearly a final agency action.

A major factor in favor of the manufacturer is whether there will be immediate economic harm. In the *Abbott* case, this would certainly have been true.[55] In *Abbott's* companion case,

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51. 5 U.S.C. § 704.
52. 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970). *See also* text accompanying note 37 *supra*.
53. 422 F.2d 944, 963 (6th Cir. 1970). *See generally* note 90 *infra*.
54. *See* notes and text accompanying notes 37 and 49 *supra*.
55. In most of the FDA cases upon which reliance is principally placed throughout this article, certain generalizations as to economic harm can be made. In all the cases where preenforcement review was permitted, vast outlays of money normally seem to have been within view if full compliance with FDA regulations was made. In *Upjohn*, for example, a $30 million dollar business was involved. 422 F.2d 944, 950 (6th Cir. 1970). Loss of confidence in the consuming and professional sectors of society, brought about by adverse publicity of any action in defiance of the regulations, would certainly have resulted in economic harm. This was true in the *Abbott* decision, even though the safety of the drugs in question there was not an issue. As such it is often impossible to distinguish between actual economic loss and loss of industry-wide goodwill; but this should be minimized, for they are inseparable factors which result in economic harm. Of course, should a manufacturer decide to defy an FDA regulation, not only would there be adverse publicity, but in addition the manufacturer could risk summary seizure of its products and thus the loss of a capacity to carry on any business whatsoever.

*Gardner v. Toilet Goods Ass'n, Inc.*,[56] where the Court also upheld a lower court's engaging in preenforcement review of regulations prescribing the use of color additives in certain foods, drugs, and cosmetics, there would also have been little doubt as to the extent of economic harm to the manufacturer. In another companion case, however, *Toilet Goods Ass'n, Inc. v. Gardner*,[57] the Court could not find irremediable adverse consequences resulting from the manufacturer being forced into a later challenge of the regulation there involved. The Court said:

> This is not a situation in which primary conduct is affected—when contracts must be negotiated, ingredients tested or substituted, or special records compiled. This regulation merely states that the Commissioner may authorize inspectors to examine certain processes or formulae; no advance action is required of cosmetics manufacturers, who since the enactment of the 1938 [*FDC*] Act have been under a statutory duty to permit reasonable inspection of a 'factory, warehouse, establishment, or vehicle and all pertinent equipment finished and unfinished materials; containers, and labeling therein.' § 704(a). Moreover, . . . unlike the other regulations challenged in this action, in which seizure of goods, heavy fines, adverse publicity for distributing 'adulterated' goods and possible criminal liability might penalize failure to comply, see *Gardner v. Toilet Goods Assn.*, . . . a refusal to admit an inspector here would at most lead only to a suspension of certification services to the particular party, a determination that can then be promptly challenged through an administrative procedure, which in turn is reviewable by a court.[58]

The Court further stated that such review would be "an adequate forum for testing the regulation in a concrete situation."[59]

The immediate economic harm in *Upjohn* is apparent also, along with certain indirect consequences, such as adverse public reaction, which ultimately affect the goodwill that the manufacturer and industry have created.[60] The question as to whether the public is adequately protected, because the drugs involved in *Upjohn* could be sold only on the prescription of a physician, relates to the harm factor. The Commissioner stated:

> The FDA thinks that the physician wants to know which drugs have been found ineffective and which present safety hazards. There are differences among physicians as well as drug companies concerning the NAS reports. The essential question is whether doctors should be informed by a responsible, objective government agency of drug findings by the top medical and scientific experts in the nation. The conclusion is that the FDA

56. 387 U.S. 167 (1967).
57. 387 U.S. 158 (1967). *See also* note 33 *supra*.
58. 387 U.S. 158, 164-65 (1967).
59. *Id.* at 165.
60. *See* note 55 *supra*.

> does have that responsibility under the law, and that physicians do want to receive that information.[61]

Lastly, *Toilet Goods Ass'n, Inc. v. Gardner*,[62] is of interest because the Court found the controversy not ripe for adjudication. By comparing the Court's reasoning in this case with *Abbott*, a more complete understanding of the ripeness doctrine, as it applied to this type of action, is possible. In *Toilet Goods*, the Court considered a regulation which permitted the Commissioner of Food and Drugs, under certain circumstances, to order the inspection of certain facilities and data, and, if a manufacturer refused to allow these inspections, *permitted* the Commissioner to refuse certification of color additives manufactured at that plant.[63] While the requirements that the regulation constituted a final agency action and that the issue raised a purely legal question were satisfied, the requirement that the regulation be phrased in such a manner as to affect the primary conduct of the parties was not. Since the regulation merely served notice that the Commissioner *might* order an inspection and that he *might* refuse certification, it had no immediate effect upon the plaintiffs:

> Whether the regulation is justified thus depends not only . . . on whether Congress refused to include a specific section of the Act authorizing such inspections, . . . but also on whether the statutory scheme as a whole justified promulgation of the regulation. . . . This will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets . . . . We believe that judicial appraisal of these factors is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case in the framework of the generalized challenge made here.[64]

In addition, the Court pointed out that the plaintiff was faced with no great hardship if relief was denied. Unlike *Abbott* or *Gardner v. Toilet Goods Ass'n, Inc.*, no heavy financial burden or likelihood of prosecution would result from a failure to enjoin the regulation. At the most, refusal to permit inspection would merely result in temporary suspension of certification services. This, the Court pointed out, could be challenged promptly through administrative procedure and judicial review.

Thus, it appears from the foregoing cases that where imme-

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61. Ley, *The Doctor, The Patient, and The FDA*, 19 CLEV. STATE L. REV. 15, 17 (1970).
62. 387 U.S. 158 (1967).
63. *Id.* at 161.
64. *Id.* at 163-64.

diate, detrimental harm[65] has resulted from agency action which may be deemed final, and where the issue raised is purely legal, the courts will more readily conclude that the case is ripe for judicial review. This is especially so when the court would not otherwise be interfering with the ongoing administration of the agency.

### *Exhaustion of Administrative Remedies*

The requirement that a case be ripe for judicial review is closely related to the inquiry into exhaustion of administrative remedies, in that both are concerned with the timing of judicial review of an administrative action. They are, however, distinguishable. The former requirement is concerned with the question of whether the controversy is within the scope of permissible judicial function; the latter is related only to the narrow question of whether a party should be required to pursue further administrative remedies before being allowed into court.[66]

In the classic case of *Myers v. Bethlehem Shipbuilding Corp.*,[67] the Supreme Court considered the question of whether a federal distsrict court had equity jurisdiction to enjoin the National Labor Relations Board from holding a hearing prior to the issuance of a regulation. Justice Brandeis, speaking for the Court, held that the district court was without power to enjoin the Board from holding the hearings. In the course of his opinion, the Justice articulated the long-settled rule of judicial administration that no one is entitled to judicial relief until all administrative remedies have been exhausted.[68] Despite this rule, however, the Supreme Court has repeatedly allowed judicial review without complete exhaustion.[69] On other occasions,

65. Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167 (1967); Abbott Labs. v. Gardner, 387 U.S. 136 (1967); Upjohn Co. v. Finch, 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970).

66. *See* L. JAFFE, JUDICIAL CONTROL OF ADMINISTRATIVE ACTION chs. 10-11 (abr. student ed. 1965).

67. 303 U.S. 41 (1938).

68. The [builder's] contention is at war with the long settled rule of judicial administration that no one is entitled to judicial relief for a supposed or threatened injury until the prescribed administrative remedy has been exhausted. That rule has been repeatedly acted on in cases where, as here, the contention is made that the administrative body lacked power over the subject matter.

Obviously, the rule requiring exhaustion of the administrative remedy cannot be circumvented by asserting that the charge on which the complaint rests is groundless and that the mere holding of the prescribed administrative hearing would result in irreparable damage. Lawsuits also often prove to have been groundless; but no way has been discovered of relieving a defendant from the necessity of a trial to establish the fact.

*Id.* at 50-52.

69. Leedom v. Kyne, 358 U.S. 184 (1958) (exhaustion not required and equity powers of court present where administrator allegedly acted outside of statutory power and statute provided no adequate alternative

however, the Court has required strict adherence to the rule.[70] The Court's reasoning is frequently very difficult to distinguish, but a reading of important cases since *Myers* indicates that the Court will relent in requiring full exhaustion where the issue presented for review relates to the possibility of the administration's having indulged in ultra vires acts. In addition, the Court has relented in situations involving immediate detrimental harm. This, of course, must be balanced by a strong desire on the part of the Court to refrain from interference with various actions taken by the agency. An important factor that helps the Court to decide what action to take is the availability of alternate remedies to the petitioning party.

In *Abbott*, exhaustion may be implied, for the administrator was found to be acting outside of his jurisdiction.[71] Justice Friendly's opinion in *Pepsico, Inc. v. FTC*,[72] seems to reveal one of the typical responses to such a problem in the area of exhaustion:

> Although the Federal Trade Commission Act limits review by a court of appeals to 'any person, partnership, or corporation required by an order of the Commission to cease and desist,' 15 U.S.C. § 45 (c), we agree with appellants that the fact that the order here assailed is not one requiring *PepsiCo* to cease and desist from anything does not lead inexorably to the conclusion that it is not reviewable, but only that it is not reviewable by petition to a court of appeals. . . . Whether it was reviewable by suit in a district court depends on the construction given to the first two sentences of § 10 (c) of the APA, now 5 U.S.C. § 704:
>
> > Agency action may be reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary,

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remedies); *accord*, Public Utils. Comm'n v. United Gas Co., 317 U.S. 456 (1943); Utah Fuel Co. v. Nat'l Bituminous Coal Comm'n, 306 U.S. 56 (1939); Skinner & Eddy Corp. v. United States, 249 U.S. 557, 562-63 (1919) (notwithstanding petitioner's failure to obtain redress from the administration itself).

70. Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950) (preliminary, non-final action by administrator is not one where exhaustion could be avoided); Aircraft & Diesel Equip. Corp. v. Hirsch, 331 U.S. 752 (1947) (where full statutory remedy scheme was provided in enabling act and act also provided for exclusive jurisdiction in agency in order to develop internally congressional policy, exhaustion will be required and court will lack equity jurisdiction to cut off, prematurely, agency disposition); Petroleum Exploration, Inc. v. Pub. Serv. Comm'n, 304 U.S. 209 (1938) (same).

71. The Court never specifically referred to exhaustion, but it must be remembered that where an action is begun in a district court to question whether the FDA has acted ultra vires its statutory authority, the action is one not within either the *FDC* or the *APA* review provisions. Rather, it is in the nature of an original action in equity to declare the FDA's action as unconstitutional for want of statutory authority and to enjoin the agency from enforcing such action. *See also* cases cited at note 69 *supra*.

72. 472 F.2d 179 (2d Cir. 1972).

> procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action.[73]

Since the *Pepsico* order was not one made reviewable by statute, its reviewability hinged on whether it constituted final agency action within *APA* § 704. Legislative history of the *APA* did not clear up the problem of what was meant by this phrase.[74] Thus, does § 704 mean that interlocutory rulings were never to be reviewed until there was finality in the traditional sense, or do the words "preliminary, procedural, or intermediate agency action or ruling *not directly reviewable*" imply that some action may be reviewed directly?[75] Since the wording of this section of the *APA* appears to be in contradistinction to the *Myers* holding which required full exhaustion, the framers of the *APA*, familiar as they must have been with that case, probably would have used stronger language had it been intended that *Myers* be overruled by the Procedure Act.[76] What the phrase "preliminary, procedural, or intermediate agency action . . ." *should* mean is that if the action otherwise meets the requisites for avoiding exhaustion, it should be *directly reviewable* at that time.

As previously stated, the decisions are both conflicting and seemingly indistinguishable.[77] An attempt, however, should always be made to distinguish between a case involving imminent harm and actual harm. The important question is, at what expense should this distinction be drawn? Abuse of overemphasizing the harm factor could give a federal district court judge the opportunity to halt the regulatory process, and to do so even on the basis of abstractions and generalities instead of a concrete fact situation.[78] The judge must have an understanding of the

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73. *Id.* at 185.
74. *Id.* at 186.
75. *Id.*
76. *Id.*
77. *Id.* Professor Davis feels that there are three key factors, however, that may help to distinguish these cases:

> [The] extent of injury from pursuit of administrative remedy, [the] degree of apparent clarity or doubt about administrative jurisdiction, and [the] involvement of specialized administrative understanding in the question of jurisdiction.

3 DAVIS, ADMINISTRATIVE LAW TREATISE § 20.03, at 69 (1958). *Compare* McGee v. United States, 402 U.S. 479 (1971) *with* McKart v. United States, 395 U.S. 185 (1969).

78. In the opinion which dissented to Gardner v. Toilet Goods Ass'n, Inc., 387 U.S. 167, 174-76 (1967), where exhaustion was not required, Mr. Justice Fortas stated that:

> I am in agreement with the Court in No. 336, *Toilet Goods Assn. v. Gardner*, that we should affirm the decision of the Court of Appeals for the Second Circuit holding that the authority of the Secretary of Health, Education, and Welfare to promulgate the regulation there involved may not be challenged by injunctive or declaratory judgment action. . . . It requires that manufacturers afford employ-

enforcement problems of the agency and the necessity for some supervision over the regulated industry.

In the *Upjohn* case, the district court did not seem to have considered the specific problem of exhaustion. The court said, merely, that the *Federal Register* announcement constituted a final order. Consideration of the nature of this announcement, however, indicates that it did not constitute a final order and that the plaintiff had not exhausted its administrative remedies. The order published in the *Federal Register*[79] provided that objections to the order could be submitted within a thirty day period and that a hearing on the objections could be requested. Despite the fact that there was no provision for a stay of the order pending a hearing on objections, the procedures described constituted additional administrative remedies available to the plaintiff. These remedies were not pursued, however, prior to the filing of the initial complaint in the district court. This failure to exhaust the available administrative remedies, even though these remedies were not statutorily prescribed, did not preclude the granting of the preenforcement injunctive relief prayed for by the plaintiff. First, had the injunctive relief been disallowed, the injury threatening the plaintiff would have been great. In addition to the loss of sales, adverse publicity and the consequent loss of confidence by physicians in its sensitive products would have constituted an enormous burden. Second, the *Upjohn* action was predicated on the theory that the FDA lacked jurisdiction to provide the additional remedies. Finally, an opportunity to be heard on the merits of a given action involving a question of administrative jurisdiction should always be available; a court is as competent as an administrator to make a judgment on that restricted question.

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ees of the agency access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates, and provides that the Commissioner of Food and Drugs 'may immediately suspend certification service' so long as access is denied. . . .

I am, however, compelled to dissent from the decisions of the Court in No. 39, *Abbott Laboratories v. Gardner*, and No. 438, *Gardner v. Toilet Goods Assn.* . . .

. . . .

The Court, by today's decisions in Nos. 39 and 438, has opened Pandora's box. Federal injunctions will now threaten programs of vast importance to the public welfare. The Court's holding here strikes at programs for the public health. The dangerous precedent goes even further. It is cold comfort—it is little more than delusion —to read in the Court's opinion that 'It is scarcely to be doubted that a court would refuse to postpone the effective date of an agency action if the Government could show . . . that delay would be detrimental to the public health or safety.' Experience dictates, on the contrary, that it can hardly be hoped that some federal judge somewhere will not be moved as the Court is here, by the cries of anguish and distress of those regulated, to grant a disruptive injunction.

79. Upjohn Co. v. Finch, 422 F.2d 944, 961 (6th Cir. 1970).

### *Standing*

Although standing ordinarily does not present a problem in a discussion involving the FDA, it certainly must be considered and dealt with when one examines the area of justiciability. With this in mind, some brief comment should be made before proceeding further.

The standing of petitioners seeking preenforcement judicial review of FDA actions should be clear. Although early cases stated the proposition that economic harm which took the form of a mere loss of competitive edge was not sufficient injury in fact,[80] today economic harm, no matter the source, should suffice, if capable of objective proof and if the petitioner is otherwise within the class of those who were intended to be protected by the relevant enabling statute.[81] This is confirmed in *APA* § 702 which states that a person aggrieved by agency action within the meaning of the relevant statute would suffice. Additionally, it is interesting to note that loss of goodwill in the form of adverse publicity is now recognized as injury in fact in preenforcement reviews of FDA actions.[82]

## Attacking the Merits

After a petitioner seeking preenforcement judicial review has been able to persuade a court of the case's present justiciable status, the petitioner must still be able to present a case which, on the merits, is capable of judicial resolution. To accomplish this latter task a petitioner may often be powerless, for the case may be either an intermediate administrative action which is not otherwise "final" within *APA* § 704 and thus not containing a purely legal issue, or the action taken may lack a record of any administrative proceeding, leaving the court with no basis upon which to make a determination as to whether the action below met the standard of review to be applied.

### *Review Without a Record*

Depending upon the statute, here the *FDC* Act, an administrator may have been given one or more of several mandatory or permissive powers in relationship to the administrative actions with which he has been charged. Under the *FDC* Act the Commissioner need not, for example, be required to hold an evidentiary hearing *before* the promulgation of any regulation.[83]

80. *E.g.*, Perkins v. Lukens Steel Co., 310 U.S. 113 (1940).
81. Association of Data Processing Serv. Orgs., Inc. v. Camp, 397 U.S. 150 (1970).
82. *See* note and text accompanying note 55 *supra*.
83. Early Supreme Court cases considering the question of a require-

When a regulation is thus promulgated, there is no "record below" of any administrative proceedings, and the courts' real

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ment for an opportunity to be heard in administrative proceedings established the rule that such hearings were mandatory. Londoner v. Denver, 210 U.S. 373, 386 (1908).

Several exceptions to this general rule, however, have been created by later cases. For example, hearings are not required where a very large number of persons are affected by the regulation and such hearings would be impractical. Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441 (1915). A more pertinent exception was articulated in United States v. Storer Broadcasting Co., 351 U.S. 205 (1956) where the Court stated: "We do not think Congress intended the Commission to waste time on applications that do not state a valid basis for a hearing. If any applicant is aggrieved by a refusal, the way for review is open." As such, the Court in *Storer* reversed a circuit court decision which required the FCC to grant a hearing prior to denying an application for a radio station. This exception to the general rule was restated by the Court of Appeals for the Tenth Circuit in Producers Livestock Marketing Ass'n v. United States, 241 F.2d 192 (10th Cir. 1957), *aff'd sub nom.* Denver Union Stockyard Co. v. Producers Livestock Marketing Ass'n, 356 U.S. 282 (1958):

> [I]t is fundamental to the law that the submission of evidence is not required to characterize 'a full hearing' where such evidence is immaterial to the issue to be decided. . . . Where no genuine or material issue of fact is presented the court or administrative body may pass upon the issues of law after according the parties the right of argument.

241 F.2d 192, 196 (10th Cir. 1957). Professor Davis has suggested that application of this exception to the general rule requires a distinction to be drawn between what he calls "adjudicative facts" and "legislative facts." The former category would include "facts about the parties and their activities, businesses, and properties," and are susceptible to evidential proof. *See, e.g.*, Londoner v. Denver, 210 U.S. 373 (1908). The latter group would include "general facts which help the tribunal decide questions of law, policy, and discretion." *See, e.g.*, Bi-Metallic Inv. Co. v. State Bd. of Equalization, 239 U.S. 441 (1915). Professor Davis points out that the administrative process is particularly well adapted to the determination of adjudicative facts, and, for this reason, a hearing should be required whenever an issue of this type is presented. Legislative facts, on the other hand, primarily involve questions of policy and discretion and, by their nature, are not susceptible to evidential proof. Formal hearings, he concluded, should not be required when the issues to be determined are entirely within this latter category. Davis, *An Approach to Problems of Evidence in the Administrative Process*, 55 HARV. L. REV. 364 (1942). *See, e.g.*, Gonzales v. United States, 348 U.S. 407 (1955).

In *Upjohn* plaintiff admitted that it had not further evidence to offer beyond that previously submitted to the FDA before it issued its decertification order, but argued that a hearing would enable it to present evidence bearing upon such questions as whether lab tests have predictive value for the use of certain drugs by man, whether a drug's widespread clinical success entitled it to probative weight in evaluating overall drug efficacy, what constituted an adequate and well controlled study, what is the acceptable incidence of side effects for antibiotics, and whether it is rational to use combination antibiotic drugs. FDC REP. 9 (December 1, 1969). As each of these questions would seem to have involved "legislative" type fact determinations rather than "adjudicative" or individualized fact findings, the Court of Appeals for the Sixth Circuit rightfully found that a hearing was not mandated before the order of May 15 was put into force and effect. One reason for such a distinction in the *Upjohn* case rests upon the fact that, as to the type of questions advanced by the drug manufacturer as outlined above, experts might testify as to their opinions on the issues there involved, but, in the final analysis, their testimony would remain nothing more than opinion to be considered by the Commissioner of Food and Drugs in exercising his judgment or discretion.

inquiry is whether such a promulgation was warranted by a view of the enabling legislation.[84] At least, however, there is an element of notice present in this situation, that in view of the administrator's promulgation there *may* be a future application of that regulation to a particular manufacturer. One might also call the questions on this type of review ones dealing solely with "legislative facts," involving primarily a determination of whether the administrator has made statutorily permissible policy determinations.[85]

A similar situation is presented when the FDA Commissioner takes summary action, such as a seizure of tainted foods, for again there is no hearing or record for a court to review. Yet the inquiry on review is not as limited as in the former case, for here there has been an adjudication, albeit one wherein no factual evidence was presented before a sanction or penalty has been imposed or threatened. Under the *FDC* Act the Commissioner may take such summary action and not be enjoined on the merits, particularly where he has not abused the discretion granted him by the enabling statute. Thus, whether there has been such an abuse of discretion is a first type of review standard, and is especially applicable where imminent physical harm to the public can be foreseen; a court will not lightly enjoin a seizure of potentially lethal substances[86] unless there has been a clear abuse of the administrator's discretionary powers.

Courts also will be reluctant to entertain a hearing on the merits where, although no physical injury factor is involved with respect to the Commissioner's action, the courts would prefer to delay a hearing for fear of interfering with the development of overall agency policy. This is particularly true in cases where a preliminary order has been issued to a given manufacturer and the agency may yet resolve the overall controversy in favor of that manufacturer. This situation was exemplified by *Toilet Goods Ass'n, Inc. v. Gardner*,[87] where a rule was promulgated to the effect that, where agency personnel have been refused entry to inspect a cosmetics manufacturer's facilities, suspension by decertification of the right to manufacture was mandated. In affirming the lower court's holding that the rule itself was not reviewable, the Supreme Court held that review on the merits could be allowed only where the rule had been applied. In the Court's reasoning, in addition to the absence of immediate harm

84. *E.g.*, Abbott Labs. v. Gardner, 387 U.S. 136 (1967); NLRB v. Hearst Pubs., Inc., 322 U.S. 111 (1944). *See* cases cited at note 69 *supra*.
85. *See* note 83 *supra*.
86. Ewing v. Mytinger & Casselberry, Inc., 339 U.S. 594 (1950).
87. 387 U.S. 158 (1967).

to any manufacturer, the agency should be given the first right or opportunity to apply its own rule within its conception of the legislative policy which it had been charged to effect. Thus, where preenforcement review and injunctive relief could disrupt ongoing agency policy determinations, a court will deny judicial review on the merits.

### *Review with a Record*

Where a regulation has been promulgated or an adjudication made on the basis of some type of evidential hearing, however, the nature and scope of judicial review greatly changes. The *FDC* Act[88] and the *APA*[89] both provide for review of record agency actions within the purview of the substantial evidence rule. In this context, however, a court may pay deference to preceding administrative determinations by taking the position that the agency is expert within its respective mandate and had the opportunity to view evidence presented on a first-hand basis.

The central issue presented by the *Upjohn Co. v. Finch*[90] case, for example, was whether the FDA could, by administrative

88. 5 U.S.C. § 371(f).
89. 5 U.S.C. § 706(2)(E).
90. 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970). As this case will supply the basis for discussion for the remainder of this section, it would be of use to more fully elucidate the background of the controversy. Under section 507(a) of the *FDC* Act, 21 U.S.C. § 357(a), the Commissioner of Food and Drugs is authorized to promulgate regulations which provide for certification of antibiotic drugs as safe and effective. In 1956, the Commissioner, acting pursuant to this statutory authority, promulgated regulations for the certification of combinations of tetracycline and novobiocin. In *Upjohn*, plaintiff's Panalba products were certified as being both safe and effective pursuant to these regulations and were marketed first in 1957.

In 1958, pursuant to section 505 of the *FDC* Act, 21 U.S.C. § 355, the Commissioner approved a New Drug Application (NDA) for the marketing of Albamycin, a drug containing calcium novobiocin and sulfamethizole. In 1964, the Commissioner promulgated section 148(j).4 of the Regulations of the Food and Drug Administration, providing for the certification of antibiotic drugs containing calcium novobiocin and sulfamethizole as safe and effective.

The *FDC* Act, as amended in 1962 by the Harris-Kefauver amendments, 21 U.S.C. § 357(a), added the premarketing criterion of drug efficacy to the existing criterion of drug safety for new drugs. The FDA took the position that these amendments constituted a mandate to review the efficacy of all drugs which had been marketed from 1938 to 1968, and which previously had received FDA premarket approval on the grounds of safety alone. Recognizing that the facilities of the FDA were inadequate to cope with the monumental task implicit in this review, the Administration on June 23, 1966, contracted with the National Academy of Sciences-National Research Council (NAS-NRC) for the conduct of this review. Despite the fact that the *FDC* Act previously had required proof of effectiveness for the certification of antibiotics, 21 U.S.C. § 357(a), antibiotic drugs were to be included in this review.

After a two year study, the NAS-NRC Drug Efficacy Study Group reported that, in its estimation, antibiotics containing combinations of sulfonamides and penicillin, the preponderance of the antibiotics then being marketed,

> are potentially dangerous drugs. Reactions to these drugs are com-

order based upon independent findings, revoke prior certification of plaintiff's antibiotic drugs. Section 507(h) of the *FDC* Act provides that regulations for the certification of such drugs as

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mon, and the reactions can be severe or even fatal. The use of both drugs simultaneously therefore increases the risk to the patient, and the combination is to be avoided for this reason. . . .

. . . The question of the control of drug dosage should always be considered when fixed drug combinations are used. In this situation, the physician never finds it possible to increase or lower the dose of one component of the mixture without at the same time affecting the dose of the other. In this circumstance, the tendency is either to raise the dose of one drug to a desired level and thus inadvertently to give an overdose of the other; or to lower the dose of one component to a desired level and consequently give an insufficient dose of the other. . . .

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. . . On these bases, it is strongly urged that use of these fixed combinations no longer be recommended.

National Academy of Sciences, Drug Efficacy Study, A Report to the Comm'r of Food and Drugs 127-28 (1969).

Following receipt of the NAS-NRC report, the Commissioner of Food and Drugs, on December 24, 1968, published a notice of intent to initiate proceedings to amend the antibiotic regulations and delete Upjohn's combination antibiotic drugs from the list of those drugs acceptable for certification. The announcement stated that the NAS-NRC study group had found these products to be ineffective as a fixed combination for the indications specified in the labeling. The announcement added that the FDA concurred with the NAS-NRC Drug Efficacy Study Group "that there [was] a lack of substantial evidence that each ingredient [in the] combinations contributes to the claimed clinical effect." 34 *Fed. Reg.* 7689. On May 15, 1969, the Administration published an order in the *Federal Register* amending the regulations so as to provide for the repeal of those regulations permitting certification of the plaintiff's drug products, revoking all certificates previously issued, and stating that no further batches would be certified. This order stated that it was based upon a lack of substantial evidence of the drugs' efficacy. The order further provided that it was to become effective thirty days after its publication "to allow time for a recall [of plaintiff's products] to be completed." In addition, objections to the order could be submitted within the thirty day period and a hearing could be requested on the basis of a statement by the objecting party which request contained reasonable grounds, identifying claimed errors in the NAS-NRC report evaluations and any adequate and well controlled investigations on the basis of which the FDA could conclude that the combination drugs would have the effectiveness claimed and would be safe for their intended use. However, there was no provision for a stay of the order pending a hearing on the objections.

On May 27, 1969, the Upjohn Company filed a complaint for declaratory judgment and for injunctive relief, alleging that defendants "acted in excess of their authority and without observance of the procedures required by law, and arbitrarily and capriciously, in that the order contravened plaintiff's right to an evidentiary hearing prior to the removal of its products from the market."

In support of its complaint, the plaintiff pointed out that it was frequently impractical or even impossible for the physician to have the specific microorganisms responsible for an infection identified so that a specific antibiotic could be selected for its treatment. In these cases, it argued, there was no alternative to the use of a broad spectrum combination of antibiotics. The components of Panalba and Albamycin were individually active against a variety of microorganisms, and the activity of each of the components of these products complemented that of the others. Panalba and Albamycin had achieved wide acceptance by the medical community; many billions of doses of these products had been used since they were introduced. The drugs frequently were considered lifesaving and constituted an accepted part of the physician's arsenal against disease. The plaintiff admitted that although it would have

were there threatened with decertification may be amended or repealed on a finding by the Commissioner

> on the basis of new information with respect to such drug evaluated together with the information before him when the application . . . was approved, that there is *a lack of substantial evidence* . . . that the drug has the effect it purports or is represented to have under such conditions of use.[91]

The specific procedures for amendment or repeal of antibiotic regulations set forth in § 507(f)[92] of the *FDC* Act provide for notice of proposed action, an opportunity to present views, and a hearing on objections which state "reasonable grounds" in opposition to any final order amending or repealing a regulation.

On September 19, 1969, the FDA Commissioner published, in the *Federal Register*,[93] his interpretation of the nature of evidence required to provide "substantial evidence" of effectiveness under the Act. The interpretation provided that only clinical investigations meeting the criteria spelled out in the regulations would be deemed as the types of adequate and well controlled investigations which could be considered as providing substantial evidence of effectiveness.[94] The regulations made clear that all other clinical tests and documented clinical experience would not be considered relevant to the determination of whether the statutory requirement had been satisfied.

The plaintiff argued this interpretation of "substantial evidence" was invalid because it imposed arbitrary criteria "in a rigid and narrow fashion not intended or authorized by Con-

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been preferable ideally to identify the specific microorganisms causing a disease and prescribe individual antibiotics for their treatment, it contended that this did not establish the ineffectiveness of the combinations of antibiotics, but merely that they were only relatively less effective than the ideal treatment. It argued that the *FDC* Act did not authorize the defendants to delete an antibiotic drug, otherwise acceptable for certification, on the grounds of *relative* efficacy.

The plaintiff prayed for the repeal of the FDA's regulation which provided for the decertification of Upjohn's products and for the order revoking certifications previously issued under those regulations to be declared null and void. Plaintiff asked that the court restrain the defendants from enforcing the order and require the defendants to continue certification of any batch of the plaintiff's products which complied with the previous regulations. As one can readily see, this is a typical example of agency action which results in the promulgation of a regulation to which a client-manufacturer very well may be bound. The importance of understanding this administrative process is also critical in determining whether agency action is "final" within the meaning of the *FDC* and *APA* Acts. *See generally* Upjohn Co. v. Finch, 303 F. Supp. 241 (W.D. Mich. 1969), *aff'd*, 422 F.2d 944 (6th Cir. 1970).

91. 21 U.S.C. § 357(h) (emphasis added).

92. *Id.*

93. 422 F.2d 944, 949 (6th Cir. 1970).

94. *Id.* at 957-60. In general, the regulations provided for "controls" in which the drug tested is compared with an inactive placebo or, where placebo therapy would be unethical, with another active drug. In rare cases, an "historical control" was permitted, in which the drug tested was compared with prior experience.

gress."[95] As thus presented, resolution of the key issue in *Upjohn* turned on the question of legislative intent in the use of the phrase "substantial evidence" in the *FDC* Act. To determine that intent, an examination of the legislative history of the 1962 Drug Act Amendments which introduced that phrase into the Act was necessary.

Part 1 of the Senate Judiciary Committee's final report on the amendments' bill contained the following comments:

> The term 'substantial evidence' is used to require that therapeutic claims for new drugs be supported by reliable pharmacological and clinical studies. When a drug has been adequately tested by qualified experts and has been found to have the effect claimed for it, this claim should be permitted even though there may be preponderant evidence to the contrary based upon equally reliable studies. There may also be a situation in which a new drug has been studied in a limited number of hospitals and clinics and its effectiveness established only to the satisfaction of a few investigators qualified to use it. There may be many physicians who would deny the effectiveness simply on the basis of a disbelief growing out of their past experience with other drugs or with the diseases involved. Again, the studies may show that the drug will help a substantial percentage of the patients in a given disease condition but will not be effective in other cases. What the committee intends is to permit the claim for this new drug to be made to the medical profession with a proper explanation of the basis on which it rests.[96]

The plaintiff argued that this indicated that the legislative purpose in establishing the "substantial evidence" test was to reflect and accommodate the fact that clinical experts often disagree as to the effectiveness of a drug and, further, that the standard was designed to insure that any drug believed by a respectable number of experts to be effective could be marketed, even if the view of the majority of experts was that the drug was not effective. The plaintiff also pointed out that the report stated:

> In such a delicate area of medicine, the committee wants to make sure that safe new drugs become available for use by the medical profession so long as they are supported as to effectiveness by a responsible body of opinion.[97]

This view, the plaintiff contended, was supported by comments made during the floor debates on the amendments. Senator Hruska, the author of the amendments which introduced the phrase "substantial evidence" into the bill, stated that the purpose of the test

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95. FDC REP. 10 (December 1, 1969).
96. S. REP. No. 1744, pt. 1, 87th Cong., 2d Sess., 1962 *U.S. Code Cong. & Admin. News* 2892.
97. *Id.*

> is to permit legitimate differences of opinion among responsible clinicians to be resolved by the medical profession in day to day practice, instead of being resolved for all doctors against the effectiveness of the drug by the fiat of the FDA staff.[98]

Senator Eastland, Chairman of the Judiciary Committee that reported the bill out, expressed the same thought:

> The committee recognized that legitimate differences of opinion may exist among responsible clinicians with respect to the effectiveness of a particular new drug. Experience has shown that a majority of so-called experts has often been wrong in initially condemning a new drug, just as new inventions in other fields are usually regarded with skepticism and often with hostility.[99]

Therefore, the dominant legislative purpose of the substantial evidence test, plaintiff argued, was inconsistent with any notion that the FDA could eliminate responsible expert opinion as to the efficacy of a drug from administrative consideration by proscribing all but a single type of acceptable clinical test. Responsible experts may disagree as to whether particular tests are adequate and well controlled and whether such tests are probative of the effectiveness of the drug. To limit acceptable evidence to that derived from a particular kind of clinical testing itself establishes a medical and pharmacological orthodoxy—precisely the result Congress sought to foreclose by the substantial evidence test.

Plaintiff pointed to the millions of doses of its products which had been administered, and to the overwhelming acceptance which their products received from the medical profession. This substantial clinical experience, Upjohn argued, together with the clinical test data submitted at the time Panalba and Albamycin were certified, should have been fairly regarded as constituting substantial evidence of effectiveness.

To rebut this argument, the Government pointed out that the *FDC* Act itself defines the phrase "substantial evidence" in § 505(d) 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 be 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 . . . .[100]

Yet the significance of this definition can be understood fully only in the context of the legislative developments of the 1962

98. 108 CONG. REC. 10,108 (1962) (remarks by Senator Hruska).
99. *Id.* at 17,366 (remarks by Senator Eastland).
100. 21 U.S.C. § 355(d) (emphasis added).

Drug Amendments. These amendments were introduced originally by Senators Kefauver and Hart as S. 1552 on April 12, 1961. The bill was reported out favorably by Senator Kefauver's Antitrust and Monopoly Subcommittee, but encountered strong opposition in the parent Judiciary Committee. Largely as a result of the now famous "thalidomide" affair,[101] which occurred at about the same time, however, there was considerable public pressure for the passage of some bill designed to strengthen the food and drug laws. Senators Eastland and Hruska, principal opponents of the Kefauver Bill, drafted a substitute measure which bore little semblance to the original Kefauver version. This variation was reported out of the Judiciary Committee on July 12, 1962,[102] and formed the basis of the final bill. It is important to note that, at this stage, the bill did *not* contain the definition of substantial evidence quoted above. Much of the legislative history cited by plaintiff concerned the earlier version of the bill and, in the light of later developments, was inapplicable to a determination of the meaning of the phrase as used in the final bill, for even the Eastland-Hruska version proved to be unacceptable to the President of the United States. On August 4, 1962, President Kennedy wrote to Senator Eastland suggesting further amendments, one of which read, in part:

> Section 8 of S. 1552 requires 'substantial evidence' of effectiveness to be submitted with each new drug application. This standard of proof is inadequate in terms of assuring that drugs that reach the market have been shown to be effective for the claims made for them.[103]

Subsequently, and in response to the President's criticism, the Senate Judiciary Committee reported out a new version of the Drug Amendments bill incorporating the above definition of substantial evidence.[104] Speaking of this version of the bill in part 2 of the Judiciary Committee's final report, Senator Eastland said:

> [A] definition of 'substantial evidence' has now been added to the bill concerning what would constitute such evidence. The amendment provides that 'substantial evidence' means 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

101. *See generally* S. REP. No. 1744, pt. 1, 87th Cong., 2d Sess., 1962 *U.S. Code Cong. & Admin. News* 2905-908.
102. *Id.* at 2884.
103. 108 CONG. REC. 15,696 (1962) (read into the Record by Senator Kefauver).
104. The revised version of S. 1552 was reported out on August 21, 1962, and passed in the Senate two days later, as Public Law 87-781 (Oct. 10, 1962).

> it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof. That is to say, a claim could be rejected if it were found (a) that the investigations were not 'adequate'; (b) that they were not 'well controlled'; (c) that they had been conducted by experts not qualified to evaluate the effectiveness of the drug for which the application is made; or (d) that the conclusions drawn by such experts could not fairly and responsibly be derived from their investigations.[105]

Careful review of the legislative history of the 1962 amendments does not reveal any further attempt to define the phrase "adequate and well controlled investigations," the key portion of the statutory definition of substantial evidence. The conclusion is inescapable, however, that Congress intended to leave the determination of what would constitute such adequate and well controlled investigations to the expertise of the FDA Commissioner.

The criteria for an adequate and well controlled investigation published by the Commissioner in the September 19, 1969 *Federal Register*,[106] far from being a revolution in the accepted standards of drug testing, as claimed by the plaintiff, represented a consensus of modern medical opinion. The Commissioner reviewed leading medical textbooks,[107] government reports,[108] and testimony by physicians[109] before arriving at these criteria. That these criteria were, in fact, generally recognized by the medical profession as being the basis of a well controlled study was evidenced by the fact that they were remarkably similar to those described in a history of the Upjohn Company written for the plaintiff itself in 1961.[110]

Where, as in *Upjohn*, the determination of a mixed question of fact and law has been delegated explicitly by statute to an administrative body, the courts have been hesitant to substitute their own judgment for that of the agency. In *Gray v. Powell*,[111] the Bituminous Coal Division of the Department of the Interior had refused to classify the Seaboard Railway Company as a "producer" of bituminous coal pursuant to statutory authority to establish such classifications. Respondents, receivers of the railway, challenged the Board's classification as

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105. S. REP. No. 1744, pt. 2, 87th Cong., 2d Sess. 6 (1962).
106. 422 F.2d 944, 949 (6th Cir. 1970).
107. *E.g.*, GOODMAN & GILMAN, THE PHARMACOLOGICAL BASIS OF THERAPEUTICS (1965).
108. World Health Org. Tech. Rep. Series No. 403, *Principles for the Clinical Evaluation of Drugs* (1967).
109. *Hearings on Drug Industry Antitrust Act before the Senate Subcomm. on Antitrust & Monopoly*, 87th Cong., 1st Sess., pt. 1, at 45 *et seq.* (1961).
110. L. ENGEL, MEDICINE MAKERS OF KALAMAZOO (1961).
111. 314 U.S. 402 (1941).

being contrary to the evidence. The Supreme Court supported the Board, stating:

> Congress, which could have legislated specifically as to the individual exemptions from the [Bituminous Coal] code, found it more efficient to delegate that function to those whose experience in a particular field gave promise of a better informed, more equitable, adjustment of the conflicting interests . . . . By thus committing the execution of its policies to the specialized personnel of the Bituminous Coal Division, Congress followed a familiar practice. . . .
>
> Where, as here, a determination has been left to an administrative body, this delegation will be respected and the administrative conclusion left untouched. Certainly, a finding on Congressional reference that an admittedly constitutional act is applicable to a particular situation does not require such further scrutiny. Although we have here no dispute as to the evidentiary facts, that does not permit a court to substitute its judgment for that of the Director. . . . It is not the province of a court to absorb the administrative functions to such an extent that the executive or legislative agencies become mere fact-finding bodies deprived of the advantages of prompt and definite action.[112]

Similarly, in *NLRB v. Hearst Publications, Inc.*,[113] the Supreme Court considered the question of whether the NLRB could properly interpret certain newsboys as "employees" under broad statutory classes set out in the National Labor Relations Act. The publisher argued that its relationship to the newsboys was clearly that of employer-independent contractor rather than that of employer-employee. The Supreme Court, in rejecting the contention that any common law standards were applicable, stated:

> Whether . . . the term 'employee' includes such workers as these newsboys must be answered primarily from the history, terms and purposes of the legislation. . . .
>
> . . . .
>
> [W]here the question is one of specific application of a broad statutory term in a proceeding in which the agency administering the statute must determine it initially, the reviewing court's function is limited. . . . [T]he Board's determination that specified persons are 'employees' under this Act is to be accepted if it has 'warrant in the record' and a reasonable basis in law.[114]

Thus, the general rule which appears to have been applied by the Supreme Court in most cases involving broad statutory terms whose interpretation and application have been delegated specifically by statute to administrative bodies, was articulated by the Court in the leading case of *Rochester Telephone Corp. v. United States*:[115]

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112. *Id.* at 411-12.
113. 322 U.S. 111 (1944).
114. *Id.* at 124, 131.
115. 307 U.S. 125, 145-46 (1939).

> So long as there is warrant in the record for the judgment of the expert body it must stand. . . . 'The judicial function is exhausted when there is found to be a rational basis for the conclusions approved by the administrative body.'

More importantly, this rule has been incorporated into the *APA*, in § 10, which defines the scope of judicial review of administrative actions, "except to the extent that . . . agency action is committed to agency discretion by law,"[116] to be that "the reviewing court shall decide all relevant questions of law, interpret . . . statutory provisions, and determine the meaning or applicability of the terms of an agency action."[117] The introductory phrase excepting agency action committed to agency discretion, clearly is a restatement of *Rochester*. The courts have continued to apply this rule subsequent to the passage of the *APA*, thus indicating their agreement with it. For example, three years after passage of the *APA*, the Supreme Court stated:

> The wisdom of the principle adopted [by the administrative agency] is none of our concern. . . .
> [W]e are free to disturb the Commission's conclusion only if it lacks any rational and statutory foundation.[118]

Moreover, it is generally recognized that administrative determinations consistent with statutory mandates and based upon complex technical considerations should be given great weight by the courts, even where the specific determination is itself subject to judicial review.[119] This deference to administrative expertise is based upon recognition of the fact that the agency is expected to have developed its field beyond that point that could be expected by the courts.[120]

It is apparent that upon application of these rules to *Upjohn*, the appellate court should have and did find for the Government. The *FDC* Act authorized the FDA Commissioner to revoke certification of antibiotic drugs upon a finding that there was a lack of substantial evidence that the drug was effective. Further, the Act defined substantial evidence as that evidence based upon adequate and well controlled investigations, and a review of the legislative history of the Act outlined above indicated that Congress intended the Commissioner to prescribe the scientific content of such investigations. The criteria which the Commissioner

116. 5 U.S.C. § 701(a)(2).
117. 5 U.S.C. § 706.
118. SEC v. Chenery Corp., 332 U.S. 194, 207 (1947). *Accord*, Consolo v. Fed. Maritime Comm'n, 383 U.S. 607 (1966); Wolff v. Selective Serv. Bd. No. 16, 372 F.2d 817 (2nd Cir. 1967); Friedman v. Schwellenbach, 159 F.2d 22 (D.C. Cir. 1946), *cert. denied*, 330 U.S. 838 (1946).
119. SEC v. Chenery Corp., 332 U.S. 194 (1947); Colorado Interstate Gas Co. v. FPC, 370 F.2d 777 (10th Cir. 1967); United States v. Great N. Ry., 337 F.2d 243 (8th Cir. 1964); Progressive Mine Workers Local 12 v. NLRB, 189 F.2d 1 (7th Cir. 1951), *cert. denied*, 342 U.S. 868 (1951).
120. 1 DAVIS, ADMINISTRATIVE LAW TREATISE § 5.05 (1958).

prescribed appeared to be consistent with the substantial weight of modern scientific and medical opinion, and could not be described as arbitrary or capricious. Thus, there was "warrant in the record" for the Commissioner's conclusion that the plaintiff failed to meet these criteria to establish substantial evidence of the effectiveness of its antibiotic drugs. Further, considering the fact that this determination was based upon highly complex technical considerations, uniquely within the competence of the FDA, the court's review of the Commissioner's determination was rightfully limited.

*The Trend*

In *Weinberger v. Hynson, Wescott & Dunning, Inc.*,[121] the Supreme Court attempted to resolve certain questions that were left unanswered in the *Upjohn* decision. After the 1962 amendments to the *FDC* Act, which also had prohibited the introduction into interstate commerce of a drug which had not been sanctioned by experts as safe and effective for the use for which it had been intended, the FDA Commissioner withdrew approval of a new drug application for respondent's drug, "Lutrexin," for which there had been prior approval in 1952. The Commissioner denied the respondent manufacturer's request for a hearing, insisting that Lutrexin was not exempt under the grandfather clause of the 1962 amendments, and further that the manufacturer had failed to submit substantial evidence that Lutrexin was not a "new drug" or that it was effective. The evidence which had been presented included a list of literature references, a copy of an unpublished study, a representative sample, a testimonial letter on behalf of the drug, and certain additional data.

On certiorari, the Supreme Court affirmed on all but the issue of Lutrexin's "new drug" status. Although it was the opinion of the Court that the FDA did not have to grant a hearing before withdrawing approval of a new drug application where the applicant had not tendered any evidence which, on its face, met the statutory standards as particularized by FDA regulations, in this instance the manufacturer's submission regarding the effectiveness of Lutrexin was sufficient to warrant a hearing. Secondly, while Lutrexin was not exempt under the grandfather clause of the 1962 amendments,[122] any decision as to Lutrexin's "new drug" status would have to await the outcome of the administrative hearing.

121. 412 U.S. 609 (1973).
122. *Id.* at 614.

The Commissioner stated that scientific data submitted by Hynson, Westcott & Dunning, Inc., was inadequate, and he published his intention to withdraw sanction of the new drug application (NDA) covering the drug, but gave Hynson the opportunity for a prewithdrawal hearing. Before the hearing took place, Hynson went before the district court for a declaratory judgment that the drug in question was exempt from the review provisions of the 1962 amendments,[123] or, in the alternative, that there was not a lack of substantial evidence[124] of the drug's effectiveness. The district court ruled that the FDA had primary jurisdiction and that Hynson had not exhausted its administrative remedies.[125]

Before the case was concluded in the district court, the FDA created new regulations which established the minimal standards for "adequate and well controlled investigations" and limited the right to a hearing to those who could present some evidence meeting those standards.[126] Hynson continued to maintain that it was not subject to the new regulations due to its initial request for a hearing preceding the issuance of the new regulations. In view of this proposition, Hynson made another hearing request and submitted certain material which it said substantiated "substantial evidence" of Lutrexin's effectiveness. The Commissioner denied the request, and withdrew the NDA for Lutrexin. The Commissioner ruled that Lutrexin was not exempt from the 1962 amendments, and that Hynson's submission attempting to prove that Lutrexin was not a new drug was insufficient. The court of appeals reversed,[127] holding that while the drugs in question did not have exempt status, Hynson was entitled to a hearing on the substantial evidence question.[128]

Congress wrote into section 505(d) of the *FDC* Act its definition of substantial evidence the necessity of "evidence consisting of adequate and well controlled investigations." The final Senate report of this 1962 amendment concerning this necessity made clear that this was an abrupt departure from previous standards relative to the marketing of drugs, based on increasing concern over the efficacy and safety of drugs.[129]

Nevertheless, the *FDC* Act definitely required the FDA to give "due notice and opportunity for hearing to the applicant" before it could withdraw its approval of a NDA. Pursuant to

123. *Id.* at 616.
124. *Id.*
125. *Id.*
126. *Id.*
127. *Id.* at 616-17.
128. *Id.*
129. *Id.* at 617-20.

this statutory requirement, the FDA, by regulation, required any applicant who desired a hearing to submit reasons

> why the application . . . should not be withdrawn, together with a well-organized and full-factual analysis of the clinical and other investigational data he is prepared to prove in support of his opposition to the notice of opportunity of a hearing.[130]

What the agency said, then, was that it would not provide a formal hearing where it was apparent at the outset that the applicant had not tendered any evidence which on its face met the statutory standards particularized by the regulations.

While the court maintained that every manufacturer of a challenged drug should have an opportunity to be heard, it further stated that § 554(e) of the *APA* does not place administrative proceedings in a straitjacket. That section provides that an agency, "in its sound discretion, may issue a declaratory order to terminate a controversy or remove uncertainty."[131] The thrust of the new procedures designed by Congress was the grant of primary jurisdiction to the FDA, the expert agency it created. Yet it is important to note that the FDA never has the final say, for a review will be had, with certain exceptions, in a court of appeals. The Court stressed this point when it said:

> FDA does not have unbridled discretion to do what it pleases. Its procedures must satisfy the rudiments of fair play. Judicial relief is available only after administrative remedies have been exhausted.[132]

The Court further stated that although the FDA was empowered to decide the threshold question of whether the drug was a "new drug," an interpretation and application of a broad statutory term, that power is only an incident to its power to approve or withdraw approvals of NDAs.[133] While that order was not therefore reviewable in an appellate court under § 505(h) of the *FDC* Act, it was possible to have preenforcement judicial review in a district court under §§ 701-704 of the *APA*.[134]

## Summary and Conclusions

This article has explored the question of the availability of declaratory and injunctive relief as a preenforcement remedy against invalid administrative regulations. Particular reference has been made to those regulations or orders promulgated pur-

130. *Id.* at 620.
131. *Id.* at 626.
132. *Id.* at 627.
133. *Id.*
134. *Id.*

suant to the *FDC* Act through an examination of their application to the complex issues presented in food and drug cases.[135]

Contrary to earlier belief, declaratory and injunctive relief may now be available in the area of FDA regulations. However, a series of jurisdictional hurdles must be overcome before such relief can be made available. Two of the most difficult of these which have been discussed are the questions of whether exhaustion of administrative remedies should be required and whether the issues presented by the case are ripe for judicial review.

The law concerning the requirement of exhaustion is, at the present, still incompletely resolved. While it is sometimes required in full, at other times no exhaustion may be required at all. Unfortunately the Supreme Court has not seen fit to articulate clearly all the factors which need to be present to obviate the requirement. The fact that *Upjohn* and *Weinberger* might seem to be in opposition on this point is illustrative, for the facts bear certain similarities.

In contrast, the question of ripeness for judicial review has been substantially clarified, especially by the *Abbott* decision and its progeny. These decisions set out the factors which the courts should consider in any issue of ripeness: the regulation in question must be a "final agency action" within the enabling statute, the issue presented must be purely legal in nature and free from the overtones of factual determinations requiring administrative expertise, and finally, the regulation must be one which immediately affects the day-to-day conduct of the parties—the harm to the petitioner denied preenforcement relief being substantial. In particular, these factors were found to exist in both *Abbott* and *Upjohn*.

Once these hurdles are overcome, and only after they are overcome, will a court consider the substantive merits raised. Most of the substantive questions in the cases discussed in this article dealt with the FDA's attempt to promulgate rulings or orders pursuant to the various amendments Congress added to the *FDC* Act in 1962.

The original Act had created a method for the premarketing administrative review of the safety of therapeutic drugs. The 1962 amendments both continued and expanded the concepts of premarketing review. The major substantive change made by Congress was to require premarketing review of the effectiveness as well as of the safety of "new drugs." Two key questions

135. For the latest developments in the recently publicized controversy involving "Red Dye No. 2," a color additive for food suspected of being cancer-causing, *see* F.D. COSM. REP. ¶ 41,494 (1975); *id.* at ¶ 41,543 (1976).

present themselves at this juncture. In *Upjohn*, the first was illustrated by the question of whether the FDA Commissioner should have been required to hold formal hearings prior to attempting to revoke certification of the petitioner's drugs. The second was whether the Commissioner was authorized, under the *FDC* Act, to revoke this certification.

Formal hearings are required only when the facts to be determined by a hearing of an adjudicatory nature are susceptible of evidential proof. Where, on the other hand, they are of a "legislative" nature, involving questions of policy determination and administrative discretion, a hearing will not often be required. The facts of *Upjohn* placed the hearing demanded by the plaintiff within this latter category; and the appellate court rightfully denied the demand. In *Weinberger*, the Court required the FDA to hold a hearing before withdrawing approval of a NDA only where it conclusively appears from the data in the application and from the reasons and factual analysis in the request for a hearing that the applicant has tendered evidence which meets statutory standards.

A determination of whether the Commissioner is authorized by the *FDC* Act to revoke certification of a petitioner's drugs, such as Lutrexin, can be made only by reference to the legislative history of the Act. It has been made clear from a review of that history that Congress intended the Commissioner should be the sole judge of whether there is substantial evidence that a given drug has the effect it purports or is represented to have, and to require him to withdraw any antibiotic drug which fails to meet the statutory standard as interpreted by the Commissioner in FDA regulations or orders. Where agency action is thus committed by law to agency discretion, the scope of judicial review becomes limited. Irrespective of the wisdom of the agency's action, it must stand as long as there was warrant in the record for the conclusions it came to as an expert body. This was found to be the case in *Upjohn*. However, in *Weinberger*, plaintiff was granted a hearing. It had submitted evidence including a list of references, an unpublished study of the drug's effect, a representative sample, and a testimonial letter. This data was found sufficient evidence to require a hearing on whether this constituted "substantial evidence." For the moment, then, a manufacturer faced with an *Upjohn* or *Weinberger* type of situation should carefully weigh the evidence it wishes to submit to a court to have the court issue a mandate for an administrative hearing before the regulation about to affect the manufacturer goes into effect.

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