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Case Comments

Administrative Law: Pre-enforcement Review of FDA Regulations

The Pharmaceutical Manufacturers Association and thirty-seven individual drug manufacturers sought pre-enforcement review¹ of regulations promulgated by the Commissioner of the Food and Drug Administration. Petitioners claimed that the regulations, which concerned labeling requirements for prescription drugs,² exceeded the statutory authority granted to the Commissioner by the Food, Drug, and Cosmetic Act. The Supreme Court *held* that the Food, Drug, and Cosmetic Act³ did not prohibit suit under the Administrative Procedure Act⁴ and Declaratory Judgment Act,⁵ whereunder federal district courts have discretionary jurisdiction to entertain actions for pre-enforcement review of FDA regulations.⁶ The Court further *held* that since the issue of the statutory validity of the labeling regulations was ripe for judicial review, the district court had exercised proper discretion in hearing this particular suit.⁷ In

1. "Pre-enforcement review" is a determination of the validity of a regulation before any attempt has been made to enforce it. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 139 n.1 (1967).

2. The Food, Drug, and Cosmetic Act requires that manufacturers print the "established" name of a drug "prominently and in type at least half as large as that used thereon for any proprietary name" on labels and other printed materials. Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(e)(1)(B) (1964). The Secretary of Health, Education, and Welfare (HEW) designates the "established" name, Food, Drug, and Cosmetic Act, 21 U.S.C. § 352(e)(2) (1964). The "proprietary" name is the brand name under which a drug is marketed. The regulations required that the established name accompany the proprietary name *each time* the proprietary name appeared on any label of, or advertisement for, a prescription drug. 21 C.F.R. §§ 1.104(g)(1), 1.105(b)(1) (1967).

3. The regulations were issued under the power granted by Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(a) (1964): "The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary." The Secretary of HEW delegated this power to the Commissioner of the Food and Drug Administration (FDA). 22 Fed. Reg. 1051 (1957); 25 Fed. Reg. 8625 (1960).

4. 5 U.S.C. § 1009 (1964) (recodified in Pub. Law 89-554, 80 Stat. 378).

5. 28 U.S.C. § 2201 (1964).

6. Some FDA regulations are subject to pre-enforcement review only in the courts of appeals. See notes 18 & 19 *infra*.

7. The district court found that the regulations were in excess of the Commissioner's statutory authority. *Abbott Laboratories v. Celebreeze*, 228 F. Supp. 855 (D. Del. 1964). The court of appeals reversed

two companion cases, the Court held that FDA regulations which dealt with the definition of "color additives" were also ripe for judicial review,⁸ but that a regulation which concerned the right of FDA employees to inspect manufacturing facilities was not.⁹ *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967).

With regard to judicial review of agency action, the Administrative Procedure Act provides:

Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—
 (a) Any person suffering legal wrong because of any agency action, or adversely affected, or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof (c) Every agency action made reviewable by statute and every agency action for which there is no other adequate remedy in any court shall be subject to judicial review.¹⁰

The meaning intended by the words "Except so far as statutes preclude judicial review" is not clear from the legislative history of the Act. The House Committee's Report indicated that it

for lack of jurisdiction. *Abbott Laboratories v. Celebreeze*, 352 F.2d 286 (3d Cir. 1965). The Court in the instant case reversed the court of appeals' decision as to jurisdiction, and remanded to the court of appeals for a consideration of the merits.

8. *Gardner v. Toilet Goods Ass'n*, 387 U.S. 167 (1967). The Food, Drug, and Cosmetic Act defines a color additive as a

dye, pigment, or other substance . . . [which] when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof is capable (alone or through reaction with other substance) of imparting color thereto

21 U.S.C. § 321(t)(1) (1964). The regulations, issued under the Commissioner's general rule-making power, implemented the definition to include "any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture . . ." 21 C.F.R. § 8.1(m) (1967). "A substance that, when applied to the human body results in coloring Lipstick, rouge, eye makeup colors, and related cosmetics intended for coloring the human body are 'color additives.'" 21 C.F.R. § 8.1(f) (1967). A third regulation concerned the statutory exemption for hair dyes, which provides that hair dyes are exempt from statutory coverage if their labels prescribe a "patch test" for determining whether the dye will cause skin irritation. 21 U.S.C. § 361(e) (1964). The regulation provides that hair dyes are exempt only if the "patch test" is an *effective* safeguard. 21 C.F.R. § 8.1(u) (1967).

9. This regulation was at issue in *Toilet Goods Ass'n v. Gardner*, 387 U.S. 158 (1967). The regulation was issued under the Commissioner's general rule-making power and provided that the Commissioner could suspend certification services if FDA employees were refused "free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived . . ." 21 C.F.R. § 8.28 (1967).

10. 5 U.S.C. § 1009 (1964) (recodified in Pub. Law 89-554, 80 Stat. 378).

required a statutory scheme which clearly superseded judicial review.¹¹ However, a statement by the Attorney General indicated that much less evidence of intent is required: "A statute may in terms preclude judicial review or be interpreted as manifesting a congressional intent to preclude review."¹² Representing a compromise between the position of the House Committee and that of the Attorney General, the standard provided by the case law emphasizes the importance of legislative history. In *Heikkila v. Barber*,¹³ the Supreme Court stated:

[T]he broadly remedial purposes of the Act counsel a judicial attitude of hospitality towards . . . judicial review Each statute in question must be examined individually; its purpose and history as well as its text are to be considered in deciding whether the courts were intended to provide relief for those aggrieved by administrative action. Mere failure to provide for judicial intervention is not conclusive; neither is the presence of language which appears to bar it.¹⁴

In *Heikkila and Schilling v. Rogers*,¹⁵ the Court held that judicial review was unavailable even though the statute in question did not clearly preclude review on its face. In both cases the Court engaged in an extensive analysis of the legislative history of the statute in question, and concluded that Congress intended to preclude judicial review. However, the Court allowed review in *United States v. Interstate Commerce Commission*¹⁶ and *Rusk v. Cort*,¹⁷ holding in both cases that neither the

11. To preclude review under this bill a statute, if not specific in withdrawing such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specifically for judicial review is certainly no evidence of an intent to withhold review.

H.R. REP. No. 1980, 79th Cong., 2d Sess. 41 (1946).

12. S. Doc. No. 248, 79th Cong., 2d Sess. 229 (1946).

13. 345 U.S. 229 (1953). Petitioner sought review of a deportation order pursuant to the Immigration Act of 1917, 39 Stat. 889. The Court held that the Administrative Procedure Act was not applicable and that review could only be obtained through a writ of habeas corpus.

14. *Id.* at 232-33.

15. 363 U.S. 666 (1960). The cases involved the Trading with the Enemy Act, 50 U.S.C. App. § 7 (1964). Petitioner sought judicial review of an administrative determination that he was not eligible for the return of property confiscated during World War II. The Court held that the agency determination was unreviewable because the first two exceptions of the Administrative Procedure Act applied, *i.e.*, that the Trading with the Enemy Act precluded review and that the determination was "by law committed to agency discretion." See note 10 *supra* and accompanying text.

16. 337 U.S. 426 (1949). The Court held that § 9 of the Interstate Commerce Act, 49 U.S.C. § 9 (1964), did not give complete finality to the Commission's determination, and that judicial review was allowable.

17. 369 U.S. 367 (1962). The case involved the Immigration and Nationality Act of 1952, 8 U.S.C. § 1503 (1964). The Act provided: "A

text of the statute in question, nor a detailed examination of its legislative history, provided the necessary "clear and convincing evidence" of a congressional intent to withhold review.

The issue of judicial review under the Food, Drug, and Cosmetic Act is complicated by the fact that the Act specifically provides for pre-enforcement review of some regulations,¹⁸ but not the type involved in the instant case.¹⁹ The paragraph containing the special review procedure is followed by a savings clause which states: "The remedies provided for in this subsection shall be in addition to and not in substitution for other remedies provided by law."²⁰ The House Report on the Food, Drug, and Cosmetic Act stated that this clause

saves as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding.²¹

A literal reading of the House Report indicates that the savings clause was included in order to allow pre-enforcement review of *any* regulation, provided that the requisite elements for a proceeding in equity were present.²² If, however, the words "a

final determination by the Attorney General that any . . . person is not entitled to admission to the United States shall be subject to review . . . in habeas corpus proceedings and not otherwise." 8 U.S.C. § 1503(c) (1964).

The petitioner sought review of the Secretary of State's ruling that he had lost his citizenship by remaining outside of the United States for purposes of avoiding military service. The Court held that review was available under the Administrative Procedure Act. 369 U.S. at 375.

18. A person "adversely affected" by certain regulations can petition to a court of appeals for judicial review. The petition must be filed within 90 days after formal issuance of a regulation. The court determines if the Secretary of HEW has "substantial evidence" to support his position. If not, the court has jurisdiction to set aside the Secretary's order "in whole or in part, temporarily or permanently." 21 U.S.C. § 371(f) (1964).

19. 21 U.S.C. § 371(f) (1964) provides for review of regulations passed pursuant to 21 U.S.C. § 341 (1964) (identity and quality standards for food); § 343(j) (misbranded food purporting to serve special dietary purposes); § 344(a) (conditions imposed on the manufacture of foods as the result of health requirements); § 346 (tolerance for pesticides); § 351(b) (deviations from strength, quality, or purity standards for drugs); § 352(d) (warnings with respect to habit-forming drugs); § 352(h) (packing and labeling of deteriorative drugs); § 356 (certification of drugs containing insulin); § 357 (antibiotic drugs). Denials of certification for new drugs are also reviewable in the courts of appeals under 21 U.S.C. § 355(h) (1964).

20. 21 U.S.C. § 371(f) (6) (1964).

21. H.R. REP. No. 2139, 75th Cong., 2d Sess. 11 (1938).

22. The elements necessary for a proceeding in equity were not entirely clear at the time the Food, Drug, and Cosmetic Act was origin-

regulation placed in effect by the Secretary" were intended to be read with reference to the specific regulations mentioned in the preceding paragraph of the Act, which sets out the special review procedure, the savings clause would encompass only those regulations which are also subject to the special review procedure.²³ Reading the clause in this way, the statute is silent as to judicial review of some regulations, but specifically preserves judicial review of others.

In similar situations under other statutes, the Court has been inconsistent. In *Schilling v. Rogers*, the Court indicated that the specification of certain remedies implied a congressional purpose to exclude all others.²⁴ In *Rusk v. Cort*, the Court held that the specification of one type of remedy did not make that remedy exclusive.²⁵ However, prior to *Abbott Laboratories* there was no clear indication of the Court's interpretation of the text and legislative history of the Food, Drug, and Cosmetic Act since the instant case represents the first attempt to obtain pre-enforcement review other than by the special review procedure.²⁶

Even if it is determined that there is statutory jurisdiction, a particular action must be "ripe" for adjudication before review will be allowed. Courts traditionally attempt to avoid entangling themselves in abstract controversies which are more properly dealt with outside the courtroom.²⁷ On the other hand, a

ally passed. See 83 CONG. REC. 7891-99 (1938). Presumably, they included such elements as the lack of an adequate remedy at law, the possibility of irreparable injury, the presence of an actual case or controversy, and an appropriateness for judicial resolution.

23. This interpretation of the savings clause was made by the dissent in *Abbott Laboratories*, 387 U.S. at 180-82.

It [the savings clause] was intended to save the remedies of injunction and declaratory judgment where the agency promulgated a . . . regulation without the hearings and findings needed to permit review in the Court of Appeals.

387 U.S. at 180 n.5. 21 U.S.C. § 371(e) (1964) provides for public notice, a public hearing, and written findings of fact before the issuance of any regulation subject to the special review procedure. See note 19 *supra*.

24. 363 U.S. at 674. Plaintiff claimed that the Trading with the Enemy Act, 50 U.S.C. App. § 7 (1964), did not preclude review. The Act specifically provided for review of some agency determinations, but not the determination which affected plaintiff.

25. 369 U.S. 367 (1962).

26. For a somewhat partisan explanation of this lack of precedent, see Sweeney, *The "Generic Everytime" Case: Prescription Drug Industry in Extremis*, 21 FOOD DRUG COSM. L.J. 226 (1966).

27. See generally *Poe v. Ullman*, 367 U.S. 497 (1961); *Massachusetts v. Mellon*, 262 U.S. 447 (1923); 3 K. DAVIS, *ADMINISTRATIVE LAW TREATISE* §§ 22.01-10 (1958); Jaffe, *Ripeness and Reviewable Orders in Administrative Law*, 61 MICH. L. REV. 1273 (1963).

party might suffer irreparable injury if judicial action is unnecessarily delayed. Thus, ripeness for review depends on an evaluation of both the appropriateness of an issue for adjudication and the hardship of denying relief.²⁸

The distinction between legislative and interpretative regulations is sometimes relevant to a determination of ripeness.²⁹ Legislative regulations are issued pursuant to a legislative power granted to an agency by a legislative body.³⁰ Like statutes, they have the force of law as soon as they are promulgated.³¹ Interpretative regulations merely represent the opinion of an agency as to the meaning of a statute and, theoretically, have no legal effect in themselves.³² The distinction is important primarily because the scope of judicial review is more restricted as to legislative regulations. Legislative regulations are valid if they are within the statutory power granted to the agency and are "reasonable."³³ However, interpretative regulations are not necessarily valid if they are reasonable because a court will ordinarily feel free to substitute its own opinion as to the meaning of a statute for that of the agency.³⁴ Thus, a legis-

28. See generally authorities cited note 27 *supra*.

29. See *American President Lines v. Federal Maritime Comm'n*, 316 F.2d 419 (D.C. Cir. 1963). But see note 56 *infra*. Cases which did not involve formal regulations, but in which review was denied because of the interpretative nature of the agency rule include *First Sav. & Loan Ass'n v. SEC*, 358 F.2d 358 (5th Cir. 1966); *Helco Prods. Co. v. McNutt*, 137 F.2d 681 (D.C. Cir. 1943).

30. The commentators disagree as to whether the power must be explicitly granted. 1 K. DAVIS, *ADMINISTRATIVE LAW TREATISE* § 5.03 (1958) (need not be explicit); Brown, *Regulations, Reenactment, and the Revenue Acts*, 54 HARV. L. REV. 377, 384-85 (1941) (must be explicit).

31. See authorities cited note 30 *supra*; see also *American President Lines v. Federal Maritime Comm'n*, 316 F.2d 419 (D.C. Cir. 1963); *Union Elec. Co. v. United States*, 305 F.2d 850, 853 (Ct. Cl. 1962).

32. See *American President Lines v. Federal Maritime Comm'n*, 316 F.2d 419 (D.C. Cir. 1963); *Boynton v. Pedrick*, 136 F. Supp. 888 (S.D.N.Y. 1954), *aff'd*, 228 F.2d 745 (2d Cir. 1955), *cert. denied*, 351 U.S. 938 (1956); 1 K. DAVIS, *ADMINISTRATIVE LAW TREATISE* §§ 5.03-.04 (1958).

33. "Reasonable" is used in the same sense as it is used by the Court in reviewing a statute for an alleged lack of due process. In *American Tel. & Tel. Co. v. United States*, 299 U.S. 232 (1936), the Court stated that it would not inquire into the *wisdom* of an administrative regulation.

34. See *American President Lines v. Federal Maritime Comm'n*, 316 F.2d 419 (D.C. Cir. 1963); *Comptroller of Treasury v. M.E. Rockhill, Inc.*, 205 Md. 226, 234, 107 A.2d 93, 98 (1954). The reliance placed upon an agency's interpretation of a statute depends on a number of factors, such as the relative expertise of the court and agency on a particular subject, and the length of time a regulation has been in effect. Com-

lative regulation will ordinarily impose greater hardship because the scope of review is more restricted, and the regulated person's chances of succeeding in a determination on the merits is correspondingly diminished. Therefore, there is more pressure on a person subject to a legislative regulation to comply with the regulation rather than risk losing in an enforcement suit, and the person subject to such a regulation presents a stronger argument for the possibility of irreparable injury if pre-enforcement review is denied.

In determining whether an administrative regulation is ripe for pre-enforcement review, the Supreme Court has emphasized the practical effect of the regulation, but has never spoken in terms of the distinction between legislative and interpretative regulations.³⁵ In *Columbia Broadcasting System v. United States*,³⁶ CBS sought pre-enforcement review of FCC "legislative"³⁷ regulations which provided that stations which entered into certain types of network contracts, such as those CBS maintained with its affiliates, would be denied a license. Since the regulations were not directly enforceable against CBS, the company would have had no alternative remedy unless one of its affiliates had decided to challenge the regulations and CBS had intervened.³⁸ CBS presented evidence that it was threatened with wholesale violation of its contracts, and the Court issued an injunction restraining enforcement until a decision could be had on the merits. *United States v. Storer Broadcasting Company*³⁹ involved a legislative regulation of the FCC which limited the number of television stations that could be licensed to a single person. Petitioner already owned the maximum allowed. The Court allowed pre-enforcement review, holding that petitioner was aggrieved insofar as he could not plan his business affairs until the validity of the regulation was determined. Al-

missioner v. Estate of Sternberger, 348 U.S. 187 (1955); 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE §§ 5.05-.07 (1958).

35. The Court, however, has apparently recognized the distinction without saying so in cases which did not deal with ripeness. As to the scope of review, compare *American Tel. & Tel. Co. v. United States*, 229 U.S. 232 (1936) (legislative regulation), with *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944) (interpretative regulation). See also 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE §§ 5.03-.04 (1958).

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

37. Professor Davis cites these regulations as an example of legislative regulations passed by an agency even though the agency did not have any explicit power to promulgate legislative regulations. 1 K. DAVIS, ADMINISTRATIVE LAW TREATISE § 5.03 n.2 (1958).

38. FED. R. CIV. P. 24(b).

39. 351 U.S. 192 (1956).

though the dissenting opinions in *CBS* and *Storer* maintained that the Court should avoid interfering with the administrative process before it became finalized by a specific application of the regulation in question, they did not mention the distinction between legislative and interpretative regulations.

In *Frozen Food Express v. United States*,⁴⁰ petitioner challenged an interpretative order of the ICC which listed commodities that could be transported without ICC supervision. Petitioner claimed that the commodities he was transporting should also have been listed. The Court allowed pre-enforcement review, reasoning that since violation entailed possible criminal penalties,⁴¹ and since petitioner could not properly plan his business affairs prior to a determination of the order's validity, he would suffer irreparable injury if pre-enforcement review were denied. The majority opinion did not discuss the distinction between legislative and interpretative regulations, and the dissent merely treated the fact that the regulation was not legislative as one reason why review should have been denied.

Thus, the standard which emerges from *CBS*, *Storer*, and *Frozen Food* is that a showing that petitioner is suffering severe business inconvenience because of an agency regulation, whether interpretative or legislative, is sufficient to make the issue of that regulation's validity ripe for judicial review. If there are factors militating against review, they will be weighed against the business inconvenience and any other factors in favor of the petitioner.

In the instant case, the government argued that the special review procedure which the Food, Drug, and Cosmetic Act provided for some regulations implied a congressional intent to preclude pre-enforcement review of all other regulations⁴² and further, that pre-enforcement review, if allowed, would delay

40. 351 U.S. 40 (1956).

41. Willful violation of an order was punishable by a \$100 fine for the first offense and not more than \$500 for any subsequent offenses. 49 U.S.C. § 10(1) (1964).

42. The government cited *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594 (1950), to support its position. Petitioner in *Ewing* was seeking review of an FDA finding that there was probable cause to believe that he was distributing "adulterated" drugs in interstate commerce. In denying review, the Court stated, "This 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 . . . [enforcement suit]." 339 U.S. at 600-01. Although this language seems to support the Government's argument, *Ewing* is clearly distinguishable on its facts from the instant case especially since no formal regulation was at issue in *Ewing*.

enforcement of the Act. The Court, however, reasoned that the special review procedure was merely intended to enlarge the scope of judicial review of certain agency factual determinations.⁴³ The Court held that the statutory scheme failed to provide the "clear and convincing evidence" of an intent to withhold review which is necessary under the Administrative Procedure Act; and that, in fact, the savings clause and its legislative history constituted a positive indication that pre-enforcement review of all regulations should be allowed. The Court further reasoned that a pre-enforcement challenge would facilitate enforcement of the Food, Drug, and Cosmetic Act since it would result in immediate compliance by manufacturers if the regulations were found to be valid, or allow the FDA to quickly revise its regulations if they were found to be invalid.

In determining that the "labeling"⁴⁴ and "definition"⁴⁵ regulations were ripe for judicial review, but that the "inspection"⁴⁶ regulation was not, the Court emphasized three determining factors: The penalties which could result from violation, the burden of compliance, and the need for a concrete factual setting. Violation of the labeling and definition regulations, unlike the inspection regulation, entailed possible criminal penalties.⁴⁷ Compliance with the labeling regulations required substantial investments in new supplies in order to change labels and other printed matter.⁴⁸ Similarly, compliance with the definition regulations required that petitioners keep detailed records⁴⁹ and make various chemical and physical tests.⁵⁰ The in-

43. The Court stated that the "substantial evidence" test provided by the special review procedure afforded "considerably more generous judicial review than the 'arbitrary and capricious' test available in the traditional injunctive suit." 387 U.S. at 143. See, e.g., *Schilling v. Rogers*, 363 U.S. 666, 676 (1960); *United States v. Interstate Commerce Comm'n*, 337 U.S. 426, 431 (1949); *Friedman v. Schwellenbach*, 159 F.2d 22, 25 (D.C. Cir. 1946), cert. denied, 330 U.S. 838 (1947); 4 K. DAVIS, ADMINISTRATIVE LAW TREATISE §§ 29.01-.11 (1958).

44. See note 2 *supra*.

45. See note 8 *supra*.

46. See note 9 *supra*.

47. Violation of either the labeling or definition regulations could entail "imprisonment for not more than one year, or a fine of not more than \$1000, or both." 21 U.S.C. § 333 (1964). Violation could also entail injunction proceedings, 21 U.S.C. § 332 (1964); or seizure of the goods, 21 U.S.C. § 334(a) (1964). The only immediate result of violating the "inspection" regulation would be a denial of certification services. See note 9 *supra*.

48. 387 U.S. at 152.

49. 21 C.F.R. §§ 8.26, 8.1(f)(m), 8.4(c), 8.50(c) (1967).

50. 21 C.F.R. § 8.4(c) (1967). One petitioner alleged that it would cost him 42 million dollars to make color additive tests.

spection regulation, however, required no advance action. In fact, many facilities of manufacturers were subject to inspection before this regulation was issued.⁵¹ The Court stated that the issue with respect to all the regulations was legal rather than factual—whether the regulations were beyond the power granted to the Commissioner by the Food, Drug, and Cosmetic Act. However, the Court found that the validity of the inspection regulations could not be determined without an understanding of the enforcement problems encountered by the FDA, as well as an understanding of the need for various sorts of supervision required to effectuate the purposes of the Act. In the Court's view, those factors could more properly be appraised in the context of a specific application of the regulation than in the generalized framework of a pre-enforcement suit.

The instant case indicates that the Court intends to continue its *ad hoc* approach to the applicability of the Administrative Procedure Act, with particular emphasis on the legislative history of the statute in question. The Court's conclusion that there is no persuasive indication of an intent to preclude review is reasonable. The Government's interpretation of the savings clause is certainly no more convincing than that of the petitioners. Thus, viewed most favorably to the government, the Act and its legislative history are inconclusive as to the availability of review. The cases interpreting the Administrative Procedure Act have required some persuasive evidence of an intent to preclude review in either the text or legislative history of the statute in question. Thus, the Court's holding in the instant case is consistent with the prior case law.

Once it is determined that there is jurisdiction for pre-enforcement review, the requirement of ripeness presents the Court with a flexible means of balancing the policies for and against allowing review. In the instant case, the principal policy argument against allowing review was the need for speedy enforcement of an Act which is vital to the public health. However, the nature of the regulations was such that the Court's decision does not materially impair the protection afforded the public by the Act. The labeling regulations were intended to make consumers aware that familiar brand name drugs can be purchased at lower prices under their "established" names. The intended effect of these regulations would probably not be felt for a considerable period of time even if they went into effect

51. 21 U.S.C. § 374(a) (1964) provides that FDA employees must be allowed to enter and inspect factories or warehouses of manufacturers.

immediately.⁵² The definition regulations encompass a very limited area in comparison with the broad field of activities covered by the Food, Drug, and Cosmetic Act. Any possible danger to the public health resulting from an injunction restraining enforcement of these regulations is amply provided for by other provisions of the Act. Moreover, petitioners in the instant case presented a more forceful case for the likelihood of irreparable injury in the event of a denial of pre-enforcement relief than was presented in either *Frozen Food* or *Storer*.⁵³ On the other hand, the inspection regulation in *Toilet Goods*, which the Court refused to enjoin, is not only directly and immediately related to the public health, but also encompasses a broad scope of potentially harmful activities.⁵⁴ Yet, in such a situation, the burden of compliance is not undue.

By determining that the labeling and definition regulations were ripe for review, but that the inspection regulation was not, the Court was consistent with *Storer* and *Frozen Food* without undermining the policies of the Food, Drug, and Cosmetic Act.⁵⁵

The Court did not discuss the government's argument that

52. See generally Sweeney, *The "Generic Everytime" Case: Prescription Drug Industry in Extremis*, 21 FOOD DRUG COSM. L.J. 226 (1966); Note, *Drug Amendments of 1962—Generic Name Prescribing: Drug Price Panacea*, 16 STAN. L. REV. 649 (1964); Note, *Drug Amendments of 1962*, 38 N.Y.U.L. REV. 1082 (1963).

53. *United States v. Storer Broadcasting Co.*, 351 U.S. 192 (1956) (business planning inconvenience); *Frozen Food Express v. United States*, 351 U.S. 40 (1956) (possible criminal penalties).

In the instant case, the penalties for violation were more serious than in *Frozen Food*. Compare note 41 with note 47 *supra*. Furthermore, in the instant case the Court went into great detail about the risks of violation and the burden of compliance. See text accompanying notes 47-50 *supra*. The Court also noted that petitioners in the instant case, unlike petitioners in *Storer* or *Frozen Food*, "deal in a sensitive industry, in which public confidence in their 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." 387 U.S. at 153.

54. See text accompanying note 51 *supra*.

55. The Court did not mention cases dealing with ripeness in the area of constitutional law, apparently intending to apply a different standard of ripeness in the area of constitutional law than in administrative law.

The government's brief cited *International Longshoreman's Union v. Boyd*, 347 U.S. 222 (1954), and *United Public Workers v. Mitchell*, 330 U.S. 75 (1947). The Court denied review in both cases, holding that the controversy was not ripe even though petitioners in those cases, as in the instant case, presented a strong case for judicial review in order to avoid possible irreparable injury.

pre-enforcement review should be denied because the regulations were interpretative rather than legislative. The distinction between legislative and interpretative regulations should not be decisive in a determination of whether regulations are ripe for pre-enforcement review. The Court's failure even to discuss the distinction indicates that it arguably *will* not be decisive.⁵⁶ The determination of whether regulations are ripe for pre-enforcement review should depend on what practical effects the issuance of regulations has on the petitioners. It can readily be seen that some interpretative regulations would have a more serious practical impact on a petitioner prior to enforcement than some legislative regulations would have. In the instant case, for example, the Court looked to the practical effects of the regulations and determined that the legislative regulation—the inspection regulation⁵⁷—was not ripe for review, but that the regulations which purported to interpret the Food, Drug, and Cosmetic Act—the labeling and definition regulations⁵⁸—were ripe. On the other hand, it is obvious that the labeling and definition regulations would have imposed an even more serious practical impact on petitioner's business, prior to enforcement, if they were considered to be legislative rather than

56. *American President Lines v. Federal Maritime Comm'n*, 316 F.2d 419 (D.C. Cir. 1963), held that review of an agency interpretative regulation was not proper even though the regulation probably had a practical effect on petitioner's business. The court of appeals stated that even if the regulation did have a practical effect on the plaintiff's business, the regulation merely represented the opinion of the agency's legal staff and was not binding on anyone. The instant Court's practical approach to the problem of pre-enforcement review as well as its failure to discuss the difference between legislative and interpretative regulations seem to indicate that *American President Lines* is no longer good law.

57. The inspection regulation had all the characteristics of a legislative regulation. It was issued under the power given to the Commissioner of Food and Drugs to issue "regulations for the efficient enforcement of" the Act. 21 U.S.C. § 371(a) (1964). The penalty for violating the regulation was specified in the regulation. The regulation did not purport to interpret any section of the Food, Drug, and Cosmetic Act.

58. These regulations had some characteristics of legislative regulations. They were issued under the power to promulgate "regulations for the efficient enforcement of" the Act. 21 U.S.C. § 371(a) (1964). They were issued according to the formal rule-making procedure of the Administrative Procedure Act, 5 U.S.C. § 1003 (1964), which includes requirements of notice to interested parties in order to allow them opportunity to object in writing. The Administrative Procedure Act, however, exempts interpretative regulations from the formal rule-making procedure. 5 U.S.C. § 1003(a) (1964). The regulations were interpretative insofar as they merely purported to interpret certain sections of

interpretative.⁵⁹ Thus, the distinction between legislative and interpretative regulations is at least a factor to be considered in a determination of ripeness. It would seem that the Court should have indicated what weight, if any, it will give to the distinction in future cases.

The dissent in *Abbott Laboratories* expressed a fear of placing a discretionary injunctive power in the hands of federal district judges, arguing that the inevitable result would be to delay enforcement of an Act which is vital to the public health.⁶⁰ The alternative would be to leave a broad discretionary power in the hands of FDA officials. There would seem to be no more basis for assuming that district judges would use their injunctive power in a manner detrimental to the public health,⁶¹ than for assuming that FDA officials would abuse their potentially coercive power. FDA officials are no doubt better equipped to deal with highly technical problems; but district judges are certainly more competent to handle questions of statutory interpretation.⁶² Furthermore, it would seem to be unhealthy for the federal judiciary system to have the Supreme Court base its decision on a distrust of federal district judges.

It is submitted that the Supreme Court's decision in *Abbott Laboratories* was correct on the facts, and that the reasons given were sound and well-considered. The purposes of the Food, Drug, and Cosmetic Act will not be undermined if district judges are selective in their issuance of injunctions, confining them to situations in which the regulations are not vital to the public health, and in which the plaintiff will suffer a genuine hardship if pre-enforcement review is denied. The Supreme Court's assumption that the district judges will so confine themselves, even if ill-founded, is a necessary adjunct of the federal judicial system.

the Food, Drug, and Cosmetic Act and did not specify any penalty for violation other than the penalties provided for violating the sections of the Food, Drug, and Cosmetic Act which they purported to interpret.

59. See text accompanying notes 34 & 35 *supra*.

60. 387 U.S. at 176, 177, 182, 183, 200.

61. Compare 387 U.S. at 156, with the dissent, note 60 *supra* and accompanying text.

62. The Court stated that the definition regulation appeared "to be susceptible of a reasoned comparison with the statutory mandate without inquiry into factual issues that ought to be first ventilated before the agency," 387 U.S. at 171 n.1.