ABBOTT LABORATORIES ET AL. *v.* GARDNER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT.

No. 39. Argued January 16, 1967.—Decided May 22, 1967.

The Commissioner of Food and Drugs, exercising authority delegated to him by the Secretary of Health, Education, and Welfare, issued regulations requiring that labels and advertisements for prescription drugs which bear proprietary names for the drugs or the ingredients carry the corresponding "established name" (designated by the Secretary) every time the proprietary or trade name is used. These regulations were designed to implement the 1962 amendment to § 502 (e)(1)(B) of the Federal Food, Drug, and Cosmetic Act. Petitioners, drug manufacturers and a manufacturers' association, challenged the regulations on the ground that the Commissioner exceeded his authority under the statute. The District Court granted the declaratory and injunctive relief sought, finding that the scope of the statute was not as broad as that of the regulations. The Court of Appeals reversed without reaching the merits, holding that pre-enforcement review of the regulations was unauthorized and beyond the jurisdiction of the District Court, and that no "actual case or controversy" existed. *Held:*

1. Pre-enforcement review of these regulations is not prohibited by the Federal Food, Drug, and Cosmetic Act. Pp. 139–148.

(a) The courts should restrict access to judicial review only upon a showing of "clear and convincing evidence" of a contrary legislative intent. *Rusk* v. *Cort,* 369 U. S. 367, 379–380. Pp. 139–141.

(b) The statutory scheme in the food and drug area does not exclude pre-enforcement judicial review. Pp. 141–144.

(c) The special-review provisions of § 701 (f) of the Act, applying to regulations embodying technical factual determinations, were simply intended to assure adequate judicial review of such agency decisions and manifest no congressional purpose to eliminate review of other kinds of agency action. P. 144.

(d) The saving clause of § 701 (f)(6) which states that the "remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law," does not foreclose pre-enforcement judicial review and should be read in harmony with the policy favoring judicial review expressed in the Administrative Procedure Act and court decisions. Pp. 144–146.

(e) *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U. S. 594, which did not concern the promulgation of a self-operative industry-wide regulation, distinguished. Pp. 146–148.

2. This case presents a controversy "ripe" for judicial resolution. Pp. 148–156.

(a) The issue of statutory construction is purely legal, and the regulations are "final agency action" within § 10 of the Administrative Procedure Act. *Columbia Broadcasting System* v. *United States*, 316 U. S. 407, and similar cases followed. Pp. 149–152.

(b) The impact of the regulations upon petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage. Pp. 152–154.

(c) Here the pre-enforcement challenge by nearly all prescription drug manufacturers is not calculated to delay or impede effective enforcement of the Federal Food, Drug, and Cosmetic Act. Pp. 154–155.

352 F. 2d 286, reversed and remanded.

Gerhard A. Gesell argued the cause and filed briefs for petitioners.

Nathan Lewin argued the cause for respondents. With him on the brief were *Solicitor General Marshall, Assistant Attorney General Vinson, Beatrice Rosenberg, Jerome M. Feit* and *William W. Goodrich.*

MR. JUSTICE HARLAN delivered the opinion of the Court.

In 1962 Congress amended the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, as amended by the Drug Amendments of 1962, 76 Stat. 780, 21 U. S. C. § 301 *et seq.*), to require manufacturers of prescription drugs to print the "established name" of the drug "prominently

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, § 502 (e)(1)(B), 21 U. S. C. § 352(e)(1)(B). 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).

A similar rule was made applicable to advertisements for prescription drugs, 21 CFR § 1.105 (b)(1).

The present action was brought by a group of 37 individual drug manufacturers and by the Pharmaceutical Manufacturers Association, of which all the petitioner companies are members, and which includes manufacturers of more than 90% of the Nation's supply of pre-

scription drugs. They challenged the regulations on the ground that the Commissioner exceeded his authority under the statute by promulgating an order requiring labels, advertisements, and other printed matter relating to prescription drugs to designate the established name of the particular drug involved every time its trade name is used anywhere in such material.

The District Court, on cross motions for summary judgment, granted the declaratory and injunctive relief sought, finding that the statute did not sweep so broadly as to permit the Commissioner's "every time" interpretation. 228 F. Supp. 855. The Court of Appeals for the Third Circuit reversed without reaching the merits of the case. 352 F. 2d 286. It held first that under the statutory scheme provided by the Federal Food, Drug, and Cosmetic Act pre-enforcement [1] review of these regulations was unauthorized and therefore beyond the jurisdiction of the District Court. Second, the Court of Appeals held that no "actual case or controversy" existed and, for that reason, that no relief under the Administrative Procedure Act, 5 U. S. C. §§ 701–704 (1964 ed., Supp. II), or under the Declaratory Judgment Act, 28 U. S. C. § 2201, was in any event available. Because of the general importance of the question, and the apparent conflict with the decision of the Court of Appeals for the Second Circuit in *Toilet Goods Assn.* v. *Gardner,* 360 F. 2d 677, which we also review today, *post,* p. 158, we granted certiorari. 383 U. S. 924.

I.

The first question we consider is whether Congress by the Federal Food, Drug, and Cosmetic Act intended to forbid pre-enforcement review of this sort of regulation

[1] That is, a suit brought by one before any attempted enforcement of the statute or regulation against him.

promulgated by the Commissioner. The question is phrased in terms of "prohibition" rather than "authorization" because a survey of our cases shows that judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress. *Board of Governors* v. *Agnew*, 329 U. S. 441; *Heikkila* v. *Barber*, 345 U. S. 229; *Brownell* v. *Tom We Shung*, 352 U. S. 180; *Harmon* v. *Brucker*, 355 U. S. 579; *Leedom* v. *Kyne*, 358 U. S. 184; *Rusk* v. *Cort*, 369 U. S. 367. Early cases in which this type of judicial review was entertained, *e. g.*, *Shields* v. *Utah Idaho Central R. Co.*, 305 U. S. 177; *Stark* v. *Wickard*, 321 U. S. 288, have been reinforced by the enactment of the Administrative Procedure Act, which 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," 5 U. S. C. § 702, so long as no statute precludes such relief or the action is not one committed by law 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 other adequate remedy in a court," 5 U. S. C. § 704. The legislative material elucidating that seminal act manifests a congressional intention that it cover a broad spectrum of administrative actions,[2] and this Court has echoed that theme by noting that the Ad-

[2] See H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946): "To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review." See also S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945).

ministrative Procedure Act's "generous review provisions" must be given a "hospitable" interpretation. *Shaughnessy* v. *Pedreiro,* 349 U. S. 48, 51; see *United States* v. *Interstate Commerce Comm'n,* 337 U. S. 426, 433–435; *Brownell* v. *Tom We Shung, supra; Heikkila* v. *Barber, supra.* Again in *Rusk* v. *Cort, supra,* at 379–380, the Court held that only upon a showing of "clear and convincing evidence" of a contrary legislative intent should the courts restrict access to judicial review. See also Jaffe, Judicial Control of Administrative Action 336–359 (1965).

Given this standard, we are wholly unpersuaded that the statutory scheme in the food and drug area excludes this type of action. The Government relies on no explicit statutory authority for its argument that pre-enforcement review is unavailable, but insists instead that because the statute includes a specific procedure for such review of certain enumerated kinds of regulations,[3] not encompassing those of the kind involved here, other types were necessarily meant to be excluded from any pre-enforcement review. The issue, however, is not so readily resolved; we must go further and inquire whether in the context of the entire legislative scheme the existence of that circumscribed remedy evinces a congressional purpose to bar agency action not within its purview from judicial review. As a leading authority in this field has noted, "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too important to be excluded on such slender and indeterminate evidence of legislative intent." Jaffe, *supra,* at 357.

[3] Embodied in §§ 701 (e), (f), 21 U. S. C. §§ 371 (e), (f), and discussed hereafter. Section 701 (e) provides a procedure for the issuance of regulations under certain specifically enumerated statutory sections. Section 701 (f) establishes a procedure for direct review by a court of appeals of a regulation promulgated under § 701 (e).

In this case the Government has not demonstrated such a purpose; indeed, a study of the legislative history shows rather conclusively that the specific review provisions were designed to give an additional remedy and not to cut down more traditional channels of review. At 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,[4] the Declaratory Judgment Act was in its infancy,[5] and the scope of judicial review of administrative decisions under the equity power was unclear.[6] It was these factors that led to the form the statute ultimately took. There is no evidence at all that members of Congress meant to preclude traditional avenues of judicial relief. Indeed, throughout the consideration of the various bills submitted to deal with this issue, it was recognized that "There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, . . . [and that] protection is given by the so-called Declaratory Judgments Act . . . ." H. R. Rep. No. 2755, 74th Cong., 2d Sess., 8. It was specifically brought to the attention of Congress that such methods had in fact been used in the food and drug area,[7] and the Department of Justice, in opposing the enactment of the special-review procedures of § 701, submitted a memorandum which was read on the floor of the House

---

[4] The Administrative Procedure Act was enacted in 1946, 60 Stat. 237.

[5] The Declaratory Judgment Act was enacted in 1934, 48 Stat. 955.

[6] See, *e. g.*, the discussion of judicial review under the equity power in the House of Representatives during the debate on these provisions. 83 Cong. Rec. 7891–7896 (1938).

[7] See, *e. g.*, 83 Cong. Rec. 7783 (remarks of Representative Leavy) (1938); Statement of Professor David F. Cavers before a Subcommittee of the Senate Committee on Commerce on S. 1944, 73d Cong., 2d Sess. (1933), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record 1110 (1938).

stating: "As a matter of fact, the entire subsection is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938).

The main issue in contention was whether these methods of review were satisfactory. Compare the majority and minority reports on the review provisions, H. R. Rep. No. 2139, 75th Cong., 3d Sess. (1938), both of which acknowledged that traditional judicial remedies were available, but disagreed as to the need for additional procedures. The provisions now embodied in a modified form in § 701 (f) were supported by those who feared the life-and-death power given by the Act to the executive officials, a fear voiced by many members of Congress. The supporters of the special-review section sought to include it in the Act primarily as a method of reviewing agency *factual* determinations. For example, it was argued that the level of tolerance for poisonous sprays on apple crops, which the Secretary of Agriculture had recently set, was a factual matter, not reviewable in equity in the absence of a special statutory review procedure.[8] Some congressmen urged that challenge to this type of determination should be in the form of a *de novo* hearing in a district court, but the Act as it was finally passed compromised the matter by allowing an appeal on a record with a "substantial evidence" test, affording a considerably more generous judicial review than the "arbitrary and capricious" test available in the traditional injunctive suit.[9]

---

[8] See, *e. g.*, 83 Cong. Rec. 7772–7773, 7781–7784, 7893–7899 (1938).

[9] See, *e. g.*, the discussion of the conference report, 83 Cong. Rec. 9096–9098 (1938).

A second reason for the special procedure was to provide broader venue to litigants challenging such technical agency determinations. At that time, a suit against the Secretary was proper only in the District of Columbia, an advantage that the Government sought to preserve. The House bill, however, originally authorized review in any district court, but in the face of a Senate bill allowing review only in the District of Columbia, the Conference Committee reached the compromise preserved in the present statute authorizing review of such agency actions by the courts of appeals.[10]

Against this background we think it quite apparent that the special-review procedures provided in § 701 (f), applying to regulations embodying technical factual determinations,[11] were simply intended to assure adequate judicial review of such agency decisions, and that their enactment does not manifest a congressional purpose to eliminate judicial review of other kinds of agency action.

This conclusion is strongly buttressed by the fact that the Act itself, in § 701 (f)(6), states, "The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." This saving clause was passed over by the Court of Appeals without discussion. In our view, however, it bears heavily on the issue, for if taken at face value it would foreclose the Government's main argument in this case. The Government deals with the clause by arguing that it should be read as applying only to review of

[10] See, *e. g.*, 83 Cong. Rec. 7772, 7892, 9092–9093 (1938).

[11] See *Toilet Goods Assn.* v. *Gardner*, 360 F. 2d 677, 683, where the court noted that "The agency determinations specifically reviewable under § 701 (e) relate to such technical subjects as chemical properties of particular products and the formulation and application of safety standards for protecting public health; Congress naturally did not wish courts to consider such matters without the benefit of the agency's views after an evidentiary hearing before it."

regulations under the sections specifically enumerated in § 701 (e). This is a conceivable reading, but it requires a considerable straining both of language and of common understanding. The saving clause itself contains no limitations, and it requires an artificial statutory construction to read a general grant of a right to judicial review begrudgingly, so as to cut out agency actions that a literal reading would cover.

There is no support in the legislative background for such a reading of the clause. It was included in the House bill, whose report states that the provision ". . . saved 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 the enforcement of the regulation, and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess., 11. The Senate conferees accepted the provision.[12] The Government argues that the clause is included as a part of § 701 (f), and therefore should be read to apply only to those sections to which the § 701 (f) special-review procedure applies. But it is difficult to think of a more appropriate place to put a general saving clause than where Congress placed it—at the conclusion of the section setting out a special procedure for use in certain specified instances. Furthermore, the Government's reading would result in an anomaly. The §§ 701 (e)–(f) procedure was included in the Act in order to deal with the problem of technical determinations for which the normal equity power was deemed insufficient. See, *supra,* pp. 142–144. There would seem little reason for Congress to have enacted § 701 (f), and at the same time to have included a clause aimed only at preserving for such determinations the

[12] H. R. Conf. Rep. No. 2716, 75th Cong., 3d Sess., 25 (1938); 83 Cong. Rec. 8731–8738 (1938) (Senate agreement to the conference report).

other types of review whose supposed inadequacy was the very reason for the special-review provisions.

Under the Government's view, indeed, it is difficult to ascertain when the saving clause would even come into play: when the special provisions apply, presumably they must be used and a court would not grant injunctive or declaratory judgment relief unless the appropriate administrative procedure is exhausted.[13] When the special procedure does not apply, the Government deems the saving clause likewise inapplicable. The Government, to be sure, does present a rather far-fetched example of what it considers a possible application of the relief saved by § 701 (f)(6), but merely to state it reveals the weakness of the Government's position.[14] We prefer to take the saving clause at its face value, and to read it in harmony with the policy favoring judicial review expressed in the Administrative Procedure Act and this Court's decisions.

The only other argument of the Government requiring attention on the preclusive effect of the statute is that *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U. S. 594, counsels a restrictive view of judicial review in the food and drug area. In that case the Food and Drug Administrator found that there was probable cause that a drug was "adulterated" because it was misbranded in such a way as to be "fraudulent" or "misleading to

[13] See Notes of the Advisory Committee on Federal Rule of Civil Procedure 57, reprinted in 28 U. S. C. App., at 6136: "A declaration may not be rendered if a special statutory proceeding has been provided for the adjudication of some special type of case . . . ." See also 6A Moore, Federal Practice § 57.08[3] (2d ed. 1966).

[14] The Government apparently views the clause as applying only when regulations falling within the special-review procedure are promulgated without affording the required public notice and opportunity to file objections and to request a public hearing. In such a case alone, the Government asserts, "an equity proceeding or a declaratory judgment action . . . might be entertained on the ground that the statutory procedures had not been followed." Brief, p. 28.

the injury or damage of the purchaser or consumer." § 304 (a), 21 U. S. C. § 334 (a). Multiple seizures were ordered through libel actions. The manufacturer of the drug brought an action to challenge directly the Administrator's finding of probable cause. This Court held that the owner could raise his constitutional, statutory, and factual claims in the libel actions themselves, and that the mere finding of probable cause by the Administrator could not be challenged in a separate action. That decision was quite clearly correct, but nothing in its reasoning or holding has any bearing on this declaratory judgment action challenging a promulgated regulation.

The Court in *Ewing* first noted that the "administrative finding of probable cause required by § 304 (a) is merely the statutory prerequisite to the bringing of the lawsuit," at which the issues are aired. 339 U. S., at 598. Such a situation bears no analogy to the promulgation, after formal procedures, of a rule that must be followed by an entire industry. To equate a finding of probable cause for proceeding against a particular drug manufacturer with the promulgation of a self-operative industry-wide regulation, such as we have here, would immunize nearly all agency rulemaking activities from the coverage of the Administrative Procedure Act.

Second, the determination of probable cause in *Ewing* has "no effect in and of itself," 339 U. S., at 598; only some action consequent upon such a finding could give it legal life. As the Court there noted, like a determination by a grand jury that there is probable cause to proceed against an accused, it is a finding which only has vitality once a proceeding is commenced, at which time appropriate challenges can be made. The Court also noted that the unique type of relief sought by the drug manufacturer was inconsistent with the policy of the Act favoring speedy action against goods in circulation that are believed on probable cause to be adul-

terated. Also, such relief was not specifically granted by the Act, which did provide another type of relief in the form of a consolidation of multiple libel actions in a convenient venue. 339 U. S., at 602.

The drug manufacturer in *Ewing* was quite obviously seeking an unheard-of form of relief which, if allowed, would have permitted interference in the early stages of an administrative determination as to specific facts, and would have prevented the regular operation of the seizure procedures established by the Act. That the Court refused to permit such an action is hardly authority for cutting off the well-established jurisdiction of the federal courts to hear, in appropriate cases, suits under the Declaratory Judgment Act and the Administrative Procedure Act challenging final agency action of the kind present here.

We conclude that nothing in the Food, Drug, and Cosmetic Act itself precludes this action.

II.

A further inquiry must, however, be made. The injunctive and declaratory judgment remedies are discretionary, and courts traditionally have been reluctant to apply them to administrative determinations unless these arise in the context of a controversy "ripe" for judicial resolution. Without undertaking to survey the intricacies of the ripeness doctrine [15] it is fair to say that its basic rationale is to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging

[15] See 3 Davis, Administrative Law Treatise, c. 21 (1958); Jaffe, Judicial Control of Administrative Action, c. 10 (1965).

parties. The problem is best seen in a twofold aspect, requiring us to evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.

As to the former factor, we 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.[16] Both sides moved for summary judgment in the District Court, and no claim is made here that further administrative proceedings are contemplated. It is suggested that the justification for this rule might vary with different circumstances, and that the expertise of the Commissioner is relevant to passing upon the validity of the regulation. This of course is true, but the suggestion overlooks the fact that both sides have approached this case as one purely of congressional intent, and that the Government made no effort to justify the regulation in factual terms.

Second, the regulations in issue we find to be "final agency action" within the meaning of § 10 of the Administrative Procedure Act, 5 U. S. C. § 704, as construed in judicial decisions. An "agency action" includes any "rule," defined by the Act as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," §§ 2 (c), 2 (g), 5 U. S. C. §§ 551 (4), 551 (13). The cases dealing with judicial review of administrative actions have interpreted the "finality" element in a pragmatic way. Thus in *Columbia Broadcasting System*

[16] While the "every time" issue has been framed by the parties in terms of statutory *compulsion,* we think that its essentially legal character would not be different had it been framed in terms of statutory *authorization* for the requirement.

262-921 O - 68 - 13

v. *United States,* 316 U. S. 407, a suit under the Urgent Deficiencies Act, 38 Stat. 219, this Court held reviewable a regulation of the Federal Communications Commission setting forth certain proscribed contractual arrangements between chain broadcasters and local stations. The FCC did not have direct authority to regulate these contracts, and its rule asserted only that it would not license stations which maintained such contracts with the networks. Although no license had in fact been denied or revoked, and the FCC regulation could properly be characterized as a statement only of its intentions, the Court held that "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 . . . ." 316 U. S., at 418–419.

Two more recent cases have taken a similarly flexible view of finality. In *Frozen Food Express* v. *United States,* 351 U. S. 40, at issue was an Interstate Commerce Commission 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 the ICC order had not included in its terms. Although the dissenting opinion noted that this ICC order had no authority except to give notice of how the Commission interpreted the Act and would have effect only if and when a particular action was brought against a particular carrier, and argued that "judicial intervention [should] be withheld until administrative action has reached its complete development," 351 U. S., at 45, the Court held the order reviewable.

Again, in *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192, the Court held to be a final agency action within the meaning of the Administrative Procedure Act an FCC regulation announcing a Commission policy that it would not issue a television license to an applicant already owning five such licenses, even though no specific application was before the Commission. The Court stated: "The process of rulemaking was complete. It was final agency action . . . by which Storer claimed to be 'aggrieved.'" 351 U. S., at 198.

We find decision in the present case following *a fortiori* from these precedents. The regulation challenged here, promulgated in a formal manner after announcement in the Federal Register and consideration of comments by interested parties [17] is quite clearly definitive. There is no hint that this regulation is informal, see *Helco Products Co.* v. *McNutt,* 78 U. S. App. D. C. 71, 137 F. 2d 681, or only the ruling of a subordinate official, see *Swift & Co.* v. *Wickham,* 230 F. Supp. 398, 409, aff'd, 364 F. 2d 241, or tentative. It was made effective upon publication, and the Assistant General Counsel for Food and Drugs stated in the District Court that compliance was expected.

The Government argues, however, that the present case can be distinguished from cases like *Frozen Food Express* on the ground that in those instances the agency involved could implement its policy directly, while here the Attorney General must authorize criminal and seizure actions for violations of the statute. In the context of this case, we do not find this argument persuasive. These regulations are not meant to advise the Attorney General, but purport to be directly authorized by the statute. Thus, if within the Commissioner's authority,

[17] Compare similar procedures followed in *Frozen Food Express, supra,* at 41–42, and *Storer, supra,* at 193–194. The procedure conformed with that prescribed in § 4 of the Administrative Procedure Act, 5 U. S. C. § 1003.

they have the status of law and violations of them carry heavy criminal and civil sanctions. Also, there is no representation that the Attorney General and the Commissioner disagree in this area; the Justice Department is defending this very suit. It would be adherence to a mere technicality to give any credence to this contention. Moreover, the agency does have direct authority to enforce this regulation in the context of passing upon applications for clearance of new drugs, § 505, 21 U. S. C. § 355, or certification of certain antibiotics, § 507, 21 U. S. C. § 357.

This is also a case in which the impact of the regulations upon the petitioners is sufficiently direct and immediate as to render the issue appropriate for judicial review at this stage. These regulations purport to give an authoritative interpretation of a statutory provision that has a direct effect on the day-to-day business of all prescription drug companies; its promulgation puts petitioners in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate.[18] As the District Court found on the basis of uncontested allegations, "Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution." 228 F. Supp. 855, 861. The regulations are clear-cut, and were made effective immediately upon publication; as noted earlier the agency's counsel represented to the District Court that immediate compliance with their terms was expected. If petitioners wish to comply they must change all their labels, advertisements, and promotional materials; they must destroy stocks of printed matter; and they must invest heavily in new printing type and new supplies.

[18] See S. Rep. No. 1005, 73d Cong., 2d Sess., 2–3 (1934); Borchard, Challenging "Penal" Statutes by Declaratory Action, 52 Yale L. J. 445, 454 (1943).

The alternative to compliance—continued use of material which they believe in good faith meets the statutory requirements, but which clearly does not meet the regulation of the Commissioner—may be even more costly. That course would risk serious criminal and civil penalties for the unlawful distribution of "misbranded" drugs.[19]

It is relevant at this juncture 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. Where the legal issue presented is fit for judicial resolution, and where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, access to the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstance, neither of which appears here.

The Government does not dispute the very real dilemma in which petitioners are placed by the regulation, but contends that "mere financial expense" is not a justification for pre-enforcement judicial review. It is of course true that cases in this Court dealing with the standing of particular parties to bring an action have held that a possible financial loss is not by itself a sufficient interest to sustain a judicial challenge to governmental action. *Frothingham* v. *Mellon,* 262 U. S. 447; *Perkins* v. *Lukens*

---

[19] Section 502 (e)(1)(B) declares a drug not complying with this labeling requirement to be "misbranded." Section 301, 21 U. S. C. § 331, designates as "prohibited acts" the misbranding of drugs in interstate commerce. Such prohibited acts are subject to injunction, § 302, 21 U. S. C. § 332, criminal penalties, § 303, 21 U. S. C. § 333, and seizure, § 304 (a), 21 U. S. C. § 334 (a).

Steel Co., 310 U. S. 113. But there is no question in the present case that petitioners have sufficient standing as plaintiffs: the regulation is directed at them in particular; it requires them to make significant changes in their everyday business practices; if they fail to observe the Commissioner's rule they are quite clearly exposed to the imposition of strong sanctions. Compare *Columbia Broadcasting System* v. *United States*, 316 U. S. 407; 3 Davis, Administrative Law Treatise, c. 21 (1958). This case is, therefore, remote from the *Mellon* and *Perkins* cases.

The Government further contends that the threat of criminal sanctions for noncompliance with a judicially untested regulation is unrealistic; the Solicitor General has represented that if court enforcement becomes necessary, "the Department of Justice will proceed only civilly for an injunction . . . or by condemnation." We cannot accept this argument as a sufficient answer to petitioners' petition. This action at its inception was properly brought and this subsequent representation of the Department of Justice should not suffice to defeat it.

Finally, the Government urges that to permit resort to the courts in this type of case may delay or impede effective enforcement of the Act. We fully recognize the important public interest served by assuring prompt and unimpeded administration of the Pure Food, Drug, and Cosmetic Act, but we do not find the Government's argument convincing. First, in this particular case, a pre-enforcement challenge by nearly all prescription drug manufacturers is calculated to speed enforcement. If the Government prevails, a large part of the industry is bound by the decree; if the Government loses, it can more quickly revise its regulation.

The Government contends, however, that if the Court allows this consolidated suit, then nothing will prevent a multiplicity of suits in various jurisdictions challenging other regulations. The short answer to this contention

is that the courts are well equipped to deal with such eventualities. The venue transfer provision, 28 U. S. C. § 1404 (a), may be invoked by the Government to consolidate separate actions. Or, actions in all but one jurisdiction might be stayed pending the conclusion of one proceeding. See *American Life Ins. Co.* v. *Stewart,* 300 U. S. 203, 215–216. A court may even in its discretion dismiss a declaratory judgment or injunctive suit if the same issue is pending in litigation elsewhere. *Maryland Cas. Co.* v. *Consumers Finance Service,* 101 F. 2d 514; *Carbide & Carbon C. Corp.* v. *United States I. Chemicals,* 140 F. 2d 47; Note, Availability of a Declaratory Judgment When Another Suit Is Pending, 51 Yale L. J. 511 (1942). In at least one suit for a declaratory judgment, relief was denied with the suggestion that the plaintiff intervene in a pending action elsewhere. *Automotive Equip., Inc.* v. *Trico Prods. Corp.,* 11 F. Supp. 292; See *Allstate Ins. Co.* v. *Thompson,* 121 F. Supp. 696.

Further, the declaratory judgment and injunctive remedies are equitable in nature, and other equitable defenses may be interposed. If a multiplicity of suits are undertaken in order to harass the Government or to delay enforcement, relief can be denied on this ground alone. *Truly* v. *Wanzer,* 5 How. 141, 142; cf. *Brillhart* v. *Excess Ins. Co.,* 316 U. S. 491, 495. The defense of laches could be asserted if the Government is prejudiced by a delay, *Southern Pac. Co.* v. *Bogert,* 250 U. S. 483, 488–490; 2 Pomeroy's Equity Jurisprudence §§ 419c–d (5th ed. Symons, 1941). And courts may even refuse declaratory relief for the nonjoinder of interested parties who are not, technically speaking, indispensable. Cf. *Samuel Goldwyn, Inc.* v. *United Artists Corp.,* 113 F. 2d 703; 6A Moore, Federal Practice ¶ 57.25 (2d ed. 1966).

In addition to all these safeguards against what the Government fears, it is important to note that the institution of this type of action does not by itself stay the effectiveness of the challenged regulation. There is

nothing in the record to indicate that petitioners have sought to stay enforcement of the "every time" regulation pending judicial review. See 5 U. S. C. § 705. If the agency believes that a suit of this type will significantly impede enforcement or will harm the public interest, it need not postpone enforcement of the regulation and may oppose any motion for a judicial stay on the part of those challenging the regulation. *Ibid.* 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, as it made no effort to do here, that delay would be detrimental to the public health or safety. See *Associated Securities Corp.* v. *SEC,* 283 F. 2d 773, 775, where a stay was denied because "the petitioners . . . [had] not sustained the burden of establishing that the requested stays will not be harmful to the public interest . . ."; see *Eastern Air Lines* v. *CAB,* 261 F. 2d 830; cf. *Scripps-Howard Radio* v. *FCC,* 316 U. S. 4, 10–11; 5 U. S. C. § 705.

Lastly, although the Government presses us to reach the merits of the challenge to the regulation in the event we find the District Court properly entertained this action, we believe the better practice is to remand the case to the Court of Appeals for the Third Circuit to review the District Court's decision that the regulation was beyond the power of the Commissioner.[20]

Reversed and remanded.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case.

[20] A totally separate issue raised in the petition for certiorari and argued by the parties in their briefs concerns the dismissal of the complaint as to certain of the plaintiffs on the ground that venue was improper as to them. All the petitioners asserted that venue was proper in Delaware not only because some of them are incorporated there but also under 28 U. S. C. § 1391 (e)(4), allowing an

[For dissenting opinions of MR. JUSTICE FORTAS and MR. JUSTICE CLARK, see *post*, pp. 174 and 201, respectively.]

---

action against a government official in any judicial district in which "the plaintiff resides . . . ." It is contended that § 1391 (e)(4) must be read to incorporate the definition of "residence" set out in 28 U. S. C. § 1391 (c): "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes." The issue of construction is whether § 1391 (c) should be read as defining corporate venue only when the corporation is a defendant, or whether it should either (1) be adopted for corporate residence in all cases when a corporation is a plaintiff, or (2) at least as the definition of "resides" as used in § 1391 (e)(4).

This question is a difficult one, with far-reaching effects, and we think it is appropriate to dismiss our writ of certiorari as to this question for the following two reasons. First, the Court of Appeals in affirming the District Court on this issue did not explicitly endorse the lower court's ruling but held only: "We find no prejudicial error in the dismissal of the complaint as to these plaintiffs . . . ." 352 F. 2d 524, 525. Review of an issue of this importance is best left to a case where it has been fully dealt with by a court of appeals. Second, one of the plaintiffs whose complaint was not dismissed is the Pharmaceutical Manufacturers Association, of which all the corporate petitioners are members, and we think it should be considered that they are adequately protected in this suit by its participation, as well as by the participation of the remaining drug companies whose interests are identical to those of the petitioners whose complaints were dismissed. Cf. *Mishkin* v. *New York*, 383 U. S. 502, 512–514. Moreover, in the further course of this litigation it will be open to the dismissed plaintiffs to seek *amicus curiae* status.