Supplementary Material

Chapter 8: The New Deal and Great Society Era—Judicial Power and Constitutional Authority

Abbott Laboratories v. Gardner, 387 U.S. 136 (1967)

The federal Food and Drug Administration (FDA) requires preapproval of all drug labels before those products can enter the marketplace. A 1962 statute required that the established name of all prescription drugs be printed on the label in lettering as large as that used for the trade name (so that doctors and consumers could recognize the similar drugs that were being sold under different trade names). The FDA adopted an "every time" regulation to enforce this provision, requiring that the established name of the drug appear beside the trade name every time the trade name was mentioned on the label, in instructions, or in advertising. A large group of drug companies filed suit in federal district court against the acting commissioner of the FDA, Sherwin Gardner, seeking an injunction and a declaration that the FDA had exceeded its statutory authority in issuing the regulation. The district court granted the motion, but the circuit court reversed on appeal, holding that there was not yet an "actual case or controversy" for the courts to resolve.

In a 5–3 decision, the U.S. Supreme Court reversed the circuit court. At issue was whether the drug companies could pursue a judicial challenge to this type of regulation before it was enforced. The companies argued that they were confronted with either complying with a regulation that they thought was legally invalid or suffering substantial financial cost and investor uncertainty by violating the regulation and awaiting federal prosecution before mounting a legal challenge. The majority agreed, concluding that once the regulation was published, the consequences to the companies were sufficiently real to establish the basis for litigation to evaluate the validity of the agency's rule.

If Article III of the Constitution requires that the court not hear hypothetical controversies, why is this case ripe for judgment? Under what circumstances can the courts hear challenges to laws before they are enforced? Had the drug companies suffered a real injury at the time of the lawsuit? Under what circumstances is the threat of enforcement too hypothetical to justify judicial intervention? Are the drug companies differently situated than other potential plaintiffs facing laws and regulations that they do not like? Should the courts lean toward accepting cases or toward denying themselves jurisdiction over disputes that might be brought to them? To what extent is "ripeness" a constitutional concern, and to what extent is ripeness a policy concern? Are courts constitutionally barred from resolving cases before they are ripe?

JUSTICE HARLAN delivered the opinion of the Court.

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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 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. . . . Early cases in which this type of judicial review was entertained . . . 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," so long as no statute precludes such relief or the action is not one committed by law to agency discretion. . . . [T]he Court [has] held that only upon a showing of "clear and convincing evidence" of a contrary legislative intent should the courts restrict access to judicial review.

Given this standard, we are wholly unpersuaded that the statutory scheme in the food and drug area excludes this type of action. . . .

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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 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 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. . . .

Second, the regulations in issue we find to be "final agency action" within the meaning of § 10 of the Administrative Procedure Act, 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." The cases dealing with judicial review of administrative actions have interpreted the "finality" element in a pragmatic way. . . . When, as here, [regulations] 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. . . . "

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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 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 . . . 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, they have the status of law and violations of them carry heavy criminal and civil sanctions. . . .

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. 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." . . .

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.

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Reversed. . . .

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

JUSTICE FORTAS, joined by CHIEF JUSTICE WARREN and JUSTICE CLARK, dissenting.[1]

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. . . The issues considered by the Court are not constitutional questions. The Court does not rest upon any asserted right to challenge the regulations at this time because the agency lacks authority to promulgate the regulations as to the subject matters involved, or because its procedures have been arbitrary or unreasonable. Its decision is based solely upon the claim of right to challenge these particular regulations at this time on the ground that they are erroneous exercises of the agency's power. . . .

With all respect, I submit that established principles of jurisprudence, solidly rooted in the constitutional structure of our Government, require that the courts should not intervene in the administrative process at this stage, under these facts and in this gross, shotgun fashion. . . .

The Court . . . 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.

. . . . I believe that this approach improperly and unwisely gives individual federal district judges a roving commission to halt the regulatory process, and to do so on the basis of abstractions and generalities instead of concrete fact situations, and that it impermissibly broadens the license of the courts to intervene in administrative action by means of a threshold suit for injunction, rather than by the method provided by statute.

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Since enactment of the Federal Food, Drug, and Cosmetic Act in 1938, the mechanism for judicial review of agency actions under its provisions has been well understood. Except for specific types of agency regulations and actions . . . , judicial review has been confined to enforcement actions instituted by the Attorney General on recommendation of the agency. As the recurrent debate over this technique demonstrates, this restricted avenue for challenge has been deemed necessary because of the direct and urgent relationship of the field of regulation to the public health.

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In evaluating the destructive force and effect of the Court's action in these cases, it is necessary to realize that it is arming each of the federal district judges in this Nation with power to enjoin enforcement of regulations and actions under the federal law designed to protect the people of this Nation against dangerous drugs and cosmetics. Restraining orders and temporary injunctions will suspend application of these public safety laws pending years of litigation—a time schedule which these cases illustrate. They are disruptive enough, regardless of the ultimate outcome. The Court's validation of this shotgun attack upon this vital law and its administration is not confined to these suits, these regulations, or these plaintiffs—or even this statute. It is a general hunting license, and, I respectfully submit, a license for mischief, because it authorizes aggression which is richly rewarded by delay in the subjection of private interests to programs which Congress believes to be required in the public interest. . . .

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[1] All the dissents were published in a companion case.

. . . . [I]n situations where a regulatory scheme designed to protect the public is involved, this Court has held that postponement of the opportunity to obtain judicial relief in the interest of avoiding disruption of the regulatory plan is entirely justifiable.

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. . . . It is clear beyond question, merely on the basis of the nature of the agency action, that these regulations, on their face, raise questions which should not be adjudicated in the abstract and in the general, but which require a "concrete setting" for determination. A threshold injunction is entirely unsuitable in these circumstances. It places the administration of a public safety statute at the mercy of counsel's ability to marshal and deploy horrible examples which logic may accommodate, but the reality of administration would repel. Our training as lawyers and judges, our respect for the administrative process, and our awareness of the complexities of life should warn us not to fall into the trap of abstract, generalized, gross review.

. . . . The Court says that this confronts the manufacturer with a "real dilemma." But the fact of the matter is that the dilemma is no more than citizens face in connection with countless statutes and with the rules of the SEC, FTC, FCC, ICC, and other regulatory agencies. This has not heretofore been regarded as a basis for injunctive relief unless Congress has so provided. The overriding fact here is—or should be—that the public interest in avoiding the delay in implementing Congress' program far outweighs the private interest, and that the private interest which has so impressed the Court is no more than that which exists in respect of most regulatory statutes or agency rules. . . . Our refusal to respond to the vastly overdrawn cries of distress would reflect not only healthy skepticism, but our regard for a proper relationship between the courts on the one hand and Congress and the administrative agencies on the other. It would represent a reasonable solicitude for the purposes and programs of the Congress. And it would reflect appropriate modesty as to the competence of the courts. The courts cannot properly—and should not—attempt to Judge in the abstract and generally whether this regulation is within the statutory scheme. . . .

JUSTICE CLARK, dissenting.

. . . . [T]he regulations here merely require common honesty and fair dealing in the sale of drugs. The pharmaceutical companies, contrary to the public interest, have through their high-sounding trademarks of long-established medicines deceitfully and exorbitantly extorted high prices therefor from the sick and the infirm. Indeed, I was so gouged myself just recently when I purchased some ordinary eyewash drops and later learned that I paid 10 times the price the drops should have cost. Likewise, a year or so ago, I purchased a brand name drug . . . at a cost of some $12, which later I learned to buy by its established name for about $1.

. . . . I submit that [the potential financial cost to the drug companies] is a lame excuse for permitting the continuance of such a dishonest practice. Rather than crying over the plight that the laboratories have brought on themselves, the Court should think more of the poor ailing folks who suffer under the practice. . . . The Commissioner was right in directing that the practice be stopped.

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