

## Syllabus

## HECKLER, SECRETARY OF HEALTH AND HUMAN SERVICES v. CHANEY ET AL.

## CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 83-1878. Argued December 3, 1984—Decided March 20, 1985

Respondent prison inmates were convicted of capital offenses and sentenced to death by lethal injection of drugs. They petitioned the Food and Drug Administration (FDA), alleging that use of the drugs for such a purpose violated the Federal Food, Drug, and Cosmetic Act (FDCA), and requesting that the FDA take various enforcement actions to prevent those violations. The FDA refused the request. Respondents then brought an action in Federal District Court against petitioner Secretary of Health and Human Services, making the same claim and seeking the same enforcement actions. The District Court granted summary judgment for petitioner, holding that nothing in the FDCA indicated an intent to circumscribe the FDA's enforcement discretion or to make it reviewable. The Court of Appeals reversed. Noting that the Administrative Procedure Act (APA) only precludes judicial review of federal agency action when it is precluded by statute, 5 U. S. C. § 701(a)(1), or "committed to agency discretion by law," § 701(a)(2), the court held that § 701(a)(2)'s exception applies only where the substantive statute leaves the courts with "no law to apply," that here there was "law to apply," that therefore the FDA's refusal to take enforcement action was reviewable, and that moreover such refusal was an abuse of discretion.

*Held:* The FDA's decision not to take the enforcement actions requested by respondents was not subject to review under the APA. Pp. 827-838.

(a) Under § 701(a)(2), judicial review of an administrative agency's decision is not to be had if the statute in question is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion. In such a case, the statute ("law") can be taken to have "committed" the decisionmaking to the agency's judgment absolutely. An agency's decision not to take enforcement action is presumed immune from judicial review under § 701(a)(2). Such a decision has traditionally been "committed to agency discretion," and it does not appear that Congress in enacting the APA intended to alter that tradition. Accordingly, such a decision is unreviewable unless Congress has indicated an intent to circumscribe agency enforcement

discretion, and has provided meaningful standards for defining the limits of that discretion. Pp. 827-835.

(b) The presumption that agency decisions not to institute enforcement proceedings are unreviewable under § 701(a)(2) is not overcome by the enforcement provisions of the FDCA. Those provisions commit complete discretion to the Secretary to decide how and when they should be exercised. The FDCA's prohibition of "misbranding" of drugs and introduction of "new drugs," absent agency approval, does not supply this Court with "law to apply." Nor can the FDA's "policy statement" indicating that the agency considered itself "obligated" to take certain investigative actions, be plausibly read to override the agency's rule expressly stating that the FDA Commissioner shall object to judicial review of a decision to recommend or not to recommend civil or criminal enforcement action. And the section of the FDCA providing that the Secretary need not report for prosecution minor violations of the Act does not give rise to the negative implication that the Secretary is required to investigate purported "major" violations of the Act. Pp. 835-837.

231 U. S. App. D. C. 136, 718 F. 2d 1174, reversed.

REHNQUIST, J., delivered the opinion of the Court, in which BURGER, C. J., and BRENNAN, WHITE, BLACKMUN, POWELL, STEVENS, and O'CONNOR, JJ., joined. BRENNAN, J., filed a concurring opinion, *post*, p. 838. MARSHALL, J., filed an opinion concurring in the judgment, *post*, p. 840.

*Deputy Solicitor General Geller* argued the cause for petitioner. With him on the briefs were *Solicitor General Lee*, *Acting Assistant Attorney General Willard*, *Samuel A. Alito, Jr.*, *Leonard Schaitman*, *John M. Rogers*, *Thomas Scarlett*, and *Michael P. Peskoe*.

*Steven M. Kristovich* argued the cause for respondents. With him on the brief were *David E. Kendall*, *Julius LeVonne Chambers*, *James M. Nabrit III*, *John Charles Boger*, *James S. Liebman*, and *Anthony G. Amsterdam*.\*

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\*A brief of *amicus curiae* urging reversal was filed for the Washington Legal Foundation by *Daniel J. Popeo*, *Paul D. Kamenar*, *George C. Smith*, and *Stephen Weitzman*.

Briefs of *amici curiae* urging affirmance were filed for the American Society of Law and Medicine et al. by *James M. Doyle*; and for the Public Citizen by *Alan B. Morrison* and *William B. Schultz*.

JUSTICE REHNQUIST delivered the opinion of the Court.

This case presents the question of the extent to which a decision of an administrative agency to exercise its "discretion" not to undertake certain enforcement actions is subject to judicial review under the Administrative Procedure Act, 5 U. S. C. § 501 *et seq.* (APA). Respondents are several prison inmates convicted of capital offenses and sentenced to death by lethal injection of drugs. They petitioned the Food and Drug Administration (FDA), alleging that under the circumstances the use of these drugs for capital punishment violated the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U. S. C. § 301 *et seq.* (FDCA), and requesting that the FDA take various enforcement actions to prevent these violations. The FDA refused their request. We review here a decision of the Court of Appeals for the District of Columbia Circuit, which held the FDA's refusal to take enforcement actions both reviewable and an abuse of discretion, and remanded the case with directions that the agency be required "to fulfill its statutory function." 231 U. S. App. D. C. 136, 153, 718 F. 2d 1174, 1191 (1983).

## I

Respondents have been sentenced to death by lethal injection of drugs under the laws of the States of Oklahoma and Texas. Those States, and several others, have recently adopted this method for carrying out the capital sentence. Respondents first petitioned the FDA, claiming that the drugs used by the States for this purpose, although approved by the FDA for the medical purposes stated on their labels, were not approved for use in human executions. They alleged that the drugs had not been tested for the purpose for which they were to be used, and that, given that the drugs would likely be administered by untrained personnel, it was also likely that the drugs would not induce the quick and painless death intended. They urged that use of these drugs for human execution was the "unapproved use of an approved drug" and

constituted a violation of the Act's prohibitions against "misbranding."<sup>1</sup> They also suggested that the FDCA's requirements for approval of "new drugs" applied, since these drugs were now being used for a new purpose. Accordingly, respondents claimed that the FDA was required to approve the drugs as "safe and effective" for human execution before they could be distributed in interstate commerce. See 21 U. S. C. § 355. They therefore requested the FDA to take various investigatory and enforcement actions to prevent these perceived violations; they requested the FDA to affix warnings to the labels of all the drugs stating that they were unapproved and unsafe for human execution, to send statements to the drug manufacturers and prison administrators stating that the drugs should not be so used, and to adopt procedures for seizing the drugs from state prisons and to recommend the prosecution of all those in the chain of distribution who knowingly distribute or purchase the drugs with intent to use them for human execution.

The FDA Commissioner responded, refusing to take the requested actions. The Commissioner first detailed his disagreement with respondents' understanding of the scope of FDA jurisdiction over the unapproved use of approved drugs for human execution, concluding that FDA jurisdiction in the area was generally unclear but in any event should not be exercised to interfere with this particular aspect of state criminal justice systems. He went on to state:

"Were FDA clearly to have jurisdiction in the area, moreover, we believe we would be authorized to decline to exercise it under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious

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<sup>1</sup>See 21 U. S. C. § 352(f): "A drug or device shall be deemed to be misbranded . . . [u]nless its labeling bears (1) adequate directions for use . . . ."

danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws, which are duly authorized statutory enactments in furtherance of proper State functions. . . .”

Respondents then filed the instant suit in the United States District Court for the District of Columbia, claiming the same violations of the FDCA and asking that the FDA be required to take the same enforcement actions requested in the prior petition.<sup>2</sup> Jurisdiction was grounded in the general federal-question jurisdiction statute, 28 U. S. C. § 1331, and review of the agency action was sought under the judicial review provisions of the APA, 5 U. S. C. §§ 701-706. The District Court granted summary judgment for petitioner. It began with the proposition that “decisions of executive departments and agencies to *refrain* from instituting investigative and enforcement proceedings are essentially unreviewable by the courts.” *Chaney v. Schweiker*, Civ. No. 81-2265 (DC, Aug. 30, 1982), App. to Pet. for Cert. 74a (emphasis in original). The court then cited case law stating that nothing in the FDCA indicated an intent to circumscribe the FDA’s enforcement discretion or to make it reviewable.

A divided panel of the Court of Appeals for the District of Columbia Circuit reversed. The majority began by discussing the FDA’s jurisdiction over the unapproved use of approved drugs for human execution, and concluded that the FDA did have jurisdiction over such a use. The court then addressed the Government’s assertion of unreviewable dis-

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<sup>2</sup> Although respondents also requested an evidentiary hearing, the District Court regarded this hearing as having “no purpose apart from serving as a prelude to the pursuit of the very enforcement steps that plaintiffs demanded in their administrative petition.” *Chaney v. Schweiker*, Civ. No. 81-2265 (DC, Aug. 30, 1982), App. to Pet. for Cert. 77a, n. 15. Respondents have not challenged the statement that all they sought were certain enforcement actions, and this case therefore does not involve the question of agency discretion not to invoke rulemaking proceedings.

cretion to refuse enforcement action. It first discussed this Court's opinions which have held that there is a general presumption that all agency decisions are reviewable under the APA, at least to assess whether the actions were "arbitrary, capricious, or an abuse of discretion." See *Abbott Laboratories v. Gardner*, 387 U. S. 136, 139-141 (1967); 5 U. S. C. § 706(2)(A). It noted that the APA, 5 U. S. C. § 701, only precludes judicial review of final agency action—including refusals to act, see 5 U. S. C. § 551(13)—when review is precluded by statute, or "committed to agency discretion by law." Citing this Court's opinions in *Dunlop v. Bachowski*, 421 U. S. 560 (1975), and *Citizens to Preserve Overton Park v. Volpe*, 401 U. S. 402 (1971), for the view that these exceptions should be narrowly construed, the court held that the "committed to agency discretion by law" exception of § 701(a)(2) should be invoked only where the substantive statute left the courts with "no law to apply." 231 U. S. App. D. C., at 146, 718 F. 2d, at 1184 (citing *Citizens to Preserve Overton Park*, *supra*, at 410). The court cited *Dunlop* as holding that this presumption "applies with no less force to review of . . . agency decisions to refrain from enforcement action." 231 U. S. App. D. C., at 146, 718 F. 2d, at 1184.

The court found "law to apply" in the form of a FDA policy statement which indicated that the agency was "obligated" to investigate the unapproved use of an approved drug when such use became "widespread" or "endanger[ed] the public health." *Id.*, at 148, 718 F. 2d, at 1186 (citing 37 Fed. Reg. 16504 (1972)). The court held that this policy statement constituted a "rule" and was considered binding by the FDA. Given the policy statement indicating that the FDA should take enforcement action in this area, and the strong presumption that all agency action is subject to judicial review, the court concluded that review of the agency's refusal was not foreclosed. It then proceeded to assess whether the agency's decision not to act was "arbitrary, capricious, or an abuse of discretion." Citing evidence that the FDA assumed

jurisdiction over drugs used to put animals to sleep<sup>3</sup> and the unapproved uses of drugs on prisoners in clinical experiments, the court found that the FDA's refusal, for the reasons given, was irrational, and that respondents' evidence that use of the drugs could lead to a cruel and protracted death was entitled to more searching consideration. The court therefore remanded the case to the District Court, to order the FDA "to fulfill its statutory function."

The dissenting judge expressed the view that an agency's decision not to institute enforcement action generally is unreviewable, and that such exercises of "prosecutorial discretion" presumptively fall within the APA's exception for agency actions "committed to agency discretion by law." He noted that traditionally courts have been wary of second-guessing agency decisions not to enforce, given the agency's expertise and better understanding of its enforcement policies and available resources. He likewise concluded that nothing in the FDCA or FDA regulations would provide a basis for a court's review of this agency decision. A divided Court of Appeals denied the petition for rehearing. 233 U. S. App. D. C. 146, 724 F. 2d 1030 (1984). We granted certiorari to review the implausible result that the FDA is required to exercise its enforcement power to ensure that States only use drugs that are "safe and effective" for human execution. 467 U. S. 1251 (1984). We reverse.

## II

The Court of Appeals' decision addressed three questions: (1) whether the FDA had jurisdiction to undertake the enforcement actions requested, (2) whether if it did have juris-

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<sup>3</sup> In response to respondents' petition, the Commissioner had explained that the FDA had assumed jurisdiction in these cases because, unlike the drugs used for human execution, these drugs were "new drugs" *intended by the manufacturer* to be used for this purpose, and thus fell squarely within the FDA's approval jurisdiction. The Court of Appeals did not explain why this distinction was not "rational."

diction its refusal to take those actions was subject to judicial review, and (3) whether if reviewable its refusal was arbitrary, capricious, or an abuse of discretion. In reaching our conclusion that the Court of Appeals was wrong, however, we need not and do not address the thorny question of the FDA's jurisdiction. For us, this case turns on the important question of the extent to which determinations by the FDA *not to exercise* its enforcement authority over the use of drugs in interstate commerce may be judicially reviewed. That decision in turn involves the construction of two separate but necessarily interrelated statutes, the APA and the FDCA.

The APA's comprehensive provisions for judicial review of "agency actions" are contained in 5 U. S. C. §§ 701-706. Any person "adversely affected or aggrieved" by agency action, see § 702, including a "failure to act," is entitled to "judicial review thereof," as long as the action is a "final agency action for which there is no other adequate remedy in a court," see § 704. The standards to be applied on review are governed by the provisions of § 706. But before any review at all may be had, a party must first clear the hurdle of § 701(a). That section provides that the chapter on judicial review "applies, according to the provisions thereof, except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." Petitioner urges that the decision of the FDA to refuse enforcement is an action "committed to agency discretion by law" under § 701(a)(2).

This Court has not had occasion to interpret this second exception in § 701(a) in any great detail. On its face, the section does not obviously lend itself to any particular construction; indeed, one might wonder what difference exists between § (a)(1) and § (a)(2). The former section seems easy in application; it requires construction of the substantive statute involved to determine whether Congress intended to preclude judicial review of certain decisions. That is the approach taken with respect to § (a)(1) in cases such as *South-*

*ern R. Co. v. Seaboard Allied Milling Corp*, 442 U. S. 444 (1979), and *Dunlop v. Bachowski*, 421 U. S., at 567. But one could read the language “committed to agency discretion by law” in § (a)(2) to require a similar inquiry. In addition, commentators have pointed out that construction of § (a)(2) is further complicated by the tension between a literal reading of § (a)(2), which exempts from judicial review those decisions committed to agency “discretion,” and the primary scope of review prescribed by § 706(2)(A)—whether the agency’s action was “arbitrary, capricious, or an *abuse of discretion*.” How is it, they ask, that an action committed to agency discretion can be unreviewable and yet courts still can review agency actions for abuse of that discretion? See 5 K. Davis, *Administrative Law* § 28:6 (1984) (hereafter Davis); Berger, *Administrative Arbitrariness and Judicial Review*, 65 *Colum. L. Rev.* 55, 58 (1965). The APA’s legislative history provides little help on this score. Mindful, however, of the common-sense principle of statutory construction that sections of a statute generally should be read “to give effect, if possible, to every clause . . . ,” see *United States v. Menasche*, 348 U. S. 528, 538–539 (1955), we think there is a proper construction of § (a)(2) which satisfies each of these concerns.

This Court first discussed § (a)(2) in *Citizens to Preserve Overton Park v. Volpe*, 401 U. S. 402 (1971). That case dealt with the Secretary of Transportation’s approval of the building of an interstate highway through a park in Memphis, Tennessee. The relevant federal statute provided that the Secretary “shall not approve” any program or project using public parkland unless the Secretary first determined that no feasible alternatives were available. *Id.*, at 411. Interested citizens challenged the Secretary’s approval under the APA, arguing that he had not satisfied the substantive statute’s requirements. This Court first addressed the “threshold question” of whether the agency’s action was at all reviewable. After setting out the language of § 701(a), the Court stated:

"In this case, there is no indication that Congress sought to prohibit judicial review and there is most certainly no 'showing of "clear and convincing evidence" of a . . . legislative intent' to restrict access to judicial review. *Abbott Laboratories v. Gardner*, 387 U. S. 136, 141 (1967). . . .

"Similarly, the Secretary's decision here does not fall within the exception for action 'committed to agency discretion.' This is a very narrow exception. . . . The legislative history of the Administrative Procedure Act indicates that it is applicable in those rare instances where 'statutes are drawn in such broad terms that in a given case there is no law to apply.' S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945)." *Overton Park, supra*, at 410 (footnote omitted).

The above quote answers several of the questions raised by the language of § 701(a), although it raises others. First, it clearly separates the exception provided by § (a)(1) from the § (a)(2) exception. The former applies when Congress has expressed an intent to preclude judicial review. The latter applies in different circumstances; even where Congress has not affirmatively precluded review, review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion. In such a case, the statute ("law") can be taken to have "committed" the decisionmaking to the agency's judgment absolutely. This construction avoids conflict with the "abuse of discretion" standard of review in § 706—if no judicially manageable standards are available for judging how and when an agency should exercise its discretion, then it is impossible to evaluate agency action for "abuse of discretion." In addition, this construction satisfies the principle of statutory construction mentioned earlier, by identifying a separate class of cases to which § 701(a)(2) applies.

To this point our analysis does not differ significantly from that of the Court of Appeals. That court purported to apply

the "no law to apply" standard of *Overton Park*. We disagree, however, with that court's insistence that the "narrow construction" of § (a)(2) required application of a presumption of reviewability even to an agency's decision not to undertake certain enforcement actions. Here we think the Court of Appeals broke with tradition, case law, and sound reasoning.

*Overton Park* did not involve an agency's refusal to take requested enforcement action. It involved an affirmative act of approval under a statute that set clear guidelines for determining when such approval should be given. Refusals to take enforcement steps generally involve precisely the opposite situation, and in that situation we think the presumption is that judicial review is not available. This Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion. See *United States v. Batchelder*, 442 U. S. 114, 123-124 (1979); *United States v. Nixon*, 418 U. S. 683, 693 (1974); *Vaca v. Sipes*, 386 U. S. 171, 182 (1967); *Confiscation Cases*, 7 Wall. 454 (1869). This recognition of the existence of discretion is attributable in no small part to the general unsuitability for judicial review of agency decisions to refuse enforcement.

The reasons for this general unsuitability are many. First, an agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables in-

volved in the proper ordering of its priorities. Similar concerns animate the principles of administrative law that courts generally will defer to an agency's construction of the statute it is charged with implementing, and to the procedures it adopts for implementing that statute. See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U. S. 519, 543 (1978); *Train v. Natural Resources Defense Council, Inc.*, 421 U. S. 60, 87 (1975).

In addition to these administrative concerns, we note that when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect. Similarly, when an agency *does* act to enforce, that action itself provides a focus for judicial review, inasmuch as the agency must have exercised its power in some manner. The action at least can be reviewed to determine whether the agency exceeded its statutory powers. See, *e. g.*, *FTC v. Klesner*, 280 U. S. 19 (1929). Finally, we recognize that an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch, inasmuch as it is the Executive who is charged by the Constitution to “take Care that the Laws be faithfully executed.” U. S. Const., Art. II, § 3.

We of course only list the above concerns to facilitate understanding of our conclusion that an agency's decision not to take enforcement action should be presumed immune from judicial review under § 701(a)(2). For good reasons, such a decision has traditionally been “committed to agency discretion,” and we believe that the Congress enacting the APA did not intend to alter that tradition. Cf. 5 Davis § 28:5 (APA did not significantly alter the “common law” of judicial review of agency action). In so stating, we emphasize that the decision is only presumptively unreviewable; the pre-

sumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers.<sup>4</sup> Thus, in establishing this presumption in the APA, Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers. Congress may limit an agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue. How to determine when Congress has done so is the question left open by *Overton Park*.

*Dunlop v. Bachowski*, 421 U. S. 560 (1975), relied upon heavily by respondents and the majority in the Court of Appeals, presents an example of statutory language which supplied sufficient standards to rebut the presumption of unreviewability. *Dunlop* involved a suit by a union employee, under the Labor-Management Reporting and Disclosure Act, 29 U. S. C. § 481 *et seq.* (LMRDA), asking the Secretary of Labor to investigate and file suit to set aside a union election. Section 482 provided that, upon filing of a complaint by a union member, "[t]he Secretary shall investigate such complaint and, if he finds probable cause to believe that a violation . . . has occurred . . . he shall . . . bring a civil action . . . ." After investigating the plaintiff's claims the Secretary of Labor declined to file suit, and the plaintiff sought judicial review under the APA. This Court held that

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<sup>4</sup>We do not have in this case a refusal by the agency to institute proceedings based solely on the belief that it lacks jurisdiction. Nor do we have a situation where it could justifiably be found that the agency has "consciously and expressly adopted a general policy" that is so extreme as to amount to an abdication of its statutory responsibilities. See, *e. g.*, *Adams v. Richardson*, 156 U. S. App. D. C. 267, 480 F. 2d 1159 (1973) (en banc). Although we express no opinion on whether such decisions would be unreviewable under § 701(a)(2), we note that in those situations the statute conferring authority on the agency might indicate that such decisions were not "committed to agency discretion."

review was available. It rejected the Secretary's argument that the statute precluded judicial review, and in a footnote it stated its agreement with the conclusion of the Court of Appeals that the decision was not "an unreviewable exercise of prosecutorial discretion." 421 U. S., at 567, n. 7. Our textual references to the "strong presumption" of reviewability in *Dunlop* were addressed only to the §(a)(1) exception; we were content to rely on the Court of Appeals' opinion to hold that the §(a)(2) exception did not apply. The Court of Appeals, in turn, had found the "principle of absolute prosecutorial discretion" inapplicable, because the language of the LMRDA indicated that the Secretary was required to file suit if certain "clearly defined" factors were present. The decision therefore was not "beyond the judicial capacity to supervise." *Bachowski v. Brennan*, 502 F. 2d 79, 87-88 (CA3 1974) (quoting Davis §28.16, p. 984 (1970 Supp.)).

*Dunlop* is thus consistent with a general presumption of unreviewability of decisions not to enforce. The statute being administered quite clearly withdrew discretion from the agency and provided guidelines for exercise of its enforcement power. Our decision that review was available was not based on "pragmatic considerations," such as those cited by the Court of Appeals, see 231 U. S. App. D. C., at 147, 718 F. 2d, at 1185, that amount to an assessment of whether the interests at stake are important enough to justify intervention in the agencies' decisionmaking. The danger that agencies may not carry out their delegated powers with sufficient vigor does not necessarily lead to the conclusion that courts are the most appropriate body to police this aspect of their performance. That decision is in the first instance for Congress, and we therefore turn to the FDCA to determine whether in this case Congress has provided us with "law to apply." If it has indicated an intent to circumscribe agency enforcement discretion, and has provided meaningful standards for defining the limits of that discretion, there is "law to apply" under §701(a)(2), and courts

may require that the agency follow that law; if it has not, then an agency refusal to institute proceedings is a decision "committed to agency discretion by law" within the meaning of that section.

### III

To enforce the various substantive prohibitions contained in the FDCA, the Act provides for injunctions, 21 U. S. C. § 332, criminal sanctions, §§ 333 and 335, and seizure of any offending food, drug, or cosmetic article, § 334. The Act's general provision for enforcement, § 372, provides only that "[t]he Secretary is *authorized* to conduct examinations and investigations . . ." (emphasis added). Unlike the statute at issue in *Dunlop*, § 332 gives no indication of when an injunction should be sought, and § 334, providing for seizures, is framed in the permissive—the offending food, drug, or cosmetic "shall be liable to be proceeded against." The section on criminal sanctions states baldly that any person who violates the Act's substantive prohibitions "shall be imprisoned . . . or fined." Respondents argue that this statement mandates criminal prosecution of every violator of the Act but they adduce no indication in case law or legislative history that such was Congress' intention in using this language, which is commonly found in the criminal provisions of Title 18 of the United States Code. See, *e. g.*, 18 U. S. C. § 471 (counterfeiting); 18 U. S. C. § 1001 (false statements to Government officials); 18 U. S. C. § 1341 (mail fraud). We are unwilling to attribute such a sweeping meaning to this language, particularly since the Act charges the Secretary only with recommending prosecution; any criminal prosecutions must be instituted by the Attorney General. The Act's enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised.

Respondents nevertheless present three separate authorities that they claim provide the courts with sufficient indicia of an intent to circumscribe enforcement discretion. Two of these may be dealt with summarily. First, we reject

respondents' argument that the Act's substantive prohibitions of "misbranding" and the introduction of "new drugs" absent agency approval, see 21 U. S. C. §§ 352(f)(1), 355, supply us with "law to apply." These provisions are simply irrelevant to the agency's discretion to refuse to initiate proceedings.

We also find singularly unhelpful the agency "policy statement" on which the Court of Appeals placed great reliance. We would have difficulty with this statement's vague language even if it were a properly adopted agency rule. Although the statement indicates that the agency considered itself "obligated" to take certain investigative actions, that language did not arise in the course of discussing the agency's discretion to exercise its enforcement power, but rather in the context of describing agency policy with respect to unapproved uses of approved drugs by physicians. In addition, if read to circumscribe agency enforcement discretion, the statement conflicts with the agency rule on judicial review, 21 CFR § 10.45(d)(2) (1984), which states that "[t]he Commissioner shall object to judicial review . . . if (i) [t]he matter is committed by law to the discretion of the Commissioner, e. g., a decision to recommend or not to recommend civil or criminal enforcement action . . . ." But in any event the policy statement was attached to a rule that was never adopted. Whatever force such a statement might have, and leaving to one side the problem of whether an agency's rules might under certain circumstances provide courts with adequate guidelines for informed judicial review of decisions not to enforce, we do not think the language of the agency's "policy statement" can plausibly be read to override the agency's express assertion of unreviewable discretion contained in the above rule.<sup>5</sup>

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<sup>5</sup> Respondents also urge, as did the Court of Appeals, that a statement by the FDA's lawyers in a footnote to their "memorandum in support of dismissal" in the District Court indicates that the agency considers the "policy statement" "binding." The footnote said that the "Federal Regis-

Respondents' third argument, based upon §306 of the FDCA, merits only slightly more consideration. That section provides:

"Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or ruling." 21 U. S. C. §336.

Respondents seek to draw from this section the negative implication that the Secretary is *required* to report for prosecution all "major" violations of the Act, however those might be defined, and that it therefore supplies the needed indication of an intent to limit agency enforcement discretion. We think that this section simply does not give rise to the negative implication which respondents seek to draw from it. The section is not addressed to agency proceedings designed to discover the existence of violations, but applies only to a situation where a violation has already been established to the satisfaction of the agency. We do not believe the section speaks to the criteria which shall be used by the agency for investigating *possible* violations of the Act.

#### IV

We therefore conclude that the presumption that agency decisions not to institute proceedings are unreviewable under 5 U. S. C. §701(a)(2) is not overcome by the enforcement provisions of the FDCA. The FDA's decision not to take the

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ter notice . . . sets forth the agency's current position of[n] the legal status of approved labeling for prescription drugs." The statement from the memorandum cites no authority, is taken out of context, and on its face does not indicate that the agency considered this position "binding" in any sense of the word. Moreover, we find it difficult to believe that statements of agency counsel in litigation against private individuals can be taken to establish "rules" that bind an entire agency prospectively. Such would turn orderly process on its head.

enforcement actions requested by respondents is therefore not subject to judicial review under the APA. The general exception to reviewability provided by § 701(a)(2) for action "committed to agency discretion" remains a narrow one, see *Citizens to Preserve Overton Park v. Volpe*, 401 U. S. 402 (1971), but within that exception are included agency refusals to institute investigative or enforcement proceedings, unless Congress has indicated otherwise. In so holding, we essentially leave to Congress, and not to the courts, the decision as to whether an agency's refusal to institute proceedings should be judicially reviewable. No colorable claim is made in this case that the agency's refusal to institute proceedings violated any constitutional rights of respondents, and we do not address the issue that would be raised in such a case. Cf. *Johnson v. Robison*, 415 U. S. 361, 366 (1974); *Yick Wo v. Hopkins*, 118 U. S. 356, 372-374 (1886). The fact that the drugs involved in this case are ultimately to be used in imposing the death penalty must not lead this Court or other courts to import profound differences of opinion over the meaning of the Eighth Amendment to the United States Constitution into the domain of administrative law.

The judgment of the Court of Appeals is

*Reversed.*

JUSTICE BRENNAN, concurring.

Today the Court holds that individual decisions of the Food and Drug Administration not to take enforcement action in response to citizen requests are presumptively not reviewable under the Administrative Procedure Act, 5 U. S. C. §§ 701-706. I concur in this decision. This general presumption is based on the view that, in the normal course of events, Congress intends to allow broad discretion for its administrative agencies to make particular enforcement decisions, and there often may not exist readily discernible "law to apply" for courts to conduct judicial review of non-enforcement decisions. See *Citizens to Preserve Overton Park v. Volpe*, 401 U. S. 402, 410 (1971).

I also agree that, despite this general presumption, "Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers." *Ante*, at 833. Thus the Court properly does not decide today that nonenforcement decisions are unreviewable in cases where (1) an agency flatly claims that it has no statutory jurisdiction to reach certain conduct, *ante*, at 833, n. 4; (2) an agency engages in a pattern of nonenforcement of clear statutory language, as in *Adams v. Richardson*, 156 U. S. App. D. C. 267, 480 F. 2d 1159 (1973) (en banc), *ante*, at 833, n. 4; (3) an agency has refused to enforce a regulation lawfully promulgated and still in effect, *ante*, at 836;<sup>1</sup> or (4) a nonenforcement decision violates constitutional rights, *ante*, at 838. It is possible to imagine other nonenforcement decisions made for entirely illegitimate reasons, for example, nonenforcement in return for a bribe, judicial review of which would not be foreclosed by the nonreviewability presumption. It may be presumed that Congress does not intend administrative agencies, agents of Congress' own creation, to ignore clear jurisdictional, regulatory, statutory, or constitutional commands, and in some circumstances including those listed above the statutes or regulations at issue may well provide "law to apply" under 5 U. S. C. § 701(a)(2). Individual, isolated nonenforcement decisions, however, must be made by hundreds of agencies each day. It is entirely permissible to presume that Congress has not intended courts to review such mundane matters, absent either some indication of congressional intent to the contrary or proof of circumstances such as those set out above.

On this understanding of the scope of today's decision, I join the Court's opinion.<sup>2</sup>

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<sup>1</sup> Cf. *Motor Vehicle Manufacturers Assn. v. State Farm Mutual Ins. Co.*, 463 U. S. 29, 40-44 (1983) (failure to revoke lawfully a previously promulgated rule is reviewable under the APA).

<sup>2</sup> I adhere to my view that the death penalty is in all circumstances cruel and unusual punishment forbidden by the Eighth and Fourteenth Amend-

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## JUSTICE MARSHALL, concurring in the judgment.

Easy cases at times produce bad law, for in the rush to reach a clearly ordained result, courts may offer up principles, doctrines, and statements that calmer reflection, and a fuller understanding of their implications in concrete settings, would eschew. In my view, the "presumption of unreviewability" announced today is a product of that lack of discipline that easy cases make all too easy. The majority, eager to reverse what it goes out of its way to label as an "implausible result," *ante*, at 827, not only does reverse, as I agree it should, but along the way creates out of whole cloth the notion that agency decisions not to take "enforcement action" are unreviewable unless Congress has rather specifically indicated otherwise. Because this "presumption of unreviewability" is fundamentally at odds with rule-of-law principles firmly embedded in our jurisprudence, because it seeks to truncate an emerging line of judicial authority subjecting enforcement discretion to rational and principled constraint, and because, in the end, the presumption may well be indecipherable, one can only hope that it will come to be understood as a relic of a particular factual setting in which the full implications of such a presumption were neither confronted nor understood.

I write separately to argue for a different basis of decision: that refusals to enforce, like other agency actions, are reviewable in the absence of a "clear and convincing" congressional intent to the contrary, but that such refusals warrant deference when, as in this case, there is nothing to suggest

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ments, see *Gregg v. Georgia*, 428 U. S. 153, 227 (1976) (BRENNAN, J., dissenting). My concurrence here should not be misread as an expression of approval for the use of lethal injections to effect capital punishment as an independent matter. The Court is correct, however, that "profound differences of opinion over the meaning of the Eighth Amendment" should not influence our consideration of a question purely of statutory administrative law. *Ante*, at 838.

that an agency with enforcement discretion has abused that discretion.

## I

In response to respondents' petition, the FDA Commissioner stated that the FDA would not pursue the complaint "under our inherent discretion to decline to pursue certain enforcement matters. The unapproved use of approved drugs is an area in which the case law is far from uniform. Generally, enforcement proceedings in this area are initiated only when there is a serious danger to the public health or a blatant scheme to defraud. We cannot conclude that those dangers are present under State lethal injection laws . . . . [W]e decline, as a matter of enforcement discretion, to pursue supplies of drugs under State control that will be used for execution by lethal injection."

The FDA may well have been legally required to provide this statement of basis and purpose for its decision not to take the action requested. Under the Administrative Procedure Act, such a statement is required when an agency denies a "written application, petition, or other request of an interested person made in connection with any agency proceedings."<sup>1</sup> 5 U. S. C. § 555(e). Whether this written explanation was legally required or not, however, it does provide a sufficient

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<sup>1</sup>All Members of the Court in *Dunlop v. Bachowski*, 421 U. S. 560 (1975), agreed that a statement of basis and purpose was required for the denial of the enforcement request at issue there. See *id.*, at 571-575; *id.*, at 594 (REHNQUIST, J., concurring in result in part and dissenting in part). Given the revisionist view the Court takes today of *Dunlop*, perhaps these statements too are to be limited to the specific facts out of which they emerged. Yet the Court's suggestion that review is proper when the agency asserts a lack of jurisdiction to act, see *ante*, at 833, n. 4, or some other basis inconsistent with congressional intent, would seem to presuppose the existence of a statement of basis and purpose explaining the basis for denial of enforcement action.

basis for holding, *on the merits*, that the FDA's refusal to grant the relief requested was within its discretion.

First, respondents on summary judgment neither offered nor attempted to offer any evidence that the reasons for the FDA's refusal to act were other than the reasons stated by the agency. Second, as the Court correctly concludes, the FDCA is not a mandatory statute that requires the FDA to prosecute all violations of the Act. Thus, the FDA clearly has significant discretion to choose which alleged violations of the Act to prosecute. Third, the basis on which the agency chose to exercise this discretion—that other problems were viewed as more pressing—generally will be enough to pass muster. Certainly it is enough to do so here, where the number of people currently affected by the alleged misbranding is around 200, and where the drugs are integral elements in a regulatory scheme over which the States exercise pervasive and direct control.

When a statute does not mandate full enforcement, I agree with the Court that an agency is generally "far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Ante*, at 831–832. As long as the agency is choosing how to allocate finite enforcement resources, the agency's choice will be entitled to substantial deference, for the choice among valid alternative enforcement policies is precisely the sort of choice over which agencies generally have been left substantial discretion by their enabling statutes. *On the merits*, then, a decision not to enforce that is based on valid resource-allocation decisions will generally not be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U. S. C. § 706(2)(A). The decision in this case is no exception to this principle.

The Court, however, is not content to rest on this ground. Instead, the Court transforms the arguments for deferential review on the merits into the wholly different notion that "enforcement" decisions are presumptively unreviewable

altogether—unreviewable whether the resource-allocation rationale is a sham, unreviewable whether enforcement is declined out of vindictive or personal motives, and unreviewable whether the agency has simply ignored the request for enforcement. But cf. *Logan v. Zimmerman Brush Co.*, 455 U. S. 422 (1982) (due process and equal protection may prevent agency from ignoring complaint). But surely it is a far cry from asserting that agencies must be given substantial leeway in allocating enforcement resources among valid alternatives to suggesting that agency enforcement decisions are presumptively unreviewable *no matter what factor caused the agency to stay its hand*.

This “presumption of unreviewability” is also a far cry from prior understandings of the Administrative Procedure Act. As the Court acknowledges, the APA presumptively entitles any person “adversely affected or aggrieved by agency action,” 5 U. S. C. § 702—which is defined to include the “failure to act,” 5 U. S. C. § 551 (13)—to judicial review of that action. That presumption can be defeated if the substantive statute precludes review, § 701(a)(1), or if the action is committed to agency discretion *by law*, § 701(a)(2), but as Justice Harlan’s opinion in *Abbott Laboratories v. Gardner*, 387 U. S. 136 (1967), made clear in interpreting the APA’s judicial review provisions:

“The legislative material elucidating [the APA] manifests a congressional intention that it cover a broad spectrum of administrative actions, and this Court has echoed that theme by noting that the Administrative Procedure Act’s ‘generous review provisions’ must be given a ‘hospitable’ interpretation. . . . [O]nly upon a showing of ‘clear and convincing evidence’ of a contrary legislative intent should the courts restrict access to judicial review.” *Id.*, at 140–141 (citations omitted; footnote omitted).

See generally H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946) (to preclude APA review, a statute “must upon its face

give clear and convincing evidence of an intent to withhold it"); cf. *Moog Industries, Inc. v. FTC*, 355 U. S. 411, 414 (1958) (Federal Trade Commission decisions to prosecute are reviewable and can be overturned when "patent abuse of discretion" demonstrated).<sup>2</sup> Rather than confront *Abbott Laboratories*, perhaps the seminal case on judicial review under the APA, the Court chooses simply to ignore it.<sup>3</sup> Instead, to support its new-found "presumption of unreviewability," the Court resorts to completely undefined and unsubstantiated references to "tradition," see *ante*, at 831, and to citation of four cases. See *United States v. Batchelder*, 442 U. S. 114 (1979); *United States v. Nixon*, 418 U. S. 683 (1974); *Vaca v. Sipes*, 386 U. S. 171 (1967); *Confiscation Cases*, 7 Wall. 454 (1869).<sup>4</sup> Because the Court's "tradition" rationale, which flies in the face of *Abbott Laboratories*, stands as a flat, unsupported *ipse dixit*, these four cases form the only doctrinal foundation for the majority's presumption of unreviewability.

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<sup>2</sup>The Senate Committee Report accompanying the APA stated: "The mere filing of a petition does not require an agency to grant it, or to hold a hearing, or engage in any other public rule making proceedings. The refusal of an agency to grant the petition or to hold rule making proceedings, therefore, would not per se be subject to judicial reversal." S. Doc. No. 248, 79th Cong., 2d Sess., 201 (1946). As Judge McGowan has observed, "this language implies that judicial review *would* sometimes be available in the circumstances mentioned" in the Report. *Natural Resources Defense Council, Inc. v. SEC*, 196 U. S. App. D. C. 124, 136, n. 14, 606 F. 2d 1031, 1043, n. 14 (1979).

<sup>3</sup>The Court did not ignore *Abbott Laboratories* in *Southern R. Co. v. Seaboard Allied Milling Corp.*, 442 U. S. 444, 454, 462-463 (1979), a denial of enforcement case that required "clear and convincing evidence" of congressional intent to preclude review of the failure to investigate a complaint.

<sup>4</sup>It is ironic that *Vaca v. Sipes* and the *Confiscation Cases* were cited by the Government in its brief in *Dunlop* when it unsuccessfully pressed the very proposition accepted today: that agency enforcement decisions are presumptively unreviewable. See Brief for Petitioner in *Dunlop v. Bachowski*, O. T. 1974, No. 74-466, pp. 25-31.

Yet these cases hardly support such a broad presumption with respect to agency refusal to take enforcement action. The only one of these cases to involve administrative action, *Vaca v. Sipes*, suggests, in dictum, that the General Counsel of the National Labor Relations Board has unreviewable discretion to refuse to initiate an unfair labor practice complaint. To the extent this dictum is sound, later cases indicate that unreviewability results from the particular structure of the National Labor Relations Act and the explicit statutory intent to withdraw review found in 29 U. S. C. § 153(d), rather than from some general "presumption of unreviewability" of enforcement decisions. See *NLRB v. Sears, Roebuck & Co.*, 421 U. S. 132, 138 (1975).<sup>5</sup> Neither *Vaca* nor *Sears, Roebuck* discusses the APA. The other three cases—*Batchelder*, *Nixon*, and the *Confiscation Cases*—all involve prosecutorial discretion to enforce the criminal law. *Batchelder* does not maintain that such discretion is unreviewable, but only that the mere existence of prosecutorial discretion does not violate the Constitution. The *Confiscation Cases*, involving suits to confiscate property used in aid of rebellion, hold that, where the United States brings a criminal action that is "wholly for the benefit of the United States," 7 Wall., at 455, a person who provides information leading to the action has no "vested" or absolute right to demand, "so far as the interests of the United States are concerned," *id.*, at 458, that the action be maintained. The half-sentence cited from *Nixon*, which states that the Executive has "absolute discretion to decide whether to prosecute a case," 418 U. S., at 693, is the only apparent support the Court actually offers for even the limited notion that prosecutorial discretion in the criminal area is unreviewable. But that half-sentence is of course misleading, for *Nixon* held it an abuse of that discre-

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<sup>5</sup> Cf. *Southern R. Co. v. Seaboard Allied Milling Corp.*, *supra* (concluding, after extensive examination of history and structure of Act, that agency decisions not to investigate under § 15(8)(a) of the Interstate Commerce Act are unreviewable).

tion to attempt to exercise it contrary to validly promulgated regulations. Thus, *Nixon* actually stands for a very different proposition than the one for which the Court cites it: faced with a specific claim of abuse of prosecutorial discretion, *Nixon* makes clear that courts are not powerless to intervene. And none of the other prosecutorial discretion cases upon which the Court rests involved a claim that discretion had been abused in some specific way.

Moreover, for at least two reasons it is inappropriate to rely on notions of prosecutorial discretion to hold agency inaction unreviewable. First, since the dictum in *Nixon*, the Court has made clear that prosecutorial discretion is not as unfettered or unreviewable as the half-sentence in *Nixon* suggests. As one of the leading commentators in this area has noted, "the case law since 1974 is strongly on the side of reviewability." 2 K. Davis, *Administrative Law* §9:6, p. 240 (1979). In *Blackledge v. Perry*, 417 U. S. 21, 28 (1974), instead of invoking notions of "absolute" prosecutorial discretion, we held that certain potentially vindictive exercises of prosecutorial discretion were both reviewable and impermissible. The "retaliatory use" of prosecutorial power is no longer tolerated. *Thigpen v. Roberts*, 468 U. S. 27, 30 (1984). Nor do prosecutors have the discretion to induce guilty pleas through promises that are not kept. *Blackledge v. Allison*, 431 U. S. 63 (1977); *Santobello v. New York*, 404 U. S. 257, 262 (1971). And in rejecting on the merits a claim of improper prosecutorial conduct in *Bordenkircher v. Hayes*, 434 U. S. 357 (1978), we clearly laid to rest any notion that prosecutorial discretion is unreviewable no matter what the basis is upon which it is exercised:

"There is no doubt that the breadth of discretion that our country's legal system vests in prosecuting attorneys carries with it the potential for both individual and institutional abuse. And broad though that discretion may

be, there are undoubtedly constitutional limits upon its exercise." *Id.*, at 365.

See also *Wayte v. United States*, *ante*, at 608. Thus, even in the area of criminal prosecutions, prosecutorial discretion is not subject to a "presumption of unreviewability." See generally Vorenberg, Decent Restraint of Prosecutorial Power, 94 Harv. L. Rev. 1521, 1537-1543 (1981). If a plaintiff makes a sufficient threshold showing that a prosecutor's discretion has been exercised for impermissible reasons, judicial review is available.

Second, arguments about prosecutorial discretion do not necessarily translate into the context of agency refusals to act. "In appropriate circumstances the Court has made clear that traditions of prosecutorial discretion do not immunize from judicial scrutiny cases in which the enforcement decisions of an administrator were motivated by improper factors or were otherwise contrary to law." *Marshall v. Jerrico, Inc.*, 446 U. S. 238, 249 (1980) (citations omitted). Criminal prosecutorial decisions vindicate only intangible interests, common to society as a whole, in the enforcement of the criminal law. The conduct at issue has already occurred; all that remains is society's general interest in assuring that the guilty are punished. See *Linda R. S. v. Richard D.*, 410 U. S. 614, 619 (1973) ("[A] private citizen lacks a judicially cognizable interest in the prosecution or nonprosecution of another"). In contrast, requests for administrative enforcement typically seek to prevent concrete and future injuries that Congress has made cognizable—injuries that result, for example, from misbranded drugs, such as alleged in this case, or unsafe nuclear powerplants, see, e. g., *Florida Power & Light Co. v. Lorion*, *ante*, p. 729—or to obtain palpable benefits that Congress has intended to bestow—such as labor union elections free of corruption, see *Dunlop v. Bachowski*, 421 U. S. 560 (1975). Entitlements to receive these benefits or to be free of these injuries often run to specific classes of individuals

whom Congress has singled out as statutory beneficiaries. The interests at stake in review of administrative enforcement decisions are thus more focused and in many circumstances more pressing than those at stake in criminal prosecutorial decisions. A request that a nuclear plant be operated safely or that protection be provided against unsafe drugs is quite different from a request that an individual be put in jail or his property confiscated as punishment for past violations of the criminal law. Unlike traditional exercises of prosecutorial discretion, "the decision to enforce—or not to enforce—may itself result in significant burdens on a . . . statutory beneficiary." *Marshall v. Jerrico, Inc.*, *supra*, at 249.

Perhaps most important, the *sine qua non* of the APA was to alter inherited judicial reluctance to constrain the exercise of discretionary administrative power—to rationalize and make fairer the exercise of such discretion. Since passage of the APA, the sustained effort of administrative law has been to "continuously narrow the category of actions considered to be so discretionary as to be exempted from review." Shapiro, *Administrative Discretion: The Next Stage*, 92 *Yale L. J.* 1487, 1489, n. 11 (1983). Discretion may well be necessary to carry out a variety of important administrative functions, but discretion can be a veil for laziness, corruption, incompetency, lack of will, or other motives, and for that reason "*the presence of discretion should not bar a court from considering a claim of illegal or arbitrary use of discretion.*" L. Jaffe, *Judicial Control of Administrative Action* 375 (1965). Judicial review is available under the APA in the absence of a clear and convincing demonstration that Congress intended to preclude it precisely so that agencies, whether in rulemaking, adjudicating, acting or failing to act, do not become stagnant backwaters of caprice and lawlessness. "Law has reached its finest moments when it has freed man from the unlimited discretion of some ruler, some civil or military official, some bureaucrat." *United States v. Wunderlich*, 342 U. S. 98, 101 (1951).

For these and other reasons,<sup>6</sup> reliance on prosecutorial discretion, itself a fading talisman, to justify the unreviewability of agency inaction is inappropriate. See generally Stewart & Sunstein, Public Programs and Private Rights, 95 Harv. L. Rev. 1195, 1285-1286, n. 386 (1982) (discussing differences between agency inaction and prosecutorial discretion); Note, Judicial Review of Administrative Inaction, 83 Colum. L. Rev. 627, 658-661 (1983) (same). To the extent arguments about traditional notions of prosecutorial discretion have any force at all in this context, they ought to apply only

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<sup>6</sup>Legal historians have suggested that the notion of prosecutorial discretion developed in England and America largely because private prosecutions were simultaneously available at the time. See Langbein, Controlling Prosecutorial Discretion in Germany, 41 U. Chi. L. Rev. 439, 443-446 (1974). Private enforcement of regulatory statutes, such as the FDCA, is of course largely unavailable.

In addition, scholars have noted that the tradition of unreviewability of prosecutor's decisions developed at a time when virtually all executive action was considered unreviewable. In asking what accounts for this "tradition," one scholar offered the following rhetorical questions:

"Is it because the tradition became settled during the nineteenth century when courts were generally assuming that judicial intrusion into any administration would be unfortunate? Is it because the tradition became settled while the Supreme Court was actuated by its 1840 remark that 'The interference of the Courts with the performance of the ordinary duties of the executive departments of the government, would be productive of nothing but mischief.' [citing *Decatur v. Paulding*, 14 Pet. 497, 516 (1840)]. Is it because the tradition became settled before the courts made the twentieth-century discovery that the courts can interfere with executive action to protect against abuses but at the same time can avoid taking over the executive function? Is it because the tradition became settled before the successes of the modern system of *limited* judicial review became fully recognized?

"On the basis of what the courts know today about leaving administration to administrators but at the same time providing an effective check to protect against abuses, should the courts not take a fresh look at the tradition that prevents them from reviewing the prosecuting function?" K. Davis, *Discretionary Justice* 211 (1969) (footnote omitted).

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to an agency's decision to decline to seek penalties against an individual for past conduct, not to a decision to refuse to investigate or take action on a public health, safety, or welfare problem.

## II

The "tradition" of unreviewability upon which the majority relies is refuted most powerfully by a firmly entrenched body of lower court case law that holds reviewable various agency refusals to act.<sup>7</sup> This case law recognizes that attempting to

<sup>7</sup>See, e. g., *Bargmann v. Helms*, 230 U. S. App. D. C. 164, 715 F. 2d 638 (1983); *Natural Resources Defense Council, Inc. v. EPA*, 683 F. 2d 752, 753, 767-768 (CA3 1982); *WWHT, Inc. v. FCC*, 211 U. S. App. D. C. 218, 656 F. 2d 807 (1981); *Carpet, Linoleum & Resilient Tile Layers, Local Union No. 419 v. Brown*, 656 F. 2d 564 (CA10 1981); *Natural Resources Defense Council, Inc. v. SEC*, 196 U. S. App. D. C. 124, 606 F. 2d 1031 (1979); *British Airways Board v. Port Authority of New York*, 564 F. 2d 1002, 1012-1013 (CA2 1977); *Pennsylvania v. National Assn. of Flood Insurers*, 520 F. 2d 11 (CA3 1975); *REA Express, Inc. v. CAB*, 507 F. 2d 42 (CA2 1974); *Davis v. Romney*, 490 F. 2d 1360 (CA3 1974); *Adams v. Richardson*, 156 U. S. App. D. C. 267, 480 F. 2d 1159 (1973) (en banc); *International Harvester Co. v. Ruckelshaus*, 155 U. S. App. D. C. 411, 478 F. 2d 615 (1973); *Rockbridge v. Lincoln*, 449 F. 2d 567 (CA9 1971); *Environmental Defense Fund, Inc. v. Ruckelshaus*, 142 U. S. App. D. C. 74, 439 F. 2d 584 (1971); *Environmental Defense Fund, Inc. v. Hardin*, 138 U. S. App. D. C. 391, 428 F. 2d 1093 (1970); *Medical Committee for Human Rights v. SEC*, 139 U. S. App. D. C. 226, 432 F. 2d 659 (1970), vacated as moot, 404 U. S. 403 (1972); *Trailways of New England, Inc. v. CAB*, 412 F. 2d 926 (CA1 1969); *International Union, United Auto., Aero. & Agric. Implement Workers v. NLRB*, 427 F. 2d 1330 (CA6 1970); *Public Citizen Health Research Group v. Aucter*, 554 F. Supp. 242 (DC 1983), rev'd in part, 226 U. S. App. D. C. 413, 702 F. 2d 1150 (1983); *Sierra Club v. Gorsuch*, 551 F. Supp. 785 (ND Cal. 1982); *Hoffmann-LaRoche, Inc. v. Weinberger*, 425 F. Supp. 890 (DC 1975); *NAACP v. Levi*, 418 F. Supp. 1109 (DC 1976); *Guerrero v. Garza*, 418 F. Supp. 182 (WD Wis. 1976); *Souder v. Brennan*, 367 F. Supp. 808, 811 (DC 1973); *City-Wide Coalition Against Childhood Lead Paint Poisoning v. Philadelphia Housing Auth.*, 356 F. Supp. 123 (ED Pa. 1973); *American Public Health Assn. v. Vene-man*, 349 F. Supp. 1311 (DC 1972).

To be sure, some of these cases involved the refusal to initiate rule-making proceedings, and the majority expressly disavows any claim that

draw a line for purposes of judicial review between affirmative exercises of coercive agency power and negative agency refusals to act, see *ante*, at 832, is simply untenable; one of the very purposes fueling the birth of administrative agencies was the reality that governmental refusal to act could have just as devastating an effect upon life, liberty, and the pursuit of happiness as coercive governmental action. As Justice Frankfurter, a careful and experienced student of administrative law, wrote for this Court, "any distinction, as such, between 'negative' and 'affirmative' orders, as a touchstone of jurisdiction to review [agency action] serves no useful purpose." *Rochester Telephone Corp. v. United States*, 307 U. S. 125, 143 (1939).<sup>8</sup> The lower courts, facing

its presumption of unreviewability applies to such refusals. See *ante*, at 825, n. 2. But the majority offers no explanation of how an enforcement request that seeks protection of the public or statutory beneficiaries from present and future concrete harms, or from loss of deserved benefits, implicates considerations substantially different from those at stake in judicial review of the refusal to initiate rulemaking proceedings.

<sup>8</sup>Justice Frankfurter went to some length in *Rochester Telephone* to expose the fallacy of any purported distinction between agency action and inaction:

"[N]egative order' and 'affirmative order' are not appropriate terms of art. . . . 'Negative' has really been an obfuscating adjective in that it implied a search for a distinction—non-action as against action—which does not involve the real considerations on which rest, as we have seen, the reviewability of Commission orders within the framework of its discretionary authority and within the general criteria of justiciability. 'Negative' and 'affirmative,' in the context of these problems, is as unilluminating and mischief-making a distinction as the outmoded line between 'nonfeasance' and 'misfeasance.'

". . . An order of the Commission dismissing a complaint on the merits and maintaining the *status quo* is an exercise of administrative function, no more and no less, than an order directing some change in status. . . . In the application of relevant canons of judicial review an order of the Commission directing the adoption of a practice might raise considerations absent from a situation where the Commission merely allowed such a practice to continue. *But this bears on the disposition of a case and should not control jurisdiction.*" 307 U. S., at 140–142 (emphasis added; footnotes omitted).

the problem of agency inaction and its concrete effects more regularly than do we, have responded with a variety of solutions to assure administrative fidelity to congressional objectives: a demand that an agency explain its refusal to act, a demand that explanations given be further elaborated, and injunctions that action "unlawfully withheld or unreasonably delayed," 5 U. S. C. § 706, be taken. See generally Stewart & Sunstein, 95 Harv. L. Rev., at 1279. Whatever the merits of any particular solution, one would have hoped the Court would have acted with greater respect for these efforts by responding with a scalpel rather than a blunderbuss.

To be sure, the Court no doubt takes solace in the view that it has created only a "presumption" of unreviewability, and that this "presumption may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Ante*, at 832-833. But this statement implies far too narrow a reliance on positive law, either statutory or constitutional, see *ibid.*, as the sole source of limitations on agency discretion not to enforce. In my view, enforcement discretion is also channelled by traditional background understandings against which the APA was enacted and which Congress hardly could be thought to have intended to displace in the APA.<sup>9</sup> For example, a refusal to enforce that stems from a conflict of interest, that is the result of a bribe, vindictiveness or retaliation, or that traces to personal or other corrupt motives ought to be judicially remediable.<sup>10</sup> Even in the absence

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<sup>9</sup>The Court cites 5 K. Davis, *Administrative Law* § 28:5 (1984), for the proposition that the APA did not alter the "common law" of judicial review of agency action; Davis' correct statement ought to make clear that traditional principles of fair and rational decisionmaking were incorporated into, rather than obliterated by, the APA, and that judicial review is available to assure that agency action, including inaction, is consistent with these principles. See also *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Curran*, 456 U. S. 353, 378 (1982) ("[W]e must examine Congress' perception of the law that it was shaping or reshaping").

<sup>10</sup>"A scheme injecting a personal interest, financial or otherwise, into the enforcement process may bring irrelevant or impermissible factors into

of statutory "guidelines" precluding such factors as bases of decision, Congress should not be presumed to have departed from principles of rationality and fair process in enacting the APA.<sup>11</sup> Moreover, the agency may well narrow its own enforcement discretion through historical practice, from which it should arguably not depart in the absence of explanation, or through regulations and informal action. Traditional principles of rationality and fair process do offer "meaningful standards" and "law to apply" to an agency's decision not to act, and no presumption of unreviewability should be allowed to trump these principles.

Perhaps the Court's reference to guidance from the "substantive statute" is meant to encompass such concerns and to allow the "common law" of judicial review of agency action to provide standards by which inaction can be reviewed. But in that case I cannot fathom what content the Court's "presumption of unreviewability" might have. If inaction can be reviewed to assure that it does not result from improper abnegation of jurisdiction, from complete abdication of statutory responsibilities, from violation of constitutional rights, or from factors that offend principles of rational and fair administrative process, it would seem that a court must always inquire into the reasons for the agency's action before deciding whether the presumption applies.<sup>12</sup> As Judge Friendly said many years ago, review of even a decision over which substantial administrative discretion exists would then be available to determine whether that discretion had been

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the prosecutorial decision and in some contexts raise serious constitutional questions." *Marshall v. Jerrico, Inc.*, 446 U. S. 238, 249-250 (1980).

<sup>11</sup> Indeed, "[t]he more general and powerful the background understanding, the less likely it is to have been stated explicitly by the legislature, even if the legislature in fact shares that understanding." Stewart & Sunstein, *Public Programs and Private Rights*, 95 Harv. L. Rev. 1195, 1231 (1982).

<sup>12</sup> When an agency asserts that a refusal to enforce is based on enforcement priorities, it may be that, to survive summary judgment, a plaintiff must be able to offer some basis for calling this assertion into question or for justifying his inability to do so.

abused because the decision was "made without a rational explanation, inexplicably departed from established policies, or rested . . . on other considerations that Congress could not have intended to make relevant." *Wong Wing Hang v. INS*, 360 F. 2d 715, 719 (CA2 1966). In that event, we would not be finding enforcement decisions unreviewable, but rather would be reviewing them on the merits, albeit with due deference, to assure that such decisions did not result from an abuse of discretion.

That is the basis upon which I would decide this case. Under § 706(A)(2) and *Abbott Laboratories v. Gardner*, 387 U. S. 136 (1967), agency action, including the failure to act, is reviewable to assure that it is not "arbitrary, capricious, or an abuse of discretion," unless Congress has manifested a clear and convincing intent to preclude review. Review of enforcement decisions must be suitably deferential in light of the necessary flexibility the agencies must have in this area, but at least when "enforcement" inaction allegedly deprives citizens of statutory benefits or exposes them to harms against which Congress has sought to provide protection, review must be on the merits to ensure that the agency is exercising its discretion within permissible bounds. See Berger, *Administrative Arbitrariness: A Synthesis*, 78 *Yale L. J.* 965 (1969); L. Jaffe, *Judicial Control of Administrative Action* 375 (1965).

### III

The problem of agency refusal to act is one of the pressing problems of the modern administrative state, given the enormous powers, for both good and ill, that agency inaction, like agency action, holds over citizens. As *Dunlop v. Bachowski*, 421 U. S. 560 (1975), recognized, the problems and dangers of agency inaction are too important, too prevalent, and too multifaceted to admit of a single facile solution under which "enforcement" decisions are "presumptively unreviewable." Over time, I believe the approach announced today will come to be understood, not as mandating that courts

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MARSHALL, J., concurring in judgment

cover their eyes and their reasoning power when asked to review an agency's failure to act, but as recognizing that courts must approach the substantive task of reviewing such failures with appropriate deference to an agency's legitimate need to set policy through the allocation of scarce budgetary and enforcement resources. Because the Court's approach, if taken literally, would take the courts out of the role of reviewing agency inaction in far too many cases, I join only the judgment today.