# Administrative Law
# Law 6400 – Section 12
# Spring 2024

# Supplementary Materials
# Part 3

**Jonathan R. Siegel**
**GW Law School**

**CAMP v. PITTS**
Supreme Court of the United States, 1973
411 U.S. 138

PER CURIAM.

In its present posture this case presents a narrow, but substantial, question with respect to the proper procedure to be followed when a reviewing court determines that an administrative agency's stated justification for informal action does not provide an adequate basis for judicial review.

In 1967, respondents submitted an application to the Comptroller of the Currency for a certificate authorizing them to organize a new bank in Hartsville, South Carolina. See 12 U.S.C. § 27; 12 CFR § 4.2 (1972). On the basis of information received from a national bank examiner and from various interested parties, the Comptroller denied the application and notified respondents of his decision through a brief letter, which stated in part: '(W)e have concluded that the factors in support of the establishment of a new National Bank in this area are not favorable.' No formal hearings were required by the controlling statute or guaranteed by the applicable regulations, although the latter provided for hearings when requested and when granted at the discretion of the Comptroller. Respondents did not request a formal hearing but asked for reconsideration. That request was granted and a supplemental field examination was conducted, whereupon the Comptroller again denied the application, this time stating in a letter that 'we were unable to reach a favorable conclusion as to the need factor,' and explaining that conclusion to some extent.[2] Respondents then brought an action in federal district court seeking review of the Comptroller's decision. The entire administrative record was placed before the court, and, upon an examination of that record and of the two letters of explanation, the court granted summary judgment against respondents, holding that de novo review was not warranted in the circumstances and finding that 'although the Comptroller may have erred, there is substantial basis for his determination, and . . . it was neither capricious nor arbitrary.' On appeal, the Court of Appeals did not reach the merits. Rather, it held that the Comptroller's ruling was 'unacceptable' because 'its basis' was not stated with sufficient clarity to permit judicial review. For the present, the Comptroller does not challenge this aspect of the court's decision. He does, however, seek review here of the procedures that the Court of Appeals specifically ordered to be followed in the District Court on remand. The court held that the case should be remanded 'for a trial de novo before the District Court' because 'the Comptroller has twice inadequately and inarticulately resolved the (respondents') presentation.' The court further specified that in the District Court, respondents 'will open the trial with proof of their application and compliance with the statutory inquiries, and proffer of any other relevant evidence.' Then, '(t)estimony may . . . be adduced by the Comptroller or intervenors manifesting opposition, if any, to the new bank.'

---

[2] The letter reads in part: 'On each application we endeavor to develop the need and convenience factors in conjunction with all other banking factors and in this case we were unable to reach a favorable conclusion as to the need factor. The record reflects that this market area is now served by the Peoples Bank with deposits of $7.2MM, The Bank of Hartsville with deposits of $12.8MM, The First Federal Savings and Loan Association with deposits of $5.4MM, The Mutual Savings and Loan Association with deposits of $8.2MM and the Sonoco Employees Credit Union with deposits of $6.5MM. The aforementioned are as of December 31, 1968.'

On the basis of the record thus made, the District Court was instructed to make its own findings of fact and conclusions of law in order to determine 'whether the (respondents) have shown by a preponderance of evidence that the Comptroller's ruling is capricious or an abuse of discretion.'

We agree with the Comptroller that the trial procedures thus outlined by the Court of Appeals for the remand in this case are unwarranted under present law.

Unquestionably, the Comptroller's action is subject to judicial review under the Administrative Procedure Act (APA), 5 U.S.C. § 701. * * * But it is also clear that neither the National Bank Act nor the APA requires the Comptroller to hold a hearing or to make formal findings on the hearing record when passing on applications for new banking authorities. See 12 U.S.C. § 26; 5 U.S.C. § 557.[3] Accordingly, the proper standard for judicial review of the Comptroller's adjudications is not the 'substantial evidence' test which is appropriate when reviewing findings made on a hearing record, 5 U.S.C. § 706(2)(E). Nor was the reviewing court free to hold a de novo hearing under § 706(2)(F) and thereafter determine whether the agency action was 'unwarranted by the facts.' It is quite plain from our decision in *Citizens to Preserve Overton Park v. Volpe* that de novo review is appropriate only where there are inadequate factfinding procedures in an adjudicatory proceeding, or where judicial proceedings are brought to enforce certain administrative actions. * * * Neither situation applies here. The proceeding in the District Court was obviously not brought to enforce the Comptroller's decision, and the only deficiency suggested in agency action or proceedings is that the Comptroller inadequately explained his decision. As *Overton Park* demonstrates, however, that failure, if it occurred in this case, is not a deficiency in factfinding procedures such as to warrant the de novo hearing ordered in this case.

The appropriate standard for review was, accordingly, whether the Comptroller's adjudication was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,' as specified in 5 U.S.C. § 706(2) (A). In applying that standard, the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court. Respondents contend that the Court of Appeals did not envision a true de novo review and that, at most, all that was called for was the type of 'plenary review' contemplated by *Overton Park.* We cannot agree. The present remand instructions require the Comptroller and other parties to make an evidentiary record before the District Court 'manifesting opposition, if any, to the new bank.' The respondents were also to be afforded opportunities to support their application with 'any other relevant evidence.' These instructions seem to put aside the extensive administrative record already made and presented to the reviewing court.

If, as the Court of Appeals held and as the Comptroller does not now contest, there was such failure to explain administrative action as to frustrate effective judicial review, the remedy was not to hold a de novo hearing but, as contemplated by *Overton Park*, to obtain from the

---

[3] Title 12 U.S.C. § 26 contemplates a wide-ranging ex parte investigation; it reads as follows: 'Comptroller to determine if association can commence business. 'Whenever a certificate is transmitted to the Comptroller of the Currency, as provide in this chapter, * * * the comptroller shall examine into the condition of such association, ascertain * * * whether such association has complied with all the provisions of this chapter required to entitle it to engage in the business of banking; and shall cause to be made and attested by the oaths of a majority of the directors, and by the president or cashier of the association, a statement of all the facts necessary to enable the comptroller to determine whether the association is lawfully entitled to commence the business of banking.' * * *

agency, either through affidavits or testimony, such additional explanation of the reasons for the agency decision as may prove necessary. We add a caveat, however. Unlike *Overton Park*, in the present case there was contemporaneous explanation of the agency decision. The explanation may have been curt, but it surely indicated the determinative reason for the final action taken: the finding that a new bank was an uneconomic venture in light of the banking needs and the banking services already available in the surrounding community. The validity of the Comptroller's action must, therefore, stand or fall on the propriety of that finding, judged, of course, by the appropriate standard of review. If that finding is not sustainable on the administrative record made, then the Comptroller's decision must be vacated and the matter remanded to him for further consideration. See *SEC v. Chenery Corp.*, 318 U.S. 80, 63 S.Ct. 454, 87 L.Ed. 626 (1943). It is in this context that the Court of Appeals should determine whether and to what extent, in the light of the administrative record, further explanation is necessary to a proper assessment of the agency's decision.

The petition for certiorari is granted, the judgment of the Court of Appeals is vacated, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

### *Notes and Questions*

1. In *Florida Light and Power v. Lorion,* 470 U.S. 729 (1985), the Supreme Court provided its most recent gloss on the principles set forth in *Overton Park* and *Camp v. Pitts*, as it considered again what a court should do when an administrative record is inadequate for judicial review. After quoting *Camp* for the proposition that "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court," the Court said:

> The task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court. *Citizens to Preserve Overton Park v. Volpe*, * * *. If the record before the agency does not support the agency action, if the agency has not considered all relevant factors, or if the reviewing court simply cannot evaluate the challenged agency action on the basis of the record before it, the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a de novo inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry. * * * The APA specifically contemplates judicial review on the basis of the agency record compiled in the course of informal agency action in which a hearing has not occurred. See 5 U.S.C. §§ 551(13), 704, 706.

2. What should a court do if it suspects that the reasons specified by an agency for the action it took are not the *real* reasons? If this fact were shown, would it be a basis for overturning the agency's action? If the taking of testimony from agency officials or other

discovery is not permitted, and the court is restricted to considering the administrative record in which the agency states its official reasons for action, how could the true reason ever be demonstrated?

3. More generally, if a court is uncertain as to why an agency took the action it took, why is a remand to the agency the best means of getting that information to the court? Why shouldn't the court just conduct its normally factfinding proceedings, as in any case in which a fact (here, the agency's reasons for acting) is in dispute?

## Statutory Background for the *Chevron* Case

Under the Clean Air Act, every state is required to meet the National Ambient Air Quality Standards (the NAAQS). An area within a state that does not meet the NAAQS is called a "non-attainment area." Typically, attainment is determined on a county-by-county basis, so a non-attainment area is typically a county.

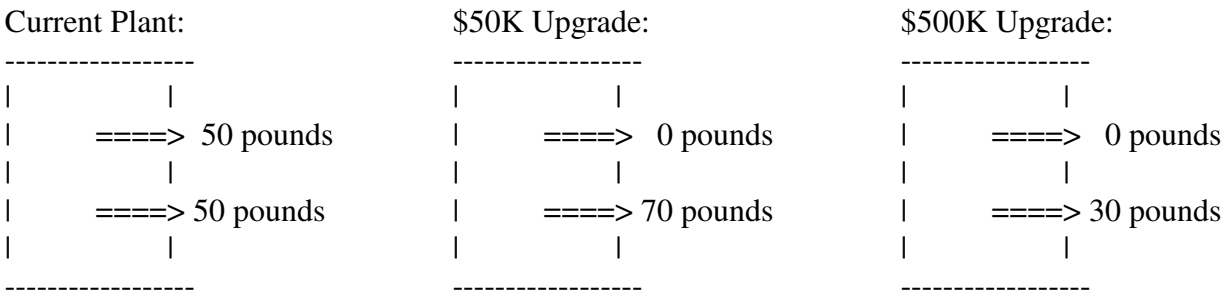
In 1970, Congress amended the Clean Air Act. As amended, the Act provided that any state that has any non-attainment areas must have a state implementation plan (SIP) for the Clean Air Act. Each SIP had to provide that any *new* stationary source of pollution in a non-attainment area must have a permit. The same was true of any *modified* stationary source of pollution in a non-attainment area. Existing stationary sources of pollution in non-attainment areas could continue to exist without permits so long as they were not modified.

The term "modified" had a special statutory definition. A stationary source was "modified" if it was changed so that it emitted more pollution than before. Changing an existing stationary source of pollution so as to reduce its emissions of pollution didn't count as "modifying" it and no permit was required. But to change a source so that it emitted more pollution than before created a "modified" source and required a permit.

The key statutory requirement was this: a permit could be issued for a new or modified stationary source of pollution in a non-attainment area only if the equipment to be used in the new or modified stationary source achieved the "lowest achievable emission rate."

As you will see in the *Chevron* case, a critical issue in the case was the definition of "stationary source of pollution." To understand the importance of this term, consider the following hypothetical situation (see next page):

A manufacturing plant has two emission pipes. Each pipe emits 50 pounds of pollutant per day. The plant owner desires to upgrade the plant's equipment. The upgrade, which will cost $50,000, will result in shutting off one of the plant's pipes entirely, but increasing the emissions of the other to 70 pounds of pollutant per day. Technology exists that would permit the plant owner to upgrade the plant so as to shut off one pipe entirely and reduce the emissions of the other to 30 pounds of pollutant per day, but the plant owner doesn't want to use that technology because it would cost $500,000 to upgrade to it. (See diagram)




Consider these questions carefully (they will be asked in class):

1. Would the owner's desired upgrade require a permit under the Clear Air Act?

2. Could a permit lawfully be issued for the owner's desired upgrade?

3. What effect did the EPA's regulation, discussed in *Chevron*, have on these questions?

## Criticism of *Chevron*

*Chevron* deference has recently been the subject of a wave of judicial and scholarly criticism. Here are some cases in which two Supreme Court Justices criticize the concept of *Chevron* deference and a scholarly article defending it.

### PEREZ v. MORTGAGE BANKERS ASS'N
135 S. Ct. 1199 (2015)

[The Department of Labor issued an interpretation of one of its own regulations. Subsequently, it issued a revised interpretation. The D.C. Circuit held that although the agency could issue the initial interpretation as an "interpretative rule" without going through notice and comment, subsequent revisions to an interpretative rule required notice and comment. The Supreme Court held that the revisions to the interpretative rule did not require notice and comment. Justice Thomas wrote a concurring opinion that considered much larger issues regarding an agency's interpretation of its governing statute and rules.]

Justice THOMAS, concurring in the judgment. . . .

[T]hese cases call into question the legitimacy of our precedents requiring deference to administrative interpretations of regulations. . . . Because this doctrine effects a transfer of the judicial power to an executive agency, it raises constitutional concerns. This line of precedents undermines our obligation to provide a judicial check on the other branches, and it subjects regulated parties to precisely the abuses that the Framers sought to prevent. . . .

I

. . . [Justice Thomas reviewed the development of judicial deference to an agency's interpretation of its own regulations.]

II

. . . The Constitution's particular blend of separated powers and checks and balances was informed by centuries of political thought and experiences. . . . Though the theories of the separation of powers and checks and balances have roots in the ancient world, events of the 17th and 18th centuries played a crucial role in their development and informed the men who crafted and ratified the Constitution.

Over a century before our War of Independence, the English Civil War catapulted the theory of the separation of powers to prominence. As political theorists of the day witnessed the conflict between the King and Parliament, and the dangers of tyrannical government posed by each, they began to call for a clear division of authority between the two. . . .

John Locke and Baron de Montesquieu endorsed and expanded on this concept. See Vile 63–64. They agreed with the general theory set forth in The Royalist's Defence, emphasizing the need for a separation of powers to protect individual liberty. . . . But they also advocated a system of checks and balances to reinforce that separation. . . .

. . . When the Framers met for the Constitutional Convention, they understood the need for greater checks and balances to reinforce the separation of powers. . . . The Framers thus separated the three main powers of Government—legislative, executive, and judicial—into the three branches created by Articles I, II, and III. . . . During the ratification debates, Madison argued that this structure represented "the great security" for liberty in the Constitution.

. . . To the Framers, the separation of powers and checks and balances were more than just theories. They were practical and real protections for individual liberty in the new Constitution. . . .

*Seminole Rock* raises two related constitutional concerns. It represents a transfer of judicial power to the Executive Branch, and it amounts to an erosion of the judicial obligation to serve as a "check" on the political branches.

1

When a party properly brings a case or controversy to an Article III court, that court is called upon to exercise the "judicial Power of the United States." Art. III, § 1. For the reasons I explain in this section, the judicial power, as originally understood, requires a court to exercise its independent judgment in interpreting and expounding upon the laws.

Those who ratified the Constitution knew that legal texts would often contain ambiguities. . . . As James Madison explained, "All new laws, though penned with the greatest technical skill and passed on the fullest and most mature deliberation, are considered as more or less obscure and equivocal...." The Federalist No. 37, at 229.

The judicial power was understood to include the power to resolve these ambiguities over time. . . . It is undoubtedly true that the other branches of Government have the authority and obligation to interpret the law, but only the judicial interpretation would be considered authoritative in a judicial proceeding. . . .

Courts act as "an intermediate body between the people and the legislature, in order, among other things, to keep the latter within the limits assigned to their authority." Federalist No. 78, at 467 (A. Hamilton). The Legislature and Executive may be swayed by popular sentiment to abandon the strictures of the Constitution or other rules of law. But the Judiciary, insulated from both internal and external sources of bias, is duty bound to exercise independent judgment in applying the law.

Interpreting agency regulations calls for that exercise of independent judgment. Substantive regulations have the force and effect of law. . . . Just as it is critical for judges to exercise independent judgment in applying statutes, it is critical for judges to exercise independent judgment in determining that a regulation properly covers the conduct of regulated parties. Defining the legal meaning of the regulation is one aspect of that determination.

*Seminole Rock* deference, however, precludes judges from independently determining that meaning. Rather than judges' applying recognized tools of interpretation to determine the best meaning of a regulation, this doctrine demands that courts accord "controlling weight" to the agency interpretation of a regulation, subject only to the narrow exception for interpretations that are plainly erroneous or inconsistent with the regulation. That deference amounts to a transfer of the judge's exercise of interpretive judgment to the agency. . . . But the agency, as part of the Executive Branch, lacks the structural protections for independent judgment adopted by the Framers, including the life tenure and salary protections of Article III. Because the agency is thus not properly constituted to exercise the judicial power under the Constitution, the transfer of interpretive judgment raises serious

separation-of-powers concerns.

2

*Seminole Rock* is constitutionally questionable for an additional reason: It undermines the judicial "check" on the political branches. Unlike the Legislative and Executive Branches, each of which possesses several political checks on the other, the Judiciary has one primary check on the excesses of political branches. That check is the enforcement of the rule of law through the exercise of judicial power.

Judges have long recognized their responsibility to apply the law, even if they did not conceive of it as a "check" on political power. . . .

Article III judges cannot opt out of exercising their check. As we have long recognized, "[t]he Judiciary has a responsibility to decide cases properly before it, even those it 'would gladly avoid.'" . . .

But we have not consistently exercised the judicial check with respect to administrative agencies. Even though regulated parties have repeatedly challenged agency interpretations as inconsistent with existing regulations, we have just as repeatedly declined to exercise independent judgment as to those claims. Instead, we have deferred to the executive agency that both promulgated the regulations and enforced them. Although an agency's interpretation of a regulation might be the best interpretation, it also might not. When courts refuse even to decide what the best interpretation is under the law, they abandon the judicial check. That abandonment permits precisely the accumulation of governmental powers that the Framers warned against. See The Federalist No. 47, at 302 (J. Madison). . . .

III

Although this Court offered no theoretical justification for *Seminole Rock* deference when announcing it, several justifications have been proposed since. None is persuasive.

A

Probably the most oft-recited justification for *Seminole Rock* deference is that of agency expertise in administering technical statutory schemes. . . .

This defense of *Seminole Rock* deference misidentifies the relevant inquiry. The proper question faced by courts in interpreting a regulation is not what the best policy choice might be, but what the regulation means. Because this Court has concluded that "substantive agency regulations have the 'force and effect of law,' " . . . such regulations should be interpreted like any other law.. . . Judges are at least as well suited as administrative agencies to engage in this task. . . .

B

Another oft-recited justification for *Seminole Rock* deference is that agencies are better situated to define the original intent behind their regulations. . . .

[But it] is the text of the regulations that have the force and effect of law, not the agency's

intent. "Citizens arrange their affairs not on the basis of their legislators' unexpressed intent, but on the basis of the law as it is written and promulgated." . . . Only the text of a regulation goes through the procedures established by Congress for agency rulemaking. And it is that text on which the public is entitled to rely. For the same reasons that we should not accord controlling weight to postenactment expressions of intent by individual Members of Congress, . . . we should not accord controlling weight to expressions of intent by administrators of agencies.

C

A third asserted justification for *Seminole Rock* deference is that Congress has delegated to agencies the authority to interpret their own regulations. . . .

This justification fails because Congress lacks authority to delegate the power. As we have explained in an analogous context, "[t]he structure of the Constitution does not permit Congress to execute the laws; it follows that Congress cannot grant to an officer under its control what it does not possess." *Bowsher v. Synar,* 478 U.S. 714, 726 (1986). Similarly, the Constitution does not empower Congress to issue a judicially binding interpretation of the Constitution or its laws. Lacking the power itself, it cannot delegate that power to an agency.

To hold otherwise would be to vitiate the separation of powers and ignore the "sense of a sharp necessity to separate the legislative from the judicial power ... [that] triumphed among the Framers of the new Federal Constitution." . . .

Although on the surface these cases require only a straightforward application of the APA, closer scrutiny reveals serious constitutional questions lurking beneath. . . . [T]he entire line of precedent beginning with *Seminole Rock* raises serious constitutional questions and should be reconsidered in an appropriate case.

### *Notes and Questions*

*Perez* involved *Seminole Rock* deference, but in the subsequent case of *Michigan v. EPA,* 135 S. Ct. 2699 (2015), Justice Thomas wrote a concurring opinion in which he applied his arguments to *Chevron* deference:

> *Chevron* deference is premised on "a presumption that Congress, when it left ambiguity in a statute meant for implementation by an agency, understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows." . . . We most often describe Congress' supposed choice to leave matters to agency discretion as an allocation of interpretive authority. . . . But we sometimes treat that discretion as though it were a form of legislative power. . . . Either way, *Chevron* deference raises serious separation-of-powers questions.
>
> As I have explained elsewhere, "[T]he judicial power, as originally understood, requires a court to exercise its independent judgment in interpreting and expounding upon the laws." . . . Interpreting federal statutes—including ambiguous ones administered by an agency—"calls for that exercise of independent judgment." . . . *Chevron* deference

precludes judges from exercising that judgment, forcing them to abandon what they believe is "the best reading of an ambiguous statute" in favor of an agency's construction. . . . It thus wrests from Courts the ultimate interpretative authority to "say what the law is," *Marbury v. Madison,* 1 Cranch 137, 177(1803), and hands it over to the Executive. . . . Such a transfer is in tension with Article III's Vesting Clause, which vests the judicial power exclusively in Article III courts, not administrative agencies. U.S. Const., Art. III, § 1.

In reality, as the Court illustrates. . ., agencies "interpreting" ambiguous statutes typically are not engaged in acts of interpretation at all. . . . Instead, as *Chevron* itself acknowledged, they are engaged in the " 'formulation of policy.' " . . . Statutory ambiguity thus becomes an implicit delegation of rule-making authority, and that authority is used not to find the best meaning of the text, but to formulate legally binding rules to fill in gaps based on policy judgments made by the agency rather than Congress.

Although acknowledging this fact might allow us to escape the jaws of Article III's Vesting Clause, it runs headlong into the teeth of Article I's, which vests "[a]ll legislative Powers herein granted" in Congress. U.S. Const., Art. I, § 1. For if we give the "force of law" to agency pronouncements on matters of private conduct as to which " 'Congress did not actually have an intent,' " . . . we permit a body other than Congress to perform a function that requires an exercise of the legislative power. . . .

These cases bring into bold relief the scope of the potentially unconstitutional delegations we have come to countenance in the name of *Chevron* deference. What EPA claims for itself here is not the power to make political judgments in implementing Congress' policies, nor even the power to make tradeoffs between competing policy goals set by Congress. . . . It is the power to decide—without any particular fidelity to the text—which policy goals EPA wishes to pursue. . . .

Perhaps there is some unique historical justification for deferring to federal agencies, . . . but these cases reveal how paltry an effort we have made to understand it or to confine ourselves to its boundaries. . . . As in other areas of our jurisprudence concerning administrative agencies, . . . we seem to be straying further and further from the Constitution without so much as pausing to ask why. We should stop to consider that document before blithely giving the force of law to any other agency "interpretations" of federal statutes.

## GUTIERREZ-BRIZUELA v. LYNCH

834 F.3d 1142 (10th Cir. 2016)

. . . [This immigration case required the 10th Circuit to consider the application of the Supreme Court's *Brand X* decision. Judge Gorsuch, then a Tenth Circuit judge, wrote the court's opinion and then added the following concurrence:]

GORSUCH, Circuit Judge, concurring: There's an elephant in the room with us today. We have studiously attempted to work our way around it and even left it unremarked. But the fact is *Chevron*

and *Brand X* permit executive bureaucracies to swallow huge amounts of core judicial and legislative power and concentrate federal power in a way that seems more than a little difficult to square with the Constitution of the framers' design. Maybe the time has come to face the behemoth.

. . . [Judge Gorsuch criticized the rule of *Brand X* but acknowledged that it follows logically from the rule of *Chevron*.]

But acknowledging this much only brings the colossus now fully into view. In the Administrative Procedure Act (APA), Congress vested the courts with the power to "interpret ... statutory provisions" and overturn agency action inconsistent with those interpretations. . . . And there's good reason to think that legislative assignments like these are often constitutionally compelled. After all, the question whether Congress has or hasn't vested a private legal right in an individual "is, in its nature, judicial, and must be tried by the judicial authority." . . . Yet, rather than completing the task expressly assigned to us, rather than "interpret[ing] ... statutory provisions," declaring what the law is, and overturning inconsistent agency action, *Chevron* step two tells us we must allow an executive agency to resolve the meaning of any ambiguous statutory provision. In this way, *Chevron* seems no less than a judge-made doctrine for the abdication of the judicial duty. Of course, *some* role remains for judges even under *Chevron*. At *Chevron* step one, judges decide whether the statute is "ambiguous," and at step two they decide whether the agency's view is "reasonable." But where in all this does a court *interpret* the law and say what it *is*? When does a court independently decide what the statute means and whether it has or has not vested a legal right in a person? Where *Chevron* applies that job seems to have gone extinct.

Transferring the job of saying what the law is from the judiciary to the executive unsurprisingly invites the very sort of due process (fair notice) and equal protection concerns the framers knew would arise if the political branches intruded on judicial functions. Under *Chevron* the people aren't just charged with awareness of and the duty to conform their conduct to the fairest reading of the law that a detached magistrate can muster. Instead, they are charged with an awareness of *Chevron*; required to guess whether the statute will be declared "ambiguous" (courts often disagree on what qualifies); and required to guess (again) whether an agency's interpretation will be deemed "reasonable." Who can even attempt all that, at least without an army of perfumed lawyers and lobbyists? And, of course, that's not the end of it. Even if the people somehow manage to make it through this far unscathed, they must always remain alert to the possibility that the agency will reverse its current view 180 degrees anytime based merely on the shift of political winds and *still* prevail. Neither, too, will agencies always deign to announce their views in advance; often enough they seek to impose their "reasonable" new interpretations only retroactively in administrative adjudications. Perhaps allowing agencies rather than courts to declare the law's meaning bears some advantages, but it also bears its costs. And the founders were wary of those costs, knowing that, when unchecked by independent courts exercising the job of declaring the law's meaning, executives throughout history had sought to exploit ambiguous laws as license for their own prerogative. . . .

Some claim to see a way out of our apparent predicament. They suggest that *Chevron* isn't so much about permitting agencies to assume the judicial function of *interpreting* the law as it is about permitting agencies to *make* the law, to effect their own preferences about optimal public policy when a statute is ambiguous. On this account, *Chevron*'s rule of deference isn't about trying to make judges out of agencies or letting them usurp the judicial function. Rather, it's about letting agencies fill legislative voids. When Congress passes ambiguous legislation, *Chevron* means we should read

that as signaling a legislative "intention" to "delegate" to the executive the job of making any reasonable "legislative" policy choices it thinks wise. And, to be sure, *Chevron* itself espouses just this view. . . .

But however that may be, none of it rescues us from our riddle. For whatever the *agency* may be doing under *Chevron*, the problem remains that *courts* are not fulfilling their duty to interpret the law and declare invalid agency actions inconsistent with those interpretations in the cases and controversies that come before them. A duty expressly assigned to them by the APA and one often likely compelled by the Constitution itself. That's a problem for the judiciary. And it is a problem for the people whose liberties may now be impaired not by an independent decisionmaker seeking to declare the law's meaning as fairly as possible—the decisionmaker promised to them by law—but by an avowedly politicized administrative agent seeking to pursue whatever policy whim may rule the day. Those problems remain uncured by this line of reply.

Maybe as troubling, this line of reply invites a nest of questions even taken on its own terms. *Chevron* says that we should infer from any statutory ambiguity Congress's "intent" to "delegate" its "legislative authority" to the executive to make "reasonable" policy choices. . . . But where exactly has Congress expressed this intent? Trying to infer the intentions of an institution composed of 535 members is a notoriously doubtful business under the best of circumstances. And these are not exactly the best of circumstances. *Chevron* suggests we should infer an intent to delegate not because Congress has anywhere expressed any such wish, not because anyone anywhere in any legislative history even hinted at that possibility, but because the legislation in question is *silent* (ambiguous) on the subject. Usually we're told that "an agency literally has no power to act ... unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374, 106 S.Ct. 1890, 90 L.Ed.2d 369 (1986). Yet *Chevron* seems to stand this ancient and venerable principle nearly on its head.

Maybe worse still, *Chevron*'s inference about hidden congressional intentions seems belied by the intentions Congress has made textually manifest. After all and again, in the APA Congress expressly vested the courts with the responsibility to "interpret ... statutory provisions" and overturn agency action inconsistent with those interpretations. 5 U.S.C. § 706. Meanwhile not a word can be found here about delegating legislative authority to agencies. On this record, how can anyone fairly say that Congress "intended" for courts to abdicate their statutory duty under § 706 and instead "intended" to delegate away its legislative power to executive agencies? The fact is, *Chevron*'s claim about legislative intentions is no more than a fiction—and one that requires a pretty hefty suspension of disbelief at that.

Even supposing, too, that we could overlook this problem—even supposing we somehow had something resembling an authentic congressional delegation of legislative authority—you still might wonder: *can* Congress really delegate its legislative authority—its power to write new rules of general applicability—to executive agencies? The Supreme Court has long recognized that under the Constitution "congress cannot delegate legislative power to the president" and that this "principle [is] universally recognized as vital to the integrity and maintenance of the system of government ordained by the constitution." . . . Yet on this account of *Chevron* we're examining, its whole point and purpose seems to be exactly that—to delegate legislative power to the executive branch.

Not only is *Chevron*'s purpose seemingly at odds with the separation of legislative and executive functions, its effect appears to be as well. While the line between legislative and executive

functions may sometimes be murky, history does teach us a couple of things about that line. First, we know that, consistent with the separation of powers, Congress may condition the application of a new rule of general applicability on factual findings to be made by the executive (so, for example, forfeiture of assets might be required if the executive finds a foreign country behaved in a specified manner). . . . Second, we know Congress may allow the executive to resolve "details" (like, say, the design of an appropriate tax stamp). . . . Yet *Chevron* pretty clearly involves neither of these kinds of executive functions and, in this way and as a historical matter, appears instead to qualify as a violation of the separation of powers. . . .

Of course, in relatively recent times the Court has relaxed its approach to claims of unlawful legislative delegation. It has suggested (at least in the civil arena) that Congress may allow the executive to make new rules of general applicability that look a great deal like legislation, so long as the controlling legislation contains an "intelligible principle" that "clearly delineates the general policy" the agency is to apply and "the boundaries of [its] delegated authority." . . . This means Congress must at least "provide substantial guidance on setting ... standards that affect the entire national economy." . . . Some thoughtful judges and scholars have questioned whether standards like these serve as much as a protection against the delegation of legislative authority as a license for it, undermining the separation between the legislative and executive powers that the founders thought essential.

But even taking the forgiving intelligible principle test as a given, it's no small question whether *Chevron* can clear it. For if an agency can enact a new rule of general applicability affecting huge swaths of the national economy one day and reverse itself the next (and that is exactly what *Chevron* permits . . .), you might be forgiven for asking: where's the "substantial guidance" in that? . . .

All of which raises this question: what would happen in a world without *Chevron*? If this goliath of modern administrative law were to fall? Surely Congress could and would continue to pass statutes for executive agencies to enforce. And just as surely agencies could and would continue to offer guidance on how they intend to enforce those statutes. The only difference would be that courts would then fulfill their duty to exercise their independent judgment about what the law *is*. Of course, courts could and would consult agency views and apply the agency's interpretation when it accords with the best reading of a statute. But *de novo* judicial review of the law's meaning would limit the ability of an agency to alter and amend existing law. It would avoid the due process and equal protection problems of the kind documented in our decisions. It would promote reliance interests by allowing citizens to organize their affairs with some assurance that the rug will not be pulled from under them tomorrow, the next day, or after the next election. And an agency's recourse for a judicial declaration of the law's meaning that it dislikes would be precisely the recourse the Constitution prescribes—an appeal to higher judicial authority or a new law enacted consistent with bicameralism and presentment. We managed to live with the administrative state before *Chevron*. We could do it again. Put simply, it seems to me that in a world without *Chevron* very little would change—except perhaps the most important things.

**Jonathan R. Siegel, *The Constitutional Case for Chevron Deference***
71 Vand. L. Rev. 937 (2018)

. . . [The article explains the attack on *Chevron* made by Justice Thomas, Justice Gorsuch, and others.]

## II. *Chevron* Defended

*Chevron*'s critics are demanding nothing less than a revolution in administrative law. *Chevron* has been a mainstay of the field for over thirty years. The critics do not wish to alter the details of *Chevron* doctrine. They propose no subtle refinement of *Chevron*'s Step One or Step Two or Step Zero. They want the very concept of *Chevron* deference declared unconstitutional.

. . . It is therefore vitally important to respond to the critique of *Chevron* deference. The key insight is that even when a court interprets a legal directive de novo, the court may discover that the best construction of the directive is that it vests decisionmaking power in some other body. In such a case, the court fulfills its judicial duty by accepting the determination of the other body, provided that determination is within the power vested in that body. The court in such a case does not shirk its duty to construe the legal directive de novo; rather, the court, having fulfilled its duty, finds that the governing law requires it to accept the other body's exercise of the discretion vested in it.

In responding to *Chevron*'s critics, this Essay begins by conceding some of the key assertions in their arguments. Let it be assumed that the critics are correct that there is a judicial duty to exercise "independent judgment." Assume that this duty is constitutionally based and cannot be displaced even by Congress. Assume also that this duty requires judges to conduct de novo review of interpretations given to legal instruments by the other branches of government. One might challenge these assumptions . . . but the point of this Essay is to demonstrate that the Article III critique of *Chevron* deference is mistaken *even if* one cedes these points to the critics.

The first step in the response to the critics is simple and not new. Monaghan published the core insight in 1983, before *Chevron* was decided, and it was not new even then. As Monaghan acknowledged, others had expressed the same idea in works going back as early as 1944.

The core insight, as Monaghan expresses it, is that "*[j]udicial deference to agency 'interpretation' of law is simply one way of recognizing a delegation of law-making authority to an agency*." That is, an ambiguous agency statute is simply another way of doing something that Congress does all the time--namely, authorize an agency to make a policy choice. Innumerable statutes expressly authorize agencies to make decisions and prescribe rules that have the force and effect of law, and such authorization is routinely approved as constitutional.

If Congress can delegate power to administrative agencies to make policy decisions, the precise form that the delegation takes should be of little importance. What should matter is the power delegated, not the form of the delegation. Therefore, delegating power to an administrative agency by allowing it to resolve statutory ambiguity should be valid whenever it would be valid for Congress to *expressly* delegate the power to choose among the potential reasonable interpretations of the statutory language.

This insight was not only articulated by Monaghan in 1983; it was adopted by the Supreme

Court in 1984 in *Chevron*. While *Chevron* articulated several possible explanations for *Chevron* deference, the theory most prominently expounded was the one just given. The Court explicitly analogized giving *Chevron* deference to agency interpretations of ambiguous statutes to respecting the exercise of powers expressly delegated to an agency. In the critical paragraph, the Court said:

> If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.

That is, the Court adopted the notion that ambiguity in an agency statute is to be considered an "implicit" delegation of power to the agency, and this power should be analogized to the "express delegations" of power to agencies that occur all the time.

Thus, the basic response to the critics is simple, already established in the scholarly literature, and already unanimously approved by the Supreme Court. *Chevron* deference is constitutionally permissible because it is merely a way of conceiving of what Congress is doing when it gives an agency ambiguous instructions. Permitting an agency to resolve such ambiguity is "simply one way of recognizing a delegation of law-making authority."[150]

So is the debate over? Not at all.

*C. Responding to the Critics' Rejoinder*

The critics are, of course, aware of the core insight discussed in the previous Section. They deny that it shows *Chevron* deference to be constitutional. Fine, the critics say, let it be assumed that Congress intends every ambiguous statutory instruction it gives to a federal agency to constitute a delegation of power to the agency to resolve the ambiguity. That wouldn't matter. Congress, the critics say, cannot displace the courts' duty to exercise independent judgment in construing statutes. That duty derives from the Constitution and cannot be changed by statute. [Philip] Hamburger [a professor at Columbia who has written on this topic], for example, says that it "makes no difference whether Congress authorizes agencies to interpret. ... [N]o amount of statutory authority for agencies can ever relieve judges of their constitutional duty."

Thus, to refute the critics, one needs more than simply the core idea previously articulated by Monaghan and embraced by the Supreme Court. One must also respond to the critics' rejoinder to the core idea.

1. What Constitutes an "Interpretation"?

The key response to the critics' rejoinder is that *Chevron* deference, properly understood, does not prevent a court from interpreting statutes. An interpretation of a statute that determines that the statute delegates authority to an administrative agency is still an interpretation. Even if one accepts the critics' understanding of the judicial duty of interpreting a statute--even assuming it to require

a court to exercise "independent judgment"--the result of exercising that duty might still be the conclusion that Congress has vested the agency with the power to make a policy choice.

Certainly there can be no Article III rule against a court's interpreting a statute to delegate power to an agency. Courts do that all the time, because statutes delegate power to agencies all the time. The Communications Act of 1934, for example, authorizes the FCC to "[m]ake such rules and regulations and prescribe such restrictions and conditions, not inconsistent with law, as may be necessary to carry out the provisions of this chapter."-Even before *Chevron* the Supreme Court interpreted this section to authorize the Commission to make important decisions about communications policy, for example, to adopt the "fairness doctrine." It would be absurd to say that the Court, in so holding, was abdicating its judicial duty to interpret the statute. The Court interpreted the statute--it interpreted the statute to authorize the agency to decide to impose the fairness doctrine.

Of course, that statute contained an express delegation of authority. The question of what constitutes an "interpretation" is, however, independent of the degree of clarity of the statute. A court that holds that an ambiguous statute constitutes a delegation of power to the agency is interpreting the statute--it is interpreting the statute to authorize the agency to make a decision. The interpretation may be right or wrong, but it is certainly an interpretation.[155]

This insight addresses the critics' complaints about *Chevron*. For example, as noted above,[156] Justice Gorsuch expresses the critics' point by asking "where in [the *Chevron* two-step process] does a court *interpret* the law and say what it *is*?" The answer is that the court *interprets* the law when it determines that the law delegates power to an administrative agency. The court says what the law *is* when it says that the law *is* that an agency is vested with the power to make a certain decision. An interpretation is no less an interpretation because it determines that an agency has the power to make a choice.

The proper exercise of the judicial duty does not have to answer every question. As the Supreme Court once remarked, the "judicial duty is not less fitly performed" when the result of exercising that duty is a determination that the court lacks jurisdiction. Similarly, the judicial duty is not less fitly performed when the result of exercising that duty is a determination that Congress has vested power in an administrative agency.

2. The Nature of the Power Conferred on the Agency

This conception of *Chevron* deference does require a subtle but important shift in the conception of what kind of power Congress implicitly delegates to an agency when it gives an agency an ambiguous statutory instruction. It is often said that under *Chevron* an ambiguity in an agency-administered statute constitutes an implicit delegation of power to the agency to *interpret* the statute. Indeed, the Supreme Court may have said this in *Chevron* itself. In the critical passages from *Chevron*, the Court said:

> If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to *elucidate* a specific provision of the statute by regulation. ... Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own *construction* of a statutory provision

for a reasonable *interpretation* made by the administrator of an agency.[161]

The Court's use of the terms "elucidate," "construction," and "interpretation" suggest, even if they do not compel, the view that an ambiguous term in an agency statute is to be taken as an implicit delegation of authority to the agency to *interpret* the statute. The Court also, however, referred to "an agency to which Congress has delegated *policymaking* responsibilities," so the opinion was not perfectly clear as to what kind of power an ambiguous statute implicitly delegates to an agency. In any event, whether *Chevron* said it or not, the notion that under *Chevron* ambiguous agency statutes are deemed to be delegations of interpretive power has become common. Moreover, in this conception of *Chevron*, the term "interpret" is being used in the strong sense explained earlier--necessarily so, as the agency always has the power to interpret statutes in the simple sense.

In light of the critics' Article III argument, this conception of *Chevron*, however accurate as a practical description of how *Chevron* works, must be shifted. Congress, it should be recognized, does not give agencies power to *interpret* ambiguous statutes that they administer, in the strong sense of "interpret." As the critics observe, that power--the power to definitively determine the meaning of statutes--belongs to the courts. Agencies may (and indeed must) interpret statutes in the simple sense, but only the courts can give them definitive meaning in a judicial proceeding.

As explained above, however, when a court exercises the power to interpret statutes, the court may determine that a statute's best interpretation is that the statute confers power on the agency. The power thus conferred should not be regarded as interpretive power, but as the power to make a policy choice. Specifically, it is the power to choose to implement any of the reasonable interpretations of the statute. An interpretation of an ambiguous statute as vesting such power in the agency is an interpretation, and giving such an interpretation to a statute may fulfill the judicial duty to exercise independent judgment. . . .

[The article responds to some further arguments, including:]

2. Questioning Whether Congress Intended *Chevron* Deference

The main focus of this Essay has been on the critics' constitutional critique of *Chevron*. Some of the critics, however, also question whether *Chevron* is correct as a matter of statutory construction. . . .

On this issue, the critics have a good point. Congress's *actual* direction to courts with regard to legal issues that arise in judicial review of administrative action, insofar as one exists, is § 706 of the Administrative Procedure Act. That statute provides that "[t]o the extent necessary to decision and when presented, the reviewing court shall *decide all relevant questions of law, interpret constitutional and statutory provisions*, and determine the meaning or applicability of the terms of an agency action." While this language is not, perhaps, completely inconsistent with deferential review, it is surely suggestive of a de novo standard. Indeed, Kenneth Culp Davis made this point almost apoplectically in his famous Administrative Law Treatise decades ago.

It is not the purpose of this Essay to defend *Chevron* against the charge that it misconstrues Congress's actual direction to courts regarding statutory interpretation. Perhaps the best that can be

said is that Congress's silence in the face of the long-standing judicial decisions giving deference to agency statutory construction--particularly since *Chevron* but going back even before that--suggests that Congress is not averse to *Chevron* deference. Of course, reasoning from congressional silence is always dangerous, and never more so than in an area in which such silence is imagined to give rise to an inference that Congress has delegated power to the executive. In such an area the president would likely veto any congressional attempt to reclaim the power, and so it would be particularly difficult for Congress to defeat the inference by express action. So the suggestion that courts may infer congressional approval of *Chevron* from Congress's failure to overturn it is offered tepidly, only so that this critical argument might receive some response. . . .

4. Does *Chevron* Violate the Nondelegation Doctrine?

As noted earlier, some of the critics acknowledge that the alleged Article III problem with *Chevron* might be ameliorated by regarding the power implicitly delegated to agencies by an ambiguous statute as being not the power to *interpret* the statute, but rather the power to make a *policy choice*. They suggest, however, that so conceived, *Chevron* may violate the nondelegation doctrine. Congress, these critics suggest, may no more give agencies the legislative power than it may give them the judicial power. *Chevron*, they contend, makes a mockery of the nondelegation doctrine's requirement that statutes granting discretion to agencies must lay down an "intelligible principle" to guide that discretion.

There can be little doubt that the nondelegation doctrine has failed to live up to that promise. Courts apply the "intelligible principle" test in theory but in practice approve delegations of power restricted by principles that can only be called unintelligible. Courts approve delegations limited by standards such as that rates be "just and reasonable," or that an agency's actions serve "the public interest, convenience, and necessity," even though these empty standards are open to "any conceivable interpretation." Courts applying the "intelligible principle" test regularly find "intelligible principles where less discerning readers find gibberish." The result is that "supposed limitations on delegations of legislative power are little more than a legal joke."

So the critics are correct that the nondelegation doctrine does little to enforce its supposed restraints on the delegation of legislative power to executive agencies. Again, however, what is missing from the critics' arguments is any real showing that *Chevron* makes things worse in this regard. Recall that, as noted earlier, Congress might have *expressly* delegated to an agency any choice that it is deemed under *Chevron* to have delegated implicitly via ambiguity. Such an express delegation of power to make a policy choice might or might not violate the nondelegation doctrine (almost certainly not, these days), but if it does not, a functionally equivalent implicit delegation of power to make the same choice should be equally valid. The nondelegation doctrine is about whether the executive is capable of receiving a given choicemaking power at all, not about whether Congress confers the power implicitly or explicitly. . . .

Justice Gorsuch argues that *Chevron* makes things worse (from the perspective of the nondelegation doctrine) by permitting agencies to change their interpretations of ambiguous statutes over time. Permitting such vacillation, he argues, erodes the limitations that the nondelegation doctrine requires on the exercise of delegated power. Again, however, *Chevron* makes things no

worse on this point. Agencies are equally allowed to change the rules they make when acting pursuant to express delegations of power. Any vacillation permitted by *Chevron* could equally be permitted by an express delegation of power to make a policy choice accompanied by express authorization to vary that choice over time in response to changing social and political conditions . . . . Again, there might or might not be a nondelegation problem, but if there is one, it derives from the scope of the power conferred, not from the fact that the power is conferred implicitly via statutory ambiguity.

Perhaps what Justices Thomas and Gorsuch mean is that the principle of *Chevron* deference violates nondelegation as it *should* be--a robust, reinvigorated nondelegation doctrine of the kind that Justice Thomas has hinted he might be willing to adopt. That may well be true. If the nondelegation doctrine were more robust, it might forbid empowering agencies to make the choices that *Chevron* posits Congress has delegated to them. But such a vigorous nondelegation doctrine would equally undermine Congress's ability to delegate those same choices to agencies expressly. Again, the issue is the vast degree of delegation that the Court has approved, not the way that *Chevron* allows the delegation to be implicit rather than express.

## Conclusion

The recent constitutional attacks on *Chevron* are misdirected. *Chevron* does not wrest the interpretive power from courts and give it to the executive. Even accepting the critics' claim that courts must exercise “independent judgment” when determining the meaning of statutes, *Chevron* does not prevent courts from exercising such judgment. *Chevron* does not prevent courts from fulfilling their duty to interpret statutes. An interpretation of a statute that concludes that the statute delegates power to an executive agency is still an interpretation

**TOILET GOODS ASSOCIATION V. GARDNER**
**387 U.S. 158 (1967)**

MR. JUSTICE HARLAN delivered the opinion of the Court.

Petitioners in this case are the Toilet Goods Association, an organization of cosmetics manufacturers accounting for some 90% of annual American sales in this field, and 39 individual cosmetics manufacturers and distributors. They brought this action in the United States District Court for the Southern District of New York seeking declaratory and injunctive relief against the Secretary of Health, Education, and Welfare and the Commissioner of Food and Drugs, on the ground that certain regulations promulgated by the Commissioner exceeded his statutory authority under the Color Additive Amendments to the Federal Food, Drug and Cosmetic Act, 74 Stat. 397, 21 U.S.C. §§321-376. . . . [The district court held the case justiciable; the court of appeals affirmed as to three of the challenged regulations but reversed as to a fourth. Both sides sought and were granted certiorari, in two separate cases. This case dealt with the fourth regulation.]

[We] agree with the Court of Appeals that judicial review of this particular regulation in this particular context is inappropriate at this stage because, applying the standards set forth in *Abbott Laboratories v. Gardner,* the controversy is not presently ripe for adjudication.

The regulation in issue here was promulgated under the Color Additive Amendments of 1960. . . . The Commissioner of Food and Drugs . . . issued the following regulation . . . :

> "(a) When it appears to the Commissioner that a person has:
>
> "(4) Refused to permit duly authorized employees of the Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived; 'he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.' " 28 Fed. Reg. 6445-6446; 21 CFR §8.28.

The petitioners maintain that this regulation is an impermissible exercise of authority, that the FDA has long sought congressional authorization for free access to facilities, processes, and formulae . . . , but that Congress has always denied the agency this power except for prescription drugs. . . . Framed in this way, we agree with petitioners that a "legal" issue is raised, but nevertheless we are not persuaded that the present suit is properly maintainable.

In determining whether a challenge to an administrative regulation is ripe for review a twofold inquiry must be made: first to determine whether the issues tendered are appropriate for judicial resolution, and second to assess the hardship to the parties if judicial relief is denied at that stage.

As to the first of these factors, we agree with the Court of Appeals that the legal issue as presently framed is not appropriate for judicial resolution. This is not because the regulation is not the agency's considered and formalized determination, for . . . there can be no question that this regulation — promulgated in a formal manner after notice and evaluation of submitted comments — is a "final agency action" under §10 of the Administrative Procedure Act, 5 U.S.C. §704. See

*Abbott Laboratories v. Gardner*, 387 U.S. 136. Also, we recognize the force of petitioners' contention that the issue as they have framed it presents a purely legal question: whether the regulation is totally beyond the agency's power under the statute, the type of legal issue that courts have occasionally dealt with without requiring a specific attempt at enforcement, . . . or exhaustion of administrative remedies. . . .

These points which support the appropriateness of judicial resolution are, however, outweighed by other considerations. The regulation serves notice only that the Commissioner may under certain circumstances order inspection of certain facilities and data, and that further certification of additives may be refused to those who decline to permit a duly authorized inspection until they have complied in that regard. At this juncture we have no idea whether or when such an inspection will be ordered and what reasons the Commissioner will give to justify his order. The statutory authority asserted for the regulation is the power to promulgate regulations 'for the efficient enforcement' of the Act, §701(a). Whether the regulation is justified thus depends not only, as petitioners appear to suggest, on whether Congress refused to include a specific section of the Act authorizing such inspections, although this factor is to be sure a highly relevant one, but also on whether the statutory scheme as a whole justified promulgation of the regulation. . . . This will depend not merely on an inquiry into statutory purpose, but concurrently on an understanding of what types of enforcement problems are encountered by the FDA, the need for various sorts of supervision in order to effectuate the goals of the Act, and the safeguards devised to protect legitimate trade secrets (see 21 CFR §130.14(c)). We believe that judicial appraisal of these factors is likely to stand on a much surer footing in the context of a specific application of this regulation than could be the case in the framework of the generalized challenge made here.

We are also led to this result by considerations of the effect on the petitioners of the regulation, for the test of ripeness, as we have noted, depends not only on how adequately a court can deal with the legal issue presented, but also on the degree and nature of the regulation's present effect on those seeking relief. The regulation challenged here is not analogous to those that were involved in [other cases], where the impact of the administrative action could be said to be felt immediately by those subject to it in conducting their day-to-day affairs. . . .

This is not a situation in which primary conduct is affected — when contracts must be negotiated, ingredients tested or substituted, or special records compiled. This regulation merely states that the Commissioner may authorize inspectors to examine certain processes or formulae; no advance action is required of cosmetics manufacturers, who since the enactment of the 1938 Act have been under a statutory duty to permit reasonable inspection of a "factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein." §704(a). Moreover, no irremediable adverse consequences flow from requiring a later challenge to this regulation by a manufacturer who refuses to allow this type of inspection. Unlike the other regulations challenged in this action, in which seizure of goods, heavy fines, adverse publicity for distributing "adulterated" goods, and possible criminal liability might penalize failure to comply, . . . a refusal to admit an inspector here would at most lead only to a suspension of certification services to the particular party, a determination that can then be promptly challenged through an administrative procedure, which in turn is reviewable by a court. Such review will provide an adequate forum for testing the regulation in a concrete situation.

It is true that the administrative hearing will deal with the "factual basis" of the suspension, from which petitioners infer that the Commissioner will not entertain and consider a challenge to his statutory authority to promulgate the regulation. Whether or not this assumption is correct, given the fact that only minimal, if any, adverse consequences will face petitioners if they challenge the regulation in this manner, we think it wiser to require them to exhaust this administrative process through which the factual basis of the inspection order will certainly be aired and where more light may be thrown on the Commissioner's statutory and practical justifications for the regulation. . . . Judicial review will then be available, and a court at that juncture will be in a better position to deal with the question of statutory authority. . . .

For these reasons the judgment of the Court of Appeals is affirmed.

MR. JUSTICE DOUGLAS dissents for the reasons stated by Judge Tyler of the District Court, 235 F. Supp. 648, 651-652.

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

MR. JUSTICE FORTAS, with whom THE CHIEF JUSTICE and MR. JUSTICE CLARK join, concurring in [*Toilet Goods*], and dissenting in [*Abbott Labs*].

. . . [E]stablished 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. . . . In none of these cases is judicial interference warranted at this stage, in this fashion, and to test—on a gross, free-wheeling basis—whether the content of these regulations is within the statutory intendment. The contrary is dictated by a proper regard for the purpose of the regulatory statute and the requirements of effective administration; and by regard for the salutary rule that courts should pass upon concrete, specific questions in a particularized setting rather than upon a general controversy divorced from particular facts.

. . . 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. . . . 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. . . .

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. . . .

The [Act authorizes] . . . the Attorney General to institute three types of proceedings. First, . . . he may apply to the district courts of the United States for injunctive relief. . . . Second, . . . the Attorney General may institute libel proceedings in the district courts and seek orders for seizure of

any misbranded or adulterated food, drug, device, or cosmetic. Third, criminal prosecution is authorized for violations. . . . The present regulations concededly would be reviewable in the course of any of the above proceedings. . . .

[The Court] 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 . ···

[Justice Fortas discussed three previous cases in which pre-enforcement review of regulations had been allowed pursuant to specific statutory authorization and noted that those cases had involved "stark, simple" regulations "which do not depend upon the specifics of a particular situation for judgment as to their consonance with statutory authority." He then contrasted the present case:]

The regulation in [*Abbott Labs*] relates to a 1962 amendment to the Act requiring manufacturers of prescription drugs to print on the labels or other printed material, 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." . . . Obviously, this requires some elucidation, either case-by-case or by general regulation or pronouncement, because the statute does not say that this must be done "every time," or only once on each label or in each pamphlet, or once per panel, etc., or that it must be done differently on labels than on circulars, or doctors' literature than on directions to the patients, etc. This is exactly the traditional purpose and function of an administrative agency. . . .

The Court, . . . moved by petitioners' claims as to the expense and inconvenience of compliance and the risks of deferring challenge by noncompliance, decrees that the manufacturers may have their suit for injunction at this time . . . . The Court says that this confronts the manufacturer with a "real dilemma." But 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. . . . [I]f the Court refused to permit this shotgun assault, experience and reasonably sophisticated common sense show that there would be orderly compliance without the disaster so dramatically predicted by the industry, reasonable adjustments by the agency in real hardship cases, and where extreme intransigence involving substantial violations occurred, enforcement actions in which legality of the regulation would be tested in specific, concrete situations. . . . The courts cannot properly—and should not—attempt to judge in the abstract and generally whether this regulation is within the statutory scheme. Judgment as to the "every time" regulation should be made only in light of specific situations, and it may differ depending upon whether the FDA seeks to enforce it as to doctors' circulars, pamphlets for patients, labels, etc.

. . . The courts do not and should not pass on these complex problems in the abstract and the general — because these regulations peculiarly depend for their quality and substance upon the facts of particular situations. We should confine ourselves—as our jurisprudence dictates—to actual, specific, particularized cases and controversies . . . .