

**MERRELL DOW PHARMACEUTICALS,  
INC. v. THOMPSON**

Supreme Court of the United States, 1986.  
478 U.S. 804, 106 S.Ct. 3229, 92 L.Ed.2d 650.

JUSTICE STEVENS delivered the opinion of the Court.

The question presented is whether the incorporation of a federal standard in a state-law private action, when Congress has intended that there not be a federal private action for violations of that federal standard, makes the action one “arising under the Constitution, laws, or treaties of the United States,” 28 U.S.C. § 1331.

I

The Thompson respondents are residents of Canada and the MacTavishes reside in Scotland. They filed virtually identical complaints against petitioner, a corporation, that manufactures and distributes the drug Bendectin. The complaints were filed in the Court of Common Pleas in Hamilton County, Ohio. Each complaint alleged that a child was born with multiple deformities as a result of the mother’s ingestion of Bendectin during pregnancy. In five of the six counts, the recovery of substantial damages was requested on common-law theories of negligence, breach of warranty, strict liability, fraud, and gross negligence. In Count IV, respondents alleged that the drug Bendectin was “misbranded” in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), because its labeling did not provide adequate warning that its use was potentially dangerous. [Plaintiffs] alleged that the violation of the FDCA “in the promotion” of Bendectin “constitutes a rebuttable presumption of negligence.” [They further] alleged that the “violation of said federal statutes directly and proximately caused the injuries suffered” by the two infants.

Petitioner filed a timely petition for removal from the state court to the Federal District Court alleging that the action was “founded, in part, on an alleged claim arising under the laws of the United States.” After removal, the two cases were consolidated. Respondents filed a motion to remand to the state forum on the ground that the federal court lacked subject-matter jurisdiction. Relying on our decision in *Smith v. Kansas City Title & Trust Co.*, the District Court held that Count IV of the complaint alleged a cause of action arising under federal law and denied the motion to remand. It then granted petitioner’s motion to dismiss on *forum non conveniens* grounds.

The Court of Appeals for the Sixth Circuit reversed. After quoting one sentence from the concluding paragraph in our recent opinion in *Franchise Tax Board v. Construction Laborers Vacation Trust*, and noting “that the FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act,” it explained:

Federal question jurisdiction would, thus, exist only if plaintiffs’ right to relief *depended necessarily* on a substantial question of federal law. Plaintiffs’ causes of action referred to the FDCA merely as one available criterion for determining whether Merrell Dow was negligent. Because the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA, the plaintiffs’ causes of action did not depend necessarily upon a question of federal law. Consequently, the causes of action did not arise under federal law and, therefore, were improperly removed to federal court.

We granted certiorari, and we now affirm.

II

Article III of the Constitution gives the federal courts power to hear cases “arising under” federal statutes. That grant of power, however, is not self-executing, and it was not until the Judiciary Act of 1875 that Congress gave the federal courts general federal-question jurisdiction. Although the constitutional meaning of “arising under” may extend to all cases in

which a federal question is “an ingredient” of the action, *Osborn v. Bank of the United States*, we have long construed the statutory grant of federal-question jurisdiction as conferring a more limited power.

Under our longstanding interpretation of the current statutory scheme, the question whether a claim “arises under” federal law must be determined by reference to the “well-pleaded complaint.” A defense that raises a federal question is inadequate to confer federal jurisdiction. Since a defendant may remove a case only if the claim could have been brought in federal court, moreover, the question for removal jurisdiction must also be determined by reference to the “well-pleaded complaint.”

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\* \* \* [T]he propriety of the removal in this case thus turns on whether the case falls within the original “federal question” jurisdiction of the federal courts. There is no “single, precise definition” of that concept; rather, “the phrase ‘arising under’ masks a welter of issues regarding the interrelation of federal and state authority and the proper management of the federal judicial system.”

This much, however, is clear. The “vast majority” of cases that come within this grant of jurisdiction are covered by Justice Holmes’ statement that a “ ‘suit arises under the law that creates the cause of action.’ ” Thus, the vast majority of cases brought under the general federal-question jurisdiction of the federal courts are those in which federal law creates the cause of action.

We have, however, also noted that a case may arise under federal law “where the vindication of a right under state law necessarily turned on some construction of federal law.”  
\* \* \*

This case does not pose a federal question of the first kind; respondents do not allege that federal law creates any of the causes of action that they have asserted. This case thus poses what Justice Frankfurter called the “litigation-provoking problem,”—the presence of a federal issue in a state-created cause of action.

In undertaking this inquiry into whether jurisdiction may lie for the presence of a federal issue in a nonfederal cause of action, it is, of course, appropriate to begin by referring to our understanding of the statute conferring federal-question jurisdiction. We have consistently emphasized that, in exploring the outer reaches of § 1331, determinations about federal jurisdiction require sensitive judgments about congressional intent, judicial power, and the federal system.

If the history of the interpretation of judiciary legislation teaches us anything, it teaches the duty to reject treating such statutes as a wooden set of self-sufficient words \* \* \*. The Act of 1875 is broadly phrased, but it has been continuously construed and limited in the light of the history that produced it, the demands of reason and coherence, and the dictates of sound judicial policy which have emerged from the Act’s function as a provision in the mosaic of federal judiciary legislation.

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[The Court sometimes has implied a private right of action in a statute or constitutional provision. Justice Stevens noted that both parties and the Court of Appeals concluded that there was no private right of action under FDCA. If there had been, the case would have come within Justice Holmes’s creation test and qualified under § 1331.]

The significance of the necessary assumption that there is no federal private cause of action thus cannot be overstated. For the ultimate import of such a conclusion, as we have repeatedly emphasized, is that it would flout congressional intent to provide a private federal remedy for the violation of the federal statute. We think it would similarly flout, or at least

undermine, congressional intent to conclude that the federal courts might nevertheless exercise federal-question jurisdiction and provide remedies for violations of that federal statute solely because the violation of the federal statute is said to be a “rebuttable presumption” or a “proximate cause” under state law, rather than a federal action under federal law.

### III

Petitioner advances three arguments to support its position that, even in the face of this congressional preclusion of a federal cause of action for a violation of the federal statute, federal-question jurisdiction may lie for the violation of the federal statute as an element of a state cause of action.

First, petitioner contends that the case represents a straightforward application of the statement \* \* \* that federal-question jurisdiction is appropriate when “it appears that some substantial, disputed question of federal law is a necessary element of one of the well-pleaded state claims.” *Franchise Tax Board*, however, did not purport to disturb the long-settled understanding that the mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction. Indeed, in determining that federal-question jurisdiction was not appropriate in the case before us, we stressed Justice Cardozo’s emphasis on principled, pragmatic distinctions: “What is needed is something of that common-sense accommodation of judgment to kaleidoscopic situations which characterizes the law in its treatment of causation \* \* \* a selective process which picks the substantial causes out of the web and lays the other ones aside.’”

\* \* \*

Given the significance of the assumed congressional determination to preclude federal private remedies, the presence of the federal issue as an element of the state tort is not the kind of adjudication for which jurisdiction would serve congressional purposes and the federal system.

\* \* \*

We simply conclude that the congressional determination that there should be no federal remedy for the violation of this federal statute is tantamount to a congressional conclusion that the presence of a claimed violation of the statute as an element of a state cause of action is insufficiently “substantial” to confer federal-question jurisdiction.<sup>12</sup>

Second, petitioner contends that there is a powerful federal interest in seeing that the federal statute is given uniform interpretations, and that federal review is the best way of insuring such uniformity. In addition to the significance of the congressional decision to pre-

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<sup>12</sup> Several commentators have suggested that our § 1331 decisions can best be understood as an evaluation of the nature of the federal interest at stake. Focusing on the nature of the federal interest, moreover, suggests that the widely perceived “irreconcilable” conflict between the finding of federal jurisdiction in *Smith v. Kansas City Title & Trust Co.*, and the finding of no jurisdiction in *Moore v. Chesapeake & Ohio R. Co.* is far from clear. For the difference in results can be seen as manifestations of the differences in the nature of the federal issues at stake. In *Smith*, as the Court emphasized, the issue was the constitutionality of an important federal statute. (“It is \* \* \* apparent that the controversy concerns the constitutional validity of an act of Congress which is directly drawn in question. The decision depends upon the determination of this issue”). In *Moore*, in contrast, the Court emphasized that the violation of the federal standard as an element of state tort recovery did not fundamentally change the state tort nature of the action. (“The action fell within the familiar category of cases involving the duty of a master to his servant. This duty is defined by the common law, except as it may be modified by legislation. The federal statute, in the present case, touched the duty of the master at a single point and, save as provided in the statute, the right of the plaintiff to recover was left to be determined by the law of the State’ ”).

The importance of the nature of the federal issue in federal-question jurisdiction is highlighted by the fact that, despite the usual reliability of the Holmes test as an inclusionary principle, this Court has sometimes found that formally federal causes of action were not properly brought under federal-question jurisdiction because of the overwhelming predominance of state-law issues.

clude a federal remedy, we do not agree with petitioner's characterization of the federal interest and its implications for federal-question jurisdiction. To the extent that petitioner is arguing that state use and interpretation of the FDCA pose a threat to the order and stability of the FDCA regime, petitioner should be arguing, not that federal courts should be able to review and enforce state FDCA-based causes of action as an aspect of federal-question jurisdiction, but that the FDCA pre-empts state-court jurisdiction over the issue in dispute. Petitioner's concern about the uniformity of interpretation, moreover, is considerably mitigated by the fact that, even if there is no original district court jurisdiction for these kinds of action, this Court retains power to review the decision of a federal issue in a state cause of action.

Finally, petitioner argues that, whatever the general rule, there are special circumstances that justify federal-question jurisdiction in this case. Petitioner emphasizes that it is unclear whether the FDCA applies to sales in Canada and Scotland; there is, therefore, a special reason for having a federal court answer the novel federal question relating to the extraterritorial meaning of the Act. We reject this argument. We do not believe the question whether a particular claim arises under federal law depends on the novelty of the federal issue. Although it is true that federal jurisdiction cannot be based on a frivolous or insubstantial federal question, "the interrelation of federal and state authority and the proper management of the federal judicial system," would be ill served by a rule that made the existence of federal-question jurisdiction depend on the district court's case-by-case appraisal of the novelty of the federal question asserted as an element of the state tort. The novelty of an FDCA issue is not sufficient to give it status as a federal cause of action; nor should it be sufficient to give a state-based FDCA claim status as a jurisdiction-triggering federal question.<sup>15</sup>

#### IV

We conclude that a complaint alleging a violation of a federal statute as an element of a state cause of action, when Congress has determined that there should be no private, federal cause of action for the violation, does not state a claim "arising under the Constitution, laws, or treaties of the United States."

The judgment of the Court of Appeals is affirmed.

*It is so ordered.*

JUSTICE BRENNAN, with whom JUSTICE WHITE, JUSTICE MARSHALL, and JUSTICE BLACKMUN join, dissenting.

\* \* \*

I believe that the limitation on federal jurisdiction recognized by the Court today is inconsistent with the purposes of § 1331. Therefore, I respectfully dissent.

#### I

While the majority of cases covered by § 1331 may well be described by Justice Holmes' adage that "[a] suit arises under the law that creates the cause of action," it is firmly settled that there may be federal-question jurisdiction even though both the right asserted and the remedy sought by the plaintiff are state created. The rule as to such cases was stated in

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<sup>15</sup> Petitioner also contends that the Court of Appeals opinion rests on a view that federal-question jurisdiction was inappropriate because, whatever the role of the federal issue in the FDCA-related count, the plaintiff could recover on other, strictly state-law claims \* \* \* (noting that "the jury could find negligence on the part of Merrell Dow without finding a violation of the FDCA"). To the extent that the opinion can be read to express such a view, we agree that it was erroneous. If the FDCA-related count presented a sufficient federal question, its relationship to the other, state-law claims would be determined by the ordinary principles of pendent jurisdiction described in [*United*] *Mine Workers v. Gibbs*. For the reasons that we have stated, however, there is no federal-question jurisdiction even with that possible error corrected.

what Judge Friendly described as “[t]he path-breaking opinion” in *Smith v. Kansas City Title & Trust Co.*<sup>1</sup>

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The continuing vitality of *Smith* is beyond challenge. We have cited it approvingly on numerous occasions, and reaffirmed its holding several times—most recently just three Terms ago by a unanimous Court \* \* \*.

\* \* \*

There is, to my mind, no question that there is federal jurisdiction over the respondents’ fourth cause of action under the rule set forth in *Smith* and reaffirmed in *Franchise Tax Board*. Respondents pleaded that petitioner’s labeling of the drug Bendectin constituted “misbranding” in violation of \* \* \* the Federal Food, Drug, and Cosmetic Act (FDCA), and that this violation “directly and proximately caused” their injuries. Respondents asserted in the complaint that this violation established petitioner’s negligence *per se* and entitled them to recover damages without more. No other basis for finding petitioner negligent was asserted in connection with this claim. As pleaded, then, respondents’ “right to relief depend[ed] upon the construction or application of the Constitution or laws of the United States.” Furthermore, although petitioner disputes its liability under the FDCA, it concedes that respondents’ claim that petitioner violated the FDCA is “colorable, and rests upon a reasonable foundation.” Of course, since petitioner must make this concession to prevail in this Court, it need not be accepted at face value. However, independent examination of respon-

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<sup>1</sup> Some commentators have argued that the result in *Smith* conflicts with our decision in *Moore v. Chesapeake & Ohio R. Co.* In *Moore*, the plaintiff brought an action under Kentucky’s Employer Liability Act, which provided that a plaintiff could not be held responsible for contributory negligence or assumption of risk where his injury resulted from the violation of any state or federal statute enacted for the safety of employees. The plaintiff in *Moore* alleged that his injury was due to the defendant’s failure to comply with the Federal Safety Appliance Act; therefore, an important issue in the adjudication of the state cause of action was whether the terms of the federal law had been violated. The Court could have dismissed the complaint on the ground that the federal issue would arise only in response to a defense of contributory negligence or assumption of risk, and that therefore there was no jurisdiction under the well-pleaded complaint rule. Instead, the Court held that “a suit brought under the state statute which defines liability to employees who are injured while engaged in intrastate commerce, and brings within the purview of the statute a breach of the duty imposed by the federal statute, should [not] be regarded as a suit arising under the laws of the United States and cognizable in the federal court in the absence of diversity of citizenship.”

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In one sense, the Court is correct in asserting that we can reconcile *Smith* and *Moore* on the ground that the “nature” of the federal interest was more significant in *Smith* than in *Moore*. Indeed, as the Court appears to believe, we could reconcile many of the seemingly inconsistent results that have been reached under § 1331 with such a test. But this is so only because a test based upon an *ad hoc* evaluation of the importance of the federal issue is infinitely malleable: at what point does a federal interest become strong enough to create jurisdiction? What principles guide the determination whether a statute is “important” or not? Why, for instance, was the statute in *Smith* so “important” that direct review of a state-court decision (under our mandatory appellate jurisdiction) would have been inadequate? Would the result in *Moore* have been different if the federal issue had been a more important element of the tort claim? The point is that if one makes the test sufficiently vague and general, virtually any set of results can be “reconciled.” However, the inevitable—and undesirable—result of a test such as that suggested in the Court’s footnote 12 is that federal jurisdiction turns in every case on an appraisal of the federal issue, its importance and its relation to state-law issues. Yet it is precisely because the Court believes that federal jurisdiction would be “ill served” by such a case-by-case appraisal that it rejects petitioner’s claim that the difficulty and importance of the statutory issue presented by its claim suffices to confer jurisdiction under § 1331. The Court cannot have it both ways.

My own view is in accord with those commentators who view the results in *Smith* and *Moore* as irreconcilable. That fact does not trouble me greatly, however, for I view *Moore* as having been a “sport” at the time it was decided and having long been in a state of innocuous desuetude. Unlike the jurisdictional holding in *Smith*, the jurisdictional holding in *Moore* has never been relied upon or even cited by this Court. *Moore* has similarly borne little fruit in the lower courts, leading Professor Redish to conclude after comparing the vitality of *Smith* and *Moore* that “the principle enunciated in *Smith* is the one widely followed by modern lower federal courts.” Finally, as noted in text, the commentators have also preferred *Smith*. *Moore* simply has not survived the test of time; it is presently moribund, and, to the extent that it is inconsistent with the well-established rule of the *Smith* case, it ought to be overruled.

dents' claim substantiates the conclusion that it is neither frivolous nor meritless. As stated in the complaint, a drug is "misbranded" under the FDCA if "the labeling or advertising fails to reveal facts material \* \* \* with respect to consequences which may result from the use of the article to which the labeling or advertising relates \* \* \* ." Obviously, the possibility that a mother's ingestion of Bendectin during pregnancy could produce malformed children is material. Petitioner's principal defense is that the Act does not govern the branding of drugs that are sold in foreign countries. It is certainly not immediately obvious whether this argument is correct. Thus, the statutory question is one which "discloses a need for determining the meaning or application of [the FDCA]," and the claim raised by the fourth cause of action is one "arising under" federal law within the meaning of § 1331.

## II

The Court apparently does not disagree with any of this—except, of course, for the conclusion. According to the Court, if we assume that Congress did not intend that there be a private federal cause of action under a particular federal law (and, presumably, *a fortiori* if Congress' decision not to create a private remedy is express), we must also assume that Congress did not intend that there be federal jurisdiction over a state cause of action that is determined by that federal law. Therefore, assuming—only because the parties have made a similar assumption—that there is no private cause of action under the FDCA,<sup>4</sup> the Court holds that there is no federal jurisdiction over the plaintiffs' claim.

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The Court nowhere explains the basis for this conclusion. Yet it is hardly self-evident. Why should the fact that Congress chose not to create a private federal *remedy* mean that Congress would not want there to be federal *jurisdiction* to adjudicate a state claim that imposes liability for violating the federal law? Clearly, the decision not to provide a private federal remedy should not affect federal jurisdiction unless the reasons Congress withholds a federal remedy are also reasons for withholding federal jurisdiction. Thus, it is necessary to examine the reasons for Congress' decisions to grant or withhold both federal jurisdiction and private remedies, something the Court has not done.

## A

In the early days of our Republic, Congress was content to leave the task of interpreting and applying federal laws in the first instance to the state courts; with one short-lived exception, Congress did not grant the inferior federal courts original jurisdiction over cases arising under federal law until 1875. The reasons Congress found it necessary to add this jurisdiction to the district courts are well known. First, Congress recognized "the importance, and even necessity of *uniformity* of decisions throughout the whole United States, upon all subjects within the purview of the constitution." *Martin v. Hunter's Lessee* (emphasis in original).<sup>a</sup> Concededly, because federal jurisdiction is not always exclusive and because federal courts may disagree with one another, absolute uniformity has not been obtained even under § 1331. However, while perfect uniformity may not have been achieved, experience indicates

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<sup>4</sup> It bears emphasizing that the Court does not hold that there is no private cause of action under the FDCA. Rather, it expressly states that "[f]or purposes of our decision, we assume that this is a correct interpretation of the FDCA." The Court simply holds petitioner to its concession that the FDCA provides no private remedy, and decides petitioner's claim on the basis of this concession. I shall do the same. Under the Court's analysis, however, if a party persuaded a court that there is a private cause of action under the FDCA, there would be federal jurisdiction under *Smith and Franchise Tax Board* over a state cause of action making violations of the FDCA actionable. Such jurisdiction would apparently exist even if the plaintiff did not seek the federal remedy.

<sup>a</sup> [EDITOR'S NOTE] Is it appropriate for Justice Brennan to use *Martin* in this way? In the last two sentences, he was talking about Congress's grant of original federal question jurisdiction to the federal trial courts in 1875. To support that, however, he quotes from *Martin*, a 1816 decision, and Justice Story's language referred to Congress's grant to the Supreme Court of *appellate* jurisdiction in cases coming from the state courts.

that the availability of a federal forum in federal-question cases has done much to advance that goal. \* \* \*

In addition, § 1331 has provided for adjudication in a forum that specializes in federal law and that is therefore more likely to apply that law correctly. Because federal-question cases constitute the basic grist for federal tribunals, “[t]he federal courts have acquired a considerable expertness in the interpretation and application of federal law.” By contrast, “it is apparent that federal question cases must form a very small part of the business of [state] courts.” As a result, the federal courts are comparatively more skilled at interpreting and applying federal law, and are much more likely correctly to divine Congress’ intent in enacting legislation.<sup>6</sup>

These reasons for having original federal-question jurisdiction explain why cases like this one and *Smith—i.e.*, cases where the cause of action is a creature of state law, but an essential element of the claim is federal—“arise under” federal law within the meaning of § 1331. Congress passes laws in order to shape behavior; a federal law expresses Congress’ determination that there is a federal interest in having individuals or other entities conform their actions to a particular norm established by that law. Because all laws are imprecise to some degree, disputes inevitably arise over what specifically Congress intended to require or permit. It is the duty of courts to interpret these laws and apply them in such a way that the congressional purpose is realized. As noted above, Congress granted the district courts power to hear cases “arising under” federal law in order to enhance the likelihood that federal laws would be interpreted more correctly and applied more uniformly. In other words, Congress determined that the availability of a federal forum to adjudicate cases involving federal questions would make it more likely that federal laws would shape behavior in the way that Congress intended.

By making federal law an essential element of a state-law claim, the State places the federal law into a context where it will operate to shape behavior: the threat of liability will force individuals to conform their conduct to interpretations of the federal law made by courts adjudicating the state-law claim. It will not matter to an individual found liable whether the officer who arrives at his door to execute judgment is wearing a state or a federal uniform; all he cares about is the fact that a sanction is being imposed—and may be imposed again in the future—because he failed to comply with the federal law. Consequently, the possibility that the federal law will be incorrectly interpreted in the context of adjudicating the state-law claim implicates the concerns that led Congress to grant the district courts power to adjudicate cases involving federal questions in precisely the same way as if it was federal law that “created” the cause of action. It therefore follows that there is federal jurisdiction under § 1331.

## B

The only remaining question is whether the assumption that Congress decided not to create a private cause of action alters this analysis in a way that makes it inappropriate to

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<sup>6</sup> Another reason Congress conferred original federal-question jurisdiction on the district courts was its belief that state courts are hostile to assertions of federal rights. Although this concern may be less compelling today than it once was, the American Law Institute reported as recently as 1969 that “it is difficult to avoid concluding that federal courts are more likely to apply federal law sympathetically and understandingly than are state courts.” In any event, this rationale is, like the rationale based on the expertise of the federal courts, simply an expression of Congress’ belief that federal courts are more likely to interpret federal law correctly.

One might argue that this Court’s appellate jurisdiction over state-court judgments in cases arising under federal law can be depended upon to correct erroneous state-court decisions and to insure that federal law is interpreted and applied uniformly. However, as any experienced observer of this Court can attest, “Supreme Court review of state courts, limited by docket pressures, narrow review of the facts, the debilitating possibilities of delay, and the necessity of deferring to adequate state grounds of decision, cannot do the whole job.” Indeed, having served on this Court for 30 years, it is clear to me that, realistically, it cannot even come close to “doing the whole job” and that § 1331 is essential if federal rights are to be adequately protected.

exercise original federal jurisdiction. According to the Court, “the very reasons for the development of the modern implied remedy doctrine” support the conclusion that, where the legislative history of a particular law shows (whether expressly or by inference) that Congress intended that there be no private federal remedy, it must also mean that Congress would not want federal courts to exercise jurisdiction over a state-law claim making violations of that federal law actionable. These reasons are “‘the increased complexity of federal legislation,’” “‘the increased volume of federal litigation,’” and “‘the desirability of a more careful scrutiny of legislative intent.’”

These reasons simply do not justify the Court’s holding. Given the relative expertise of the federal courts in interpreting federal law, the increased complexity of federal legislation argues rather strongly in favor of recognizing federal jurisdiction. And, while the increased volume of litigation may appropriately be considered in connection with reasoned arguments that justify limiting the reach of § 1331, I do not believe that the day has yet arrived when this Court may trim a statute solely because it thinks that Congress made it too broad.

This leaves only the third reason: “‘the desirability of a more careful scrutiny of legislative intent.’” I certainly subscribe to the proposition that the Court should consider legislative intent in determining whether or not there is jurisdiction under § 1331. But the Court has not examined the purposes underlying either the FDCA or § 1331 in reaching its conclusion that Congress’ presumed decision not to provide a private federal remedy under the FDCA must be taken to withdraw federal jurisdiction over a private state remedy that imposes liability for violating the FDCA. Moreover, such an examination demonstrates not only that it is consistent with legislative intent to find that there is federal jurisdiction over such a claim, but, indeed, that it is the Court’s contrary conclusion that is inconsistent with congressional intent.

The enforcement scheme established by the FDCA is typical of other, similarly broad regulatory schemes. Primary responsibility for overseeing implementation of the Act has been conferred upon a specialized administrative agency, here the Food and Drug Administration (FDA). Congress has provided the FDA with a wide-ranging arsenal of weapons to combat violations of the FDCA \* \* \*. Significantly, the FDA has no independent enforcement authority; final enforcement must come from the federal courts, which have exclusive jurisdiction over actions under the FDCA. Thus, while the initial interpretive function has been delegated to an expert administrative body whose interpretations are entitled to considerable deference, final responsibility for interpreting the statute in order to carry out the legislative mandate belongs to the federal courts.

Given that Congress structured the FDCA so that all express remedies are provided by the federal courts, it seems rather strange to conclude that it either “flout[s]” or “undermine[s]” congressional intent for the federal courts to adjudicate a private state-law remedy that is based upon violating the FDCA. That is, assuming that a state cause of action based on the FDCA is not preempted, it is entirely consistent with the FDCA to find that it “arises under” federal law within the meaning of § 1331. Indeed, it is the Court’s conclusion that such a state cause of action must be kept out of the federal courts that appears contrary to legislative intent inasmuch as the enforcement provisions of the FDCA quite clearly express a preference for having federal courts interpret the FDCA and provide remedies for its violation.

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