Chapter 4

Limits on State Regulatory and Taxing Power

A. Preemption of State and Local Laws

1. Express Preemption (casebook, p. 436)

In Altria v. Good, as in Lorillard Tobacco Co. v. Riley, the Supreme Court considered the meaning of an express preemption provision in a federal law regulating labeling of cigarettes. The issue in Altria was whether the federal law barred state tort liability for fraud in marketing low tar and nicotine cigarettes.

ALTRIA GROUP, INC. v. GOOD
129 S.Ct. 558 (2008)

Justice Stevens delivered the opinion of the Court.

Respondents, who have for over 15 years smoked “light” cigarettes manufactured by petitioners, Philip Morris USA, Inc., and its parent company, Altria Group, Inc., claim that petitioners violated the Maine Unfair Trade Practices Act (MUTPA). Specifically, they allege that petitioners’ advertising fraudulently conveyed the message that their “light” cigarettes deliver less tar and nicotine to consumers than regular brands despite petitioners’ knowledge that the message was untrue. Petitioners deny the charge, asserting that their advertisements were factually accurate. The merits of the dispute are not before us because the District Court entered summary judgment in favor of petitioners on the ground that respondents’ state-law claim is pre-empted by the Federal Cigarette Labeling and Advertising Act, as amended (Labeling Act). The Court of Appeals reversed that judgment, and we granted certiorari
to review its holding that the Labeling Act neither expressly nor impliedly pre-empts respondents' fraud claim. We affirm.

I

Respondents are Maine residents and longtime smokers of Marlboro Lights and Cambridge Lights cigarettes, which are manufactured by petitioners. Invoking the diversity jurisdiction of the Federal District Court, respondents filed a complaint alleging that petitioners deliberately deceived them about the true and harmful nature of “light” cigarettes in violation of the MUTPA. Respondents claim that petitioners fraudulently marketed their cigarettes as being “light” and containing “[l]owered [t]ar and [n]icotin” to convey to consumers that they deliver less tar and nicotine and are therefore less harmful than regular cigarettes.

II

Article VI, cl. 2, of the Constitution provides that the laws of the United States “shall be the supreme Law of the Land; ... any Thing in the Constitution or Laws of any state to the Contrary notwithstanding.” Consistent with that command, we have long recognized that state laws that conflict with federal law are “without effect.”

Our inquiry into the scope of a statute’s pre-emptive effect is guided by the rule that “[t]he purpose of Congress is the ultimate touchstone in every pre-emption case.” Congress may indicate pre-emptive intent through a statute’s express language or through its structure and purpose. If a federal law contains an express pre-emption clause, it does not immediately end the inquiry because the question of the substance and scope of Congress’ displacement of state law still remains. Pre-emptive intent may also be inferred if the scope of the statute indicates that Congress intended federal law to occupy the legislative field, or if there is an actual conflict between state and federal law.

When addressing questions of express or implied pre-emption, we begin our analysis “with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States. Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily “accept the reading that disfavors pre-emption.”

Congress enacted the Labeling Act in 1965 in response to the Surgeon General’s determination that cigarette smoking is harmful to health. The
Limits on State Regulatory and Taxing Power

Act required that every package of cigarettes sold in the United States contain a conspicuous warning, and it pre-empted state-law positive enactments that added to the federally prescribed warning. Congress amended the Labeling Act a few years later by enacting the Public Health Cigarette Smoking Act of 1969. The amendments strengthened the language of the prescribed warning, and prohibited cigarette advertising in "any medium of electronic communication subject to [FCC] jurisdiction." They also broadened the Labeling Act's pre-emption provision. The Labeling Act has since been amended further to require cigarette manufacturers to include four more explicit warnings in their packaging and advertisements on a rotating basis.

The stated purpose of the Labeling Act is "to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby—

1. the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and
2. commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.

As amended, the Labeling Act contains two express pre-emption provisions. Section 5(a) protects cigarette manufacturers from inconsistent state labeling laws by prohibiting the requirement of additional statements relating to smoking and health on cigarette packages. Section 5(b), which is at issue in this case, provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter."

Together, the labeling requirement and pre-emption provisions express Congress' determination that the prescribed federal warnings are both necessary and sufficient to achieve its purpose of informing the public of the health consequences of smoking. Because Congress has decided that no additional warning statement is needed to attain that goal, States may not impede commerce in cigarettes by enforcing rules that are based on an assumption that the federal warnings are inadequate. Although both of the Act's purposes are furthered by prohibiting States from supplementing the federally prescribed warning, neither would be served by limiting the States' authority to prohibit deceptive statements in cigarette advertising.
Although it is clear that fidelity to the Act's purposes does not demand the pre-emption of state fraud rules, the principal question that we must decide is whether the text of § 1334(b) nevertheless requires that result.

III

Respondents' claim that the deceptive statements "light" and "lowered tar and nicotine" induced them to purchase petitioners' product alleges a breach of the duty not to deceive. To be sure, the presence of the federally mandated warnings may bear on the materiality of petitioners' allegedly fraudulent statements, "but that possibility does not change [respondents'] case from one about the statements into one about the warnings."

It is true, as petitioners argue, that the appeal of their advertising is based on the relationship between smoking and health. And although respondents have expressly repudiated any claim for damages for personal injuries, their actual injuries likely encompass harms to health as well as the monetary injuries they allege. These arguments are unavailing, however, because the text of § 1334(b) does not refer to harms related to smoking and health. Rather, it pre-empts only requirements and prohibitions i.e., rules—that are based on smoking and health. The MUTPA says nothing about either "smoking" or "health." It is a general rule that creates a duty not to deceive.

In sum, we conclude now, as the plurality did in Cipollone, that "the phrase 'based on smoking and health' fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements."

IV

As an alternative to their express pre-emption argument, petitioners contend that respondents' claim is impliedly pre-empted because, if allowed to proceed, it would present an obstacle to a longstanding policy of the FTC. According to petitioners, the FTC has for decades promoted the development and consumption of low tar cigarettes and has encouraged consumers to rely on representations of tar and nicotine content based on Cambridge Filter Method testing in choosing among cigarette brands. Even if such a regulatory policy could provide a basis for obstacle pre-emption, petitioners' description of the FTC's actions in this regard are inaccurate. The Government itself disavows any policy authorizing the use of "light" and "low tar" descriptors.

In 1966, following the publication of the Surgeon General's report on smoking and health, the FTC issued an industry guidance stating its view
that "a factual statement of the tar and nicotine content (expressed in milligrams) of the mainstream smoke from a cigarette," as measured by Cambridge Filter Method testing, would not violate the FTC Act. The Commission made clear, however, that the guidance applied only to factual assertions of tar and nicotine yields and did not invite "collateral representations . . . made, expressly or by implication, as to reduction or elimination of health hazards." A year later, the FTC reiterated its position in a letter to the National Association of Broadcasters. The letter explained that, as a "general rule," the Commission would not challenge statements of tar and nicotine content when "they are shown to be accurate and fully substantiated by tests conducted in accordance with the [Cambridge Filter Method]." In 1970, the FTC considered providing further guidance, proposing a rule that would have required manufacturers to disclose tar and nicotine yields as measured by Cambridge Filter Method testing. The leading cigarette manufacturers responded by submitting a voluntary agreement under which they would disclose tar and nicotine content in their advertising, and the FTC suspended its rulemaking.

Based on these events, petitioners assert that "the FTC has required tobacco companies to disclose tar and nicotine yields in cigarette advertising using a government-mandated testing methodology and has authorized them to use descriptors as shorthand references to those numerical test results." As the foregoing history shows, however, the FTC has in fact never required that cigarette manufacturers disclose tar and nicotine yields, nor has it condoned representations of those yields through the use of "light" or "low tar" descriptors.

Subsequent Commission actions further undermine petitioners' claim. After the tobacco companies agreed to report tar and nicotine yields as measured by the Cambridge Filter Method, the FTC continued to police cigarette companies' misleading use of test results. In 1983, the FTC responded to findings that tar and nicotine yields for Barclay cigarettes obtained through Cambridge Filter Method testing were deceptive because the cigarettes in fact delivered disproportionately more tar to smokers than other cigarettes with similar Cambridge Filter Method ratings. And in 1995, the FTC found that a manufacturer's representation "that consumers will get less tar by smoking ten packs of Carlton brand cigarettes than by smoking a single pack of the other brands" was deceptive even though it was based on the results of Cambridge Filter Method testing.

This history shows that, contrary to petitioners' suggestion, the FTC has no longstanding policy authorizing collateral representations based on Cambridge Filter Method test results. Rather, the FTC has endeavored
to inform consumers of the comparative tar and nicotine content of different cigarette brands and has in some instances prevented misleading representations of Cambridge Filter Method test results. The FTC’s failure to require petitioners to correct their allegedly misleading use of “light” descriptors is not evidence to the contrary; agency nonenforcement of a federal statute is not the same as a policy of approval.

V

We conclude that the Labeling Act does not pre-empt state-law claims like respondents’ that are predicated on the duty not to deceive. We also hold that the FTC’s various decisions with respect to statements of tar and nicotine content do not impliedly pre-empt respondents’ claim. Respondents still must prove that petitioners’ use of “light” and “lowered tar” descriptors in fact violated the state deceptive practices statute, but neither the Labeling Act’s pre-emption provision nor the FTC’s actions in this field prevent a jury from considering that claim.

JUSTICE THOMAS, with whom THE CHIEF JUSTICE, JUSTICE SCALIA, and JUSTICE ALITO join, dissenting.

The question before us is whether state-law claims alleging that cigarette manufacturers misled the public about the health effects of cigarettes are pre-empted by the Federal Cigarette Labeling and Advertising Act. The Labeling Act requires that specific health warnings be placed on all cigarette packaging and advertising, in order to eliminate “diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health.” To that end, § 5(b) of the Labeling Act pre-empts any “requirement or prohibition based on smoking and health... imposed under State law with respect to the advertising or promotion of any cigarettes.”

Respondents’ lawsuit under the Maine Unfair Trade Practices Act (MUTPA), is expressly pre-empted under § 5(b) of the Labeling Act. The civil action is premised on the allegation that the cigarette manufacturers misled respondents into believing that smoking light cigarettes would be healthier for them than smoking regular cigarettes. A judgment in respondents’ favor will thus result in a “requirement” that petitioners represent the effects of smoking on health in a particular way in their advertising and promotion of light cigarettes. Because liability in this case is thereby premised on the effect of smoking on health, I would hold that respondents’ state-law claims are expressly pre-empted by § 5(b) of the Labeling Act. I respectfully dissent.
Sixteen years later, we must resolve whether respondents' class-action claims for fraudulent marketing under the MUTPA are pre-empted by § 5 (b) of the Labeling Act.

There is no authority for invoking the presumption against pre-emption in express pre-emption cases. The text of the statute must control.

Every products liability action, including a failure-to-warn action, applies generally to all products. Thus, the "duty" or "rule" involved in a failure-to-warn claim is no more specific to smoking and health than is a common-law fraud claim based on the "duty" or "rule" not to use deceptive or misleading trade practices.

Furthermore, contrary to the majority's policy arguments, faithful application of the statutory language does not authorize fraudulent advertising with respect to smoking and health. Any misleading promotional statements for cigarettes remain subject to federal regulatory oversight under the Labeling Act. The relevant question thus is not whether "petitioners will be prohibited from selling as 'light' or 'low tar' only those cigarettes that are not actually light and do not actually deliver less tar and nicotine." Rather, the issue is whether the Labeling Act allows regulators and juries to decide, on a state-by-state basis, whether petitioners' light and low-tar descriptors were in fact fraudulent, or instead whether § 5(b) charged the Federal Government with reaching a comprehensive judgment with respect to this question.

Congress chose a uniform federal standard. Under the Labeling Act, Congress "establish[ed] a comprehensive Federal Program to deal with cigarette labeling and advertising," so that "commerce and the national economy may... not [be] impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health." The majority's distorted interpretation of § 5(b) defeats this express congressional purpose, opening the door to an untold number of deceptive-practices lawsuits across the country. The question whether marketing a light cigarette is "'misrepresentative'" in light of compensatory behavior "would almost certainly be answered differently from State to State." This will inevitably result in the nonuniform imposition of liability for the marketing of light and/or low-tar cigarettes—the precise problem that Congress intended § 5(b) to remedy.

Applying the proper test—i.e., whether a jury verdict on respondents' claims would "impos[e] an obligation" on the cigarette manufacturer
"because of the effect of smoking upon health," respondents' state-law claims are expressly pre-empted by § 5(b) of the Labeling Act. Respondents, longtime smokers of Marlboro Lights, claim that they have suffered an injury as a result of petitioners' decision to advertise these cigarettes as "light" and/or "low-tar and low nicotine products." They claim that petitioners marketed their cigarettes as "light" and/or "low-tar and low-nicotine products" despite knowledge that light-cigarette smokers would engage in compensatory behavior causing them to inhale at least as much tar and nicotine as smokers of regular cigarettes. Respondents thus allege that they were misled into thinking that they were gaining a health advantage by smoking the light cigarettes, and, as a result, petitioners' conduct was an "unfair or deceptive act or practice" under the MUTPA.

Respondents' claims seek to impose liability on petitioners because of the effect that smoking light cigarettes had on their health. The alleged misrepresentation here—that "light" and "low-tar" cigarettes are not as healthy as advertised—is actionable only because of the effect that smoking light and low-tar cigarettes had on respondents' health. Otherwise, any alleged misrepresentation about the effect of the cigarettes on health would be immaterial for purposes of the MUTPA and would not be the source of the injuries that provided the impetus for the class-action lawsuit. Therefore, with this suit, respondents seek to require the cigarette manufacturers to provide additional warnings about compensatory behavior, or to prohibit them from selling these products with the "light" or "low-tar" descriptors. This is exactly the type of lawsuit that is pre-empted by the Labeling Act.

Because the proper test for pre-emption is to look at the factual basis of a complaint to determine if a claim imposes a requirement based on smoking and health, there is no meaningful distinction to be drawn in this case between common-law failure-to-warn claims and claims under the MUTPA. As the majority readily admits, both types of claims impose duties with respect to the same conduct—i.e., the marketing of "light," "low-tar," and "low-nicotine" cigarettes. If the claims arise from identical conduct, the claims impose the same requirement or prohibition with respect to that conduct. And when that allegedly wrongful conduct involves misleading statements about the health effects of smoking a particular brand of cigarette, the liability and resulting requirement or prohibition are, by definition, based on smoking and health.

Because I believe that respondents' claims are pre-empted under § 5 (b) of the Labeling Act, I respectfully dissent.
When Congress has the authority to legislate, it can exclude within a statute a provision expressly preempting state regulation in the area. In *Altria Group, Inc. v. Good*, 129 S.Ct. 538 (2008), the Court considered the scope of the preemption provision in the federal Cigarette Label and Advertising Act. The provision at issue, Section 5(b), provides that “[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter.”

The question before the Court was whether this provision preempted suits against cigarette companies, under the Maine Unfair Trade Practices Act, for fraud in marketing and advertising low tar and nicotine cigarettes. In a 5-4 decision, with Justice Stevens writing for the majority, the Court concluded that there was no preemption. Justice Stevens stressed “[w]hen the text of an express pre-emption clause is susceptible of more than one plausible reading, courts ordinarily accept the reading that disfavors pre-emption.” The Court concluded that “the phrase ‘based on smoking and health’ fairly but narrowly construed does not encompass the more general duty not to make fraudulent statements.” Thus, tobacco companies could be sued for fraud in the marketing of “light” cigarettes.

2. Implied Preemption

   a. Conflicts Preemption (casebook, p. 443)

If federal law and state law conflict, such as if they are mutually exclusive, then the state law is preempted. But this inevitably raises the question of whether the federal law is the minimum of regulation and states can go further, or if it is the maximum of regulation and states cannot add to it. This is the question in *Wyeth v. Levine*, which raised the issue of whether approval of a prescription drug warning label precluded state tort liability on a failure-to-warn theory.

*Wyeth v. Levine*
129 S.Ct. 1187 (2009)

Justice STEVENS delivered the opinion of the Court.

Directly injecting the drug Phenergan into a patient’s vein creates a significant risk of catastrophic consequences. A Vermont jury found that petitioner Wyeth, the manufacturer of the drug, had failed to provide an
adequate warning of that risk and awarded damages to respondent Diana Levine to compensate her for the amputation of her arm. The warnings on Phenergan’s label had been deemed sufficient by the federal Food and Drug Administration (FDA) when it approved Wyeth’s new drug application in 1955 and when it later approved changes in the drug’s labeling. The question we must decide is whether the FDA’s approvals provide Wyeth with a complete defense to Levine’s tort claims. We conclude that they do not.

I

Phenergan is Wyeth’s brand name for promethazine hydrochloride, an antihistamine used to treat nausea. The injectable form of Phenergan can be administered intramuscularly or intravenously, and it can be administered intravenously through either the “IV-push” method, whereby the drug is injected directly into a patient’s vein, or the “IV-drip” method, whereby the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient’s vein. The drug is corrosive and causes irreversible gangrene if it enters a patient’s artery.

Levine’s injury resulted from an IV-push injection of Phenergan. On April 7, 2000, as on previous visits to her local clinic for treatment of a migraine headache, she received an intramuscular injection of Demerol for her headache and Phenergan for her nausea. Because the combination did not provide relief, she returned later that day and received a second injection of both drugs. This time, the physician assistant administered the drugs by the IV-push method, and Phenergan entered Levine’s artery, either because the needle penetrated an artery directly or because the drug escaped from the vein into surrounding tissue (a phenomenon called “perivascular extravasation”) where it came in contact with arterial blood. As a result, Levine developed gangrene, and doctors amputated first her right hand and then her entire forearm. In addition to her pain and suffering, Levine incurred substantial medical expenses and the loss of her livelihood as a professional musician.

After settling claims against the health center and clinician, Levine brought an action for damages against Wyeth, relying on common-law negligence and strict-liability theories. Although Phenergan’s labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. More broadly, she alleged that Phenergan is not reasonably safe for
intravenous administration because the foreseeable risks of gangrene and loss of limb are great in relation to the drug’s *therapeutic benefits*.

Wyeth filed a motion for summary judgment, arguing that Levine’s failure-to-warn claims were *pre-empted by federal law*. The court found no merit in Wyeth’s pre-emption argument. Answering questions on a special verdict form, *the jury* found that Wyeth was negligent, that Phenergan was a defective product as a result of inadequate warnings and instructions, and *that no intervening cause* had broken the causal connection between the product defects and the plaintiff’s injury. It awarded total damages of $7,400,000, which the court reduced to account for Levine’s earlier settlement with the health center and clinician. The Vermont Supreme Court affirmed.

II

Wyeth makes two separate pre-emption arguments: first, that it would have been impossible for it to comply with the state-law duty to modify Phenergan’s labeling without violating federal law, and second, that recognition of Levine’s state tort action creates an unacceptable “obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” because it substitutes a lay jury’s decision about drug labeling for the expert judgment of the FDA. As a preface to our evaluation of these arguments, we identify two factual propositions decided during the trial court proceedings, emphasize two legal principles that guide our analysis, and review the history of the controlling federal statute.

The trial court proceedings established that Levine’s injury would not have occurred if Phenergan’s label had included an adequate warning about the risks of the IV-push method of administering the drug. The record contains evidence that the physician assistant administered a greater dose than the label prescribed, that she may have inadvertently injected the drug into an artery rather than a vein, and that she continued to inject the drug after Levine complained of pain. Nevertheless, the jury rejected Wyeth’s argument that the clinician’s conduct was an intervening cause that absorbed it of liability. In finding Wyeth negligent as well as strictly liable, the jury also determined that Levine’s injury was foreseeable. That the inadequate label was both a but-for and proximate cause of Levine’s injury is supported by the record and no longer challenged by Wyeth.

The trial court proceedings further established that the critical defect in Phenergan’s label was the lack of an adequate warning about the risks of IV-push administration. But, as the *Vermont Supreme Court explained*,
the jury verdict established only that Phenergan’s warning was insufficient. It did not mandate a particular replacement warning, nor did it require contraindicating IV-push administration. We therefore need not decide whether a state rule proscribing intravenous administration would be pre-empted. The narrower question presented is whether federal law pre-empts Levine’s claim that Phenergan’s label did not contain an adequate warning about using the IV-push method of administration.

Our answer to that question must be guided by two cornerstones of our pre-emption jurisprudence. First, “the purpose of Congress is the ultimate touchstone in every pre-emption case.” Second, “[i]n all pre-emption cases, and particularly in those in which Congress has ‘legislated . . . in a field which the States have traditionally occupied,’ . . . we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.’”

III

Wyeth first argues that Levine’s state-law claims are pre-empted because it is impossible for it to comply with both the state-law duties underlying those claims and its federal labeling duties. The FDA’s premarket approval of a new drug application includes the approval of the exact text in the proposed label. Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency’s approval. Among other things, this “changes being effected” (CBE) regulation provides that if a manufacturer is changing a label to “add or strengthen a contraindication, warning, precaution, or adverse reaction” or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.

Wyeth argues that the CBE regulation is not implicated in this case because a 2008 amendment provides that a manufacturer may only change its label “to reflect newly acquired information.” Resting on this language (which Wyeth argues simply reaffirmed the interpretation of the regulation in effect when this case was tried), Wyeth contends that it could have changed Phenergan’s label only in response to new information that the FDA had not considered. And it maintains that Levine has not pointed to any such information concerning the risks of IV-push administration. Thus, Wyeth insists, it was impossible for it to discharge its state-law obligation to provide a stronger warning about IV-push
administration without violating federal law. Wyeth’s argument mis-apprehends both the federal drug regulatory scheme and its burden in establishing a pre-emption defense.

Wyeth could have revised Phenergan’s label even in accordance with the amended regulation. As the FDA explained in its notice of the final rule, “newly acquired information” is not limited to new data, but also encompasses “new analyses of previously submitted data.” The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments.

Wyeth argues that if it had unilaterally added such a warning, it would have violated federal law governing unauthorized distribution and mis-branding. Its argument that a change in Phenergan’s labeling would have subjected it to liability for unauthorized distribution rests on the assumption that this labeling change would have rendered Phenergan a new drug lacking an effective application. But strengthening the warning about IV-push administration would not have made Phenergan a new drug. Nor would this warning have rendered Phenergan misbranded. The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include “adequate warnings.”

Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer’s supplemental application, just as it retains such authority in reviewing all supplemental applications. But absent clear evidence that the FDA would not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements. Wyeth has offered no such evidence.

Impossibility pre-emption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan’s label does not establish that it would have prohibited such a change.

IV

Wyeth also argues that requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug labeling regulation. Levine’s tort claims, it maintains, are pre-empted because they interfere with
“Congress’s purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives.” We find no merit in this argument, which relies on an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.

Wyeth contends that the FDCA establishes both a floor and a ceiling for drug regulation: Once the FDA has approved a drug’s label, a state-law verdict may not deem the label inadequate, regardless of whether there is any evidence that the FDA has considered the stronger warning at issue. The most glaring problem with this argument is that all evidence of Congress’ purposes is to the contrary. Building on its 1906 Act, Congress enacted the FDCA to bolster consumer protection against harmful products. Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA’s 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

In keeping with Congress’ decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the post-marketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA’s premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.
We conclude that it is not impossible for Wyeth to comply with its state and federal law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.

Justice Thomas, concurring in the judgment.

I agree with the Court that the fact that the Food and Drug Administration (FDA) approved the label for petitioner Wyeth's drug Phenergan does not pre-empt the state-law judgment before the Court. I write separately, however, because I cannot join the majority's implicit endorsement of far-reaching implied pre-emption doctrines. In particular, I have become increasingly skeptical of this Court's "purposes and objectives" pre-emption jurisprudence. Under this approach, the Court routinely invalidates state laws based on perceived conflicts with broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not embodied within the text of federal law. Because implied pre-emption doctrines that wander far from the statutory text are inconsistent with the Constitution, I concur only in the judgment.

In order "to ensure the protection of our fundamental liberties," the "Constitution establishes a system of dual sovereignty between the States and the Federal Government." The Framers adopted this "constitutionally mandated balance of power," to "reduce the risk of tyranny and abuse from either front," because a "federalist structure of joint sovereigns preserves to the people numerous advantages," such as "a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society" and "increase[d] opportunity for citizen involvement in democratic processes." Furthermore, as the Framers observed, the "compound republic of America" provides "a double security... to the rights of the people" because "the power surrendered by the people is first divided between two distinct governments, and then the portion allotted to each subdivided among distinct and separate departments." The Federalist No. 51, p. 266 (M. Beloff ed., 2d ed.1987).

Under this federalist system, "the States possess sovereignty concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." In this way, the Supremacy Clause gives the Federal Government "a decided advantage in [a] delicate balance" between federal and state sovereigns. "As long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States." That is an "extraordinary power in a federalist system."
In light of these constitutional principles, I have become “increasingly reluctant to expand federal statutes beyond their terms through doctrines of implied pre-emption.” My review of this Court’s broad implied pre-emption precedents, particularly its “purposes and objectives” pre-emption jurisprudence, has increased my concerns that implied pre-emption doctrines have not always been constitutionally applied. Under the vague and “potentially boundless” doctrine of “purposes and objectives” pre-emption, in [this case], the relevant federal law did not give Wyeth a right that the state-law judgment took away, and it was possible for Wyeth to comply with both federal law and the Vermont-law judgment at issue here. The federal statute and regulations neither prohibited the stronger warning label required by the state judgment, nor insulated Wyeth from the risk of state-law liability. With no “direct conflict” between the federal and state law, then, the state-law judgment is not pre-empted.

The origins of this Court’s “purposes and objectives” pre-emption jurisprudence and its broad application illustrate that this brand of the Court’s pre-emption jurisprudence facilitates freewheeling, extratextual, and broad evaluations of the “purposes and objectives” embodied within federal law. This, in turn, leads to decisions giving improperly broad pre-emptive effect to judicially manufactured policies, rather than to the statutory text enacted by Congress pursuant to the Constitution and the agency actions authorized thereby. Because such a sweeping approach to pre-emption leads to the illegitimate—and thus, unconstitutional—invalidation of state laws, I can no longer assent to a doctrine that pre-empts state laws merely because they “stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives” of federal law, as perceived by this Court.

Justice Alito, with whom the Chief Justice and Justice Scalia join, dissenting.

This case illustrates that tragic facts make bad law. The Court holds that a state tort jury, rather than the Food and Drug Administration (FDA), is ultimately responsible for regulating warning labels for prescription drugs. That result cannot be reconciled with or general principles of conflict pre-emption. I respectfully dissent.

I

The Court frames the question presented as a “narrow” one—namely, whether Wyeth has a duty to provide “an adequate warning about using the IV-push method” to administer Phenergan. But that ignores the antecedent question of who—the FDA or a jury in Vermont—has the
authority and responsibility for determining the “adequacy” of Phenergan’s warnings. Moreover, it is unclear how a “stronger” warning could have helped respondent, after all, the physician’s assistant who treated her disregarded at least six separate warnings that are already on Phenergan’s labeling, so respondent would be hard pressed to prove that a seventh would have made a difference.

More to the point, the question presented by this case is not a “narrow” one, and it does not concern whether Phenergan’s label should bear a “stronger” warning. Rather, the real issue is whether a state tort jury can countermand the FDA’s considered judgment that Phenergan’s FDA-mandated warning label renders its intravenous (IV) use “safe.” Indeed, respondent’s amended complaint alleged that Phenergan is “not reasonably safe for intravenous administration.” [R]espondent’s attorney told the jury that Phenergan’s label should say, “Do not use this drug intravenously,” respondent’s expert told the jury, “I think the drug should be labeled ‘Not for IV use,’” and during his closing argument, respondent’s attorney told the jury, “Thank God we don’t rely on the FDA to . . . make the safe[ty] decision. You will make the decision . . . . The FDA doesn’t make the decision, you do.” Federal law, however, does rely on the FDA to make safety determinations like the one it made here. The FDA has long known about the risks associated with IV push in general and its use to administer Phenergan in particular. Whether wisely or not, the FDA has concluded—over the course of extensive, 54-year-long regulatory proceedings—that the drug is “safe” and “effective” when used in accordance with its FDA-mandated labeling. The unfortunate fact that respondent’s healthcare providers ignored Phenergan’s labeling may make this an ideal medical-malpractice case. But turning a common-law tort suit into a “frontal assault” on the FDA’s regulatory regime for drug labeling upsets the well-settled meaning of the Supremacy Clause and our conflict pre-emption jurisprudence.

II

To the extent that “[t]he purpose of Congress is the ultimate touchstone in every pre-emption case,” Congress made its “purpose” plain in authorizing the FDA—not state tort juries—to determine when and under what circumstances a drug is “safe.” Where the FDA determines, in accordance with its statutory mandate, that a drug is on balance “safe,” our conflict pre-emption cases prohibit any State from countermanding that determination.
A faithful application of this Court’s conflict pre-emption cases compels the conclusion that the FDA’s 40-year-long effort to regulate the safety and efficacy of Phenergan pre-empts respondent’s tort suit.

Phenergan’s warning label has been subject to the FDA’s strict regulatory oversight since the 1950’s. For at least the last 34 years, the FDA has focused specifically on whether IV-push administration of Phenergan is “safe” and “effective” when performed in accordance with Phenergan’s label. The agency’s ultimate decision—to retain IV push as one means for administering Phenergan, albeit subject to stringent warnings—is reflected in the plain text of Phenergan’s label (sometimes in boldfaced font and all-capital letters). And the record contains ample evidence that the FDA specifically considered and reconsidered the strength of Phenergan’s IV-push-related warnings in light of new scientific and medical data. The majority’s factual assertions to the contrary are mistaken.

By their very nature, juries are ill-equipped to perform the FDA’s cost-benefit-balancing function. Juries tend to focus on the risk of a particular product’s design or warning label that arguably contributed to a particular plaintiff’s injury, not on the overall benefits of that design or label; “the patients who reaped those benefits are not represented in court.” Indeed, patients like respondent are the only ones whom tort juries ever see, and for a patient like respondent—who has already suffered a tragic accident—Phenergan’s risks are no longer a matter of probabilities and potentialities.

In contrast, the FDA has the benefit of the long view. Its drug-approval determinations consider the interests of all potential users of a drug, including “those who would suffer without new medical [products]” if juries in all 50 States were free to contradict the FDA’s expert determinations. And the FDA conveys its warnings with one voice, rather than whipsawing the medical community with 50 (or more) potentially conflicting ones. After today’s ruling, however, parochialism may prevail.

To be sure, state tort suits can peacefully coexist with the FDA’s labeling regime, and they have done so for decades. But this case is far from peaceful coexistence. The FDA told Wyeth that Phenergan’s label renders its use “safe.” But the State of Vermont, through its tort law, said: “Not so.”