

## Preemption Analysis

The material in this assignment consist of a summary of preemption analysis followed by three recent preemption cases decided by the United States Supreme Court.

When Congress exercises a power granted to it in the Constitution, Congress can choose to have the federal law it enacts supersede state laws that regulate in the same area due to the operation of the Supremacy Clause of Article VI. The displacement of state law is called preemption. In a preemption challenge, the challenger is claiming that a state law is unconstitutional because it has been preempted by a valid federal law. Under this analysis, the state law violates the Supremacy Clause of Article VI because the federal government has enacted a law that prohibits the state from acting in a particular way and the state law being challenged is one in which the state is acting in the prohibited manner.

There are two different kinds of preemption arguments. The first is express preemption. When making such an argument, the challenger argues that a valid federal law contains language that expressly preempts state law. In such cases, a court must first decide if the federal law is valid (within the scope of one of Congress's powers). Second, the Court must decide if the language in the federal statute should be read to expressly preempt state law. Third, the court must decide how to interpret the scope of the preemption language. This issue arises because frequently Congress intends to partially, but not completely, preempt state law. Therefore, the court must decide which state laws fall within the scope of the intended preemption and which state laws fall outside the scope of the intended preemption.

The second kind of preemption argument is implied preemption. Implied preemption occurs in situations where Congress has not inserted express preemptive language in a federal law, but where it is possible to conclude, nonetheless, that Congress intended the federal statute to preempt certain types of state laws. The job of the courts in such cases is to discern the intent of Congress.

There are three different kinds of implied preemption arguments that can be asserted. The first contends that there is a conflict between state and federal law and the conflict makes it impossible to comply with both state and federal law at the same time. In such a situation, if a court agrees that compliance with both laws is impossible, it will conclude that Congress intended federal law to supersede state law and it will invalidate the state law as a violation of the Supremacy Clause.

A second type of conflict preemption asserts that a state law undermines the objectives of federal law. In this kind of case, even though if it is possible to comply with both state and federal law at the same time, a court will consider whether Congress intended to preclude state law from creating a particular obstacle to the accomplishment of the federal purpose. To decide whether this type of implied preemption exists, a court will examine the provisions of the federal law and its legislative history to determine what the purpose of the federal law is and whether the operation of the state law interferes with accomplishing the objectives of the federal law.

In addition to the two types of conflict preemption, there is one other type of implied preemption. This is called field preemption. This occurs where Congress has enacted a law and a

court concludes that the federal law was intended to occupy the entire field of regulation, leaving no room for state laws on the same subject even if those state laws are consistent with the objectives of the federal law . The more comprehensive the federal law is, the more likely Congress will be found to have such an intent. Field preemption is often difficult to discern. Therefore, the courts use several presumptions or default rules. In general, a court is less likely to find field preemption if the field Congress is regulating is one where the states have traditionally played an important role. This is because courts presume that Congress did not intend to oust the states from a traditional field of state regulation if Congress has not clearly expressed such an intent. By contrast, a court is more likely to find field preemption if the field Congress is regulating is one where the federal government has traditionally been dominant.

Multiple preemption arguments are often asserted in a case. A challenger may argue there is express preemption, but alternatively argue there is implied preemption. Similarly, several different forms of implied preemption can often be asserted in the same case.

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

Stevens, J., delivered the opinion of the Court, in which Kennedy, Souter, Ginsburg, and Breyer, JJ., joined. Breyer, J., filed a concurring opinion. Thomas, J., filed an opinion concurring in the judgment. Alito, J., filed a dissenting opinion, in which Roberts, C. J., and Scalia, J., joined.

**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 either Wyeth's field pre-emption argument, which it has since abandoned, or its conflict 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.

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. 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. Levine also offered evidence that the IV-push method should be contraindicated and that Phenergan should never be administered intravenously, even by the IV-drip method. 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: "There may have been any number of ways for [Wyeth] to strengthen the Phenergan warning without completely eliminating 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.'"

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, 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 misapprehends both the federal drug regulatory scheme and its burden in establishing a pre-emption defense.

We need not decide whether the 2008 CBE regulation is consistent with the FDCA and the previous version of the regulation because 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.

The record is limited concerning what newly acquired information Wyeth had or should have had about the risks of IV-push administration of Phenergan because Wyeth did not argue before the trial court that such information was required for a CBE labeling change. Levine did, however, present evidence of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation. After the first such incident came to Wyeth's attention in 1967, it notified the FDA and worked with the agency to change Phenergan's label. In later years, as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug.

Wyeth argues that if it had unilaterally added such a warning, it would have violated federal law governing unauthorized distribution and misbranding. 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.

Wyeth's cramped reading of the CBE regulation and its broad reading of the FDCA's misbranding and unauthorized distribution provisions are premised on a more fundamental misunderstanding. Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate.

Indeed, prior to 2007, the FDA lacked the authority to order manufacturers to revise their labels. When Congress granted the FDA this authority, it reaffirmed the manufacturer's ultimate responsibility for its label. Thus, when the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval.

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. We accordingly cannot credit Wyeth's contention that the FDA would have prevented it from adding a stronger warning about the IV-push method of intravenous administration.

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.

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.

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 short, Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.

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.

**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 general principles of conflict pre-emption. I respectfully dissent.

The Court frames the question presented as a “narro[w]” one—namely, whether Wyeth has a duty to provide “an adequate warning about using the IV-push method” to administer Phenergan. 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.”

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.

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.

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.” The state-law rule at issue here is squarely pre-empted.

**PLIVA, Inc. v. Mensing**  
131 S. Ct. 2567 (2011)

Thomas, J., delivered the opinion of the Court, except as to Part III-B-2. Roberts, C. J., and Scalia and Alito, JJ., joined that opinion in full, and Kennedy, J., joined as to all but Part III-B-2. Sotomayor, J., filed a dissenting opinion, in which Ginsburg, Breyer, and Kagan, JJ., joined.

**Justice Thomas** delivered the opinion of the Court, except as to Part III-B-2. Justice Kennedy joins all but Part III-B-2 of this opinion.

These lawsuits involve state tort-law claims based on failure to provide adequate warning labels for generic metoclopramide. The question presented is whether federal drug regulations directly conflict with, and thus pre-empt, these state-law claims. We hold that they do.

I

Metoclopramide is a drug designed to speed the movement of food through the digestive system. The Food and Drug Administration (FDA) first approved metoclopramide tablets, under

the brand name Reglan, in 1980. Five years later, generic manufacturers also began producing metoclopramide. The drug is commonly used to treat digestive tract problems.

Evidence has accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder. Studies have shown that up to 29% of patients who take metoclopramide for several years develop this condition. Accordingly, warning labels for the drug have been strengthened and clarified several times. In 1985, the label was modified to warn that "tardive dyskinesia . . . may develop in patients treated with metoclopramide." In 2004, the brand name Reglan manufacturer requested, and the FDA approved, a label change to add that "[t]herapy should not exceed 12 weeks in duration." And in 2009, the FDA ordered a black box warning — its strongest — which states: "Treatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases."

Gladys Mensing and Julie Demahy were prescribed Reglan in 2001 and 2002, respectively. Both received generic metoclopramide from their pharmacists. After taking the drug as prescribed for several years, both women developed tardive dyskinesia. In separate suits, Mensing and Demahy sued the generic drug manufacturers that produced the metoclopramide they took (Manufacturers). Each alleged, as relevant here, that long-term metoclopramide use caused her tardive dyskinesia and that the Manufacturers were liable under state tort law (specifically, that of Minnesota and Louisiana) for failing to provide adequate warning labels. They claimed that "despite mounting evidence that long term metoclopramide use carries a risk of tardive dyskinesia far greater than that indicated on the label," none of the Manufacturers had changed their labels to adequately warn of that danger.

In both suits, the Manufacturers urged that federal law pre-empted the state tort claims. According to the Manufacturers, federal statutes and FDA regulations required them to use the same safety and efficacy labeling as their brand-name counterparts. This means, they argued, that it was impossible to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label. The Courts of Appeals for the Fifth and Eighth Circuits rejected the Manufacturers' arguments and held that Mensing and Demahy's claims were not pre-empted. We granted certiorari, consolidated the cases, and now reverse each.

## II

Pre-emption analysis requires us to compare federal and state law. We therefore begin by identifying the state tort duties and federal labeling requirements applicable to the Manufacturers.

### A

It is undisputed that Minnesota and Louisiana tort law require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe. Mensing and Demahy have pleaded that the Manufacturers knew or should have known of the high risk of tardive dyskinesia inherent in the long-term use of their product. They have also pleaded that the Manufacturers knew or should have known that their labels did not adequately warn of that risk. The parties do not dispute that, if these allegations are true, state law required

the Manufacturers to use a different, safer label.

## B

Federal law imposes far more complex drug labeling requirements. Under the 1962 Drug Amendments to the Federal Food, Drug, and Cosmetic Act, a manufacturer seeking federal approval to market a new drug must prove that it is safe and effective and that the proposed label is accurate and adequate. Meeting those requirements involves costly and lengthy clinical testing.

Originally, the same rules applied to all drugs. In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly called the Hatch-Waxman Amendments. Under this law, "generic drugs" can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved. This allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug. A generic drug application must also "show that the [safety and efficacy] labeling proposed is the same as the labeling approved for the [brand-name] drug."

As a result, brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.

The parties do not disagree. What is in dispute is whether, and to what extent, generic manufacturers may change their labels after initial FDA approval. Mensing and Demahy contend that federal law provided several avenues through which the Manufacturers could have altered their metoclopramide labels in time to prevent the injuries here. The FDA, however, tells us that it interprets its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same — thus, generic drug manufacturers have an ongoing federal duty of "sameness." The FDA's views are "controlling unless plainly erroneous or inconsistent with the regulation[s]" or there is any other reason to doubt that they reflect the FDA's fair and considered judgment.

First, Mensing and Demahy urge that the FDA's "changes-being-effected" (CBE) process allowed the Manufacturers to change their labels when necessary. The FDA denies that the Manufacturers could have used the CBE process to unilaterally strengthen their warning labels. The agency interprets the CBE regulation to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions. The FDA argues that CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's.

We defer to the FDA's interpretation of its CBE and generic labeling regulations. We do not find the agency's interpretation "plainly erroneous or inconsistent with the regulation." We therefore conclude that the CBE process was not open to the Manufacturers for the change required by state law.

Next, Mensing and Demahy contend that the Manufacturers could have used "Dear Doctor" letters to send additional warnings to prescribing physicians and other healthcare professionals. Again, the FDA disagrees, and we defer to the agency's views. The FDA argues that Dear Doctor letters qualify as "labeling." Thus, any such letters must be "consistent with and not contrary to [the drug's] approved . . . labeling." As with the CBE regulation, we defer to the FDA. Accordingly, we conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.

Though the FDA denies that the Manufacturers could have used the CBE process or Dear Doctor letters to strengthen their warning labels, the agency asserts that a different avenue existed for changing generic drug labels. According to the FDA, the Manufacturers could have proposed — indeed, were required to propose — stronger warning labels to the agency if they believed such warnings were needed. If the FDA had agreed that a label change was necessary, it would have worked with the brand-name manufacturer to create a new label for both the brand-name and generic drug.

According to the FDA, a "central premise of federal drug regulation is that the manufacturer bears responsibility for the content of its label at all times." The FDA reconciles this duty to have adequate and accurate labeling with the duty of sameness in the following way: Generic drug manufacturers that become aware of safety problems must ask the agency to work toward strengthening the label that applies to both the generic and brand-name equivalent drug.

The Manufacturers and the FDA disagree over whether this alleged duty to request a strengthened label actually existed. The FDA argues that it explained this duty in the preamble to its 1992 regulations implementing the Hatch-Waxman Amendments. The Manufacturers claim that the FDA's 19-year-old statement did not create a duty. Because we ultimately find pre-emption even assuming such a duty existed, we do not resolve the matter.

## C

To summarize, the relevant state and federal requirements are these: State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. Taking Mensing and Demahy's allegations as true, this duty required the Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels. But, we assume, federal law also required the Manufacturers to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label, so that all corresponding generic drug manufacturers could do so as well. We turn now to the question of pre-emption.

## II

The Supremacy Clause establishes that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U. S. Const., Art. VI, cl. 2. Where state and federal law "directly conflict," state law must give way. We have held that state and federal law conflict where it is "impossible for a private party to

comply with both state and federal requirements."

A

We find impossibility here. It was not lawful under federal law for the Manufacturers to do what state law required. If the Manufacturers had independently changed their labels to satisfy their state-law duty, they would have violated federal law. Taking Mensing and Demahy's allegations as true, state law imposed on the Manufacturers a duty to attach a safer label to their generic metoclopramide. Federal law demanded that generic drug labels be the same as the corresponding brand-name drug labels. Thus, it was impossible for the Manufacturers to comply with both their state duty to change the label and their federal duty to keep the label the same.

The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling. State law demanded a safer label; it did not instruct the Manufacturers to communicate with the FDA about the possibility of a safer label.

B

1

Mensing and Demahy contend that, while their state-law claims do not turn on whether the Manufacturers asked the FDA for assistance in changing their labels, the Manufacturers' federal affirmative defense of pre-emption does. Mensing and Demahy argue that if the Manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires. That is true enough. The Manufacturers "freely concede" that they could have asked the FDA for help. If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the Manufacturers would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide.

This raises the novel question whether conflict pre-emption should take into account these possible actions by the FDA and the brand-name manufacturer. Federal law does not dictate the text of each generic drug's label, but rather ties those labels to their brand-name counterparts. Thus, federal law would permit the Manufacturers to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so.

Mensing and Demahy assert that when a private party's ability to comply with state law depends on approval and assistance from the FDA, proving pre-emption requires that party to demonstrate that the FDA would not have allowed compliance with state law. Here, they argue, the Manufacturers cannot bear their burden of proving impossibility because they did not even try to start the process that might ultimately have allowed them to use a safer label. This is a fair argument, but we reject it.

The question for "impossibility" is whether the private party could independently do under federal law what state law requires of it. Accepting Mensing and Demahy's argument would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory. We can often imagine that a third party or the Federal Government might do something that makes it lawful for a private party to accomplish under federal law what state law requires of it. In these cases, it is certainly possible that, had the Manufacturers asked the FDA for help, they might have eventually been able to strengthen their warning label. Following Mensing and Demahy's argument to its logical conclusion, it is also possible that, by asking, the Manufacturers could have persuaded the FDA to rewrite its generic drug regulations entirely or talked Congress into amending the Hatch-Waxman Amendments.

If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express pre-emption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to pre-emption that renders conflict pre-emption all but meaningless.

2

Moreover, the text of the Clause — that federal law shall be supreme, "any Thing in the Constitution or Laws of any State to the Contrary notwithstanding" — plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law. The provision suggests that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.

To consider in our pre-emption analysis the contingencies inherent in these cases — in which the Manufacturers' ability to comply with state law depended on uncertain federal agency and third-party decisions — would be inconsistent with the Supremacy Clause. We do not think the Supremacy Clause contemplates that sort of contingent supremacy. The provision suggests that pre-emption analysis should not involve speculation about ways in which federal agency and third-party actions could potentially reconcile federal duties with conflicting state duties. When the "ordinary meaning" of federal law blocks a private party from independently accomplishing what state law requires, that party has established pre-emption.

3

To be sure, whether a private party can act sufficiently independently under federal law to do what state law requires may sometimes be difficult to determine. But this is not such a case. Before the Manufacturers could satisfy state law, the FDA had to undertake special effort permitting them to do so. To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.

Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take — asking for the FDA's help — is not a matter of state-law concern. Mensing and Demahy's tort

claims are pre-empted.

## C

Wyeth v. Levine, 555 U. S. 555, 567 (2009), is not to the contrary. In that case, as here, the plaintiff contended that a drug manufacturer had breached a state tort-law duty to provide an adequate warning label. The Court held that the lawsuit was not pre-empted because it was possible for Wyeth, a brand-name drug manufacturer, to comply with both state and federal law. Specifically, the CBE regulation permitted a brand-name drug manufacturer "to unilaterally strengthen its warning" without prior FDA approval. Thus, the federal regulations allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.

We recognize that from the perspective of Mensing and Demahy, finding pre-emption here but not in Wyeth makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. We acknowledge the unfortunate hand that federal drug regulation has dealt Mensing, Demahy, and others similarly situated.

But "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.

**Justice Sotomayor**, with whom Justice Ginsburg, Justice Breyer, and Justice Kagan join, dissenting.

The Court today invokes the doctrine of impossibility pre-emption to hold that federal law immunizes generic-drug manufacturers from all state-law failure-to-warn claims because they cannot unilaterally change their labels. I cannot agree. We have traditionally held defendants claiming impossibility to a demanding standard: Until today, the mere possibility of impossibility had not been enough to establish pre-emption.

The Food and Drug Administration (FDA) permits — and, the Court assumes, requires — generic-drug manufacturers to propose a label change to the FDA when they believe that their labels are inadequate. If it agrees that the labels are inadequate, the FDA can initiate a change to the brand-name label, triggering a corresponding change to the generic labels. Once that occurs, a generic manufacturer is in full compliance with both federal law and a state-law duty to warn. Although generic manufacturers may be able to show impossibility in some cases, Manufacturers

have shown only that they might have been unable to comply with both federal law and their state-law duties to warn respondents. This, I would hold, is insufficient to sustain their burden.

The Court strains to reach the opposite conclusion. It invents new principles of pre-emption law out of thin air to justify its dilution of the impossibility standard. It effectively rewrites our decision in *Wyeth v. Levine*, 555 U. S. 555 (2009). And a plurality of the Court tosses aside our repeated admonition that courts should hesitate to conclude that Congress intended to pre-empt state laws governing health and safety. As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug. The Court gets one thing right: This outcome "makes little sense."

This brings me to the Manufacturers' pre-emption defense. Two principles guide all pre-emption analysis. 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."

These principles find particular resonance in these cases. The States have traditionally regulated health and safety matters. Notwithstanding Congress' "certain awareness of the prevalence of state tort litigation" against drug manufacturers, Congress has not expressly pre-empted state-law tort actions against prescription drug manufacturers, whether brand-name or generic. Notably, although Congress enacted an express pre-emption provision for medical devices in 1976, it included no such provision in the Hatch-Waxman Amendments eight years later. Congress' "silence on the issue . . . is powerful evidence that [it] did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."

Impossibility pre-emption, we have emphasized, "is a demanding defense." Because pre-emption is an affirmative defense, a defendant seeking to set aside state law bears the burden to prove impossibility. To prevail on this defense, a defendant must demonstrate that "compliance with both federal and state [law] is a physical impossibility." In other words, there must be an "inevitable collision" between federal and state law. "The existence of a hypothetical or potential conflict is insufficient to warrant" pre-emption of state law.

The Manufacturers contend that it was impossible for them to provide additional warnings because federal law prohibited them from changing their labels unilaterally. They concede, however, that they could have asked the FDA to initiate a label change. If the FDA agreed that a label change was required, it could have asked, and indeed pressured, the brand-name manufacturer to change its label, triggering a corresponding change to the Manufacturers' generic labels. Thus, had the Manufacturers invoked the available mechanism for initiating label changes, they may well have been able to change their labels in sufficient time to warn respondents. Having failed to do so, the Manufacturers cannot sustain their burden to demonstrate that it was impossible for them to comply with both federal and state law.

This is not to say that generic manufacturers could never show impossibility. If a generic-manufacturer defendant proposed a label change to the FDA but the FDA rejected the proposal, it would be impossible for that defendant to comply with a state-law duty to warn. Likewise, impossibility would be established if the FDA had not yet responded to a request for a label change at the time a plaintiff's injuries arose. A generic manufacturer might also show that the FDA had itself considered whether to request enhanced warnings in light of the evidence on which a plaintiff's claim rests but had decided to leave the warnings as is. But these are questions of fact to be established through discovery. Because the burden of proving impossibility falls on the defendant, I would hold that federal law does not render it impossible for generic manufacturers to comply with a state-law duty to warn as a categorical matter.

This conclusion flows naturally from the overarching principles governing our pre-emption doctrine. Our "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'" *Wyeth*, 555 U. S., at 565-566, n. 3. It is for this reason that we hold defendants asserting impossibility to a "demanding" standard. *Wyeth*, 555 U. S., at 573. This presumption against pre-emption has particular force when the Federal Government has afforded defendants a mechanism for complying with state law, even when that mechanism requires federal agency action. In such circumstances, I would hold, defendants will usually be unable to sustain their burden of showing impossibility if they have not even attempted to employ that mechanism. Any other approach threatens to infringe the States' authority over traditional matters of state interest — such as the failure-to-warn claims here — when Congress expressed no intent to pre-empt state law.

Today's decision introduces a critical distinction between brand-name and generic drugs. Consumers of brand-name drugs can sue manufacturers for inadequate warnings; consumers of generic drugs cannot. These divergent liability rules threaten to reduce consumer demand for generics. They may pose "an ethical dilemma" for prescribing physicians. And they may well cause the States to rethink their efforts to promote generic use. These consequences are directly at odds with the Hatch-Waxman Amendments' goal of increasing consumption of generic drugs. Nothing in the Court's opinion convinces me that Congress intended these absurd results.

**Mutual Pharmaceutical Company, Inc. v. Bartlett**  
133 S. Ct. 2466 (2013)

Alito, J., delivered the opinion of the Court, in which Roberts, C. J., and Scalia, Kennedy, and Thomas, JJ., joined. Breyer, J., filed a dissenting opinion, in which Kagan, J., joined. Sotomayor, J., filed a dissenting opinion, in which Ginsburg, J., joined.

**Justice Alito** delivered the opinion of the Court.

We must decide whether federal law pre-empts the New Hampshire design-defect claim under which respondent Karen Bartlett recovered damages from petitioner Mutual Pharmaceutical, the manufacturer of sulindac, a generic nonsteroidal anti-inflammatory drug

(NSAID). New Hampshire law imposes a duty on manufacturers to ensure that the drugs they market are not unreasonably unsafe, and a drug's safety is evaluated by reference to both its chemical properties and the adequacy of its warnings. Because Mutual was unable to change sulindac's composition as a matter of both federal law and basic chemistry, New Hampshire's design-defect cause of action effectively required Mutual to change sulindac's labeling. But, as this Court recognized two Terms ago in *PLIVA, Inc. v. Mensing*, federal law prohibits generic drug manufacture from independently changing their drugs' labels. Accordingly, state law imposed a duty on Mutual not to comply with federal law. Under the Supremacy Clause, state laws that require a private party to violate federal law are pre-empted and, thus, "without effect."

The Court of Appeals' solution — that Mutual should simply have pulled sulindac from the market in order to comply with both state and federal law — is no solution. Rather, adopting the Court of Appeals' stop-selling rationale would render impossibility pre-emption a dead letter and work a revolution in this Court's pre-emption case law. Accordingly, we hold that state-law design-defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA*. We thus reverse the decision of the Court of Appeals below.

## I

Under the Federal Food, Drug, and Cosmetic Act (FDCA) drug manufacturers must gain approval from the United States Food and Drug Administration (FDA) before marketing any drug in interstate commerce. In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). The process of submitting an NDA is both onerous and lengthy. In order to provide a swifter route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, popularly known as the "Hatch-Waxman Act." Under Hatch-Waxman, a generic drug may be approved without the same level of clinical testing required for approval of a new brand-name drug, provided the generic drug is identical to the already-approved brand-name drug in several key respects.

Once a drug — whether generic or brand-name — is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including active ingredients." Generic manufacturers are also prohibited from making any unilateral changes to a drug's label.

## II

In 1978, the FDA approved a nonsteroidal anti-inflammatory pain reliever called "sulindac" under the brand name Clinoril. When Clinoril's patent expired, the FDA approved several generic sulindacs, including one manufactured by Mutual Pharmaceutical. In a very small number of patients, NSAIDs — including both sulindac and popular NSAIDs such as ibuprofen, naproxen, and Cox2-inhibitors — have the serious side effect of causing two hypersensitivity skin reactions characterized by necrosis of the skin and of the mucous membranes: toxic epidermal necrolysis, and its less severe cousin, Stevens-Johnson Syndrome.

In December 2004, respondent Karen L. Bartlett was prescribed Clinoril for shoulder pain. Her pharmacist dispensed a generic form of sulindac, which was manufactured by petitioner

Mutual Pharmaceutical. Respondent soon developed an acute case of toxic epidermal necrolysis. The results were horrific. Sixty to sixty-five percent of the surface of respondent's body deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind.

At the time respondent was prescribed sulindac, the drug's label did not specifically refer to Stevens-Johnson Syndrome or toxic epidermal necrolysis, but did warn that the drug could cause "severe skin reactions" and "[f]atalities." However, Stevens-Johnson Syndrome and toxic epidermal necrolysis were listed as potential adverse reactions on the drug's package insert. In 2005 — once respondent was already suffering from toxic epidermal necrolysis — the FDA recommended changes to the labeling of all NSAIDs, including sulindac, to more explicitly warn against toxic epidermal necrolysis.

Respondent sued Mutual in New Hampshire state court, and Mutual removed the case to federal court. Respondent initially asserted both failure-to-warn and design-defect claims, but the District Court dismissed her failure-to-warn claim based on her doctor's "admi[ssion] that he had not read the box label or insert." After a trial on respondent's design-defect claim, a jury found Mutual liable and awarded respondent over \$21 million in damages. The Court of Appeals affirmed. As relevant, it found that neither the FDCA nor the FDA's regulations pre-empted respondent's design-defect claims. It distinguished *PLIVA, Inc. v. Mensing* by arguing that generic manufacturers facing design-defect claims could simply "choose not to make the drug at all" and thus comply with both federal and state law. We granted certiorari.

### III

Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly preempted where it is "impossible for a private party to comply with both state and federal requirements." In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted.

We begin by identifying petitioner's duties under state law. Respondent is correct that New Hampshire has adopted the doctrine of strict liability in tort as set forth in Section 402A of the Restatement (Second) of Torts. Under the Restatement — and consequently, under New Hampshire law — "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused" even though he "has exercised all possible care in the preparation and sale of the product."

That New Hampshire tort law imposes a duty on manufacturers is clear. As discussed below, New Hampshire requires manufacturers to ensure that the products they design, manufacture, and sell are not "unreasonably dangerous." The New Hampshire Supreme Court has recognized that this duty can be satisfied either by changing a drug's design or by changing its labeling. Since Mutual did not have the option of changing sulindac's design, New Hampshire law ultimately required it to change sulindac's labeling.

Respondent argues that, even if New Hampshire law does impose a duty on drug manufacturers, that duty does not encompass either the "duty to change sulindac's design" or the duty "to change sulindac's labeling." That argument cannot be correct. New Hampshire imposes design-defect liability only where "the design of the product created a defective condition unreasonably dangerous to the user." To determine whether a product is "unreasonably dangerous," the New Hampshire Supreme Court employs a "risk-utility approach" under which "a product is defective as designed if the magnitude of the danger outweighs the utility of the product." That risk-utility approach requires a "multifaceted balancing process involving evaluation of many conflicting factors."

While the set of factors to be considered is ultimately an open one, the New Hampshire Supreme Court has repeatedly identified three factors as germane to the risk-utility inquiry: "the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses."

In the drug context, either increasing the "usefulness" of a product or reducing its "risk of danger" would require redesigning the drug. In the present case, however, redesign was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug on which it is based. Consequently, the Court of Appeals was correct to recognize that "Mutual cannot legally make sulindac in another composition."

Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's "risk-utility" profile — and thus to escape liability — was to strengthen "the presence and efficacy of [sulindac's] warning" in such a way that the warning "avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses." Thus, New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings.

For these reasons, it is unsurprising that allegations that sulindac's label was inadequate featured prominently at trial. And, the District Court repeatedly instructed the jury that it should evaluate sulindac's labeling in determining whether Mutual's sulindac was unreasonably dangerous. Thus, in accordance with New Hampshire law, the jury was presented with evidence relevant to, and was instructed to consider, whether Mutual had fulfilled its duty to label sulindac adequately so as to render the drug not "unreasonably dangerous." In holding Mutual liable, the jury determined that Mutual had breached that duty.

The duty imposed by federal law is far more readily apparent. As PLIVA made clear, federal law prevents generic drug manufacturers from changing their labels.

When federal law forbids an action that state law requires, the state law is "without effect." Because it is impossible for Mutual and other similarly situated manufacturers to comply with

both state and federal law, New Hampshire's warning-based design-defect cause of action is pre-empted with respect to FDA-approved drugs sold in interstate commerce.

#### IV

The Court of Appeals reasoned that Mutual could escape the impossibility of complying with both its federal — and state-law duties by "choos[ing] not to make [sulindac] at all." We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting. Adopting the First Circuit's stop-selling rationale would mean that the vast majority — if not all — of the cases in which the Court has found impossibility pre-emption, were wrongly decided. The prospect that a regulated actor could avoid liability under state and federal law by simply leaving the market is irrelevant to our analysis.

**Justice Breyer**, with whom Justice Kagan joins, dissenting.

It is not literally impossible here for a company like petitioner to comply with conflicting state and federal law. A company can comply with both either by not doing business in the relevant State or by paying the state penalty, say damages, for failing to comply with, as here, a state-law tort standard. But conflicting state law that requires a company to withdraw from the State or pay a sizable damages remedy in order to avoid the conflict between state and federal law may nonetheless "stan[d] as an obstacle to the accomplishment' of" the federal law's objective, in which case the relevant state law is pre-empted.

Normally, in deciding whether there is such a conflict I would pay particular attention to the views of the relevant agency. Here, however, I cannot give special weight to the FDA's views. The FDA, in developing its views, has held no hearings on the matter or solicited the opinions, arguments, and views of the public. The FDA has set forth its positions only in briefs filed in litigation, not in regulations, interpretations, or similar agency work product. Finally, the FDA has set forth conflicting views on this matter in different briefs filed at different times.

Without giving the agency's views special weight, I would conclude that it is not impossible for petitioner to comply with both state and federal regulatory schemes and that the federal regulatory scheme does not pre-empt state common law (read as potentially requiring petitioner to pay damages or leave the market). Moreover, the federal statute before us contains no general preemption clause. Furthermore, I have found no convincing reason to believe that removing this particular drug from New Hampshire's market, or requiring damage payments for it there, would

be so harmful that it would seriously undercut the purposes of the federal statutory scheme.

**Justice Sotomayor**, with whom Justice Ginsburg joins, dissenting.

In *PLIVA, Inc. v. Mensing*, this Court expanded the scope of impossibility pre-emption to immunize generic drug manufacturers from state-law failure-to-warn claims. Today, the Court unnecessarily and unwisely extends its holding in *Mensing* to pre-empt New Hampshire's law governing design-defects with respect to generic drugs.

The Court takes this step by concluding that petitioner Mutual Pharmaceutical was held liable for a failure-to-warn claim in disguise, even though the District Court clearly rejected such a claim and instead allowed liability on a distinct theory. Of greater consequence, the Court appears to justify its revision of Karen Bartlett's state-law claim through an implicit and undefended assumption that federal law gives pharmaceutical companies a right to sell a federally approved drug free from common-law liability. Remarkably, the Court derives this proposition from a federal law that, in order to protect consumers, prohibits manufacturers from distributing new drugs in commerce without federal regulatory approval, and specifically disavows any intent to displace state law absent a direct and positive conflict.

Karen Bartlett was grievously injured by a drug that a jury found was unreasonably dangerous. The jury relied upon evidence that the drug posed a higher than normal risk of causing the serious skin reaction that produced her horrific injuries; carried other risks; and possessed no apparent offsetting benefits compared to similar pain relievers, like aspirin. The Court laments her "tragic" situation, but responsibility for the fact that Karen Bartlett has been deprived of a remedy for her injuries rests with this Court. If our established pre-emption principles were properly applied, and if New Hampshire law were correctly construed, then federal law would pose no barrier to Karen Bartlett's recovery. I respectfully dissent.

I begin with "two cornerstones of our pre-emption jurisprudence," *Wyeth v. Levine*, 555 U. S. 555, 565 (2009), that should control this case but are conspicuously absent from the majority opinion. First, "'the purpose of Congress is the ultimate touchstone' in every pre-emption case." Second, we start from the "assumption that the historic police powers of the States [are] not to be superseded by [a] Federal Act unless that was the clear and manifest purpose of Congress." "That assumption," we have explained, "applies with particular force when," as is the case here, "Congress has legislated in a field traditionally occupied by the States."

The Court applied both of these principles to the Federal Food, Drug, and Cosmetic Act (FDCA) in *Levine*, where we held that a state failure-to-warn claim against a brand-name drug manufacturer was not pre-empted by federal law. Tracing the history of federal drug regulation from the 1906 Federal Food and Drugs Act up to the FDCA and its major amendments, the Court explained that federal drug law and state common-law liability have long been understood to operate in tandem to promote consumer safety. That basic principle, which the majority opinion elides, is essential to understanding this case.

Congress' preservation of a role for state law generally, and common-law remedies specifically, reflects a realistic understanding of the limitations of ex ante federal regulatory review in this context. On its own, even rigorous preapproval clinical testing of drugs is "generally . . . incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect subpopulations not included or adequately represented in the studies." Moreover, the FDA, which is tasked with monitoring thousands of drugs on the market and considering new drug applications, faces significant resource constraints that limit its ability to protect the public from dangerous drugs. Tort suits can help fill the gaps in federal regulation by "serv[ing] as a catalyst" to identify previously unknown drug dangers.

Perhaps most significant, state common law provides injured consumers like Karen Bartlett with an opportunity to seek redress that is not available under federal law. While the Court has not always been consistent on this issue, it has repeatedly cautioned against reading federal statutes to "remove all means of judicial recourse for those injured" when Congress did not provide a federal remedy. And in fact, the legislative history of the FDCA suggests that Congress chose not to create a federal cause of action for damages precisely because it believed that state tort law would allow injured consumers to obtain compensation.

In light of this background, Mutual should face an uphill climb to show that federal law pre-empts a New Hampshire strict-liability claim against a generic drug manufacturer for defective design. The majority nevertheless accepts Mutual's argument that "compliance with both federal and state [law was] a physical impossibility." But if state and federal law are properly understood, it is clear that New Hampshire's design-defect claim did not impose a legal obligation that Mutual had to violate federal law to satisfy.

Impossibility pre-emption "is a demanding defense," *Levine*, 555 U. S., at 573, that requires the defendant to show an "irreconcilable conflict" between federal and state legal obligations. The key inquiry is to identify whether state law "require[s] the doing of an act which is unlawful under" federal law. Impossibility does not exist where the laws of one sovereign permit an activity that the laws of the other sovereign restricts or even prohibits. So, to modify the previous example, if federal law permitted (but did not require) a labeling practice that state law prohibited, there would be no irreconcilable conflict; a manufacturer could comply with the more stringent regulation. And by the same logic, impossibility does not exist where one sovereign's laws merely create an incentive to take an action that the other sovereign has not authorized because it is possible to comply with both laws.

Of course, there are other types of pre-emption. Courts may find that state laws that incentivize what federal law discourages or forbid what federal law authorizes are preempted for reasons apart from impossibility: The state laws may fall within the scope of an express pre-emption provision, pose an obstacle to federal objectives, or intrude upon a field that Congress intended for federal law to occupy exclusively. But absent a direct conflict between two mutually incompatible legal requirements, there is no impossibility and courts may not automatically assume that Congress intended for state law to give way. Instead, a more careful inquiry into congressional intent is called for, and that inquiry should be informed by the

presumption against pre-emption. Cases that actually find pre-emption on that basis are rare. Nothing in *Mensing*, nor any other precedent, dictates finding impossibility pre-emption here.

To assess whether it is physically impossible for Mutual to comply with both federal and state law, it is necessary to identify with precision the relevant legal obligations imposed under New Hampshire's design-defect cause of action. The majority insists that Mutual was required by New Hampshire's design-defect law to strengthen its warning label. In taking this position, the majority effectively recharacterizes Bartlett's design-defect claim as a de facto failure-to-warn claim. The majority then relies on that recharacterization to hold that the jury found Mutual liable for failing to fulfill its duty to label sulindac adequately, which *Mensing* forbids because a generic drug manufacturer cannot independently alter its safety label. But the majority's assertion that Mutual was held liable in this case for violating a legal obligation to change its label is inconsistent with both New Hampshire state law and the record.

The design-defect claim that was applied to Mutual subjects the manufacturer of an unreasonably dangerous product to liability, but it does not require that manufacturer to take any specific action forbidden by federal law. Specifically, and contrary to the majority, New Hampshire's design-defect law did not require Mutual to change its warning label. To be sure, New Hampshire's design-defect claim creates an incentive for drug manufacturers to make changes to its product, including the label, to try to avoid liability. But exposure to liability is not equivalent to a legal mandate for a regulated party to take (or refrain from taking) a specific action. This difference is a significant one: A mandate leaves no choice for a party that wishes to comply with the law, whereas an incentive may only influence a choice.

The most troubling aspect of the majority's decision to once again expand the scope of this Court's impossibility doctrine is what it implies about the relationship between federal premarket review and state common-law remedies more generally. Central to the majority's holding is an assumption that manufacturers must have a way to avoid state-law liability while keeping particular products in commerce. This assumption will always create an automatic conflict between a federal premarket review requirement and state-law design-defect liability because premarket review, by definition, prevents manufacturers from unilaterally changing their products. That is true of the designs of brand-name drugs no less than it is for generic drugs.

This expanded notion of impossibility pre-emption threatens to disturb a considerable amount of state law. This could have serious consequences for product safety. State design-defect laws play an important role not only in discovering risks, but also in providing incentives for manufacturers to remove dangerous products from the market promptly. If manufacturers of products that require preapproval are given de facto immunity from design-defect liability, then the public will have to rely exclusively on imperfect federal agencies with limited resources and sometimes limited authority. And consumers injured by those products will have no recourse.