Levine v. Wyeth (2004-384)

2006 VT 107

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2006 VT 107

No. 2004-384

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| Diana Levine | Supreme Court |
| v. | On Appeal from<br>Washington Superior Court |
| Wyeth | October Term, 2005 |

Geoffrey W. Crawford, J.

Richard I. Rubin and Kerry B. DeWolfe of Rubin, Kidney, Myer & DeWolfe, Barre, for Plaintiff-Appellee.

Allan R. Keyes and R. Joseph O'Rourke of Ryan, Smith & Carbine, Ltd., Rutland, and Bert W. Rein, Karyn K. Ablin and Sarah E. Botha of Wiley Rein & Fielding LLP, and Daniel S. Pariser of Arnold & Porter LLP, Washington, D.C., for Defendant-Appellant.

PRESENT: Reiber, C.J., Dooley and Johnson, JJ., and Morris, D.J., and Allen, C.J. (Ret.), Specially Assigned

¶ 1. JOHNSON, J. Defendant Wyeth, a drug manufacturer, appeals from a jury verdict in favor of plaintiff Diana Levine, who suffered severe injury and the amputation of her arm as a result of being injected with defendant's drug Phenergan. Plaintiff claimed at trial that defendant was negligent and failed to provide adequate warnings of the known dangers of injecting Phenergan directly into a patient's vein. Defendant argues that the trial court should not have allowed the jury to consider plaintiff's claims because the claims conflict with defendant's obligations under federal law regulating prescription drug labels. We hold that there is no conflict between state and federal law that requires preemption of plaintiff's claim. Defendant also raises two claims of error relating to the jury instructions on damages. We hold that the court's rulings on these jury instructions were correct, and we affirm.

¶ 2. In April 2000, plaintiff was injected with defendant's drug Phenergan at Northeast Washington County Community Health, Inc. ("the Health Center"). The drug was administered to treat plaintiff's nausea resulting from a migraine headache. Plaintiff received two injections. The drug was first administered by intramuscular injection. Later the same day, when plaintiff's nausea continued, she received a second dose by a direct intravenous injection into her arm, using a procedure known as "IV push." The second injection resulted in an inadvertent injection of Phenergan into an artery. As a result, the artery was severely damaged, causing gangrene. After several weeks of deterioration, plaintiff's hand and forearm were amputated.

¶ 3. Plaintiff brought a superior court action for negligence and failure-to-warn product liability, alleging that defendant's inadequate warning of the known dangers of direct intravenous injection of Phenergan caused her injuries. During a five-day jury trial, both parties presented expert testimony regarding the adequacy of the warnings defendant placed on Phenergan's label. Plaintiff's experts testified that the label should not have allowed IV push as a means of administration, as it was safer to use other available options, such as intramuscular injection or administration through the tubing of a hanging IV bag. Defendant's expert testified that allowing IV push with instructions cautioning against inadvertent arterial injection was sufficient. The court instructed the jurors that they could consider the FDA's approval of the label in use at the time of plaintiff's injury, but that the label's compliance with FDA requirements did not establish the adequacy of the warning or prevent defendant from adding to or strengthening the warning on the label. At the conclusion of the trial, the jury found in favor of plaintiff on both the negligence and product-liability claims and awarded her $2.4 million in economic damages and $5 million in non-economic damages. Pursuant to the parties' stipulation, this award was reduced to a total of $6,774,000 to account for pre-judgment interest and plaintiff's recovery in a settlement of a separate action she had filed against the Health Center.

¶ 4. In a summary judgment motion prior to trial, as well as in its timely motion for judgment as a matter of law following trial, both of which the superior court denied, defendant argued that federal law preempted plaintiff's claim. These arguments rested in part on defendant's contention that it had submitted an adequate warning to the FDA, but that the FDA rejected the change because it did not favor strengthening the warning.(FN1) Plaintiff contended that neither warning would have been adequate. The trial court stated, in its decision on defendant's motion for judgment as a matter of law, that although the FDA had rejected a new warning, the agency's "brief comment" failed to explain its reasoning or demonstrate that it "gave more than passing attention to the issue of whether to use an IV infusion to administer the drug. The proposed labeling change did not address the use of a free-flowing IV bag." The court concluded that there was "no basis for federal preemption" and upheld the jury's verdict.

¶ 5. Defendant claims the superior court erred by: (1) failing to dismiss plaintiff's claim on the basis that the Food and Drug Administration's approval of the Phenergan label preempted state common law claims that the label was inadequate; (2) failing to instruct the jury to reduce plaintiff's damages by the amount of fault attributable to the Health Center; and (3) failing to instruct the jury to calculate the

present value of plaintiff's damages for future non-economic losses. We reject these claims of error, and we affirm.

## I. Federal Preemption

¶ 6. Defendant's principal argument on appeal is that the court should have dismissed plaintiff's claim because it was preempted by federal law. Defendant asserts that any state common law duty to provide a stronger warning about the dangers of administering Phenergan by IV push conflicts with the FDA's approval of the drug's label. As preemption is a question of law, we review the trial court's decision de novo. Office of Child Support v. Sholan, 172 Vt. 619, 620, 782 A.2d 1199, 1202 (2001) (mem.). We hold that the jury's verdict against defendant did not conflict with the FDA's labeling requirements for Phenergan because defendant could have warned against IV-push administration without prior FDA approval, and because federal labeling requirements create a floor, not a ceiling, for state regulation.

¶ 7. The United States Constitution provides that federal law is the supreme law of the land. U.S. Const. art. VI, cl. 2. The Supremacy Clause is the basis for the doctrine of preemption, according to which "state law that conflicts with federal law is 'without effect.' " Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)). In Cipollone, the Court described the relevant analysis for determining whether Congress intended a federal statute to preempt state law:

> Congress' intent may be explicitly stated in the statute's language or implicitly contained in its structure and purpose. In the absence of an express congressional command, state law is pre-empted if that law actually conflicts with federal law, or if federal law so thoroughly occupies a legislative field as to make reasonable the inference that Congress left no room for the States to supplement it.

Id. (quotations and citations omitted). Absent clear congressional intent to supersede state law, including state common law duties, there is a presumption against preemption. Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action."); Cipollone, 505 U.S. at 516 ("Consideration of issues arising under the Supremacy Clause 'start[s] with the assumption that the historic police powers of the States [are] not to be superseded by . . . Federal Act unless that [is] the clear and manifest purpose of Congress.' " (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947))). This presumption has "add[ed] force" when there has been a "long history of tort litigation" in the area of state common law at issue. Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

¶ 8. Defendant concedes that Congress has not expressly preempted state tort actions through the Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. ¶¶ 301-399, and that Congress did not intend the FDCA to occupy the entire field of prescription drug regulation. Rather, it asserts that plaintiff's action "actually conflicts with federal law." Cipollone, 505 U.S. at 516. This requires defendant to show either that "it is impossible for a private party to comply with both state and federal

requirements," or that Vermont's common law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (quotations and citations omitted).

¶ 9. Defendant presents two alternative bases for its assertion of conflict preemption: (1) in the specific context of the Phenergan label, the FDA was aware of the dangers of IV-push administration and specifically ordered defendant to use the warning it used, making it impossible for defendant to comply with both its state common-law duty and the requirements of federal law; and (2) by penalizing drug companies for using FDA-approved wording on drug labels, state tort claims like plaintiff's present an obstacle to the purpose of the FDA's labeling regulations. Before reaching these issues, we briefly examine the FDA's role in regulating prescription drug labels and the general approach courts have taken to the preemptive effect of federal labeling requirements.

A. Regulatory Background

¶ 10. Prior to distributing a prescription drug such as Phenergan, the manufacturer must submit a New Drug Application (NDA) for FDA approval. 21 U.S.C. ¶ 355(a). The FDA must approve the application unless it fails to meet certain criteria, including whether test results and other information establish that the drug is "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof," whether there is "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof," and whether, "based on a fair evaluation of all material facts, such labeling is false or misleading in any particular." Id. ¶ 355(d).

¶ 11. "FDA regulations mandate the general format and content of all sections of labels for all prescription drugs as well as the risk information each section must contain," and "[f]inal approval of the NDA is 'conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed label prior to marketing.' " McNellis v. Pfizer, Inc., 2005 WL 3752269, at *4 (D.N.J.) (citing 21 C.F.R. ¶¶ 201.56, 201.57, and quoting 21 C.F.R. ¶ 314.105(b)). Once a drug and its label have been approved, any changes to the label ordinarily require submission and FDA approval of a "Supplemental NDA."
Id.; 21 C.F.R. ¶ 314.70(b)(2)(v)(A).

¶ 12. If the NDA process and the submission of changes for FDA approval were the exclusive means of creating and altering prescription drug labels, this might be a very different case. A key FDA regulation, however, allows a drug's manufacturer to alter the drug's label without prior FDA approval when necessary. The regulation provides in relevant part:

> (6) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved application may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to:

. . . .

(iii) Changes in the labeling . . . to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction;

. . . .

(B) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product[.]

21 C.F.R. ¶ 314.70(c).

¶ 13. Section 314.70(c) creates a specific procedure allowing drug manufacturers to change labels that are insufficient to protect consumers, despite their approval by the FDA. "The FDA's approved label . . . can therefore be said to set the minimum labeling requirement, and not necessarily the ultimate label where a manufacturer improves the label to promote greater safety." McNellis, 2005 WL 3752269, at *5. While specific federal labeling requirements and state common-law duties might otherwise leave drug manufacturers with conflicting obligations, ¶ 314.70(c) allows manufacturers to avoid state failure-to-warn claims without violating federal law. Id. ("[I]t is apparent that prior FDA approval need not be obtained, nor will a product be deemed mislabeled, if the manufacturer voluntarily or even unilaterally strengthens the approved warnings, precautions or potential adverse reactions upon the label pursuant to 21 C.F.R. ¶ 314.70(c)(6)(iii)(A)."). There is thus no conflict between federal labeling requirements and state failure-to-warn claims. Section 314.70(c) allows, and arguably encourages, manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to protect consumers. State tort claims simply give these manufacturers a concrete incentive to take this action as quickly as possible.

B. Conflict Preemption in Other Jurisdictions

¶ 14. In light of the leeway created by ¶ 314.70(c) for drug manufacturers to add warnings, courts have been nearly unanimous in holding that state failure-to-warn tort claims do not conflict with federal law. See, e.g., McNellis, 2005 WL 3752269, at *7 ("[T]he FDCA and the FDA's regulations do not conflict with New Jersey's failure to warn law because those federal regulations merely set minimum standards with which manufacturers must comply."). McNellis is the latest in a series of recent cases addressing this issue as it relates to the anti-depressant Zoloft, which allegedly increases the risk of suicide in some patients. See id., at *7-8 (denying summary judgment and rejecting conflict preemption in Zoloft case); accord Zikis v. Pfizer, Inc., 2005 WL 1126909, at *2-3 (N.D. Ill.); Witczak v. Pfizer, Inc., 377 F. Supp. 2d 726, 729-30 (D. Minn. 2005); Motus v. Pfizer, Inc., 127 F. Supp. 2d 1085, 1096-1100 (C.D. Cal. 2000); see also Cartwright v. Pfizer, Inc., 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005) ("With little exception, courts that have considered this exact issue have concluded that state failure to warn claims are not preempted by the FDCA and its attendant regulations."). Contra Needleman v. Pfizer, Inc., 2004 WL 1773697, at *1 (N.D. Tex.) (granting summary judgment to the

defendant on basis of conflict preemption).

¶ 15. The Zoloft cases are representative of a general rule that FDA approval of a drug's label does not preempt state failure-to-warn claims. See, e.g., Eve v. Sandoz Pharm. Corp., 2002 WL 181972, at *1-3 (S.D. Ind.) (rejecting conflict preemption of failure-to-warn claim regarding the drug Parlodel); Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1032 (S.D. Ill. 2001) (same); Bryant v. Hoffman-La Roche, Inc., 585 S.E.2d 723, 725 (Ga. Ct. App. 2003) (heart medication); Bell v. Lollar, 791 N.E.2d 849, 854-55 (Ind. Ct. App. 2003) (prescription pain medication); Kurer v. Parke, Davis & Co., 2004 WI App 74, 21, 679 N.W.2d 867 (oral contraceptive). But see Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (granting summary judgment to defendant on basis of conflict preemption of claim regarding the drug Adderall).

¶ 16. Defendant cites two cases, Needleman and Ehlis, that support the preemptive effect of the FDCA in failure-to-warn cases regarding prescription drug labels. Needleman, 2004 WL 1773697, at *1; Ehlis, 233 F. Supp. 2d at 1198. Needleman is not particularly helpful under the circumstances here. Its holding relied on the facts of the Zoloft litigation, particularly an FDA statement that the warning advocated by the plaintiff would have been misleading. 2004 WL 1773697, at *1. The courts in the other Zoloft cases took a different approach to the FDA's statement, in part because the FDA's statement was not "an official agency position," and in part because the FDA later retracted its position regarding the link between Zoloft and suicide. See, e.g., Witczak, 377 F. Supp. 2d at 730. Here, the FDA has not indicated that a stronger warning would be misleading, so the reasoning of Needleman appears inapplicable to this case. Ehlis interpreted ¶ 314.70(c) as allowing unapproved changes to a label only temporarily, and only under "limited circumstances." 233 F. Supp. 2d at 1197-98. We can find no support for this interpretation in the language of the regulation, which appears to allow unilateral changes to drug labels whenever the manufacturer believes it will make the product safer, and places no limit on the duration of pre-approval warnings unless the FDA disapproves of the change. 21 C.F.R. ¶ 314.70(c).

¶ 17. Defendant next attempts to draw a comparison to the regulation of medical devices under the FDCA, citing medical device cases in which state tort law has been preempted. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (holding that "fraud-on-the-FDA" claim relating to device regulated by Medical Device Amendments to FDCA was preempted); Horn v. Thoratec Corp., 376 F.3d 163, 177 (3d Cir. 2004) (holding that failure-to-warn claim was preempted by Medical Device Amendments). We find this analogy unpersuasive. Neither Buckman nor Horn weakens the force of the drug-labeling cases cited above. The claim that was preempted in Buckman was for "fraud on the FDA," not failure to warn; the Court held that the presumption against preemption applies only when a claim implicates " 'the historic primacy of state regulation of health and safety,' " which is not the case when the claim arises from a federal statute. 531 U.S. at 347-48 (quoting Medtronic, 518 U.S. at 485). Plaintiff's negligence and product-liability claims fall squarely within the scope of traditional state regulation, so it is appropriate to apply the presumption against preemption here. In Horn, the Third Circuit relied on an express preemption clause in the FDCA that relates only to medical devices. 376 F.3d at 176. Because no such clause exists for prescription drugs, Horn's reasoning does not apply to this case.

¶ 18. Finally, defendant cites a third group of cases relating generally to the United States Supreme Court's recent use of conflict preemption in other fields. This argument relies primarily on Geier v. American Honda Motor Co., 529 U.S. 861 (2000). In Geier, the Court held that state tort claims based on the production of automobiles without airbags conflicted with federal regulations making airbags one of several permissible safety equipment options. 529 U.S. at 881. Geier, however, rested on the conclusion that the Department of Transportation's intent in drafting the regulation at issue was to provide a range of different safety options, thus precluding any state determination that a specific type of equipment should be required. Id. The history of the regulation at issue indicated that the agency intended to phase in automobile safety requirements gradually, allowing the public to choose between mandatory seatbelt laws at the state level and a federal passive-restraint requirement. Id. at 880-81. Allowing state tort claims based on the lack of a particular safety mechanism would have conflicted with both the agency's phase-in plan and its intent to provide consumers with a range of safety options. Id. at 881. The Court explicitly stated that in a different context, an agency could promulgate regulations that provided a floor, but not a ceiling, for state regulation. Id. at 870.

¶ 19. The FDA's labeling requirements are exactly that type of regulation. Section 314.70(c) does not allow us to interpret FDA approval of a drug label as anything but a first step in the process of warning consumers. When further warnings become necessary, the manufacturer is at least partially responsible for taking additional action, and if it fails to do so, it cannot rely on the FDA's continued approval of its labels as a shield against state tort liability. While a state common-law duty may encourage departure from a label that the FDA has approved in great detail, such a duty does not create a conflict with federal requirements because the FDA and the state share the purpose of encouraging pharmaceutical companies to alter their drug labels when they are inadequate to protect consumers. We agree with the significant majority of courts that state failure-to-warn claims are generally not preempted by federal labeling requirements.

¶ 20. We must now apply this reasoning to defendant's two original contentions: (1) notwithstanding the fact that it is generally possible for manufacturers to comply with both federal and state law through the procedures created by ¶ 314.70(c), the FDA's specific actions with respect to Phenergan made it impossible for defendant to comply with both federal and state law; and (2) even if plaintiff's claim and the cases cited above do not make it impossible for manufacturers to comply with both state and federal law, they present an obstacle to federal objectives.

C. Impossibility of Compliance

¶ 21. Defendant contends that in this case, it was impossible to comply with both state and federal law because the FDA prohibited the use of a stronger warning with respect to IV-push administration of Phenergan. This claim is not supported by the evidence defendant presented to the trial court. The record lacks any evidence that the FDA was concerned that a stronger warning was not supported by the facts, that such a stronger warning would distract doctors from other provisions in the drug's label, or that the warning might lead to less effective administration of the drug. Instead, defendant essentially relies on two factual assertions: 1) the FDA approved the label that was in use in 2000; and 2) the FDA, in

reviewing the label for use in a different version of Phenergan, expressed its opinion of the adequacy of the warning in the original label by stating, "Retain verbiage in current label." AB 5, 5 n.7

¶ 22. With respect to defendant's first assertion, our analysis above demonstrates that FDA approval of a particular label does not preempt a jury finding that the label provided insufficient warning, as defendant was free under ¶ 314.70(c) to strengthen the warning without prior FDA approval. Defendant's second assertion depends on the meaning of the instruction, "[r]etain verbiage in current label." Tort liability for defendant's failure to strengthen its warning could have created a direct conflict requiring federal preemption only if the FDA intended the instruction to prohibit any language strengthening the original warning. In other words, unless we interpret the FDA's statement as evidence that it would have rejected any attempt by defendant to strengthen its label through ¶ 314.70(c), we cannot conclude that it was impossible for defendant to comply with its state common-law duty without violating federal law.

¶ 23. Defendant argues that the instruction reflected the FDA's opinion not only that a stronger warning was unnecessary, but also that it would have harmed patients by eliminating IV push as an option for administering Phenergan. The record does not support this interpretation. Defendant has provided a number of letters exchanged by the FDA and defendant regarding Phenergan's label, but these letters do not indicate the FDA's opinion of the value of IV-push administration. Neither the letters nor any other evidence presented to the jury indicated that the FDA wished to preserve the use of IV push as a method of administering Phenergan. Nor can we infer such concern from the agency's instruction to "[r]etain current verbiage" instead of adopting the proposed warning. The specific warning the agency rejected in favor of the original label did not indicate any more clearly than the original label that IV-push administration was unsafe, which is what plaintiff argued made the original label inadequate. The FDA could have rejected the new warning for any number of reasons, including clarity or technical accuracy, without implicitly prohibiting a stronger warning. Defendant's unsupported hypothesis that the FDA saw the new warning as harmful seems among the least likely explanations, as the rejected proposal would not have eliminated IV push as an option for administering Phenergan.(FN2) With respect to IV administration, the original label read, "When administering any irritant drug intravenously it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily," while the proposed label stated, "[i]njection through a properly running intravenous infusion may enhance the possibility of detecting arterial placement. In addition, this results in delivery of a lower concentration of any arteriolar irritant." See supra 4 n.1 (comparing proposed and original warnings). Simply stated, the proposed warning was different, but not stronger. It was also no longer or more prominent than the original warning, so it could not have raised a concern that it might overshadow other warnings on the label or drive doctors away from prescribing the drug. There is no evidence that the FDA intended to prohibit defendant from strengthening the Phenergan label pursuant to ¶ 314.70(c).(FN3) Thus, we cannot conclude that it was impossible for defendant to comply with its obligations under both state and federal law.

D. Obstacle to Congressional Purposes and Objectives

¶ 24. Defendant next contends that state common-law liability for its use of an FDA-approved label presents an obstacle to federal objectives. We hold that plaintiff's claim does not interfere with any objective that can legitimately be ascribed to Congress. We agree with the reasoning in the cases cited above, supra 14-15, that federal labeling requirements pursuant to the FDCA create a floor, not a ceiling, for state regulation. Defendant presents a new FDA rule containing language disputing this reasoning, but this statement does not alter our conclusion that there is no conflict between federal objectives and Vermont common law.

1. The Purposes and Objectives of Congress

¶ 25. In the absence of a conflict that makes it impossible for a regulated entity to comply with both state and federal law, federal law will preempt state law only if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Freightliner, 514 U.S. at 287 (quotations omitted). We must therefore examine what "the full purposes and objectives of Congress" were with respect to federal labeling requirements for prescription drugs. We agree with the McNellis court that a system under which "federal regulations merely set minimum standards with which manufacturers must comply" is

> fully consistent with Congress' primary goal in enacting the FDCA, which is "to protect consumers from dangerous products," United States v. Sullivan, 332 U.S. 689, 696 (1948), as well as Congress' stated intent that the FDCA " 'must not weaken the existing laws,' but on the contrary 'it must strengthen and extend that law's protection of the consumer.' " United States v. Dotterweich, 320 U.S. 277[, 282] (1943) [quoting S. Rep. No. 152, 75th Cong., 1st Sess., p. 1].

2005 WL 3752269, at *7; see also Witczak, 377 F. Supp. 2d at 731 ("Congress certainly did not intend to bar drug companies from protecting the public when enacting the FDCA; its goal was to protect the public. . . . Any contrary interpretation of Congress's intent is perverse.").

¶ 26. In fact, Congress has expressed its purposes clearly, not only in the general sense that the statute was intended to "protect the public," but also more specifically, with respect to the FDCA's preemptive effect. In the 1962 amendments to the FDCA, Congress included a clause expressly limiting the preemptive effect of the statute: "Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of State law." Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87 781, ¶ 202, 76 Stat. 780, 793 (1962).

¶ 27. This amendment essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress. Congress intended that the FDCA would leave state law in place except where it created a "direct and positive conflict" between state and federal law. Drug Amendments ¶ 202. This language "simply restates the principle that state law is superseded in cases of an actual conflict with federal law such that 'compliance with

both federal and state regulations is a physical impossibility.' " See S. Blasting Servs., Inc. v. Wilkes County, 288 F.3d 584, 591 (4th Cir. 2002) (interpreting "direct and positive conflict" language in the preemption clause of a federal statute governing explosive materials to allow states to "impose more stringent requirements than those contained in the federal regulations") (quoting Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 713 (1985)).(FN4) In other words, under any circumstances where it is possible to comply with both state law and the FDCA, the state law in question is consistent with the purposes and objectives of Congress. Thus, our discussion above regarding defendant's impossibility argument, supra 21-23, provides a complete answer to the question of preemption.

¶ 28. We recognize that our dissenting colleague has reached the opposite conclusion. There is little to say, beyond what we have already said, except that we respectfully disagree with his analysis of the FDCA, the FDA's regulations, and the specific context of this lawsuit. Numerous courts have concluded, over the course of decades, that the FDCA provides a floor, not a ceiling, for state regulation. See supra, 14-15. While the dissent cites favorably the minority view, we agree with the majority view. There is much to be said for the policy arguments employed by courts adopting this minority view, including the argument that permitting too much state activity in this area will make beneficial drugs less available to consumers. Similarly, there is merit to the majority perspective that eliminating lawsuits like the one at issue here would leave consumers without recourse in the event the FDA cannot move quickly enough to require strengthened warnings when they are appropriate. Our view is that neither policy argument is relevant here. The plain language of the statute indicates that Congress did not intend to interfere with state prerogatives except where doing so is absolutely necessary, see supra, 25-27, and the plain language of the regulation makes such interference unnecessary here, see supra, 12-13. This analysis is consistent with the constitutionally rooted presumption against preemption. To look more broadly at arguments relying on assumptions about safety and economic efficiency is to apply the opposite presumption-the presumption that Congress could not possibly have intended to allow states to intrude on what seems, intuitively, to be an area of federal expertise. It is neither our responsibility, nor that of the FDA, to question the policy judgments of Congress. The litigation at issue here does not pose a direct and positive conflict with federal law, and thus, there is no basis for federal preemption.

2. The FDA's New Statement on Preemption

¶ 29. Defendant, after oral argument in this case, cited a new FDA regulation that contains a statement relating to the preemptive effect of the FDCA. The substance of the regulation changes certain aspects of labeling requirements for prescription drugs, but these changes are irrelevant to this appeal because the new rule did not take effect until June 2006. Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, Supplementary Information, 71 Fed. Reg. 3922, 3922 (Jan. 24, 2006). The rule's "Supplementary Information" section, however, contains a broad statement regarding the preemption of state common-law failure-to-warn claims. Id. at 3933-36. In this statement, the FDA asserts that recent cases rejecting preemption of these claims, including those cited above, pose an obstacle to the agency's enforcement of the labeling requirements. Id. Among the interpretations the agency claims are incorrect are: (1) those rejecting preemption on the basis of ¶ 314.70(c); and (2) those

stating that federal labeling requirements are minimum standards and that "[s]tate law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA under the act." Id. at 3934.

¶ 30. We are ordinarily required to defer to an agency's interpretation of a statute it administers. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer . . . ."). Plaintiff, however, urges us not to defer to the FDA's statement because it "was adopted without the requisite comment period" and "lack[s] the force of law." Presumably, if we were to credit plaintiff's argument, we would owe the statement only the limited deference due to agency statements made outside the agency's rulemaking authority. See United States v. Mead Corp., 533 U.S. 218, 226-27 (2001) (stating that Chevron deference applies only "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority"). We need not decide this difficult question of administrative law, however, because we conclude that irrespective of the level of deference we might apply, the statement would not affect the outcome of this appeal.

¶ 31. Under Chevron, deference to an agency's interpretation is appropriate only when a statute is "silent or ambiguous with respect to the specific issue" the agency has considered; otherwise, "the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." 467 U.S. at 842-43. Moreover, "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent." Id. at 843 n.9. "If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect." Id. When an agency's interpretation is not the type of interpretation entitled to Chevron deference, we must still grant it some respect, but only "a respect proportional to its 'power to persuade.' " Mead, 533 U.S. at 235 (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944)).

¶ 32. Under either standard, the FDA's statement deserves no deference. We have already concluded, supra 26-27, that Congress intended the FDCA to preempt only those state laws that would make it impossible for manufacturers to comply with both federal and state requirements. Nothing in the FDA's new statement alters our conclusion that it would be possible for defendant to comply with both its federal obligations and the obligations of state common law. The regulatory framework for prescription drug labeling allows drug manufacturers to add or strengthen a warning "to increase the safe use of the drug product" without prior FDA approval. See supra 10-13 (citing 21 C.F.R. ¶ 314.70(c)(6)(iii)(C)). Even if the new rule eliminated or altered this provision, the change in the regulation did not take effect until June 2006.(FN5) Without such a change, it is possible for manufacturers to comply with both FDA regulations and duties imposed by state common law, and there is no "direct and positive conflict" between state and federal law.

¶ 33. The FDA does not attempt to establish such a conflict or explain the inconsistency between its position and the language of the preemption amendment. The statement cites the amendment, but then proceeds as if Congress had not spoken on the issue of preemption. The agency relies on Geier to support its disregard of Congress's "direct and positive conflict" language, asserting that "[t]he existence of a legislative provision addressing pre-emption does not bar the operation of ordinary principles of implied preemption." 71 Fed. Reg. at 3935 (citing Geier, 529 U.S. at 869). Geier does state that implied preemption applies even when a statute addresses preemption expressly, 521 U.S. at 869, but it does not allow courts or agencies to preempt state laws that have been expressly preserved by Congress. Instead, it simply stands for the proposition that Congress's intent not to preempt a provision of state law cannot be inferred from either (1) an express preemption clause that does not include the state law in question in its scope, or (2) a clause that prevents regulated entities from using compliance with federal law as a defense in state common-law suits. Id. at 869-70. According to Geier, the former clause does not support a negative inference that Congress must have intended to preserve laws it did not expressly preempt; the latter indicates only that Congress intended to preserve some common-law claims, not that it intended to allow even claims that conflict with federal requirements. Id. But see id. at 870 (stating that even the latter clause would "preserve[] those actions that seek to establish greater safety than the minimum safety achieved by a federal regulation intended to provide a floor").

¶ 34. Here, we are not attempting to infer the effect of statutory language that only indirectly addresses the specific state law at issue. Instead, we are interpreting an unambiguous express preemption clause that specifically preserves the type of state law at issue. Under these circumstances, ordinary preemption principles must give way to Congress's intent to preserve state laws that do not create a "direct and positive conflict" with federal law. Drug Amendments ¶ 202. There is no such conflict here. Accordingly, the FDA's statement is neither an authoritative interpretation of an ambiguous statutory provision entitled to deference, Chevron, 467 U.S. at 842-43, nor a persuasive policy statement entitled to respect. Mead, 533 U.S. at 235. Plaintiff's claim does not impose conflicting obligations on defendant or present an obstacle to the objectives of Congress. We therefore agree with the trial court that the claim is not preempted by federal law.

## II. Apportionment of Damages

¶ 35. Defendant next contends the court erred by failing to instruct the jury to reduce plaintiff's damages by the amount of fault attributable to the Health Center. "Reversing a jury verdict based on allegedly faulty jury instructions is warranted where the party claiming error establishes that the instructions were erroneous and prejudicial." Simpson v. Rood, 2005 VT 21, 5, 178 Vt. 474, 872 A.2d 306 (mem.). We hold that there was no error in the court's failure to require apportionment of damages between defendant and the Health Center.

¶ 36. Defendant argues that pursuant to Vermont's comparative negligence statute, a defendant is liable for only the portion of the plaintiff's damages attributable directly to that defendant's negligence. 12 V.S.A. ¶ 1036. Our traditional rule is that multiple tortfeasors are

jointly and severally liable. See Zaleskie v. Joyce, 133 Vt. 150, 158, 333 A.2d 110, 115 (1975) ("[T]he law of this state . . . permits a plaintiff to pursue all, or any part, of his recovery from either joint tortfeasor"). According to defendant, ¶ 1036 applies not only under circumstances where comparative negligence is alleged on the part of the plaintiff, and not only when multiple defendants are sued in the same action, but also any time the plaintiff recovers from someone besides the defendant. Thus, because plaintiff and the Health Center reached a settlement in a separate lawsuit related to the same injury, defendant claims the jury should have been required to calculate the Health Center's proportion of causal negligence and subtract that percentage from the verdict.

¶ 37. Section 1036 states, under the heading of "Comparative negligence,"

> Contributory negligence shall not bar recovery in an action by any plaintiff, or his legal representative, to recover damages for negligence resulting in death, personal injury or property damage, if the negligence was not greater than the causal total negligence of the defendant or defendants, but the damage shall be diminished by general verdict in proportion to the amount of negligence attributed to the plaintiff. Where recovery is allowed against more than one defendant, each defendant shall be liable for that proportion of the total dollar amount awarded as damages in the ratio of the amount of his causal negligence to the amount of causal negligence attributed to all defendants against whom recovery is allowed.

12 V.S.A. ¶ 1036. We interpreted this statute under slightly different circumstances in Plante v. Johnson, 152 Vt. 270, 565 A.2d 1346 (1989). In Plante, the defendant resisted joinder of the plaintiffs' claims against her and a third party, resulting in a joint trial with two separate verdicts. The jury first returned a verdict against the third party for the entire amount of the plaintiff's damages, then found against the defendant for the same amount, and the court consolidated the judgments. The defendant appealed, arguing that the first verdict made the third party's share of the fault 100%. She concluded that under ¶ 1036, she was entitled to a ruling apportioning 100% of the liability for the plaintiff's damages to the third party. The defendant failed to argue this point at trial, making a holding regarding ¶ 1036 unnecessary. We nevertheless examined the statute in depth to demonstrate that our determination that the defendant was not entitled to apportionment was "more than a technical omission." Id. at 272, 565 A.2d at 1347. We concluded that the statute did not apply to the defendant in Plante because "the statute provides for apportionment among defendants, suggesting that only those joined in the same action should be considered in apportioning damages," and "there is no allegation that the plaintiff was negligent in this case."(FN6) Id. at 273, 565 A.2d at 1347-48.

¶ 38. In reaching this conclusion, we relied in part on the fact that "the New Hampshire Supreme Court has held that its nearly identical statute does not apply to create several liability in the absence of an allegation of negligence on the part of the plaintiff." Id., 565 A.2d at 1348 (citing Lavoie v. Hollinracke, 513 A.2d 316, 319-20 (N.H. 1986)). Defendant points out that Lavoie has since been overruled, but the decision overruling it, Nilsson v. Bierman, 839 A.2d 25 (N.H. 2003), relied on a

legislative revision of New Hampshire's statute that placed the concepts of comparative negligence and apportionment under separate headings. Id. at 29. In the absence of action by the Legislature to amend Vermont's comparative negligence statute, we see no reason to depart from the interpretation of ¶ 1036 contained in Plante. The Health Center was not a party to plaintiff's action against defendant, and defendant does not allege that plaintiff was comparatively negligent, so ¶ 1036 does not apply in this case.

¶ 39. Defendant argues that whether or not ¶ 1036 applies, we can depart from our common law and determine that joint and several liability should no longer prevent apportionment among joint tortfeasors when one tortfeasor has settled in a previous action. We decline to do so. In Howard v. Spafford, 132 Vt. 434, 321 A.2d 74 (1974), which also involved an interpretation of ¶ 1036, we expressed our hesitation to depart from the rule precluding contribution among joint tortfeasors, preferring not to "substitute judicial fiat for legislative action." Id. at 435, 321 A.2d at 75. Among the many reasons cited in Howard for adhering to the common law was the sheer number of alternative schemes adopted by other states. Id. at 436-37, 321 A.2d at 75-76. This reasoning applies here as well. Our choice is not between the traditional rule and a uniform new rule, but rather between a traditional rule and a number of potential new rules or combinations of rules. The Nilsson court pointed out the divide among states requiring jury verdicts to be reduced by the dollar amount of the plaintiff's settlement with a third party (pro tanto), those requiring verdicts to be reduced by the percentage of the settling party's fault (proportional share), and those requiring verdicts to be divided among all joint tortfeasors equally (pro rata). 839 A.2d 30-31. That court pointed out that while "[t]he American Law Institute favors the proportional share approach . . . , the overwhelming majority of States reject the proportional share approach in favor of some version of the pro tanto approach," and New Hampshire's legislature chose a combination of the two. Id. at 31 (citations and quotations omitted). It is important to note that if we were to adopt the majority rule, our decision would have no effect on this case, as plaintiff and defendant have stipulated to a pro tanto reduction. Like the New Hampshire court, we will allow the Legislature to determine which approach is best, if it has not done so already by leaving ¶ 1036 in place after our interpretation in Plante.

## III. Present Value of Damages

¶ 40. Finally, defendant contends the court erred by failing to instruct the jury to calculate the present value of plaintiff's damages for future non-economic losses, such as pain and suffering. Defendant claims that the jury's verdict, which granted plaintiff $5 million in non-economic damages, exceeded the present value of plaintiff's requested amount by $856,073. In rejecting defendant's proposed instruction, the court pointed out that defendant failed to provide the jury with expert guidance as to how present value should be calculated, and that "[j]udges and lawyers are universally incapable of performing the discount calculations with or without a calculator and the tables of historic interest rates and inflationary factors." We agree that it would have been inappropriate to instruct the jury to make such a calculation under these circumstances.

¶ 41. Even if defendant had presented testimony allowing the jury to make an informed calculation, we would have upheld the jury's verdict for several reasons. First, defendant's assertion that the jury

did not take account of the present value of plaintiff's non-economic damages is pure speculation, as plaintiff's calculation of her economic damages was presented in terms of its present value, and "the jury was not required to demonstrate its calculations" with respect to plaintiff's non-economic damages. Debus v. Grand Union Stores of Vt., 159 Vt. 537, 543, 621 A.2d 1288, 1292 (1993). Second, we limit pre-judgment interest to economic damages because non-economic damages are "inchoate and rarely ascertainable at the time of injury." Turcotte v. Estate of LaRose, 153 Vt. 196, 200 n.2, 569 A.2d 1086, 1088 n.2 (1989). These damages become no less inchoate following a judgment, and we will not require juries to apply a precise economic calculation to a figure we have identified as inherently imprecise.

¶ 42. Finally, most jurisdictions and the Restatement (Second) of Torts reject the concept of requiring juries to make present-value calculations with respect to non-economic damages. See, e.g., Taylor v. Denver & Rio Grande W. R.R., 438 F.2d 351, 353 (10th Cir. 1971) (holding that instruction requiring present-value reduction for pain and suffering was error and stating that most courts that have considered the issue have decided "that the better reasoned authority supports the rule that future pain and suffering should not be reduced to current worth"); Restatement (Second) of Torts ¶ 913A cmt. a (1979) (stating that while future pecuniary losses should be reduced to present value, "an award for future pain and suffering or for emotional distress is not discounted in this fashion"). But see Olivieri v. Delta S.S. Lines, Inc., 849 F.2d 742, 750-51 (2d Cir. 1988) (stating that "[i]f we were writing on a clean slate, we might be inclined to accept the view of the other circuits and reject any discounting of future non pecuniary losses," but previous Second Circuit holdings required such discounting in some form). Defendant's reliance on our decision in Parker v. Roberts, 99 Vt. 219, 131 A.2d 21 (1925), is misplaced, as Parker, while it required a jury instruction on the present value of future losses, did not address the distinction between pecuniary and non-pecuniary losses. Id. at 224-25, 131 A.2d at 23. The trial court did not err in refusing to instruct the jury to reduce plaintiff's non-economic damages to present value.

Affirmed.

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Associate Justice

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Dissenting

¶ 43. REIBER, C.J., dissenting. The overarching issue in this appeal is whether plaintiff's common-law claim for failure to warn conflicts with the FDA's regulation of Phenergan, the drug responsible for plaintiff's injuries. I would conclude that the jury's verdict in this case conflicts with federal law for two reasons.

¶ 44. First, it would be impossible for defendant Wyeth to comply with the requirements of both state and federal law. Specifically, the FDA approved IV administration of Phenergan and required that IV administration be listed on the Phenergan label. By contrast, plaintiff's

theory of the case required Wyeth either to remove this approved use from the Phenergan label, add a warning that would directly contradict the label's indication that IV administration was a safe and effective use, or, at a minimum, add a warning that only certain types of IV administration should be used. Thus, compliance with state law in this case would require Wyeth to eliminate uses of Phenergan approved by the FDA and required to be included in the Phenergan labeling.

¶ 45. Second, plaintiff's state-law claim conflicts with federal law in that it poses an obstacle to federal purposes and objectives. In short, by approving Phenergan for marketing and distribution, the FDA concluded that the drug-with its approved methods of administration and as labeled-was both safe and effective. See 21 U.S.C. ¶ 355(d) (listing criteria for drug approval). In finding defendant liable for failure to warn, a Vermont jury concluded that the same drug-with its approved methods of administration and as labeled-was "unreasonably dangerous." See Town of Bridport v. Sterling Clark Lurton Corp., 166 Vt. 304, 308, 693 A.2d 701, 704 (1997) (to succeed on failure-to-warn claim, plaintiff must show that "failure to warn made the product unreasonably dangerous and therefore defective"). These two conclusions are in direct conflict.

¶ 46. For both of these reasons I would conclude that the state-law cause of action is preempted. I respectfully dissent.

## I. Impossibility of Compliance

¶ 47. As explained by the majority, because there is no clause in the FDCA expressly preempting state law, Wyeth must demonstrate that preemption is implied by showing either that federal law thoroughly occupies the regulatory field (a claim that Wyeth does not advance) or that there is an actual conflict between state and federal law. Actual conflict, in turn, can be demonstrated in one of two ways: by showing that it is impossible for the regulated party to comply with both state and federal law or that state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (quotations omitted).

¶ 48. The majority in essence concludes that it is not impossible for Wyeth to comply with both federal and state standards because Wyeth never sought FDA approval of a "stronger warning" of the type advocated by plaintiff. According to the majority, because the FDA was not presented with, and therefore did not explicitly reject, such strengthened language, there is no reason to presume that the FDA would disapprove. Therefore, the majority reasons, there is no actual conflict between state and federal law. See ante ¶ 21-22. It is inaccurate, however, to characterize the requirements imposed by the jury verdict in this case as merely requiring a "stronger warning." Rather, what plaintiff sought was an elimination of a use of Phenergan that had been approved by the FDA. Furthermore, the FDA's rejection of Wyeth's efforts to alter the language of the warning in 2000 supports Wyeth's claim that the FDA had an affirmative preference for the language of the original warning.

### A.

¶ 49. The crux of plaintiff's claim was not based on the label

warnings per se, but on the approved uses listed there. See, e.g., ante ¶ 3 ("Plaintiff's experts testified that the label should not have allowed IV push as a means of administration . . .."). A review of plaintiff's complaint and the evidence presented at trial makes clear that the standard plaintiff sought to establish (i.e., the change to the label that would be required in light of the jury's finding of liability) was to remove IV administration-or at least certain types-as an approved use. For example, plaintiff's complaint asserted that the warnings on the label were inadequate and that:

> [t]he Phenergan sold by defendant is . . . NOT REASONABLY SAFE FOR INTRAVENOUS ADMINISTRATION because the foreseeable risks of harm posed by intravenous administration of the drug are sufficiently great in relation to its foreseeable theraputic benefits that reasonable health care providers, knowing of such foreseeable risks and benefits, WOULD NOT PRESCRIBE THE DRUG INTRAVENOUSLY FOR ANY CLASS OF PATIENTS."

(Emphasis added.) In her appellate brief, plaintiff characterizes the evidence as revealing "that Wyeth was aware of research indicating that DIRECT IV ADMINISTRATION OF PHENERGAN WAS UNSAFE." (Emphasis added.) Plaintiff further refers to expert testimony "that the LABEL SHOULD HAVE RESTRICTED PHENERGAN TO INTRAMUSCULAR INJECTIOn as this method of administration presents no risk of inadvertent arterial injection; or, alternatively, that if IV administration is used, it must be by injecting the Phenergan into a hanging IV bag, not through a direct IV." (Emphasis added.)

¶ 50. Here, the FDA clearly addressed the risks attending IV administration of the drug. The label approved IV administration generally, and specifically warned of the dangers of direct IV administration, including inadvertent arterial injection possibly resulting in amputation. In light of this, it cannot be argued that the FDA did not (1) assess the risk of IV administration, including direct IV administration and the associated risk of amputation due to inadvertent arterial injection; (2) conclude that the benefits of allowing IV administration with appropriate warnings outweighed the risk; and (3) reach a decision regarding precisely what warning language should be used. These assessments are, in fact, the very essence of the FDA's approval and are in furtherance of the federal objective of advancing public health by balancing the risks and benefits of new drugs and facilitating their optimal use. See 21 U.S.C. ¶ 355(d) (listing factors to be considered in approving or refusing new drug application); 21 U.S.C. ¶ 393(b)(1), (b)(2)(B) (FDA is charged with promoting public health by acting promptly on new drug applications and protecting public health by ensuring that new drugs are both safe and effective).

¶ 51. The majority reconciles this manifest conflict by relying on 21 C.F.R. ¶ 314.70(c), which allows a drug manufacturer to alter a label "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" or "add or strengthen an instruction about dosage and administration" prior to FDA approval.(FN7) On this basis, the majority concludes that Wyeth "was free under ¶ 314.70(c) to strengthen the warning without prior FDA approval." Ante ¶ 22. But, it is an overstatement to claim that manufacturers are "free" to change drug labels under ¶ 314.70(c). To the contrary, a manufacturer may change a label

only to add or strengthen a warning, not to eliminate an approved use, as plaintiff would require here. In other words, what plaintiff advocates is not a stronger warning but language that would directly contradict language approved and mandated by the FDA.

¶ 52. Further, the apparent purpose of ¶ 314.70(c) is to allow manufacturers to address newly-discovered risks. See 44 Fed. Reg. 37434, 37447 (June 26, 1979) (allowing supplement to label "whenever possibly harmful adverse effects associated with the use of the drug are discovered"). Even courts that conclude that ¶ 314.70(c) provides manufacturers broad latitude to add warnings to labels acknowledge that such supplements are aimed at previously unknown and unanalyzed risks. See McNellis v. Pfizer, Inc., 2005 WL 3752269, at *6 (D.N.J.) (concluding that ¶ 314.70(c) "was promulgated precisely to allow drug manufacturers to quickly strengthen label warnings when evidence of new side effects [is] discovered") (citing 30 Fed. Reg. 993 (Jan. 20, 1965)); Kurer v. Parke, Davis & Co., 2004 WI App 74, 18, 679 N.W.2d 867 (noting that, under ¶ 314.70(c), "[d]rug manufacturers can strengthen warnings or petition for additional warnings when new risk information arises"). Another section of the regulation makes clear that any changes to a label that exceed the scope of ¶ 314.70(c) are considered "major changes" that require prior approval before the drug may be distributed. ¶ 314.70(b), (b)(2)(v). In short, the regulation does not allow manufacturers to simply reassess and draw different conclusions regarding the same risks and benefits already balanced by the FDA. Here, the FDA had already evaluated the risk of inadvertent arterial injection from direct IV administration of Phenergan, and had mandated warning language for the label to reflect that risk assessment.

¶ 53. In addition, any change accomplished under ¶ 314.70(c) is subject to ultimate FDA review and approval. See ¶ 314.70(c)(7) (providing that FDA may order manufacturer to cease distribution of drug if it disapproves supplemental application); see also Needleman v. Pfizer, Inc., 2004 WL 1773697, at *3 (N.D. Tex. 2004) (noting that changes to label under ¶ 314.70(c) are temporary and "must later be approved by the FDA"). Thus, any additional or different warnings must ultimately be supported by scientific research that meets the FDA's standards. Neither a manufacturer, a state court, nor a state legislature can permanently substitute its judgment of the risk-benefit analysis for that of the FDA.

¶ 54. At its core, plaintiff's argument in this case was not that the warnings on the label were inadequate, but that an approved use (direct IV administration) was in fact unreasonably unsafe. Plaintiff did not seek to "add or strengthen" a warning or a dosage/administration instruction, but rather to eliminate an approved use of the drug. This is a disagreement that cannot be overcome by operation of ¶ 314.70(c). Plaintiff's claim in this case-that a method of administration of the drug should be partially if not entirely eliminated from the labeling-represents a substantive disagreement with FDA policy that goes beyond labeling/warning issues alone. This disagreement creates opposing requirements and a manufacturer could not satisfy both at once.

B.

¶ 55. Wyeth argues that even if ¶ 314.70(c) theoretically allows a manufacturer to make unilateral changes to a drug label, in this case, the FDA actually rejected Wyeth's attempts in 2000 to change the

warning regarding intra-arterial injection and amputation. The trial court concluded that the FDA gave only "passing attention" to the risks of IV administration in 2000. Ante ¶ 4. The majority similarly concludes that the record does not indicate "that the FDA wished to preserve the use of IV push as a method of administering Phenergan." Ante ¶ 23. I cannot agree with this assessment of the record.

¶ 56. Both the original label and Wyeth's proposed alternative were titled "INADVERTENT INTRA-ARTERIAL INJECTION." On the original label, the first two sentences of the warning read:

> Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of [Phenergan], usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances.

On the proposed label, the first sentence of the warning read: "There are reports of necrosis leading to gangrene, requiring amputation, following injection of [Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the needle is now suspect." While the proposed change to the warning language may not reflect what plaintiff would require in a warning, it cannot be disputed that Wyeth's proposed alternative warning (1) placed greater emphasis on the risk of necrosis and amputation by referencing it in the first sentence, and (2) gave the FDA the opportunity to consider the specific, alternative warning advanced by Wyeth, as well as the adequacy of the warning in general. Despite this opportunity, the FDA mandated that Wyeth retain the language of the existing warning. The alleged extent of the FDA's consideration of the issue is not relevant, in my view.

¶ 57. In 2000, the FDA confirmed its assessment that health care professionals should be permitted to choose IV administration in its various forms as a means of delivering the drug, where appropriate. Wyeth could not both list all forms of IV administration as an approved use, as required by the FDA, and exclude all or some forms of IV administration as unsafe, as required by the jury's verdict in this case. It would be impossible to comply with both requirements.

## II. Obstacle to Federal Purposes and Objectives

¶ 58. I would further conclude that Wyeth has demonstrated actual conflict preemption by showing that plaintiff's state-law failure-to-warn claim poses an obstacle to federal purposes and objectives. The majority does not address this issue, concluding that Wyeth does not have the option of proving this form of actual conflict preemption. The majority reaches this conclusion by relying on the following clause in the 1962 amendments to the FDCA:

> Nothing in the Amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as

> invalidating any provision of State law . . . unless there is a direct and positive conflict between such amendments and such provision of state law.

Ante ¶ 26 (quoting Drug Amendments of 1962 (Harris Kefauver Act), Pub. L. No. 87 781, ¶ 202, 76 Stat. 780, 793 (1962)). Citing Southern Blasting Services, Inc. v. Wilkes County, 288 F.3d 584, 591 (4th Cir. 2002), the majority concludes that the provision "essentially removes from our consideration the question of whether common-law tort claims present an obstacle to the purposes and objectives of Congress," because the 1962 provision "simply restates the principle that state law is superseded in cases of actual conflict with federal law such that compliance with both federal and state regulations is a physical impossibility." Ante ¶ 27 (internal quotations omitted). "In other words," the majority explains, "under any circumstances where it is possible to comply with both state law and the FDCA, the state law in question is consistent with the purposes and objectives of Congress." Id. Thus, the majority eliminates the possibility of proving actual conflict preemption independently through the "obstacle" prong of that standard.

¶ 59. But neither the passage in Southern Blasting on which the majority relies nor the United States Supreme Court decision (FN8) cited as authority in that passage provide an explanation or even an affirmative statement that the phrase "direct and positive conflict" in the 1962 amendment eliminates the "obstacle" prong of the actual conflict preemption standard. Thus, the majority eliminates one of the two means by which Wyeth may show actual conflict based on a single, unclearly-reasoned Fourth Circuit decision that is itself lacking in case law support. There is no basis for eliminating this prong of the actual conflict standard, and I disagree with the majority's conclusion to the contrary.(FN9)

¶ 60. Assuming, then, that Wyeth may demonstrate actual conflict preemption by showing that state law is an obstacle to federal regulatory purposes and objectives, I believe the facts here support the conclusion that the state tort-law verdict in this case is preempted. The United States Supreme Court's decision in Geier v. American Honda Motor Co., 529 U.S. 861 (2000), is controlling on the question of when state law poses an obstacle to federal purposes and objectives. In that case, the Department of Transportation had issued a safety standard that required automobile manufacturers "to equip some but not all of their 1987 vehicles with passive restraints." Id. at 864-65. Among the optional passive restraints were air bags. Honda was in compliance with this standard. Nonetheless, the plaintiff was seriously injured in a car accident while driving a 1987 Honda that was not equipped with an air bag, but with another form of passive restraint. The plaintiff brought suit, alleging Honda was negligent in failing to install a driver's-side air bag in the car. Honda argued that the federal safety standard preempted the plaintiff's state-law negligence claim. The Supreme Court held that a lawsuit premising negligence on the failure to install an air bag conflicted with the objectives of the federal safety standard and was therefore preempted. Id. at 866.

¶ 61. In reaching this conclusion, the Court noted that the plaintiff and the dissenting opinion-like the majority in the instant case-viewed the federal regulation as setting a minimum safety standard that states were free to supplement or strengthen. Id. at 874. However, by examining the comments accompanying the regulation, the Court concluded

that a safety standard allowing a choice of passive restraint systems while not mandating any particular system was a deliberate decision that reflected a balance of diverse policy concerns. See id. at 875 (noting that allowing mix of available safety devices available over time would "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance"). "In sum, . . . the 1984 version of [the safety standard] embodies the Secretary's judgment that safety would best be promoted if manufacturers installed alternative protection systems in their fleets rather than one particular system in every car." Id. at 881 (quotations omitted). Accordingly, the Court concluded that the tort action sought to impose a duty on manufacturers to impose air bags, rather than other types of passive restraint systems, and that this state-law requirement was an obstacle to the federal objective of allowing a mix of safety devices.

¶ 62. Application of the Supreme Court precedent in Geier dictates the same result in this case. As with the DOT in Geier, the FDA is primarily concerned with public safety. The conclusion of what is best for public safety is arrived at by considering various policy factors that are sometimes in tension with one another. For example, in developing the safety regulation at issue in Geier, the DOT considered not only which passive-restraint systems were safest on an absolute scale, but which were most cost-effective and which would gain consumer acceptance. Similarly, here the FDA balances its assessment of a drug's safety against concerns for the drug's efficacy, taking into account that a safer but less effective drug is not necessarily best for the public health overall. See 21 U.S.C. ¶ 355(d) (FDA must consider safety and efficacy); 21 U.S.C. ¶ 393(b)(1), (b)(2)(B) (FDA's mission is to protect public from unsafe drugs and to promote public health by approving regulated products in timely manner). In the specific context oarnings on drug labels, the FDA considers not only what information to include, but also what to exclude. As the Eighth Circuit has noted in the medical device context, "[t]here are . . . a number of sound reasons why the FDA may prefer to limit warnings on product labels." See Brooks v. Howmedica, Inc., 273 F.3d 785, 796 (8th Cir. 2001). For example, "warnings about dangers with less basis in science or fewer hazards could take attention away from those that present confirmed, higher risks." Id.

¶ 63. No drug is without risks. The FDA balances the risks of a drug against its benefits to maximize the availability of beneficial treatments. The FDA's decision in approving a drug, its uses and labeling reflect consideration of these and other policy factors. While a state-court jury presumably shares the FDA's concern that drugs on the market be reasonably safe, the jury does not assess reasonableness in the context of public health and the associated risk-benefit analysis. A jury does not engage in a measured and multi-faceted policy analysis. Rather, a jury views the safety of the drug through the lens of a single patient who has already been catastrophically injured. Such an approach is virtually guaranteed to provide different conclusions in different courts about what is "reasonably safe" than the balancing approach taken by the FDA. In act, different conclusions were reached in this case.

¶ 64. The jury in this case was instructed that "[a] prescription drug is unreasonably dangerous due to inadequate warnings or instructions if reasonable instructions regarding foreseeable risks of harm are not provided to the physician and other medical professionals who are in a position to reduce the risks of harm." Faced with plaintiff's tragic

injuries, the jury concluded that allowing Phenergan to be delivered through IV administration was "unreasonably dangerous." The jury's verdict conflicts squarely with the FDA's assessment of precisely the same issue: whether Phenergan is safe and effective when delivered through IV administration. The claim is preempted.

¶ 65. For the above reasons, I dissent.

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Chief Justice

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Footnotes

FN1. The warning on the label that was in use in 2000 read in relevant part:

> INADVERTENT INTRA-ARTERIAL INJECTION: Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of [Phenergan], usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs . . . .
>
> When used intravenously [Phenergan] should be given in a concentration no greater than 25 mg per ml and at a rate not to exceed 25 mg per minute. WHEN ADMINISTERING ANY IRRITANT DRUG INTRAVENOUSLY IT IS USUALLY PREFERABLE TO INJECT IT THROUGH THE TUBING OF AN INTRAVENOUS INFUSION SET THAT IS KNOWN TO BE FUNCTIONING SATISFACTORILY.

(Emphasis added.) The revised warning the FDA failed to adopt read in relevant part:

> INADVERTENT INTRA-ARTERIAL INJECTION: There are reports of necrosis leading to gangrene, requiring amputation, following injection of [Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the needle is now suspect. . . .
>
> There is no established treatment other than prevention:
>
> 1. Beware of the close proximity of arteries and veins at commonly used injection sites and consider the possibility of aberrant arteries.

> 2. When used intravenously, [Phenergan] should be given in a concentration no greater than 25 mg/ml and a rate not to exceed 25 mg/minute. INJECTION THROUGH A PROPERLY RUNNING INTRAVENOUS INFUSION MAY ENHANCE THE POSSIBILITY OF DETECTING ARTERIAL PLACEMENT. IN ADDITION, THIS RESULTS IN DELIVERY OF A LOWER CONCENTRATION OF ANY ARTERIOLAR IRRITANT.
>
> (Emphasis added.)

FN2. The dissent appears to interpret any warning that would eliminate IV-push administration as inherently inconsistent with the FDA's approval of Phenergan for IV administration in general. We see no such inconsistency, as an approval of a drug for IV administration is not the same as a conclusion that all methods of IV administration are safe. In any case, a jury verdict in a failure-to-warn case simply establishes that the relevant warning was insufficient; it does not mandate a particular replacement warning. There may have been any number of ways for defendant to strengthen the Phenergan warning without completely eliminating IV-push administration. Our purpose in pointing out that the proposed warning the FDA rejected did not eliminate IV push is simply that rejecting this warning could not be seen as an affirmative effort by the FDA to preserve IV push as an option.

FN3. We also reject defendant's argument that it would have been prosecuted for "misbranding" if it had strengthened the label without prior approval. See Witczak, 377 F. Supp. 2d at 731, 729 ("[T]he validity and authority of state law . . . does not depend on speculative hypotheticals" regarding "assumptions of what the FDA would have done" in response to a stronger warning.).

FN4. The debate surrounding the amendment helps confirm that it was intended to preserve the right of states to regulate beyond the federal requirements of the FDCA. During the floor debate in the House, the subject of preemption arose several times. First, Congressman Smith of California expressed concern that the bill, as reported, contained "no language . . . which says anything to the effect that this particular measure will not preempt all State food and drug laws," and thus, might risk interfering with the efforts of some states to make their own, stricter regulations. 108 Cong. Rec. 21046 (1962) ("[I]t seems to me that if we are going to pass this law, someone ought to offer an amendment to make certain that the passage of this bill, which gives all of this power to the Department of Health, Education, and Welfare and the Food and Drug Administration, will not preempt any State laws"). Shortly thereafter, Congressman Harris of Arkansas, the primary House sponsor of the bill, offered his opinion that "there is nothing in this bill that in any way preempts the authority and prerogatives of the States." Id. at 21047. Congressman Schenck of Ohio agreed, stating, "[m]any very helpful State laws are in effect; many such laws in some instances are even stronger than Federal laws for the protection of human health in the public interest." Id. at 21056.

Congressmen Schenck and Harris, despite insisting that the bill as written would not preempt stronger state laws, eventually supported the "direct and positive conflict" amendment, and Schenck reiterated that preemption should not apply in the "many instances where State laws in the area of food and drugs and health are even stronger than some of the Federal laws." Id. at

21083. Neither the desirability of allowing states to regulate beyond the FDCA nor the intent of the amendment to protect such regulation from preemption was called into question during the debate.

FN5. The only alteration the new rule appears to make to ¶ 314.70 is that changes to the new "Highlights" section of a drug label may not be made without prior approval. 71 Fed. Reg. at 3934.

FN6. We also listed as an additional reason, not applicable here, that the third party whose liability was at issue in Plante was held liable under a different theory of liability that was not clearly within the scope of ¶ 1036. Id. at 273, 565 A.2d at 1348.

FN7. This is also the approach employed by the numerous federal district court decisions cited by the majority. Ante ¶ 14. Because I disagree with this analysis of the import of ¶ 314.70(c), I do not find these decisions to be persuasive. Instead, I side with the minority view expressed in Needleman, which concludes that ¶ 314.70(c) gives manufacturers very little latitude in unilaterally revising drug labels. Needleman v. Pfizer, Inc., 2004 WL 1773697, at *3 (N.D. Tex.).

FN8. See Hillsborough v. Automated Med. Labs., 471 U.S. 707, 713 (1985). The cited passage in Hillsborough does not interpret the phrase "direct and positive conflict." It merely cites the different forms of preemption, including the "obstacle" prong. It is worth noting that the federal statute at issue in Geier v. American Honda Motor Co., 529 U.S. 861 (2000) (discussed below), contained an even broader savings clause than the 1962 amendment to the FDCA. The provision in Geier stated simply that the federal safety standard at issue did "not exempt any person from any liability under common law." Id. at 868.

FN9. Nonetheless, the Court concluded that all ordinary preemption principles-including actual conflict preemption and the obstacle prong of the standard-applied. The Court rejected the notion that Congress would so limit the effect of preemption as to allow an actual conflict with a federal objective: "Insofar as petitioners' argument would permit common-law actions that 'actually conflict' with federal regulations, it would take from those who would enforce a federal law the very ability to achieve the law's congressionally mandated objectives that the Constitution, through the operation of ordinary pre-emption principles, seeks to protect." Id. at 872.