(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 withn 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 warningcould 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 in-

dicate 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.

> 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 replacment 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.).

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.

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 pree-

> mpts 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.

¶ 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 Administation, 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.

> 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.

¶ 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 ofordinary 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, mak-

ing 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.

> 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.

¶ 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 vale 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 calcula-

tions 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.

¶ 43. REIBER, C.J., dissenting.

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 admin-

istration, including direct IV administrationand 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.

> 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.).

¶ 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