

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

PROVIDENCE, SC.

Filed May 11, 2006

SUPERIOR COURT

ANNETTE M. COUTU and JOEL L.
COUTU, SR., Individually and as
Co-Administrators of the ESTATE of
JOEL L. COUTU, JR.
Plaintiffs

V.

THOMAS F. TRACY, JR., M.D.,
UNIVERSITY SURGICAL
ASSOCIATES, INC., CHRISTOPHER
K. BREUER, M.D., RHODE ISLAND
HOSPITAL, ASTRAZENECA
PHARMACEUTICALS LP and
ZENECA INC.
Defendants

C.A. NO.: PC/00-3720

DECISION

GIBNEY, J. Before this Court are Defendants AstraZeneca Pharmaceuticals, L.P. and Zeneca Inc.’s (collectively “AstraZeneca” or “defendants”) motions for summary judgment on two claims brought by the plaintiffs, Annette M. Coutu and Joel L. Coutu, Sr. (“Coutus” or “plaintiffs”). AstraZeneca argues that it is entitled to judgment as a matter of law on the plaintiffs’ claim that it was negligent in providing warnings about the dangers associated with administering the drug Propofol to children because the claim is preempted by federal law. In addition, AstraZeneca requests that this Court grant summary judgment in its favor on the plaintiffs’ claim of negligent infliction of emotional distress (“NIED”) because the facts of this case do not permit recovery under such a theory. For the reasons set forth herein, the Court grants the defendants’ motion on the NIED claim and declines to grant the defendants’ motion with respect to the negligence claim.

Facts and Travel

It is only necessary to provide a brief summary of the alleged facts because the issues now before the Court primarily concern legal questions. The plaintiffs' suit alleges that their son, Joel Coutu, Jr., received negligent care and treatment from agents, servants, or employees of Rhode Island Hospital between July 19, 1998 and July 22, 1998. Additionally, the plaintiffs allege that AstraZeneca failed to provide appropriate warnings with regard to adverse affects its drug Propofol exhibited in children. In summary, the plaintiffs claim that the negligence of all the defendants contributed to the improper administration of Propofol to their son, resulting in his untimely death at the age of thirteen.

Joel Coutu, Jr. was admitted to the hospital following an incident in which he sustained injuries to his throat. In order to prevent his throat from swelling to the point where he would be unable to breath, the doctors performed an intubation procedure. Joel Jr. was administered Propofol to induce an unconscious state. (Breuer Depo. at 133-34.) The plaintiffs allege that their son was continually given Propofol, to varying degrees, while in their presence and throughout his stay at the hospital. (Annette Coutu's Ans. to R.I. Hosp.'s Int. No. 4.) According to Annette Coutu, at approximately 4:00 AM on July 21, 1998, she observed a change in the color of her son's urine and, subsequently, notified the hospital staff. Id. From that point on, the Coutus watched as their son's condition worsened. Id. The Coutus were told their son may need to be airlifted to another hospital, may need a liver transplant, may need a kidney transplant, and would need a pacemaker. (Annette Coutu's Ans. to R.I. Hosp.'s Int. No. 4; Coutus' Ans. to AstraZeneca's Int. No. 15.) Furthermore, the plaintiffs maintain that "the doctors did not know what was causing the dramatic and terrible changes to his condition." (Pls.' NIED Brief at 5.) Joel Jr. suffered cardiac arrest and the plaintiffs watched as the hospital staff attempted to

resuscitate their son. (Annette Coutu’s Ans. to R.I. Hosp.’s Int. No. 4; Coutus’ Ans. to AstraZeneca’s Int. No. 15.) Ultimately, the Coutus were present when Joel Jr. was pronounced dead on the morning of July 22, 1998. Id.

Summary Judgment Standard

On a motion for summary judgment, the Court reviews admissible evidence in the light most favorable to the nonmoving party to determine whether the moving party is entitled to judgment as a matter of law. Weaver v. Am. Power Conversion Corp., 863 A.2d 193, 197 (R.I. 2005). “[A] party who opposes a motion for summary judgment carries the burden of proving by competent evidence the existence of a disputed material issue of fact and cannot rest on allegations or denials in the pleadings or on conclusions or legal opinions.” Id. at 197 (quoting Accent Store Design, Inc., 674 A.2d 1223, 1225 (R.I. 1996)). With respect to the motions currently before this Court, the Court will assume that there are no material facts in dispute as the arguments present only legal questions. See Murray v. McWalters, 868 A.2d 659, 662 (R.I. 2005).

Preemption

AstraZeneca seeks summary judgment as a matter of law on the plaintiffs’ claim that the defendants were negligent in failing to provide additional warnings—either on the label or through some other means, such as a “dear doctor letter”—on its coma inducing drug Propofol regarding its adverse effects on children. AstraZeneca argues that the Coutus’ claim is preempted by federal law. More specifically, the defendants assert that a recent proclamation made by the Food and Drug Administration in its amended regulations, which are to become effective June 30, 2006, supports a finding that the plaintiffs’ negligent labeling/warning state law claim is preempted. In opposition, the plaintiffs highlight a long history of decisions finding

that similar state law claims are not preempted by the FDA's regulations and, additionally, argue that an agency cannot declare, *sua sponte*, that its regulations preempt state law.

The Supremacy Clause of Article VI of the United States Constitution “preempts or invalidates state law that interferes or conflicts with any federal law.” Verizon New England, Inc. v. R.I. Pub. Utilities Comm’n, 822 A.2d 187, 192 (R.I. 2003). The preemption doctrine recognizes three specific types of preemption: (1) express preemption, (2) field preemption, and (3) conflict preemption. Id. (citing Shaw v. Delta Airlines, Inc., 463 U.S. 85, 95-96 (1983)). For there to be a finding of express preemption the federal statute must expressly provide that it supersedes all related state law and the state law at issue must fall within the class of laws that Congress intended to preempt. Id. (citing Gade v. National Solid Wastes Management Association, 505 U.S. 88, 95-97 (1992)). Both field preemption and conflict preemption “reflect the congressional intent to preempt state laws based upon ‘the federal statute’s structure and purpose.’” Id. at 193 (citing and quoting Barnett Bank of Marion County, N.A. v. Nelson, 517 U.S. 25, 31 (1996)). “Field preemption prohibits state regulations in an area in which Congress implemented a comprehensive regulatory framework, thereby indicating its intention to reserve that area solely for federal control.” Id. Finally, conflict preemption exists when compliance with both federal regulations and state law is impossible and when the challenged state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives Congress.” Id. (citing and quoting Florida Lime and Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963); Crosby v. National Foreign Trade Council, 530 U.S. 363, 373 (2000)). A party attempting to establish implied, rather than express, preemption carries a particularly heavy burden. National Foreign Trade Council v. Baker, 26 F. Supp. 2d 287, 293 (D. Mass. 1998) (citing Philip Morris, Inc. v. Harshbarger, 122 F.3d 58, 67 (1st Cir. 1997)).

In the instant matter, there is neither an assertion by AstraZeneca, nor is there any proffered evidence, that Congress expressly preempted state law claims relating to the labeling of drugs. Therefore, AstraZeneca's motion for summary judgment rests on this Court's determination of whether Congress intended FDA regulations to preempt the field and whether the application of state negligence law would stand as an obstacle to the objectives of Congress with respect to the labeling of drugs. As both parties acknowledged at the May 5, 2006 hearing regarding this issue, there are countless decisions refusing to apply federal preemption under the circumstances presented in this case. See Hill v. Searle Labs, 884 F.2d 1064, 1068 (8th Cir. 1989) ("FDA approval is not a shield to liability. . . . FDA regulations are generally minimal standards of conduct unless Congress intended to preempt common law, which Congress has not done in this area."); Wells v. Ortho Pharmaceutical Corp., 788 F.2d 741, 746 (11th Cir. 1986) ("[a]n FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes"); Brochu v. Ortho Pharmaceutical Corp., 642 F.2d 652, 658 (1st Cir. 1981) (acknowledging that FDA approval of a drug label is not conclusive in a common law failure to warn action); Motus v. Pfizer Inc., 127 F. Supp. 2d 1085 (C.D.Cal. 2000), summary judgment granted, 196 F. Supp. 2d 984, 986 (C.D.Cal. 2001), aff'd, 2004 U.S. App. LEXIS 1944 (9th Cir. Feb. 9, 2004). Despite this significant history of cases, AstraZeneca requests that this Court consider the FDA's recent comment/clarification regarding the purpose and effect of its regulations and, subsequently, find that the plaintiffs' failure to warn claim is preempted by federal law.

In a section of the FDA's amended regulations, entitled "Comments on Product Liability Implications of the Proposed Rule", the FDA declares that "[it] believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new

format, preempts conflicting or contrary State law.” 21 Fed. Reg. 3933-34 (Jan. 24, 2006). The FDA comment continues by referencing amicus briefs written by the United States Department of Justice, on behalf of the FDA, addressing the issue and by explaining its position with respect to its regulations and the preemption of state law. See 21 Fed. Reg. 3934. In summary, the FDA believes that its labeling standards set forth both the “floor” and the “ceiling” for drug companies and that stricter warning requirements promulgated by the states act to frustrate the FDA’s purpose. See 21 Fed. Reg. 3935. The FDA maintains that its labeling criteria is extremely thorough and that in many circumstances it has consciously discouraged stricter warnings because suspected negative side effects were unsubstantiated by scientific evidence. Id.

This interpretation of its role squarely conflicts with the FDA’s previous stance that the amendment, which was then a proposed amendment, would:

“establish minimum graphical requirements for labeling. This proposal would also eliminate certain unnecessary statements on prescription drug product labels and move other, less important information to labeling. Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. In addition, this proposed rule does not preempt State law.” See 65 Fed. Reg. 81082, 81103 (2000).

The United States Supreme Court has articulated its preference to discount federal agencies’ interpretations of their regulations where said interpretations “contradict the agenc[ies]’ own previous construction that [the] Court [has] adopted as authoritative.” Norfolk Southern Railway Co. v. Shanklin, 529 U.S. 344, 356 (2000). The underlying concern is the effect such changes in interpretation have on *stare decisis*.

After considering the arguments of both parties, this Court finds that AstraZeneca has failed to meet its heavy burden to establish preemption and, therefore, the defendants’ motion for summary judgment is denied. A substantial number of courts have previously declined to find

that state law failure to warn claims are preempted by the FDA approval process. Furthermore, there does not appear to be any congressional intent to preempt state law under such circumstances. Finally, the Supreme Court has discouraged federal agencies from changing positions regarding issues that have been previously decided by courts. Ultimately, given these factors, this Court refuses to find that the plaintiffs' claim is preempted. This Court is not convinced that state laws, encouraging more stringent warning standards, frustrate the purpose of the FDA. Courts have consistently held that FDA regulations regarding labels and warnings for drugs do not preempt state law.

Negligent Infliction of Emotional Distress

The defendants argue that they should be granted summary judgment as a matter of law on the plaintiffs' NIED claim because, according to the defendants, the doctrine is inapplicable to the facts of this case. The defendants assert that, in order to prevail on a NIED claim, the negligent act must occur in the presence of the plaintiff and the plaintiff must have had knowledge that the defendant's act was negligent at the time it occurred. The defendants maintain that neither requirement was met in the case at hand. First, the defendants suggest that the negligent act was the defendants' failure to properly warn the doctors/hospital about the danger of administering Propofol to children and that said negligence was not witnessed by the plaintiffs because it occurred over a long, drawn out period of time. Second, the defendants argue that the plaintiffs in this case cannot recover under a NIED theory because they were not aware until after the traumatizing events that their son's death was caused by the negligent administration of the drug by the hospital/doctors.

In opposition, the plaintiffs assert that their NIED claim is legally viable and that genuine issues of material fact exist regarding their NIED allegations. The plaintiffs maintain that the

second prong of the test articulated in Marchetti only requires the relatives' presence and awareness of the injury, not knowledge of the negligence causing the injury. Furthermore, the plaintiffs argue that it is not necessary for them to observe the event constituting the negligent act. The plaintiffs submit that the facts demonstrate that they were present when their son received Propofol, they were aware that he was suffering, and they have documented physical symptomatology, in the form of major depression, significant sleep disturbance, frequent crying fits, etc. Therefore, they request that this Court deny the defendants' motion for summary judgment.

The Rhode Island Supreme Court initially adopted the "bystander" exception to the negligent infliction of emotional distress ("NIED") doctrine in its decision in D'Ambra v. United States, 114 R.I. 643, 338 A.2d 524 (1975). The doctrine has since been discussed and developed further in subsequent opinions of our Supreme Court. See Caparco v. Lambert, 121 R.I. 710, 402 A.2d 1180 (1979) (upholding trial justice's decision to dismiss NIED claim where the party alleging NIED did not witness the accident); Reilly v. United States, 547 A.2d 894 (R.I. 1988) (the Court explained that a plaintiff must exhibit physical symptomatology in order to recover for NIED); Marchetti v. Parsons, 638 A.2d 1047 (R.I. 1994) (parents could not recover on NIED claim because they were not present at the scene of the accident); Perrotti v. Gonicberg, 877 A.2d 631 (R.I. 2005) (plaintiff could not recover under NIED for anxiety suffered as a result of worrying about potential injury to an unborn child following a car accident because there was no physical symptomatology). In Marchetti, the Court articulated the three elements necessary for recovery on a negligent infliction of emotional distress claim:

"a party must (1) be a close relative of the victim, (2) be present at the scene of the accident and be aware that the victim is being injured, and (3) as a result of experiencing the accident, suffer serious emotional injury that is accompanied by physical symptomatology." Id., 638 A.2d at 1052.

In the instant action, the precise meaning of the second prong of this test is at the genesis of the parties' dispute.

Although the NIED doctrine has been discussed and developed over the years by our Supreme Court, the Court has never wrestled with the precise issues now before this Court. A literal reading of the elements of a NIED claim set forth in Marchetti, without considering the context in which they were laid out, supports the plaintiffs' position. However, considering the Marchetti opinion as a whole, and our Supreme Court's philosophy towards the NIED doctrine, this Court finds that the defendants' motion for summary judgment should be granted.

In Marchetti, the Court acknowledged that in expanding the negligent infliction of emotional distress doctrine beyond the "zone-of-danger limitation" it was "adopt[ing] the reasoning of the California Supreme Court." Id., 638 A.2d at 1049 (citing Dillion v. Legg, 441 P.2d 912 (Cal. 1968)). The Court continued by discussing further developments in the California law regarding the bystander exception to the NIED doctrine and, ultimately, concluded by stating: "we find the reasoning of the California Supreme Court persuasive and follow its lead in modifying the [standard.]" Id. at 1052. Considering the extent to which our Supreme Court has cited California law with approval, it seems appropriate to contemplate the California cases which have dealt with the issues now before this Court.

In Marchetti, our Supreme Court relied heavily on the California case Thing v. La Chusa, 771 P.2d 814 (Cal. 1989), in which the California Supreme Court attempted to clarify its NIED rule and held that:

"a plaintiff may recover damages for emotional distress caused by observing the negligently inflicted injury of a third person if, but only if, said victim: (1) is closely related to the injur[ed] victim; (2) is present at the scene of the injury producing event at the time it occurs and is then aware that it is causing injury to the victim; and (3) as a result suffers serious emotional distress—a reaction

beyond that which would be anticipated in a disinterested witness and which is not an abnormal response to the circumstances.” Id., 638 A.2d at 1052 (quoting Thing, 771 P.2d at 829-30.)

The Thing decision also highlighted language from an earlier California decision, Ochoa v. Superior Court of Santa Clara County, 703 P.2d 1 (Cal. 1985)—a decision which the plaintiffs relied on and discussed extensively in their brief—where the court declared, “when there is observation of the defendant’s conduct and the child’s injury and contemporaneous awareness the defendant’s conduct or lack thereof is causing harm to the child, recovery is permitted.” Thing, 771 P.2d at 824-25 (quoting Ochoa, 703 P.2d at 8). In summarizing the meaning of its previous decision, the court explained, “Ochoa held only that recovery would be permitted if the plaintiff observes both the defendant’s conduct and the resultant injury, and is aware at that time that the conduct is causing the injury.” Id. at 825.

A more recent decision by the California Supreme Court, Bird v. Saenz, 51 P.3d 324, 329 (Cal. 2002), “interpret[ed] Thing’s policy statement as a requirement that plaintiffs experience a contemporaneous sensory awareness of the causal connection between the negligent conduct and the resulting injury.” Moreover, the court acknowledged with approval other California NIED cases based on alleged medical negligence where “courts have not found a layperson’s observation of medical procedures to satisfy the requirement of contemporary awareness of the injury-producing event.” Id. The Bird decision also engaged in an extensive, and favorable, discussion of a Court of Appeal of California case, Goldstein v. The Superior Court of the City and County of San Francisco, 223 Cal. App. 3d 1415 (1990), which is significantly analogous to the case at hand. Id. at 329-31.

In Goldstein, the parents of a nine-year-old boy, who died as the result of the negligent administration of an overdose of radiation while undergoing cancer treatment, brought a claim

for negligent infliction of emotional distress. Id., 223 Cal. App. 3d at 1417. The overdose in radiation resulted in terminal radiation poisoning and the facts established that the parents were present while their son’s condition deteriorated. Id. at 1418. In disallowing the NIED claim, the court stated that “understanding perception of the injury-causing event is an essential component of . . . recovery.” Id. at 1427. The court noted that the parents were “informed of the excessive radiation after the fact” and that “during the radiation therapy they were unaware [their son] was being overexposed.” Id. at 1418. Ultimately, the court found that there was no “contemporaneous sensory awareness of the causal connection between the negligent conduct and the resulting injury” under the circumstances. Id. at 1427.

Applying the reasoning of the California courts to the facts of the present case, it is clear that the plaintiffs’ claim for negligent infliction of emotional distress should be dismissed. Like the plaintiffs in Goldstein, here, there is no evidence that the Coutus had a contemporaneous awareness of the causal connection between the alleged negligence of the defendants—their failure to heed appropriate warnings regarding Propofol’s administration to children—and their son’s suffering. As the plaintiffs stated in their brief, even the hospital staff “couldn’t figure out what was going on with Joel.” (Pls.’ Brief at 4.) Furthermore, as in Goldstein, there is no evidence that the Coutus were aware their son was being administered a drug that wasn’t recommended for use with children—and that could be potentially lethal—at the time it was given to him.

It should also be noted that the Goldstein court opined, and the California Supreme Court later confirmed in Bird, that the state’s Supreme Court would not accept an alternate conclusion under the facts of the case because such a result would almost automatically allow NIED recovery “to [any] medical malpractice plaintiff who observes only the suffering of the victim

and not the actual event that causes that suffering.” Goldstein, 223 Cal. App. 3d at 1427 n.3; Bird, 51 P.3d at 329. This finding harmonizes well with the sentiments expressed by our Supreme Court in the Marchetti opinion where it reinforced the Court’s philosophy with respect to NIED claims as originally articulated in the Reilly case. Specifically, the Court stated it was focusing ““not on the nature of the plaintiff’s loss, but on the source and scope of the defendant’s liability.”” Marchetti, 638 A.2d at 1050 (quoting Rielly, 547 A.2d at 897-98). Furthermore, the Court explained that it was ““reluctant to impose potentially unlimited and undeserved liability upon a defendant who is guilty of unintentional conduct.”” Id.

Given our Supreme Court’s cautious approach towards the bystander exception and its clear acquiescence with the California Supreme Court’s reasoning, this Court finds that the NIED doctrine is not applicable to the facts of this case. As a result, AstraZeneca’s motion regarding the plaintiffs’ NIED claim is granted.

Conclusion

The defendants’ motion for summary judgment on the plaintiffs’ negligence claim is denied. AstraZeneca has failed to meet its heavy burden to establish that the plaintiffs’ claim is preempted by federal law. With respect to the Coutus’ claim against AstraZeneca for negligent infliction of emotional distress, the defendants’ motion for summary judgment is granted because recovery under a NIED theory is not available under the facts of this case. The parties shall submit the appropriate judgment for entry.