

779 A.2d 453 (2001)

343 N.J. Super. 574

**Bobbie K. HOUSLEY, Plaintiff-Appellant,**

**v.**

**WAVE ENERGY SYSTEMS, INC., Johnson & Johnson Medical, Inc., Physicians Sales and Services (improperly named as Lee Surgical), General Medical, and Metrex Research Corp., Defendants-Respondents, and**

**HIP, Health Plan of New Jersey, Defendant.**

**Kathleen Schirmer, individually; Carol Dayton Ieva and Ronald Ieva, her husband; Maria Sawler and Patrick Sawler, her husband; Carol Young, individually; and Patricia Lewis and Neil Lewis, her husband, Plaintiffs-Appellants,**

**v.**

**Wave Energy Systems, Inc., Johnson & Johnson Medical, Inc., Physicians Sales and Services (improperly named as Lee Surgical), General Medical, and Metrex Research Corp., Defendants-Respondents, and**

**Cottrell, Ltd., Central New Jersey Medical Group (RCHP, New Brunswick), and HIP, Health Plan of New Jersey, Defendants.**

**Superior Court of New Jersey, Appellate Division.**

Argued May 1, 2001.

Decided August 14, 2001.

Ronald B. Grayzel, Edison, argued the cause for appellant Housley (Levinson, Axelrod, Wheaton, Grayzel, Caulfield, Marcolus & Dunn, attorneys; Mr. Grayzel, on the joint brief).

George W. Conk, of counsel, South Orange, argued the cause for appellants Schirmer, Ieva, Sawler, Young, and Lewis (Wysoker, Glassner, Weingartner, Gonzalez & Lockspeiser, attorneys; Robert C. \*454 Krieger, New Brunswick and Mr. Conk, on the joint brief).

Eric L. Harrison, Edison, argued the cause for respondents Wave Energy Systems, Inc. and Physician Sales and Services (**Methfessel & Werbel**, attorneys; Mr. Harrison, on the brief).

Jodi Sydell Rosenzweig, Florham Park, argued the cause for respondent Johnson & Johnson Medical, Inc. (Drinker Biddle & Shanley, attorneys; Jeffrey A. Peck, of counsel; Ms. Rosenzweig and Ethan D. Stein, on the brief).

Frank R. Cinquina, Montclair, argued the cause for respondent Metrex Research Corp. (Garrity, Graham, Favetta & Flinn, attorneys; Mr. Cinquina, on the brief).

Jeffrey S. Kluger, Florham Park, argued the cause for respondent General Medical Corp., Inc. (McGivney & Kluger, attorneys; Mr. Kluger, on the brief).

Before Judges KESTIN and CIANCIA.

The opinion of the court was delivered by KESTIN, J.A.D.

In these consolidated products liability cases, six nurses sued the manufacturers and suppliers of chemical substances used to sterilize medical devices and instruments, among other defendants. The husbands of three of the nurses sued *per quod*. Plaintiffs claimed damages on account of occupational respiratory illnesses suffered by the nurses from exposure to defendants' chemicals. The complaints were filed in February and March, 1995. The products liability defendants moved for summary judgment in the fall of 1997. After allowing a period for additional discovery, the trial court heard argument on those motions on September 18, 1998, as well as on plaintiffs' motion to dismiss the products liability defendants' preemption defenses.

For the reasons stated in a well-considered, comprehensive oral opinion rendered on October 21, 1998, Judge Chambers granted those defendants' motions on the ground that plaintiffs' claims were preempted under federal law, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C.A. §§ 136-136y. We affirm substantially for the reasons articulated by Judge Chambers, and set out in full the portion of her bench opinion resolving this issue:

This is a lawsuit that has been brought by the plaintiffs who are nurses employed by the Garden State Medical Group and Central Jersey Medical Group of HIP facilities. The plaintiffs claim that they were exposed to the defendants' product[s] in the work place for a period from 1990 to 1994. The product[s] in question are glutaraldehyde based products that are used to sterilize medical devices such as surgical instruments, and the plaintiffs maintain that they were exposed to these products in the work place and that as a result of that exposure they sustained respiratory problems.

The plaintiffs allege that the defendants failed to provide adequate warnings of a risk attendant to using the products. Specifically, the plaintiffs' expert... alleges that the material safety data sheets for the products are deficient and that they do not describe the possible chronic effects from exposure to glutaraldehyde nor do they indicate that respiratory protection is needed when using the products. The specific products in question [are] Wavicide ..., manufactured by Wave Energy [Systems, Inc. (Wave Energy);] Metricide..., manufactured by Metrex [Research Corp. (Metrex);] and [Cidex], manufactured \*455 by [Johnson & Johnson Medical, Inc. (J & J Medical)].

Up until 1996 and during the entire time that the plaintiffs were exposed to these products, the products were regulated by the Federal Insecticide, Fungicide & Rodenticide Act known as FIFRA, in accordance with EPA [Environmental Protection Agency] regulations. Each of these products had a label approved under the FIFRA Act. The federal statute similarly provides that a FIFRA label would preempt state law, and I'm referring to 7 [U.S.C.A. § ] 136[v(b):] A state may not impose or effect any requirement for labeling or packaging in addition to or different from those required under this section.

A failure to warn claim such as the plaintiffs assert here constitutes a labeling requirement. In other words, the plaintiffs are invoking state law to say that the defendants should have inserted additional warnings on the label. To permit this claim to proceed, New Jersey would be, in effect, imposing additional labeling requirements on these products, something that the federal statute says a state may not do. This issue has been recently and specifically addressed by New Jersey's highest Court in the case of Lewis v. American Cyanamid Co., 155 N.J. 544, 715 A.2d 967 (1998). The New Jersey Supreme Court held that FIFRA preempted a claim that the warning label on an insecticide was inadequate.

Interestingly, in two federal cases claims by medical workers for failure to warn brought against these same defendants, the defendants involved in this case, also found that the claims were preempted by FIFRA. In the case of Kenepp v. American Edwards Laboratories, 859 F.Supp. 809 (E.D.Pa.1994), it's probably as close a case on all fours as one can get. The case involved a nurse who claimed that she had developed respiratory problems from using the defendants' products, and the defendants in that case were the same defendants in this case, Johnson & Johnson, Wave Energy and Metrex. The Court granted the defendants' motion for a summary judgment finding that the plaintiff's failure to warn theory could not proceed due to the preemption of FIFRA.

Similarly, in Sowers v. Johnson & Johnson Medical, Inc., 867 F.Supp. 306 (E.D.Pa.1994), a nurse working in the hospital claimed personal injury from using ... cold sterilant disinfectant products containing glutaraldehyde to sterilize medical equipment. The products were manufactured by the same defendants involved in this case, J & J, Metrex and Wave Energy. The products had their labels approved by the EPA under FIFRA. The Court found that the plaintiffs' claim for inadequate warnings and instructions was preempted by FIFRA and granted summary judgment in favor of the defendants. See also Helms v. Sporicidin International, 871 F.Supp. 837 (E.D.N.C. 1994). There it was held that the FIFRA preempted a failure to warn claim brought against the manufacturer of a cold sterilizing solution. Also, Lowe v. Sporicidin, 47 F.3d 124 (4th Cir.1995), FIFRA preempted a failure to warn claim brought by a hospital worker suing for respiratory problems due to inhaling cold sterilant solutions.

Thus, the law is resoundingly clear that if a product label is approved by the EPA pursuant to FIFRA, a state law claim for failure to warn must fail due to the preemption provisions under FIFRA. Here, the plaintiffs, in their argument before this Court, have attempted to circumvent this clear law by turning \*456 to the FDA [Food and Drug Administration] law. Unlike products with

labels regulated by FIFRA, products such as these, which are regulated by the FDA, may still be subject to suits under state law. That is, the general clearance and approval process by the FDA does not, in and of itself, preempt state law. See Baird v. American Medical Optics, 155 N.J. 54, 713 A.2d 1019 (1998).

The plaintiffs maintain that during the period of plaintiffs' exposure the products were not only regulated by FIFRA but they were also regulated by the FDA and that therefore, the rule under FDA law of no preemption should apply here.

Indeed, it does appear that prior to enactment of the Food Quality Protection Act of 1996 [(FQPA), codified at 7 U.S.C.A. § 136i-2, 136r-1, 136w-5, 136w-6, and 136w 7; amending 7 U.S.C.A. § 136, 136a, 136a-1, 136d, 136q, 136s, 136w, 136w-3, 136x, and 136y; amending 21 U.S.C.A. §§ 321, 331, 333, 342, and 346a; and enacting provisions set out as notes under 7 U.S.C.A. § 136i-2 and 21 U.S.C.A. §§ 301 and 346a,] these products fell within the scope of the pesticide regulation by the EPA under FIFRA and also would be considered class three medical devices regulated by the FDA. A brief sketch of this regulatory history is as follows. Prior to 1990, the defendants' class of products, liquid sterilants, were regulated by the EPA under FIFRA and not by the FDA. During ... 1990, the FDA began the process of undertaking regulation of the products. Under the FDA procedure the defendants were required to make what is called a Section 510(k) application for clearance to market the product and the FDA eventually did issue a Section 510(k) clearance for these products.... [D]efendant... J & J Medical ... applied for the clearance in July of 1992 and obtained it in March of 1994. Defendant Wave Energy applied for the clearance in, I believe,... January of 1992 and received clearance in August of `95. Metrex applied for the clearance in April ..., I believe it may also be `92 and obtained the clearance in December of `94. Obviously, the clearance process took a considerable period of time. During that time period the products were, of course, not removed from the market given the need for their use within health facilities and, of course, they had already been subject to the labeling requirements of FIFRA.

On June 3rd, 1993, the FDA and the EPA entered into an agreement providing that the FDA would have primary jurisdiction. In 1996, Congress passed the [FQPA] which entirely removed the liquid sterilants from the EPA jurisdiction under FIFRA and gave the FDA exclusive jurisdiction.

457 While the regulatory overlap between the FDA and the EPA under FIFRA during this transition period of 1990 to 1996, which encompasses the period of the plaintiffs' exposure is interesting and complex, it does not change the basic fact that during this period the products were required to meet FIFRA labeling criteria, that they did, indeed, meet the FIFRA labeling requirements and that under federal law FIFRA labeling requirements preempted any state failure to warn claim. Nothing in the FDA laws or regulations overruled, during that period, the FIFRA labeling or preemption provisions. Frankly, this Court doesn't see, then, any conflict between FDA and FIFRA. The products were labeled under FIFRA and the federal preemption rule applied. There's no reason why the fact that the products also fell within the jurisdiction of the \*457 FDA should change that. There was never a time, for example, when FIFRA and the FDA regulations were in conflict, that is, that there wasn't a time when FIFRA regulated one label and the FDA was requiring something different during the time period of the plaintiffs' exposure.

To the extent that FIFRA, with its preemption provision and the FDA without preemption dealing with labeling have an apparent conflict in statutory law, certainly two rules of statutory construction would resolve that potential conflict in favor of the defendants. One law is that, of course, we give the more specific rule precedence over a general rule. Here, the preemption of the labeling under FIFRA was clear and limited and the FDA regulations are much broader, of course, than just labeling. And secondly, we try to read statutes..., to the extent possible, ... to create some harmony between the two.

The plaintiffs' interpretation of ... this FDA and FIFRA law would really make the FIFRA preemption provision meaningless. On the other hand, giving effect to the FIFRA preemption provision would not interfere, or could not interfere, with the FDA's regulatory function. Or, to put it another way, the FDA's regulation of the product during this time period was not inhibited by FIFRA's preemption. Rather, FIFRA's preemption prohibited the states from exercising regulatory power over these products. It didn't prohibit powers within the scope of FDA regulation.

For these reasons, I believe that the FIFRA preemption provision that existed during the period of plaintiffs' exposure, and the fact that the FDA also had some regulatory powers over these products can be read together harmoniously.

I also note as an aside that the plaintiffs, in effect, seem to be asking the Court to look at the fact that Congress changed the law in 1996 to indicate what the intent of Congress was during the period of plaintiffs' exposure, which was prior to 1996, and I just feel compelled to point out that when we're looking at legislative intent, we have to look at the intent of the legislature when it passed the legislation. We can't look at what the legislature did down the road and say, well, if they changed it in 1996 they really would have intended to change it in 1994. We can't impose that new intent exhibited by new legislation retroactively on old legislation.

In conclusion, as the law stood in 1990, it was changed in 1996. The defendants' products labels were regulated by FIFRA and, under FIFRA, federal law preempted a state cause of action for failure to warn. The FIFRA preemption is specific and clear. There are numerous federal cases, as well as a case from the New Jersey Supreme Court this very year that indicate that the intent was to preempt state law warnings claims. Hence, the state cause of action for failure to warn must fail.

\* \* \*

For all of these reasons, then, the motion for summary judgment by Wave Energy is granted and the motion for summary judgment by J & J Medical is also granted. The motion for summary judgment by defendant Metrex is denied without prejudice since plaintiff has not completed discovery against that defendant.

458 The orders memorializing this ruling also granted summary judgment to "Physicians Sales and Services (Improperly named as Lee Surgical)." Metrex's motion was granted a few months later, and plaintiffs' complaints against General Medical \*458 were dismissed a few months after that in two separate orders entered on different dates. Plaintiffs appeal from the dismissals in favor of Wave Energy, J & J Medical, Metrex, Physicians Sales and Services, and General Medical. All other claims against all other defendants were either settled or dismissed on grounds not pertinent to this appeal.

Plaintiffs advance six arguments on appeal impugning the trial court's preemption ruling:

POINT I THE TRIAL COURT IMPROPERLY DISMISSED, AS PREEMPTED BY FEDERAL LAW, PLAINTIFFS' PRODUCT LIABILITY CLAIMS AGAINST THE DEFENDANTS, WHO MANUFACTURED AND SOLD LIQUID HOSPITAL STERILANTS-REGULATED MEDICAL DEVICES-WHICH THEY MARKETED AGAINST THE FDA'S COMMAND, WITHOUT THE REQUIRED FDA § 510(k) PRE-MARKET APPROVAL, AND WHICH PRODUCTS ARE NOT SUBJECT TO ANY SPECIFIC FEDERAL REGULATORY REQUIREMENTS COMPELLING FEDERAL PREEMPTION.

POINT II BECAUSE NO OTHER COURT HAS EVALUATED LIQUID CHEMICAL GERMICIDES AS FDA-REGULATED MEDICAL DEVICES THE ISSUE HERE IS ONE OF FIRST IMPRESSION.

POINT III THE HISTORY OF CONGRESSIONAL OVERSIGHT AND THE REGULATORY HISTORY DEMONSTRATE THAT CONGRESS ALWAYS INTENDED HOSPITAL STERILANTS TO BE PRIMARILY REGULATED BY THE FDA, SINCE THE PRODUCTS ARE SOLD TO STERILIZE CRITICAL SURGICAL AND OTHER MEDICAL DEVICES AND ARE THEMSELVES MEDICAL DEVICES.

POINT IV THE TRIAL COURT ERRED IN ITS CONCLUSION THAT THE DEFENDANTS' MARKETING OF THEIR PRODUCTS WITHOUT FDA APPROVAL WAS NECESSARY AND PROPER AND THAT THERE WAS NO "CONFLICT" BETWEEN THE FOOD, DRUG & COSMETIC ACT AND FIFRA.

POINT V THE RULE OF RESOLVING AN AMBIGUITY IN A GENERAL LAW BY REFERENCE TO A MORE SPECIFIC LAW WAS INAPPROPRIATELY APPLIED BY THE TRIAL COURT.

POINT VI CONGRESSIONAL INTENT CAN PROPERLY BE INFERRED FROM THE RATIFICATION OF THE REGULATORY AGENCIES UNDERSTANDING THAT EPA'S AUTHORITY DID NOT EXTEND TO LICENSING CLASS III MEDICAL DEVICES SUCH AS DEFENDANTS' PRODUCTS WHICH WERE SOLD FOR USE AS HOSPITAL STERILANTS.

459 None of these arguments avails to overcome the holdings relied upon by the trial court, especially the Supreme Court's in \*459 *Lewis, supra*, 155 N.J. 544, 715 A.2d 967. We note that the same standard governs the liability of defendant distributors, General Medical and Physicians Sales and Services, as applies to defendant manufacturers, Wave Energy, J & J Medical, and Metrex. Plaintiffs' contention in Point I that the products at issue had not received § 510(k) pre-market approval from the FDA is of no consequence given the basis of the trial court's opinion, and plaintiffs offer no ground upon which we might conclude that

Judge Chambers's expressed determination to the contrary was erroneous.

Despite plaintiffs' efforts to establish an FDA focus in this matter, the fact remains, as the trial court held, that at the time plaintiffs were experiencing the exposures which led to their alleged injuries, the substances involved were subject to FIFRA standards and, perforce, to the preemption provisions of that statute.

A 1993 "Memorandum of Understanding" between the EPA and the FDA relied upon by plaintiffs cannot be taken to be an effective modification of the statutory scheme. That memorandum provided, in part:

The FD&C Act [Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. §§ 301-97] grants FDA authority to regulate devices as defined in 21 U.S.C. § 321(h). Under section 321(h), the term "device" includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory that is intended to cure, mitigate, treat, or prevent disease in man, or is intended to affect the structure or any function of the body of man. Liquid chemical germicides intended for use in conjunction with a variety of articles that fit within the statutory definition of "device," such as operating instruments, medical examining tables, hospital scales, and other hospital equipment, also fall within the definition of "device" because they are considered accessories to these devices.

Plaintiffs argue that this acknowledgment of FDA's assumption of some administrative responsibility for the substances at issue here removed those substances from FIFRA's ambit. Both the federal courts and our State's courts employ the same principle of according deference to an agency's construction of a statute it is assigned to administer, especially in resolving an ambiguity. See, e.g., *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45, 104 S.Ct. 2778, 2781-83, 81 L.Ed.2d 694, 702-04 (1984); *Kasper v. Bd. of Trustees of Teachers' Pension and Annuity Fund*, 164 N.J. 564, 580-81, 754 A.2d 525 (2000). Under both federal and state standards, however, no agency construction of a statute will be affirmed which is at variance with the legislature's clear intent. See *Chevron, supra*, 467 U.S. at 844, 104 S.Ct. at 2782, 81 L.Ed.2d at 703; *In re Repeal of N.J.A.C. 6:28*, 204 N.J. Super. 158, 160-61, 497 A.2d 1272 (App.Div.1985). There was no ambiguity in the law that applied at the time of plaintiffs' exposure, and we reject plaintiffs' use of subsequent events to establish one. We also subscribe to the trial court's rejection of the notion advanced by plaintiffs that a statutory amendment post-dating the exposures complained of and the regulatory regime prevailing at the time can be used as a basis for interpreting the earlier statutory provisions in a way that is clearly at variance with their plain meaning.

460 Although the respective complaints each contain a product-defect count as well as a failure-to-warn count, and the FIFRA pre-emption of labeling requirement goes only to failure to warn, we are constrained \*460 nevertheless to affirm the trial court's dismissal of the complaints in their entirety. As far as we can discern from the record before us on appeal, the matter was developed and presented as a failure-to-warn case and the product defect issue was not preserved as an independent claim. At oral argument before us, counsel for plaintiffs concluded their presentation with a reference to risk/utility analysis, noting that this issue was always in the case. To the extent risk/utility analysis imports theories of liability going beyond failure to warn, see *Dreier on New Jersey Products Liability & Toxic Torts Law* § 6:3-8 (Dreier, Katz and Goldman ed.2001), it is clear that no such theories were squarely raised before the trial court in its consideration of the motions for summary judgment. We will not consider on appeal any "questions or issues not properly presented to the trial court[.]" *Nieder v. Royal Indem. Ins. Co.*, 62 N.J. 229, 234, 300 A.2d 142 (1973).

Affirmed.

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