MONTOYA V. MENTOR CORP., 1996-NMCA-067, 122 N.M. 2, 919 P.2d 410

ABEL MONTOYA and JOANN MONTOYA, Plaintiffs-Appellants,
vs.
MENTOR CORPORATION Defendant-Appellee, AND ST JOSEPH HEALTH CARE SYSTEM, and JOHN DOES 1-5, Defendants.

Docket No. 16,407

COURT OF APPEALS OF NEW MEXICO

1996-NMCA-067, 122 N.M. 2, 919 P.2d 410

May 29, 1996, Filed

APPEAL FROM THE DISTRICT COURT OF BERNALILLO COUNTY. ROBERT L. THOMSON, District Judge.

Released for Publication July 1, 1996. As Corrected August 5, 1996.

COUNSEL

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JUDGES

RUDY S. APODACA, Chief Judge. WE CONCUR: BENNY E. FLORES, Judge, RICHARD C. BOSSON, Judge.

AUTHOR: RUDY S. APODACA

OPINION

*{*3}* OPINION

APODACA, Chief Judge.

{1} Plaintiffs Abel and Joann Montoya appeal the trial court's order granting summary judgment and dismissing their complaint alleging product liability claims against Defendant Mentor Corporation. The trial court ruled that the Medical Device

Amendments of 1976, 21 U.S.C. Sections 360c-360l (1994) (the MDA), preempted Plaintiffs' causes of action. We disagree, reverse the trial court, and remand for trial.

I. FACTUAL AND PROCEDURAL BACKGROUND

{2} This appeal arose as a result of injuries suffered by Plaintiff Abel Montoya and allegedly caused by a medical implant. In January 1986, a device known as the Angelchik prosthesis, manufactured and sold by Defendant, was implanted in Mr. Montoya by Dr. Oberdorfer at St. Joseph Hospital, as treatment for a hiatal hernia. The Angelchik is a C-shaped silicone-filled device encased in a silicone shell. A Dacron strip surrounds the silicone shell and is laminated with silicone on the outer surface to make the strip a smooth surface. The device was secured around Mr. Montoya's esophagus at the gastroesophageal junction with the strip of Dacron. The device is designed to be placed unsecured in this motile area of the gut so that it moves whenever the person breathes, talks, swallows, eats, and digests food.

{3} With the passage of time, the device bled silicone, and the movement of the device caused silicone debris to be released into Mr. Montoya's abdominal cavity, causing damage to adjacent organs, an inflammatory reaction, adhesions, and immunodeficiency. As the silicone wore off the outer surface of the Dacron strip, an abrasive surface was left, causing irritation. As a result of that irritation, the device became surrounded by dense scar tissue, and eventually it migrated into Mr. Montoya's stomach. The device had to be surgically removed in December of 1986, at which time the damage to Mr. Montoya's internal organs was repaired. He developed serious complications from the surgery, and, since the removal of the device, his condition has worsened. We will develop additional facts in the discussion.

{4} Plaintiffs' complaint against Defendant specifically alleged claims of strict products liability, negligence in products liability, negligence per se, and strict liability for a peculiar risk or ultrahazardous activity. Defendant's answer raised the affirmative defense of federal preemption. Defendant's motion for summary judgment contended that, under any state of facts, Plaintiffs could not recover because all of Plaintiffs' claims were preempted by federal law and regulations *{*4}* governing medical devices. The trial court agreed and granted summary judgment.

II. DISCUSSION

A. Standard Of Review

{5} The relevant facts are not disputed. In reviewing the grant of summary judgment in a case where there are no disputed issues of material fact, this Court considers whether the trial court correctly interpreted the relevant law. **Bybee v. City of Albuquerque**, 120 N.M. 17, 18, 896 P.2d 1164, 1165 (1995).

B. General Preemption Principles

{6} The principle of federal preemption of state law arises directly from Article VI of the United States Constitution. Article VI states that "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof[,] . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Under this constitutional authority, Congress may preempt state law. Whether a federal law preempts state law is ultimately a question of congressional intent. **Hawaiian Airlines v. Norris**, 129 L. Ed. 2d 203, 114 S. Ct. 2239, 2243 (1994).

{7} There is a strong presumption against preemption. Consideration of preemption issues begins with the "'assumption that the historic police powers of the States [are] not to be superseded by . . . [a] Federal Act unless that [is] the clear and manifest purpose of Congress.'" **Cipollone v. Liggett Group, Inc.**, 505 U.S. 504, 516, 120 L. Ed. 2d 407, 112 S. Ct. 2608 (1992) (quoting **Rice v. Santa Fe Elevator Corp.**, 331 U.S. 218, 230, 91 L. Ed. 1447, 67 S. Ct. 1146 (1947)). There is thus a reluctance to preempt state laws relating to health and safety matters because those matters have been the exclusive concern of the states. **See New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.**, 131 L. Ed. 2d 695, 115 S. Ct. 1671, 1680 (1995); **Hillsborough County, Fla. v. Automated Medical Labs, Inc.**, 471 U.S. 707, 715, 85 L. Ed. 2d 714, 105 S. Ct. 2371 (1985). There is also a presumption against preemption if it would deny an injured party all judicial remedies, especially in the face of congressional silence. **Silkwood v. Kerr-McGee Corp.**, 464 U.S. 238, 251-52, 78 L. Ed. 2d 443, 104 S. Ct. 615 (1984).

{8} "Pre-emption will not lie unless it is 'the clear and manifest purpose of Congress.'" **CSX Transp., Inc. v. Easterwood**, 507 U.S. 658, 664, 123 L. Ed. 2d 387, 113 S. Ct. 1732 (1993) (quoting **Rice**, 331 U.S. at 230). Thus, our focus in this appeal is to determine Congress' intent. When Congress has considered the issue of preemption and has included in the legislation a provision expressly addressing the issue, it is unnecessary to infer congressional intent to preempt state law. **Cipollone**, 505 U.S. at 517. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." **Id.** Consequently, because, as noted below, Congress has enacted a preemption provision for the MDA, "we need only identify the domain expressly pre-empted" by the statute. **Id.**

C. The MDA Regulatory Scheme

{9} In 1976, Congress enacted the MDA in response to the public outcry following the injuries suffered by women using the Dalkon Shield contraceptive device. See Ministry of Health, Province of Ontario, Can. v. Shiley Inc., 858 F. Supp. 1426, 1434 (C.D. Cal. 1994). It had become clear that the pace of the medical device industry had far surpassed the ability of the Food and Drug Administration (FDA) to control it. **Id.** at 1434. As a result, Congress sought "to assure the reasonable safety and effectiveness of medical devices intended for human use." H.R. Conf. Rep. No. 1090, 94th Cong., 2d. Sess. **reprinted in** 1976 U.S.C.C.A.N. 1070, 1103.

{10} The MDA gave the FDA broad regulatory power over medical devices. It set up a classification system requiring the FDA to assign a particular device to one of three statutory categories. Regulation of a particular device by the FDA depends on the class of the device. The regulatory scheme reflects *{*5}* the wide range of hazards associated with products classified as medical devices. Class I devices consist of simple, relatively risk-free products not requiring extensive regulation to protect the public health and safety, such as tongue depressors and elastic bandages. 21 U.S.C. § 360c(a)(1)(A). Class II devices present greater risks and require some regulation regarding performance standards and guidelines for their use. 21 U.S.C. § 360c(a)(1)(B). Examples of these devices are syringes, tampons, and hearing aids. Class III devices present the greatest risk because they are implanted into consumers' bodies and are therefore subject to the most extensive regulation by the FDA. 21 U.S.C. § 360c(a)(1)(C). Among this class of devices are pacemakers, intraocular lenses, and the device at issue in this appeal.

{11} With two exceptions, which are unimportant here, Class III devices require an extensive premarket approval process before being placed on the market. The approval process requires the device's manufacturer to obtain approval from the FDA for the device's design, manufacturing process, and advertising. 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20(b)(2)-(12) (1994). Once a device has been approved for marketing, federal regulations prohibit the device from being "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the [premarket] approval order for the device." 21 C.F.R. § 814.80. This "'premarket approval process is designed to provide a "reasonable assurance of . . . safety and effectiveness" for medical devices [that] are too dangerous or unknown to permit less regulation.'" **King v. Collagen Corp.**, 983 F.2d 1130, 1131 (1st Cir.), **cert. denied**, 126 L. Ed. 2d 52, 114 S. Ct. 84 (1993) (quoting 21 U.S.C. § 360c(a)(1)(C)).

{12} The device in question went through the premarket approval process in 1979 when it was developed by Heyer-Schulte Corporation. Once the device was approved by the FDA, Heyer-Schulte sold the product to Defendant. Defendant was required to provide additional information to the FDA in order to receive approval to change the labeling of the device. Defendant received approval to market the device from the FDA in 1984.

D. Preemption Under The MDA

1. Interpretation By Other Jurisdictions

{13} The MDA contains an express preemption provision that provides:

> (a) General rule
>
> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may . . . exempt from subsection (a) . . . a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter . . .; or

(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

{14} 21 U.S.C. § 360k. A number of courts have read this language as creating an expansive federal preemption of state law, thus preempting any state tort claims dealing with safety, effectiveness, or any other aspect governed by the FDA's premarket approval process. **See, e.g.**, **Martello v. Ciba Vision Corp.**, 42 F.3d 1167, 1169 (8th Cir. 1994), **cert. denied**, 132 L. Ed. 2d 857, 115 S. Ct. 2614 (1995). Many of these courts begin their analysis by relying on the plurality decision of the United States Supreme Court in **Cipollone**, for the proposition that the phrase "any requirement" found in subsection *{*6}* (a) encompasses state common law causes of action. **See, e.g.**, **Mitchell v. Collagen Corp.**, 67 F.3d 1268, 1275 (7th Cir. 1995), **petition for cert. filed**, 64 U.S.L.W. 3593 (1996).

{15} Cipollone concerned various tort claims brought by the estate of a smoker against a cigarette manufacturer. The statutes under review were the Federal Cigarette Labeling and Advertising Act of 1965, 15 U.S.C. §§ 1331-1340, and the Public Health Cigarette Smoking Act of 1969, which amended the 1965 Act. Part of the amendment included a change in the language of the preemption section. 15 U.S.C. § 1334. The Court focused on the change in the language to support its determination that the 1969 Act preempted some state common law claims. The 1969 Act preempted any "requirement or prohibition based on smoking and health . . . imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this chapter." 15 U.S.C. § 1334(b).

{16} The Supreme Court in **Cipollone** stated that the phrase "no requirement or prohibition," in contrast to the language "no statement relating to smoking" found in the

1965 Act, 15 U.S.C. § 1334(a), suggested no distinction between positive statutory enactments and common law and that the words easily encompassed obligations taking the form of common law rules. 505 U.S. at 522. The Court noted that "common law damages actions . . . are premised on the existence of a legal duty[,] and it is difficult to say that such actions do not impose 'requirements or prohibitions.'" **Id.** Concluding that it was the essence of common law to enforce duties that were either affirmative **requirements** or negative **prohibitions** (i.e. damages arising from tort claims), the Court determined that common law causes of action could be included in the preemption legislation. It did not hold, however, that all common law causes of action were preempted, but instead analyzed each claim to determine whether the legal duty forming the predicate of the action constituted a requirement or prohibition based on smoking and health with respect to advertising or promotion. **Id.** at 524.

{17} As noted previously, various courts, relying on **Cipollone**, have denied tort claims based on federal preemption. A majority of these courts relied on **Cipollone** as support for the holding that the word "requirement" in the context of an express preemption provision included state common law claims and, thus, such claims were preempted by the MDA. The courts so held despite the fact that **Cipollone** did not determine that the word "requirement" by itself indicated preemption, and, even when construed with other considerations, did not constitute a blanket preemption. **Cipollone** interpreted "requirement" only in the context of the 1969 Act; it did not hold that the word "requirement" would encompass common law actions whenever it was used. **Cipollone** also stated that "there is not general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law actions." **Id.** at 518. We thus disagree with those courts because we believe they have applied **Cipollone** too broadly, and we should not perpetuate that mistake.

{18} Additionally, the fact that the word "requirement" appears in both the statute in **Cipollone** and the MDA is not reason enough to conclude that all state common law causes of action are preempted by the MDA. The federal statute at issue in **Cipollone** contained considerably detailed and specific requirements for cigarette warnings and advertising, including actual wording that must appear on cigarette packages. 15 U.S.C. § 1333. The purpose of the statute was to inform the public of the health hazards of smoking and to protect the national economy from the burden imposed by diverse, nonuniform cigarette labeling and advertising regulations. 15 U.S.C. § 1331. In contrast, the MDA is a broad act attempting to bring some safety regulation to a range of medical devices that are constantly being developed and revised. There is also no reason to believe that Congress' use of the word "requirement" in two different acts is the same. To understand a statute's meaning, we must examine the words used, the context within which the words are used, the purpose of the *{*7}* statute, and its legislative history. **See, e.g.**, **United States v. Feroni**, 655 F.2d 707, 710 (6th Cir. 1981); **State ex rel. Helman v. Gallegos**, 117 N.M. 346, 871 P.2d 1352 (1994); **Madrid v. University of Cal.**, 105 N.M. 715, 737 P.2d 74 (1987).

2. Language Of Section 360k

{19} We begin our analysis of the preemption provision with an examination of the words contained in subsection (a) of the statute. We note that the word "requirement" was used three times in that provision. Two of those three uses (the latter two) clearly refer to legislative type rules because they relate to requirements under the MDA. (The FDA has no authority to impose requirements under common law tort actions). **See** Robert S. Adler & Richard A. Mann, **Preemption and Medical Devices: The Courts Run Amok**, 59 Mo. L. Rev. 895, 926 (1994). The third use of the word is the source of this litigation. However, we consider it unlikely that Congress adopted two separate meanings of the same word within one section of the same statute. **See State v. Bea**, 318 Ore. 220, 864 P.2d 854, 857 (Or. 1993) (en banc) (where the legislature uses the same term throughout a statute, the court infers the term has the same meaning).

3. Context Of Section 360k

{20} Equally important, we believe that subsection (b) provides insight to Congress' intent regarding preemption. Subsection (b) allows a state or political subdivision to apply for an exemption from subsection (a) if its requirement is more stringent than a requirement under the Act or compliance with the requirement would not cause the device to be in violation of any requirement under the Act. Interpreting the term "requirement" in subsection (a) to mean state common law tort claims is completely inconsistent with the meaning of the term in subsection (b). How is a state to apply for an exemption involving a common law tort claim? **See Callan v. G.D. Searle & Co.**, 709 F. Supp. 662, 667 (D. Md. 1989). This incongruity would appear to make subsection (b) meaningless if we were to interpret subsection (a) to include common law tort claims. We have always rejected an interpretation of a statute that would make parts of it mere surplusage or meaningless. **Whitely v. New Mexico State Personnel Bd.**, 115 N.M. 308, 311, 850 P.2d 1011, 1014 (1993); **Slygh v. RMCI, Inc.**, 120 N.M. 358, 359, 901 P.2d 776, 777 .

4. Legislative History

{21} Legislative history provides additional support for holding that state common law tort actions are not preempted by the MDA. As noted previously, the primary purpose of the MDA was to ensure the reasonable safety and effectiveness of medical devices intended for human use. If Congress' purpose in enacting the MDA was the promotion of safety, it makes absolutely no sense that, with the same stroke of the pen, it would eliminate the safety aspects inherent in tort law. It is also difficult to conclude that Congress would remove all tort claims without mentioning it as a consequence of passing the bill. **See Silkwood**, 464 U.S. at 251 ("It is difficult to believe that Congress would, without comment, remove all means of recourse for those injured by illegal conduct.").

{22} Additionally, during the years of debate over the MDA, there was nothing in the record indicating Congress' intent to preempt common law tort actions by passing the legislation. **See** D. O'Keefe, Jr. & R.A. Spiegel, **An Analytical Legislative History of the Medical Device Amendments of 1976** (1976). In fact, the only mention of a state

requirement in the legislative history involved a California statute that established a form of regulation of medical devices that could only be exempted upon permission of the FDA. **Id.** app. III at 45-46. Because this was the only example of a state requirement, we believe that Congress did not intend to include state court decisions within the meaning of "requirements," as that term is used in the MDA. Rather, we conclude that Congress was concerned about the different kinds of regulations in different states that would be unduly burdensome on interstate commerce. **See id.** at 45. There is no indication that Congress was concerned with *{*8}* the effect of state tort actions against the manufacturers of these devices.

5. FDA's Interpretation

{23} Finally, the regulations promulgated by the FDA to implement the statute do not support preemption of state common law tort actions. An agency's interpretation of its own statute is given deference. **See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.**, 467 U.S. 837, 842-45, 81 L. Ed. 2d 694, 104 S. Ct. 2778 (1984); **Garcia v. County of Bernalillo**, 114 N.M. 440, 443, 839 P.2d 650, 653 . Here, there are several regulations explaining the preemption provision. 21 C.F.R. § 808.1(b) (1994) states:

> No State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device.

{24} Several courts have used the parenthetical as evidence that the term "requirement" includes common law tort claims because the parenthetical contains the words "court decision." **Mendes v. Medtronic, Inc.**, 18 F.3d 13, 18 (1st Cir. 1994); **Gile v. Optical Radiation Corp.**, 22 F.3d 540, 544 (3d Cir.), **cert. denied**, 130 L. Ed. 2d 342, 115 S. Ct. 429 (1994). Specific advisory opinions issued by the FDA, however, clarify that the parenthetical does not mean that common law remedies and tort claims are preempted. **See** Adler & Mann, **supra**, at 939. Instead, the inclusion of court decisions is simply to cover court decisions interpreting state statutes, ordinances, or regulations. **Ministry of Health**, 858 F. Supp. at 1435-36. Even if there is some ambiguity concerning the meaning of this part of the regulation, when it is read together with other parts of the regulation, any ambiguity is resolved.

{25} Section 808.1(d)(1) states that "Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." "State common law is a law of general applicability." **Kennedy v. Collagen Corp.**, 67 F.3d 1453, 1459 (9th Cir. 1995), **petition for cert. filed** (Apr. 11, 1996). It does not relate solely to or regulate any particular

device or product to the exclusion of other devices or products. **Id.** It is thus not a specific requirement that might be preempted by the MDA.

{26} Additionally, Section 808.1(d) provides that:

> state or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements.

{27} Section 808.1(d) is explicit in its dictate that state or local requirements are **only** preempted where there exist **specific** counterpart regulations applicable to a **particular** device.

{28} Defendant argues, and many courts have determined, that the premarket approval process for Class III devices constituted a "specific requirement" under the regulation. **Mitchell**, 67 F.3d at 1279 n.6. We consider more persuasive the analysis of the Ninth Circuit in **Kennedy** In that case, the court stated:

> **{29}** It makes little sense to hold that the FDA's premarket approval process qualifies as a " **specific** requirement applicable to a **particular** device." **All** Class III devices are required to obtain premarket approval before being sold in interstate commerce. The fact that the premarket approval process involves specific requirements must not be confused with the premarket approval requirement itself acting as a **specific** requirement.

67 F.3d at 1459 (citations omitted).

{30} In fact, the reasoning used in those cases holding there is preemption for *{*9}* Class III devices is in direct contrast to those cases addressing the issue for Class II devices. **Id.** at 1458. In the cases involving Class II devices, the courts have consistently focused on the specificity of the federal requirements and the particularity of the device involved. **Id.** ; **see Moore v. Kimberly-Clark Corp.**, 867 F.2d 243, 246 (5th Cir. 1989). Those cases hold that, because there is no specific regulation regarding the particular product, the state law claims were not preempted. **Anguiano v. E.I. Du Pont de Nemours & Co.**, 44 F.3d 806, 810 (9th Cir. 1995). Thus, the courts have required specific regulations for a particular device if it is a Class II device, but have ignored that requirement for Class III devices. **Kennedy**, 67 F.3d at 1458. We see no reason why a distinction dependent on the class of the device should be made. **See id.** at 1459. "A particular device" means just that. It does not mean all devices in a particular class. **See Oja v. Howmedica, Inc.**, 848 F. Supp. 905, 907 (D. Colo. 1994).

6. Public Policy

{31} We realize that Class III devices are required to undergo a rigorous premarket approval process before entering the market. However, that does not guarantee that the device is safe and effective. **See Haudrich v. Howmedica, Inc.**, 267 Ill. App. 3d 630, 642 N.E.2d 206, 214, 204 Ill. Dec. 744 (Ill. App. Ct. 1994). In fact, the information made available during the premarket approval process is provided by the manufacturer. The FDA does not independently test each device, but relies on the manufacturer to disclose information regarding safety and effectiveness. A manufacturer can receive premarket approval for an unsafe or ineffective device by simply failing to provide the FDA with adverse reports. Therefore, a premarket approval does not establish conclusively that a device is safe and effective and, thus, that a consumer does not need the protection of tort law.

{32} With the stated intent of Congress in enacting the MDA to ensure that safe and effective devices were introduced into the market, we do not believe that Congress intended that a whole class of devices, those that are most capable of causing injury, would be preempted from state causes of action simply because the device received premarket approval from the FDA.

> The federal law requiring the premarket approval of Class III devices was not enacted in order to free manufacturers from the everyday burdens of the marketplace after they are permitted to enter it. Premarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers.

Kennedy, 67 F.3d at 1459-60.

{33} As noted in **Kennedy**, state regulation of manufacturers directly governs their actions in releasing their goods into the market. **Id.** at 1459. State common law imposes only an indirect effect on manufacturers. **Id.** Defendants in a common law damages action retain the freedom to choose their own response to the legal challenge they face. Adler & Mann, **supra**, at 908. They can alter their product or bear the cost of any lawsuits that may result. **Id.** at 909; **Kennedy**, 67 F.3d at 1459. In contrast, a positive state enactment requires the manufacturer to conform its product to law. Thus, state common law serves a different purpose than state regulation. We agree with the **Kennedy** court that state common law "is unlikely to have been the target of congressional attempts to promote the introduction of safe medical devices onto the market or even to curb dual regulation of the medical devices industry." 67 F.3d at 1459. In fact, "the state law tort system currently acts as an incentive for manufacturers to continue to improve their products as well as to disclose developments in product safety and their side effects." **Bravman v. Baxter Healthcare Corp.**, 842 F. Supp. 747, 760 (S.D.N.Y. 1994).

{34} We find it difficult to accept that Congress, concerned with the safety of medical devices, would take away the sole means of redress for injuries caused by those devices. The result of determining federal preemption of all state common law tort claims for Class III devices would be to leave an injured party with no remedy

whatsoever, and, ironically, with less protection than they enjoyed before passage of the MDA. Such could not have been the intent of Congress in an area *{*10}* where that legislative body has sought to protect the consumer. There simply must be some avenue for redress, and the MDA does not provide it. "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S10688 (daily ed. Apr. 17, 1975) (statement of Sen. Kennedy).

{35} In this context, Plaintiffs' counsel's reference at oral argument to **Marbury v. Madison**, 5 U.S. 137, 2 L. Ed. 60 (1803), was most appropriate. In that legendary case, Chief Justice Marshall, speaking for the Court, posed the crucial question: "If [a person] has a right, and that right [is] violated, do the laws of [this] country afford him a remedy?" **Id.** at 162. The Supreme Court's answer, which we adopt in reaching our holding, was that "the very essence of civil liberty certainly consists in the right of every individual to claim the protection of the laws, whenever he receives an injury." **Id.** at 163.

III. CONCLUSION

{36} Based on our review of the language and the context of the MDA, its legislative history, and FDA regulations, we hold that Congress has not expressed an intent to preempt all state common law causes of action arising from injuries resulting from the use of a Class III medical device. We therefore reverse the award of summary judgment to Defendant and remand for trial. Plaintiffs are awarded costs on appeal.

IT IS SO ORDERED.

RUDY S. APODACA, Chief Judge

WE CONCUR:

BENNY E. FLORES, Judge

RICHARD C. BOSSON, Judge