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1997 Survey of Rhode Island Law: Cases: Products Liability

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Products Liability. *Fry v. Allergan Medical Optics*, 695 A.2d 511 (R.I. 1997). Where a plaintiff suffers an injury from a Class III medical device regulated by the Medical Devise Amendments to the Federal Food, Drug and Cosmetic Act (MDA), recovery under theories of negligence, strict liability and breach of warranty are preempted because they impose additional requirements on the manufacturer.[1] As these additional requirements impose different or additional duties on the manufacturer in the form of a court judgment, they are in conflict with the MDA.

FACTS AND TRAVEL

In March of 1990, Arthur Fry (Fry) underwent eye surgery at Kent County Memorial Hospital.[2] Fry was a seventy-two-year-old veteran with a history of recurring eye problems.[3] His surgery was precipitated by a cataract that had formed in his left eye and impaired his vision.[4] To correct this condition, plaintiff's ophthalmologist removed the natural lens from Fry's eye and replaced it with an AC-21B Anterior Chamber Intraocular Lens (Lens) manufactured by Allergan Medical Optics (Allergan).[5] The Lens was created to "rest behind the eye's pupil and iris" and to replace Fry's damaged natural lens.[6]

The performance of the Lens was less than satisfactory.[7] The Lens "became dislocated twice, was repositioned surgically and ul-

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1. The MDA provide in part:

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

Medical Device Amendments to Federal Food, Drug, and Cosmetic Act, § 521(a), 21 U.S.C.A. § 360k(a) (West Supp. 1997).

2. *See* Fry v. Allergan Med. Optics, 695 A.2d 511, 512 (R.I. 1997).

3. *See id.* (stating that Mr. Fry's chronic condition included "a detached retina, glaucoma and cataracts").

4. *See id.*

5. *See id.*

6. *Id.*

7. *See id.*

timately had to be removed."[8] Because of problems attributed to the dislocation and the removal of the Lens, Fry contended that he endured chronic eye pain and acquired a loss of vision.[9] In April of 1993, Fry brought suit in Rhode Island Superior Court. He named as defendants eight medical-device manufacturers.[10] He sought damages based on claims of negligence, strict liability and breach of express and implied warranties.[11] Mr. Fry was later allowed to amend his compliant to name the defendant, Allergan, because it was later discovered that none of the originally named defendants manufactured the Lens. Allergan filed a motion for summary judgment. The superior court granted the motion stating that the MDA preempted state-law claims against the manufacturer of a Class III medical device.[12]

BACKGROUND

The MDA were codified in 1976.[13] As amendments to the Federal Food, Drug and Cosmetic Act, they were initiated by Congress primarily out of concern for the safety of medical devices.[14] The MDA grants jurisdiction over medical devices to the Food and Drug Administration (FDA).[15] The MDA creates three classifications of medical devices based on risk.[16] The type of devise used on Fry was a Class III devise which required extensive testing and licencing by the FDA.[17] Since the FDA's controls regarding the Class III devises cannot by themselves ensure their safe use or safety, the FDA requires the devise to undergo "premarket ap-

8. *Id.*
9. *See id.*
10. *See id.*
11. *See id.*
12. *See id.*
13. Medical Device Amendments to Federal Food, Drug, and Cosmetic Act, § 521(a), 21 U.S.C.A. § 360K(a) (West Supp 1997).
14. *See id.*
15. *See id.*
16. *See id.* ("Class I devices, which include tongue depressors and ice bags, consist of posing the lowest level of risk and are subject only to 'general controls.' 21 U.S.C. § 360c(a)(1)(A). Class II devices, which include hearing aids and syringes are moderately regulated through 'special controls.' 21 U.S.C. § 360 (a)(1)(B). Class II devices, however, like class I devices, may be marketed without advance approval by the FDA . . . . Class III medical devices consist of those devices that are important for sustaining human life and well-being but which may, notwithstanding, present a potentially unreasonable risk of illness or injury.").
17. *See Fry*, 695 A.2d at 513.

proval."[18] This process consists of an involved review process conducted by the FDA of the "ingredients, components, manufacturing methods and proposed labeling of the medical devise."[19]

The FDA takes approximately 1200 hours to review each application for premarket approval.[20] However, the FDA still retains the right to withdraw the product from the market following the pre-market approval process.[21] Furthermore, any additional changes made to the product in its labeling or manufacturing that might affect the safety or quality of the devise must have prior FDA approval.[22]

Congress created two exemptions from the premarket approval scheme.[23] Devises prior to 1976 that were already in the stream of commerce were grandfathered, and devises that were substantially similar to grandfathered devises were granted approval.[24] The lens used by Fry was a Class III devise submitted for approval on July 3, 1987 and was granted approval on September 29, 1989.[25] Consequently, the lens did not fall within either of the above two exceptions.

ANALYSIS

The appeal in this case centers around the extent to which the MDA preempts the plaintiff's state-law claims.[26] As part of the FDA regulatory program, the MDA falls under the guise of federal preemption.[27] The supremacy clause is illustrative of Congress's plenary power to legislate in this arena. The Rhode Island Supreme Court rationalized its interpretation of the supreme power of the federal government by stating that "if Congress in-

18. *Fry*, 695 A.2d at 513; *see also* 21 U.S.C.A. § 360e(a) (West Supp. 1997).

19. *Fry*, 695 A.2d at 513; *see also* 21 U.S.C.A. § 360e(c)(1)(A)-(G) (West Supp. 1997).

20. *See Fry*, 695 A.2d at 513.

21. *See id.*; *see also* 21 U.S.C.A. § 360e(e)(1)(A)-(B) (West Supp. 1997).

22. *Fry*, 695 A.2d at 513; *see also* 21 U.S.C.A. § 360e(e)(1)(B), (E) (West Supp. 1997); 21 C.F.R. § 814.39(a) (1997).

23. *See Fry*, 695 A.2d at 513.

24. *See id.*

25. *See id.*

26. *See id.* at 514.

27. *See* U.S. Const. art. VI, cl. 2.

tends, state laws may be preempted by federal law and will be considered to be 'without effect.'"[28]

Allergan relied specifically on the express language in the statute to assert that the plaintiff's claims were preempted.[29] In establishing this theory, the defendant claimed that allowing a state-law claim would add requirements that would be "different from, or in addition to" the premarket-approval process.[30] The plaintiff claimed that Congress did not intend for the premarket approval process or judgments rendered on state-law claims to be requirements under the language established in 21 U.S.C. § 360(k)a.[31] Therefore, the interpretation of the word "requirement" was directly related to the success of the plaintiff's claim.[32]

The Rhode Island Supreme Court found that a state-law claim is preempted when the party bringing suit does not base the claim on the failure of the manufacturer to comply with requirements imposed by the FDA under the MDA.[33] In reaching this conclusion, the court found that bringing suit against a medical-devise manufacturer would require the plaintiff to show that the defendant failed to follow federally prescribed guidelines.[34] Absent a manifest relationship between the complaint and requirements promulgated by the MDA, allowing the plaintiff's action to proceed would have the net effect of adding procedure to the MDA.[35]

The court reasoned that sanctioning additional procedures would augment federal law, which is prohibited by the supremacy clause.[36] As the plaintiff was not asserting any specific failure of the manufacturer to comply with requirements set forth by the MDA, his claim was prohibited.[37]

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28. *Fry*, 695 A.2d at 514 (quoting Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Maryland v. Louisiana, 451 U.S. 725, 746 (1981)); *see also* Narragansett Elec. Co. v. Burke, 381 A.2d 1358, 1361 (R.I. 1977).

29. *See Fry*, 695 A.2d at 514; *see also supra* note 2.

30. *Fry*, 695 A.2d at 514.

31. *See id.*

32. *See id.*

33. *See id.* at 517.

34. *See id.*; *see also* Medtronic, Inc. v. Lohr, 116 S.Ct. 2240, 2257 (1996) (establishing the preemption rule by holding that Congress intended preemption "only where a particular state requirement threatens to interfere with a specific federal interest").

35. *See Fry*, 695 A.2d at 517.

36. *See id.*

37. *See id.* (stating that the plaintiff sought recovery under theories of negligence, strict liability and breach of warranty).

CONCLUSION

The plaintiff's claims of negligence, strict liability and breach of warranty were based on theories not related to the manufacturer's failure to comply with the approval process set forth by the MDA and are therefore preempted by federal law. The premarket-approval process is a specific federal interest, and the process establishes strict federal requirements on manufacturers of medical devices. The FDA is the proper entity to address enforcement issues.

Allowing the plaintiff's action would effectively allow state courts to supplement the procedural requirements of the MDA with alternative regulatory schemes, albeit judicial in form. As this new "requirement" would be arbitrarily promulgated by a state court against a federal agency, it is constitutionally untenable.[38] Had the plaintiff claimed that the procedures set forth by the MDA were somehow circumvented by Allergan, the plaintiff would not have been preempted by federal law.

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38. *Fry*, 695 A.2d at 514 (referring to Article VI, clause 2 of the United States Constitution).