Fifty State Survey of FDCA-Related Tort Causes of Action

A Report of the Pharmaceuticals and Biologicals Subcommittee
Products Liability Committee

Ronald Jay Cohen
Section Chair

John B. Isbister
Beth L. Kaufman
Co-Chairs, Products Liability Committee

Charles R. Beans
Gary J. Spahn
Co-Chairs, Pharmaceuticals and Biologicals Subcommittee

James M. Beck
Editor

SECTION OF LITIGATION
American Bar Association

Defending Liberty
Pursuing Justice

MARYLAND LAW REGARDING FDCA-RELATED TORT CLAIMS

Daniel W. Whitney
Whitney & Bogris, LLP
Twelfth Floor
401 Washington Avenue
Towson, MD 21204
Phone: (410) 583-8000
Fax: (410) 583-1786

Private FDCA Right of Action

Maryland state courts have not addressed whether a private right of action exists under the Food, Drug & Cosmetic Act ("FDCA"). However, the Fourth Circuit, applying Maryland substantive law, stated that a private right of action seeking enforcement of FDA regulations has not been recognized in Maryland. Griffin v. Medtronic, Inc., 82 F.3d 79, 83, n4 (4th Cir. 1996), rev'd on other grounds, 114 F.3d 39 (4th Cir. 1997) (citing Rodriguez v. SK&F Co., 833 F.2d 8, 9 (1st. Cir. 1987)). See also Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (Maryland law), cert. denied, 510 U.S. 1197 (1994).

FDCA-Based Negligence Per Se

Maryland does not recognize the negligence per se doctrine. In re Sabin Oral Polio Vaccine Products Liability Litigation, 774 F. Supp. 952 (D. Md. 1991). Instead, Maryland allows parties to admit violations of statutes as evidence of negligence. Id. at 956 (holding that in negligence cases "[the federal] regulations are highly relevant in assessing what constitutes 'reasonable care.' As a general rule, regulations are to be considered in defining the scope of a tort duty.") (quoting Pahanish v. Western Trails, Inc., 69 Md. App. 342, 362, 517 A.2d 1122, 1132 (1986)); see also Restatement (Second) of Torts §286 (1965). An alleged violation of a statute may provide evidence of negligence if the person alleging the negligence is within the class of persons sought to be protected and the harm is of the type of harm the statute intended to prevent. Atlantic Mutual Insurance Co. v. Kenney, 591 A.2d 507, 510-11 (Md. 1991).

Fraud on The FDA

Maryland case law is sparse. In a recent decision the local federal court hinted that fraud on the FDA is not a cognizable claim under Maryland law. Strange v. Sofamor Danek Group, Inc., 1999 WL 1129704, at *1 n.1 (D. Md. 1999) (stating that "a state law fraud-on-the-FDA claim could be viable if the state had adopted §310 of the Restatement (Second) of Torts or a similar common law rule. . . . Maryland does not appear to have done so").

Another federal case, Nichols v. G.D. Searle & Co., 783 F. Supp. 233, 242 (D. Md. 1992), discussed fraud on the FDA but did not indicate whether it was a cognizable claim in Maryland. In Nichols the plaintiffs set forth two claims – negligence and fraudulent misrepresentation – that incorporated fraud on the FDA as an element of the action. Id. The court dismissed the case for lack of personal jurisdiction and never discussed the fraud on the FDA element of the plaintiff's case. Id. at 245.

Informed Consent

Maryland courts, state or federal, have not examined whether a physician's obligation to provide informed consent includes discussing the FDA regulatory status with the patient.

In general, "the doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo such treatment." Sard v. Hardy, 379 A.2d 1014, 1020 (Md. 1977).

Rather than the traditional professional standard of care in medical malpractice cases, Maryland employs a reasonable patient standard for informed consent cases. "The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever is material to the decision. Thus, the test for determining whether a potential peril must be divulged is its materiality to the patient's decision." Id. at 1022 (quoting Cobbs v. Grant, 104 Cal. Rptr. 505, 515 (1972)). A material risk is defined as "one which a physician knows or ought to know would be significant to a reasonable person in [the] patient's position in deciding whether or not to submit to a particular medical treatment or procedure." Id.

Other Issues – Preemption

Since the Supreme Court's ruling in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), local federal courts have held that "state common-law causes of action may constitute requirements, but such requirements are preempted only when they conflict with a specific regulation promulgated by the FDA with respect to the particular device in question or a device-specific requirement imposed by the MDA. Accordingly, state-law claims pertaining to medical devices subject only to the general controls imposed by the §510(k) notification process, GMPs [good manufacturing practice], or labeling requirements are not preempted." Duvall v. Bristol-Myers-Squibb Company, 103 F.3d 324, 330 (4th Cir. 1996).

In Duvall, the plaintiff brought an action against the manufacturer of a penile prosthesis, asserting products liability and breach of warranty claims alleging that the prosthesis did not work. Id. at 326. The Fourth Circuit held that §360k(a) did not preempt the plaintiff's state-law failure to warn, breach of implied warranty, negligence, and strict liability claims. Id. The court also found that the plaintiff's express warranty claims were not preempted: "[N]either the §510(k) notification process nor the general controls on labeling found in 21 C.F.R. part 801 impose requirements on a device sufficient to result in preemption of additional or different state requirements." Id. at 332 (citing Medtronic).

In 1996, prior to Lohr and Duvall, the Fourth Circuit held that a plaintiff's implied warranty, strict liability, negligence, and intentional misrepresentation claims were preempted by §360k. Griffin, 82 F.3d at 82. The plaintiff was a recipient of a heart pacemaker brought a products liability ac-

tion against the manufacturer of the pacemaker. Id. at 79. The pacemaker at issue in this case was a Class III medical device, brought to market under the "substantially equivalent" process. Id. at 82 n2. The court reasoned that if the plaintiff were to prevail on those claims, the defendant manufacturer would be "burdened with requirements different from or in addition to those applicable to pacemakers under the MDA." Id.

Following the Fourth Circuit's decision in Griffin, the U.S. Supreme Court granted certiorari and vacated the court's judgment for further consideration in light of Lohr. Griffin v. Medtronic, Inc., 519 U.S.1104(1997). The Fourth Circuit subsequently remanded Griffin to the district court for their reconsideration under Lohr and Duvall. Griffin v. Medtronic, Inc., 114 F.3d 39 (1997).

Maryland state courts have not addressed FDCA-related preemption in any published opinion.