J. A44006/00

2001 PA Super 29

FRANK CABIROY,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellee	:	
	:	
v.	:	
	:	
C. RICHARD SCIPIONE, M.D.,	:	
	:	
Appellant	:	No. 2198 EDA 1999

Appeal from the Order dated June 30, 1999
in the Court of Common Pleas of Philadelphia County,
Civil, at No. 1882, March Term, 1995.

BEFORE: DEL SOLE, JOHNSON and BECK, JJ.

OPINION BY DEL SOLE, J.: Filed: January 30, 2001

¶ 1 This is an appeal from a trial court order granting Appellee-Plaintiff's request for post-trial relief and awarding a new trial. We affirm.

¶ 2 Appellee commenced this action alleging Appellant committed medical malpractice when he treated Appellee with injections of liquid silicone to cosmetically improve a nasal deformity. It was alleged that the silicone injections caused lumps to form on Appellee's nose, which later had to be shaved off with a scalpel. It was established at trial that the FDA had never approved the use of liquid silicone for injections and that Appellee signed a consent form stating he understood that silicone injections were not FDA approved. At the close of Appellee's case, the trial court granted Appellant's motion for non-suit on the issue of negligence *per se* for violation of FDA statutes and regulations. The court also charged the jury that the FDA had no authority to regulate the practice of medicine by a physician treating a

patient. The jury returned a verdict in favor of Appellant, in response to which Appellee filed post-trial motions. Appellee claimed the court erred in granting the non-suit on the issue of negligence *per se* and that the court's charge to the jury on the lack of the FDA's authority to regulate the practice of medicine was in error. The trial court accepted these arguments and ordered a new trial. This appeal followed.

¶ 3 Appellant challenges both grounds on which the court ordered a new trial. Initially Appellant claims that the court erred in ruling that the jury should have been permitted to consider the claim of negligence *per se*.

¶ 4 The concept of negligence *per se* establishes both duty and the required breach of duty where an individual violates an applicable statute, ordinance or regulation designed to prevent a public harm. A plaintiff, however, having proven negligence *per se*, cannot recover unless it can be proven that such negligence was the proximate cause of the injury. ***J.E.J. v. Tri-County Big Brothers/Big Sisters,*** 692 A.2d 582, 585 (Pa. Super. 1997). A violation of a statute may be negligence *per se* and liability may be grounded on such negligence but the plaintiff cannot recover unless such negligence is the proximate and efficient cause of the injury in question. The doctrine of negligence *per se* does no more than satisfy a plaintiff's burden of establishing a defendant's negligence. It does not end the inquiry. The plaintiff still bears the burden of establishing causation. ***Congini v.***

Portersville Valve Co., 470 A.2d 515 (Pa. 1983); ***Kaplan v. Philadelphia Transp. Co.***, 171 A.2d 166 (Pa. 1961).

¶ 5 At issue in this case are the provisions of the FDA. The passage of the Medical Device Amendments (MDA) to the Food, Drug and Cosmetic Act in 1976 gave the federal Food and Drug Administration comprehensive jurisdiction of all "devices intended for human use." 21 U.S.C.A. 360c(a)(1), ***Green v. Dolsky***, 685 A.2d 110 (Pa. 1996). The MDA classifies medical devices, depending upon their potential danger to the public, as Class I, II or III. ***Id.*** Liquid injectable silicone is classified by the FDA as a Class III device. Class III devices are the most heavily regulated and before they obtain FDA approval they must undergo a detailed premarket approval process or it must be established that they are substantially equivalent to a device already on the market. ***Id.***, 1 U.S.C. 360c(1)(C); 21 U.S.C. 360e(b)(1)(A). The FDA has never approved liquid silicone injections. The trial court summarized the following evidence obtained at trial regarding liquid silicone injections:

> Dow Corning was the only company that manufactured, distributed or sold liquid silicone in the United States. Liquid silicone was first marketed as an industrial grade in the 1950's. However, early in the 1960's Dow Corning developed "medical Grade 360," a type of liquid silicone used to coat needles and the inside of glass. Purchasers of medical grade silicone were required to sign affidavits stating that the silicone would not be injected in humans. In July, 1965, Dow Corning filed an Investigational Exemption of a new New Drug application with the FDA, authorizing the investigational use of liquid injectable silicone. The silicone used, marketed under the label MDX 4-4011, was a highly purified, sterilized silicone, without any

> impurities. This study authorizing physicians to inject silicone into humans, ran from 1965 through 1971. Only eight investigators were authorized to participate in the study.
>
> In 1974, Dow applied to the FDA for permission to market silicone for human injection. Approximately two years later, Dow applied for a new investigational exemption for liquid injectable silicone. Twenty-six investigators, selected and approved by the FDA, were authorized to participate in a three-year treatment program and seven-year follow-up of one hundred twenty-eight patients with severe facial deformities. This study, conducted under strict controls, concluded in 1981.

Trial Court Opinion 6/2/00 at 4-5.

¶ 6 In 1989, Appellant injected Appellee with liquid silicone after advising him that the FDA had not approved the use of liquid injectable silicone, but that in Appellant's opinion it soon would be approved. Appellant testified that he received his supply of liquid injectable silicone from a Richard Webster, M.D., now deceased. Appellant testified that he believed it to be medical grade silicone which was used for the injection, although it was housed in an eight ounce glass bottle which was not sealed, or sterile, and which did not bear a manufacturer's label. It was also established at trial that neither Appellant nor Dr. Webster was an authorized investigator under the approved FDA study.

¶ 7 Appellee sought to establish at trial that Appellant was negligent *per se* for violating the FDA. Specifically the negligence was based on a violation of 21 U.S.C. § 331. In relevant part it provides:

> The following acts and the causing thereof are hereby prohibited:
> . . .

> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

21 U.S.C. § 331(c).

¶ 8 The trial court found that Appellant's actions were in direct violation of the statute. Appellant obtained through interstate commerce an unlabeled container of a matter he believed to be injectable liquid silicone, which he knew was not approved for use by the FDA, and he delivered that substance to his patient, Appellee, in the form of an injection.

¶ 9 In analyzing whether a claim based on negligence *per se* for violating this provision exists, Appellee must establish whether the purpose of the statute is to protect the interest of a group of individuals, as opposed to the general public, and whether the statute clearly applies to the conduct of the defendant. ***Wagner v. Anzon, Inc.***, 684 A.2d 570, 574 (Pa. Super. 1996.)

¶ 10 Appellant argues that the trial court only considered whether Appellant violated the statute in question and failed to consider that its provisions are intended for the protection of the public welfare and not to protect a particular group of individuals. In support Appellant cites to this court's decision in ***Wagner***. In ***Wagner*** the appellant sought to establish that the trial court erred in granting a directed verdict on a negligence *per se* claim based upon the appellee's violations of the Philadelphia Air Management Code of 1969. The court noted that the statute or regulation at issue must be designed to protect a class of persons which includes the one whose

interest is invaded. ***Id.*** (citing ***Congini v. Portersville Valve Co.***, 470 A.2d 515 (Pa. 1983)). It concluded that the purpose of the Philadelphia Air Management Code was to protect the atmosphere over the city of Philadelphia "with a concomitant benefits [sic] to its 'inhabitants'." ***Wagner***, 684 A.2d at 574. The court wrote: "[t]here is no indication in these findings that the Code was meant to protect a particular class of individuals, rather it was enacted in 'furtherance of the health and welfare of the City's inhabitants, to the conduct of the normal pursuits of life, recreation, commerce and individual activity, and to sustaining life in an urban area'." ***Id.*** at 575.

¶ 11 The ***Wagner*** court contrasted those cases allowing negligence *per se* claims to proceed for violations of the Vehicle Code. The court reasoned: "[a] statute governing traffic has as its primary purpose the safety of those who use the roadways, while a statute governing air quality, by its nature, is directed to the population in general." ***Id.*** It further noted that the statute in question did not provide for a private cause of action which could act as an indicator that the statute did not contemplate enforcement for individual harms.

¶ 12 We conclude that although no private cause of action is set forth in the Act, it was certainly designed to protect a particular class of individuals - those such as Appellee who may be receiving some type of drug or devices. In ***Stanton v. Astra Pharmaceutical Products, Inc.***, 718 F.2d 553 (3d

Cir. 1983) an action was brought after an eight-month old child suffered a severe adverse reaction, including cardiac and respiratory arrest, to Xylocaine, a local anesthetic. It was alleged that Astra, the manufacturer, had been negligent in failing to file with the FDA certain reports concerning the drug as required by federal statutes and regulations. The court wrote "[u]nder Pennsylvania law, the violation of a governmental safety regulation constitutes negligence per se if the regulation 'was, in part, intended to protect the interest of another as an individual [and] the interest of the plaintiff which was invaded, was one which the act intended to protect.'" ***Id.*** at 563 (citing ***Majors v. Brodhead Hotel***, 205 A.2d 873, 875 (Pa. 1965)). The court concluded that the reporting requirements of the FDA were "promulgated to protect individuals such as [the plaintiff] from precisely the type of harm that here occurred – an unexpected adverse reaction to Xylocaine." ***Stanton***, 718 F.2d at 564.

¶ 13 In this case, Appellee did not assert that the Act created a private statutory cause of action. Rather, his claim was based on a basic common-law tort action for negligence.[1] In ***Green v. Dolsky***, 685 A.2d 110 (Pa. 1996) where the plaintiff developed an autoimmune disorder after receiving an injection of Zyderm Collagen Implant, the Court wrote that "there is no private right of action under the MDA, and in the absence of state law

[1] The courts of this Commonwealth have noted the differences between a statutory civil cause of action and one arising under common law. See ***Alfred M. Lutheran Distributors, Inc. v. A. P. Weilersvacher, Inc.***, 650 A.2d 83 (Pa. Super. 1994) (citing ***Manning v. Andy***, 310 A.2d 75, 78-81 (Pa. 1973)).

claims, a party injured by a medical device would have no cause of action against any person or entity." 685 at 115. The court went on to consider whether the state law claims were preempted by the Act but found that "state claims which allege that FDA requirements have not been met are cognizable." ***Id.*** at 117.

¶ 14 It must be recalled that Appellee sought only to have the jury consider its negligence *per se* claim. "[T]he doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort." ***In re: Orthopedic Bone Screw Products Liability Litigation***, 193 F.3d 781, 790 (3d Cir. 1999).

¶ 15 In ***Shamnoski v. P G Energy***, 2000 PA Super 367, this court found that violations of the Dam Safety and Encroachment Act did constitute negligence *per se* and that the statute was designed to protect the interest of a specific class of individual, those with property downstream from a dam. The court found that the statute applied to the Appellant's conduct as owner and operator of dammed reservoirs and there was a direct connection between the harm meant to be prevented and the injury suffered to downstream residents by flooding.

¶ 16 In this case the statute was designed to protect an individual such as Appellee from being administered a non-labeled, non-sterile unapproved drug to avoid unexpected negative results. Through proof of such violation,

Appellee proved as a matter of law the first two elements of his cause of action, the duty and the breach of duty. This coupled with any evidence presented on causation and damages were matters for the jury's consideration. The trial court properly reversed its ruling granting a non-suit on the issue of negligence *per se.*

¶ 17 We turn now to the second issue, which challenges the trial court award of a new trial based on its conclusion that it erred in charging the jury on the FDA's lack of authority to regulate the practice of medicine. The court gave the jury the following instruction: "The United States Food and Drug Administration has no authority to regulate the practice of Medicine by a physician treating a patient." N.T., 8/14/98, at 853. Upon reflection the trial court accepted Appellee's claim that this charge "gave the jury the impression that a physician can use any drug he wants, irrespective of whether it has been approved or disapproved by the FDA." Trial Court Opinion, 6/2/00, at 10. The court noted that the charge given was made before this court's decision in ***Southard v. Temple University Hospital***, 731 A.2d 603 (Pa. Super. 1999).

¶ 18 The plaintiff in ***Southard*** underwent a spinal fusion surgery in which bone screws were implanted at a time when the FDA had not classified the screws as safe and effective for spinal use. The court ruled that the doctors involved had a duty to disclose the FDA classification to the plaintiff. Upon so ruling this court noted that "the FDA generally does not regulate the

practice of medicine" and that "a physician, using his best medical judgment for the benefit of his patient, generally is free to use a medical device in a manner different from that for which the FDA has approved the device for commercial sale." ***Id.*** 731 A.2d at 611. In a footnote the court also remarked: " We note, however, that the FDA at least minimally regulates the practice of medicine in several ways. For example, it requires that a medical device be approved for sale for at least one use before a physician may use it for another 'off-label' use." ***Id.***, fn.11.

¶ 19 Appellant would have us discount this language because it is contained in a footnote regarding an informed consent case. This we decline to do. Doctors do not have sole and absolute discretion in treating their patients. The Commonwealth Court, in remarking on a physician's claim that he was denied his civil right to prescribe and administer drugs according to his medical judgment, wrote:

> He cites no authority for the proposition that a licensed physician has a right to treat patients wholly in accordance with his personal beliefs and we have found none. On the contrary, the state's power to regulate the practice of medicine in the interest of public health and safety is as clear as it is necessary.

Commonwealth, Dep't of Health v. DeMarco, 416 A.2d 623, 626 (Pa. Commw. 1980).

¶ 20 Thus we find no error in the trial court's decision to award a new trial in an effort not to mislead the jury regarding a physician's role in providing treatment to the patient.

¶ 21 Order affirmed.

¶ 22 Judge Beck concurs in the result.