10-7-1999

In Re Orthopedic Bone Screw Litigation

Filed October 7, 1999

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 98-1762 & 98-1829

IN RE: ORTHOPEDIC BONE SCREW PRODUCTS
LIABILITY LITIGATION

Plaintiffs Legal Committee,
Appellant at 98-1762

American Academy of Orthopaedic Surgeons,
North American Spine Society, and Scoliosis
Research Society (the Medical Associations),
Appellants at 98-1829

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
MDL No. 1014
(Honorable Louis C. Bechtle)

Argued April 26, 1999

Before: SCIRICA, ROTH and McKAY,* Circuit Judges

(Filed October 7, 1999)

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*The Honorable Monroe G. McKay, United States Circuit Judge for the Tenth Judicial Circuit, sitting by designation.

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OPINION OF THE COURT

SCIRICA, Circuit Judge.

This is an appeal of the District Court's dismissal under Fed. R. Civ. P. 12(b)(6) of conspiracy and concert of action claims alleged by thousands of plaintiffs in multidistrict litigation involving allegedly defective bone screw implantation devices. The District Court held the claims, insofar as they alleged a conspiracy to violate the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C.A. S 301-397 (West Supp. 1999), did not state a cause of action

upon which relief can be granted. Accordingly, the court granted defendants' motions to dismiss those claims.

The District Court also made several rulings unfavorable to the defendants. The court denied with prejudice their motions to dismiss based on improper pleading and First Amendment protection. Additionally, the District Court denied the motions of several defendants for attorney's fees, costs, and sanctions. These rulings are now challenged on cross-appeal.

We will affirm the judgment of the District Court on all issues.

I. BACKGROUND

This multidistrict litigation comprises more than 2,000 civil actions originally filed in approximately sixty of the ninety-four federal districts. In August 1994, the cases were consolidated in the Eastern District of Pennsylvania under 28 U.S.C. S 1407. All of the approximately 5,000 individual plaintiffs claim to have suffered physical injuries caused by defective orthopedic bone screw devices affixed to the pedicles of their spines during spinal fusion surgery. The devices, which are intended to stabilize the spine and achieve fusion of the vertebrae, consist of rods or plates that are screwed into the vertical axis of the lumbar spine. In most cases, plaintiffs allege the devices broke after being implanted in their spines. In some instances, plaintiffs have undergone surgery to have the devices removed; in others, the broken devices could not be removed.

Plaintiffs' original claims, filed in early 1994, set forth causes of action based on both federal statutes and state law tort and contract principles. Generally, they named as defendants only the manufacturers and distributors of the bone screw devices. Subsequent actions named a broader array of defendants and stated additional theories of recovery. In particular, hundreds of so-called "omni" actions, first brought in October 1995, name as defendants the manufacturers, designers, and distributors of the devices; trade associations that conducted seminars on their use; regulatory consultants; and physicians who promoted the product. There are two types of omni actions.

The Plaintiffs' Legal Committee ("PLC") actions allege both a horizontal conspiracy involving manufacturers and a vertical conspiracy involving all of the defendants. The Lestelle actions (so named after the attorney who drafted the form complaint that served as the basis of these actions) allege only a horizontal conspiracy involving manufacturers. In addition to the conspiracy and concert of action claims, the omni complaints allege fraud; negligent misrepresentation; strict liability in tort; liability per se; negligence; breach of implied warranty of merchantibility; and (in some cases) loss of consortium.

In August 1996, the District Court dismissed the PLC omni complaints in their entirety because the complaints failed to demonstrate subject matter jurisdiction. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL No. 1014, 1996 WL 482977 (E.D. Pa. Aug. 22, 1996) (Pretrial Order No. 477). The court also dismissed the conspiracy claims in both the PLC and the Lestelle complaints for failure to state a claim upon which relief could be granted, and it dismissed the fraud claims in the Lestelle complaints because the circumstances of fraud were not averred with sufficient particularity. See id. All of these dismissals were without prejudice. Plaintiffs subsequently filed hundreds of amended omni complaints, which are the subject of this appeal.1

Twice before, we have issued decisions in this litigation. First, we denied the petitions of some defendants for a writ of mandamus invalidating the District Court's dismissal of the conspiracy and concert of action claims. See In re Orthopedic Bone Screw Prods. Liability Litig., No. 97-1426, 1427, 1438, 1450, 1453, 1465, mem. op. (3d Cir. Nov. 10, 1997) (unpublished opinion). There we considered two of the arguments raised by defendants here: their claim that the First Amendment prohibits imposition of liability for their speech at the seminars, and their contention that the omni complaints fail to plead reliance and causation adequately. Although these arguments did not persuade us to grant the "extraordinary remedy" of mandamus relief, In

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1. For ease of reference, we will refer to the amended omni complaints simply as the "omni complaints."

re Asbestos Sch. Litig. (Pfizer Inc.), 46 F.3d 1284, 1288 (3d Cir. 1994), we noted that the standards governing a mandamus petition are more stringent than those governing a direct appeal, and that our disposition did not preclude defendants from asserting their arguments at a later stage in the proceedings. Accordingly, our denial of a writ of mandamus has no binding effect in the present appeal. More recently, we determined that plaintiffs' state law claims of fraud on the FDA were not preempted by the Medical Device Amendments of 1976, 21 U.S.C.A. SS 360c-360k (West Supp. 1999) ("MDA"). See In re Orthopedic Bone Screw Prods. Liability Litig., 159 F.3d 817 (3d Cir. 1998).

A. Regulatory Framework

The conspiracy and concert of action claims at issue here require some discussion of the regulatory framework governing orthopedic bone screw devices. It is undisputed that the devices are regulated by the FDCA, as amended by the MDA. At the time the lawsuits were filed, the FDA had classified the bone screw devices as "Class III" devices because they "present a potential unreasonable risk of illness or injury." 21 U.S.C. S 360c(a)(1)(C)(ii)(II). Consequently, one must receive "premarket approval" before commercially distributing or selling them. Id. S 360e(a). To obtain the data to support an application for premarket approval, a manufacturer may use the device in clinical trials under active FDA supervision pursuant to the FDCA's Investigational Device Exemption ("IDE") provisions and accompanying federal regulations. Id. S 360j(g); 21 C.F.R. pt. 812 (1998). Premarket approval will be granted only if the IDE investigation proves the device is sufficiently safe and effective.

Premarket approval is not required if the FDA determines the device is "substantially equivalent" to a legally marketed "predicate device" (that is, a device marketed before the Medical Device Amendments went into effect on May 28, 1976) in terms of its intended use, technological characteristics, safety, and effectiveness. 21 U.S.C. S 360e(b)(1)(B); 21 C.F.R. S 807.100(b). A determination of substantial equivalence is called "510(k) clearance" in reference to the applicable section of the original Act. If a device obtains 510(k) clearance, it may be introduced into

commerce without premarket approval. Alternatively, the FDA may issue an order declaring the device "not substantially equivalent" ("NSE"), which means that it cannot be marketed without premarket approval.

Thus, a person who wishes to market or sell a Class III device has two primary avenues of obtaining FDA approval: premarket approval, based on safety and efficacy data from non-clinical laboratory studies or IDE investigation; or 510(k) clearance, based on a showing that the device is substantially equivalent to one that was in commerce prior to May 28, 1976.2 If a Class III medical device is introduced into commerce without one of these two approvals, it is deemed "adulterated" and the person who introduced the device into commerce is criminally liable. See 21 U.S.C. S 331(a). Similarly, it is a crime to introduce into commerce a Class III device that is "misbranded," meaning that it does not bear adequate directions for its intended use. See id.

B. The Omni Complaints

According to the omni complaints, in 1984 AcroMed Corporation -- and shortly thereafter, Sofamor, Inc. and other sellers and manufacturers -- sought 510(k) clearance to market pedicle screw devices. The FDA denied 510(k) clearance but approved a series of IDE clinical trials between 1986 and 1993. Because the trials failed to generate sufficient safety data, the FDA denied premarket approval after each one. Allegedly, defendants then conspired to market their bone screw devices without the necessary FDA approvals.

The omni complaints allege two distinct conspiracies. The first is entitled, variously, the "Sofamor Conspiracy," the "ASFSI Conspiracy," or the "Danek Conspiracy," depending on the particular manufacturer being sued. It is alleged that the manufacturer entered into written agreements with spinal surgeons and other health care professionals in which the manufacturer agreed to provide them royalties

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2. Premarket approval is also not required upon a showing that the device in question was itself introduced into interstate commerce for commercial distribution before May 28, 1976. See 21 U.S.C. S 360e(b)(1)(A).

and stock options in exchange for their participation in "seminars" instructing physicians how to use the manufacturer's bone screw device. According to the complaints, although the seminars were conducted in the guise of educating fellow members of the medical profession, they were actually akin to "Tupperware parties" in that their true purpose was purely commercial. Plaintiffs also claim that the physicians who conducted the seminars did not disclose to attendees that the bone screw device had not received FDA premarket approval or 510(k) clearance for use in pedicle fixation surgery; that clinical trials had actually raised serious questions about its safety and efficacy; and that they, the physicians, had a direct financial stake in the sale of the device.

The complaints also describe an "Intercompany/ Association Conspiracy." Under this theory, plaintiffs claim that manufacturers of the bone screw devices paid various professional associations to sponsor and conduct seminars for orthopedic surgeons. The purpose of the seminars, again, was to promote the use of orthopedic bone screws in surgery. At the seminars, the Intercompany/Association conspirators allegedly concealed the same basic facts as in the first conspiracy: namely, that the FDA had not approved the use of the devices in pedicle fixation surgery; that studies had raised serious doubts about the safety of using the devices in such a procedure; and that the associations were being paid by the manufacturers to promote the devices. Later, the Intercompany/Association conspirators allegedly implemented a two-part scheme to avoid civil and criminal liability for these activities. First, they established a trade association known as the"Spinal Implant Manufacturers Group" to conduct a retrospective study (the "Cohort Study") of pedicle screwfixation. The results of the Cohort Study were reported to the FDA and published in Spine magazine in October 1994, allegedly to achieve reclassification of the bone screw device as a Class I or II device (obviating the need for premarket approval) and to serve as a defense in potential criminal or civil litigation.3 According to plaintiffs, the Cohort study was an

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3. In July 1998, the FDA reclassified most pedicle screw fixation devices as Class II devices. See Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems, 63 Fed. Reg. 40,025 (1998) (codified at 21 C.F.R. S 888.3070).

intentional fraud, relying on selective data and ignoring unfavorable results. Second, defendants Danek and AcroMed allegedly agreed to mislead the FDA into believing Zimmer4 had marketed a bone screw device for pedicle fixation surgery in the United States before 1976, in an attempt to obtain 510(K) clearance on the ground that the bone screw device was "substantially equivalent" to a predicate device.

C. District Court Proceedings

The District Court determined that although the two conspiracies outlined in the omni complaints differ in some respects, both essentially allege that defendants agreed to a scheme to market and sell bone screw devices without the necessary FDA approvals. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL No. 1014, Pretrial Order No. 861, mem. op. at 18 (E.D. Pa. Apr. 16, 1997) [hereinafter "PTO 861"] (noting that each conspiracy "had the same single objective: to promote and sell pedicle screw fixation devices in violation of the FDCA").5 The court held the claims failed to state a cause of action upon which relief could be granted, see id. at 27, because civil conspiracy and concert of action claims require an independent basis of tort liability, which the FDCA does not provide. In accordance with this ruling, the Judicial Panel for Multidistrict Litigation began to remand all actions containing a claim of conspiracy to violate the FDCA to transferor courts for summary judgment proceedings and trial. Numerous transferor courts have granted summary judgment for defendants on such claims, concluding that PTO 861 is the law of the case on that issue.

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4. Zimmer, Inc., a manufacturer of the pedicle screw device, initially was included as a defendant in the Intercompany/Association Conspiracy claim brought by PLC. PLC and Zimmer have since settled their respective claims against each other.

5. In addition, the omni complaints alleged that defendants conspired to commit fraud by actively concealing material facts at the seminars. After PTO 861 was entered, however, plaintiffs moved for voluntary dismissal with prejudice of their conspiracy to defraud claims, which the District Court granted. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL 1014, Memorandum and Pretrial Order No. 1543, op. at 6 (E.D. Pa. Aug. 13, 1998).

Also in PTO 861, the District Court denied defendants' motion to dismiss all claims premised upon their speech at the seminars. Defendants had argued that such speech is protected by the First Amendment and therefore cannot be the basis for imposing civil liability. The District Court rejected this argument, holding that the complaints allege false and misleading commercial speech, which does not qualify for First Amendment protection. The court also declined to dismiss plaintiffs' claims on the basis that they failed to plead reliance and causation adequately, and it denied the motions of several defendants -- the American Academy of Orthopedic Surgeons, the Scoliosis Research Society, and the North American Spine Society -- for attorney's fees and sanctions under 28 U.S.C. S 1927, Fed. R. Civ. P. 54(d), and the court's inherent powers.

Because there is complete diversity of all plaintiffs and defendants, the District Court had jurisdiction over each civil action under 28 U.S.C. S 1332. In In re Orthopedic Bone Screw Prods. Liability Litig., MDL 1014, Memorandum and Pretrial Order No. 1543, (E.D. Pa. Aug. 13, 1998), the District Court issued certification for final judgment under Fed. R. Civ. P. 54(b) on all of plaintiffs' conspiracy and concert of action allegations and complaints encompassed in MDL No. 1014. Therefore, we have jurisdiction under 28 U.S.C. S 1291.

II. ANALYSIS

A. Dismissal of the Conspiracy and Concert of Action Claims

We first address the dismissal of plaintiffs' conspiracy and concert of action claims. This ruling was premised upon the District Court's determination that civil conspiracy does not provide a right of action in the absence of an underlying tort; rather, it "renders each conspirator vicariously liable for the commission of an act that is independently actionable under state law and is in furtherance of the conspiracy." PTO 861, at 23. Therefore, the court held that plaintiffs' claims failed to state a cause of action upon which relief could be granted. See id. at 25. We exercise plenary review of this conclusion. See

Steamfitters Local Union No. 420 v. Phillip Morris, Inc., 171 F.3d 912, 919 (3d Cir. 1999).

No federal court of appeals has addressed the legal cognizability of a claim for conspiracy to violate the FDCA.6 It is well settled, however, that the FDCA creates no private right of action. See 21 U.S.C. S 337(a) (restricting FDCA enforcement to suits by the United States); In re Orthopedic Bone Screw Prods. Liability Litig., 159 F.3d 817, 824 (3d Cir. 1998) ("It is . . . well established that Congress has not created an express or implied private cause of action for violations of the FDCA or the MDA."); PDK Labs., Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding that plaintiff 's suit "represents an impermissible attempt to enforce the FDCA through a private right of action"); Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1139 (4th Cir. 1993) (same). The question, then, is whether violation of a federal statute imposing criminal penalties but establishing no private right of action may serve as a basis for civil recovery under state conspiracy law.

The established rule is that a cause of action for civil conspiracy requires a separate underlying tort as a predicate for liability. Thus, one cannot sue a group of defendants for conspiring to engage in conduct that would not be actionable against an individual defendant. Instead, " `actionable civil conspiracy must be based on an existing

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6. In addition to the District Court here, one other federal district court has addressed the issue:

> [A] conspiracy is only actionable if the acts in question, when committed by a single person, would also be actionable. Defendant . . . alleges that the acts complained of in count II are simply violations of the FDCA, the act which comprehensively regulates the marketing of prescription drugs in the United States, and that the FDCA does not create a private right of action for enforcement by private individuals such as plaintiffs.
>
> To the extent that plaintiffs were attempting to assert a cause of action under the FDCA, defendant would be correct.

Hawkins v. Upjohn Co., 890 F. Supp. 609, 611 (E.D. Tex. 1994) (applying Texas law). The Hawkins court found that plaintiffs' complaint, though poorly worded, actually alleged a conspiracy to commit fraud and therefore was independently actionable under state law. See id.

independent wrong or tort that would constitute a valid cause of action if committed by one actor.' " Posner v. Essex Ins. Co., 178 F.3d 1209, 1218 (11th Cir. 1999) (quoting Williams Elec. Co. v. Honeywell, Inc., 772 F. Supp. 1225, 1239 (N.D. Fla. 1991)) (applying Florida law); accord Applied Equip. Corp. v. Litton Saudi Arabia Ltd., 869 P.2d 454, 457 (Cal. 1994) ("Standing alone, a conspiracy does no harm and engenders no tort liability. It must be activated by the commission of an actual tort."); Stoldt v. City of Toronto, 678 P.2d 153, 161 (Kan. 1984) ("Conspiracy is not actionable without commission of some wrong giving rise to a cause of action independent of the conspiracy."); Alleco, Inc. v. Harry & Jeanette Weinberg Found., Inc., 665 A.2d 1038, 1045 (Md. 1995) ("No action in tort lies for conspiracy to do something unless the acts actually done, if done by one person, would constitute a tort.") (citation omitted); Alexander & Alexander of N.Y., Inc. v. Fritzen, 503 N.E.2d 102, 102-03 (N.Y. 1986) ("[A] mere conspiracy to commit a tort is never of itself a cause of action. Allegations of conspiracy are permitted only to connect the actions of separate defendants with an otherwise actionable tort.") (citations omitted).

Because this multidistrict litigation implicates the state law of many different jurisdictions, we have reviewed the law of every applicable jurisdiction on this point. Having done so, we are unaware of any jurisdiction that recognizes civil conspiracy as a cause of action requiring no separate tortious conduct. To the contrary, the law uniformly requires that conspiracy claims be predicated upon an underlying tort that would be independently actionable against a single defendant.7 Because plaintiffs here could

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7. See, e.g., Hanten v. School Dist. of Riverview Gardens, 183 F.3d 799, 809 (8th Cir. 1999) ("[A] claim of civil conspiracy `does not set forth an independent cause of action but rather is sustainable only after an underlying tort claim has been established . . . .' " (quoting K & S Partnership v. Continental Bank, N.A., 952 F.2d 971, 980 (8th Cir. 1991)) (applying Missouri law); Gaming Corp. of America v. Dorsey & Whitney, 88 F.3d 536, 551 (8th Cir. 1996) ("[C]onspiracy is based on the commission of an underlying tort.") (applying Minnesota law); Halberstam v. Welch, 705 F.2d 472, 479 (D.C. Cir.1983) ("Since liability for civil conspiracy depends on performance of some underlying tortious act, the

not sue an individual defendant for an alleged violation of the FDCA, it follows that they cannot invoke the mantle of conspiracy to pursue the same cause of action against a group of defendants. A claim of civil conspiracy cannot rest solely upon the violation of a federal statute for which there is no corresponding private right of action.

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conspiracy is not independently actionable; rather, it is a means for establishing vicarious liability for the underlying tort.") (applying District of Columbia law); Cunningham v. PFL Life Ins. Co., 42 F. Supp.2d 872, 884 (N.D. Iowa 1999) ("[C]onspiracy does not state an independent cause of action, but rather requires the commission of an underlying wrong for which liability may be extended to an additional defendant by virtue of a conspiracy.") (applying Iowa law); University Sys. of N.H. v. United States Gypsum Co., 756 F. Supp. 640, 652 (D.N.H. 1991) ("For a civil conspiracy to exist, there must be an underlying tort which the alleged conspirators agreed to commit. Conspiracy, then, serves as a device through which vicarious liability for the underlying tort may be imposed on all who commonly plan, take part in, further by cooperation, lend aid to, or encourage the wrongdoers' acts.") (applying New Hampshire law); In re North Dakota Personal Injury Asbestos Litig. No. 1, 737 F. Supp. 1087, 1095 (D.N.D. 1990) ("One of the parties must commit some act in pursuance of the agreement that is itself a tort for civil conspiracy to exist.") (applying North Dakota law); McGlasson v. Barger, 431 P.2d 778, 780 (Colo. 1967) ("[U]nless a civil action in damages would lie against one of the conspirators, if the act was done by him alone, it will not lie against many acting in concert.") (quoting Pullen v. Headberg, 127 P. 954, 955 (Colo. 1912)); O'Neal v. Home Town Bank of Villa Rica, 514 S.E.2d 669, 675 (Ga. Ct. App. 1999) ("Absent the underlying tort, there can be no liability for civil conspiracy."); Cohen v. Bowdoin, 288 A.2d 106 (Me. 1972) (" `[C]onspiracy' fails as the basis for the imposition of civil liability absent the actual commission of some independently recognized tort; and when such separate tort has been committed, it is that tort, and not the fact of combination, which is the foundation of the civil liability."); Admiral Ins. Co. v. Columbia Casualty Ins. Co., 486 N.W.2d 351, 359 (Mich. Ct. App. 1992) ("Because [plaintiff] has failed to state any tortious action, its conspiracy action must also fail."); Middlesex Concrete Prods. & Excavating Corp. v. Carteret Indus. Ass'n, 181 A.2d 774, 779 (N.J. 1962) ("[A] conspiracy cannot be made the subject of a civil action unless something has been done which, absent the conspiracy, would give a right of action."); Nix v. Temple Univ., 596 A.2d 1132, 1137 (Pa. Super. Ct. 1991) (" `Absent a civil cause of action for a particular act, there can be no cause of action for civil conspiracy.' ") (quoting Pelagatti v. Cohen, 536 A.2d 1337, 1342 (Pa. Super. Ct. 1987)).

Plaintiffs contend the doctrine of per se liability (often called "negligence per se") establishes that violations of federal statutes can be the basis of common law tort liability.8 They cite the following passage from the Restatement of Torts:

> Even where a legislative enactment contains no express provision that its violation shall result in tort liability, and no implication to that effect, the court may, and in certain types of cases customarily will, adopt the requirements of the enactment as the standard of conduct necessary to avoid liability for negligence. The same is true of municipal ordinances and administrative regulations.

Restatement (Second) of Torts S 285 cmt. c (1977). In addition, plaintiffs rely on numerous cases in which courts, in determining common law tort liability, have considered whether the defendant's conduct violated federal law. See, e.g., Stanton ex rel. Brooks v. Astra Pharmaceutical Prods., Inc., 718 F.2d 553, 565 (3d Cir. 1983) (holding that failure to comply with FDA regulations constituted negligence per se under Pennsylvania law); Orthopedic Equip. Co. v. Eutsler, 276 F.2d 455, 461 (4th Cir. 1960) ("[W]e think that a violation of the Federal Food, Drug, and Cosmetic Act is negligence per se in Virginia . . . .").

In these and many other cases, courts have found that violations of a federal statute or regulations constituted negligence per se under state law. But the cases make clear the 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. See, e.g. , Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc., 720 F. Supp. 714, 716 (N.D. Ill. 1989) ("Grove Fresh relies on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FDCA or its accompanying

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8. The phrase "per se liability" is used primarily in the antitrust context,
in which horizontal price-fixing arrangements are held to violate the Sherman Act regardless of their reasonableness. See FTC v. Superior Ct. Trial Lawyers Ass'n, 493 U.S. 411, 435 (1990); United States v. Socony-Vacuum Oil Co., 310 U.S. 150, 225-26 n.59 (1940).

regulations in that fashion."). Liability per se enables plaintiffs to establish as a matter of law that the defendant's conduct constituted a breach of duty in a negligence action, so that only causation and damages need be proved. See In re TMI, 67 F.3d 1103, 1118 (3d Cir. 1995) ("[W]here defendants violated the relevant statute or regulation, courts have held as a matter of law that plaintiffs have satisfied the first two elements of their cause of action: the duty and breach of duty."); Stanton, 718 F.2d at 564 n.22 (noting, in the FDCA context, that "Pennsylvania law views a statutory violation as conclusive evidence of negligence, in the absence of an excuse for that violation . . . . We emphasize, however, that the nomenclature `negligence per se' does not mean that a plaintiff seeking to recover under that doctrine may dispense with establishing proximate cause."). See generally 1 J.D. Lee & Barry A. Lindahl, Modern Tort Law: Liability & Litigation S 3.33, at 102 (1980) ("Under the per se rule, the violation of an applicable statute is conclusive proof of negligence, leaving only the question of causation to be determined.") (citation omitted).

The theory of per se liability advanced by the plaintiffs here is quite different. Plaintiffs do not invoke the statutory violations to prove defendants' liability for a separate underlying tort, but instead contend the violations themselves form a cause of action. This interpretation of per se liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government. See 21 U.S.C.A.S 337(a) (West Supp. 1999).9 Plaintiffs' theory would undermine section 337(a) by establishing a private, state-law cause of action for violations of the FDCA, so long as those actions are brought against more than one defendant. We do not believe the concept of per se liability supports such a result.

Nor are we persuaded by plaintiffs' argument that

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9. The statute also permits state governments to bring suit in certain limited circumstances, but only upon approval by the Secretary of Health and Human Services. See id. S 337(b).

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) and In re Orthopedic Bone Screw Prods. Liability Litig., 159 F.3d 817 (3d Cir. 1998) (Bone Screw I) dictate reversal of the District Court. In Medtronic, the Supreme Court held the Medical Device Amendments ("MDA") do not preempt state common law negligence claims against manufacturers of defective medical devices. The Court observed that interpretation of a preemption provision does not occur in a "contextual vacuum," 518 U.S. at 485, but must be informed by two additional considerations: (1) the presumption against preemption unless clearly and manifestly indicated by Congress; and (2) the principle that "the purpose of Congress is the ultimate touchstone" in determining the extent of preemption. Id. Finding that Congress did not intend the MDA to foreclose state-law negligence lawsuits, the Court allowed plaintiffs' claims to proceed.

In Bone Screw I, we interpreted Medtronic to mean that common law claims of fraudulent misrepresentation are not preempted by the MDA, even if the conduct underlying those claims violated the FDCA. See 159 F.3d at 825 (holding that Medtronic "overrules everything in [Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995)] that would prevent a plaintiff from pursuing a cause of action for fraudulent misrepresentation based on common law principles"). Notably, we reserved judgment on whether the plaintiffs had stated a claim under state law upon which relief could be granted. See id. at 829.

Although plaintiffs concede the District Court here"did not explicitly invoke preemption principles," they claim that "its decision was plainly based on a construction of legislative intent." (Appellants' Br. at 31 n.21.) They argue Medtronic and Bone Screw I stand for the proposition that Congress did not intend to foreclose state law remedies based on violations of federal medical device law, and the District Court therefore erred in dismissing claims based on conspiracy to violate the FDCA. Medtronic and Bone Screw I are crucially different from this case, however. Both raised the issue whether state common law claims were preempted by the FDCA and Medical Device Amendments. After Medtronic, it is clear that such claims survive, and Bone Screw I so held. Consequently, state law claims such

as negligence, breach of implied warranty, and fraudulent misrepresentation are viable, even to the extent they seek recovery for conduct that may also have violated the FDCA. But neither Medtronic nor Bone Screw I purports to allow private plaintiffs to sue directly for violations of a federal statute in the absence of a separate underlying cause of action. They merely hold that such causes of action as previously existed under state law were not preempted by the FDCA and Medical Device Amendments.

We will therefore uphold the District Court's dismissal of the conspiracy and concert of action claims alleging a conspiracy to violate the FDCA.

B. First Amendment Protection

The District Court also denied defendants' motions to dismiss the conspiracy and concert of action claims on First Amendment grounds. These claims are based largely upon the allegation that defendants conspired to commit fraud by actively concealing material facts at the seminars. Allegedly, speakers at the seminars failed to disclose that they had a direct financial stake in the use of the devices, that the devices had not yet been approved by the FDA, and that testing had raised concerns about their safety. According to defendants, imposition of liability for their speech at the seminars would violate their First Amendment rights.

The First Amendment's prohibition on abridging the freedom of speech applies to the states through the Due Process Clause of the Fourteenth Amendment. See Duncan v. Louisiana, 391 U.S. 145, 148 (1968). Imposition of civil liability, such as the award of money damages, is treated no less stringently than direct regulation on speech: "The fear of damage awards . . . may be markedly more inhibiting than the fear of prosecution under a criminal statute." New York Times Co. v. Sullivan, 376 U.S. 254, 279-280 (1964); see also Cohen v. Cowles Media Co., 501 U.S. 663, 676 n.4 (1991) (Blackmun, J., dissenting) ("[W]e have long held that the imposition of civil liability based on protected expression constitutes `punishment' of speech for First Amendment purposes.").

The Supreme Court has long recognized a " `common-sense distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech.' " Bolger v. Youngs Drug Prods. Corp., 463 U.S. 60, 65 (1983) (quoting Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 455-56 (1978)). Commercial speech is accorded a lesser degree of First Amendment protection than other kinds of speech. For instance, the government may enact content-based restrictions on false or misleading commercial messages. See, e.g., Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557, 562-63 (1980) ("[T]here can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it . . . ."); Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 771-72 n.24 (1976). In addition, "the First Amendment does not protect commercial speech about unlawful activities." 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 497 n.7 (1996); accord Pittsburgh Press Co. v. Pittsburgh Comm'n on Human Relations, 413 U.S. 376 (1973) (same). Thus, an issue of primary significance here is whether defendants' speech at the seminars was commercial speech, and if so whether it was false and misleading, or concerned unlawful activities.

Commercial speech is "broadly defined as expression related to the economic interests of the speaker and its audience, generally in the form of a commercial advertisement for the sale of goods and services." U.S. Healthcare, Inc. v. Blue Cross of Greater Phila., 898 F.2d 914, 933 (3d. Cir. 1990) (citing Bolger, 463 U.S. at 66-67; Central Hudson, 447 U.S. at 561). In deciding whether speech is commercial, we consider the following factors: "(1) is the speech an advertisement; (2) does the speech refer to a specific product or service; and (3) does the speaker have an economic motivation for the speech. An affirmative answer to all three questions provides `strong support' for the conclusion that the speech is commercial." U.S. Healthcare, 898 F.2d at 933 (citation omitted). At the same time, we must be mindful of the "difficulty of drawing bright

lines that will clearly cabin commercial speech in a distinct category." City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 419 (1993). Often, speech consists of"complex mixtures of commercial and noncommercial elements." Bolger, 463 U.S. at 81 (Stevens, J., concurring). Where the commercial and noncommercial elements of speech are "inextricably intertwined," the court must apply the "test for fully protected expression." Riley v. National Fed'n of the Blind of N.C., Inc., 487 U.S. 781, 796 (1988).

At this stage in the proceedings, it is difficult to determine precisely what portion of the seminars, if any, consisted of a sales pitch to the attendees and what portion was non-commercial medical discussion. The defendants characterize the seminars as teaching events aimed at promoting "continuing medical education" and accordingly contend that the speech is entitled to the highest level of First Amendment protection. Plaintiffs, on the other hand, liken the seminars to medical "Tupperware parties" at which defendants' sole objective was to generate sales of their products.

We believe there is a sufficient factual dispute about the nature of the seminars to preclude granting defendants' motion to dismiss on First Amendment grounds. The amended omni complaints allege, inter alia, that the seminars were organized by sales representatives employed by the participating manufacturers; that these representatives invited spinal surgeons to attend and later followed up with phone calls in an effort to generate sales; that employees of the manufacturers staffed sales booths and distributed videotapes, product catalogues, and other literature at the seminars; and that the speakers at the seminars were doctors and scientists who had entered into lucrative royalty agreements giving them a direct financial stake in the sales of bone screw devices. If true, these allegations would provide strong support for characterizing the seminars as commercial speech.

Defendants argue that even if their speech at the seminars was commercial in nature (which they deny), it constitutes "truthful, nonmisleading speech about a lawful product" and therefore is protected. 44 Liquormart, 517 U.S. at 504; see also Greater New Orleans Broadcasting

Ass'n v. United States, ___ U.S. ___, 119 S. Ct. 1923 (1999) (holding that a state may not ban nonmisleading advertisements of legal gambling). Plaintiffs respond that the speech at the seminars was highly misleading and deceptive. The amended omni complaints allege defendants knowingly withheld material facts at the seminars and falsely represented to the physicians in attendance that the devices were safe and effective for use in pedicle screw fixation surgery.

Clearly, there is a considerable and unresolved factual dispute regarding key elements of the speech at issue. In order to dismiss the claims on First Amendment grounds, we would have to determine either that defendants' speech at the seminars was noncommercial in nature, or that it was truthful or nonmisleading commercial speech concerning a lawful product. In view of our obligation to accept as true the factual allegations of the nonmoving party, we are unwilling to do either at this point. Whether the allegations in the omni complaints are true remains to be determined. But dismissal is warranted only if"it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957). We do not believe this standard has been met; therefore, we will uphold the District Court's denial of defendants' motions to dismiss. Of course, defendants are free to raise their First Amendment argument in the transferor courts after the factual record is more fully developed.

C. Plaintiffs' Theory of Damages

Defendants North American Spine Society, American Academy of Orthopedic Surgeons, and Scoliosis Research Society (collectively "the medical associations") submitted a joint brief in which they argue that plaintiffs' claims should be dismissed for failure to plead causation adequately. In particular, they contend plaintiffs have not properly alleged a causal connection between the seminars and the decisions of individual physicians to use the bone screw devices in surgery. They argue that in order to allege proximate cause adequately, each plaintiff must demonstrate that his or her surgeon relied upon defendants' statements at the seminars in making the

decision to use the devices for pedicle fixation surgery, and that this decision in turn caused the injury upon which relief is sought. Plaintiffs' theory of causation, they claim, eschews proof of individualized reliance in favor of an unjustified extension of the "fraud-on-the-market-theory" of liability developed in securities law. See Basic Inc. v. Levinson, 485 U.S. 224 (1988).10 For their part, plaintiffs claim their market theory of causation extended only to the fraud aspect of their conspiracy claims, which they have now discontinued, and they also dispute that they are required to prove individualized causation. They argue it is sufficient to show that the seminars contributed to the creation of an unlawful black market for pedicle screw fixation devices, in the absence of which plaintiffs would not have been injured.

We believe these issues are best resolved under a plenary standard in the transferor courts, rather than on the appeal of a motion to dismiss. Whether plaintiffs have adequately alleged causation depends greatly on the particulars of the state law governing each claim. This fact alone counsels against dismissing all claims on this basis. See Bone Screw I, 159 F.3d at 826 ("While we are not in a position to canvass all the potentially applicable law [of the transferor jurisdictions], what we know about tort law generally makes us unwilling to say that all of the plaintiffs' claims will fail for want of the kind of a causation that will give rise to liability."). There is no uniform rule governing the level of specificity with which proximate cause must be proven in the various jurisdictions involved in this litigation. Moreover, many jurisdictions have adopted a "substantial factor" test that does not lend itself to facile predictions about which theories of damages will suffice. See, e.g.,

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10. As noted, the medical associations previouslyfiled a petition for a writ of mandamus invalidating plaintiffs' fraud-on-the-market theory as a matter of law. In denying the writ, we observed that plaintiffs had represented to the Court that they planned to assemble evidence of individualized reliance through the discovery process, and that they would rely on a fraud-on-the-market theory only in those cases where reliance could not be proven. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL No. 1014, mem. op. at 8-9 (3d Cir. Nov. 10, 1997) (unpublished opinion).

Parks v. AlliedSignal, Inc., 113 F.3d 1327, 1332 (3d Cir. 1997) ("When addressing causation, Pennsylvania has rejected the `but for' test and adopted the `substantial factor' test . . . ."); Dawson v. Bunker Hill Plaza Assocs., 673 A.2d 847, 853 (N.J. Super Ct. App. Div. 1996) ("Liability attaches not only to the dominating cause but also to any cause which constitutes at any event a substantial factor in bringing about the injury.") (internal quotation marks omitted); Abrahams v. Young & Rubicam, Inc., 692 A.2d 709, 712 (Conn. 1997) ("[I]t is axiomatic that proximate cause is an actual cause that is a substantial factor in the resulting harm.") (internal quotation marks omitted); State v. Hubka, 480 N.W.2d 867, 869 (Iowa 1992) ("The general rule is that a defendant's conduct is the proximate cause of injury or death to another if (1) her conduct is a `substantial factor' in bringing about the harm and (2) there is no other rule of law relieving the defendant of liability because of the manner in which her conduct resulted in the harm.").

We believe the transferor courts are in the best position to determine whether the applicable state law permits plaintiffs to recover damages without proving individual reliance. Accordingly, we decline to dismiss plaintiffs' claims on this basis.

D. Costs and Sanctions

The medical associations filed cross-motions for costs and sanctions under 28 U.S.C. S 1927, Fed. R. Civ. P. 54(d), and the court's inherent judicial powers. In support, they argued that plaintiffs acted in bad faith and needlessly multiplied the litigation by bringing the conspiracy to defraud claim despite having no means of proving individualized reliance. The District Court denied these motions, finding that defendants had not demonstrated "willful bad faith" on the part of the plaintiffs. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL 1014, Memorandum and Pretrial Order No. 1543, op. at 8-9 (E.D. Pa. Aug. 13, 1998) ("PTO 1543").

We review the denial of attorney's fees and costs for abuse of discretion. See Gioioso v. Stuebben, 979 F.2d 956, 959 (3d Cir. 1992). Such an abuse occurs when the court's

decision " `rests upon a clearly erroneousfinding of fact, an errant conclusion of law or an improper application of law to fact.' " Morgan v. Perry, 142 F.3d 670, 682 (3d Cir. 1998) (quoting Hanover Potato Prods., Inc. v. Shalala, 989 F.2d 123, 127 (3d Cir. 1993)).

Imposition of attorney's fees and costs under section 1927 is reserved for behavior " `of an egregious nature, stamped by bad faith that is violative of recognized standards in the conduct of litigation.' " Baker Indus., Inc. v. Cerberus Ltd., 764 F.2d 204, 208 (3d Cir. 1985) (quoting Colucci v. New York Times Co., 533 F. Supp. 1011, 1014 (S.D.N.Y. 1982)). Thus, fees may not be awarded unless there is "a finding of willful bad faith on the part of the offending attorney." Baker, 764 F.2d at 209. An award of fees under the court's inherent powers requires a similar finding. See Chambers v. NASCO, Inc., 501 U.S. 32, 45-46 (1991) (court may assess fees under inherent powers when a party has acted " `in bad faith, vexatiously, wantonly, or for oppressive reasons' ") (quoting Alyeska Pipeline Serv. Co. v. Wilderness Soc'y, 421 U.S. 240, 258-59 (1975)).

We agree with the District Court that no finding of bad faith was warranted here. As noted, several of plaintiffs' claims were premised upon a theory of damages that defendants characterize as a "fraud-on-the-market" theory. They contend this theory is so lacking in merit that it should never have been advanced, and that plaintiffs' reliance on it needlessly multiplied the proceedings and incurred wasteful expense. Regardless of whether plaintiffs' theory of causation is ultimately accepted by transferor courts, we cannot say the plaintiffs acted in bad faith in raising it. The Supreme Court has specifically instructed that courts should be wary of chilling legitimate advocacy by imposing fees too hastily: "[I]t is important that a district court resist the understandable temptation to engage in post hoc reasoning by concluding that, because a plaintiff did not prevail, his action must have been unreasonable or without foundation. This kind of hindsight logic could discourage all but the most airtight claims . . . ." Christiansburg Garment Co. v. EEOC, 434 U.S. 412, 421-22 (1978); accord Baker, 764 F.2d at 208 (bad-faith requirement is "necessary to avoid chilling an attorney's

legitimate obligation to represent his client zealously"). Restraint is particularly important where, as here, the case presents complex factual and legal issues. See In re Kunstler, 914 F.2d 505, 523 (4th Cir. 1990) (sanctioning powers should be exercised with restraint to avoid chilling "novel factual or legal theories"); Barney v. Holzer Clinic, Ltd., 110 F.3d 1207, 1213 (6th Cir. 1997) (holding that an award of fees under section 1927 was not warranted where the "central issue was one of first impression"); United States v. Alexander, 981 F.2d 250, 253 (5th Cir. 1993) (vacating an assessment of sanctions because of"the absence of authority in this Circuit combined with the complexity of the issue").

Additionally, we believe the history of this litigation undermines any claim that plaintiffs acted in "actual" or "willful" bad faith, as required for an award of fees under section 1927. Baker, 764 F.2d at 208-09. Early in consolidated pretrial proceedings, the District Court raised the issue whether the original omni complaints satisfied the requirements of Fed. R. Civ. P. 11, which provides for the imposition of sanctions upon attorneys who submit complaints lacking a sufficient legal and factual basis. In response, plaintiffs submitted a 750-page Particularized Statement of Facts accompanied by numerous exhibits, explicating in more detail their claims for relief. The District Court then determined that the complaints did not violate Rule 11 but still were not pleaded with sufficient particularity, and granted plaintiffs' leave to replead. See In re Orthopedic Bone Screw Prods. Liability Litig., MDL No. 1014, Pretrial Order No. 477 (E.D. Pa. Aug. 22, 1996). In response, the PLC developed amended "form" complaints that were expressly authorized by the District Court before being transmitted to the various plaintiffs' attorneys, who modified them as necessary to suit the particulars of their clients' cases. Although this history is not dispositive, we believe it strongly supports the District Court's determination that plaintiffs' counsel did not act in bad faith; to the contrary, they responded to the court's request to cure potential defects in the complaints before proceeding further.

Finally, we also note that defendants' principal argument for imposing costs -- namely, that plaintiffs cannot prove

that defendants' conduct at the seminars was the proximate cause of their injuries -- is largely a question of fact which remains unresolved. Plaintiffs still contend that individual reliance can be proven in many cases, and we will not second-guess this representation on the appeal of a motion for attorney's fees. As the District Court aptly observed, "If this court imposed sanctions for prosecuting these claims the court would implicitly engage in fact finding that is typically reserved for a jury." PTO 1543, at 10. We therefore see no abuse of discretion in the court's denial of the medical associations' motion for attorney's fees and costs.

III. CONCLUSION

We hold that the District Court properly dismissed plaintiffs' conspiracy and concert of action claims based on violations of the FDCA, because these claims failed to state a claim upon which relief can be granted. We alsofind no error in the District Court's denial of defendants' motions to dismiss. At this stage in the proceedings, it would be premature to conclude that even if plaintiffs' allegations are true, defendants' speech at the seminars could not possibly form the basis of civil liability under the First Amendment. Similarly, we do not believe plaintiffs' theory of damages is so devoid of legal support in all jurisdictions that it can be dismissed outright in consolidated pretrial proceedings. Defendants, of course, are free to challenge its legal viability in the transferor courts. We will also uphold the denial of the medical associations' motions for attorney's fees and costs.

Accordingly, we will affirm the judgment of the District Court.

A True Copy:
Teste:

Clerk of the United States Court of Appeals
for the Third Circuit