

American Health Lawyers Association 2003 Year in Review

By Elizabeth Christian, Esq.

1. FOOD AND DRUG LAW

U.S. Court In Pennsylvania Finds Medical Device Amendments To FDCA Pre-Empted Common Law Tort Claims Against Device Manufacturer That Obtained FDA Premarket Approval

Thermo Cardiosystems, Inc. (TCI), which manufactures heart pumps, was sued for negligence, strict liability, and breach of warranty. The plaintiff alleged that the heart pump was defective because of a design flaw. TCI moved for summary judgment, arguing that the common law claims were preempted by Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act.

The District Court for the Middle District of Pennsylvania granted TCI's motion, finding that the MDA preempted the common law claims because the heart pump had undergone the FDA's pre-market approval (PMA) process. The MDA, in 21 U.S.C. § 360k(a), pre-empts certain state requirements that are "different from or in addition to, any requirement applicable under this chapter to the device" and "which relate to the safety or effectiveness of the device." The court noted two guidelines for determining the MDA preemption issue: (1) whether the FDA has established specific counterpart requirements applicable to the particular device; and (2) whether the state claim is different from, or in addition to, specific FDA requirements. The court concluded that the PMA process is a specific federal requirement applicable to the heart pump and that the FDA, through the rigorous PMA process, determined that the heart pump was safe and effective. The court also concluded that the common law claims imposed requirements that were different from or in addition to the PMA process. Accordingly, the court granted TCI's motion for summary judgment.

Horn v. Thermo Cardiosystems, Inc., No.4:CV-00-779,2002 WL 31487756 (M.D. Pa. Nov. 7, 2002)

This case is important because it limits the availability of state common law claims in litigation involving a medical device which has undergone pre-market approval.

2. FOOD AND DRUG LAW

Ninth Circuit Upholds Injunction Barring Government From Revoking Physicians' DEA Registration Based On Recommendation For Medical Use of Marijuana

The California Compassionate Use Act of 1996 allows medical use of marijuana where use "is deemed appropriate and has been recommended by a physician who has determined that the person's health would benefit from the use of marijuana." In response, the Office of National Drug Control Policy stated unequivocally that the DEA would seek to revoke the registrations of physicians who recommended or prescribed Schedule I controlled substances, including marijuana. A class of physicians, patients, and others brought suit in federal court, seeking to enjoin the government from enforcing any federal law that would punish physicians for discussing the medical use of marijuana within the context of a bona fide physician-patient relationship. The court permanently enjoined the government from revoking a physician's DEA registration based on the recommendation for the use of medical marijuana and from initiating an

investigation solely on that ground. Defendants appealed. The Ninth Circuit affirmed, agreeing that “the government’s professed enforcement policy threatens to interfere with expression protected by the First Amendment.” Although the court acknowledged that a physician who recommends the medical use of marijuana may anticipate that the patient will use the recommendation to obtain marijuana in violation of federal law, the court explained that such anticipation “does not translate into aiding and abetting, or conspiracy.” The appeals court found that the government’s enforcement policy threatened First Amendment interests of doctors and patients because the policy sought to punish physicians based on the content of communications within a physician-patient relationship.

Conant v. Walters, 309 F.3d 629 (9th Cir. Oct. 29, 2002).

This case illustrates the tension between governmental enforcement of controlled substance laws and medical marijuana usage legislation.

1. FRAUD AND ABUSE

U.S. Court In Illinois Holds Government’s Allegations Under False Claims Act Satisfied Pleading Requirements Of FRCP 9(b)

The United States filed a complaint against various corporate defendants, alleging violations of the False Claims Act as well as other claims. Defendants moved to dismiss the complaint, arguing that the complaint did not satisfy the pleading requirements of Fed. R. Civ. Proc. 9(b) because it did not identify “the specific persons who made the fraudulent misrepresentations; the time, place, and content of the misrepresentations; and the method by which the representations were communicated to the government.” The U.S. District Court for the Northern District of Illinois denied the motion to dismiss. The court found that the government made specific allegations of fraud by defendants’ employees. The court also found that the government alleged the substance of the misrepresentations, which was sufficient to state a general outline of the alleged fraud. The court rejected defendants’ argument that the complaint did not adequately inform them of their role in the alleged fraud, holding that “in cases of corporate fraud where the false or misleading information is conveyed in prospectuses, registration statements, annual reports, press releases, or other group-published information, it is reasonable to presume that these are collective actions of the officers.”

United States v. Rogan, No. 02 C3310, 2002 WL 31433390 (N.D. Ill. Oct. 31, 2002)

This case is significant because it sets forth standards for pleading causes of action under the False Claims Act.

GIORDANO, HALLERAN & CIESLA

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW

125 Half Mile Road, Red Bank, NJ 07701 • (732) 741-3900

441 East State St., Trenton, NJ 08608 • (609) 695-3900

www.ghclaw.com

1. CRIMINAL LAW

CFO's Habeas Motion Recommended For Denial Based On Failure To Raise Constitutional Challenges To Admission Of Victim Testimony And Restitution Order

The CFO of a Medicaid-reimbursed provider was convicted of healthcare fraud for writing unauthorized payroll checks to himself. He was sentenced to twenty-seven months of imprisonment and was ordered to pay \$392,922 in restitution. He moved for habeas relief under 28 U.S.C. § 2255, arguing that the trial judge had erred in allowing victim testimony at the sentencing hearing and challenging the \$392, 992 restitution amount.

A magistrate for the U.S. District Court for the District of Maine recommended denial of the motion. The magistrate emphasized that sentence challenges brought pursuant to § 2255 must assert “that the sentence was imposed in violation of the Constitution or laws of the United States, or that the court was without jurisdiction to impose such sentence, or that the sentence was in excess of the maximum authorized by law, or is otherwise subject to collateral attack.” The magistrate concluded that the defendant’s failure to raise the issue before or at sentencing, along with his failure to not take a direct appeal, would warrant denial of the claim outright due to the procedural default.

United States v. Morin-Smith, Nos, CR. 01-47-B-S, Civ. 02-122-B-S, 2002 WL 31414110 (Mag. D. Me. Oct. 24, 2002)

This case illustrates the importance of raising constitutional challenges to the admission of victim testimony prior to sentencing and preserving such challenges through the filing of a direct appeal.

GIORDANO, HALLERAN & CIESLA

A PROFESSIONAL CORPORATION

ATTORNEYS AT LAW

125 Half Mile Road, Red Bank, NJ 07701 • (732) 741-3900

441 East State St., Trenton, NJ 08608 • (609) 695-3900

www.ghclaw.com