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## Medical Device Amendments Act Does Not Preempt All State Law Claims

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relationship with the excluding PPO. In this case, the court found that DHJ was not injured in the aggregate by its exclusion from SMA since DHJ soon affiliated with a larger PPO after leaving SMA. Furthermore, the court found that consumers were not injured because the availability of health care providers to consumers in the neighborhood was not reduced.

### ***Court Found Each § 1 Allegation Lacked Genuine Issues of Material Fact***

Next, DHJ claimed that prices for hospital services in the market increased because of Defendants' antitrust activities. DHJ's expert economist testified that East Jefferson's prices were higher than DHJ's which indicated an antitrust violation. The court, however, reasoned that DHJ's expert did not adequately define East Jefferson's market power in a meaningful geographic market. Furthermore, the court reasoned that price increases may be indicative of positive aspects of East Jefferson, such as better quality services; therefore, DHJ failed to show that the higher prices were a direct result of a lack of competition.

DHJ's second § 1 claim was also rejected by the court. DHJ alleged

that its exclusion from SMA reduced consumer choice for consumers who used SMA. The court, however, found that the number of hospitals available to patients in general, and users of SMA in particular, had not been reduced. The availability of the hospitals to various customers might have changed, but any reduction in hospital availability was insufficient to decrease market competition. Furthermore, any price increase that DHJ was forced to incur due to its realignment would not eliminate DHJ as a potential provider to most of its former SMA patients.

Finally, DHJ's last § 1 complaint was that it was substantially weakened as a competitor because its exclusion from SMA caused it to lose profits and to lose its membership in a premiere PPO. The court held that, while injury to a competitor may be evidence of an injury to market competition, the specific injury to DHJ was insufficient to create a factual issue regarding damage to competition. In fact, DHJ's own injury was insignificant enough that its long term viability as a market competitor was unaffected as it maintained membership in numerous managed care plans. Thus, DHJ showed that it could not compete without an affiliation with SMA.

### ***Court Rejected the § 2 Claim for Failure to Properly Define a Market***

Next, DHJ claimed damage resulting from a violation of § 2 of the Sherman Act, but this claim also failed because it did not present a genuine issue of material fact. Section 2 of the Sherman Act prevents parties from engaging in conspiracies to monopolize relevant markets. To maintain a § 2 claim, DHJ had to properly define a market that East Jefferson allegedly was trying to monopolize. The appellate court found that DHJ defined its geographic market too narrowly because there was too much PPO patient migration to and from the market DHJ defined. Thus, the court concluded that DHJ's § 2 claim should fail.

In conclusion, although DHJ was able to establish standing to bring an antitrust suit, it failed to establish that there were grounds for such a suit. Therefore, the Fifth Circuit affirmed the lower court's decision to grant Defendants' motion for summary judgment because Plaintiff could not present a genuine issue of material fact to support either its § 1 or § 2 claims.

**CLR**

## ***Medical Device Amendments Act Does Not Preempt All State Law Claims***

*by Brad Kenneth Lindow*

In *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997), the United States Court of Appeals for the Seventh Circuit, on remand from the Supreme Court of the United States, reconsidered its prior holding in *Mitchell v. Collagen Corp.*, 67

F.3d 1268 (7th Cir. 1995), that the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c-k, to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-95, preempted some of Plaintiffs' state law claims. The Supreme Court

remanded the Mitchells' case and instructed the Seventh Circuit to reconsider its prior ruling in light of the ruling in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Upon doing so, the Seventh Circuit reaffirmed the judgment of the district court

granting Collagen Corporation's ("Collagen") motion for summary judgment against Plaintiffs Barbara and Gregory Mitchell ("Mitchells"). The claims that were not preempted by the MDA were dismissed because the Mitchells failed to establish sufficient facts to warrant a trial.

### ***Effects of Zyderm Injections Led Mitchells to Sue***

Barbara Mitchell experienced serious medical complications after receiving several injections of Zyderm in 1988. Zyderm is a product made by Collagen that is injected into the skin to replace lost soft tissue. Since Zyderm is classified as a Class III medical device — one that is used "to sustain human life" — the Food and Drug Administration ("FDA") required Collagen to follow rigorous procedures to obtain premarket approval ("PMA") before introducing Zyderm into the marketplace. The FDA uses the PMA process to ensure that a product is reasonably safe and effective under the MDA. The FDA initially approved Collagen's PMA in 1981 and reaffirmed its decision in 1991-92.

### ***Preemption Analysis Underwent Round One of Appellate Review***

The Mitchells sued Collagen in Indiana state court alleging "strict liability, negligence, fraud, mislabeling, misbranding, adulteration and breach of warranty." On removal to federal court, the district court granted Collagen's motion for summary judgment based on its finding that the MDA preempted Mitchells' state law claims. The MDA prohibits states from creating "any requirement . . . which is different from, or in addition to, any [federal] requirement" mandated by the MDA. 21 U.S.C. § 360k(a). The

court noted that according to the MDA regulations, a "state requirement" includes court-imposed requirements. The district court concluded that the PMA process was a requirement under the MDA. Since common law causes of action would impose requirements different from the PMA process, the court held that these causes of action were preempted by the MDA. Therefore, the district court dismissed all the state law claims as preempted by the MDA except for Mr. Mitchells' loss of consortium claim, which the court dismissed because the claim was derivative to the preempted claims.

The Seventh Circuit affirmed the judgment of the district court, based in part on preemption grounds. Rather than reaching a blanket conclusion that all state law claims were preempted by the MDA as the district court did, the appellate court examined the state law claims individually to determine whether each would impose requirements "different from, or in addition to" PMA requirements. Finding that the state law claims — with the exception of the adulteration, express warranty, and one fraud claim — imposed additional requirements, the court held the MDA preempted these claims. The court granted summary judgment for the adulteration, express warranty, and one fraud claim because the Mitchells' evidence was insufficient to warrant trial. The Supreme Court, acting on the Mitchells' petition for *certiorari*, vacated the Seventh Circuit's earlier decision and instructed it to reconsider the Mitchells' claims in light of its decision in *Medtronic*.

### ***The Seventh Circuit Examined Medtronic***

In examining the *Medtronic* decision, the Seventh Circuit noted

that the factual situation in *Medtronic* was substantially different from the case at hand. Specifically, unlike the present case, the *Medtronic* case involved a medical device, a malfunctioning pacemaker, that did not go through the PMA process. The pacemaker was exempted from the PMA process because the FDA determined it to be "substantially equivalent" to a device already on the market. 21 C.F.R. § 814.1(c)(1).

The Supreme Court split as to the proper method of analysis. Justice Stevens, joined by three Justices, considered the notion implausible that common law actions were preempted. Justice Stevens reasoned that because Congress considered medical device safety sufficiently important so as to require regulation, it would be peculiar, in effect, to grant immunity from design defect liability to an entire industry. Focusing on legislative intent, Justice Stevens found that nowhere had the drafters of the MDA feared that the state common law system interfered with the purposes of the MDA. Instead, Justice Stevens felt the preemptive term "requirement" meant a specific legal measure created by a state legislative or administrative body.

On the other hand, Justice O'Connor, joined by three Justices, reasoned that a common law cause of action might impose a different or additional requirement and therefore could be preempted by the MDA. Because *Medtronic's* device was the substantial equivalent of another device already on the market and as such did not go through a process with any "requirement[s]," Justice O'Connor concluded that the MDA did not preempt the defective design claim. Justice O'Connor also believed that the MDA did not preempt a cause of action based on a

failure to comply with federal requirements because “enforcement of a federal requirement is not a requirement ‘different from, or in addition to,’ the requirements imposed by federal law.” Nevertheless, these Justices held that some claims did add requirements and these claims would be preempted.

Justice Breyer provided the deciding vote holding that because the MDA could preempt a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would similarly preempt a state law tort action that imposed behavior or a standard of care. Justice Breyer concluded that the preemptive language of the MDA was broad and ambiguous and thus Congress intended the courts to rely on the relevant agency’s regulations in determining what specific causes of action should be preempted. In *Medtronic*, the relevant agency was the FDA, and the FDA regulation provided that state requirements are preempted only when “‘specific [federal] requirements applicable to a particular device’ made ‘any existing divergent State . . . requirements applicable to the device different from, or in addition to, the specific [federal] requirements.’” 21 C.F.R. § 808.1(d) (1995).

From these three perspectives, the *Medtronic* court unanimously held that the FDA’s “substantially equivalent” determination did not preempt the state law claims based on defective design. Furthermore, the Court held that a common law action which mirrors FDA regulations would not be preempted. Finally, additional state requirements that narrow the federal requirements rather than broaden them would not be preempted.

Regarding the manufacturing and labeling claims, the views of Justice

Breyer and Justice Stevens’s camp formed a majority. Since the FDA’s regulations stated that “state requirements are preempted only when the FDA has established ‘specific counterpart regulations,’” state law claims are not automatically preempted. In reviewing cases, courts “are to be mindful that state requirements of general applicability are not preempted unless they establish a substantive requirement for a specific device and that the federal requirements, to be preemptive, must be specific to a particular device.” The Court concluded that the MDA preempted none of the manufacturing and labeling claims because of the generality and nondescript nature of the relevant federal and state requirements.

#### *Seventh Circuit Distinguished Medtronic from the Mitchells’ Case*

The Seventh Circuit expressed the difficulty inherent in applying *Medtronic*’s rationale due to an apparent tension between the majority opinion and Justice Breyer’s view that at least some state-based causes of action are preempted. Even though the Seventh Circuit found the *Medtronic* decision difficult to apply, the court held that *Medtronic* required at least some state-based common law causes of action to be considered “requirements” under the MDA.

In reaching its decision, the Seventh Circuit held that the PMA process — unlike *Medtronic*’s “substantially equivalent” process — constituted a specific federal regulation of a product which could have a preemptive effect. To determine whether a specific state law claim is preempted by a MDA requirement, a court must examine the claim “at a sufficiently precise level of generality to determine

whether the final judgment of the state court would impose on the manufacturer a burden incompatible with the requirements imposed by the FDA.” The court found this decision consistent with those reached in other circuits.

The Seventh Circuit applied this holding to each of the Mitchells’ claims. First, the court addressed the Mitchells’ claims of strict liability and negligence. The court found that because the “unreasonably dangerous” standard of the strict liability claim created a requirement different from the FDA’s product-specific approval of the design, labeling, performance, etc. in the PMA process, the MDA preempted that claim. Likewise, the MDA preempted the negligence claim because it imposed a requirement different from the PMA process. Specifically, a state court’s finding of negligence would “necessarily conflict” with the FDA’s determination via the PMA process that the product was safe.

Next the court addressed the Mitchell’s claims of mislabeling, misbranding, and adulteration. The court noted that if the claims alleged that Collagen failed to meet the requirements created by the PMA process, the mislabeling and misbranding claims would not be preempted because they would merely enforce existing PMA requirements. However, the Mitchells did not base their claims on the PMA process but rather on different requirements. Thus, the court held that the claims were preempted. Additionally, the court held that the Mitchells failed to present sufficient evidence to survive summary judgment for the adulteration claim. Therefore, summary judgment on the mislabeling, misbranding, and adulteration claims was proper.

The Seventh Circuit also dismissed all of the Mitchells’ fraud

claims. Regarding the first fraud claim, that Collagen committed fraud through its representations to the FDA during the PMA process, the court upheld its decision finding that its original decision was unaffected by *Medtronic*. Also, the MDA preempted the claim that Collagen had committed fraud through misrepresentations about the product for the same reasons that the misbranding and mislabeling claims were preempted. Furthermore, even though the Mitchells' claimed fraud in advertising and promotional materials, the court held that the claims must fail because an FDA regulation controlled Collagen's promotional materials as part of the PMA process and was preemptive in the absence of an allegation that the material was non-conforming.

Finally, the court granted summary

judgment on the Mitchells' warranty claim even though the vagueness of the warranty precluded the court from determining whether an expressed or implied warranty was alleged. If an implied warranty claim had been intended, the MDA preempted it because of the warranty's interference with the standards set by the FDA during the PMA process. If the Mitchells had intended to submit an express warranty claim, the claim would still fail. Since warranties arise from the parties themselves as part of their bargain, the court stated that an express warranty claim would not necessarily interfere with the PMA and warrant preemption. However, since the Mitchells failed to assert a proper express warranty claim earlier in the litigation, they were estopped from doing so now. Therefore, the court found summary judgment was

proper.

After reconsidering the Mitchells' claims in light of *Medtronic*, the Seventh Circuit reaffirmed the district court's granting of summary judgment to Collagen on all of the Mitchells' claims. Specifically, the court held that the MDA preempts common law causes of action unless the claims merely allege non-compliance with PMA requirements because they would impose a requirement "different from, or in addition to" the PMA process. In arriving at this conclusion, the court distinguished *Medtronic*, holding that it applied only to products that went through the "substantially equivalent" process, as opposed to the PMA process, which is more specific and thus within the preemptive scope of the MDA.

**CLR**

## Telemarketing Company Lacked Standing in Antitrust Suit

By James Saranteas

In *Barton & Pittinos, Inc. v. Smithkline Beecham Corp.*, 118 F.3d 178 (3rd Cir. 1997), the United States Court of Appeals for the Third Circuit affirmed a district court decision holding that an injury alleged by a pharmaceutical marketing company bringing suit was not the type of injury the antitrust laws were intended to prevent. Since the marketing company bringing suit was not a competitor in the market in which trade was allegedly restrained, the marketing company lacked standing under the antitrust laws. The Third Circuit affirmed the district court's grant of summary judgment dismissing Barton's antitrust claims for lack of standing and dismissing Barton's other claims for lack of supplemental jurisdiction.

### Marketing Plan Led to Litigation

The litigation sprung from the broken pieces of a novel plan that Barton & Pittinos, Inc. ("Barton"), a pharmaceutical marketing company, developed to market Smithkline Beecham Corporation's ("Smithkline") Hepatitis-B vaccine ("the vaccine") to nursing homes. Barton developed the marketing plan in response to an Occupational Safety and Health Administration ("OSHA") mandate that was directed at certain employers, such as nursing homes, whose employees could be exposed to the Hepatitis-B virus. The mandate required nursing homes to educate their employees about the Hepatitis-B vaccine and make the vaccine available to their employees.

In response to OSHA's regulatory mandate, Barton developed a two-part plan for marketing the vaccine to nursing homes and presented this plan to Smithkline, which was one of only two manufacturers of the vaccine. Barton and Smithkline then entered into an agreement to put the marketing program in action.

In the first part of the program, Barton was to provide nursing homes with educational and regulatory material about the vaccine and Smithkline would pay Barton a flat fee. Then, Barton was to phone nursing homes and solicit orders for the vaccine. Since Barton lacked the requisite federal licensing to sell the vaccine, Barton was to give vaccine orders that it solicited to General Injectables and Vaccines, Inc.