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COURT BARS *QUI TAM* SUIT ALLEGING FRAUD ON THE FDA

(*U.S. ex rel. Gilligan v. Medtronic, Inc.*)

The U.S. Court of Appeals for the Sixth Circuit this week dismissed a lawsuit that sought to second-guess decisions of the Food and Drug Administration (FDA) authorizing the sale of drugs or medical devices. The decision was a victory for WLF, which filed a brief in support of the manufacturer whose product was being challenged. In a brief filed in *U.S. ex rel. Gilligan v. Medtronic, Inc.*, WLF argued that permitting such suits to go forward would undermine the integrity of FDA's product-approval system and could result in patients being denied access to life-saving medical products.

"This case is yet another example of plaintiffs' lawyers running amuck and undermining public health by filing unwarranted lawsuits," said WLF Chief Counsel Richard Samp after reviewing the court's decision. "FDA should be the sole arbiter of whether a medical product is sufficiently safe and effective to be marketed; once FDA has acted, neither state nor federal courts have any business hearing tort suits that have the effect of challenging FDA's authority," Samp said.

The case involved two medical devices manufactured by Medtronic, Inc. The devices (pacemaker leads used in heart surgery) have been approved for sale by FDA for nearly 20 years. In the mid-1990s, two lawyers in Cincinnati (Louis Gilligan and Gregory Utter) filed a series of product liability suits against Medtronic under Ohio law. The suits included a claim that the devices never should have been approved for sale and that Medtronic obtained approval only by providing false and fraudulent evidence to FDA. The fraud-on-the-FDA claims were dismissed by the Sixth Circuit in 2000; the court held that Congress did not intend to permit states (through application of state tort law) to second-guess an FDA decision to approve the sale of a medical device. The U.S. Supreme Court later affirmed the Sixth Circuit's reasoning in a separate case (*Buckman Co. v. Plaintiffs' Legal Committee*).

Following that dismissal, Gilligan and Utter filed a new suit against Medtronic, raising the very same fraud-on-the-FDA claim. But this time, they based the suit not on state law but on the False Claims Act (FCA), a federal law that permits individuals to file *qui tam* suits (*i.e.*, suits in which the plaintiff is acting as a private attorney general on behalf of the U.S.). Gilligan and Utter new suit alleged that Medtronic submitted "false claims" to the federal government by certifying that their medical devices were approved for sale by FDA, when in fact (according to

the plaintiffs) FDA's approval was automatically revoked because Medtronic obtained FDA approval through fraud.

The trial court denied Medtronic's motion to dismiss the case. It held that the Supreme Court's *Buckman* decision did not preclude the filing of fraud-on-the-FDA suits under the FCA. The trial court stated that *Buckman* held only that Congress intended to preempt fraud-on-the-FDA suits based on *state* law and has no application when the plaintiff is invoking a *federal* law (such as the FCA) to raise a fraud-on-the-FDA claim. Medtronic appealed that decision to the Sixth Circuit, which this week reversed.

WLF argued in its brief that the trial court adopted an overly narrow interpretation of *Buckman*. WLF argued that *Buckman* intended to preclude *all* claims that a medical device manufacturer obtained FDA approval through fraud, not merely those claims based on state law. WLF argued that if an individual believes that a manufacturer has defrauded FDA, the proper course is for the individual to bring his information to the attention of FDA and to let agency officials decide what, if any, enforcement action to take. WLF argued that if "private attorneys general" were permitted to maintain suits based on a fraud-on-the-FDA theory, such suits would quickly proliferate and would soon call into question the finality of FDA product-approval decisions.

Although it dismissed the lawsuit, the Sixth Circuit did not address WLF's *Buckman* argument but instead invoked a far narrower ground. The Sixth Circuit held that the information on which Gilligan and Utter based their False Claims Act lawsuit was publicly available before they filed suit. The appeals court held that under those circumstances, the False Claims Act (FCA) suit was barred by the "public disclosure" bar, which eliminates federal court jurisdiction over an FCA claim where the plaintiff is not the original source of the allegations and the allegations have been publicly disclosed before the suit was filed. The court explained that the point of the citizen-suit provision of the FCA is to encourage private citizens to come forward with information about frauds of which the federal government is unaware. The government does not need that type of assistance from private citizens once the information is publicly disclosed but rather can file suit on its own, the court explained.

WLF filed two separate briefs in this case in support of Medtronic. In June 2003, it filed a brief urging the Sixth Circuit to grant Medtronic's appeal on an interlocutory basis. After the appeals court agreed to hear the case, WLF filed a second brief urging dismissal. WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to reining in excessive litigation.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. Copies of WLF's two briefs are posted on its web site, www.wlf.org.