Litigation Update

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COURT AGREES TO REVIEW *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 in Cincinnati this week agreed to review a lower-court decision that permits individual litigants to file suits designed 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 the Washington Legal Foundation (WLF), which filed a brief urging the court to hear the case, *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. Now that review has been granted, WLF has pledged to file another brief, urging the appeals court to overturn the lower-court decision.

"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 appeals court 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 involves 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 now allege 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. The Sixth Circuit has now agreed to review the trial court's denial of the motion to dismiss.

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 against the manufacturer. 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.

WLF is a public interest law and policy center with supporters in all 50 states. WLF devotes a substantial portion of its resources to promoting tort reform and reining in excessive litigation.

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For further information, contact WLF Chief Counsel Richard Samp, (202) 588-0302. A copy of WLF's brief is posted on its web site, www.wlf.org.