News Release

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COURT URGED NOT TO PERMIT LAWYERS TO SECOND-GUESS FDA PRODUCT APPROVALS

***(Buckman Co. v. Plaintiffs' Legal Committee,* No. 98-1768)**

The Washington Legal Foundation (WLF) today asked the U.S. Supreme Court to prohibit plaintiffs' lawyers from second-guessing Food and Drug Administration (FDA) product-approval decisions by filing state-law suits against the product manufacturer.

In a brief filed in *The Buckman Company v. Plaintiffs' Legal Committee*, WLF argued that federal law does not permit such challenges because they would undermine FDA's authority to regulate the pharmaceutical industry. WLF also argued that the suit before the Supreme Court threatens public health because it could result in manufacturers no longer providing truthful information about their products.

"Plaintiffs' lawyers have been attempting for decades to strike it rich by scaring the American public into believing that commonly available medical products are not safe," said WLF Chief Counsel Richard Samp after filing WLF's brief. "But once FDA -- the final authority on medical product safety and effectiveness in this country -- has ruled a product safe for marketing, plaintiffs lawyers should not be permitted to make an end-run around the product-approval process by filing a state-law suit that, in effect, challenges FDA approval," Samp said.

The suit was brought by plaintiffs' lawyers against The Buckman Company, a regulatory consultant to medical device manufacturers. In the mid-1980s, Buckman assisted AcroMed Corp. in winning FDA approval for a brand of orthopedic bone screw. FDA approved the marketing of the bone screws with the understanding that they were intended to be used in surgery involving arm and leg bones. Not long afterward, however, surgeons began using the AcroMed screws in back surgery; the screws were implanted in the pedicles of the spine.

The plaintiffs in this case all had AcroMed screws implanted in their spines and claimed that they were injured when the screws allegedly were not effective. The plaintiffs filed suit against Buckman under state law, claiming that Buckman had committed "fraud on the FDA." They claimed that Buckman lied to the FDA about the screws' intended use and that it knew all along that doctors would use the screws for back surgery. The plaintiffs claimed that but for Buckman's fraud, the AcroMed screws would never have received FDA approval, the screws never would have been marketed, and thus the plaintiffs would never have suffered back injury.

A federal law, 21 U.S.C. § 360k(a), prohibits states from imposing any requirements on FDA-approved medical devices "different from, or in addition to" FDA requirements. Buckman argued in the lower courts that § 360k(a) barred the "fraud on the FDA" suit because the suit was an attempt to use state law to second-guess an FDA decision to permit the marketing of the AcroMed screws. The U.S. Court of Appeals for the Third Circuit rejected that argument, and the Supreme Court has agreed to review the Third Circuit's decision.

In its brief filed with the High Court, WLF argued that "fraud on the FDA" claims are barred by § 360k(a). The plaintiffs argue that they are simply attempting to invoke standard common-law prohibitions against fraud, and that there is nothing unusual about states taking action to prohibit fraud. WLF responded that FDA has stood by its 1986 approval of the AcroMed screws, an approval that FDA has not seen fit to rescind despite repeated entreaties from plaintiffs' attorneys. Because FDA is standing by its decision, WLF argued, this lawsuit can only be viewed as a challenge to the propriety of FDA's approval. Federal law prohibits state courts from second-guessing the FDA approval process, WLF argued.

WLF's also noted that the plaintiffs' lawyers are basing their fraud claims primarily on evidence that screw manufacturers from time-to-time provided doctors with truthful information about use of their products in back surgery. WLF responded, however, that AcroMed and other screw manufacturers never labeled their products for use in back surgery, nor did they ever engage in direct promotion of their products for off-label use. Rather, they limited themselves to providing truthful information about off-label use of their screws (for "pedicle fixation" back surgery) in response to inquiries from surgeons. WLF argued that public health would be seriously endangered if manufacturers were prevented from providing this information, and that the effect of this suit (if successful) would be to dissuade manufacturers from providing information about off-label uses for fear that they too would be accused of defrauding FDA.

WLF is a public interest law firm that is dedicated to protecting individuals and businesses from excessive government regulation. WLF recently won a lawsuit against FDA on First Amendment grounds, barring FDA from taking steps to prevent manufacturers from disseminating truthful information about off-label uses of their FDA-approved products.

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