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U.S. Supreme Court

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High court urged to hear False Claims Act case

BY CHRIS RIZO

WASHINGTON (Legal Newsline)-A leading conservative public interest law firm has urged the U.S. Supreme Court to review a lower court decision that allows trial lawyers to use the federal False Claims Act as a tool for regulating the marketing activities of pharmaceutical companies and medical device manufacturers.

In urging the nation's highest court to hear Ortho Biotech Products, L.P. v. United States ex rel. Duxbury, the Washington Legal Foundation said the appeals court ruling in the case threatens to suppress truthful speech about off-label uses of medical products approved by federal regulators.

"WLF is concerned that over the last two decades, excessive False Claims Act activity has spawned abusive litigation against businesses, both large and small, to the detriment of those businesses, their employees and shareholders, and the public at large," WLF's brief said.

The False Claims Act -- also known as the "Lincoln Law" -- allows whistleblowers who are not affiliated with the government to file actions against federal contractors, alleging fraud against the government. Under the law, whistleblowers stand to receive a portion of recovered damages.

The case involves Ortho Biotech Products, the manufacturer of Procrit -- the brand name for epoetin alfa - which is a medication for the treatment of anemia.

The plaintiff in the case, a former OBP employee, filed suit under the FCA, alleging that OBP defrauded the federal government by improperly promoting Procrit for uses not approved by the U.S. Food and Drug Administration.

He also alleged that OBP, a division of Janssen-Ortho Inc., paid kickbacks to health care providers to induce them to prescribe Procrit, and that the submission of a reimbursement claim for any drug purchased in connection with a kickback scheme is by definition a false claim.

U.S. district court in Boston dismissed the complaint. Overturning U.S. District Court Judge Rya Zobel, the 1st U.S. Circuit Court of Appeals reinstated the lawsuit. Ortho Biotech Products appealed to the U.S. Supreme Court.

The WLF amicus brief said the issue in this case is whether the drug company violated the False Claims Act, not whether it improperly marketed its products to physicians.

"The complaint cannot state a cause of action under the FCA given its failure to allege with particularity even a single false claim submitted to the federal government for payment," the group's brief said.

The group told the justices that it is particularly concerned about cases like this one because if these sorts of lawsuits survive motions to dismiss it would harm the business community, warning that businesses would be forced to settle even insubstantial FCA claims in order to avoid the prohibitive costs of pre-trial discovery.

In a separate brief, the American Hospital Association, urging the high court to hear the case, said if the appeals court decision is allowed to stand that two requirements for False Claims Act actions -- that a relator not trade on allegations of fraud already disclosed to the public and that a relator have specific pre-filing knowledge of some false or fraudulent claims - would be eroded.

"Both requirements impose important limitations on who can bring an FCA suit and what knowledge of wrongdoing a plaintiff must have before filing suit," the AHA brief said.

The group also told the justices: "These boundaries of FCA jurisprudence are necessary aids to discerning between cases prosecuted by legitimate relators with credible knowledge of undisclosed fraud and parasitic FCA cases."



U.S. Supreme Court building