

WRF Client Brown & Williamson Tobacco Corporation Scores Supreme Court Victory over FDA Jurisdiction

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Washington, DC—In an important victory for WRF client Brown & Williamson Tobacco Corporation, the United States Supreme Court has rejected the United States Food and Drug Administration's (FDA's) attempt to assert regulatory authority over cigarettes and smokeless tobacco products as "drugs" and "medical devices." Justice Sandra Day O'Connor, writing for the majority in , No. 98-1152 (March 21, 2000), stated that "Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products."

In 1995, after decades of asserting that the Food, Drug and Cosmetic Act (FDCA) precludes it from regulating tobacco products as customarily marketed, the FDA issued a proposed rule that would give the agency jurisdiction over cigarettes and smokeless tobacco and would virtually eliminate tobacco advertising. Brown & Williamson, along with other tobacco manufacturers, retailers, wholesalers and advertisers (the Companies) sued in federal court to have the agency's assertion of jurisdiction overturned. After the Agency issued its final rule regulating tobacco, a North Carolina federal district court struck down the advertising prohibitions proposed by the FDA, but held that FDA was not precluded from regulating tobacco under the FDCA. The Companies appealed to the United States Court of Appeals for the Fourth Circuit, which reversed the trial court and held that FDA had no jurisdiction over tobacco products. The United States appealed to the Supreme Court on behalf of FDA.

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The Supreme Court, adopting the arguments advanced by Brown & Williamson and the Companies, concluded that FDA's claim of jurisdiction over tobacco products overreached the authority Congress delegated to the agency under the Federal Food, Drug and Cosmetic Act. The Court recognized that FDA's assertion of authority over tobacco products directly contradicted the intent of Congress that FDA's "core objective" be to ensure that drugs and devices be "safe" and "effective" for their intended uses. FDA itself had acknowledged that contradiction for decades, repeatedly reminding Congress and the public of its own conclusion that the agency had no jurisdiction over tobacco.

The Court also held that Congress reinforced its intent to preclude FDA jurisdiction over tobacco and ratified FDA's own traditional position on the subject by enacting a series of statutes directly regulating cigarettes and smokeless tobacco. The Court cited six different tobacco-specific statutes, ranging from the requirement of the Surgeon General's warning on packages to making certain block grants to states contingent upon enactment and enforcement of age restrictions on the sale of cigarettes, that Congress enacted in keeping with its intent to reserve regulation of tobacco products to itself. As the Court noted,

Congress has enacted several statutes addressing the particular subject of tobacco and health, creating a distinct regulatory scheme for cigarettes and smokeless tobacco. In doing so, Congress has been aware of tobacco's health hazards and its pharmacological effects. It has also enacted this legislation against the background of the FDA repeatedly and consistently asserting that it lacks jurisdiction under the FDCA to regulate tobacco products as customarily marketed. Further, Congress has persistently acted to preclude a meaningful role for any administrative agency in making policy on the subject of tobacco and health. Moreover, the substance of Congress' regulatory scheme is . . . incompatible with FDA jurisdiction. *Slip op. at 33*. As a result, the Court concludes, "[r]eading the FDCA as a whole, as well as in conjunction with Congress' subsequent tobacco-specific legislation, it is plain that Congress has not given FDA the authority it seeks to exercise here."

WRF attorneys Andrew S. Krulwich, Bert W. Rein and Thomas W. Kirby were on the filed in the Supreme Court on behalf of Brown & Williamson, which specifically addressed FDA's overbroad construction of "intended use" in reaching its conclusion that cigarettes were intended to affect the structure and function of the body and thus subject to the FDCA. Bruce L. McDonald, William A. McGrath and Benjamin Reed also represented Brown & Williamson in bringing this litigation to a successful conclusion.