

KEY QUOTES FROM THE U.S. SUPREME COURT'S FDA RULING

On March 21, 2000, the U.S. Supreme Court released its 5-4 ruling that the U.S. Food and Drug Administration (FDA) does not have any regulatory authority over tobacco products or tobacco marketing, rejecting FDA's assertion of authority based on the Food, Drug, and Cosmetic Act (FDCA). The following are key quotes from the majority and dissenting opinions in the case, *Food and Drug Administration, et al. v. Brown & Williamson Tobacco Corporation et al.*, 529 U.S. ____ (March 21, 2000). PDF versions of the full text of the Supreme Court ruling, as well as the Dissent, are available at www.tobaccofreekids.org. In the quotes below, the page numbers from the PDF versions are in parentheses.

From the Majority Opinion Rejecting FDA Authority Over Tobacco

"This case involves one of the most troubling public health problems facing our Nation today: the thousands of premature deaths that occur each year because of tobacco use." (1)

"We find that Congress has directly spoken to the issue here and precluded the FDA's jurisdiction to regulate tobacco products." (10)

"The FDCA's misbranding and device classification provisions therefore make evident that were the FDA to regulate cigarettes and smokeless tobacco, the Act would require the agency to ban them." (13)

"A ban of tobacco products by the FDA would . . . plainly contradict congressional policy." (16)

"As the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect." (19)

"The FDA, consistent with the FDCA, may clearly regulate many 'dangerous' products without banning them. Indeed, virtually every drug or device poses dangers under certain conditions . . . What the FDA may not do is conclude that drug or device cannot be used safely for any therapeutic purpose and yet, at the same time, allow that product to remain on the market." (19)

"A fundamental precept of the FDCA is that any product regulated by the FDA – but not banned – must be safe for its intended use. Various provisions of the Act make clear that this refers to the safety of using the product to obtain its intended effects, not the public health ramifications of alternative administrative actions by the FDA. That is, the FDA must determine that there is a reasonable assurance that the product's therapeutic benefits outweigh the risk of harm to the consumer. According to this standard, the FDA has concluded that, although tobacco products might be effective in delivering certain pharmacological effects, they are 'unsafe' and 'dangerous' when used for these purposes. Consequently, if tobacco products were within the FDA's jurisdiction, the Act would require the FDA to remove them from the market entirely. But a ban would contradict Congress' clear intent as expressed in its more recent, tobacco-specific legislation." (19-20)

The inescapable conclusion is that there is no room for tobacco products within the FDCA's regulatory scheme. If they cannot be used safely for any therapeutic purpose, and yet they cannot be banned, they simply do not fit." (20)

“The FCLAA [Federal Cigarette Labeling and Advertising Act] evidences Congress’ intent to preclude *any* administrative agency from exercising significant policymaking authority on the subject of smoking and health.” (26)

“In reaction to the FTC’s attempt to regulate cigarette labeling and advertising, Congress enacted a statute reserving exclusive control over both subjects to itself.” (27)

“A separate statement in the Senate Report [on 1975 legislation eliminating the Consumer Product Safety Commission’s authority to regulate tobacco products] underscored that the legislation’s purpose was to ‘unmistakably reaffirm the clear mandate of the Congress that the basic regulation of tobacco and tobacco products is governed by the legislation dealing with the subject, . . . and that any further regulation in this sensitive and complex area must be reserved for specific Congressional action.’” (29)

“Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA. As a result, Congress’ tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed.” (34)

“Owing to its unique place in American history and society, tobacco has its own unique political history. Congress, for better or for worse, has created a distinct regulatory scheme for tobacco products, squarely rejected proposals to give the FDA jurisdiction over tobacco, and repeatedly acted to preclude any agency from exercising significant policymaking authority in the area.” (37)

“By no means do we question the seriousness of the problem . . . tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.” (39)

“‘In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop.’” (39)

From the Dissent

“The Food and Drug Administration (FDA) has the authority to regulate ‘articles (other than food) intended to affect the structure or any function of the body . . . In its own interpretation, the majority nowhere denies the following two salient points. First, tobacco products (including cigarettes) fall within the scope of this statutory definition, read literally. . . . Second, the statute’s basic purpose – the protection of public health – supports the inclusion of cigarettes within its scope.’” (1)

“The Court holds today that a regulatory statute aimed at unsafe drugs and devices does not authorize regulation of a drug (nicotine) and a device (a cigarette) that the court itself finds unsafe. Far more than most, this particular drug and device risks the life-threatening harms that administrative regulation seeks to rectify. The majority’s conclusion is counter-intuitive. (32)