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## Dow Jones Business News

### Supreme Court Appears Skeptical Of FDA's Authority Over Tobacco

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WASHINGTON -(Dow Jones)- Several Supreme Court justices Wednesday questioned the Clinton administration's claim that the Food and Drug Administration has the authority to regulate cigarettes and smokeless tobacco.

In an hour of spirited arguments Wednesday, justices debated whether Congress intended for the FDA to police the \$45 billion tobacco industry. At issue is a ruling from the Fourth U.S. Circuit Court of Appeals in Richmond, Va., which last year said the FDA lacks the power to regulate cigarettes and smokeless tobacco. The Supreme Court is expected to decide the case this spring.

Justice Sandra Day O'Connor jumped into the debate early, noting that the 1938 Food, Drug and Cosmetics Act - upon which the FDA bases its jurisdictional claims - requires FDA-regulated products to be safe and effective.

"Is it the position of the government that tobacco is safe and effective?" O'Connor asked Solicitor General Seth P. Waxman, who argued the government's case. If not, O'Connor said, tobacco just doesn't fit under the statute. "It strains credibility to say these products can be safe," she said.

Waxman said it would remain up to the FDA to go through the process of classifying tobacco, weighing its risks against its benefits. He conceded, however, that the FDA would have the power to ban cigarettes and other tobacco products.

The possibility of a ban under the FDA is an important point in the debate. Cigarette makers say that the FDA would necessarily have to take cigarettes off the market as unsafe, something Congress has never had any intention of doing.

"The FDA's assertion of jurisdiction here is lawless," said Richard M. Cooper, who is representing the tobacco industry.

Waxman argued that the FDA could weigh the benefits of smoking against the risks of leaving millions of addicted people without cigarettes.

The FDA in 1995 concluded that nicotine was a drug, and declared its authority to regulate the manufacture of cigarettes as nicotine-delivery devices. A federal judge in Greensboro, N.C., upheld the agency's regulatory authority over tobacco but rejected proposed FDA marketing restrictions. Both sides appealed, leading to the Fourth Circuit ruling.

Arguing for the government Wednesday, Waxman said the nicotine in cigarettes met the law's definition of a drug because it's "intended to affect the structure or any function of the body." He said tobacco companies intended to sell a product that satisfies an addiction, helps with weight loss and acts as both a stimulant and depressant.

Some justices questioned why the FDA was just recently finding this out. Chief Justice William H. Rehnquist noted that the U.S. Surgeon General in the early 1960s began warning smokers of the hazards of cigarettes.

A key part of the debate is what tobacco makers "intended." Tobacco companies say they've never made medical or health claims in marketing their products.

Justice John Paul Stevens seemed sympathetic to the FDA's argument. He said the tobacco industry may have only recently "intended" to sell an addictive product. "Seems to me that's at least theoretically possible," he said.

Cigarette makers have long argued that it's Congress' job to set rules for the industry - not the FDA's. They point to a series of statutes - from the 1960s through the early 1990s - that established a national tobacco policy.

Justice David H. Souter said he agreed with the government's arguments on many of the technical points. The difficulty, he said, was weighing the overall history of the government's tobacco policy.

"It's the global problem, not the technical problem," he said. Justice Anthony M. Kennedy said he shared some of Justice Souter's concerns.

In the U.S., nearly 50 million people - roughly 23% of adults - smoke cigarettes, according to industry estimates. Tobacco foes say medical and other expenses caused by smoking-related illnesses cost the U.S. economy more than \$130 billion a year. Some 400,000 people die each year from tobacco-related health problems, they said.

Tobacco companies involved in the case include Brown & Williamson Tobacco Corp., a unit of British American Tobacco PLC (BTI); Philip Morris Cos. (MO); R.J. Reynolds Tobacco Co., a unit of RJR Nabisco Holdings Corp. (RN); and Lowes Corp.'s (LTR) Lorillard Inc. subsidiary.

The appeal follows an agreement inked last fall between 46 states and the nation's four biggest tobacco companies, which will pay as much as \$206 billion to settle smoking-related lawsuits. Attorneys general from Mississippi, Florida, Texas and Minnesota had already reached settlements, valued at \$36 billion, for their suits to recoup smoking-related health costs.

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