

Supreme Court rules that FDA cannot regulate tobacco industry

Scott Gottlieb *New York*

The United States Supreme Court, rejecting the Clinton administration's unprecedented effort to control how cigarettes are sold and marketed in the United States, has ruled that the Food and Drug Administration (FDA) lacks the power to regulate tobacco.

In the 5 to 4 ruling, the judges said that the FDA overreached its authority when it reversed a decades old policy in 1996 and sought to crack down on cigarette sales to minors.

"By no means do we question the seriousness of the problem that the FDA has sought to address," Justice Sandra Day O'Connor wrote for the court. "The agency has amply demonstrated that tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States."

However, she added, "It is plain that Congress has not given the FDA the authority that it seeks to exercise here."

Justice O'Connor was joined in her opinion by the Supreme Court's more politically conservative jurists—Chief Justice William Rehnquist and Justices Antonin Scalia, Anthony

Kennedy, and Clarence Thomas. Dissenting were Justices Stephen Breyer, John Paul Stevens, David Souter, and Ruth Bader Ginsburg.

Writing on behalf of the four dissenters, Justice Breyer said that federal law does allow the FDA to regulate tobacco. "Far more than most, this particular drug and device risks the life threatening harms that administrative regulation seeks to rectify," he added.

The FDA's antismoking initiative would have required retailers to check the identification of cigarette buyers under the age of 27 and would have prohibited cigarette vending machines except in bars and other adult only places. Although the rules were restrained by some standards, they had far more symbolic importance as the first test of FDA authority to control the powerful tobacco industry.

The Clinton administration called the 1996 initiative the FDA's most important public health and safety effort in the past 50 years. The best way to cut down on smoking was to reduce the number of teenagers who started the habit, officials contended.

The FDA has said for decades that under a 1938 law it



Traders on the New York stock exchange—on the day that tobacco shares rose because the Supreme Court ruled that the FDA could not regulate tobacco

lacked authority to regulate tobacco as long as cigarette makers did not claim that smoking provided health benefits. But the agency reversed its view in 1996, saying that it could regulate tobacco because of new evidence that the industry intended its products to feed consumers' nicotine habits.

Tobacco companies sued, and the 4th US Circuit Court of Appeals ruled in 1998 that the FDA could not regulate tobacco. The court said that regulations on tobacco were the responsibility of Congress, which previously had banned broadcast advertising of tobacco, prohibited smoking on airlines, and required warning

labels on cigarette packages.

During an appeal of that ruling before the Supreme Court last December, the solicitor general, Seth Waxman, argued on behalf of the Clinton administration that the FDA could regulate tobacco as a drug because nicotine was "highly addictive." It also acted as a stimulant, a sedative, an appetite suppressant, and fed smokers' addictions.

Forty states backed the government's appeal. But the tobacco industry's lawyer argued that if FDA regulations were allowed, the government would be forced to ban tobacco products because they had not been shown to be safe. □

Australia to consider a class action against tobacco industry

Christopher Zinn *Sydney*

The chief law officers of Australia and New Zealand are to examine the legal options for a massive multibillion pound action against tobacco companies to recover the costs of treating smoking related diseases.

The attorneys general have decided to establish a working party to assess the viability of a class action in a similar case to one in the United States, in which the tobacco companies

were ordered to pay \$200bn (£125bn) in compensation over 25 years.

Queensland's attorney general, Matt Foley, who raised the issue, said that such a class action would be difficult and costly, but necessary: "We believe that the great loss and damage suffered by the community through tobacco related illness is something that governments have a duty to investigate."

But the federal government has backed away from the action, with its attorney general, Darryl Williams, saying that it is already investigating how and if it could proceed against the companies.

"While similar litigation has been successful in the United States, the Australian govern-

ment solicitor has advised that there are significant differences between Australian and US laws," he said.

The Doctors' Reform Society backed the attorneys' move but said that, although it was a good start, all governments benefit from tax revenue from cigarette sales, which makes them partly to blame for the problem.

The Cancer Foundation of Western Australia said that the initiative could be the most important development in the smoking and health campaign in decades. The chief executive, Mike Daube, said that if action is undertaken and succeeds, the tobacco industry will pay a heavy price.

"They of course will oppose it and will bluff and posture and mislead, but at the end of the

day they will have to face the force of the law and they will have to pay out as a result of the appalling health consequences of their products," he said.

An expert on class actions, Melbourne lawyer Peter Gordon of Slater and Gordon, said that the states would have to prove the amount of losses they had sustained in the provision of hospital and medical care to injured smokers with conditions such as lung cancer and emphysema.

"Having established that, they would need to go on and establish that those costs have been incurred basically because the smokers themselves have been the victims of the tobacco companies' negligence and their misleading and deceptive conduct," he said. □