

FDA Rule At-A-Glance

The U.S. Food and Drug Administration (FDA) 1996 assertion of authority over tobacco products and its issuance of the FDA rule to prevent and reduce tobacco use by children represented the most comprehensive initiative to date to protect the public health from tobacco and reduce youth tobacco consumption. Unfortunately, in response to cigarette company legal challenges, on March 21, 2000 the U.S. Supreme Court ruled 5-4 that existing law does not provide the FDA with jurisdiction to regulate tobacco products or cigarette company marketing practices.

The Court found that “Congress has clearly precluded the FDA from asserting jurisdiction to regulate tobacco products” – despite the fact that “tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States.” Because of the Court’s ruling, neither FDA nor any other federal entity may exercise jurisdiction over tobacco products or implement measures to restrict tobacco marketing to kids unless Congress passes new legislation that expressly provides the authority to do so. In addition, the FDA Rule has been eliminated – including its previously active provisions that set 18 as the nationwide minimum legal age for purchasing tobacco and required that retailers check photo identification before selling cigarettes to persons who appear younger than 27 years of age (the rest of the Rule’s provisions had never been implemented because of the legal proceedings).

Why is the authority of FDA over tobacco and the August 1996 FDA Rule so important?

No federal agency currently has any authority over tobacco products for health and safety purposes. Consequently, the tobacco companies do not have to disclose in a meaningful way what is in their products or what they knew about the harms caused by their products. No agency has the authority to require the tobacco companies to remove ingredients in tobacco products that have been found to cause cancer and other diseases or to take any other steps to reduce the harm caused by their products.

When it asserted jurisdiction over tobacco in August 1996, the FDA determined that the best way to begin to reduce the harm caused by tobacco was to reduce the number of children who became addicted. Thus, the FDA Rule was designed to create a meaningful national policy to limit kids’ access to tobacco and to prevent the tobacco industry from marketing its products to children. Now, that Rule is dead – and no other comprehensive and meaningful restrictions on tobacco company marketing exist.

But the need to reduce tobacco use by children has never been greater. Tobacco use among children skyrocketed in the 1990s and is now near a 19 year high. Today, 4.5 million kids age 12-17 are current smokers. More than 3,000 additional kids become new regular smokers each and every day, and roughly a third of them will ultimately die of tobacco-related causes. Unless current trends change, over five million kids alive today will ultimately die prematurely from smoking.

What are the highlights of the FDA Rule?

First, the Rule would have reduced youth access to tobacco by banning most cigarette vending machines, self-service displays, and free samples, and by requiring retailers to verify age for all over-the-counter sales. Second, it sought to reduce tobacco’s appeal to youth by prohibiting tobacco advertising within 1,000 feet of schools and playgrounds, restricting outdoor ads and ads and in publications with a significant teen readership to black and white text-only, prohibiting

tobacco brand names and images on baseball caps, T-shirts, gym bags and other products that appeal to kids, and prohibiting tobacco brand sponsorship of sporting and entertainment events.

Didn't the FDA Rule's advertising restrictions violate the First Amendment?

No. The First Amendment allows the government to restrict commercial speech, including advertising, if the restriction directly advances a substantial government interest. Preventing children from becoming addicted to tobacco products meets that test. More specifically, the FDA Rule satisfied the four-part test used by the Supreme Court to evaluate restrictions on commercial speech.

1. It is illegal for tobacco products to be sold to children. The forms of tobacco marketing addressed by the FDA Rule were designed to eliminate only those marketing tools which make tobacco products more appealing to children.
2. The government's asserted interest in regulating the tobacco marketing -- reducing tobacco use among kids -- is substantial.
3. The Rule's advertising restrictions directly advance the government's interest. Numerous studies have shown that tobacco advertising is a major factor in inducing kids to start smoking; and the Rule would have reduced youth exposure to tobacco advertising and made it less attractive to kids.
4. The FDA Rule was carefully tailored to reduce youth tobacco use by restricting tobacco company marketing practices that affect kids without significantly hindering the tobacco companies' ability to provide product information and otherwise advertise to legal tobacco customers.

Why should the FDA, rather than some other agency, have jurisdiction over tobacco?

The FDA is the only government agency that can provide comprehensive oversight and regulation of all aspects of tobacco product sales, marketing, and manufacture, including the tobacco industry's failure to reduce or eliminate harmful constituents or ingredients, their manipulation of nicotine, and their sales and marketing efforts that make these products more accessible and appealing to kids. The FDA also has the ability to modify its regulations as new information and evidence becomes available or to respond to tobacco industry marketing or manufacturing changes. FDA jurisdiction over tobacco products would subject tobacco products to the same kind of regulatory oversight that is already applied to other products legally consumed by U.S. citizens.