

Chronology of FDA Rule and Other Important Dates

- August 23, 1996 President Clinton announces the U.S. Food and Drug Administration's (FDA) Tobacco Rule
- August 28, 1996 FDA Rule is published in the *Federal Register*
- October 15, 1996 Tobacco industry files briefs supporting its lawsuit against the FDA Rule:
- [Brief One](#): Argues that FDA has no authority over tobacco products under the Food, Drug, and Cosmetic Act
- [Brief Two](#): Argues that tobacco products are neither drugs not drug delivery devices
- [Brief Three](#): Argues that FDA Rule's marketing restrictions violate the First Amendment
- November 27, 1996 [Amicus \(friend of the court\) brief](#) in support of FDA authority and the FDA Rule filed by Public Citizen, Campaign for Tobacco-Free Kids, American Cancer Society, American Heart Association, and others.
- December 2, 1996 U.S. Department of Justice files the [U.S. government's brief](#) that opposes each of the tobacco industry's arguments and supports FDA jurisdiction over cigarettes and smokeless tobacco products and its regulations restricting those products to protect children and adolescents
- December, 1996 [Amicus brief](#) in support of FDA authority and the FDA Rule filed by the state of Minnesota on behalf of itself and 32 other states.
- December 23, 1996 Tobacco industry files replies to the government's response brief:
- [Brief One](#) regarding claim that FDA has no authority over tobacco products under the Food, Drug, and Cosmetic Act
- [Brief Two](#) regarding claim that tobacco products are neither drugs not drug delivery devices
- [Brief Three](#) regarding claim that FDA Rule's marketing restrictions violate the First Amendment
- February 10, 1997 U.S. District Court for the Middle District of North Carolina hearing in Greensboro, NC

- April 25, 1997** U.S. District Court Judge William Osteen issues [District Court Ruling](#) that upholds the FDA's legal authority to regulate cigarettes and smokeless tobacco products. Judge Osteen also rules the FDA has statutory authority to regulate access but does not have the specific authority to issue the FDA Rule's provision that regulates advertising and promotion. He stays the FDA Rule's implementation, pending appeal, except for the photo identification provisions. Both sides appeal
- May 9, 1997** Point of Purchase Advertising Institute files motion asking Judge Osteen to amend his Order to say that self-service tobacco displays are advertising and promotion beyond the FDA's reach
- June 4, 1997** Judge Osteen rejects the Point of Purchase Advertising Institute's motion and declines to amend his order
- June 11, 1997** U.S. Department of Justice files the U.S. government's [opening brief](#) to U.S. Court of Appeals for the Fourth Circuit in support of FDA's authority to restrict tobacco product advertising and promotion, and opposing the District Court's stay of the FDA rule's implementation
- June 27, 1997** Tobacco industry files [opening brief](#) in the U.S. Court of Appeals for the Fourth Circuit that opposes FDA authority over tobacco products and responds and responds to Government's opening brief
- June 1997** Amicus briefs filed by same groups that filed amicus briefs with the District Court.
- July 14, 1997** Government files [response](#) to tobacco industry brief
- July 28, 1997** Industry files [reply brief](#)
- August 11, 1997** A panel of the U.S. Court of Appeals for the Fourth Circuit hears oral argument on the issues raised by these appeals in Warm Springs, VA
- November 7, 1997** Senator McCain introduces Universal Tobacco Settlement Act ("McCain Bill"). McCain Bill is referred to the Committee on Commerce
- April 1, 1998** Senate Committee on Commerce passes a significantly revised McCain Bill by a 19 to 1 vote; the revised Bill includes many of the elements of the FDA Rule
- April 16, 1998** Judge Russell, member of Warm Springs panel, dies

May 13, 1998	McCain Bill referred to Committee on Finance
May 19-June 17, 1998	McCain Bill considered by U.S. Senate
June 9, 1998	FDA case re-argued to a three judge panel of the U.S. Court of Appeals for the Fourth Circuit in Charleston, WV due to Judge Russell's death
June 17, 1998	McCain Bill defeated in the U.S. Senate
August 14, 1998	U.S. Court of Appeals for the Fourth Circuit judicial panel votes 2 to 1 that the FDA has no statutory authority to regulate tobacco products, overruling the U.S. District Court decision. Because it rules that FDA has no authority, the 4 th Circuit does not rule on whether the FDA rule's marketing restrictions violate the 1 st Amendment. Appellate Court Ruling.
September 25, 1998	Government petitions the U.S. Court of Appeals for the Fourth Circuit for rehearing by the panel or by the Court <i>en banc</i> .
November 10, 1998	U.S. Court of Appeals for the Fourth Circuit denies the government's petition
November 18, 1998	In response to the government's request, the U.S. Court of Appeals for the Fourth Circuit grants a 30 day stay of issuance of the mandate to permit FDA to continue to enforce photo identification requirements.
November 23, 1998	Multistate Settlement Agreement (MSA) execution date.
December 17, 1998	Stay extended for another 30 days.
January 19, 1999	Solicitor General files U.S. Government's Petition for a Writ of Certiorari to the U.S. Supreme Court (asking Court to hear arguments that 4 th Circuit Court of Appeals ruling should be overturned).
March 22, 1999	Tobacco companies files Reponse Brief In Opposition to Petition for <i>Writ of Certiorari</i> .
April 7, 1999	Solicitor General files Reply Brief for the Petitioners.
April 26, 1999	U.S. Supreme Court grants Petition for <i>Writ of Certiorari</i> .
July 12, 1999	The Solicitor General files opening brief in the Supreme Court seeking reversal of the August 14, 1998 decision of the United States Court of the Appeals that rejected FDA authority over tobacco products. [Supreme Court will not consider issue of whether FDA Rule's advertising restrictions violate 1 st

Amendment because 4th Circuit did not rule on that issue. 1st Amendment issue will go back to the 4th Circuit if Supreme Court rules that FDA has authority over tobacco products]

July 1999

Public Citizen, the American Medical Association, the American Heart Association, the American Cancer Society, the American Lung Association, the Campaign for Tobacco-Free Kids, and 40 other public health and children's organizations file an [Amicus Curiae Brief](#) in support of FDA authority and the reversal of the Fourth Circuit court's decision. Additional [Amicus briefs](#) are filed by other organizations, as well.

September 10, 1999

The tobacco industry files [five reply briefs of respondents](#).

October 12, 1999

Solicitor General files [reply brief](#)

December 1, 1999

Oral argument before the Supreme Court.

March 21, 2000

In an majority opinion written by Justice O'Connor, the U.S. Supreme Court issues a 5-4 ruling that existing law does not provide FDA authority over tobacco or tobacco marketing. The Court finds 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."

Source of Additional Information:

The web site of the Campaign for Tobacco-Free Kids (www.tobaccofreekids.org) provides additional information on FDA authority and the FDA Rule, and why both are needed, as well as links to the full text of the FDA Rule and to copies of all of the major legal briefs and court rulings that are available via the internet.