*Id.* at 2618 (citations omitted) (emphasis added).

The Court found that the preemption provisions "merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels" and held that the preemption provisions did not constitute an absolute prohibition against all Federal and State action. *Id.* 

The Supreme Court in *Freightliner* Corp. v. Myrick, 115 S. Ct. 1483 (1995) clarified its language in Cipollone. The Court stated "[t]he fact that an express definition of the preemptive reach of a statute "implies"—i.e., supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption." Id. at 1488 (emphasis added.) The Court noted that it would still be appropriate to conduct the proper analysis to determine if preemption should be implied. Having said that, the Court stated that such an analysis had been done in Cipollone. Finally, the Court found no implied preemption in Freightliner even in the absence of federal regulation.

The California Supreme Court, in Mangini v. R.J. Reynolds Tobacco Co. 875 P.2d 73 (Cal. en banc), cert. denied, 115 S.Ct. 577 (1994), considered whether the Cigarette Act precluded an action under California law for engaging in an "unlawful, unfair, or fraudulent business act or practice" by using "unfair, deceptive, untrue, or misleading advertising." The petitioner claimed that R.J. Reynolds had illegally targeted minors in its Joe Camel advertising campaign. R.J. Reynolds asserted that its cigarettes were properly labeled and, therefore, that California could not impose any regulation regarding cigarette advertising if the regulation were based on smoking and health. It added that a prohibition against selling cigarettes to minors was based on underlying health concerns and that only the Federal Government could prevent advertisements that urge minors to smoke. The California Supreme Court applied the analysis in Cipollone and held that, while the petitioner's action would prohibit cigarette advertising directed at minors, the underlying legal duty for the petitioner's action was not based on smoking and health. The California Supreme Court held that, "The predicate duty is to not engage in unfair competition by advertising illegal conduct or encouraging others to violate the law." Id. at 80. As for the argument that allowing state law claims to proceed would violate congressional policy favoring a comprehensive

Federal program for cigarette labeling and advertising, the court disagreed, stating,

State law prohibitions against advertisements targeting minors do not require Reynolds to adopt any particular label or advertisement "with respect to any relationship between smoking and health;" rather, they forbid any advertisements soliciting unlawful purchases by minors. The prohibitions do not create "'diverse, nonuniform, and confusing" standards. Unlike state law obligations concerning the warning necessary to render a product 'reasonably safe,' state law proscriptions" against advertisements targeting minors 'rely on a single, uniform standard:"' do not target minors.

*Id.* at 80 (quoting 112 S.Ct. at 2624). Consequently, the court held that,

It is now asserted that plaintiff's effort to tread upon Tobacco Road is blocked by the nicotine wall of congressional preemption. The federal statute does not support such a view. Congress left the states free to exercise their police power to protect minors from advertising that encourages them to violate the law. Plaintiff may proceed under that aegis.

Id. at 83. The Supreme Court later denied R.J. Reynolds' petition for a writ of certiorari. See 115 S.Ct. 577 (1994). Although Mangini concerned preemption of State action, the California Supreme Court's decision and the U.S. Supreme Court's denial of certiorari indicate a judicial intent not to extend the Cigarette Act's preemption provisions beyond its literal terms. Thus, restrictions on cigarette companies allegedly targeting children are not restrictions based on "smoking and health." See also Banzhaf v. Federal Communication Commission, 405 F.2d 1082, 1089 (D.C. Cir. 1968), cert. denied, 396 U.S. 842 (1969) (preemption provision of the 1965 Cigarette Act did not bar the Federal Communication Commission from requiring radio and television stations to broadcast anti smoking messages: "Nothing in the Act indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation." (footnote omitted))

Applying these cases to FDA's proposed rule, the agency believes that the proposed requirement for a brief statement about smoking and health is not preempted.

## 2. The Smokeless Act

For smokeless tobacco products, the Smokeless Act states in part:

## (a) Federal action

No statement relating to the use of smokeless tobacco products and health, other than the statements required by [this title,] shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

15 U.S.C. 4406(a). The proposal would not require any messages in advertising because the Smokeless Act's preemption provision is broader than the preemption provision in the Cigarette Act and preempts any Federal (as well as State) action mandating health/safety messages in advertising.

Thus, given these statutory restrictions and court precedent, FDA has determined that neither the Cigarette Act nor the Smokeless Act preempts any aspect of the proposed rule.

D. Constitutional Issues—Regulation of Speech and the First Amendment

The proposed rule's restrictions on commercial speech are consistent with the First Amendment's protection of freedom of expression. The Supreme Court distinguishes between commercial speech and other forms of speech with respect to First Amendment rights. Traditionally, commercial speech was not granted any protection under the Constitution. More recently, the Supreme Court has granted commercial speech limited constitutional protection. See Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456, reh'g denied, 439 U.S. 883 (1978); Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748 (1976); Bigelow v. Virginia, 421 U.S. 809, 818 (1975). The Supreme Court, in Edenfield v. Fane, 113 S. Ct. 1792 (1993), stated:

[c]ommercial speech [] is "linked inextricably" with the commercial arrangement that it proposes, \* \* \* so the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. \* \* \* For this reason, laws restricting commercial speech, unlike laws burdening other forms of protected expression, need only be tailored in a reasonable manner to serve a substantial state interest in order to survive First Amendment scrutiny.

Id. at 1798 (citations omitted).

It is undisputed that the "Constitution
\* \* \* affords a lesser protection to
commercial speech than to other
constitutionally guaranteed expression."
United States and Federal
Communication Commission v. Edge
Broadcasting Co., 113 S.Ct. 2696, 2703
(1993) (citations omitted). Accord, City
of Cincinnati v. Discovery Network, Inc.,
113 S.Ct. 1505, 1513 (1993); Board of
Trustees of the State University of New
York v. Fox, 492 U.S. 469, 475, mot.
denied, 493 U.S. 887 (1989); Central
Hudson Gas and Electric Corp. v. Public