FDA's Proposed Regulation of the Sale and Promotion of Tobacco Products to Minors

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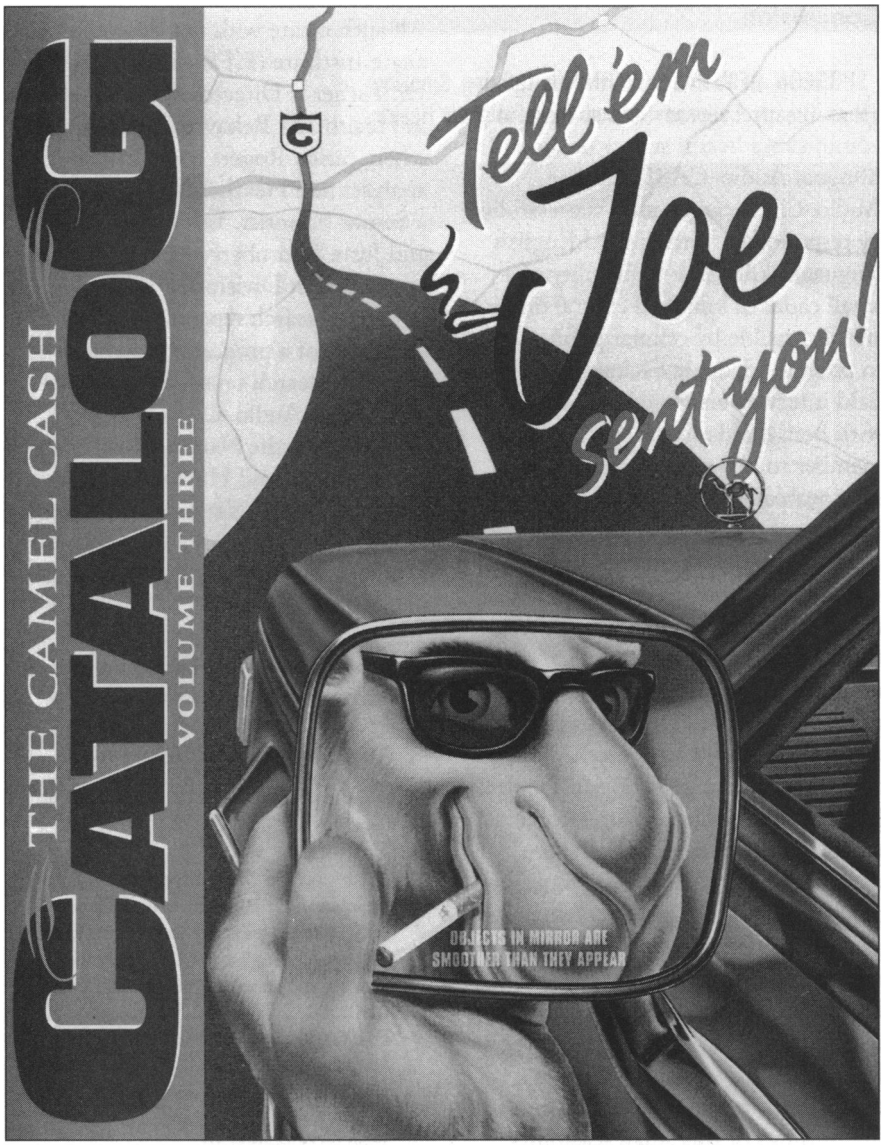

Until last year, the Food and Drug Administration (FDA) had never sought to exert general regulatory control over cigarettes and smokeless tobacco products. Rather, the FDA had specifically stated that tobacco products did not fall within its jurisdiction except where a manufacturer made health claims in connection with its product, thus bringing that product within one part of the statutory definition of "drugs." For example, in the 1950s, the promotional campaign of Fairfax cigarettes, marketed as effective in preventing colds, influenza, pneumonia, acute sinusitis, and other diseases, brought that brand within the FDA's authority.[1]

On August, 11, 1995, however, the FDA issued a lengthy proposal to regulate the sale and promotion of tobacco cigarettes and smokeless tobacco products to minors. The proposal is based on the FDA's authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to regulate drugs and medical devices. It is not based on a change in the law but rather on a massive evidentiary record recently compiled by the FDA, comprised of documents showing that the tobacco industry precisely controls and manipulates the content and form of nicotine within its products. These documents demonstrate that the industry intends its products to affect the structure or function of the body, thus bringing tobacco products within another part of the statutory definition of "drugs."

Through its regulation, the FDA hopes to protect children and adolescents from being enticed by the industry's sophisticated advertising and promotional efforts into experimenting with tobacco products. The proposal does not directly address adults' use of tobacco. Nonetheless, because the vast majority of adult tobacco users become addicted to nicotine before age 18, the FDA hopes that reducing tobacco use by minors will prevent future generations of adult nicotine addicts.

The FDA's proposal presents a reasonable, balanced approach to blocking the avenues that the tobacco industry uses to promote its products to minors, while leaving open ample channels of communication between the tobacco industry and adults who may wish to use its products. Moreover, the FDA has done a remarkable job in amassing a record that provides a solid foundation for the regulations it has proposed. Nonetheless, tobacco companies and advertisers have already filed lawsuits alleging that the

FDCA does not authorize the FDA to regulate tobacco products and seeking to prevent the FDA from implementing the proposed regulations. The lawsuits further assert that FDA regulation of tobacco products is precluded by prior FDA statements, is preempted by other federal laws, and/or violates the First Amendment. In fact, however, with few exceptions, the FDA's proposal should withstand legal challenge.

The Proposed Regulations

The FDA proposal includes three categories of regulations. The first category centers on the prohibition on sales to minors and would establish a variety of measures designed to reduce the likelihood that individuals under age 18 will be able to obtain cigarettes illegally. These measures include a requirement that retailers verify the age of purchasers; requirements that all sales be made directly by a salesperson, who can verify the age of the purchaser, rather than by vending machines or other mechanical devices; and a prohibition on mail order sales and free samples.

Second, the FDA proposes a series of measures intended to limit the ability of the industry to market their products to minors. Among those measures are a prohibition on the use of brand names of other products to market cigarettes (a tobacco company could not start selling a Calvin Klein brand, for example); a ban on the sale or distribution of promotional products (such as caps, T-shirts, towels, and sweatshirts) bearing the name, logo, or other identifying feature of a tobacco product; a ban on billboard and other outdoor poster advertising of tobacco products within 1000 feet of schools or playgrounds; and limitations on the ability of tobacco companies to use sponsorship of athletic, musical, or other similar events to attract an underage audience. In addition, the FDA would require tobacco advertisements to be in a black and white, text-only format. (Adult publications, defined as having 85% of their readership over age 18 and not more than two million readers under age 18, would be exempt from this requirement.) The format restrictions would also apply to all point of sale promotional materials. Finally, all cigarette advertising, except for point of sale promotional materials and cigarette packages, would have to include the product's name and intended use—for example, "Cigarettes—A Nicotine Delivery Device"—as well as a brief statement such as "About one out of three kids who become smokers will die from smoking."

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Third, the FDA's proposed rules would establish a public educational program directed at providing information about the dangers of smoking to counteract the seductive messages that the industry has been issuing for years and will continue to issue to the extent not forbidden by these rules.

Legal Basis for the FDA's Proposal

The tobacco industry has portrayed the FDA proposal as a major about-face in the FDA's interpretation of its statutory authority. In fact, the proposal is based not on a change in the Agency's view of the law but on its recent compilation of a tremendous amount of evidence showing that nicotine, as used in tobacco products, is intended by manufacturers to act as a drug.

Under the statutory authority of the FDCA, the FDA regulates drugs, medical devices, cosmetics, and many foods. The FDA proposes to regulate cigarettes and smokeless tobacco products as "drug-delivery systems." For the FDA to have authority over such "combination products," the products must (*a*) contain a "drug," as that term is defined by the FDCA, and (*b*) have the primary purpose of delivering or aiding in the delivery of a drug. Cigarettes and smokeless tobacco products meet both of these requirements.

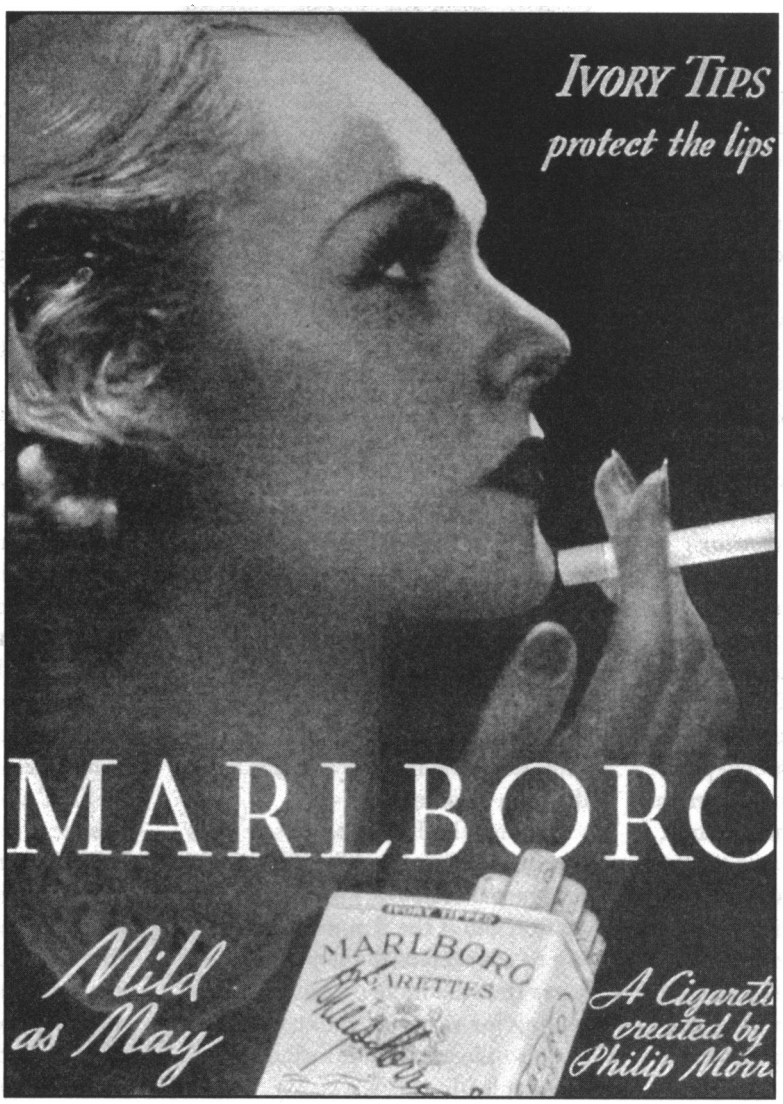
Nicotine as a drug. The FDCA defines the term "drugs" as, among other things, "articles intended for the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and . . . articles (other than food) intended to affect the structure or any function of the body of man or other animals." Nicotine has pharmacological effects in the human body. That fact is undisputed, even by the industry. Consequently, the FDCA authorizes the FDA to regulate nicotine when it is intended for therapeutic use *or* intended to affect the structure or any function of the body. That fact is also not in serious dispute. Indeed, the FDA already regulates other nicotine products, such as nicotine patches and nicotine chewing gum, and the tobacco industry has not challenged the FDA's assertion of

jurisdiction over those products.

The general public is well aware that nicotine affects the structure or function of the body. Therefore, even without direct evidence that tobacco product manufacturers possess such knowledge, it is fair to impute this knowledge to them. Under the objective intent standard that is integrated into the FDCA's definition of "drugs," manufacturers are charged as a matter of law with having foreseen the reasonable consequences of their actions.[2] And the reasonable consequence of the tobacco manufacturers' actions in carefully controlling the amount, form, and delivery of nicotine in their products is an effect on the structure and function of the bodies of consumers of tobacco products. Because the effect is so great—addiction to the nicotine in cigarettes results in more American deaths each year than AIDS, alcohol, car accidents, murders, suicides, and fires combined—and because numerous dangers associated with tobacco use have been well known to the public for at least 30 years, any claim that such consequences are not foreseeable is not credible.

Specifically, the substantial body of evidence before the FDA demonstrates that the tobacco companies, through their manufacturing processes, can and do control the amount, form, and delivery of nicotine in their products.[3,4] The materials cited by the FDA in support of its proposal demonstrate that manufacturers have the ability to remove nicotine from tobacco products entirely, as Philip Morris's Next cigarette brand demonstrated. Manufacturers also have the ability to increase the amount of nicotine and to control its delivery. As a consequence of the tobacco companies' control and manipulation of nicotine in their products, millions of Americans are hooked on cigarettes and smokeless tobacco products, more than 400,000 people die each year of diseases attributable to tobacco use, and nearly one in five eighth graders and one in three twelfth graders smoke cigarettes.

Furthermore, the tobacco manufacturers' own documents reveal not only that the companies knew that nicotine has pharmacological effects but that they conducted extensive research to learn how nicotine affects the body and then used this knowledge to engineer their products to administer precisely the doses of nicotine smokers craved. For example, a Brown & Williamson document regarding a debate over whether to buy a company that produces nicotine patches included a comparison of nicotine patches and cigarettes as drug-delivery devices.[5] Reports of tobacco industry researchers in the 1970s and 1980s confirmed the physiological and psychological effects of nicotine. And industry documents before the FDA show that manufacturers have consciously controlled the delivery of nicotine, with its pharmacological effects firmly in mind.[4]



Cigarettes and smokeless tobacco products as nicotine-delivery systems. Because nicotine is a drug and is intended by tobacco product manufacturers to have drug effects, cigarettes and smokeless tobacco products fit precisely into one of the categories of "combination products" established by the FDA. Pursuant to a preexisting agree-

ment between the FDA's Center for Drug Evaluation and Research (CDER) and its Center for Devices and Radiological Health (CDRH), the FDA treats devices with the primary purpose of delivering or aiding in the delivery of a drug and which are distributed containing a drug ("pre-filled drug delivery systems") as combination products, which may be regulated under either the drug or device approval processes, under the purview of either the CDER or the CDRH.

Among the products in the "pre-filled drug delivery system" category are transdermal patches, such as nicotine patches. Nicotine patches are intended to affect the function of the body by providing specific doses of nicotine to the user. Similarly, the FDA's evidence demonstrates that manufacturers of tobacco products also intend their products to affect the function of the body by providing doses of nicotine. (In a document obtained by the FDA, a Philip Morris scientist states, "Think of the cigarette as a dispenser for a dose unit of nicotine.") Given this key similarity between the two types of nicotine-delivery systems—patches and tobacco products—the FDA's undisputed authority to regulate transdermal patches provides direct precedent for the FDA's decision to regulate tobacco products as nicotine-delivery systems with the status of combination products.

The delivery of a drug to the body through the means used by tobacco cigarettes or smokeless tobacco products is not unique. Cigarettes deliver the drug nicotine to the body through inhalation into the lungs. Other combination products that deliver drugs to the body through inhalation include nebulizers and inhalers. In addition, other types of cigarettes have been specifically marketed for drug delivery. For example, Asthmador cigarettes were sold as an asthma treatment in the United States as recently as the 1970s. In France, products such as *Cigarettes Escouflaire* and *Cigarettes Schulze Bengaiais* today use the cigarette form to deliver stramonium leaf, potassium leaf, and, in the latter case, digitalis leaf to the body to treat respiratory system disorders.

The FDA already regulates other nicotine products, such as nicotine patches and nicotine chewing gum.

Smokeless tobacco products deliver nicotine to the body through absorption into the buccal pouch, the inner lining of the cheek. This means of delivery is particularly effective because a drug can directly enter the bloodstream from the buccal pouch, in contrast to the slower passage of a pill through the stomach. Other products that deliver drugs to the body through the membranes lining the mouth, without being swallowed, include various nitrates used to treat chest pain, such as angina; Fentanyl Oralet, a lollipop which delivers an anesthetic by initial rapid absorption through the mouth, as well as slower delivery through the gastrointestinal tract; Aspergum; and nicotine gum.

Furthermore, designation of cigarettes and smokeless tobacco as combination products, subject to regulation under the device laws, is justified by evidence that the delivery of nicotine is not unavoidable but is a primary goal of the manufacturing process.

Device laws. Because tobacco products are properly classified as drug-delivery systems, the FDCA provision regarding combination products allows the FDA to regulate them pursuant to the device laws. Section 520(e) of the statute, entitled "Restricted Devices," empowers the Agency

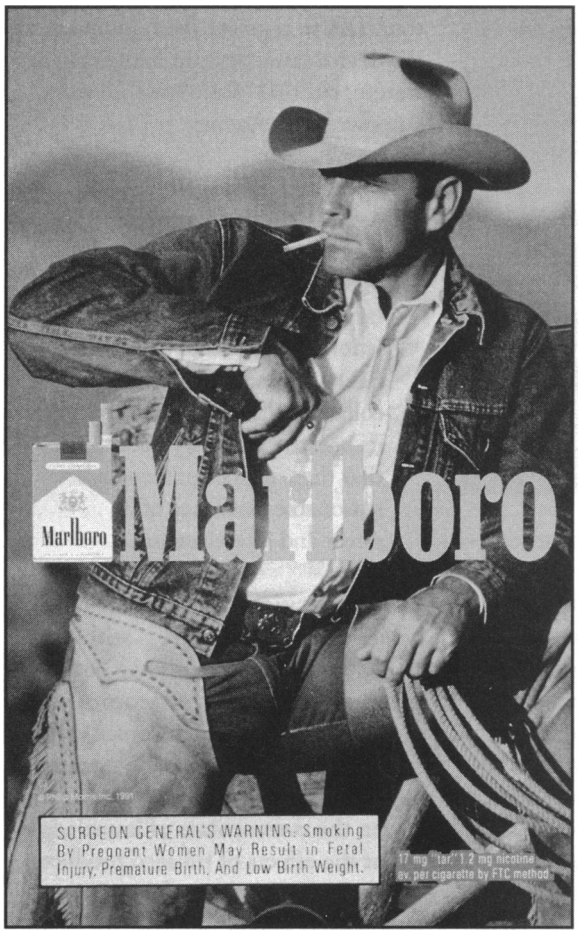
> by regulation [to] require that a device be restricted to sale, distribution, or use...upon such other conditions as the Secretary may prescribe in such regulation, if, because of the potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness....

The decision whether to regulate a device under this section is within the FDA's discretion. The FDA's proposal and the evidence in the record adequately demonstrate the "potentiality for harmful effect" from use of cigarettes and smokeless tobacco products. Given the current state of knowledge about the effects of tobacco products on the body, this potentiality cannot legitimately be questioned.

Evidence amassed by the FDA. Although the FDA has not previously regulated nicotine products such as cigarettes and smokeless tobacco, the FDA has not previously had before it evidence that tobacco product manufacturers actually control the level and delivery of nicotine in their products.[6] Now, evidence revealing the tobacco industry's intentional control over the level and form of nicotine in its products warrants the regulation that the

FDA has proposed.[7]

The FDA's current proposal is fully consistent with its earlier position regarding its authority to regulate tobacco products. The FDA's position has always recognized the possibility of regulating tobacco products when they are accompanied by health claims



or when the manufacturer controls levels and forms of nicotine to affect the structure or function of the body. Notwithstanding the FDA's position, Congress has never amended the FDCA to exclude tobacco products from the scope of the statute, as it has with other statutes.

In comments submitted to the FDA on behalf of R.J. Reynolds Tobacco Company in November of 1994 and in papers filed in pending litigation brought by tobacco companies to block the FDA's proposed regulations, tobacco companies have argued that the "intent" component of the definition of a drug can be satisfied *only* by industry statements making express claims regarding health. Because manufacturers make no "therapeutic claims" for their products, the industry argues that the FDA cannot regulate them. As support for this argument, the industry relies on statements made at congressional hearings, in which FDA representatives stated that tobacco products marketed without therapeutic claims do not meet the FDCA definitions of drugs or devices. The industry also relies on the FDA's response to a 1977 petition to the FDA filed by Action on Smoking and Health, which urged the FDA to assert jurisdiction over cigarettes sold without therapeutic claims. The FDA denied that petition, although it did not contest Action on Smoking and Health's factual assertions: that nicotine is a drug, that manufacturers intend cigarettes to affect the structure or any function of the body, and that a cigarette is an instrument designed to administer controlled amounts of nicotine to the smoker.

These prior FDA statements are not relevant to, and certainly do not resolve, the question of whether the FDCA grants the FDA authority over tobacco products. In the past, the FDA had no *proof* that companies purposefully engineered their products as drugs to ensure that users receive certain doses of nicotine and the attendant pharmacological effects. That is, in the past, the FDA had no evidence that tobacco companies controlled the amount and form of nicotine in their products to manipulate the responses of smokers, for example to get smokers hooked. Making explicit therapeutic claims is one way to manifest intent to use a product as a drug. But industry documents showing awareness of the affects of the products, the ability to control those affects, and actual efforts to exercise such control may also manifest such intent.[8]

Indeed, the statutory definition of "drugs" recognizes that intent encompasses more than express therapeutic claims. As discussed above, that definition includes "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," that is, articles intended for therapeutic uses. Thus, if a cigarette manufacturer made a therapeutic claim for cigarettes, the product would qualify as a "drug" under this definition. "Drugs" further include, however, "articles (other than food) intended to affect the structure or any function of the body." Both logic and the basic rules of statutory construction dictate that this part of the definition must include items for which no therapeutic claims are made; otherwise it would be redundant of the first part of the definition.[9]

The industry's contention that the FDA has conceded away any claim to authority over tobacco products is off target. Until the FDA secured evidence that tobacco manufacturers deliberately control nicotine levels and the form of nicotine in their products, both to keep users hooked and to provide whatever satisfaction nicotine gives, the *only* provision under which the FDA could

find that the nicotine in tobacco products was subject to regulation as a drug was the first part of the FDCA definition of "drugs." The tobacco industry well understood how to avoid their products' falling within that definition: they had simply to avoid making any direct therapeutic claims. As long as the FDA lacked evidence to support an assertion of jurisdiction under the second part of the definition, the industry's practice of carefully avoiding express health claims left the FDA with no practical choice but to disclaim jurisdiction over tobacco products. Thus, even if the FDA believed years ago that nicotine itself had pharmacological effects, it lacked the *evidence* on which its current proposal is based. The evidence before the FDA today changes that situation and brings tobacco products within the FDA's purview under the FDCA.

The FDA's proposal marks an important step toward the goal of protecting impressionable children and adolescents from the enticements of the tobacco industry.

Conclusion

The FDA has filed motions to dismiss the lawsuits that seek to block its regulations. These motions are pending. Although the FDA is likely to issue a final regulation to implement its proposal later this year, the courts may not allow the regulation to take effect until the lawsuits have wound their way through the court system, which could take up to several years. And, eventually, the scope of the FDA's authority to regulate tobacco products may be specifically addressed by Congress.

In the meantime, the FDA's proposal marks an important step toward the goal of protecting impressionable children and adolescents from the enticements of the tobacco industry. A few of the specific proposals have weaker support in the FDCA than others, and the proposal as a whole may require some fine tuning. The FDA's basic determination, however—that the FDCA authorizes it to end the flood of advertising and promotional material with which our nation's children are inundated every day—is well supported by the statute. In regulating tobacco products intended as drug-delivery systems by their manufacturers, the FDA has wisely chosen its priority: ending the deadly practice of advertising directed at minors, which induces experimentation with, and ultimately addiction to, tobacco products.

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This article is adapted from a document entitled *Comments of Public Citizen, Inc., Regarding the FDA's Proposal to Regulate the Sale and Promotion of Tobacco Products to Minors*, which was submitted to the FDA.[10]

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References

1. *United States v. 46 Cartons, More or Less, Containing Fairfax Cigarettes*, 113 F. Supp. 336 (D.N.J. 1953) (cigarette a drug when marketed to mitigate, prevent, or cure disease). *See also United States v. 354 Bulk Cartons*, 178 F. Supp. 847 (D.N.J. 1959) (cigarette a drug when marketed as effective for weight reduction).
2. 21 C.F.R. § 201.128 (drugs), § 801.4 (devices).
3. *See also* Wall Street Journal 1995 Oct 18;Sect A:1(col 6).
4. *See also* Wall Street Journal 1995 Dec 8;Sect B:1(col 6).
5. Washington Post 1995 Oct 9;Sect A:8(col 1).
6. *See Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir. 1980) (FDA position based on lack of evidence that manufacturers or vendors intend cigarettes "to affect the structure or any function of the body").
7. *See generally* 60 Fed. Reg. 41462, 41467-784 (1995); *see also Action on Smoking and Health*, 655 F.2d at 239 ("Nothing in this opinion should suggest that the [Food and Drug] Administration is irrevocably bound by any long-standing interpretation and representations thereof to the legislative branch" regarding FDA jurisdiction over tobacco products).
8. *See also United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992) ("All of the circumstances surrounding the promotion and sale of the product constitute the 'intent.' It is not enough for the manufacturer to merely *say* that he or she did not 'intend' to sell a particular product as a device").
9. *See National Insulation Transportation Comm. v. ICC*, 683 F.2d 533, 537 (D.C. Cir. 1982) (court must, if possible, give effect to every phrase of a statute so that no part is rendered superfluous); *Symons v. Chrysler Corp. Loan Guarantee Board*, 670 F.2d 238, 270 (D.C. Cir. 1981) (rejecting interpretation that would render statutory phrase superfluous because statutes should be construed, if possible, to give effect to every word used by Congress).
10. Zieve AM, Morrison AB. Comments of Public Citizen, Inc., regarding FDA's proposal to regulate the sale and promotion of tobacco products to minors. Washington DC: Public Citizen Litigation Group, 1996.