Butt Out!! Why the FDA Lacks Jurisdiction To Curb Smoking of Adolescents and Children

Margaret A. Boyd

Follow this and additional works at: http://scholarship.law.edu/jchlp

Recommended Citation
Available at: http://scholarship.law.edu/jchlp/vol13/iss1/11
BUTT OUT!!
WHY THE FDA LACKS JURISDICTION
TO CURB SMOKING OF ADOLESCENTS
AND CHILDREN

Introduction

On August 28, 1996, the Food and Drug Administration ("FDA") \(^1\) issued a final rule governing the sale and distribution of cigarettes and smokeless tobacco products to persons under eighteen years of age.\(^2\) The

\(^1\) 21 U.S.C. § 393(a) (1994) ("There is established in the Department of Health and Human Services the Food and Drug Administration.").


The Final Rule was first announced as a proposed rule in 1995 entitled, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (1995) (to be codified at 21 C.F.R. pt. 801, 803, 804, 897) (proposed Aug. 11, 1995) [hereinafter Proposed Rule]. The proposed rule was released for comment until November 9, 1995. Id. at 41,314. Due to public interest in this issue, the comment period was extended to January 2, 1996. FDA Proposed Rule on Tobacco Scrutinized as Comment Period Ends, BNA HEALTH CARE DAILY, Jan. 3, 1996, available in LEXIS, Nexis Library, BNA File. The FDA received over 2,000 pages of comments and 45,000 pages of supporting documents from the tobacco industry alone. Id. According to Steven C. Parrish, senior vice president for Phillip Morris, most of the comments submitted by the tobacco industry indicate that the FDA restrictions will not reduce smoking by minors. Id. See also, Betsy Wagner, Tobacco Fights Back, U.S. News & WORLD REP., Jan. 15, 1995, at 12 (when the comment period ended, the FDA had received 641,000 letters, an agency record. The letters came from smokers and the tobacco industry who said the government should not be involved in this issue, and from scientists who urged even stronger restrictions).

The purpose for both the Final Rule and the Proposed Rule are the same, "[a]s stated in the 1995 Proposed Regulation, the objective of the final rule is to meet the goal of the report 'Healthy People 2000,' by reducing roughly by half children's and adolescent's use of tobacco products." Final Rule at 44,423.

Tobacco sales to minors are already regulated by every state and the District of Columbia. Many jurisdictions regulate the locations of vending machines. In addition, the cigarette industry is already impacted by: (1) Department of Agriculture regulations for production quotas and price levels; (2) a ban on television, radio, and other electronic media that has been in place for 25 years; (3) warning label requirements on cigarette packages; (4) the Federal Trade Commission rule on compliance with health hazard warnings; (5) the monitoring of "ingredients used in cigarettes and smokeless tobacco products . . . by the Department of Health and Human Services;" (6) federal, state, and local government taxes on tobacco products which amount to $13 billion a year; and, (7) state and local
FDA developed the rule, entitled, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents ("new FDA rule"), to meet the goals of "Healthy People 2000" — a U.S. Public Health Service study outlining national health targets for the year 2000. 

"Healthy People 2000" sets forth 300 national health care objectives to be accomplished by the year 2000. Tobacco is the third priority item under health promotion. The new FDA rule is specifically intended to address failure in the civil law. James T. O'Reilly, A Consistent Ethic of Safety Regulation: The Case for Improving Regulation of Tobacco Products, 3 Admin. L.J. 215, 224 (1989). When the public can be protected by legal means such as tort law, regulation may not be needed. Id. Civil law has not been able to protect consumers in the context of tobacco issues. Id. The cost of tort litigation against the tobacco industry is high, and recovery is rare. Id.

See also, Ann Mileur Boeckman, An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco Products, 45 Cath. U. L. Rev. 991, 1040 (1996)(concluding that the FDA did not have jurisdiction to promulgate the Proposed Rule).

3. Final Rule, supra note 2, at 44,423. The term "adolescents and children" is used throughout the final rule, but is not separately defined in the Definitions Section, section 897.3 of the rule. Id. at 44,616. However, Section 897.14(a) states, "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age." Id. The age limit of 18 was selected by the FDA for a number of reasons:

First, as stated in the preamble to the 1995 Proposed Rule, all States prohibit the sale of tobacco products to persons under the age of 18; currently only four States prohibit cigarette sales to persons over 18. . . . Second, selecting 18 as the minimum age is consistent with the age Congress established under section 1926 of the PHS Act, which conditions a State's receipt of substance abuse grants on State laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under the age of 18. Id. at 44,441.

"Cigarette" is generally defined in section 897.3(a) as "any product which contains nicotine, is intended to be burned under ordinary conditions of use." Id. at 44,616. "Smokeless tobacco products" are defined in Section 897.3(i) as "any product that consists of cut, ground, powdered, or leaf tobacco that contains nicotine and this is intended to be placed in the oral cavity." Id.


6. Id. at 1124. The three broad goals of health for the nation are: "(1) [t]o increase the span of healthy life for Americans; (2) [t]o reduce health disparities among Americans; and (3) [t]o achieve access to preventative services for all Americans." Id. at 1123.

"Healthy People 2000" was based on previous national health targets for 1990 and was a
reduce by half the number of children who use tobacco by the year 2000 through addressing the potential health risks related to cigarette and smokeless tobacco product usage. Although the new FDA rule was issued in 1996, most provisions are not effective until August 28, 1997.

The new FDA rule is broad-based and will cover any entity that is involved in the sale, distribution, or advertising of nicotine-containing cigarettes and smokeless tobacco products to persons under eighteen years of age. The new FDA rule imposes restrictions on cigarettes in two primary areas: (1) cigarette sales, and (2) labeling and advertising. The sales restrictions require that each retailer verify that cigarette purchasers are at least eighteen years old and that retailers, manufacturers, and distributors distribute only packages containing at least twenty cigarettes; discontinue use of vending machines in places where those under eighteen are permitted; and eliminate free samples and mail orders. The result of public hearings and a national consortium of health officials from the 50 states and 300 professional and voluntary national membership organizations. "Healthy People 2000" was issued in September 1990. See also, RUTH BRECHER ET AL., THE CONSUMERS UNION REPORT ON SMOKING AND THE PUBLIC INTEREST 80 (1963)(studies have shown that cigarette smokers are more likely than non-smokers to die from lung and other cancers, cardiovascular disease, and various other conditions. In the Hammond-Horn study, the death toll for cigarette smokers was 7,316 compared with only 4,651 that would have been expected if smokers had the same death rate as non-smokers. Thus, among cigarette smokers there were 2,665 more deaths than should have occurred). The proposed rule does not apply to pipe tobacco or cigars because the FDA does not have evidence that persons under 18 use them. Specifically, the final rule concerning sales: (1) establishes 18 as the federal minimum age for the purchase of cigarettes; (2) prohibits cigarette vending machines except in places where the retailer ensures that no person under 18 is present, free samples, mail-order sales, and self-service displays; (3) requires retailers to verify the age of purchasers; (4) eliminated sponsorship of athletic, musical, artistic, or social event using the tobacco product brand name. Cigarettes can only be sold in face-to-face exchanges between the retailer and consumer. The rule also restricts the name of...
restrictions on labeling and advertising are even more far-reaching, requiring that: (1) no outdoor advertising be placed within 1,000 feet of a playground or school; (2) text advertising be limited to black text with a white background; (3) manufacturers not market, license, distribute, or give as a gift any item that bears a name or logo identified with tobacco use; and (4) manufacturers refrain from sponsoring any sporting or cultural event using the logo or brand name of a tobacco product.

The new FDA rule was promulgated under the Federal Food, Drug and Cosmetic Act ("FDCA"). The FDCA allows the FDA to regulate items that fall within the jurisdiction of the Act by regulating their sale, distribution, and use. Failure to comply with regulations renders the product misbranded under the FDCA, which can result in civil penalties or imprisonment for not more than one year or a $1,000 fine, or both. Generally, the FDCA prohibits the introduction, delivery, misbranding, and manufacture of any food, drug, device, or cosmetic in interstate commerce. No section of the FDCA specifically mentions cigarettes or cigarettes to the trade names in effect as of January 1, 1995 — thus, new product names introduced after this date cannot use catchy or chic names of non-tobacco products, thereby restricting product names to those in force prior to January 1, 1995. Id.

13. Id. at 44,617. Section 897.30(b) requires that “[n]o outdoor advertising may be placed within 1,000 feet of the parameter of any public playground in a public area . . . elementary school, or secondary school.” Id.

14. Id. Section 897.32(a) states that the black text and white background does not apply to advertising appearing in adult publications. An adult publication is one in which 85% of the readers are age 18 or older, and has fewer than two million readers under the age of 18. Id.

15. Id. Section 897.34(a) covers any item that has any indication of product identification with cigarettes or is similar to those used for tobacco products. Id.

16. Id. at 44,618. Section 897.34(c) will allow the use of a corporate name to sponsor a sporting or cultural event provided that both the corporation and the registered corporate name were in existence prior to January 1, 1995. Id.

17. 21 U.S.C. §§ 301-93 (1994). “The Secretary, through the Commissioner, shall be responsible for executing this chapter.” Id. § 393(b)(2).

18. Id. § 360j(c).

19. Final Rule, supra note 2, at 44,616 section 897.1(b); 21 U.S.C. § 333 (1994). “Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.” Id. § 331(a)(1). If there is another violation after the first conviction, or there is intent to defraud or mislead, then the violator could face imprisonment of up to three years, or a fine of $10,000, or both. 21 U.S.C. § 331(a)(2). See also, Gary E. Gamerman, Intended Use and Medical Devices: Distinguishing Nonmedical "Devices" from Medical "Devices" Under 21 U.S.C. 321(h), 61 GEO. WASH. L. REV. 806, 810 (1993) (if an article is deemed a device, it is subject to comprehensive regulation by the FDA. Failure to comply can result in severe criminal and civil punishments).

their regulation. The FDA has determined, however, that cigarettes fall within the FDCA jurisdiction as a "device."  

The new FDA rule is controversial. Tobacco manufacturers are challenging it in federal court on a number of bases, including the FDA’s jurisdiction over cigarettes.  

This Comment critically examines whether the FDA’s enabling legislation, the Federal Food, Drug and Cosmetic Act, provides the FDA with jurisdiction to promulgate regulations pertaining to cigarettes. This Comment explores the FDA’s contention that although cigarettes are not with foreign Nations, and among the several States, and with the Indian Tribes." U.S. CONST. art. I, § 8, cl. 3.


22. Final Rule, supra note 2, at 44,396. “Device” is defined as:
an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its principle intended purposes.


23. See Complaint for Declaratory and Injunctive Relief at 1, Coyne Beahon Inc. v. United States Food and Drug Admin., United States District Court For The Middle District Of North Carolina Greensboro Division [hereinafter Complaint] (alleging the regulations are unlawful because they are: (1) contrary to legislative intent; (2) precluded by the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331; (3) violations of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-93; and (4) violations of the free speech and due process clauses in the United States Constitution amend. I and V). See U.S. Asks Federal Court to Dismiss Lawsuit Filed by Tobacco Companies, CHARLESTON GAZETTE, October 7, 1995, at A7. See also WILLIAM F. FOX, JR., UNDERSTANDING ADMINISTRATIVE LAW, § 17 (1992) (explaining that the federal Administrative Procedures Act permits a court to determine whether an agency is functioning within its jurisdiction, and that the authority of the courts to make this determination was also established by the Supreme Court in Crowell v. Benson, 285 U.S. 22 (1932)); Tobacco Growers Help Collect Over One Million Signatures Opposing FDA Regulation of Tobacco, The Tobacco Institute, Jan. 10, 1995 (unpublished news release) (on file with author) (pointing out that tobacco farmers in all 23 tobacco growing states are also challenging FDA regulations through a petition drive to try to stop the FDA regulations).


specifically mentioned in the FDCA, the FDA has jurisdiction over them as a "device." Part I identifies the controversy surrounding the new FDA rule. Part II discusses the process of rulemaking by the FDA. Part III reviews the legislative history and evolution of the "device" definition. Part IV analyzes the courts' definition of a "device" test under the FDCA. Part V analyzes cigarettes in light of this test. Finally, this Comment concludes that the current test for a "device," although broadened in recent years, still turns on the manufacturer's intent and is not satisfied for cigarette products.

I. The Controversy

Today, approximately fifty million Americans smoke cigarettes. Cigarette smoking kills "more Americans each year than . . . AIDS, alcohol, car accidents, murders, suicides, illegal drugs, and fires combined." Three million adolescents and children smoke, and it is estimated that every day an additional three thousand become regular smokers. Studies also suggest that of adult smokers, 82% had their first cigarette before the age of eighteen. Indeed, those who did not smoke prior to age eighteen are unlikely to begin smoking. One study found that from the period of 1984 to 1989, smoking increased 5.5% among adolescents (aged fourteen to seventeen), while smoking actually steadily decreased for adults.

Also, studies of adolescents' attitudes towards smoking show many are unaware of its harmful effects. For example, in a 1993 study of persons between ten and twenty-two years old, only 61% of high school sopho-

27. Id. The United States Surgeon General has issued annual reports summarizing medical data that show that tobacco use causes cancer, heart disease, respiratory problems, and death. In addition, there are more than 300,000 tobacco-related deaths each year. O'Reilly, supra note 2, at 217-18.
29. Id. The United States Surgeon General began studying the consequences of tobacco in the early 1960s. Since that time, there have been thousands of studies, both national and international, which confirm that smoking is a serious health hazard. Micheal S. Burkhard & M. Allison Despard, Cigarette Classification a Burning Issue, 6 Loy. CONSUMER L. REP. 116, 116 (1994).
31. Center for Disease Control and Prevention, Trends In Smoking Initiation Among Adolescents And Young Adults - United States, 1980-1989, 274 JAMA 513, 528 (1995). The study was conducted using data from the Tobacco Use Supplement of the 1992 and the 1993 Current Population Surveys which are monthly surveys sent to 56,000 households. Id.
32. Department of Health and Human Serv., Health-care Provider Advice on Tobacco Use to Persons Aged 10-22 years - United States, 1993, 44 MORBIDITY & MORTALITY WKLY
mores believed that the risk of smoking was great and only 44% believed that the risk of using smokeless tobacco products was significant.\(^{33}\)

Although it is recognized that smoking by children and adolescents is a national concern and it would be politically unpopular to suggest that the young should smoke, the politics and money behind those for and those opposed to the new FDA rule are tremendous. The stakes in the regulation of tobacco are high. Tobacco is a forty-seven billion dollar a year industry with strong lobbying power in Congress.\(^{34}\) Tobacco is the seventh largest cash crop in the United States and employs 48,800 people in manufacturing alone.\(^{35}\)

The tobacco industry does not argue that children should smoke. In fact one cigarette manufacturer, Phillip Morris USA, began a twenty million dollar “Action Against Access” initiative to discourage juvenile smoking.\(^{36}\) The initiative places notices on all cigarette packs and cartons stating, “Underage Sale Prohibited,” discontinues free cigarette samples to consumers, and denies retail incentives to stores fined or convicted of selling cigarettes to minors.\(^{37}\) The tobacco industry, however, asserts that the FDA is attempting a power grab by regulating the distribution of cigarettes to adolescents and children and that the real “hidden” agenda is to restrict all smoking.\(^{38}\)

Some industry insider groups have intimated that

---

\(^{33}\) Sherry E. Mark and Robert L. Honeck, supra note 29, at 117. See generally Brecher et al., supra note 7, at 122-23 (The practice of non-tobacco smoking goes back to the time of the ancient Greeks, but was considered for medicinal purposes rather than pleasure. Tobacco was native only to the Americas and the first users, were the American Indians who smoked it through a Y-shaped pipe. Once Christopher Columbus discovered America, he and other explorers purchased tobacco seeds and brought the plant back to Europe.).

\(^{34}\) Andrew Kaplan, Reaction Mixed on PM Campaign: Wholesalers' Reaction to Philip Morris Inc.'s Advertising Campaign Against Cigarette Sales to Minors, U.S. DISTRIBUTION J., Aug. 15, 1995, at 5.

\(^{35}\) Marlene Cimons, Cigarette Regulation Plan Challenged; Tobacco: Five Major Companies Along with Pro-Smoker, Advertising and Trade Groups Claim FDA has No
the Commissioner of the FDA, Dr. David A. Kessler, is out to get the tobacco industry because he has an addiction to media attention, undisguised opportunism, and a desire for a more powerful FDA.\(^3\)

Industry representatives claim that the FDA is engaged in "jurisprudential gymnastics" by trying to regulate cigarettes as devices,\(^4\) and the industry is challenging this action in federal court on a number of bases including the FDA's jurisdiction over cigarettes.\(^5\) Yet, to cover all their bases of support, the tobacco industry contributes heavily to Congressional campaigns. Since 1985, the industry has contributed more than seventeen million dollars in political action committee money and "soft money" to congressional candidates and national parties.\(^6\) In the first six months of 1995, the tobacco industry gave a record 1.5 million dollars to national parties.\(^7\) The industry has taken this approach to ensure that

---

39. Peter Samuel, The Kessler Kastle: Smoke and Mirrors, NAT'L REV., Oct. 9, 1995, at 48 (stating that insiders have dubbed a proposed new FDA complex in Clarksburg, Maryland "Kessler Kastle" to intimate their disapproval with Dr. Kessler's need for power). See also Tobacco Growers Help Collect Over One Million Signatures Opposing FDA Regulation of Tobacco, The Tobacco Institute, (Jan. 10, 1995) (unpublished news release) (on file with author) (quoting F. H. "Buzz" Shackelford, Jr., a North Carolina tobacco grower as saying, "FDA Commissioner Dr. David Kessler's attempt to gain power over cigarettes suggests that he is more interested in a political and personal agenda than in the mission which Congress has defined for the FDA").


41. See Complaint, supra note 23, at 1.

42. The Senate Campaign Spending Limits and Election Reform Act of 1995: Hearings on S. 1219 Before the Senate Rules Committee, 104 Cong., 2nd Sess. (1996) [hereinafter Hearings] (statement of Ann McBride, President, Common Cause). "Soft money" is money given to nonfederal accounts where the amount of the contribution is unlimited. Penny Loeb et al., The Greening of America. Candidates Will Spend More Money Than Ever to Buy Votes, U.S. NEWS & WORLD REP., Feb. 12, 1996, at 34, 35. For example, individuals can only give up to $1,000 to a presidential campaign and $20,000 to a national party, but can give an unlimited amount to a nonfederal account for party building and voter registration drives. Id. Tobacco companies "Phillip Morris . . . and Brown & Williamson were among the top soft-money givers to the Republicans in the first half of 1995." Id. This soft-money is important because it buys access to decision makers. Id. "Political Action Committees" ("PACs") are formed by those with particular industry interests. Michael Lind, Me and Mrs. Smith: Will the GOP betray political reform?, NEW REPUBLIC, Feb. 5, 1996, at 16. The first large and influential PAC was organized by the AFL-CIO, and was interested in labor issues, but PACs have expanded to include those with corporate interests and certain ideologies. Id. There are now more than 4,000 PACs compared with only 600 in 1974. Id.

43. Hearings, supra note 42.
when the new FDA rule becomes effective, Congress will not fund the program, effectively killing the rule.\textsuperscript{44} Already, thirty-two senators, including those from tobacco growing states, have sent letters to the agency opposing the new FDA rule.\textsuperscript{45}

On the other side of the issue, anti-smoking activists praise the new FDA rule.\textsuperscript{46} These activists state that the new FDA rule is not a first step in a total ban of tobacco, and that the industry is merely using this argument to cause opposition to the new FDA rule.\textsuperscript{47} In fact, twenty-eight attorneys general, who were looking for a plan to combat the six billion

\begin{quote}

It didn't take long for the budget-cutting efforts of House Republicans to be felt at OSHA's [Occupational Safety and Health Administration] offices a few blocks away from the Capitol. The cuts they have made at the agency are part of a concerted effort to scale back Washington's regulatory reach. And they illustrate the kind of de facto deregulation that is changing how many rule-making agencies do their jobs, even as broader regulatory reform legislation remains stalled in Congress . . . . For years, congressional Republicans have made no secret of their dislike for OSHA, portraying it as a nibbling bureaucracy that inconsistently applies the law or, worse, as a regulatory bully.


Under pressure from congressional Republicans, budget cuts and the Clinton administration's efforts to cut red tape, the federal agencies charged with protecting Americans from unhealthy workplaces, pollution and unsafe products have begun to fundamentally change the way they do their job. Bureaucrats who for a generation dictated enormous volumes of rules are more readily compromising with the industries they regulate. Others are finding that they don't have enough money to enforce rules or conduct inspections. Still others find themselves ordered practically overnight to reverse longstanding policy. The result is a de facto deregulation of American business that marks a significant departure from decades of government policy.

\textit{Id.}

\textsuperscript{45} \textit{FDA Proposed Rule on Tobacco Scrutinized As Comment Period Ends}, \textit{BNA Health Care Daily}, Jan. 3, 1996, \textit{available in LEXIS}, Nexis Library, BNA File. The two Senators who signed the letter that are from tobacco growing states are Jesse Helms, Republican from North Carolina, and Wendell Ford, Democrat from Kentucky. \textit{See also} O'Reilly, \textit{supra} note 2, at 221-3.

The decision by Congress to micro-manage the issue of tobacco products is extremely inconsistent with its delegation of power. This decision cannot be explained in terms other than the financial or electoral rewards for individuals in Congress to protect the particular industry involved. . . . \[T]he system which strives to prevent consumer cancer but ignores tobacco has no consistent rationale with which to explain its glaring omission.

\textit{Id.} at 222.

\textsuperscript{46} Levy, \textit{supra} note 36, at D1.

\textsuperscript{47} \textit{Id.} (discussing the remarks of Scott Ballin, Chairman of the Coalition on Smoking or Health).
dollar annual advertising and promotional campaigns of the tobacco industry, requested that the FDA propose regulation of tobacco with regard to adolescents and children.\(^{48}\)

In announcing the new FDA rule, President Clinton\(^{49}\) said that he does not want to ban smoking for adults. According to the President, information showing that 3,000 young people begin to smoke cigarettes every day was a compelling reason to regulate the industry because young people are more vulnerable and susceptible to the temptation to smoke.\(^{50}\) However, President Clinton also stated that he prefers a more permanent, legislated solution to this issue, rather than a regulatory one via the FDA.\(^{51}\)

Thus, the true issue regarding the propriety of the new FDA rule is not whether teens should smoke. After all, both sides of the controversy agree that smoking at a young age is harmful; rather, the issue is whether current law permits the regulation of cigarettes. To uncover the current law, this Comment looks at FDA rulemaking procedures, the legislative history of the FDCA pertaining to devices, and case law interpretation of the FDCA.

II. AGENCY PROPOSED RULEMAKING PROCESS

FDA rulemaking is governed by the FDCA, the Administrative Procedures Act ("APA"),\(^{52}\) and agency regulations.\(^{53}\) The APA and agency regulations are procedural in nature, but the FDCA is substantive.\(^{54}\) The FDCA gives the FDA authority to promulgate regulations for the efficient enforcement of the statute,\(^{55}\) thereby allowing rulemaking, provided

\(^{48}\) Id. See also John Schwartz, Group Targets Tobacco Use Among Youth Association-Backed Center Shares Cause With FDA, WASH. POST, Feb. 12, 1996, at A17 (a new 30 million dollar National Center for Tobacco-Free Kids was created by anti-smoking activists to find ways to keep children from smoking. The group plans to spend money to create and place advertisements intended to promote the control of tobacco products, draw-together disparate anti-smoking groups, and combat the six billion dollars the tobacco industry spends each year to market tobacco products.).

\(^{49}\) Protecting Young People From "the Awful Dangers of Tobacco," WASH. POST, Aug. 11, 1995, at A14.

\(^{50}\) Id.

\(^{51}\) Id.


\(^{54}\) "As a general rule, laws which fix duties, establish rights and responsibilities among and for persons, natural or otherwise, are 'substantive laws' in character, while those which merely prescribe the manner in which such rights and responsibilities may be exercised and enforced in a court are 'procedural laws.'" BLACK'S LAW DICTIONARY 1203 (6th ed. 1990).

the agency follows the APA and agency regulations. The APA gives basic requirements for all agencies to follow in promulgating regulations. The APA criteria for rulemaking are less specific than the agency regulations, but generally require publication of proposed rules in the Federal Register and a period for the submission of written comments or views by any interested party.

According to agency regulations, the FDA "Commissioner may propose and promulgate regulations for the efficient enforcement of the laws administered by FDA whenever it is necessary or appropriate to do so." Agency regulations require the publication of any proposed rules in the Federal Register and allow public comment for sixty days. The Commissioner may shorten this period to no less than ten days or extend the comment time for good cause. An extension is made when any interested party submits a written request to the FDA Commissioner stating the grounds for the extension. The Commissioner may then grant or deny the extension of time. Any extension of thirty days or more will be published in the Federal Register. Once the comment period ends, the Commissioner reviews the entire administrative record for the rule, including all comments, and then will either "terminate proceedings, issue a new proposed rule, or promulgate a final regulation."

The proposed FDA rule pertaining to restriction of cigarette sales to children and adolescents was published in the Federal Register on August 11, 1995. The initial Federal Register notice stated that the period for written public comments and recommendations was open until November 9, 1995. Numerous tobacco companies and the Food Marketing Institute, however, requested that the FDA extend the comment period on the grounds that some of the data referenced in the proposed FDA rule

57. 5 U.S.C. § 553(b)-(c).
59. 21 C.F.R. § 10.40(b). A notice of proposed rulemaking published in the Federal Register must contain certain information, such as the nature of the action, a summary of the substance of the rule, and the name and number of an agency contact. Id. § 10.40(b)(1)(ii), (iii), (v).
60. Id. § 10.40(2).
61. Id. § 10.40(b)(3).
62. Id. § 10.40(b)(3)(i).
63. Id. § 10.40(b)(3)(ii).
64. Id. § 10.40(b)(5)(c).
65. Proposed Rule, supra note 2, at 41,314.
66. Id.
was not available for review. In addition, the regulatory issues were complex and controversial, therefore more time was needed to prepare comments. In response, the FDA extended the comment period to January 2, 1996. On August 28, 1996, the FDA issued the new FDA rule, however, most provisions are not effective until August 28, 1997.

III. LEGISLATIVE HISTORY OF THE "DEVICE" DEFINITION

The FDA promulgated its new rule under the Federal Food, Drug and Cosmetic Act ("FDCA"). The FDCA allows the FDA to regulate items that fall within the jurisdiction of the Act by regulating the sale, distribution, and use of the item. Failure to comply with regulations can result in civil and criminal penalties. Generally, the FDCA prohibits the introduction, delivery, misbranding, and adulteration of any food, drug, device, or cosmetic in interstate commerce. No provision of the FDCA specifically mentions cigarettes or their regulation. The FDA has determined, however, that cigarettes fall within the FDCA jurisdiction as a "device" intended to affect the structure or function of the body. Thus,

---

67. Id. at 53,560.
68. Id.
69. Id.
70. Final Rule, supra note 2, at 44,396.
71. 21 U.S.C. § 301-393 (1994). “The Secretary, through the Commissioner, shall be responsible for executing this chapter.” Id.
72. Id. § 360(e).
73. Id. § 333. See also Gamerman, supra note 19, at 810 (If an article is a device, it is subject to comprehensive FDA regulation. Failure to comply with regulations can result in civil and criminal penalties.).
75. 21 U.S.C. §§ 301-93.
76. Final Rule, supra note 2, at 44,396. “Device” is defined as:
   an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is —
   (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
   (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
   (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principle intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principle intended purposes.
because cigarettes are not specifically mentioned in the language of the FDCA, a deciding court would have to look to legislative history to determine whether Congress intended to include cigarettes within the "device" definition of the FDCA.77

The current definition of a device under section 20178 of the FDCA developed through an evolutionary process of amendments, primarily in 1938, 1976, and 1990, in response to prevailing societal problems.79 Although the term "drug" was defined in the Federal Food and Drug Act of June 30, 1906, there was no separate definition of "device."80 Congress was dissatisfied with the weakness of the 1906 Act, however, particularly the requirement for "knowing fraud" as a precondition of regulation.81 Congressional sponsors of new legislation wanted greater control over drugs that were injurious to health.82 Specifically, Congress wanted to address national problems such as the elixir sulfanilamide tragedy.83 More than one hundred people around the country were killed in that incident when a chemist for a well-known drug company developed and sold an elixir that was actually a deadly poison when ingested in recommended amounts.84

In 1938, Congress passed the FDCA which included a new definition of "device" that paralleled that of "drugs:"85

The term "device" . . . means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.86

---

77. See Gamerman, supra note 19, at 815. "The proper test of FDA's interpretation of its organic statute is whether its interpretation coincides with legislative intent; if that intent is ambiguous, then the issue is whether its interpretation is rational and consistent." Id.
78. 21 U.S.C. § 321(h).
82. O'REILLY, supra note 81, at § 13.02.
83. Id.
84. Id.
86. Id.
Congress included the definition for "device" in order to bring under the purview of the FDCA quack products that manifested a fraud on society. One product specifically mentioned in Congressional debate was a machine that diagnosed the consumer's illness with a spinning indicator that stopped randomly at appendicitis, meningitis, or some other ailment listed on the wheel.

The original FDCA definition of "device" was in place for nearly forty years, until Congress changed the definition to address defective medical products. The original "device" definition from the 1938 FDCA simply did not protect the public from fraudulent or unsafe medical products which were in abundance at the time. Congress was specifically concerned with The Dalkon Shield intrauterine contraceptive device which caused miscarriages and killed many women.

On May 28, 1976, Congress passed the Medical Device Amendments of 1976 which added regulations pertaining to medical devices and also amended the general definition of a "device" in section 201(h). The new "device" definition from the 1976 Act retained the "intended use" limitation in the FDCA, but added some new items to be considered devices, such as implants, in vitro reagents and items recognized in the official National Formulary or United States Pharmacopeia.

---

87. See Gamerman, supra note 19, at 817 n.67.
90. See Gamerman, supra note 19, at 820 n.89.
91. Id. at 820.
92. Id. at 857 n.89. Congress was also concerned with the number of deaths related to pacemakers. Id.
94. Id.
See Gamerman, supra note 19, at 824.
97. 90 Stat. at 539, 575.

The term 'device'... means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article including any component, part, or accessory which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes
Butt Out!!

In 1990, Congress again dealt with regulating medical devices and modified the general definition of “device” within section 201(h) of the FDCA. Congress passed the Safe Medical Devices Act of 1990 to address the Bjork-Shiley scandal involving heart valve prostheses that were improperly designed and manufactured, and could cause death. The Act changed the definition of the term “drug” by striking out the portion which said a device could not be a drug and also changed the “device” definition to clarify primary versus principal intended purpose. Thus, although Congress has changed the FDCA definition of “device” to include more items under its jurisdiction, each revision retained the “intended use” limitation in the definition.

In debate concerning the breadth of the FDCA, Congress repeatedly has been made aware that the FDA cannot assert jurisdiction over cigarettes absent health claims made by manufacturers. In fact, former FDA Commissioners have testified to Congress that “[c]igarettes and other tobacco products would be drugs subject to the Federal Food, Drug, and Cosmetic Act if medical claims are made for the product... [H]owever, cigarettes recommended for smoking pleasure are beyond the Federal Food, Drug, and Cosmetic Act.”

During debate over the FDCA and subsequent amendments, Congress knew that the definitions of drugs and devices could be difficult to interpret and at the same time, did not want the FDA to have authority that was too broad. Congress recognized that the FDA should restrain “it-
self and exercise no more authority than . . . necessary to protect the public." Congressman Rogers provided an explanation of Congress' position when he said:

What we have done is write a bill specific enough so that we do not turn over broad authority to the FDA and let them write regulations any way they want to. We have been specific because we believe Congress should write the law specifically. The committee does not intend to allow regulatory agencies to do anything they want to. Further, in the early 1960's, when the United States Surgeon General began investigating the health consequences of smoking, Congress passed the Federal Cigarette Labeling and Advertising Act ("Labeling Act") rather than amend the FDCA. The Labeling Act required that cigarette manufacturers place a warning label on each package of cigarettes and banned cigarette advertising from television and radio. Additionally, as recently as 1994, legislation was proposed in the United States House of Representatives to give the FDA regulatory authority over the "manufacture, sale, labeling, advertising, and content of tobacco products." The legislation was offered as an amendment to an Agriculture Department spending bill, but ultimately was not passed because the House Rules Committee prevented consideration of the amendment.

Thus, Congress has purposely limited device jurisdiction for the FDCA at the same time that it has recognized that cigarettes do not fall within the current statutes. This is well-established by the fact that the separation of power the FDA could regulate, "well nigh everything in creation." Id. at 816 n.59.

107. Id. at 822.
108. Id. There was fear that the FDA, like many other agencies, would extend jurisdiction beyond that originally given by Congress. Id. at 821-22.
111. See Burkhard & Despard, supra note 29, at 116 (citing to 15 U.S.C. § 1333 (1994)).
112. Move In Congress To Put Tobacco Under FDA Control, Pantagraph, June 14, 1994, at A1, available in LEXIS, Nexis Library, AP file. Congressman Dick Durbin, Congressman Mike Synar, and Congressman Ron Wyden offered the legislation as an amendment to the agriculture spending bill. Id. The legislation "would prohibit the FDA from banning tobacco . . . but would give FDA authority to regulate the manufacture, sale, labeling, advertising and content of tobacco products." Id.
113. Id.
114. Congress has delegated many health related tasks to administrative agencies in the past. O'Reilly, supra note 2, at 221. Delegation occurs mainly because the agencies have the technical expertise to resolve complicated health issues. However, the regulation of tobacco is one area where Congress has not delegated power. Id. This inconsistency in
rate Labeling Act was required for cigarettes and also by the introduction of legislation designed to bring cigarettes within the FDCA.\textsuperscript{115} The subsequent guides in determining whether cigarettes fall within the purview of the FDCA are judicial decisions.

IV. Definition of the “Device” Test

A. The Courts

The FDA has stated that jurisdiction over cigarettes is based upon the definition of “device,” specifically, upon the third prong of the definition which states that the product is intended to affect the structure or function of the human body.\textsuperscript{116} The courts focused on the meaning of the term “intent.” “Intent” describes a person’s “desire[] to cause consequences of his act, or [his belief] that the consequences are substantially certain to result.”\textsuperscript{117} Intent is separate from motive which “is what prompts a person to act.”\textsuperscript{118}

One of the first cases involving cigarette regulation was actually brought by the Federal Trade Commission (“FTC”) rather than the FDA.\textsuperscript{119} In \textit{Federal Trade Commission v. Liggett & Meyers Tobacco Co.},\textsuperscript{120} the FTC attempted to enjoin the dissemination of Chesterfield cigarettes as a drug\textsuperscript{121} under the Federal Trade Commission Act.\textsuperscript{122} The company’s advertising claimed that Chesterfield cigarettes “can be smoked by any smoker without inducing any adverse affect upon the nose, throat, and accessory organs of the smoker.”\textsuperscript{123} The term “drug” under the Federal Trade Commission Act had the same statutory defini-
tion as that of the FDCA. The United States District Court for the Southern District of New York examined whether cigarettes were intended to affect the structure or function of the human body. The court decided that legislative intent was the proper test for the case and found that legislators did not mean the phrase "intend to affect" to be all-inclusive. The court held that in construing its powers, an "agency must not exceed the bounds of its statute." Further, the court said that legislative history coupled with administrative interpretations lead to the conclusion that Congress, had the matter been considered, would not have intended cigarettes to be included as an article 'intended to affect the functions of the body of man' or in any other definition of 'drug.'

Also, there are two cases from the 1950's in which the government sought to regulate cigarettes as drugs based on manufacturer's intent under the FDCA. Although declining to apply the definition of "device" to cigarettes in these cases, the court holdings pertaining to intent are relevant because the definitions for "drugs" and "devices" are essentially parallel and the device definition was added for semantic reasons. Thus, reviewing intent under the "drug" definition is the same as that under "device" definition.

In the first case, United States v. 46 Cartons, More Or Less, Containing

124. See Burkhard & Despard, supra note 29, at 118.
126. Id.
127. Id.
128. Id.
130. United States v. An Article of Drug ... Bacto-Unidisk, 394 U.S. 784, 797 (1963). In the 1950's when the cases concerning cigarettes as drugs were decided, the definition of drug was:

(1) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
(4) articles intended for use as a component of any article specified in clause (1), (2) or (3); but does not include devices or their components, parts, or accessories.

Federal Food, Drug and Cosmetic Act, Pub. L. No. 717, 52 Stat. 1040, 1041 (1938) (emphasis added). The term device included: "instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." Id.
Fairfax Cigarettes, the company had a leaflet accompanying the cigarettes that suggested that the cigarettes were effective in “preventing respiratory diseases, common cold, influenza, pneumonia, acute sinusitis, acute tonsillitis, scarlet fever, whooping cough, measles, meningitis, tuberculosis, mumps, otitis media (middle ear infection), [and] meningopneumonitis psittacosis (parrot fever).” The United States District Court of New Jersey considered the manufacturer’s representations of the product and pronounced that there is an indication that the item was intended for the cure, mitigation, treatment, or prevention of disease; thus, the item is a drug within the meaning of the Act. It is clear that the manufacturer’s representations of the product are determinant of intent for the “drug” test under the FDCA. Thus, the district court held that absent intent on the part of the manufacturer, the “drug” test is not met.

The second case pertaining to FDA jurisdiction over cigarettes was also in the United States District Court of New Jersey and took place six years later. In United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, the manufacturer claimed that the Trim Reducing-Aid cigarettes were effective in the reduction of body weight of the users and were safe for use by human beings. In reviewing whether a cigarette was a drug, the district court again considered the intent of the manufacturer. It concluded that because tartic acid was added to the cigarette and the “[c]laimant readily concede[d] that its product [was] intended to affect the structure and functions of the human body by reducing the appetite for the ingestion of food and thereby achieving a reduction in the body’s weight,” the product was a drug.

Thus, in these two cases involving the regulation of cigarettes, the courts established that the test for intending to affect the structure or function of the human body was to look at the manufacturer’s representation. Neither of these cases were challenged or appealed.

One of the few cases reaching the United States Supreme Court on the

132. Id. at 337.
133. Id.
134. Id.
135. Id.
137. Id.
138. Id. at 848-49.
139. Id. at 851.
issue of the definition of drugs and devices under the FDCA, was United States v. An Article of Drug . . . Bacto-Unidisk. There the Court looked at legislative history as a guide to its decision. In Batco-Unidisk, an antibiotic sensivity disc, which was used as a screening device in determining the proper antibiotic drug to administer to patients, was condemned on the assumption it was a drug, and therefore, subject to premarket approval. The United States District Court for the Eastern District of Michigan found that the disc was not a drug and the United States Court of Appeals for the Sixth Circuit affirmed.

After granting certiorari, the Supreme Court reversed the Sixth Circuit and held that the disc was a drug within the meaning of the FDCA. Here, the Court first looked at the language of the statute to determine whether the discs were drugs or devices. The Court, however, found that the statutory language was insufficiently precise, so it looked at statutory purpose. The Court concluded that, "legislative history, read in light of the statute's remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as is possible to the types of items Congress suggested in debates, such as electric belts, [and] quack diagnostic scales." Thus, the Supreme Court limited the definition of a device to items where there is either intent on the part of the manufacturer or where Congress has expressly named the article.

Relying on this prior case law, a citizen petition was filed in 1977 with the FDA requesting that the agency regulate cigarettes as a drug or device. The FDA denied the petition and suit was filed in the United States District Court for the District of Columbia in Action on Smoking and Health v. Califano. The district court granted summary judgment because it found the FDA was consistent in its position that cigarettes

140. 394 U.S. 784 (1969). The court held that antibiotic sensitivity disc is a drug per the FDCA. Id. at 800.
141. Id. at 799.
142. Id. at 785.
143. Id.
144. Id. at 800-01. "[W]e are supported in the decision to uphold the FDA's determination that the sensitivity discs fall under the coverage of the Act and specifically under the drug provision." Id. at 800.
145. Id. at 789.
146. Id. at 799.
147. Id. at 799-800.
149. Civ. No. 78-338 (D.D.C. Jan. 16, 1976), cited in Harris, 655 F.2d at 237. This case was filed on March 1, 1978 subsequent to Action on Smoking's request being denied by the FDA. Harris, 655 F.2d at 237.
were not a drug. The district court stated that the FDA Commissioner rejected the plaintiff's request to have the FDA assert jurisdiction over cigarettes because the FDA has had a "consistent position that cigarettes will not be deemed a drug unless health claims are made by the vendors." In denying the citizen petition, the FDA Commissioner pointed out that jurisdiction over cigarettes could not be predicated upon evidence of a serious health hazard. Rather, "the FDA has asserted jurisdiction over cigarettes only when health claims were made by the vendors or manufacturers." Further, the Commissioner of the FDA stated that "labeling or banning cigarettes is a step that can be take[n] only by the Congress. Any such move by the FDA would be inconsistent with the clear congressional intent."

An appeal was filed with the United States Court of Appeals for the District of Columbia Circuit in Action on Smoking and Health v. Harris. The Court of Appeals agreed with the FDA and district court, holding that the test used to determine what falls under the FDCA jurisdiction as a device is vendor's intent. The court went on to say that vendor intent can be established "based upon subjective vendor claims or objective evidence such as labeling, promotional materials, advertising," or other relevant sources. The appeals court added a caveat to the test, however, that when vendor intent is not shown subjectively or objectively, consumer intent can be used if the evidence "is strong enough to justify an inference as to vendors' intent." The burden of showing that vendor intent is derived from consumer use is higher than showing intent from vendor claims. To meet the higher standard, "consumers must use the product predominantly—in fact nearly exclusively—with the appropriate intent before [vendor] intent can be inferred." However, the

---

150. Harris, 655 F.2d at 237.
151. Id. at 239.
152. Id. In the Commissioner's denial letter he cited the support for his health claim using both United States v. 46 Cartons, More Or Less, Containing Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953) and United States v. 354 Bulk Cartons... Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959). Harris, 655 F.2d at 239 n.7.
153. Harris, 655 F.2d at 239.
154. 655 F.2d 236 (1980).
155. Id. at 239.
156. Id. See also Hanson v. U.S., 417 F. Supp. 30, 35 (D. Minn.), aff'd, 540 F.2d 947 (8th Cir. 1976) ("It is well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.").
157. Harris, 655 F.2d at 239.
158. Id. at 239-40.
court ruled that the plaintiff "did not establish, and arguably cannot establish, the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or any function of the body.'" The Harris court concluded that Congress, not the judiciary, has authority to broaden the statute to incorporate cigarettes; this holding was not challenged and has not been overturned in subsequent cases.

Thus, from the early 1950's through 1980, federal district courts, courts of appeal, and the Supreme Court have stated the "intended use" test pertaining to cigarette regulation under the FDCA is determined by looking at the vendor's intent. In 1989, the United States District Court for the Central District of Utah agreed that "whether a product is a device turns solely on the product's intended use." In United States v. 22 Rectangular or Cylindrical Finished Devices, the district court considered the jurisdiction of the FDA over a sterilization device under the

159. Id. at 240.
160. Id. at 243.
161. See U.S. v. Two Plastic Drums, More or Less . . . Black Currant Oil, 761 F. Supp. 70 (C.D. Ill. 1991), aff'd, 984 F.2d 814 (7th Cir. 1993). Here the United States District Court for the Central District of Illinois was confronted with the issue of whether two drums of black currant oil were food additives pursuant to the Federal Food, Drug and Cosmetic Act. Id. at 71. The court determined that the proper test for the definition of a food additive was (1) whether the oil was intended to be used as a component of food, and (2) whether the oil is regarded as safe within the meaning of the statute. Id. The court, using the "intent test" from Action in Smoking v. Harris, said intent was determined by examining "a wide range of evidence, including the vendor's stated intent, actual use of the product, consumer use of the product, product labeling, and product marketing." Id. at 72. The court held that the oil was not a food additive because the company did not claim the oil was a food additive. Id. at 74. See also American Health Products Co. v. Hayes, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), aff'd, 744 F.2d 912 (2d Cir. 1984) (The United States District Court for the Southern District of New York, in determining whether starchblockers was a food, drew on the language of Harris. The court looked at the phrase "intent to affect the structure or function of the human body" and determined that under Harris, to determine intent, one must look at specific marketing representations of the manufacturer.). See also E.R. Squibb & Sons v. Bowen, 870 F.2d 678 (D.C. Cir. 1989). The United States Court of Appeals for the District of Columbia Circuit reviewed the statutory definition of a drug as it pertained to the product Mysteclin. Id. at 682. The court used the language of Harris to reiterate that Congress intended to limit the definition of intent to items that "purport literally to change the physical structure of the body." Id. at 683.

162. See also O'Reilly, supra note 2, at 231 (stating that both the United States District Court for the District of New Jersey in United States v. 46 Carton . . . Fairfax Cigarettes and the United States Court of Appeals for the District of Columbia Circuit in Action on Smoking v. Harris, support the holding that without a specific health claim by the manufacturer, cigarette promotion for normal smoking use does not qualify cigarettes as a drug).

164. Id. at 1159.
FDCA. \textsuperscript{165} Analogous to the United States Court of Appeals for the District of Columbia Circuit in \textit{Harris}, the district court held that objective intent is shown by product labeling, advertising, or written statements relating to the product’s distribution and the product’s use. \textsuperscript{166}

Therefore, the test is clear. No matter what product is deemed a device under the Federal Food, Drug and Cosmetic Act, the vendor’s intent determines whether the item falls within the jurisdiction of the Act.

The courts have used the “intended use” test to reject the classification of other products as devices. \textsuperscript{167} In \textit{United States v. An Article of Drug . . . Ova II}, \textsuperscript{168} the United States District Court for the District of New Jersey found that a home pregnancy test was neither a drug nor a device because pregnancy is not a disease and the kits were not intended for use in affecting the woman’s body. \textsuperscript{169} \textit{Ova II} is especially relevant to FDA jurisdiction over cigarettes in that Congress and the FDA wanted to regulate home pregnancy tests, but could not do so under the FDCA. Congress overruled the \textit{Ova II} case by passing the Medical Device Amendments of 1976 which amended the definition of device to include products such as the Ova II. \textsuperscript{170}

\textbf{B. Agency Regulations}

The FDA has codified its interpretation of “intended use” in a similar manner as the courts. The agency has stated that “[t]he words ‘intended use’ . . . refer to the objective intent of the persons legally responsible for the labeling of devices.” \textsuperscript{171} The regulations further state that the objective intent can “be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.” \textsuperscript{172} The agency, however, added that intent can be shown by circumstances where persons legally responsible for the product have knowledge that the product is “used for a purpose for which it is neither labeled nor advertised.” \textsuperscript{173} This showing of intent has not been tested in the courts.

---

\textsuperscript{165} Id. at 1161.
\textsuperscript{166} Id. at 1165.
\textsuperscript{167} See Gamerman, \textit{supra} note 19, at 821. “FDA success with its regulatory strategy of expansion ended in 1975, when it argued that a home pregnancy test kit was either a drug or a device and failed at both.” \textit{Id}.
\textsuperscript{169} Id. at 664-65.
\textsuperscript{170} See Gamerman, \textit{supra} note 19, at 857 n.233.
\textsuperscript{171} 21 C.F.R. § 801.4 (1995).
\textsuperscript{172} Id.
\textsuperscript{173} Id.
Having addressed the legislative history of the FDCA, relevant case law, and agency regulations limiting the definition of a device based on the intent of manufacturers, the next issue is whether cigarettes meet this burden.

V. CIGARETTES IN LIGHT OF THE "INTENDED USE" TEST

A. FDA's Jurisdiction Analysis

In promulgating its proposed regulation of cigarettes, the FDA took the unprecedented step of preparing and publishing a legal analysis of its position. The FDA analysis states that the definitions of "drug" and "device" are parallel and that the agency has jurisdiction over cigarettes if they are intended to treat a disease or to affect the structure or any function of the human body. The FDA further stated that it was asserting jurisdiction over cigarettes because cigarette "manufacturers intend to market and distribute products that affect the structure or function of the [human] body within the meaning of the [FDCA]."

The FDA contends that the language of the FDCA supports an objective intent standard that includes statements showing the vendor's actual purpose in marketing the product or refuting their claims concerning intended use. However, in its analysis, the FDA takes the objective intent test to a new level which has not yet been addressed by the courts. The FDA asserts that a seller's awareness of how a product is actually used and affects the structure or function of the body is enough to meet the intent test, regardless of how the product is labeled or advertised. Notably, the FDA's interpretation is based on regulatory policy decisions, not court decisions. The agency's own administrative decisions that are unchallenged in the courts are not sufficient to show that these regu-

175. Id. at 41,463.
176. Id. at 41,464.
177. Id. at 41,473.

The language of the FDCA supports an objective standard that allows consideration of information about the foreseeable uses of the product for pharmacological purposes, as well as any statements or actions by the vendor that might show the vendor's actual purpose in marketing a product, or refute the vendor's claims regarding the product's intended use.

178. Proposed Rule, supra note 2, at 41,474.
179. Id. at 41,475 (citing a rule on vaginal products for over-the-counter use, the FDA said that the mere presence of a pharmacologically active ingredient could make a product a drug even in the absence of explicit claims).
lations are within the FDA's authority. The FDA goes on to state that although a cigarette manufacturer's stated purpose may be to provide taste or smoking pleasure, under the objective standard, intent may be shown by the foreseeable consequences of consumers' use of cigarettes. The FDA claims that consumer use is demonstrated by research conducted since the 1980's, which shows that nicotine is addictive and dependance-producing.

The FDA also used segments of case law that seemingly supported its argument, but a review of the entire case reveals a lack of support. For example, the FDA analysis cites Action On Smoking and Health \(\text{ASH} \) v. \text{Harris}\ which notes that "the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or function of the body of man,' would be sufficient by itself to establish that cigarettes are drugs within the meaning of the FDCA." The precise language used by the United States Court of Appeals for the District of Columbia, however, states "ASH did not establish, and arguably cannot establish, the near-exclusivity of consumer use of cigarettes with the intent 'to affect the structure or any function of the body of man.'" Thus, the court decided that none of the consumer use evidence concerning cigarettes would meet the intent test.

Another assertion made by the agency is that consumers use cigarettes to obtain the pharmacological effects of nicotine. The FDA cites studies that show a large portion of consumers use cigarettes for relaxation, weight control, or reduction of negative feelings. These uses are not

---

181. Proposed Rule, supra note 2, at 41,483.
182. Id.
183. 655 F.2d 236 (D.C. Cir. 1980).
184. Proposed Rule, supra note 2, at 41,480.
185. \text{Harris}, 655 F.2d at 240.
186. Proposed Rule, supra note 2, at 41,490.

Although 32 million of the estimated 46 million American smokers reportedly want to quit, only 2% to 3% successfully kick the habit each year. At the same time, more females are taking up smoking, and are projected to outnumber male smokers by the year 2000. Why this backslide, even after lung cancer has topped breast cancer as a killer of women?

The answer in part is that women are dying for a smaller dress size. The five-pound to 10-pound weight gain that accompanies quitting is seen by some as too high a price to pay in our fat-phobic culture.

From the earliest cigarette advertising ("Reach for a Lucky instead of a sweet")
suggested by the manufacturer, however, and therefore do not meet the true test needed to assert jurisdiction.\textsuperscript{188}

A third argument made by the FDA is that tobacco manufacturers know that nicotine is addictive and that consumers use the product for the addictive effect.\textsuperscript{189} The FDA obtained research from the tobacco companies showing that industry researchers and executives had knowledge that cigarettes act as a drug and that consumers use cigarettes to obtain the addicting affect of nicotine.\textsuperscript{190} The FDA has also found that "tobacco manufacturers have conducted numerous studies to identify the dose of nicotine that will elicit the pharmacological effects sought by the products' users."\textsuperscript{191} Essentially, the FDA claims that cigarettes are devices because:

\begin{quote}
[t]he primary purpose of parts of the cigarette, each of which is a device or device component within the Act's meaning, and the cigarette itself, a consciously engineered instrument, is to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed.\textsuperscript{192}
\end{quote}

Even though the FDA purported in the proposed rule to have jurisdiction based on the arguments mentioned above, the FDA realized that its analysis was vulnerable. If the manufacturer did not objectively state their intent on cigarette packages or in advertising, the FDA knew it was on shaky ground in asserting that general awareness and foreseeable consumer use were enough for jurisdiction. The final FDA rule added a new requirement, not contained in the proposed rule, that cigarette and smokeless tobacco packages state, "Nicotine-Delivery Device for Persons 18 or Older."\textsuperscript{193} This is the ultimate in hypocrisy—the FDA says they have jurisdiction regardless of what advertising and packaging materials say; but, just in case that does not work, it will impute intent upon the manufacturer, distributor and retailer by requiring the product state it is a nicotine-delivery device.

---

\textsuperscript{188} Proposed Rule, supra note 2, at 41,576 n.145.
\textsuperscript{189} Id. at 41,491.
\textsuperscript{190} Id. at 41,499.
\textsuperscript{191} Id. at 41,504.
\textsuperscript{192} Id. at 41,522.
\textsuperscript{193} Final Rule, supra note 2, at 44,617, section 897.25.
B. FDA's Position Versus Legislative History and the Courts

According to the courts, the first step in testing whether an item is a device is to look at the plain meaning of the statute.\(^\text{194}\) If the statute is not determinative, then the court turns to legislative history and case law precedent.\(^\text{195}\) Applying this test, the courts cannot find that cigarettes are devices regardless of the evidence of health risk presented by the FDA.

The FDA statute is clear: an item is not considered to be a device unless the device is "intended to affect the structure or any function of the body of man or other animals."\(^\text{196}\) As Judge Kaufman of the United States District Court for the Southern District of New York stated, however, "[s]urely the legislators did not mean [this phrase] to be all-inclusive as a literal interpretation of this clause would compel us to be."\(^\text{197}\) For if this were the case, then the FDA could regulate "well nigh everything in creation."\(^\text{198}\) Thus, the issue is what Congress meant by the terminology of "intended to affect."

In examining the legislative history of the FDCA, Congress clearly defined intent to mean the intent of the manufacturer in its representation of the product.\(^\text{199}\) Congress also specifically delineated the type of products it had in mind when it developed the device definition. For example, Congress envisioned quack products such as medical scales that provide disease diagnosis to be included in the definition of device and subject to FDA regulation.\(^\text{200}\)

Indeed, Congress itself recognized the limitations of the FDCA pertaining to cigarettes. There was no attempt to impose cigarette labeling and advertising through the FDCA\(^\text{201}\) because Congress recognized that separate legislation was necessary to promulgate labeling and advertising

\(^{194}\) \textit{Bacto-Unidisk}, 394 U.S. at 1415.
\(^{195}\) \textit{Id.}
\(^{197}\) \textit{Liggett & Meyers Tobacco Co.}, 180 F. Supp. at 576.
\(^{198}\) \textit{See Gamerman, supra} note 19, at 812 n.59 (quoting Representative Collus).
\(^{199}\) \textit{Supra} note 99.
\(^{200}\) \textit{See Gammerman, supra} note 19, at 819.
\(^{201}\) \textit{See supra} notes 109-10 and accompanying text.
standards for cigarette packages.\textsuperscript{202} Prior FDA Commissioners and FDA rulings have stated that cigarettes are not within the purview of the FDCA and that any attempt to regulate cigarettes under the FDCA would violate legislative intent.\textsuperscript{203} Finally, in 1994, legislation was introduced to bring cigarettes within the FDCA, but the measure failed.\textsuperscript{204}

Moreover, the weight of judicial opinion has determined that cigarettes do not fall within the FDCA device jurisdiction absent representations of a claim from the vendor or manufacturer that it affects the structure or function of the human body. In the four cases\textsuperscript{205} previously discussed concerning cigarette regulation, the courts did not find that cigarettes were a drug or device: (1) absent a showing that the manufacturer intended to affect the structure or function of the human body; or, (2) without evidence of the near-exclusivity of consumer use of cigarettes from which manufacturer or vendor intent can be inferred.\textsuperscript{206} It is obvious that cigarette companies today no longer claim that their products do anything more than provide taste or smoking pleasure,\textsuperscript{207} and the test to show near-exclusive consumer use as intended by the manufacturer is almost impossible to establish.\textsuperscript{208}

The only issue that has changed within the FDA from the time of the FDCA's enactment to today is that more studies have been conducted regarding the health risks of smoking.\textsuperscript{209} Although these new studies may make cigarette regulation morally compelling or even "politically correct," they do not meet the intent test for a device under the FDCA. As stated by one former FDA Commissioner, FDA jurisdiction over cigarettes cannot be predicated solely upon evidence of a serious health hazard.\textsuperscript{210}

\begin{itemize}
\item \textsuperscript{202} Id.
\item \textsuperscript{203} See supra notes 103-4 and accompanying text.
\item \textsuperscript{204} See supra notes 11-12 and accompanying text.
\item \textsuperscript{206} See supra notes 118-60 and accompanying text.
\item \textsuperscript{207} Proposed Rule, supra note 2, at 41,483.
\item \textsuperscript{208} Harris, 655 F.2d at 240.
\item \textsuperscript{209} See supra notes 177-82 and accompanying text.
\item \textsuperscript{210} Harris, 655 F.2d at 239 (quoting statement of Mr. Donald Kennedy, former Commissioner of the FDA).
\end{itemize}
VI. Conclusion

Although the goal of regulating cigarette availability to three million adolescent smokers and the three thousand that begin each day is noble, the current law does not provide a mechanism for that type of regulation. Since the promulgation of the Pure Food and Drug Act of 1906, Congress has constantly amended FDA regulations to deal with challenges that were not previously covered within the FDCA jurisdiction. Actions that took on a national character, such as the elixir tragedy, the Dalkon Shield scare, and the Bjork-Shiley scandal were all difficult for the public to accept, but regulation under the statutes in effect at the time of these incidents was insufficient to bring these products within the FDCA. Congress responded by promulgating new regulations.

Restriction of cigarette sales falls into the same historical category. Although regulation of cigarettes to those under eighteen years old is important, the current law does not provide the FDA with the jurisdiction to regulate these products. Review of legislative history, case law, and prior FDA statements clearly shows that cigarettes were not meant to be covered by the FDCA. Case law and legislative history show that the determination of FDA jurisdiction over devices turns on vendor or manufacturer intent.

Vendors and manufacturers of cigarettes have not demonstrated the intent required to place cigarettes within the jurisdiction of the FDA. In fact, they have not made any claims about cigarettes beyond saying that they provide taste or smoking pleasure. Although this may constitute a clever evasion of existing FDA jurisdiction on the part of the tobacco industry, the fact remains that such limited claims by the vendors and manufacturers are simply not sufficient to meet the FDCA jurisdictional requirements. If the reduction in cigarette smoking by adolescents and children is truly a national priority, then Congress must act to pass new legislation or amend the current FDCA.

Margaret A. Boyd, CPA