June 30, 1997

Tobacco Meeting – Access Advertising and Labeling Group

* ↓ smoking by kids by 50% over a 7 year period.
  - Is 18 the right age? Does the FDA have the authority to raise the age to 21? FDA should have the flexibility to raise it in the future. Flex. would be for other things, too.

Access – you can only buy cigs. if you're 18 or more, in a face-to-face sale (w/ ID)
  → ban vending machines
  → behind the counter (give a message that this is a special product) – no self-service displays

* COMPLIANCE IS KEY HERE!

$300 million to enforce the access provisions — you need to focus on the retailers.

Whose responsibility is it to bring stores into compliance. Who owns the sale?

The ability to revoke a retailer's license is valuable — enforcement, etc. is hard. Penalties won't work for chain stores — FDA should have alot of discretion on the amt. of the penalty.

Licensing people is going to be a huge admin. burden

p. 26 2d bullet — Justice will come up w/ a list of preemptive rules — are we complementing St. rules?

Access rules are essentially non-preemptive. Sts. can ask for exceptions and come up w/more onerous rules.

Are there access provisions we wish were in here?
think about this

Advertising in black & white text only, except in mature magazines and adults-only facilities.

Bans on promotional merchandise and billboards.

Will they agree to stay off the Internet. Make the Internet provision broader.

Direct, short warnings.

3 provisions that deal w/ low tar & light ads. – deception rec. these terms indicate these cigs. are healthier. Request for disclosure/disclaimer means they want to keep these cigs. & that the terms are effective advertising.

Ban on human/animal cartoon images in ads. – that leaves alot.

Ban on paying for product placements in movies. You need to have 1 paymt. process for consent. Also what is glamorizing? What is appealing to kids?

It's vague as to whether new healthier cigs. would be free of the ad restrictions.

There remains the 1st A question.

Labeling

There are the coloring warnings everyone has always wanted that will take up 25% of the pack.

- to add
  - put warning on front + back
  - black + white texts that conveys facts only

Education

The program appears to be unrestricted, but the funding seems to end after 8 years.

Proposed § 897.14(b) would prevent the retailer or an employee of the retailer from using any electronic or mechanical device in providing cigarettes or smokeless tobacco products to the purchaser. Requiring the retailer's employees to hand cigarettes or smokeless tobacco products to customers, after checking identification, has the practical effect of making access to such products more difficult for young people.

Proposed § 897.14(c) would prohibit the retailer or an employee of the retailer from opening a cigarette, cigarette tobacco, or smokeless tobacco product package to sell or distribute a cigarette, or cigarettes (often referred to as "singles" or "loosies") or any quantity of cigarette tobacco or of a smokeless tobacco product from that package. The agency is proposing this restriction because the primary market for "loosies" is children and adolescents. One California study found that 101 of 206 stores sold single cigarettes to minors and adults, and more stores sold single cigarettes to minors than to adults.[25] A survey in Nashville, TN, found that one-quarter of the stores sold single cigarettes.[26]

Additionally, the IOM noted that the sale of single cigarettes is attractive to children due to the low costs, could make children more willing to experiment with tobacco products, and that single cigarettes may be easier for children to shoplift.[27] Consequently, the IOM advocated banning the sale of single cigarettes.[28] Several States, including Mississippi, Oklahoma, South Dakota, Tennessee, and Washington, already restrict the sale of unpackaged tobacco products, and a working group of State attorneys general recently recommended that single cigarette sales be prohibited.[29]

4. Section 897.16—Conditions of Manufacture, Sale and Distribution

a. *Restrictions on product names.* Proposed 897.16(a) would prohibit prospectively the use of a trade or brand name for a non-tobacco product as the trade or brand name for a cigarette or smokeless tobacco product. The agency is aware of three brands of cigarettes that have used this strategy: Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes. In the final rule, the agency intends to exempt those brands that already use the trade or brand name of a non-tobacco product. This provision would complement the requirements in proposed subpart D (regarding labeling and advertising) that would reduce the appeal of cigarettes and smokeless tobacco products to people younger than 18. FDA believes that this provision is necessary to prevent manufacturers from circumventing the purpose of this proposed rule. As discussed elsewhere, the imagery associated with tobacco products is an important factor in why young people smoke. This provision would prevent tobacco manufacturers from capitalizing on the imagery of other consumer products by using the brand name of those products for tobacco products.

b. *Minimum package size.* Proposed § 897.16(b) would make 20 cigarettes the minimum package size for cigarettes. FDA selected 20 because the vast majority of cigarette packs in the United States contain 20 cigarettes. The proposal is intended to preclude firms from manufacturing packages that contain fewer than 20 cigarettes; these packs, sometimes referred to as "kiddie" packs, usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-size packs. (Young people, who generally have little disposable income, can be particularly sensitive to the price of cigarettes and may choose not to smoke as the price increases.[30]) Further, FDA is aware that Lorrilard Tobacco Company is offering a pack containing only 10 cigarettes of its Newport brand for sale and that another firm is experimenting with single cigarettes packed in individual tubes.[31]

One study showed that 56.3 percent of all 14 to 15 year old adolescent smokers surveyed in one urban area of Australia had purchased kiddie packs in the month prior to the survey, compared with only 8.8 percent of adult smokers. The study concluded, "If we fail to take strong action against the well targeted marketing methods of tobacco companies then the adolescent smoking rates recorded in this study are likely to remain high."[32]

The Nova Scotia Council on Smoking and Health reported that 49 percent of tobacco users in the sixth grade purchased kiddie packs of 15 cigarettes.[33] Another study of Australian schoolchildren reported that 30 percent of the 12-year olds preferred packages containing 15 cigarettes compared to 11 percent of the 17-year olds.[34] The Australian study, however, also reported that older children preferred cigarette packages that contained 25 cigarettes. Consequently, even though FDA has no evidence that firms intend to market cigarette packages that contain more than 20 cigarettes, the agency invites comment as to whether proposed § 897.16(b) should also state the maximum package size for cigarettes.

c. *Impersonal modes of sale.* Proposed § 897.16(c) would permit cigarettes and smokeless tobacco products to be sold only in a direct, face-to-face exchange between the retailer or the retailer's employees and the consumer. The proposal would prohibit specifically cigarette vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons.

i. *Vending Machines.* Studies indicate that a significant percentage of adolescents are able to obtain their cigarettes from vending machines and that such purchases occur regardless of locks, warning signs, and other restrictions. In 1994, CDC examined 15 recent tobacco inspection surveys to investigate underage sales to minors. While 73 percent of over-the-counter outlets made illegal sales to children and adolescents, 96 percent of vending machine sales were successful.[35]

A 1989 survey of 10th grade students in Minnesota indicated that 71 percent had purchased tobacco from vending machines.[36] Another 1989 report found that, in California, minors between the ages of 14 and 16 were able to purchase cigarettes from vending machines 100 percent of the time.[37] A 1992 study in Minnesota involving minors between the ages of 12 and 15 reported a 79 percent success rate in purchasing cigarettes from vending machines.[38] Children in the Washington, D.C. area, New York, Colorado, and New Jersey who were sent to purchase cigarettes from vending machines achieved 100 percent success rates.[39] The 1994 Surgeon General's Report examined nine studies on cigarette purchases from vending machines and found that underage persons were able to purchase cigarettes 82 to 100 percent of the time, with a weighted-average rate of 88 percent.[40]

Moreover, younger children use vending machines to purchase cigarettes more often than older adolescents. A study commissioned by the vending machine industry revealed that 22 percent of 13-year olds who smoke reported purchasing cigarettes from vending machines "often" compared with only 2 percent of 17-year olds. Twenty-two percent of 13- to 17-year-olds who smoke report purchasing cigarettes from vending machines "often"or "occasionally."[41]

FDA is aware that some jurisdictions have attempted to place locks, post warning signs, or restrict placement of vending machines to curtail access by young people. These efforts have had only limited success. A 1992 report examining vending machines in St. Paul, MN, indicates the limitations of requiring locking devices on vending machines. Despite a 1990 city ordinance requiring locking devices on vending machines, the rate of noncompliance by

merchants was 34 percent after 3 months and 30 percent after 1 year.[42] Underage buying increased from 30 percent 3 months after the ordinance had been enacted to 48 percent after 1 year.[43] Further, in those locations where locking devices were not placed on vending machines, underage buying was successful 91 percent of the time.[44] The study concluded that the use of locking devices on vending machines was less effective than a vending machine ban.

In 1994, CDC examined minors' access to cigarette vending machines in Texas. CDC noted that Texas law requires cigarette vending machine owners to post signs on their machines stating that sales to persons under the age of 18 are illegal. Despite these laws, minors between the ages of 15 and 17 successfully bought cigarettes from vending machines 98 percent of the time.[45]

Laws restricting placement of vending machines also appear to be ineffective. In one study, 14-year-old children were able to purchase cigarettes from vending machines 77 percent of the time despite State laws requiring the machines to be "in the immediate vicinity, plain view and control of an employee" and to bear signs concerning illegal purchases by minors.[46] Six surveys conducted in bars, taverns, private clubs, and liquor stores in five states found that minors were able to successfully purchase cigarettes in vending machines between 70 percent and 100 percent of the time, about the same rate as elsewhere.[47] In these surveys, the sales rates for "adult only" locations were similar to the rates for vending machine cigarette sales located elsewhere in the communities, indicating that restricting cigarette vending machines to places such as bars and liquor stores does not serve as an impediment to young people buying cigarettes. Additionally, according to the vending machine industry's research, 77.5 percent of all cigarette vending machines are already in "adult" areas such as bars, lounges, offices, college campuses, and industrial plants.[48] Therefore, it is likely that restricting cigarette vending machines to these areas would have a minimal effect on reducing sales to young people.

Studies also have shown that the use of vending machines by young people appears to be highest in those areas with strong access restrictions. In Santa Fe, New Mexico, where selling to minors was not against the law, vending machines were used 18 percent of the time by teen smokers.[49] By contrast, in Vallejo, California, where local merchants were actively requiring photographic identification, a survey found that teen smokers used vending machines 56 percent of the time (thereby making vending machines the most common source of cigarettes for young people.[50]) Therefore, if access restrictions are imposed such as requiring retailers to verify age, it is likely that vending machines may become an even more important source of cigarettes for young people.

Because minors, especially very young children who try smoking, rely on vending machines to purchase tobacco products, and because State and local laws restricting placement of, or requiring locking devices on, vending machines appear to be ineffective, the agency believes that the only practical approach to curtailing young people's access to such products is to eliminate vending machines and other impersonal modes of sale. Moreover, government enforcement of vending machine locking devices would entail a greater regulatory burden than enforcing a complete ban because authorities would need to ensure the devices were installed and operating properly, and that store employees were using them correctly.[51]

Consequently, proposed § 897.16(c) would require retailers to hand the product to the consumer. This proposed requirement would have the added effect of preventing persons younger than 18 from evading the proposed rule's age requirement by shifting their purchasing patterns from stores to vending machines or mail orders. Further, the agency notes that this aspect of the proposed rule is consistent with recommendations from the IOM,[52] the Public Health Service,[53] a working group of State attorneys general,[54] and findings by the Office of the Inspector General, DHHS.[55]

Finally, data from the vending machine industry show that cigarettes account for a small and declining portion of total vending machine revenues.[56] Using industry data from 1993, calculations indicate that daily sales from cigarette vending machines average approximately $10 per machine/per day.[57] In 1993, cigarettes comprised 4.7 percent of total vending machine revenues compared to 45.5 percent in 1960.[58] Between 1992 and 1993, vending machine revenues from cigarettes dropped 25 percent.[59] While total revenues from cigarette vending machines have been decreasing, revenues from most other product categories sold in vending machines, such as juice and other cold drinks, rose dramatically.[60] Further, the number of cigarette vending machines decreased significantly from 373,800 to 181,755 between 1988 and 1993.[61] Recognizing that more and more states and localities have enacted restrictions or bans on cigarette vending machines, machines are being produced that can be converted to dispense other products.[62] Furthermore, according to the National Automatic Merchandising Association, the association representing the vending machine industry, virtually no new shipments of cigarette vending machines have been made since 1990, compared with 32,065 shipments in 1976.[63]

ii. *Self-service displays.* Proposed § 897.16(c) would also prohibit self-service displays. Self-service displays enable young people to quickly, easily, and independently obtain tobacco products. This restriction is intended to prevent young people from helping themselves to tobacco products and to increase the direct interaction between the sales clerk and the underage customer. This restriction is also consistent with the 1994 IOM Report's recommendation. IOM reviewed surveys of grade school students in New York, and Wisconsin, and noted that many students—over 40 percent of daily smokers in Erie County, NY and Fond du Lac, WI—shoplifted cigarettes from self-service displays.[64] IOM found that eliminating self-service displays would make it more difficult for children to obtain cigarettes, especially if the children had to purchase the cigarettes from a store clerk (as would be required under this proposal). IOM further noted that "placing the products out of reach reinforces the message that tobacco products are not in the same class as candy or potato chips."[65]

A California study compared smoking prevalence among minors in five counties before and after the institution of ordinances prohibiting self-service merchandising (display and sale) and requiring only vender-assisted sales. The rate of tobacco sales to minors in the five counties dropped 40 to 80 percent and the decrease was still in evidence 2 years after the survey. Moreover, the study found that the ban on self-service significantly increased the checking of young purchasers' identification by retail clerks and, in particular, discouraged younger adolescents from attempting to buy tobacco.[66]

iii. *Mail-order sales.* In addition to prohibiting the sale of tobacco products in vending machines and the use of self-service displays, proposed § 897.16(c) would prohibit mail-order sales and redemption of mail-order coupons. Mail-order sales provide no face-to-face interaction to verify the age of the consumer. The current industry practice merely requires that the customer provide a birth date or check a box on

generally required either a physical invasion of the property or a denial of all economically beneficial or productive use of the property (other than real property), and have examined the degree to which the governmental action serves the public good, the economic impact of that action, and whether the action has interfered with "reasonable investment-backed expectations." See *Lucas* v. *South Carolina Coastal Council*, _____ U.S. _____, 112 S.Ct. 2886, 2893 (1992); *Andrus* v. *Allard*, 444 U.S. 51, 65 (1979) (reduction in value is not necessarily a taking); *Golden Pacific Bancorp* v. *United States*, 15 F.3d 1066, 1071–73 (Fed. Cir. 1994) (heavily regulated bank could not have developed a historically rooted expectation of compensation so Federal take-over did not require compensation), *cert. denied*, 115 S.Ct. 420 (1994); *Midnight Sessions, Ltd.* v. *City of Philadelphia*, 945 F.2d 667 (3rd Cir. 1991) (denial of license to operate an all-night dance hall did not constitute a taking because it did not deny all economically viable use of the property), *cert. denied*, 503 U.S. 984 (1992); *Elias* v. *Town of Brookhaven*, 783 F.Supp. 758 (E.D.N.Y. 1992) (loss of profit or the right to make the most profitable use does not constitute a taking); *Nasser* v. *City of Homewood*, 671 F.2d 432 (11th Cir. 1982) (deprivation of most beneficial use of land or severe decrease in property value does not constitute a taking). Indeed, in *Andrus* v. *Allard*, the Supreme Court wrote,

> Suffice it to say that government regulation—by definition—involves the adjustment of rights for the public good. Often this adjustment curtails some potential for the use or economic exploitation of private property. To require compensation in all such circumstances would effectively compel the government to regulate by *purchase*. "Government hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law."

Andrus, 444 U.S. at 65 (emphasis in original; citations omitted).

Here, the proposed rule would not require the government to physically invade or occupy private property, so the first inquiry is whether the proposed rule, if finalized, would deny all economically beneficial or productive use of property. The proposal would prohibit outdoor advertising from being located within 1,000 feet of any elementary or secondary school or playground. However, cases involving advertising restrictions illustrate that restrictions on the size and placement of advertising may be acceptable if they represent a valid exercise of governmental authority or do not deny all economically viable uses of the property. See *Sign Supplies of Texas, Inc.* v. *McConn*, 517 F.Supp. 778, 782 (S.D. Tex. 1980) (city ordinance on sign and billboard size, height, and location did not constitute a taking and was a valid regulation of injurious and unlawful acts). In this instance, the proposed restriction against outdoor advertising represents an exercise of the agency's statutory authority to restrict certain devices and permit labeling and advertising to continue under certain conditions.

Neither would the proposed rule effect a taking of vending machines or self-service displays. Although vending machines would no longer be permitted to be used to sell cigarettes or smokeless tobacco products, they would continue to have economic value if they were modified for other uses. FDA notes that a recent issue of *Vending Times* stated that cigarette vending sales declined in 1993 and that:

> Many traditional machines were modified to sell both full-value and generic/subgeneric styles at two prices, and glass-front machines gained favor as cigarette merchandisers because of their high selectivity, flexible pricing, attractive display, and *convertibility to other uses if cigarette vending becomes illegal.*

"Vending Cigarettes," *Vending Times, Census of the Industry Issue*, 1994 at p. 42 (emphasis added).

This statement indicates that compliance with this regulation would not result in a "taking" of vending machines. Similarly, self-service displays, in many instances, could be moved, adapted, or locked to comply with the requirement of direct transfer from retailers to consumers. Thus, like vending machines, self-service displays would retain their utility rather than losing their value.

Non-tobacco items that bear the brand name, logo, symbols, mottos, selling messages, or any other indicia of a cigarette or smokeless tobacco product are often given away free as promotional items or packaged with tobacco products as incentives to purchase the product. Banning brand identifiable non-tobacco items as a marketing tool and limiting sponsorship of events would not constitute a taking because, like vending machines and self-service displays, they can be modified or adapted to fit other needs. FDA notes that the FTC, in 1991, had to consider whether its proposal to require warning messages on "utilitarian objects" bearing the names, logos, or selling messages of smokeless tobacco product firms or brands constituted a taking. The FTC acknowledged that small businesses and one advertising association claimed that the FTC's rule would impose economic burdens on them, but felt that such claims were unsubstantiated. The FTC quoted an authority in consumer product regulation as stating that firms that produce these "utilitarian items" must be "adaptable and flexible to meet different needs of changing marketplace demands" and that they are able to transfer resources to other potential customers with only short term sales transaction costs. See 56 FR 11653, at 11661 (Mar. 20, 1991); see also *Georgia-Pacific Corp.* v. *United States*, 640 F.2d 328, 360 (Ct. Cl. 1980) ("It is settled that not all losses suffered by the owner are compensable under the fifth amendment. The government must pay only for what it takes, not for opportunities which the owner may have lost.") (citation omitted). FDA also notes that, until a final rule becomes effective, firms could easily adjust their business practices to adapt to the proposed regulations or to phase out utilitarian items and, therefore, not have such items in stock when the rule becomes effective.

Finally, prohibiting the use of non-tobacco names on tobacco products and requiring labels, labeling, and advertising to carry the product's established name and a brief statement would represent too slight a "taking" to warrant constitutional concern. With respect to the prohibition against the use of non-tobacco names, the non-tobacco product firm would lose its ability to license its name to any tobacco company, but it would be free to exploit its trade name with any other industry. There have been very few instances (such as "Harley- Davidson' cigarettes) of tobacco companies licensing a non-tobacco trade name. The agency recognizes that these brands might still be in the marketplace and would apply this provision prospectively only.

Nevertheless, even if the agency's proposed actions could constitute a "taking," FDA finds that the actions are consistent with section 4(d) of the order. The labels, labeling, and advertising for cigarettes and smokeless tobacco products convey images of status, sophistication, maturity, and adventure or excitement that are particularly appealing to young people. Their effectiveness at attracting young people is reflected in studies showing that young people tend to smoke the most heavily advertised brands and that very young children are able to recognize brand logos and imagery. The appeal generated by labels, labeling, and advertising, coupled with easy access, creates the risk that young people will

smoke cigarettes or use smokeless tobacco products, thereby exposing themselves to the long-term health risks associated with those products. Consequently, FDA has carefully drafted the proposed rule to convey information regarding warnings, precautions, side effects, and contraindications in order to inform consumers about the use of these products. The advertising requirements in proposed subpart D are also narrowly drafted to allow advertising to continue under certain conditions rather than prohibit all advertising. This will enable adults to continue receiving advertising messages while decreasing the advertisements' appeal to young people.

Vending machines and self-service displays offer young people easy access to cigarettes and smokeless tobacco products even though State laws prohibit cigarette sales to minors and some States or localities require locking devices on or specific placement of vending machines. Thus, the requirement that retailers physically provide the product to the consumer substantially advances the purpose of protecting the public health by eliminating easy, unmonitored access to such products by underage persons. This requirement is not disproportionate to the risk presented by vending machines and self-service displays because many studies demonstrate how easily minors can purchase cigarettes from vending machines, and other documents indicate that shoplifting is another method young people use to acquire these products.

Non-tobacco items and sponsored events that bear the brand name, logo, symbols, mottos, selling messages, or any other indicia of a cigarette or smokeless tobacco product act like advertising, conveying images of status, sophistication, maturity, and adventure or excitement that appeal to young people. Reports demonstrate that many young people, even those under the legal age, possess these items or seek coupons or certificates to obtain these items. The items, in conjunction with labeling, other advertising activities, and sponsored events, create the impression that smoking or smokeless tobacco product use is more prevalent and acceptable in society than it actually is and, as a result, increase the risk that young people will smoke cigarettes or use smokeless tobacco products and expose themselves to the long-term health risks associated with those products. Thus, banning tobacco promotions on non-tobacco items and in conjunction with sponsored events is appropriate.

As for the estimated potential cost to the government in the event that a court finds a taking to exist, FDA is unable to provide an approximate figure. There is little publicly available and precise data or information on each activity that would arguably be the subject of a regulatory taking, and section 704 of the act prohibits FDA from requiring financial, sales, or pricing data during an inspection. Consequently, the agency would appreciate receiving information to enable it to determine the potential cost to the government if a court found the actions described in this proposed rule to be a taking.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8), (a)(11), and (e)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96-354) and under the Unfunded Mandates Reform Act (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000, (adjusted annually for inflation). That Act also requires (in Section 205) that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective or least burdensome alternative that achieves the objective of the rule. The following analysis, in conjunction with the remainder of this preamble, demonstrates that this proposed rule is consistent with the principles set in the Executive Order and in these two statutes. In addition, this document has been reviewed by the Office of Management and Budget as an economically significant regulatory action under Executive Order 12866.

The estimated benefits of the proposed rule were based on FDA's finding that compliance with the proposed requirements would help to achieve the Department's "Healthy People 2000" goals. Each year, an estimated 1 million adolescents begin to smoke cigarettes. This analysis calculates that at least 24 percent of these youngsters will ultimately die from causes related to their nicotine habit. (Other epidemiological studies suggest even higher rates of excess mortality. For example, CDC projections indicate that 1 in 3 adolescents who smoke will die of smoking-related disease.) As a result, FDA projects that the achievement of the "Healthy People 2000" goals would prevent well over 60,000 early deaths, gaining over 900,000 future life-years for each year's cohort of teenagers who would otherwise begin to smoke. At a 3 percent discount rate, the monetary value of these benefits are projected to total from about $28 to $43 billion per year and are comprised of about $2.6 billion in medical cost savings, $900 million in productivity gains from reduced morbidity, and $24.6 to $39.7 billion per year in willingness-to-pay values for averting premature fatalities. (Because of the long periods involved, a 7 percent discount rate reduces total benefits to about $9.1 to $10.4 billion per year.) In addition, the proposed rule would prevent numerous serious illnesses associated with the use of smokeless tobacco products.

The full realization of this goal would require the active support and participation of State and local governments, civic and community organizations, tobacco manufacturers, and retail merchants. Even if only a fraction of the goal were achieved, the benefits would be substantial. For example, as shown in Table 1, halting the onset of smoking for only 1/20 of the 1 million adolescents who become new smokers each year would provide annual benefits valued at from $2.9 to $4.3 billion a year.

To comply with the initial requirements of the rule, FDA projects that manufacturers and retailers of tobacco products would incur one-time costs ranging from $26 to $39 million and annual operating costs of about $227 million (see Table 2). Manufacturers would be responsible for about $15 to $28 million of the one-time costs and $175 million of the annual

increasing the number of adult nonsmokers by 250,000 per year. Since each adult smoker consumes about 500 packs per year, lost sales revenues would amount to an additional $113 million per year.

In sum, FDA estimates that annual cigarette revenues would decline slowly over time; falling by $143 million in the first year (while only teenagers are affected), by $593 million in the fifth year, and by $1.2 billion in the tenth year. The U.S. Bureau of the Census reports the value of 1992 cigarette shipments at $28.8 billion. Thus, this regulation is projected to reduce revenues from cigarette sales by only 0.5 percent in the first year, 2.1 percent in the fifth year, and 4.0 percent in the tenth year following implementation. While these reductions are significant, the gradual phasing of the impacts would significantly dissipate any associated economic disruption. For example, data from a 1992 report on the contribution of the tobacco industry to the U.S. economy prepared by Price Waterhouse for the Tobacco Institute [52] implies that, over a 10-year period, a 4 percent reduction in sales would result in the displacement of about 1,000 jobs annually among warehousers, manufacturers, tobacco growers and wholesalers.

2. Vending Machine Operators

The proposed regulation would prohibit all vending machine sales of regulated tobacco products. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. FDA does not have a definitive estimate of the intensity of this decline, but is aware of two industry surveys that confirm its importance. The Vending Times 48th Annual Census of the Industry [53] shows a 6 percent drop in the number of cigarette vending machines from 1992 to 1993, but a 39 percent decline since 1983. The total number of packs sold reportedly dropped almost 60 percent over this decade, from 2.7 billion to 1.1 billion. A second survey, the "1994 State of the Industry Report," *Automatic Merchandiser* (The Monthly Management Magazine for Professional Vending and OCS Operators) [54] found an even steeper recent decline; reporting that the projected number of cigarette vending machines fell from 250,425 in 1992 to 181,755 in 1993, a drop of over 27 percent. That survey shows operator revenues from cigarettes falling from $835 million in 1992 to $624 million in 1993, down 25 percent. While the impact of this one product area is significant for the vending operators, the report found that this sector currently generates about $18 billion in total sales volume and explains that "Cigarettes, which have been on the downslide for several years, are fortunately only a small percentage (3.4 percent in 1993) of the total pie, thus the drop did not hurt total revenues significantly." The proposed prohibition of vending sales would require these firms to develop new markets to replace these sales revenues.

3. Advertising Sector

In their annual reports to the FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of $6.0 billion and $119 million, respectively. Approximately $1.9 billion (31 percent) of these outlays would be significantly impacted by the proposed rule as they are primarily directed to consumer advertising and promotion. Of the remaining outlays, about $2.6 billion (43 percent) go to consumers as financial incentives to induce further sales (e.g., coupons, cents-off, buy-one-get one free, free samples), and $1.6 billion (26 percent) to retailers to enhance the sale of their product. The affect on these expenditures would be much more modest.

FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but can foresee some fall in the approximately $1.0 billion worth of current advertising that would be affected by the proposed "text only" requirement. (The "text only" restriction does not apply to publications where children comprise less than 15 percent of the readership or are fewer than 2 million.) The impact of these restrictions on the various advertising media and agencies is difficult to determine. For example, in response to Canada's recently imposed advertising ban, that country's billboard industry "quickly replaced $20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer." [55] "In 1971, network TV ad revenue dropped 6 percent without cigarette advertising * * *, but by 1972 network TV * * * had recouped its ad base." [56] Current advertising revenues affected by the restrictions on billboard advertising near schools and playgrounds are also likely to be replaced by advertising revenues for other products. Nevertheless, if the tobacco industry were to cut its advertising outlays by one-half of the "text only" categories, this dollar figure amounts to less than one-half of 1 percent of the reported $131.3 billion spent on U.S. media advertising in 1992.[57] FDA is also aware that prohibiting the distribution of nontobacco specialty items bearing the name or logo of tobacco products would affect a substantial number of specialty manufacturers. In comments to the FTC,[58] the Specialty Advertising Association International noted that it "represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses." To the extent that these products include only a corporate name without brand association, they could remain marketable. However, it is likely that some of these firms would, at least initially, lose part of this $760 million market and would experience short-term costs while exploring other business options.

4. Retail Outlets

In addition to incurring the direct costs of compliance described above, some retail establishments may receive smaller promotional allowances (slotting fees) from manufacturers, following the prohibition of self-service displays and advertising imagery. Industry promotional allowances totaled about $1.6 billion in 1993, or $2,600 per outlet if spread evenly among the estimated 600,000 retail outlets currently selling tobacco products over-the-counter. It is likely that, notwithstanding these restrictions, manufacturers would continue to compete vigorously for the best display space available, so that few fees would be discontinued. For example, a recent Canadian study [59] suggests that, "[i]n the absence of advertising and promotion outlets * * * the cigarette industry may be expected to provide greater incentives to retailers to provide more and better shelf space for their brands in order to provide availability to the buyer in the store." In addition, alternative opportunities for point of purchase (POP) advertising have climbed briskly, as POP experts "cite in-store advertising as the fastest growing segment of the media industry." [60] Nevertheless, the agency is aware of at least one report indicating the "[l]oss of industry-paid slotting fees to some retail merchants because of the removal of self-service promotional tobacco displays, racks and kiosks." [61]

5. Other Private Sectors

The Tobacco Institute's Price Waterhouse report [62] purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. It calculates that induced or multiplier effects result in 2.4 jobs for every 1 job

in the core and supplier sectors combined, and over $3 in compensation for every $1 in the other two sectors. However, other analysts conclude that such ratios should not be used to assess longer term national economic impacts, because resources diverted from the production of tobacco would be reallocated to the production of other goods and services. "If the focus is longer term, involving a period of, say, more than two years, then the induced effect should not be included in the measure because money not spent in one industry would find another outlet with equal (undistinguishable) induced effects." [63] Furthermore, over the long term, regional impacts of the regulation would be similarly diffused.

6. State Tax Revenues

The proposed rule would decrease State tobacco tax revenues as fewer youths become addicted to tobacco products. These excise tax losses would increase as more of these youths become non-smoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled $6.2 billion for the year ending June 30, 1993.[64] Since State excise taxes on other tobacco products (including smokeless tobacco) were $226 million, FDA assumes that the total State excise taxes on tobacco products affected by this proposal are about $6.3 billion annually. As described above, FDA estimated that compliance with this proposal would reduce cigarette sales by a gradually increasing rate over time, falling by 0.5 percent in the first year, 2.1 percent in the fifth year, and 4 percent in the tenth year. Thus, the proposed rule would decrease State excise taxes on affected tobacco products by from $31 million in the first year to $252 million in the tenth year. Since tobacco taxes represented less than 1 percent of total State tax revenues in 1992,[65] even the estimated tenth year impact measures only 0.03 percent of all State tax revenues. Nonetheless, if necessary, State governments could raise tobacco product excise rates to offset these revenue losses. The issue is complex, however, because a full evaluation of the fiscal consequences of this proposal must consider a variety of public health impacts. For example, state Medicaid programs would benefit from reduced medical care expenditures, but they may also need to finance nursing home expenditures that climb with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to determine whether the effects of regulatory options would impose a significant impact on a substantial number of small entities and to consider those options which would minimize these impacts. Although most manufacturers of tobacco products are large corporations, the distribution of the product involves numerous small enterprises that would be affected by the proposed rule. For example, as explained earlier, the proposal would initially reduce the revenues of vending machine operators by at least 3.4 percent and almost three quarters of all vending machine operators are small businesses, having annual sales of less than $1 million.[66] Further, the proposed rule would affect the distribution of specialty items showing a tobacco product logo or name. According to the Specialty Advertising Association International, 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below $2 million. While the market place in which these firms compete traditionally demands a quick response to constantly shifting market trends, this rule would have at least short-term impacts on many of these firms.

The proposed regulation would also affect numerous retail establishments, primarily convenience stores, but also small grocery stores, small general merchandise stores and small gasoline stations. Table 4 displays the relative share of the tobacco market for major types of tobacco-dispensing outlets in 1987. As shown, food stores and service stations received almost 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 6 percent of the total sales of many of these establishments. The great majority of these retail outlets are small businesses.

TABLE 4.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1987

[Establishments with Payroll Only]

Establishment type	Tobacco sales		% of total sales	
	($ mils)	(%)	Establishments handling tobacco	All establishments
[illegible]	23,231	100	5.0	1.6
[illegible]	13,057	56	5.0	4.3
[illegible] Proprietary	4,280	18	6.5	4.2
[illegible]	2,152	9	5.1	4.0
[illegible]	1,470	6	2.1	0.8
[illegible] Dining	706	3	7.2	3.8
[illegible]	182	1	2.4	0.1

[illegible] Census of Retail Trade, Merchandise Line Sales.

[illegible] the effects of this [illegible] typical small retail store, [illegible] estimated the likely [illegible] costs for an average-sized [illegible] store that sells 300 [illegible] tobacco products daily, of [illegible] might be purchased by [illegible] aged 18 to 26. Based on the cost assumptions described above, the outlet's first year costs would total about $320, with the largest single cost, $285, the labor cost for checking identification. For those stores that already verify the age of young customers of tobacco products, the additional costs fall to $35. This estimate does not account for the possible reduction in promotional allowances, although these allowances might fall following a ban on self-service marketing. Alternatively, as noted above, manufacturers would continue to compete for the best shelf space for their products, perhaps even