The agency declines to amend the rule as suggested by the comment. Section 897.3(a) define a cigarette, in part, as any product that consists of any roll of tobacco; it does not establish a minimum quantity of tobacco. Thus, while manufacturers can develop such a product, it would still be a cigarette under this rule and subject to all restrictions for cigarettes.

(56) Two comments would amend the minimum package size by increasing it to 200 cigarettes or a carton of cigarettes. The comments explained that making cartons the minimum package size would further reduce access to cigarettes by young people because cartons would be more expensive than single packs and would be harder to shoplift. The comment said that adults would not be adversely affected by such a change because adults generally buy cartons.

The agency declines to make 200 cigarettes or one carton the minimum ''package'' size. Eliminating cigarette packages would unduly affect those adults who prefer to purchase cigarette packs rather than cartons due to limited funds or other reasons, and would unduly affect manufacturers, distributors, and retailers because, at the very least, they would need to revise manufacturing practices or machines and/or revise or reconfigure product storage practices and units to accommodate only cartons. It is even possible that some adults might consume more cigarettes if the minimum package size were increased to 200 cigarettes.

(57) One comment challenged the agency's authority for proposed § 897.16(b). The comment argued that requiring a minimum package size exceeds FDA's authority under the act because it does not purport to provide reasonable assurance of the product's safety and effectiveness to potential users.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to impose restrictions on the sale, distribution, and use of a device. Establishing a minimum package size is a restriction on the sale and distribution of these devices and is reasonably related to assuring the product's safety for those persons, namely young people, whom this rule protects. Cigarettes and smokeless tobacco either cause or are associated with serious adverse health effects, and the evidence suggests that ''kiddie packs'' appeal to young people. Hence, establishing a minimum package size that is larger than a ''kiddie pack'' should help reduce young people's access to these products and, as a result, protect them from those potential adverse health effects.

(58) One comment stated that the agency lacks factual support for a minimum package size, claiming that there is no evidence that young people buy such products or that ''kiddie packs'' are especially popular with young people. The comment claimed that the studies cited by FDA in the preamble to the 1995 proposed rule are flawed due to small sample size. The comment disputed the results of those studies, arguing that the studies did not show whether young people favored small package sizes because they are easily concealed—a reason identified by FDA in the preamble to the 1995 proposed rule—or because they are less expensive. The comment added that FDA's rationale is further undermined by the fact that FDA has claimed both that young people are price sensitive and that they do not purchase inexpensive brands. According to the comment, it is not possible to have it both ways.

Specifically, the comment questioned the validity of the 1987 Australian study by Wilson.[45] The comment argued that the authors could not assure that the subject population of 14- and 15-year olds was representative and, because selection criteria for the adult subjects differed, the results from the adult population could not be compared to the results from the 14- to 15-year old subjects. The comment disputed the study's finding that young Australians favored smaller cigarette packages because the small packs were more ''concealable,'' stating that the study did not explain whether a pack containing 15 cigarettes was significantly smaller than a pack containing 20 cigarettes. The comment also criticized the study for being unclear as to whether the researchers surveyed youth smokers alone or young smokers and other youths to determine why young people purchased the 15-cigarette package, and it criticized FDA for not mentioning that the third most popular reason for purchasing 15-cigarette packs was ''reducing smoking.''

FDA is not persuaded that the studies are unreliable. The comment's criticisms of the Wilson study do not acknowledge that the study's authors compensated for the lack of a population-based probability sample by using a sample size that exceeded the required size for a simple random sample. The authors used a cross-sectional sample of 649 young people between the ages of 14 and 15. This number exceeded the 363 persons required for a simple random sample, based on an estimate that 40 percent of the 25,000 South Australian children aged 14 to 15 years old would be smokers and using 95 percent confidence intervals of 35 to 45 percent, and exceeded the 567 person sample size that would be obtained when the random sample size is multiplied by a factor of 1.3 to allow for a clustered design and increased 20 percent to allow for persons dropping out of the survey.

Additionally, while the study did say that the sample of 14- and 15-year old children was a ''sample of convenience,'' that, alone, does not make the study unreliable. Many studies use a sample of convenience rather than a representative sample, and the application of a study's results or findings to a broader population depends on the study's methodology.

The comment's criticism of the different selection methods lacks merit because it neglects to consider the context for the selection method. The authors selected schools in order to obtain underage subjects; this selection method precluded getting a representative sample of adults (because they would not be in schools). For the adult subjects, selection was based on a probability-based method of selection instead of school affiliation. Both selection methods were scientifically valid.

Moreover, two well-conducted studies provide a reasonable basis for comparison, even between different populations. This is especially true for the Wilson study because both the adolescent and adult studies were performed under the auspices of the South Australian Health Commission and were drawn from the same geographical area within 2 weeks of each other. Thus, one can reasonably assume that the studies were well conducted and that comparisons between the adolescent and adult groups were appropriate.

Finally, the comment's criticism of Wilson's findings is also misplaced. Contrary to the comment's assertion, the issue is not whether 15-cigarette packs are smaller or more easily concealed than full-sized packs. Nor is the issue whether underage smokers, as opposed to underage smokers and other young

[45] Wilson, D. H., et al., ''15's: They Fit in Everywhere—Especially the School Bag: A Survey of Purchases of Packets of 15 Cigarettes by 14 and 15 Year Olds in South Australia,'' Supplement to Community Health Studies XI (1), pp. 16s–20s, 1987.

people, prefer 15-cigarette packs. Instead, the issue is whether young people, for whatever reason, favor and purchase smaller packs. The study indicated that over 90 percent of the young people surveyed preferred 15-cigarette packs because they considered them to be less expensive, easier to conceal, or helpful to reduce smoking. This led the authors to state that, ''if adolescents did not have available to them these cheaper brands, or the price was raised considerably, or packaging in a way that is more appealing to adolescent budgets was prohibited then the current popularity of 15's would be reduced considerably.'' [46]

(59) The same comment challenged a study by Hill. [47] The preamble to the 1995 proposed rule cited this study to show that younger children (12-year olds in the study) preferred 15-cigarette packages more than older children (17-year olds) and that older children preferred packages containing 25 cigarettes. However, the comment interpreted the Hill study in a much different manner, noting that, according to the study, the youngest age group experienced the greatest decline in smoking prevalence in the period following the introduction of the 15-cigarette package. Thus, the comment asserted that, ''[t]his fact suggests that smaller packages are associated with less youth smoking, rather than more.'' The comment further stated that the researchers' opinion that price and ''concealability'' make smaller packages appealing to young people is contradicted by the findings that children in all age groups preferred 25- and 30-cigarette packages.

FDA believes that the comment misinterprets the study. While the study did indicate that the proportion of Australian students, aged 12 to 17 years, who smoked weekly declined from 1984 to 1987 (with the greatest declines in the youngest age groups), the study did not attribute the decline to the introduction of a smaller cigarette package. Instead, the study attributed the decline to ''the health education and promotional campaigns that were established in Australia during the period between the surveys.'' [48]

Similarly, a closer examination of the study does not support the comment's assertion that the popularity of larger cigarette packages among Australian schoolchildren refutes FDA's statement that the price and ''concealability'' of smaller packages appeal to young people. The study found that 42 percent of the children surveyed smoked cigarettes from 25-cigarette packages, with the next most popular size being 30-cigarette packages. Nearly 20 percent smoked cigarettes from 15-cigarette packages, and ''preference for packets of this size showed a marked inverse relationship with age, decreasing from 30% of 12-year-old school children to 11% of 17-year-old school children.'' [49] The study did not attribute the popularity of the smaller package size to lower price or concealability but merely cited the Wilson study to say that young people ''presumably'' prefer the smaller packages for those reasons. Yet, regardless of the reason, the Hill study illustrates that a significant percentage of young people prefer smaller package sizes and that the percentage increases in the younger age groups.

(60) The same comment also criticized the Nova Scotia study. [50] FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages. The comment criticized the Nova Scotia study for the ''absurdly small size of this population sample (37 students).'' The comment also criticized the Nova Scotia study's assertion that price and concealability motivate young people to purchase small cigarette packages. The Nova Scotia study indicated that only 3 percent of the sixth grade students surveyed (or one out of the 37 students) purchased single cigarettes compared to 11 percent of the twelfth grade students (or 12 students out of the 123 surveyed). The comment argued that the Nova Scotia study showed that twelfth grade students ''were four times as likely as the sixth-graders to purchase *single* cigarettes'' and that, ''[i]f price and 'concealability' were the key factors for young people, those in the youngest age group would surely be purchasing single cigarettes, not 15's''.

The comment misconstrues the importance of the study. FDA cited this study to show that 49 percent of tobacco users in the sixth grade purchased 15-cigarette packages, but the agency did not rely solely on the Nova Scotia study as evidence that young people prefer small cigarette packages. Instead, the agency cited the Nova Scotia study and the Hill study that surveyed 19,166 Australian schoolchildren to show that the youngest children prefer smaller cigarette packages. So, even if the Nova Scotia study used a small sample size, the study's findings are consistent with the Australian study that surveyed 19,166 children.

The agency also disagrees with the comment's claim that the Nova Scotia study contradicts FDA's view that young people purchase ''kiddie packs'' due to their low price and small size. The study did not examine specific reasons for purchasing single cigarettes as opposed to 15-, 20-, or 25-cigarette packages, and so it would be inappropriate to draw any conclusions based on different purchase rates alone. In other words, the percentage of students who purchase a particular package size may offer little or no insight as to the reasons why a student selected a particular package size.

Other factors might also explain the low rate of single cigarette sales relative to cigarette packages. Low price and concealability might be important factors in purchasing behavior, but they may not be the controlling or sole factors behind a purchase. For example, the preamble to the 1995 proposed rule stated, among other things, that single cigarettes make children more willing to experiment with tobacco products (60 FR 41314 at 41324), and stated that young people see or use tobacco products as a badge or method of conveying or creating a certain image for themselves (60 FR 41314 at 41329). A single cigarette, sold without a package, is an ineffective ''badge'' compared to the more conspicuous cigarette pack. Additionally, very young children may not opt for single cigarettes because such products are typically purchased from retailers that may question the children's age. (See 60 FR 41314 at 41325 (very young children rely on vending machines more often than older children).) The Nova Scotia study, however, did not examine reasons for purchasing single cigarettes as opposed to purchasing 15-cigarette packages, and so the agency declines to draw any conclusions solely from different sales rates for single cigarettes compared to those for cigarette packages.

(61) One comment suggested amending § 897.16(b) to prohibit manufacturers, distributors, and retailers from selling or causing to be sold, distributing or causing to be distributed, ''cigarettes unless contained in packages of at least 20 cigarettes.'' The comment said that the rule did not prevent anyone other than retailers from selling individual cigarettes.

[46] *Id.*, p. 19s.

[47] Hill, D. J., et al., ''Tobacco and Alcohol Use Among Australian Secondary Schoolchildren in 1987,'' *Medical Journal of Australia*, vol. 152, pp. 124–130, 1990.

[48] *Id.*, p. 128.

[49] *Id.*, p. 126.

[50] ''Students and Tobacco,'' The Nova Scotia Council on Smoking and Health Survey, Final Report, March 1991.

FDA believes the comment misinterpreted the rule. Section 897.3 defines a ''retailer'' as any person who sells cigarettes or smokeless tobacco to individuals for personal consumption. Thus, a manufacturer or distributor who attempted to sell single cigarettes to a consumer would, under the final rule, be considered a ''retailer'' for purposes of that transaction and would be in violation of the individual cigarette restriction in § 897.14.

(62) One comment suggested amending the rule to create a minimum package size for smokeless tobacco. The comment would make the minimum package size for smokeless tobacco equivalent to 20 doses of nicotine, but it did not state what a dose would be.

The agency agrees that a minimum package size for smokeless tobacco may be helpful, but lacks sufficient information to determine what that size should be for the various forms of smokeless tobacco on the market. Unlike cigarettes, which are generally sold in packages of 20, smokeless tobacco comes in various forms and sizes, and, with the possible exception of prepackaged forms, can be used in quantities determined by the user. One individual, for example, might place more chewing tobacco in his or her mouth than another individual. Consequently, absent more information, the agency is unable to establish a minimum package size for smokeless tobacco.

(63) The agency, on its own initiative, has amended § 897.16(b) (minimum cigarette package size) to add the introductory phrase, ''Except as otherwise provided under this section.'' This amendment became necessary because, as discussed in greater detail in section IV.E.4.a. of this document, the agency has concluded that vending machine sales should be permitted in facilities that are inaccessible to young people, and FDA is aware of at least one type of vending machine that sells packaged, single cigarettes. The agency is aware of vending machines that dispense cartons, packages, and now packaged, single cigarettes and has made an exception for packaged, single cigarettes due to their unique nature (relatively high price compared to ''loosies,'' packaging in compliance with labeling and tax requirements, and sale only in adult locations). Additionally, FDA, on its own initiative, has revised the rule to state that no manufacturer, distributor, or retailer ''may'' sell (rather than ''shall'' sell) cigarette packages containing less than 20 cigarettes.

3. Maximum Package Size

The preamble to the 1995 proposed rule also invited comment as to whether a maximum package size should be established. The preamble to the 1995 proposed rule cited one study that found that older Australian children favored cigarette packs containing 25 cigarettes (60 FR 41314 at 41324).

(64) Several comments offered suggestions regarding a maximum package size. One comment noted that packages containing 10 and 25 cigarettes have been sold in the United States and suggested that, when considering a maximum package size, FDA should consider the attractiveness of the pack and whether a larger pack would encourage increased consumption. The comment added that one option would be to limit sales to 200 units (or one carton). Another comment would make 20 cigarettes the maximum package size, but conceded that there is insufficient evidence to make a strong recommendation.

In contrast, one comment stated that the agency has no authority or evidence to justify creating a minimum package size and so it lacks authority and evidence to create a maximum package size.

Based on the comments, there is insufficient evidence to establish a maximum package size for cigarettes. There is little experience in the United States with package sizes greater than 20 cigarettes. As a result, the final rule does not establish a maximum package size for cigarettes.

4. Impersonal Modes of Sale

Proposed § 897.16(c) would have permitted cigarettes and smokeless tobacco to be sold only in a direct, face-to-face exchange between the retailer, or the retailer's employees, and the consumer. Thus, the proposal would have prohibited the use of vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons. Implicit in this provision, and in subpart B of part 897, is the notion that transactions involving restricted devices should involve a sense of ''formality'' or gravity that conveys to both the seller and the buyer the seriousness of the transaction and of the products themselves. FDA has amended this provision in response to comments. As discussed in section IV.E.4.c. of this document, certain mail-order sales are now exempted from this requirement, as are vending machines and self-service merchandisers in facilities not admitting individuals under the age of 18.

a. *Vending machines*. The preamble to the 1995 proposed rule cited numerous studies and surveys showing that significant percentages of young people are able to purchase cigarettes from vending machines, even in jurisdictions that have laws restricting the placement of those machines or requiring the use of locking devices. In some cases, young people successfully bought cigarettes from vending machines 100 percent of the time (60 FR 41314 at 41324 through 41325). Consequently, the agency elected to prohibit the use of vending machines rather than restrict their placement or require locking devices.

FDA's proposal to eliminate the use of vending machines (§ 897.16(c)) generated more comments than any other provision aimed at reducing children's and adolescents' access to tobacco products; the agency received thousands of comments on this provision. While agreeing that children and adolescents should not use tobacco products, comments submitted by adult smokers, the tobacco industry, and vending machine owners and operators, strenuously objected to the provision. Nearly all of the comments in opposition stated that the provision would be unnecessary if State and local jurisdictions enforced existing laws prohibiting the sale of tobacco products to children and adolescents under the age of 18.

By contrast, concerned adults, parents, educators, State and local public health agencies, and medical professionals overwhelmingly supported the provision. In addition, tens of thousands of school children wrote letters asking that vending machines be eliminated. Nearly all comments in favor of the provision pointed to the serious health risks that a lifetime of nicotine addiction poses to children and adolescents who begin to smoke, arguing that vending machines offer children and adolescents who choose to begin to smoke easy access to cigarettes.

(65) Several comments asserted that the proposed restriction pertaining to vending machines would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. As discussed in greater detail in the paragraph below, FDA has amended the final rule to permit vending machines in facilities that are inaccessible to young people at all times. Additionally, given the character of this regulation and the lack of reasonable investment-backed expectations in personal property, its

economic impact, while potentially significant for some persons, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI. of this document.

(66) Most comments submitted by adult smokers and nearly all of the comments submitted by the cigarette and vending machine industries stated that the provision would not effectively reduce children's and adolescents' access to cigarettes. The comments argued that the proposed elimination of vending machines is not supported by the evidence in the record, either because the studies cited by FDA do not measure children's and adolescents' actual purchasing habits, or because the percentage of children and adolescents who reportedly buy cigarettes from vending machines is not significant. Finally, many adult smokers and some parents argued that determined teenagers will find a way to obtain cigarettes whether or not vending machines are eliminated.

On the other hand, almost all of the children, parents, adults who do not smoke, medical professionals, and public interest groups commented that the provision would effectively reduce children's access to cigarettes. These comments generally cited personal experience in concluding that vending machines provide an easy source of cigarettes for many children who smoke. For example, the executive director of a public health education program wrote: ''It is outrageous that we allow tobacco, a most addictive drug, to be sold through vending machines where anyone can purchase it!'' Comments overwhelmingly concluded that the elimination of vending machines, coupled with the other proposed access and advertising restrictions and the proposed education campaign, would effectively reduce the availability of cigarettes to children.

Several comments analyzed currently available studies and concluded that ''easy access to vending machines * * * enable[s] young people to obtain cigarettes, and that high proportions of vending machine users are people under 18.'' Moreover, several comments in support of the provision cited their own studies indicating the ease with which children and adolescents obtain cigarettes from vending machines. For example, a coalition dedicated to preventing and reducing tobacco use submitted its 1994 annual report, which included an article describing an undercover buying survey, the largest of its kind, conducted in Spring, 1994. One hundred and seven teenagers participated in the 12-county survey by entering stores under the supervision of an adult and attempting to purchase cigarettes, and:

> [k]ids were more successful attempting to buy cigarettes through vending machines [than through retail outlets], without any adults trying to stop them. Teens made 21 of 24 successful attempts to purchase cigarettes through vending machines, an 88 percent success rate.

Similarly, the manager of a youth tobacco prevention program in Washington State's Department of Health commented that ''[a] recent survey in one Washington county found that youth can still purchase tobacco from vending machines at a 75 percent success rate.'' The comment recommended that all tobacco vending machines be eliminated.

Finally, comments submitted by children, parents, and nonsmoking adults indicate that these groups believe tobacco vending machines are easily accessible to children and adolescents. One comment, typical of those submitted by children, stated: ''I especially agree with getting rid of vending machines. That, I think, is probably the most common way that children get their cigarettes.'' The director of a public health center in California submitted the results of a poll indicating that 75 percent of Californians support banning cigarette vending machines.

Vending machines certainly represent one of the major ways that children currently obtain cigarettes. In addition to studies depicting how easily children and adolescents could purchase cigarettes from vending machines, the 1995 proposed rule cited surveys of children's actual purchasing behavior (60 FR 41314 at 41324 through 41325). Relying on both types of evidence, the agency concluded that the provision would eliminate one of the primary sources of cigarettes for at least 2 percent of 17-year-old smokers and 22 percent of 13- to 17-year-old smokers. Moreover, the agency finds that the number of children and adolescents in these two groups is substantial.

While the agency agrees that some children and adolescents who are determined to smoke may find or create new ways of obtaining cigarettes, the removal of vending machines from sites accessible to young people will eliminate what is currently a popular and easy means of access to tobacco, especially for younger children. In addition, if other access restrictions are imposed, such as requiring customers to provide proof of age, without also eliminating vending machines, use of vending machines among children between the ages of 13 and 17 years would likely increase (60 FR 41314 at 41325). Therefore, the agency has concluded that the provision is an important part of the overall scheme to reduce children's and adolescents' access to cigarettes.

(67) The agency received many comments regarding the location of vending machines. A trade association representing the cigarette industry stated that most vending machines are currently inaccessible to children and adolescents because they are located either in areas that are off-limits to young people, such as nightclubs or casinos, or in areas that young people rarely frequent, such as industrial plants and private offices. Thus, the comment concluded, eliminating vending machines will not discourage youth smoking.

The vending machine industry and establishments that currently have vending machines unanimously opposed the provision. Some comments suggested that the agency specifically allow vending machines in locations where young people are not present. One vending machine operator commented, ''[m]any cigarette machine vendors are small businessmen like myself; 95 percent of our locations are in taverns and lounges, where no one under 21 years old is allowed in.'' Other comments argued that, even if retail purchases become increasingly difficult, vending machines in establishments that are not open to the public should not be eliminated because children and adolescents cannot enter these places.

Both the cigarette and vending machine industries argued that FDA's conclusion, that children and adolescents can easily purchase cigarettes from vending machines even in ''adult'' locations, was based on flawed studies. Comments argued that the sting operations, on which these studies were based, do not demonstrate where teenagers actually or usually go. One comment, submitted by an association representing 1,700 vending machine companies, argued that: ''it is highly questionable if minors might have alone and without encouragement entered taverns or bars in restaurants just to purchase cigarettes without exemption from the district attorney's office.'' Moreover, these comments argued, local sting operations do not establish the national cigarette purchasing habits of children and adolescents.

In contrast, a national public health organization concluded that available studies indicate that restricting the location of vending machines is an ineffective method of controlling sales of tobacco to young people. Another comment opposed to weakening the provision characterized as unreliable the number of machines currently in ''adult'' locations. The comment attacked as statistically unsound a vending machine industry survey that concluded that 77 percent of all vending machines are in ''adult locations.''

FDA has determined that cigarettes should not be dispensed to consumers from vending machines that are accessible to children and adolescents. While young people's actual current purchasing habits provide irrefutable evidence of accessibility, available evidence demonstrates that cigarette vending machines also are accessible to children and adolescents even in locations that are not often or currently frequented by young people. FDA has determined that cigarette vending machines should be eliminated from locations that are accessible to children and adolescents, whether or not children and adolescents currently use them.

While the IOM recommended that vending machines be eliminated altogether, it cautioned that, if partial bans were to be enacted, the definition of ''adult'' location must be narrowly drawn.

> Youths do not now report ''adult'' locations as major sources of tobacco, but there is evidence that minors can often easily enter ''adult'' locations, and once inside, can easily buy tobacco products * * *. If partial vending machine bans are to be effective, the statutes must define ''adult'' locations carefully and narrowly. For example, the bar area of a restaurant is not sufficiently inaccessible to minors to deter their purchases. * * * Many bars only restrict access to alcohol; they do not restrict entrance by age. Accordingly, if vending machine are permitted at all, they should be permitted only in locations to which minors may not be admitted.[51]

Based on comments, FDA has determined that some ''adult'' locations can be made sufficiently secure to prevent young people's access and that vending machines should remain available to adults in these locations. For example, some establishments, such as nightclubs or casinos, require that patrons present proof of age before they are permitted to enter or post a guard at the door to prohibit underage access. In 1994, CDC analyzed 15 recent studies of children's access to tobacco and noted that ''[s]ome inspections of private clubs and bars were not carried out because access to the outlet was blocked by a doorman or security guard.''[52] FDA finds that those establishments where people under the age of 18 are legally prohibited from entering and where a system exists to ensure that children are prevented from entering, can, in fact, be sufficiently inaccessible to children that the goals of the rule would not be significantly advanced by prohibiting vending machines in those limited locations.

Other ''adult'' establishments prohibit children and adolescents from entering, as a matter of establishment policy. For example, some private clubs do not grant membership to persons under the age of 18 and require that members provide proof of membership before entering the club. Similarly, for example, some industrial or manufacturing facilities not open to the public may, for safety reasons, prohibit the hiring of persons under the age of 18, and require that employees present proof of employment upon entering the facility. FDA finds that these establishments, like some nightclubs or casinos, can be similarly inaccessible to children and, if so, should be permitted to make cigarette vending machines available to their adult members or employees.

Futhermore, an exemption for vending machines located in areas where no person under 18 is present or permitted to enter is consistent with the ''Prohibition of Cigarette Sales to Minors in Federal Buildings and Lands Act'' (Pub. L. 104–52, sec. 636). This particular statute, which became law on November 19, 1995, prohibits the sale of tobacco products in vending machines located ''in or around any Federal building,'' but the statute authorizes the Administrator of the General Services Administration (GSA) or the head of an agency to exempt areas that prohibit the ''presence of minors'' (whom the statute defines as individuals under age 18). See also 41 CFR 101–20.109(d) (Administrator of the GSA or agency head may designate areas where vending machine sales of tobacco products may occur ''if the area prohibits minors''); 61 FR 2121, January 25, 1996.

Consequently, § 897.16(c) exempts vending machines located in establishments that are totally inaccessible to persons under 18. The owner of the facility must ensure, by means of photographic identification or some other means, that no one under 18 enters the facility. Thus, the rule would permit a vending machine in an establishment only where persons under 18 are not present, or permitted to enter, at any time. FDA emphasizes that this narrowly drawn exemption accommodates adults only in locations where young people, in fact, have no access at any time. For example, a vending machine might be permitted in a facility that employs only adults and where guards prevent any person under 18 from entering. A vending machine would not be permitted in a facility that employs only adults but also permits employees to bring children to work. The agency further emphasizes that it is the exempt establishment's responsibility to ensure that no one under 18 is present, or permitted to enter the premises, at any time.

In addition, under § 897.16(c), a vending machine in an exempt establishment must be entirely inaccessible to children. Thus, an establishment must place the machine entirely inside the premises, beyond the point where persons are required to present proof of age, membership, or employment. Vending machines are prohibited from any public area in or around the establishment, including, for example, lobbies, parking lots, and entrances.

FDA emphasizes that the final rule exempts only establishments that are, in fact, inaccessible to young people at all times. FDA will monitor young people's access to cigarettes from vending machines in exempt establishments, and, after 2 years, will assess whether the vending machine exemption has been effective. At that time, the agency finds that vending machines continue to be accessible to young people, FDA will propose further restrictions.

(68) Several comments suggested that, rather than eliminate vending machines or restrict their location, FDA require that they be supervised. These comments would allow vending machines to be placed anywhere, even in locations frequented by children and adolescents, as long as the machines were supervised.

FDA disagrees that supervising vending machines would prevent illegal sales to children and adolescents. Comments opposed to the provision offered no evidence that supervision of vending machines would sufficiently impede a young person's access to cigarettes. In fact, studies indicate that young people are able to purchase

[51] IOM Report, p. 214.

[52] ''Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors,'' Battelle, prepared for the CDC, OSH, p. 17, April 1994.

cigarettes even from vending machines under the immediate vicinity and control of employees.

One study conducted in a State requiring that vending machines be supervised demonstrated that youths were able to purchase from 72 percent of vending machines, in bars and taverns, within clear view of an employee.[53] Another report examining vending machine sales in New York City demonstrated that 11- and 12-year-olds successfully purchased cigarettes from supposedly supervised vending machines in bars and taverns 100 percent of the time. The study found that children and adolescents ''had no more difficulty buying cigarettes from vending machines in bars than they had buying cigarettes from restaurants, pizza parlors, or video arcades. In all instances, the barman and/or patrons watched but did not intervene.''[54]

In other studies, employees helped children and adolescents to illegally purchase cigarettes by providing change for the cigarette vending machine[55] or suggesting that the children and adolescents go next door where cigarettes were cheaper.[56]

Additionally, each provision in subpart B of part 897 is intended to eliminate a popular source of cigarettes and smokeless tobacco for children. The vending machine restriction is intended to complement, and be reinforced by, the other restrictions.

The preamble to the 1995 proposed rule cited studies indicating that the use of vending machines by adolescents is greater in jurisdictions that have stronger access restrictions (60 FR 41314 at 41325). Based on those studies and comments that it received, FDA concludes that decreasing the supply of tobacco products to children and adolescents by one means of access, such as restricting self-service displays, would cause an increased demand by another means of access, such as cigarette vending machines. FDA remains persuaded that, without eliminating cigarette vending machines accessible to children and adolescents, other access restrictions would cause an increase in illegal vending machine sales.

(69) Most comments submitted by the tobacco and vending machine industries recommended that, rather than eliminate vending machines, FDA should require that they be equipped with electronic locking devices (devices that render the machine inoperable until activated by an employee) or token mechanisms (which require consumers to purchase tokens from an employee in order to use a vending machine). Either method would require a face-to-face transaction between the purchaser and the retailer.

The cigarette and vending machine industries commented that studies do not support FDA's conclusion that locking devices are ineffective. Comments asserted that the studies failed to include vending machines fitted with locking devices in traditionally adult locations or to account for the lack of enforcement in the jurisdiction in which the study was conducted. In addition, several comments pointed out that the tobacco sales ordinance in Woodridge, IL, where illegal tobacco sales were reduced from 70 percent to less than 5 percent 2 years later, included a locking device requirement rather than a ban on cigarette vending machines.

On the other hand, one comment from a public interest group strongly supported FDA's proposal to eliminate vending machines altogether and urged that FDA not permit the use of locking devices. The comment cited a survey, conducted by an association of public health officials in New Jersey, in which young people successfully purchased cigarettes from supposedly locked vending machines in 11 of 15 attempts. The comment noted that ''[i]n some instances, the remote control device to operate the machine was sitting on top of the machine to save store personnel the bother of having to press the switch.''

FDA acknowledges that properly installed locking devices require that vending machine purchasers engage in a face-to-face transaction, increasing the likelihood that children would be prevented from purchasing cigarettes. However, as explained in the preamble to the 1995 proposed rule, available evidence indicates that the industry is slow to install the locking devices, and that, after a short period, the locking devices are often disabled (60 FR 41314 at 41324 through 41325).

FDA agrees that the Woodridge, IL, community was able to dramatically reduce illegal tobacco sales while permitting the use of locking devices on cigarette vending machines. However, FDA notes that when the community implemented its tobacco ordinance in May, 1989, the community had only six vending machines, and when the study was completed December, 1990, the number of vending machines had dropped to two. Moreover, despite the requirement of locking devices and persistent compliance checks by law enforcement, a child was able to purchase cigarettes from one of the two remaining vending machines in December, 1990.[57]

Similarly, in 1990, Minnesota enacted a law eliminating vending machines in public areas unless the machines were only operable by activation of an electronic switch or token and were under the direct supervision of a responsible employee. One year after the law was passed, a study conducted in four cities found many machines had not been fitted with the required devices and, of those fitted with the devices, there was no significant reduction in purchase success.[58]

IOM reviewed the available evidence and determined that locking devices do not effectively prevent youth access to cigarette vending machines. IOM noted that ''although fewer cigarettes are sold to youths than where vending machines are completely unrestricted, businesses that installed locking devices on vending machines were still more likely to sell cigarettes to young people than businesses that used over-the-counter sales.''[59]

Finally, the Inspector General reported that Utah experienced limited success with locking devices:

> Reportedly, clerks would simply activate the machine without checking the age of the purchaser. Since the locking devices require employee participation, they are often not as effective in busy places, such as bars or restaurants, where employees are more likely to simply activate the machine.[60]

FDA has not been persuaded that vending machines equipped with locking devices sufficiently guard

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[53] Cismoski, J., and M. Sheridan, ''Availability of Cigarettes to Under-age Youth in Fond du Lac, Wisconsin,'' *Wisconsin Medical Journal*, vol. 92, No. 11, pp. 626–630, 1993.

[54] ''Cigarette Vending Machines Sell Cigarettes to Children, 11–15 Years Old, 100% of the Time,'' Smokefree Educational Services, Inc., October 1990. ''Critics Target Vending Machines,'' *The Christian Science Monitor*, p. 6, April 1990.

[55] Mead, R., ''Teen Access to Cigarettes in Green Bay, Wisconsin,'' *Wisconsin Medical Journal*, pp. 23–24, January, 1993.

[56] ''Springfield Teen Tobacco Purchase Survey,'' Stop Teenage Addiction to Tobacco (STAT), 1993.

[57] Jason, L. A., P. Y. Ji, M. D. Aneo, and S. H. Birkhead, ''Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors,'' *JAMA*, vol. 266, No. 22, pp. 3159–3161, December 11, 1991.

[58] Kotz, K., ''An Evaluation of the Minnesota Law to Restrict Youth Access to Tobacco,'' presented to the American Public Health Association (APHA) 121st Annual Meeting, San Francisco, CA, October 24–28, 1993.

[59] IOM Report, p. 213.

[60] ''Youth Access to Cigarettes,'' Department of Health and Human Services (DHHS), Office of the Inspector General, Pub. No. OEI–02–90–02310, p. 9, May 1990.

against children's access to tobacco products. Comments provided no evidence, and FDA is not aware of any studies, on whether law enforcement efforts affect children's ability to access tobacco products through locked vending machines. However, one study examined the effect of law enforcement efforts on illegal vending machine sales in three comparable communities that did not require locking devices. Despite the fact that merchants in one of the three communities received a letter describing the State law and warning them of the city's intention to enforce the law, there was no significant difference in the rate of illegal vending machine sales among the communities. [61]

Comments also provided no evidence that restricting the location of cigarette vending machines equipped with a locking device renders the machines less accessible to children and adolescents. FDA notes that, if locking devices were effective, the location of the machine would be of no consequence. Yet, as discussed in the preceding paragraphs, FDA is persuaded that some establishments are entirely inaccessible to young people. Accordingly, the final rule allows the use of vending machines in those establishments without requiring that the machines be equipped with a locking device.

FDA declines to grant an exception for tokens in the absence of evidence that machines operated only by tokens prevent children from obtaining cigarettes. Several comments suggested, rather than eliminate vending machines, that FDA require either locking devices or tokens. These comments focused on locking devices, without offering any evidence of the number of vending machines currently operating with tokens, the extent to which tokens have been tested in the marketplace, or whether the technology prevents children and adolescents from obtaining cigarettes from vending machines. FDA is aware that three States whose laws restrict the use of vending machines permit the use of locking devices or tokens. However, FDA is not aware of any evidence indicating that the use of tokens prevents young people's access to cigarettes from vending machines that are otherwise accessible to children.

(70) The most common concern raised by adult smokers was that the elimination of vending machines would inconvenience them. Most adult smokers stated that vending machines are closer than retail outlets to their homes or places of work. Some adult smokers stated that they would be unable to purchase cigarettes late at night if vending machines were eliminated. Others indicated that vending machines provide the only means of obtaining their brand, or of obtaining cigarettes altogether.

In contrast, while acknowledging that adult smokers would be somewhat inconvenienced, comments in support of eliminating vending machines pointed out that adult smokers would still be able to purchase their products in retail transactions. Nearly all comments in support of the provision, including comments from grade school students, parents, and health professionals, said that the significant reduction in children's access to cigarettes would outweigh any inconvenience experienced by adult smokers.

The agency is persuaded that the provision would not unduly burden adult smokers, who could continue to purchase cigarettes in retail transactions, and that the inconvenience some smokers would experience is a small burden when compared to the significant public health benefit of reducing children's and adolescents' access to tobacco.

(71) A few comments questioned the propriety of using young people in ''sting'' operations to determine the level of compliance with existing laws restricting the sale of tobacco products to children. One comment suggested that these operations taught children how and where to purchase cigarettes, concluding that the operations ''have done more to increase smoking in our youth than any tobacco company or advertisement could have.''

FDA relied on several types of evidence in proposing these regulations, including teen surveys and peer-reviewed studies. Compliance testing involves sending underage children and adolescents into tobacco outlets to attempt to purchase cigarettes or smokeless tobacco. This type of study provides reliable evidence of children's ability to illegally obtain tobacco products.

A 1994 review [62] of the design of recent studies indicates children who participated in these studies received specific instructions about the method and purpose of the study and were escorted by at least one adult. Some adults waited outside the outlet for the young person while others went inside to observe the child attempt the purchase. In response to comments on the final rule on substance abuse prevention and treatment block grants (suggesting that participating in sting operations could be detrimental to children and adolescents), DHHS explained that ''proper training and adult supervision can reduce any potential risk of negative consequences toward youth'' (61 FR 1492 at 1494, January 19, 1996). In addition, DHHS offered States assistance in developing compliance testing procedures.

FDA is not persuaded that participating in compliance testing entices children to smoke. The agency believes that, with proper training and adult supervision, children and adolescents who participate in compliance testing will understand that their role in this testing is to help reduce teenage smoking by identifying places that illegally sell tobacco products to children, and that, after identification and publicity or enforcement action, these places will stop illegal sales.

(72) Several adult smokers commented that the provision, either alone or in conjunction with other provisions, would cause a decrease in tobacco consumption. To compensate for this loss, they argue, tobacco companies will raise their prices and governments will increase taxes. Overwhelmingly, adult smokers commented that the price of a package of cigarettes is already unfairly high.

The agency has narrowly tailored the final regulations to prevent only young people's use of cigarettes and smokeless tobacco. Because sales to children account for a small percentage of total tobacco sales, industry revenues will be significantly diminished only after many years have passed. Moreover, the long-term effect on product prices is difficult to forecast because reduced product demand could easily result in price decreases.

(73) In contrast, one comment cited a 1995 survey in which three-quarters or more of those Californians polled supported increasing the tobacco tax by 25 cents. Another comment suggested that an additional portion of excise taxes be allocated to smoking cessation programs and to prenatal care, especially antismoking messages targeted to pregnant women. Other comments noted that increased prices

[61] Forster, J. L., M. Hourigan, and P. McGovern, ''Availability of Cigarettes to Underage Youth in Three Communities,'' *Preventive Medicine*, vol. 21, No. 3, pp. 320–328, May 1992.

[62] ''Design of Inspections Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors,'' Battelle, prepared for CDC, OSH, p. 14, April 1994.

could serve to deter some children and adolescents from purchasing cigarettes.

The agency cannot act on these comments as it lacks the authority to levy taxes or mandate prices.

(74) One comment submitted by cigarette manufacturers characterized as misleading FDA's claim that its proposal to eliminate vending machines is consistent with recommendations from IOM, PHS, a working group of State attorneys general, and the Inspector General of DHHS (60 FR 41314 at 41325). FDA disagrees. IOM and PHS specifically recommended that vending machines be eliminated. IOM advocated that less restrictive measures be adopted only if shown to be effective, [63] while PHS cautioned that alternatives be examined carefully. [64] Moreover, PHS specifically noted that Utah found disabling devices to be ''ineffectual in practice.'' [65]

The State attorneys general determined that ''very young children rely heavily on vending machines as a major source of tobacco products,'' and that ''their use of these machines is difficult to police.'' [66] Consequently, the group recommended that retail stores ''remove cigarette vending machines from their premises and sell tobacco products only from the controlled settings recommended above.'' [67] The referenced controlled settings included the use of electronic price scanners to prompt retail clerks to check a customer's identification and to display the last acceptable date of birth, using price scanner systems with tobacco ''locks,'' and requiring tobacco products to be kept behind sales counters. The State attorneys general did acknowledge that, ''at a minimum,'' vending machines should be modified to require tokens that could be purchased only from a store manager or be programmed to operate only if a cashier activates a remote switch, but their principal recommendation was the removal of vending machines.

While the Inspector General made no recommendation, his report noted that 42 percent of State health department officials believe that total bans are the only way to prevent teens from using cigarettes. [68]

FDA believes the provision on vending machines is consistent with the positions taken by the IOM, PHS, State attorneys general, and the Inspector General of DHHS.

(75) One comment suggested that the rule define ''vending machine'' to avoid regulating machines that dispense cigarettes to salespersons rather than customers. The comment described a machine designed to limit theft and to control the inventory of cigarettes and other similarly packaged items in retail stores, principally supermarkets. The machine requires that a computer command be entered before it dispenses a package of cigarettes. The comment asserted that among the machine's benefits is its ability to exclude customer access to cigarettes.

FDA did not contemplate the type of inventory machine described by the comment, and the provision, as drafted, would not include this type of machine. Section 897.16(c) is intended, in part, to eliminate mechanical devices that dispense cigarettes or smokeless tobacco to purchasers in locations that are accessible to children. FDA declines at this time to define ''vending machine'' so as to exclude from the rule mechanical devices developed in the future, including those intended to aid in preventing theft.

(76) One comment opposed to the provision interpreted it as prohibiting a vending machine that dispenses single cigarettes, packaged separately in tubes, each bearing the Surgeon General's warning and in compliance with tax laws. The comment explained that in some adult locations, such as cocktail lounges and casinos, many adults would like to purchase a single cigarette, and that the person submitting the comment developed the machine to fill this perceived gap in the marketplace.

The proposal did not contemplate the type of machine described by the comment. Accordingly, § 897.16(c) has been amended to permit the sale of a packaged, single cigarette in locations inaccessible to persons under the age of 18. This exception is restricted to packaged, single cigarettes that comply with other applicable laws and regulations.

b. *Self-service displays.* Proposed § 897.16(c) also would have prohibited the use of self-service displays. The preamble to the 1995 proposed rule explained that self-service displays enable young people to quickly, easily, and independently obtain cigarettes and smokeless tobacco. FDA cited one report that reviewed surveys of grade school students; the report found that over 40 percent of the students who smoked daily shoplifted cigarettes from self-service displays (60 FR 41314 at 41325). The agency also cited one study showing that tobacco sales to young people dropped 40 to 80 percent after enactment of ordinances prohibiting self-service displays and requiring vendor-assisted sales (60 FR 41314 at 41325). The proposed provision, therefore, was intended to prevent young people from helping themselves to these products and to increase the amount of interaction between the sales clerk and the underage customer.

The preamble to the 1995 proposed rule also referred to the IOM Report which stated that placing products out of reach ''reinforces the message that tobacco products are not in the same class as candy or potato chips.'' [69]

In response to the comments, the agency has amended this section to except certain self-service displays (merchandisers) in facilities inaccessible to persons under the age of 18.

(77) Several comments asserted that the proposed restriction pertaining to self-service displays would effect takings compensable under the Fifth Amendment.

The agency disagrees with the comments. Given the character of the section, as modified in this final rule, and the lack of reasonable investment-backed expectations in personal property, its economic impact, while potentially significant for some parties, is not such as to effect a taking. The agency addresses Fifth Amendment issues in greater detail in section XI.A. of this document.

(78) Several comments challenged FDA's basis and authority for prohibiting self-service displays. The comments focused, in part, on the studies and reports cited by the agency. They argued that active enforcement of laws, rather than elimination of self-service displays, led to decreases in young people's access to cigarettes and smokeless tobacco. Other comments disputed whether significant shoplifting occurs from self-service displays. According to these comments, FDA did not provide any evidence to suggest that eliminating self-service displays is necessary to prevent shoplifting.

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[63] IOM Report, p. 214.

[64] ''Model Sale to Tobacco Products to Minors Control Act, A Model Law Recommended for Adoption by States of Localities to Prevent the Sale of Tobacco Products to Minors,'' DHHS, p. 2, May 24, 1990.

[65] *Id.*, p. 5.

[66] ''No Sale: Youth Tobacco and Responsible Retailing Developing Responsible Retail Sales Practices and Legislation to Reduce Illegal Tobacco Sales to Minors, Findings and Recommendations of a Working Group of State Attorneys General,'' pp. 31–32, December 1994.

[67] *Id.*, p. 32.

[68] ''Youth Access to Cigarettes,'' DHHS, Office of the Inspector General, Pub. No. OEI–02–90–02310, pp. 8–9, May 1990.

[69] IOM Report, p. 215.

One comment examined studies that FDA did not cite in the 1995 proposed rule and found one study estimating that less than 5 percent of the adolescents surveyed had shoplifted cigarettes. Also, a number of comments stated that, if shoplifting were truly a significant problem, retailers would have a financial interest in reducing their losses and would remove self-service displays themselves. The comments implied that shoplifting is not a significant problem, and several claimed FDA's rationale was inconsistent because, if young people could purchase cigarettes and smokeless tobacco easily from retailers, they would not have to steal them from self-service displays.

In contrast, several comments supported the prohibition on self-service displays, reiterating FDA's position that displays encourage shoplifting, and their absence increases the likelihood of age verification. For example, a drug addiction counselor commented that teens do not want to go to the counter and ask for cigarettes since there is a greater likelihood that they will be asked to show their identification and they might be embarrassed. One comment also asserted that retailers get products for displays at a discount, and such discounts are, in effect, a subsidy for shoplifting. Another comment alleged that, in one area of the country, low-priced brands are put in displays and that retailers are compensated for any shoplifting losses.

Comments from other areas of the country agreed that shoplifting occurs, sometimes at significant rates. One comment stated that a 1993 survey of 9th-grade students in one county revealed that 51 percent had shoplifted cigarettes. Another comment, reflecting on experiences conducting retailer compliance checks in three small towns, stated that its teenage volunteers ''commented on the ease with which they could have lifted cigarettes from free-standing displays.'' A comment describing practices in a rural part of the country stated that theft was one method of acquiring smokeless tobacco, and that young people often began using such products at the age of 10, 11, or 12.

Other comments suggested an additional reason for eliminating self-service displays. These comments indicated that young people can easily pick up products from displays, leave their money at the cashier's desk, and leave the premises without being challenged by a retailer or before the retailer can request proof of age.

FDA believes there is ample evidence to support a restriction on self-service displays. The preamble to the 1995 proposed rule cited surveys suggesting that a significant percentage of children and adolescents (40 percent in the two areas surveyed) shoplift cigarettes (60 FR 41314 at 41325), and at least one comment reported an even higher percentage (50 percent). Although one comment from cigarette manufacturers suggested the shoplifting rate to be only 5 percent, FDA emphasizes that, even if one accepts the 5 percent figure, the numbers of young people engaging in shoplifting can be very large. For example, 5 percent of the estimated 3 million young people who smoke cigarettes daily equals 150,000 children and adolescents. Five percent of the estimated 3 million smokeless tobacco product users under the age of 21 also equals 150,000 people.

These numbers may even be artificially low because they exclude the number of young people who do not smoke or use smokeless tobacco daily, and these numbers may be extremely low if the 40 or 50 percent shoplifting rates identified by the agency or by other comments prove to be more accurate than the 5 percent rate cited by the cigarette manufacturers.

FDA also disagrees with those comments claiming that shoplifting is not a significant problem. Generally, such comments asserted that the problem is not significant because, if it were, retailers would move self-service displays, and most have not done so. Such comments, however, misconstrue the significance of the problem. The agency did not, and does not, claim that individual retailers are suffering significant shoplifting losses (although FDA did receive one comment containing information showing that shoplifting losses at two stores amounted to several thousands of dollars worth of cigarettes annually). Instead, FDA is stating that significant numbers of young people shoplift these products. The distinction is critical. To illustrate, if 1,000 retailers each lose 1 cigarette package to shoplifting, each retailer might feel that the shoplifting rate, from its perspective, is insignificant. However, if 1,000 young people acquire cigarettes by shoplifting, the shoplifting problem, from a public health perspective, then becomes much more significant.

(79) Several comments argued that the studies cited by the agency, having been conducted at only two locations in the United States (Erie County, NY, and Fond du Lac, WI), cannot be used to justify a nationwide prohibition against self-service displays.

The agency disagrees with these comments. The comments offered no evidence to show that these communities are so distinct or unique from the remainder of the United States to require FDA to discount or to ignore their findings. To the contrary, FDA received other comments from various parts of the nation supporting the rule, and these comments often agreed that young people shoplift these products from displays.

FDA also notes that it does not require clinical investigations for product approvals to be conducted on a national scale. One important aspect of any study, whether it is submitted as part of an investigational product exemption, marketing application, or rulemaking, is whether the study is conducted and analyzed in a scientifically valid way that permits the results to be extrapolated to a broader population. In other words, the methodology and analysis are more important than where the study was conducted. If the agency could only act after nationwide studies had been conducted, it would be unable to act or to respond promptly, even in response to significant public health problems or emergencies.

(80) Several comments questioned the evidence supporting the proposed restriction on self-service displays. The comments stated that FDA had no evidence to support the assertion that removing self-service displays will increase the likelihood of retail clerks requesting proof of age. One comment stated that the one document cited by FDA (which compared smoking practices in five California counties before and after the institution of ordinances prohibiting self-service merchandising)[70] cannot be used to justify a rule with nationwide application because the document, which the comment correctly identified as a ''position paper'' rather than a study, did not: (a) Indicate whether the ordinances contained other provisions that would have led to enhanced compliance with minimum age laws; and (b) disclose whether retailers were told of the compliance testing operation before or after the fact, such that, had the retailers known, they would have been more vigilant in ensuring

[70] Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' Stop Tobacco Access for Minors Project (STAMP), North Bay Health Resources Center, November 3, 1994.

compliance regardless of how their products were displayed. This comment further asserted that the act of adopting the ordinances, and the penalties they contained, may have made retailers more vigilant in ensuring compliance with minimum age laws than the restrictions in the ordinances themselves. Finally, the comment stated that the document was not a controlled study and that there was no indication that it was not biased, was subjected to peer review, or was even published in a scientific journal. The comment stated that the document would not be acceptable to FDA if it had been submitted as proof of a product's effectiveness.

Another comment echoed criticism of the document, stating that factors besides the restriction on self-service displays could have reduced tobacco use by young people and so the document does not support a prohibition against self-service displays.

FDA acknowledges that the document omitted details regarding the author's methodology and the ordinances in the 5 California counties and the 24 cities covered in the document. The agency disagrees, however, with the comments' assertion that factors other than the restriction on self-service displays or other features of the ordinances may have been principally responsible for decreasing tobacco use among young people. Such comments overlook the document's statement that the ordinances were to ''prohibit self-service merchandising (display and sale) of tobacco products and point-of-sale tobacco promotional products and require only vendor-assisted sales of tobacco products and point-of-sale tobacco promotional products in retail stores.'' [71] This statement suggests that the ordinances focused on restricting self-service displays (or merchandisers) and point-of-sale promotional products rather than other activities.

Other criticisms of the document are inappropriate as well. For example, the comment claimed that other provisions in the ordinances or other factors may have contributed to the decline in tobacco use in young people so that a restriction on self-service displays, alone, may not have been a significant factor in reducing tobacco use among young people. This criticism, however, overlooks the fact that the rule's restriction on self-service displays is also complemented by other provisions (such as requiring retailers to verify age and prohibiting distribution of free samples) that will, both individually and collectively, reduce young people's access to cigarettes and smokeless tobacco.

Similarly, FDA does not agree that the document is flawed because retailers were not informed of the compliance testing operation before it was conducted. Alerting a retailer to an upcoming compliance test would bias any results because the retailer would alter its behavior in order to ''pass'' the test.

Additionally, in drafting the 1995 proposed rule, FDA used the best evidence available to it. The comments did not provide any studies to contradict the cited document, and while some criticisms of the document may be valid, such criticisms do not require the agency to revoke the provision entirely. The document was not FDA's sole basis for proposing to restrict self-service displays. The preamble to the 1995 proposed rule indicated that such a restriction would also reduce shoplifting, eliminate the ''message'' that displays send to young people, and increase interaction between retailers and their customers. These other justifications, and the comments pertaining to them, are discussed in greater detail in this document.

(81) Other comments objected to a prohibition on self-service displays because, according to these comments, the rule did not impose any sanctions on young people or contain any provisions that would modify a young person's behavior so that he or she would not shoplift. Some comments suggested that, instead of restricting the use of self-service displays, shoplifters should be prosecuted, but these same comments also declared that State or local government authorities usually decline to prosecute young shoplifters.

As stated earlier, it would be inappropriate for FDA to amend the rule to impose penalties on young people who purchase or possess cigarettes or smokeless tobacco. The main focus of the act is on the introduction, shipment, holding and sale of goods in interstate commerce. Thus, whether young people should be prosecuted for shoplifting, and the penalty for shoplifting are appropriately matters for State or local law.

(82) Several comments challenged the statement in the preamble to the 1995 proposed rule that removing self-service displays would reinforce the message to children that tobacco products are not as acceptable as candy or potato chips. The comments said that young people know that tobacco products are not like candy or potato chips and that there is no evidence to show that the statement is true. A small number of comments added that FDA's rationale would force retailers to remove other ''unhealthy'' products (such as products containing fat or cholesterol) from displays.

In contrast, a few comments agreed that self-service displays for cigarettes and smokeless tobacco convey an implied message that these products are acceptable. One comment from a local government reported that young people often see tobacco products as being socially acceptable (or less harmful to health) because they are openly displayed. The comment noted that the local jurisdiction had restricted displays to being within 20 feet of the checkout counter and in a direct line of sight, but expressed regret that it had not eliminated displays altogether. Other comments noted that many retailers display cigarettes next to candy, baseball cards, and other items that appeal to children and adolescents. These comments concluded that it is necessary to eliminate self-service displays so that young children do not associate cigarettes with other products that they find amusing or that adults give to children and adolescents as treats.

The IOM Report advanced the theory that young people see self-service displays as an implied message regarding the acceptability or safety of cigarettes and smokeless tobacco. The IOM report represents the informed decisions, opinions, and recommendations of a body of experts, and so, with respect to this issue, the agency disagrees with those comments that would have FDA dismiss the IOM's opinion.

FDA also disagrees with those comments arguing that the agency would have to eliminate self-service displays for potato chips, candy, and other supposedly ''unhealthy'' products. These food products do not present the same range or magnitude of adverse health effects or effects on the body to warrant tighter restrictions on their sale, distribution, or use.

(83) Several comments challenged FDA's claim that removing self-service displays would increase direct interaction between sales clerks and underage consumers. The comments asserted that removing self-service displays will not prompt sales clerks to check for proof of age and that FDA had no evidence to support this proposition. Other comments opposed any restriction on self-service displays

[71] *Id.*, p. 3.

because, they claimed, retail clerks, rather than self-service displays, are responsible for sales to young people. If retail clerks consistently demanded proof of age, these comments would permit self-service displays to be used.

Other comments asserted that FDA has no reasonable basis to assume that clerks will check for proof of age when clerks already ignore State laws.

In contrast, a few comments agreed that eliminating self-service displays would increase interaction between clerks and underage consumers or deter young people from attempting to purchase cigarettes or smokeless tobacco. One comment from a local board of health stated that it eliminated self-service displays because its evidence indicated that young people in the locality are less likely to purchase cigarettes if they have to request them from retail clerks. Another comment reflected on the author's own experience as a child when she would purchase cigarettes and said it is easy to grab a cigarette package, leave money on the counter, and simply leave a store before the sales clerk can react.

Section 897.14(b)(1) requires retailers to verify that persons purchasing cigarettes or smokeless tobacco are not under the age of 18. This provision, in conjunction with the prohibition against sales to anyone under 18 in § 897.14(a), the restriction on self-service displays in § 897.16(c), the sanctions that are available under the act, and the likelihood that State agencies will devote more attention to illegal sales to young people as a result of section 1926 of the PHS Act should increase the probability that retailers will verify the age of prospective purchasers.

Yet logically, removing self-service displays should increase interaction between retailers and potential consumers because the retailer, under this rule, must physically hand the product to the consumer. While this action probably will take little time (the preamble to the 1995 proposed rule and to this final rule estimate that the elimination of self-service displays would require 10 seconds of additional labor time for many retail transactions), nevertheless it increases the interaction between the retailer and potential customers. Furthermore, by restricting self-service displays, the rule eliminates a young person's ability to take a package of cigarettes or smokeless tobacco, leave money on the counter, and leave the retailer's premises without having to provide proof of age.

(84) Many comments opposed any restriction on self-service displays because they said eliminating self-service displays would adversely affect adult consumers or would be ''inconvenient'' because adults would not be able to purchase products quickly; see, handle, or choose products; or obtain information about a product or a special promotion. A few comments asserted, without any supporting evidence, that self-service displays are not or cannot be used by young people, and, therefore, should not be regulated.

Conversely, one comment supporting the provision recommended that FDA clarify or modify the term ''self-service displays'' to distinguish self-service sales or merchandisers from advertising displays.

The comments opposing the rule misinterpreted how it would apply. The final rule prohibits self-service displays from being in facilities that are accessible to young people. Eliminating self-service displays from such facilities simply means that a consumer will not be able to take physical possession of a product without the retailer's assistance. Any inconvenience to an adult should be slight. For example, it is extremely unlikely that adults will suffer undue hardship or wait an unreasonable amount of time if they must ask a retail clerk to hand a product to them. Moreover, the provision does not prevent adults from seeing or choosing a product or from seeing or receiving information about a product; products would remain visible, but they would be behind a counter or in an area accessible only to the retailer.

Deleting self-service displays from the rule because adults wish to avoid contact with clerks would be inappropriate as well. As a practical matter, adults who use self-service displays would not be able to avoid all contact with a retailer because they presumably still interact with the retailer when they pay for the product. An important component of these regulations is to eliminate those modes of sale used by young people that do not require them to show proof of age or otherwise do not challenge a young person to show that he or she is legally entitled to purchase the product.

FDA does agree, however, that the rule should be clarified so that the reference to displays in § 897.16(c) is understood to cover self-service sales or merchandisers rather than advertising displays that contain no products and has amended the rule accordingly. However, advertising displays are restricted under the advertising provisions in this rule.

(85) The preamble to the 1995 proposed rule expressed a belief that retailers, in order to comply with a prohibition on self-service displays, could move displays behind a retail counter or create an area that would be accessed only by the retailer's employees.

Many comments rejected this notion, claiming that, due to space constraints, many retailers would be unable to move displays behind a counter and would be obliged to build areas where access would be controlled. The comments said such construction and remodeling could be expensive and could force some retailers to scale back their tobacco sales or abandon them completely; such actions would lead to decreased sales by the retailer and trigger reductions in staff and in State or local Government tax revenues.

One comment estimated that, for convenience stores, the average remodeling cost would be as high as $7,000 per store and noted that tobacco purchases account for 28 percent of convenience store sales. So, instead of eliminating self-service displays, some comments advocated alternative approaches. The alternatives included attaching electronic article surveillance tags to products (although the comment suggesting this alternative conceded that new technology or assistance at the manufacturer's level would be needed); ''source tagging,'' where random packages contain an electronic tag so that would-be shoplifters would not know which packages were tagged and, as a result, would be less inclined to shoplift products; and requiring displays to be within a certain distance of a cash register or the cashier's line of sight, supplemented by posting signs against underage sales and by training sales clerks. ''Source tagging'' would require manufacturers, rather than retailers, to insert tags into packages.

The alternatives identified by the comments appear to be less effective or less practical than removing self-service displays from places that are accessible to young people. For example, surveillance tags and, to a lesser extent, ''source tagging'' might deter shoplifting, but this would require all manufacturers to agree to place such tags in their products and would require retailers to install machines or gates to detect those tags. More importantly, comments from manufacturers did not address the creation or use of such tags. A ''line-of-sight'' or restricted-placement alternative (requiring a display to be within a certain distance of a retail employee) would require no changes by

manufacturers and few changes by retailers, yet the preamble to the 1995 proposed rule cited studies where similar requirements for vending machines failed to prevent illegal sales to young people (60 FR 41314 at 41325). Employees might also be distracted or blocked from seeing the displays, thereby reducing the effectiveness of any ''line-of-sight'' or restricted placement alternative. Furthermore, the alternatives would fail to eliminate the implied message that self-service displays send regarding the acceptability or safety of these products. Because FDA is unaware of any effective alternative, the agency declines to amend the rule as suggested by the comments.

FDA has, however, amended the rule to permit self-service displays (merchandisers only) in facilities that are inaccessible to people under 18 at all times. The agency made this change in response to comments stating that some facilities are inaccessible to young people and so certain requirements, such as restrictions against vending machines and self-service displays, should not apply. This exception is subject to the same restrictions as the exception on vending machine sales.

(86) Many comments, particularly from retailers, opposed eliminating self-service displays, stating that they derive a significant portion of their revenue from displays and slotting fees provided by manufacturers. Several cited figures that were in the hundreds of thousands of dollars. The comments generally stated that eliminating self-service displays would decrease or eliminate a significant portion of their revenue and, according to some, lead to layoffs or prevent them from hiring young people.

Similarly, FDA received a few comments from firms that manufacture or sell displays. These comments stated that the firms would lose significant amounts of revenue or would be forced out of business if self-service displays were eliminated.

A few comments, however, disputed whether retailers would lose slotting fees. One comment explained that manufacturers would continue to pay fees to ensure that their products would be placed in strategic locations behind the counter, while another comment noted that many retailers in a northern California region where self-service displays were eliminated did not lose slotting fees.

The agency declines to amend the rule because of the possible loss of slotting fees or other revenue from manufacturers. The theoretical loss of fees that are, at best, tangential to the sale of these products is an inappropriate basis for determining whether this provision denies young people's access to these products effectively. Furthermore, FDA appreciates that such fees may be important to certain retailers, but, as stated earlier, the agency has no reason to conclude that all manufacturers will discontinue those fees because of this rule. The preamble to the 1995 proposed rule (see 60 FR 41314 at 41369) and one comment cited experience in California to show that retailers might not suffer significant economic losses if self-service displays are removed.

FDA reiterates that removing self-service displays from places that are accessible to young people does not mean that cigarettes and smokeless tobacco must be hidden from public view. It simply means that retailers will be required to hand these products to consumers. Presumably, if the products are moved behind the counter, manufacturers still have an incentive to ensure that their products are strategically placed in order to attract adult consumers.

(87) Several comments objected to a restriction on self-service displays, claiming that retailers have a ''right'' to advertise and sell products in their own establishments in any manner they select.

As mentioned in section IV.B. of this document earlier, section 520(e) of the act states, in part, that the agency may issue regulations to establish conditions on the sale, distribution, or use of a restricted device. Restrictions on cigarette and smokeless tobacco sales are appropriate given the potential adverse health effects caused by or associated with the use of these products and their accessibility and appeal to young people.

(88) A few comments said that eliminating self-service displays will make it difficult or impossible for marginal brands of cigarettes or smokeless tobacco to compete against established brands.

FDA reiterates that eliminating self-service displays from places that are accessible to young people does not mean that the products must be hidden from view; it simply means that consumers will not be able to take physical possession of the product without the retailer's assistance. Consequently, all products will face the same constraints, insofar as retailer space is concerned.

(89) Many comments would delete a prohibition against self service displays because, according to these comments, the prohibition would be ineffective. These comments stated that self-service displays do not entice young people to smoke, do not increase consumption of tobacco products, or are only used where retailers check the consumer's age. Others stated that young people would get the products anyway, so there was no need to prohibit the use of self-service displays.

The preamble to the 1995 proposed rule stated, among other things, that young people shoplift products from displays (60 FR 41314 at 41325). Additionally, the preamble to the 1995 proposed rule indicated that young people will adjust or shift their purchasing behavior as certain avenues of obtaining these products are eliminated. (See 60 FR 41314 at 41325 (citing different vending machine use rates depending on the access restrictions used in the jurisdiction).) Given this evidence, it is reasonable to assume that, as young people are precluded from purchasing these products, they may be inclined to acquire them by theft and other means. Thus, when properly framed, the issue is not whether displays entice young people to smoke or to use smokeless tobacco (which FDA did not advance as the principal justification for the rule), but whether the agency should eliminate self-service displays as an avenue that young people use to obtain these products. The agency concludes that self service displays must be eliminated from places that are accessible to young people as part of the general restriction against impersonal modes of sale.

(90) Several comments opposed elimination of self-service displays because they claimed that retailers would be forced to hire additional staff. These comments contrasted sharply with the majority of comments from retailers who predicted that the loss of self-service displays would compel them to lay off staff. One comment explained that a self-service display frees the retailer's staff to perform other tasks. The other asserted that the rule would compel retailers to hire additional staff in order to sell these products and that this would result in an ''unfunded mandate'' in violation of the Unfunded Mandates Reform Act.

The preambles to the 1995 proposed rule and to this final rule estimate that eliminating self-service displays would require 10 seconds of additional labor time for many retail transactions involving cigarette cartons (60 FR 41314 at 41367). The ''Analysis of Impacts''

discussion in section XV. of this document places the labor cost for this time at approximately 2.6 cents per carton. Thus, for a retailer to be compelled to hire additional staff to compensate for the loss of self-service displays, cigarette and smokeless tobacco product purchases would have to account for a substantial number of transactions. Some retailers may indeed feel that they need to hire additional staff, but the agency believes that the rule's benefits—reducing young people's access to cigarettes and smokeless tobacco nationwide—outweigh the hiring and accompanying economic burdens that might be imposed on some retailers. Moreover, because the final rule permits self-service displays (merchandisers only) in facilities that are inaccessible to under 18 people at all times, the final rule's impact on some retailers may be reduced.

FDA also disagrees with the comment claiming that the agency violated the Unfunded Mandates Reform Act. The preamble to the 1995 proposed rule contained a discussion of the Unfunded Mandates Reform Act as well as the estimated added labor costs in the ''Analysis of Impacts'' (60 FR 41314 at 41367 and 41359 through 41372).

(91) One comment disputed FDA's estimate that eliminating self-service would result in 10 seconds of additional labor time for most retail transactions. The comment, however, did not provide any estimate of the time that would be required.

The agency did not receive any data to suggest that the additional labor time would be greater or less than 10 seconds. While some transactions may take more than 10 seconds, the agency believes that the additional labor time will be so negligible that it will not be a significant burden on the retailer.

c. *Mail-order sales and mail-order redemption of coupons.*—i. *Mail-order sales.* Proposed § 897.16(c) would also have prohibited the use of mail-order sales and mail-order redemption of coupons. The preamble to the 1995 proposed rule stated that mail-order sales and mail-order redemption of coupons do not involve a face-to-face transaction that would enable verification of the consumer's age.

The agency received thousands of comments on the proposed restriction against the mail-order sale of cigarettes and smokeless tobacco. Comments supporting the proposed restriction noted that it would make cigarettes and smokeless tobacco more difficult for young people to obtain. Specifically, comments stated that ''mail-order sales should be prohibited since the seller has obvious difficulties verifying the age of the purchaser in selling where there is no face-to-face encounter.'' A comment from 26 State attorneys general stated that ''ending distribution of tobacco by mail-order * * * will greatly assist our efforts to enforce compliance with our state laws.'' As a result of some comments discussed in detail below, however, the final rule permits mail-order sales, except for redemption of coupons and free samples.

(92) The agency received hundreds of comments opposing the proposed restriction against mail-order sales. Many comments were submitted by older smokers (senior citizens, retirees on fixed incomes, etc.) who identified themselves as pipe tobacco smokers who purchased tobacco products through the mail; most individuals appeared to be clients from one tobacco product supply house in Tennessee. These comments stated that young people do not smoke pipe tobacco and added that they would like to continue to purchase their pipe tobacco through the mail.

The agency believes that the comments misinterpreted the 1995 proposed rule. The preamble to the 1995 proposed rule stated that the rule did not apply to pipe tobacco or to cigars because FDA has no evidence demonstrating that pipe tobacco and cigars are drug delivery devices under the act or that young people use such products to any significant degree (60 FR 41314 at 41322).

(93) One comment asserted that the proposed mail-order provision is unauthorized and contrary to law. According to the comment, neither section 520 of the act nor any other provision of the act gives FDA the authority to declare matter unmailable. The comment explained that, under the Prescription Drug Marketing Act (PDMA), prescription drug samples may be sent through the mail to those authorized by law to obtain them. Furthermore, the comment argued, Congress has specifically determined and legislated what products should not be sent through the mail (39 U.S.C. 3001(f) and (g) (Federal statute on ''nonmailable matter'')).

The agency disagrees with the comment. Section 520(e) of the act expressly authorizes the agency to issue regulations pertaining to the sale, distribution, or use of a restricted device. Restrictions on the sale or distribution of such a device through the mail are clearly within the scope of FDA's authority under that section.

Additionally, FDA does not agree that the PDMA or 39 U.S.C. 3001 prevents the agency from acting on mail-orders. The PDMA's mail-order restrictions represented a congressional response to a specific problem, namely the diversion of adulterated prescription drug products (including drug samples) into illegal markets. Here, the products in question are devices rather than prescription drugs, and the rule does not purport to address the diversion of adulterated cigarettes or smokeless tobacco or samples of those products.

Similarly, the Postal Service provision (39 U.S.C. 3001) on ''nonmailable matter'' does not preclude FDA from issuing regulations pertaining to the distribution of a regulated device. The provision simply states that certain items or types of items are nonmailable and directs the United States Postal Service (USPS), in certain situations, to issue regulations (such as regulations pertaining to fragrance advertising samples). FDA interprets 39 U.S.C. 3001, therefore, as establishing certain ''nonmailable'' items for USPS purposes rather than precluding FDA from regulating the sale and distribution of a device pursuant to its device authority. Nevertheless, as discussed in comment 94 below, FDA has amended the rule to permit mail order sales, so the issue of the USPS restrictions on nonmailable matter is moot.

(94) The agency received many comments from individuals who contended that the proposed mail-order restriction is unwarranted because the agency cited no studies to demonstrate that young people actually use the mail to obtain cigarettes. One comment noted that IOM acknowledges that ''the extent of mail-order purchase of tobacco products by minors is not known.'' According to the comment, the mail-order restriction must be based on actual evidence that a substantial number of young people use the mail to purchase cigarettes and not based on ''theoretical purchasability.''

Other comments stated that young people do not obtain cigarettes through the mail because they do not possess checks or credit cards to effectuate mail-order purchases. In addition, the comments questioned whether young people are patient enough to wait several weeks to obtain tobacco products. A few comments, including a comment from a mail-order firm, contended that mail-order purchases would be too expensive for young people, either because of the cost or the

minimum order sizes (which, according to one comment, usually consists of several pounds of tobacco). These comments opposed the proposed mail-order restriction on the basis that it would not effectively reduce young people's access to tobacco products and would instead eliminate an adult's access to entirely legal tobacco products.

Other comments from firms with a significant mail-order business stated that the elimination of mail-order sales would force the firms to terminate staff or go out of business.

The agency also received many comments from adults opposing the proposed mail-order restriction. These comments stated that because mail-order sales are highly preferable to purchases in retail stores the products sold through the mail are unavailable in stores or are less expensive than those sold in stores. Other comments (including one from a prison inmate) said that because mail-order sales serve those in rural or isolated areas, eliminating mail-order sales would eliminate the principal or sole source of tobacco for those adults.

After carefully reviewing the comments, the agency has decided to delete mail-order sales from § 897.16. The restriction was intended to preclude young people from having easy access to cigarettes and smokeless tobacco. However, there is inadequate evidence demonstrating that young people use mail-order sales to any significant degree. This lack of evidence may indicate that it is not relatively easy for young people to purchase cigarettes and smokeless tobacco through the mail.

FDA also considered the impact of the proposed mail-order restriction on adults. The agency does not intend to unreasonably interfere with an adult's ability to obtain legally his or her preferred tobacco products.

Consequently, FDA has amended § 897.16(c) to allow mail-order sales of cigarettes and smokeless tobacco. The agency emphasizes, however, that the final rule retains the restrictions against the redemption of coupons and distribution of free samples through the mail. This amendment is consistent with the IOM Report which recommended a suitably limited Federal ban on the distribution of tobacco products through the mail as part of a long-term access strategy and, at a minimum, restrictions against the mail-order redemption of coupons and the distribution of free samples through the mail. [72]

FDA remains concerned, however, that young people may turn to mail-order sales as the rule's restrictions against other forms of access (such as vending machines and retail stores) become effective. Accordingly, FDA strongly advises mail-order firms to take appropriate steps to prevent sales to young people and reminds mail-order firms that § 897.14(a) prohibits the sale of cigarettes and smokeless tobacco to anyone under age 18. The agency will monitor the sales of mail-order tobacco products, and if FDA determines that young people are obtaining cigarettes or smokeless tobacco through the mail, the agency will take appropriate action to address the situation.

(95) Several comments criticized the agency for failing to consider less restrictive alternatives. The comments noted that tobacco mail-order houses require payment by check or credit card. Other comments would amend the rule to require firms to maintain records evidencing compliance with proof of age requirements. Another comment suggested a requirement for photocopies of photographic identification cards, such as an identification with a drivers license number, for mail-order transactions.

As stated previously, FDA has amended the final rule to permit mail-order sales, but will monitor such sales to ensure that young people do not obtain cigarettes or smokeless tobacco through the mail. The agency, therefore, strongly advises firms to take appropriate measures to prevent sales to young people.

(96) Several comments expressed concern about the financial well being of the USPS. These comments predicted that the USPS would lose income if tobacco products could no longer be sent by mail. The comments predicted that the USPS would be forced to raise postal rates to compensate, thus affecting product users and nonusers alike.

As stated previously, the agency has amended the rule to permit mail-order sales to continue. However, FDA notes that speculative or theoretical impacts on the USPS are not an appropriate basis for determining how or whether to regulate a restricted device under the act.

(97) One comment representing the concerns of specialty tobacco products noted that 90 percent of its manufacturer-distributor-retailer distribution system uses the mail or other commercial carriers. This comment requested that FDA clarify that the proposed restriction on mail-order sales pertained to mail-order sales to the ultimate user rather than to inter-company transfers.

Proposed § 897.16(c) was intended to address sales and distributions to consumers. Transactions and shipments between manufacturers, distributors, and retailers, therefore, are not subject to the restrictions on mail-order sales of cigarettes and smokeless tobacco. However, because the final rule permits mail-order sales, there is no need to amend the rule to clarify this point.

(98) One comment supported the restriction against mail-order sales in part because, the comment claimed, such sales permit the purchaser to avoid taxes on these products (by purchasing the products from firms in States with lower taxes). The comment also stated that eliminating these sales would help Canadians because American mail-order firms are not subject to high Canadian taxes and can sell comparatively lower-cost cigarettes in Canada. The comment said this practice increases cigarette consumption in Canada and undermines the health benefits resulting from high Canadian taxes.

The issues raised by the comments are beyond the scope of this rule and FDA's authority.

ii. *Mail-order redemption of coupons.* Proposed § 897.16(c) would have prohibited mail-order redemption of coupons. The preamble to the 1995 proposed rule addressed mail-order redemption of coupons in conjunction with mail-order sales, and the restriction against mail-order redemption of coupons was meant to apply only to coupons that a prospective purchaser would send through the mail (regardless of whether the prospective purchaser used the USPS or a private carrier) to a firm to obtain cigarettes or smokeless tobacco.

(99) Most comments on this issue mistakenly assumed that FDA was proposing to ban all direct mail coupons. These comments contended that direct mail coupons are redeemed during face-to-face transactions at larger retail establishments such as grocery stores. For the most part, these comments suggested that young people do not routinely use coupons to purchase tobacco products, noting that the smaller, convenience stores where young people frequently obtain cigarettes and smokeless tobacco often do not accept coupons.

[72] IOM Report, pp. 108, 225–226.

In contrast, FDA also received several comments supporting the proposal to eliminate mail-order redemption of cigarette and smokeless tobacco coupons. For example, the attorney general for a populous northeastern State commented that ''[i]n another operation conducted by my office earlier this year, 30 minors mailed in coupons to obtain free samples of smokeless tobacco products from United States Tobacco Company. Virtually all of the minors were provided with such free samples.''

Proposed § 897.16(c)'s reference to mail-order redemption of coupons was directed at the redemption of coupons through the mail. The provision was not intended to prevent adults from redeeming coupons at a point of sale or from receiving coupons through the mail. FDA based this provision on the IOM Report which, among other things, noted that value added promotions, including coupons, constituted the largest market expenditure by the tobacco industry in 1991, that coupons are accessible to young people through direct mail campaigns, and that price-sensitive young people are attracted to such schemes or may be increasingly attracted to such schemes as their other sources of tobacco products are restricted. [73]

Comments supporting this provision confirmed the need for prohibiting mail-order redemption of coupons. These comments reported incidents where one or more young people obtained several packages of cigarettes or smokeless tobacco by sending in coupons (usually for free samples). Consequently, the final rule retains the restriction against mail-order redemption of coupons. FDA adds that, for purposes of this subpart, ''mail'' is not confined to USPS delivery but includes items shipped through private carriers.

d. *Free samples.* Proposed § 897.16(d) would have prohibited manufacturers, distributors, and retailers from distributing or causing to be distributed any free samples of cigarettes or smokeless tobacco. The agency proposed this restriction because free samples are often distributed at ''mass intercept locations,'' such as street corners and shopping malls, and at events such as festivals, concerts, and games. The preamble to the 1995 proposed rule stated that free samples represent a ''risk-free and cost-free'' way for young people to obtain and possibly use cigarettes or smokeless tobacco and that, when free samples are distributed at cultural or social events, peer pressure may lead some young people to accept and to use the free samples (60 FR 41314 at 41326).

The preamble to the 1995 proposed rule also cited surveys and reports demonstrating that young people, including elementary school children, can obtain free samples easily. Young people were able to obtain free samples despite industry-developed, voluntary codes that supposedly restrict distribution of free samples to underage persons. The agency cited the IOM Report which suggested that distribution of free samples to young people occurs because the samplers are often placed in crowded places and operating under time constraints that may limit their ability to request proof of age. The IOM Report added that the samplers are usually young themselves and, as a result, ''may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group'' (60 FR 41314 at 41326).

(100) FDA received a few comments that opposed any restrictions on free samples, claiming that eliminating free samples would violate the ''rights'' of adult consumers, reduce choices for adults, or deprive adults of the opportunity to save money.

In contrast, many comments supported proposed § 897.16(d), including several that opposed the remainder of the rule but expressly supported a prohibition on the distribution of free samples. Several comments stated that young people can easily obtain free samples; a few comments, including two from 12-year old students, mentioned that their classmates were able to receive free samples or reported that young people were able to receive free samples without being asked to show proof of age. One comment even reported that a young person was able to receive 4 cigarette packages through the mail as free samples, while another claimed to have seen 12 cans of smokeless tobacco being given to teenagers.

Another comment supported the provision, based on the author's own experience when he was 15 years old; a neighborhood grocer gave him and his friends free cigarettes ''until we were hooked'' and then the grocer ''had steady paying customers.'' Other comments supported this provision for the same reason that they supported eliminating single-cigarette sales and establishing a minimum package size: Such items encourage young people to experiment with cigarettes or they represent, as a consortium of State attorneys general said, ''sales and marketing practices that provide young people with the easiest access to tobacco.''

The agency agrees that § 897.16(d) will affect adults by effectively requiring them to purchase cigarettes and smokeless tobacco rather than receive them free of charge. However, the comments opposing the elimination of free samples did not offer any suggestions as to how to prevent free samples from reaching young people. In view of the evidence showing that young people obtain free samples despite any industry-imposed restrictions or (in the case of at least one comment) that they obtain free cigarettes from a retailer, the agency concludes that the benefits of eliminating free samples as a source for young people outweigh the inconvenience to adults.

FDA also disagrees with the comments asserting that eliminating free samples adversely affects an adult's ability to choose products or otherwise violates adult ''rights.'' The final rule does not alter an adult's ability to select or purchase cigarettes and smokeless tobacco.

(101) Several comments submitted by manufacturers or their representatives opposed the prohibition against the distribution of free samples, stating that manufacturers use free samples to introduce new products, to encourage adult consumers to switch brands, or to thank their adult consumers for their patronage. Others comments added that free samples do not encourage young people to smoke or to use smokeless tobacco or that eliminating free samples would not reduce cigarette or smokeless tobacco use by young people.

The agency is eliminating free samples because they are an inexpensive and easily accessible source of these products to young people and, when distributed at cultural or social events, may increase social pressure on young people to accept and use free samples (60 FR 41314 at 41326). The preamble to the 1995 proposed rule cited studies and reports to support the agency's views; those documents contradict the comments' claim that free samples do not encourage young people to use these products or affect use by young people.

As for the rule's impact on manufacturers' practices, the public health benefits from eliminating free samples as an avenue that young people use to obtain cigarettes and smokeless tobacco outweigh any inconvenience to

[73] *Id.*

manufacturers who will be obliged to devise new ways to introduce new products, to get adults to switch brands, or to thank adult consumers. FDA believes that manufacturers will be able to devise new approaches to promote new brands or to attract new adult customers that comply with these regulations.

(102) One comment expressed strong opposition to proposed § 897.16(d). The comment argued that FDA lacked authority to ban free samples, especially when the agency would permit sales to adults, and that the agency had no evidence to support a ban on free samples. The comment added that the act did not extend to device samples and argued that Congress knows how to give FDA authority over samples, as evidenced by sampling provisions in the PDMA. The comment further stated that the term ''sample'' was over-broad because it was not limited to products distributed in public settings for promotional purposes; thus, the comment continued, any complimentary gift could be a ''sample'' under proposed § 897.16(d).

FDA disagrees with the comment. Section 520(e) of the act states that the agency may ''require that a device be restricted to sale, distribution, or use * * * upon such other conditions as the Secretary may prescribe by * * * regulation.'' Restricting free samples is clearly a restriction on the product's distribution.

As for the PDMA, the comment's claim that the PDMA's sampling restrictions shows that Congress has not authorized FDA to regulate device samples (due to the absence of express language on device samples) fails to take into account the fact that FDA's restricted device authority is broader than its prescription drug authority. Also, the comment fails to take into account the reasons behind enactment of PDMA. PDMA was enacted not to give FDA new authority over prescription drug samples, but to curtail the illegal diversion of drugs, including samples, into the market. (See S. Rept. 100–303, 100th Cong., 2d sess. 2–3 (1988).) Before PDMA was enacted, FDA regulated prescription drug samples in the same manner as prescription drug products. Thus, PDMA is not intended to give FDA new authority over samples; instead, it reflects a congressional decision to give FDA a comprehensive and explicit set of new authority to prevent illegal diversions of prescription drug products, including the diversion of prescription drug samples to illegal markets.

FDA also declines to amend the rule to allow ''gifts.'' Allowing ''gifts'' would enable parties to declare that their free samples were now ''gifts'' and therefore outside the rule and could lead to disputes as to whether an item was a prohibited ''sample'' or an allowable ''gift.'' However, the agency will exercise discretion in interpreting and enforcing this rule. For example, a manufacturer's employee who sends cigarettes or smokeless tobacco to an adult relative to celebrate a birthday would not be subject to regulatory action under the free sample restriction in § 897.16(c).

(103) One comment stated that, notwithstanding the preamble to the 1995 proposed rule, FDA has no evidence to support a restriction on the distribution of free samples. The comment stated that the rule overestimated the prevalence of sample activities and that cigarette sampling accounted for only 0.7 percent of the total spent on cigarette advertising and promotion in 1993. The comment also said that FDA relied on an outdated version of the cigarette manufacturers' voluntary code. According to the comment, the outdated code prohibited distribution of cigarette samples within two blocks of any ''center of youth activities'' and ''required samplers to demand proof of age in doubtful cases.'' The revised code adds that ''[s]ampling shall not be conducted in or on public streets, sidewalks or parks, except in places that are open only to persons to whom cigarettes lawfully may be sold.''

In contrast, two comments cautioned FDA against deferring to a voluntary code or relying on the industry. One comment stated that, in Maine, the industry agreed to submit reports on sampling activities to the State in place of legislation that would have curtailed sampling activities, but the industry discontinued these reports as soon as State authorities stopped sending reminders that the reports were due. Another comment stated that, in Massachusetts, a lawsuit over sampling practices by a smokeless tobacco firm ended in a settlement whereby the firm would require photocopies of identification cards for all mail-in requests for samples. The comment said that the settlement represented an improvement over requiring no proof of age at all, but noted that the firm refused to apply this practice outside the State and that the restriction did not apply to other smokeless tobacco firms. The comment also claimed that firms often agree to restrict sampling activities only after adverse publicity or agree to restrict sampling activities without setting any measurable performance goals.

FDA disagrees with the comment asserting that the agency has no evidence to support a restriction on free samples. The preamble to the 1995 proposed rule cited several reports and surveys showing that young people, including elementary school children, obtain free samples easily (60 FR 41314 at 41326). The agency also has no assurance that the revised cigarette industry code will be any more effective than earlier versions. Moreover, as mentioned earlier in this document, FDA received comments stating that young people continue to receive free samples of cigarettes and smokeless tobacco. The comments refute the claim that voluntary industry restrictions on sampling preclude the need for FDA regulation of free samples.

Additionally, the rule offers several important advantages over voluntary codes. The rule creates enforceable obligations which, if violated, may subject the manufacturer, distributor, or retailer to sanctions under the act. These sanctions, in turn, create an incentive for regulated parties to adhere to the act and its implementing regulations. A voluntary code also applies only to the parties that accept the code or fall within the same industry; for example, a voluntary manufacturers' code might not extend to distributors or to retailers, or, as the comment recognized, a voluntary cigarette manufacturers' code might differ from a voluntary smokeless tobacco manufacturers' code.

Furthermore, a regulation creates uniform standards and policies for the same product. Those standards apply regardless of whether a firm is a member of a voluntary organization.

Finally, the agency notes that, while the comment said that ''only 0.7 percent of the total spent on cigarette advertising and promotion'' in 1993 went to cigarette sampling activities, this percentage still translates into a large sum. Cigarette advertising and promotion expenditures, according to the same FTC report cited by the comment, were approximately $6 billion in 1993. Thus, the seemingly small percentage devoted to cigarette sampling activities, when translated into dollars, represents $42 million.

(104) Several comments supported the prohibition against the distribution of free samples, but suggested that FDA amend the rule to prevent distribution of cigarettes and smokeless tobacco at prices below their fair market value. One comment would define a product's

fair market value as the average retail price in the region. Another comment would amend § 897.16(d) to prohibit sales or distribution of cigarettes and smokeless tobacco ''in return for nominal consideration.''

The agency declines to amend the rule as suggested by comments. While the comments have merit, FDA usually has no role in the prices charged for an FDA-regulated product. Additionally, it would be difficult for FDA to monitor fair market values for various products, and disputes would inevitably arise as to whether the ''market'' should cover a broader or narrower geographic area, the data used to determine the fair market value, and how compliance actions would be affected by fluctuations in the fair market value. Similar disputes would arise regarding ''nominal consideration.'' Furthermore, regardless of the price at which the product is sold, other provisions in this subpart should deter or reduce access by young people.

e. *Restrictions on labeling and advertising.* The agency on its own initiative has added § 897.16(e) as a point of clarification to the final rule. This provision states that ''no manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with the restrictions in Subparts C and D * * *.'' The restrictions on labels, advertising, and labeling in subparts C and D of part 897 are authorized, in part, under section 520(e) of the act and are considered conditions of sale, distribution, and use. Therefore, § 897.16(e) clarifies the statutory obligations of manufacturers, distributors, or retailers under this rule.

V. Label

In the 1995 proposed rule (60 FR 41314, August 11, 1995), subpart C of part 897 was entitled ''Labels and Educational Programs,'' and contained two provisions. Proposed § 897.24, would have required cigarette or smokeless tobacco packages to contain the appropriate ''established name'' of the product; the final rule retains that provision and does not make any substantive changes to it. Proposed § 897.29 would have required manufacturers to establish and maintain a national educational program to discourage children from using cigarettes and smokeless tobacco. Based on issues raised by comments, proposed § 897.29 has been deleted from the final rule, and instead, the Food and Drug Administration (FDA) has determined that issuing notification orders under section 518 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) would be the most practicable and appropriate means of requiring tobacco manufacturers to inform young people of the unreasonable health risks. Discussion of the comments received regarding this education provision is included in section VII. of this document.

A. Established Name (§ 897.24)

Proposed § 897.24 would have required that each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed bear whichever of the following established names is appropriate: ''Cigarettes,'' ''Cigarette Tobacco,'' ''Loose Leaf Chewing Tobacco,'' ''Plug Chewing Tobacco,'' ''Twist Chewing Tobacco,'' ''Moist Snuff,'' or ''Dry Snuff.''

The preamble to the 1995 proposed rule explained that this provision was intended to implement section 502(e)(2) of the act (21 U.S.C. 352(e)(2)), which states that a device shall be deemed misbranded if its label fails to display the established name for the device. Section 502(e)(4) of the act, in turn, explains that the ''established name'' for a device is the applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), the official title in a compendium if the device is recognized in an official compendium but has no official name, or ''any common or usual name of such device.'' In this case, no official names have been designated under section 508 of the act, and no compendium provides an established name for these products. Consequently, § 897.24 proposed designating ''cigarettes,'' ''cigarette tobacco,'' and the common or usual names for smokeless tobacco (such as ''moist snuff'' or ''loose leaf chewing tobacco'') as established names for these products.

(1) The agency received few comments on proposed § 897.24. One comment that opposed the provision stated that it was unnecessary and would produce anomalous results. The comment stated that, because cigarettes are already required to be labeled ''cigarettes'' under regulations adopted by the Bureau of Alcohol, Tobacco and Firearms (BATF) under the Internal Revenue Code (27 CFR 270.215 (1995)), ''Cigarettes'' is already the common and usual name and, therefore, there is no need to designate an ''established name.''

The agency has concluded that the BATF requirement does not conflict with the act's requirement that the label bear the established name of these products. The agency recognizes that BATF regulations currently require cigarette packages to include the word ''cigarettes'' on the package or on a label securely affixed to the package (27 CFR 270.215). For smokeless tobacco and chewing tobacco, BATF regulations require the packages to include the words ''snuff'' or ''chewing tobacco,'' or alternatively, ''Tax Class M'' or ''Tax Class C,'' respectively (27 CFR 270.216). These terms also describe the established name, as required in section 502(e) of the act.

Many of the labeling provisions of the act, including section 502(e)(2), are intended to provide important basic information to consumers and others coming in contact with a regulated product. In this case, the act requires that the established or common name be placed on the product's label in a clear way so that it is easily seen and consumers can readily identify the product. Congress provided an exception only for cases where compliance with this provision is ''impracticable.'' If a manufacturer believes that it cannot comply with this provision of the rule, the manufacturer should consult with the agency to determine if it qualifies for an impracticability exception under section 502(e)(2) of the act.

(2) One comment that supported the provision on established name recommended that, in addition to the established names set forth in the 1995 proposed rule, little cigars and tobacco sticks should also be listed as separate products with their own specific established names, ''little cigars'' and ''tobacco sticks'' ''in keeping with the manner and style of the established names to be used for smokeless tobacco products.''

One comment that opposed the provision stated that since proposed § 897.3(a) would define ''cigarettes'' to include little cigars, the same package of little cigars that must be labeled ''small cigars'' or ''little cigars'' (under current BATF regulations, 27 CFR 270.214(c) (1995)), would also have to carry the established name of ''cigarettes'' under the proposed FDA regulation. The comment argued that such a conflicting labeling requirement is absurd, and would create confusion where none now exists.

The agency has modified the definition of ''cigarette'' found in proposed § 897.3(a) to exclude little

cigars from the final rule. The agency also advises that, to the best of its knowledge, tobacco sticks currently are not sold in the United States. If tobacco sticks were to be marketed in this country, the agency advises that such products would be subject to premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807, and could be included under the established name of ''cigarette tobacco,'' and therefore do not need to be listed as separate products at this time.

B. Package Design

(3) Several comments noted that the 1995 proposed rule did not include any action to eliminate the use of the tobacco product package itself to influence children. A few comments cited a March 1995 Canadian study, which found that package designs affect the ability of teens to associate lifestyle and personality imagery to specific brands and detract from the health message.[74] Another study found that the ''badge'' value of cigarette packages for youths was decreased when the packages were stripped of their unique characteristics.[75] The comment suggested that the provisions of proposed § 897.30, requiring text only with black text on a white background, should be extended to cigarette packages. One comment pointed out that FDA has the authority to require plain packaging without violating the Federal Cigarette Labeling and Advertising Act (the Cigarette Act), 15 U.S.C. 1334(a), which prohibits additional statements related to smoking and health on cigarette packages.

The agency agrees with the comments that cigarette package design and imagery are powerful tools that increase the appeal of the product, especially to young people. In the preamble to the 1995 proposed rule the agency cited several studies demonstrating that ''[i]magery ties the products to a positive visual image'' (60 FR 41314 at 41335). Another study showed that ''children and adolescents react more positively to advertising with pictures and other depictions than to advertising (or packaging) that contains only print or text'' (60 FR 41314 at 41335).

The agency has considered extending the requirements of § 897.30 (text only, black on white background) to the package itself, but believes at this time these measures are not necessary considering the comprehensive nature of the regulatory scheme contained in this rule. Therefore, the agency is not extending the requirements applicable to advertising and labeling to the package itself.

C. Ingredient Labeling

The agency specifically requested comments on whether it should implement recommendations from the Ad Hoc Committee of the President's Cancer Panel, which recommended, among other things, that the range of tar, nicotine, and carbon monoxide delivered by each product be communicated to consumers. In addition, the Ad Hoc Committee recommended that smokers be informed of ''other hazardous smoke constituents.''

(4) The agency received several comments suggesting that tar and nicotine delivery or yield information should be disclosed on product packages in order to assist consumers in making more informed decisions about the use of cigarettes. Some of these comments also suggested that labels list the toxins present in, or delivered from, cigarettes and state their effect, e.g., ''known carcinogen.''

One comment stated that it cannot be claimed that the ingredients are trade secret information and, therefore, cannot be disclosed, because the tobacco companies voluntarily released a list of ingredients to the public in 1995. The comment noted that, under current case law, only items kept confidential qualify as trade secrets. (See *Kewanee Oil* v. *Bicron Corp.*, 416 U.S. 470 (1974); *Avtect Systems* v. *Peiffer*, 21 F.3d 568 (4th. Cir. 1994).) The comment noted further that because companies can and do perform reverse engineering on another company's products, the ingredients are not trade secret. The comment proposed that, at a minimum, FDA should designate a partial list of previously disclosed ingredients and require that the list be included on package labels. Another comment stated that only a reasonable number of ingredients should be listed on the label or in a package insert.

One comment stated that ingredient listing is not barred by the Cigarette Act or by the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Act). (See 15 U.S.C. 1331 *et seq.* and 15 U.S.C. 4401 *et seq.*) These statutes require the current Surgeon General's warnings on tobacco products and preempt any additional statements relating to smoking or health from being required on cigarette or smokeless tobacco packages. The comment asserted that a list of ingredients is not a statement, and cannot be reasonably construed as a statement relating to smoking and health, because a statement expresses a point of view, whereas an ingredient list does not.

One comment noted that the Cigarette and Smokeless Acts require manufacturers to submit annually to the Department of Health and Human Services (DHHS) a list of ingredients added to tobacco products, and the statutes further require that the lists be treated as confidential commercial or trade secret information. (See 15 U.S.C. 1335(a) and 15 U.S.C. 4403.) The comment stated that the confidentiality provisions in both statutes bind the Secretary of DHHS with respect to trade secrets, but do not restrict FDA's authority to require ingredient listing.

FDA agrees that accurate information about the tar, nicotine, and carbon monoxide delivery from a cigarette to the user would be useful information. FDA is aware of the Federal Trade Commission's (FTC's) recent efforts to develop a system to measure, more accurately than the current test, the tar, nicotine, and carbon monoxide delivered by cigarettes. FTC has announced that it will issue a report of its findings regarding a new test method in the near future. FDA believes that it would be premature to require manufacturers to put any of this information on tobacco product labels before FTC has issued its report and made recommendations on accurately measuring the delivery of tar, nicotine, and carbon monoxide to product users.

With regard to ingredients other than tar, nicotine, and carbon monoxide, the agency agrees that it has authority under the act to require labeling or listing of other substances present or delivered by cigarettes. (See section 502(r) of the act.) The agency notes that there are hundreds of ingredients added to or delivered by cigarettes and smokeless tobacco. Even if the agency were to require listing of only a ''reasonable number,'' current methodologies are not adequate to accurately identify and quantify the added ingredients or the constituents delivered by these products. Moreover, at this time there is not enough data to enable the agency to determine what a ''reasonable'' number of ingredients would be or to determine which ingredients should be listed and

[74] ''When Packages Can Speak: Possible Impacts of Plain and Generic Packaging of Tobacco Products,'' Health Minister of Canada, March 1995.

[75] Rootman, I., B. R. Flay, and D. Flay, ''A Study on Youth Smoking, Plain Packaging Health Warnings, Event Marketing and Price Reductions, Key Findings,'' A Joint Research Project by University of Toronto, University of Illinois, York University, Ontario Tobacco Research Unit, Addiction Research Foundation, p. 7, 1995.

which should not. Therefore, the agency is not requiring the listing of ingredients in the rule.

As discussed in the preamble to the 1995 proposed rule, cigarettes and smokeless tobacco are subject to various pre-existing requirements in the statute and the regulations. The preamble stated that such ''regulations include the general labeling requirements for devices at part 801 (21 CFR part 801) (excluding § 801.62)'' (60 FR 41314 at 41352). The parenthetical reference was a typographical error because the 1995 proposed rule would have exempted such products from § 801.61, not § 801.62 (60 FR 41314 at 41342). Section 801.62 states the requirements for ''Declaration of net quantity of contents.'' This provision requires that the label of an over-the-counter device bear a declaration of the net quantity and weight of the contents, e.g., ''20 cigarettes.'' The agency fully expects manufacturers to comply with this provision and, as discussed below, also expects manufacturers to comply with § 801.61.

D. Labeling for Intended Use

(5) The agency received comments suggesting that FDA require intended use information on the package label of cigarettes and smokeless tobacco. Proposed § 801.61(d) would have exempted cigarettes and smokeless tobacco from the statement of identity and labeling for intended use requirements of § 801.61. The comments stated that such information informs the public about the product's intended use. One comment supported proposed § 801.61(d).

Based on the comments received, the agency has reconsidered the matter and concluded that it is appropriate to require that this information appear on the label. Consequently, the agency has deleted § 801.61(d) from the final rule.

All over-the-counter devices are required to comply with § 801.61 and bear the ''common name of the device followed by an accurate statement of the principal intended action(s) of the device'' on the principal display panel of the package. (See § 801.61.) As over-the-counter devices, cigarettes and smokeless tobacco are legally required to comply with this provision.

In the 1995 proposed rule, the agency proposed to exempt these products because ''section 801.61 stems, in part, from the Fair Packaging and Labeling Act (FPLA), and [t]obacco products are exempt from the statute's requirements'' (60 FR 41314 at 41342). Further evaluation revealed that the requirements in § 801.61 are also based on FDA labeling authorities including, but not limited to, section 502(a), (c), (e), (f), and (q) of the act, and not the FPLA.

Furthermore, section 1460 of the FPLA contains ''Savings provisions'' (15 U.S.C. 1460). The provisions state that ''Nothing contained in this Act [15 U.S.C. 1451 et. seq.] shall be construed to repeal, invalidate, or supersede * * *(b) the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et. seq*.] * * *.'' Thus, because FDA's assertion of jurisdiction over these products is under its statutory authority under the act, any conflict between the two statutes shall be resolved in favor of the act. (See *Jones* v. *Rath Packing*, 430 U.S. 519 (1977).) Consequently, section 1459 of the FPLA, which removes tobacco from the definition of ''consumer commodity,'' and thus, removes it from jurisdiction under the FPLA, is superseded by FDA's coverage of these products under the act.

As stated in the preamble to the 1995 proposed rule, manufacturers of cigarette and smokeless tobacco are expected to comply with the general labeling requirements in part 801 (60 FR 41314 at 41352). For purposes of § 801.61, the ''common name of the device'' is the established name as set forth in § 897.24.

To more accurately reflect the permitted intended use of these products, the agency has modified the statement of intended use set forth in the proposal. The agency proposed that the intended use of these products be described as a ''nicotine delivery device.'' Under this rule, these products may be intended for use only by persons 18 years of age and older. Thus, a more accurate statement of the permitted intended use of these products is ''Nicotine Delivery Device For Persons 18 or Older.''

Further authority for this requirement stems from section 520(e)(2) of the act (21 U.S.C. 360j(e)(2). This provision states that: ''The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.'' The statement of intended use, in essence, incorporates the statement of one of the principal restrictions FDA is imposing on these products.

Accordingly, a provision has been added to § 897.25 that codifies this intended use statement and statement of restrictions for purposes of § 801.61.

E. Adequate Directions for Use and Warnings Against Use (Section 502(f) of the act)

(6) A few comments stated that FDA failed to discuss or provide for adequate directions for use, as required in section 502(f) of the act. The comments stated that FDA's silence on this issue is a tacit acknowledgment that the agency cannot have jurisdiction over these products because adequate directions for use cannot be prepared for them.

The agency disagrees with these comments. It does not logically follow that because the agency was silent on this issue, it does not have jurisdiction over tobacco products. In fact, in the preamble to the 1995 proposed rule, the agency cited one of the authorities for the labeling requirements for these products as section 502 of the act.

According to section 502(f) of the act, a device shall be deemed misbranded:

> Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

For devices, ''adequate directions for use'' means ''directions under which the layman can use a device safely and for the purposes for which it is intended'' (§ 801.5). These regulations outline the type of information which, if missing, may lead to a product being deemed to be misbranded. Such information includes conditions, purposes, and uses for which the device is intended; quantity of dose; frequency, duration, time, route or method of administration; or preparation for use (§ 801.5).

The agency acknowledges that it is very difficult to establish adequate directions for use for cigarettes and smokeless tobacco, primarily because of the inherent nature of the products, their addictiveness, the numerous hazards associated with their use, and because the behavior of each user (e.g., the depth of inhalation, the duration of puff, whether the filter holes are covered, and length of time in mouth) determines the amount of tar and nicotine delivered to the user from the device.

Section 502(f) of the act provides for an exemption for adequate directions for use if they are ''not necessary for the

protection of the public health.'' For example, the agency has established exemptions from adequate directions for use where adequate directions for common uses of certain devices are known to the ordinary individual. (See § 801.116.) Tobacco products have a very long history of use in this country, and they are one of the most readily available consumer products on the market today. Consequently, the way in which these products are used is common knowledge. FDA believes that the public health would not be advanced by requiring adequate directions for use. Accordingly, the agency has added a provision to the final rule exempting cigarette and smokeless tobacco from the requirement of having adequate directions for use. Section 801.126, states, ''Cigarette and smokeless tobacco as defined in part 897 of this chapter are exempt from section 502(f)(1) of the Federal, Food, Drug, and Cosmetic Act.''

The agency has considered the requirement in section 502(f)(2) of the act that the labeling of a medical device must provide ''adequate warnings against use * * * by children where its use may be dangerous to health.'' In the agency's view, the warnings mandated by the Cigarette Act (15 U.S.C. 1333) and the Smokeless Act (15 U.S.C. 4402) satisfy this requirement. Additionally, the Surgeon General's warnings provide information warning against use in persons with certain conditions, i.e., pregnant women. Consequently, cigarettes and smokeless tobacco are not exempt from the statutory requirements under section 502(f)(2) of the act.

F. Package Inserts

(7) Several comments stated that FDA should require cigarette and smokeless tobacco packages to contain package inserts that contain health information and information about the chemicals added to cigarettes and smokeless tobacco. One comment stated that FDA has statutory authority to require package inserts under sections 502(a) and (q) and 520(e) of the act. Another comment stated that the agency is not preempted from requiring package inserts because sections 1334(a) and 4406 of the Cigarette Act and the Smokeless Act, respectively, preempt statements related to health ''on any package,'' not *in* any package.

FDA agrees with the comments that it has statutory authority under the act to require package inserts for these products. Under section 502(a) of the act, a device is misbranded if its labeling is false or misleading in any particular. Section 201 of the act (21 U.S.C. 321), the ''Definitions'' section of the act, describes the concept of ''misleading'' in the context of labeling and advertising. Section 201(n) of the act explicitly provides that, in determining whether the labeling of a device is misleading, there shall be taken into account not only representations or suggestions made in the labeling, but also the extent to which the labeling fails to reveal facts that are material in light of such representations or material with respect to the consequences that may result from use of the device under the conditions for use stated in the labeling or under customary or usual conditions of use.

These statutory provisions, combined with section 701(a) of the act (21 U.S.C. 371(a)), authorize FDA to issue a regulation designed to ensure that persons using a medical device will receive information that is material with respect to the consequences that may result from use of the device under its labeled conditions. In the prescription drug context, this interpretation of the act and the agency's authority to require patient labeling for prescription drug products have been upheld. (See *Pharmaceutical Manufacturers Assn.* v. *FDA*, 484 F.Supp. 1179 (D. Del. 1980) *aff'd per curiam*, 634 F.2d 106 (3rd Cir. 1980).)

Additionally, on several occasions, the agency has required patient package inserts for devices, and has specified either the express language for the patient package insert or the type of information to be included in the patient package insert. These devices include hearing aids (§ 801.420), intrauterine devices (§ 801.427), and menstrual tampons (§ 801.430).

The agency also agrees with the comment that it is not prohibited from requiring patient package inserts due to the preemption clauses in the Cigarette Act and the Smokeless Act. Each of the clauses in these statutes specifically prohibits requirements that statements relating to smoking and health be placed on the package. Package inserts, by nature, are typically found in the package.

Although the agency believes that package inserts for these products are authorized under the act and would provide useful information to users, further evaluation would be needed to determine what specific information a package insert would contain. Therefore, the agency is not requiring them as part of this rule.

VI. Advertising

A. Subpart D—Restrictions on Advertising and Labeling of Tobacco Products

Subpart D in part 897 contains the restrictions for advertising and labeling of cigarettes and smokeless tobacco. Subpart D of part 897 in the Food and Drug Administration's (FDA's) August 11, 1995, proposed rule (60 FR 41314) (the 1995 proposed rule) provoked some of the strongest and most passionate comments from both supporters and opponents of the proposed restrictions. Many comments from the tobacco industry, the advertising industry, public interest groups, and individuals expressed major concerns about the legality, constitutionality, and wisdom of the advertising restrictions in general and about the underlying support for individual sections of the 1995 proposed rule. Comments from the largest organization of psychologists in the world, public interest and health groups, individual advertisers, and individuals expressed strong support for the legality and constitutionality of the proposal, provided information supporting various provisions of the proposal, and emphasized the necessity for comprehensive advertising regulations.

The purpose of the advertising regulations is to decrease young people's use of tobacco products by ensuring that the restrictions on access are not undermined by the product appeal that advertising for these products creates for young people. (See *Central Hudson Gas and Electric Corp.* v. *Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 569 (1980).) Proposed subpart D of part 897 included a range of restrictions that attempted to preserve the informational components of advertising and labeling which can provide useful product information for adult smokers, while eliminating the imagery and color that make advertising appealing and compelling to children and adolescents under 18 years of age.

Briefly, the 1995 proposed rule included four provisions. Section 897.30 would have defined those media in which labeling and advertising for cigarettes or smokeless tobacco may appear. In addition, it would prohibit outdoor advertising within 1,000 feet of elementary and secondary schools and playgrounds. Proposed § 897.32 would limit all advertising to black text on a white background. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Further, all

cigarette and smokeless tobacco product advertisements would be required to include the product's established name and intended use, e.g., ''Cigarettes—A Nicotine Delivery Device,'' and cigarette advertisements would be required to include a brief statement, such as ''About one out of three kids who become smokers will die from their smoking.'' Proposed § 897.34 would prohibit the sale and distribution of nontobacco items, contests and games of chance, and sponsored events using any indicia of product identification (e.g., brand name, logo, recognizable pattern of color). Finally, proposed § 897.36 outlined those conditions under which the agency would find the advertising or labeling of any cigarette or smokeless tobacco product to be false or misleading.

In response to comments filed, FDA has modified the proposed regulations. Briefly, some of the more substantive changes include: The definition of adult-oriented publications remains unchanged, but the preamble makes clear that the responsibility will be assigned specifically to the manufacturer, distributor, or retailer of tobacco products that wishes to place advertisements to gather and retain competent and reliable evidence that the readership of the publication meets the criteria for an adult-oriented publication. Moreover, unrestricted advertising, i.e., with color and imagery, may be displayed at facilities described in § 897.16(c)(2)(ii) that may sell tobacco from vending machines and self-service provided that the advertising, e.g., posters and signs, must be displayed so that they are not visible from outside the facility and are affixed to a wall or fixture in the facility.

The revised intended use statement is ''Nicotine Delivery Device for Persons 18 or Older,'' and the agency will not require a brief statement other than the Surgeon General's warnings.

As provided in the 1995 proposed rule, the final rule states that any event sponsored by a manufacturer, distributor, or retailer of tobacco products is to be sponsored only in the corporate name. Teams and entries also may be sponsored but only in the corporate name. The regulation includes a ban on all brand-identified nontobacco items, including those transactions based upon proofs-of-purchase. However, the proposed ban on contests and games has been deleted. Finally, the agency has decided to delete the definition of false or misleading advertising and labeling from this final rule because it is duplicative and unnecessary in light of the underlying requirements in sections 201(n), 502(a), and 502(q) (21 U.S.C. 321(n), 352(a), and 352(q)) of the Federal Food, Drug, and Cosmetic Act (the act).

Section VI.B. of this document provides a general discussion of the rationale for including significant advertising restrictions in the final regulation, including a discussion in response to comments concerning the theory of advertising and the importance of color and imagery to advertising's appeal, especially for young people. This section also provides a discussion of the effects of advertising on young people, including expert opinion and research evidence provided by the American Psychological Association.

Section VI.C. of this document provides responses to questions raised about the constitutionality of the regulations. Section VI.D. of this document includes a discussion of the evidence that cigarettes and smokeless tobacco advertising plays a direct and material role in young people's decisions to purchase and use these products. This part also explains why restricting tobacco advertising will advance the Federal Government's interest in preventing the use of tobacco products by young people, and provides responses to comments about the evidence. Finally, section VI.E. of this document responds to comments concerning the factual evidence provided by FDA in support of its proposed regulation in a section-by-section format, as well as to comments claiming that each of these sections was not narrowly tailored to minimize the burden on commercial speech. [76]

B. The Need for Advertising Restrictions

In the preamble to the proposed 1995 rule, FDA tentatively asserted that a preponderance of the quantitative and qualitative studies of cigarette advertising suggested: (1) A causal relationship between tobacco advertising and tobacco use by young people, and (2) a positive effect of stringent advertising measures on smoking rates and on youth tobacco use. In arriving at this tentative finding, FDA relied heavily on the National Academy of Sciences Institute of Medicine's (IOM's) Report entitled *Growing Up Tobacco Free, Preventing Nicotine Addiction in Children and Youths*, Washington, DC 1994 (the IOM Report) and the Department of Health and Human Services' (DHHS') Center for Disease Control and Prevention's (CDC's) Report entitled *Preventing Tobacco Use Among Young People, A Report of the Surgeon General* (1994) (1994 SGR). Both indicated that advertising was an important factor in young people's tobacco use, and that restrictions on advertising must be part of any meaningful approach to reducing smoking and smokeless tobacco use among young people. In addition, FDA was careful to note that industry statements and actions and examples of youth oriented advertising and marketing campaigns lent support to the agency's findings.

FDA's review and consideration of the comments received has led the agency to conclude that advertising plays a material role in the decision by those under 18 to use tobacco products.

1. Advertising and Young People

(1) Comments from the tobacco industry argued that FDA had simply assumed that young people found cigarette and smokeless tobacco advertising to be appealing, and that there was no empirical evidence of how young people actually perceived the imagery displayed in cigarette and smokeless tobacco advertisements. The comments argued that the research cited by the agency relates primarily to the role of imagery in brand choice decisions. In addition, several comments disputed FDA's evidence that young people are particularly vulnerable to image-oriented advertisements. To respond to these comments, it is necessary to describe the function of advertising and how it affects young people.

a. *Function of advertising.* Advertisers use a mix of advertising and promotional vehicles to call attention to the product they are selling—to describe its properties, to convey its superiority over other products, and in some cases to give it an allure above and beyond the qualities of the product itself. (A red convertible can be a mode of transportation; it can also tell people a

[76] For the purposes of section VI. of this document, the agency will refer to advertising and labeling merely as ''advertising.'' As the agency pointed out in the preamble to the 1995 proposed rule, advertising and labeling often perform the same function: to convey information about the product; to promote consumer awareness, interest, and desire; to change or shape consumer attitudes and images about the product; and/or to promote good will for the product (60 FR 41314 at 41328). Moreover, most court cases involving advertising do not distinguish between the forms of advertising that FDA calls labeling and those referred to as advertising. When there is a need to distinguish between the two forms of promotion, for example, when labeling and advertising are subject to different statutory requirements, this document will make clear what is being discussed.

lot about who you are, or who you think you are or want to be.)

Advertising creates a matrix of attributes for a product or product category and beliefs about the product and its possessor. It can serve to convey images that are recalled later when an event prompts the consumer to think about a purchase. Consumers, as a general rule, overestimate the effect that advertising has on the market in general, but they routinely underestimate its effect upon them and their own purchasing choices. [77]

As discussed in sections VI.B.1.b. and VI.B.1.c. of this document, advertising that is diverse, image-laden, and colorful can be particularly effective in attracting attention in a cluttered advertising environment. Further, advertising that is repeated frequently and in as many different media as possible is most likely to ensure that its message is received by the maximum number of consumers. This trend toward the use of many media in a coordinated effort to communicate an advertising message supports the need for a comprehensive approach to mitigating the effects of tobacco advertising. [78]

Every presentation can add to and build upon the imagery and appeal created for a product category or a particular brand. Print advertising, direct mail, and outdoor advertising help to create an image of the brand (and sometimes an image of the brand's user) and provide information about price, taste, relative safety, and product developments for current or prospective users. William Campbell, Chief Executive Officer of Philip Morris, explained the importance of linking the brand imagery in various media in relationship to the success in marketing its Marlboro product:

[W]e've managed to take what was originally tunnel vision advertising and positioning * * * into every kind of avenue * * *. For example, our auto racing activities are just another way to express the Marlboro positioning. Some would say the Marlboro Cup is different from Marlboro Country, but it is absolutely consistent. [79]

The use of many different media is also important in advertising directed to children. An example of a successful multimedia approach directed to children is the cigarette smoking prevention program conducted by Flynn et al., in Vermont, New York, and Montana, and cited in the preamble to the 1995 proposed rule. [80] This effort combined school cigarette smoking prevention programs with a mass media intervention featuring more than 50 different television and radio spots over a 4-year period. Some communities received the school cigarette smoking prevention programs alone, and others received the school program in combination with the mass media intervention. By the final year of the program, students exposed to both school and mass media interventions were 35 percent less likely to have smoked during the past week than students exposed only to the school program. Further, this preventive effect persisted for at least 2 years following the completion of the program. [81] The researchers attributed the effectiveness of their program in part to the fact that their intervention used a wide variety of messages and message styles over a significant period of time.

Thus, all media collectively along with the amount of exposure time to young people, can increase the effectiveness of the advertiser's message. For example, billboards near schools or playgrounds expose children to unavoidable advertising messages for a more prolonged period of time than billboards they pass on the highway. Further, sponsored events that typically last for 2 to 3 hours ensure that those attending the event or viewing it at home on television are exposed for a sustained period of time.

b. *Color contributes.* Color is an important component of advertising. It can be used to promote a ''feeling'' and a message—blue is cool, red is hot, green is menthol. Studies have shown that four-color advertisements significantly increase attention and recall relative to two color or black- and white- advertisements. [82] Moreover, the importance of color in advertising becomes more salient when it is considered that most consumer behavior occurs in conditions of ''low involvement.'' [83] Low involvement conditions are those that occur when a reader skims a magazine advertisement rather than carefully searching for an advertisement for information about price, taste, relative ''safety'' of the product, or product improvement.

A recent article in *The European* [84] described the importance of color:

[S]ecuring a brand colour is more important than ever, particularly for companies chasing a youth market. The main reason is the increasing use of fast and furious graphics in advertising and marketing communications generally. ''This makes owning a colour more and more important. You can keep changing the graphics, but the colour remains constant in the consumer's mind.'' Owning a colour also helps when sponsoring a sports event, for instance, ''All Pepsi now has to do is put up lots of blue,'' said Brant. [85]

c. *The importance of imagery.* Imagery also enhances the ability of advertising to communicate more quickly in low involvement situations and in quick exposure contexts. Pictorial information is remembered much better than verbal information, as pictures perform a function of ''organizing'' the qualities of the product as depicted with an image. Generally, as the pictures or images in an advertisement increase (both in number and the proportion of the advertisement occupied by the image), the advertisement is more likely to be recognized, and the brand name more likely to be remembered. In most cases, pictorial or image advertising is a more robust and flexible communications medium and can be used to communicate with the functionally illiterate or the young person in a hurry. [86]

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[77] Gunther, A. C., and E. Thorson, ''Perceived Persuasive Effects of Product Commercials and Public Service Announcements: Third Person Effects in New Domains,'' *Communication Research*, vol. 19, pp. 574–575, 1992.

[78] Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, ''Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs,'' *American Journal of Public Health*, vol. 82, pp. 827–834, 1992.

[79] ''Philip Morris Keeps Smoking—Campbell Sees Growth for Tobacco Unit in Declining Industry,'' *Advertising Age*, p. 20, Nov. 19, 1990.

[80] Flynn, B. S., J. K. Worden, R. H. Secker-Walker, G. J. Badger, B. M. Geller, and M. C. Costanza, ''Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs,'' *American Journal of Public Health*, vol. 82, pp. 827–834, 1992.

[81] Flynn, B. S., J. K. Worden, R. H. Secker-Walker, P. L. Pirie, G. J. Badger, and B. M. Geller, ''Mass Media Interventions for and School Interventions for Cigarette Smoking Prevention: Effects Two Years After Completion,'' *American Journal of Public Health*, vol. 84, pp. 1148–1150, 1994.

[82] Hanssens, D., and B. Weitz, ''The Effectiveness of Industrial Print Advertisements Across Product Categories,'' *Journal of Marketing Research*, vol. 17, pp. 294–306, 1980.

[83] MacInnis, D. J., and L. L. Price, ''The Role of Imagery in Information Processing: Review and Extensions,'' *Journal of Consumer Research*, vol. 13, pp. 473–491, 1987.

[84] Short, D., ''The Colour of Money,'' *The European*, p. 21, April 10, 1996.

[85] *Id.* Brant was commenting on Pepsi's decision to change its brand color to blue.

[86] Lutz, K. A., and R. J. Lutz, ''Effects of Interactive Imagery on Learning: Applications to Advertising,'' *Journal of Applied Psychology*, vol. 62, pp. 493–498, 1977; Hendon, D. W., ''How Mechanical Factors Affect Ad Perception,'' *Journal of Advertising Research*, vol. 13, pp. 39–45, 1973; See also Holbrook, M. B., and D. R. Lehmann, ''Form Versus Content in Predicting Starch Scores,'' *Journal of Advertising Research*, vol. 20, pp. 53–62, 1980; Twedt, D. W., ''A Multiple Factor Analysis of

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An executive from Griffin Bacal, one of the largest advertising agencies in New York, explained how visual imagery scored with young people:

Pictures sell. Visuals count * * * even those visuals that seemingly have nothing to do with the product sale. * * * [including locations, sets, props, wardrobe, colors, numbers, sexes and ages of people in the ads] * * * Kids want to be like each other. Group acceptance, and living the life of the gang, is critical. * * * Similarly, kids define themselves by the product choices they make and share. Be sure your advertising makes the ''world'' accessible and ''invites'' the viewer to join. [87]

Evidence from social psychology and marketing research shows image-based advertising, such as that employed by the cigarette and smokeless tobacco industry, is particularly effective with young people, and that the information conveyed by imagery is likely to be more significant to young people than information conveyed by other means in the advertisement.

According to the ''elaboration-likelihood model of persuasion,'' persuasive communications, such as advertisements, can persuade people either: (1) By the ''central route,'' or (2) by the ''peripheral route.'' [88] The central route refers to the process by which a person reads the messages or information contained in the advertisement and thinks carefully about it and is influenced by the strength of its arguments. The peripheral route is a process in which individuals, particularly young people, are more likely to pay attention and be persuaded by peripheral cues such as attractive models, color and scenery, which are unrelated to the primary parts of the message. Therefore, a young person, or anyone who is unmotivated or unable to carefully consider the arguments in a message, is likely to be persuaded via the peripheral route.

In markets where most brands in a product category are similar (as is the case with cigarettes and smokeless tobacco products), most advertising provides little, if any, new information. Thus, peripheral cues (such as color and imagery) take on added significance. Moreover, according to the model, for children, the motivation and ability to ''elaborate'' upon the arguments (pay attention to and think about the factual information) contained in cigarette and smokeless tobacco advertising are relatively low, making young people more susceptible to influence from peripheral cues such as color and imagery.

Finally, according to the comment from the nation's largest psychological association, children generally have less information-processing ability than adults, and they are less able or less willing to pay attention to the factual information in the advertisements. This comment stated that because any possible negative health consequences associated with using tobacco products are relatively far in the future for them, children are less motivated than adults to carefully consider information such as tar and nicotine content or the Surgeon General's warnings, which are contained in cigarette and smokeless tobacco advertising. Thus, the comment concludes, color and imagery in advertisements are important components for young people. [89]

A communications researcher who provided comments on FDA's 1995 proposed rule for the consolidated comment of the cigarette industry asserted that the elaboration likelihood model was relevant to the way children respond to tobacco advertising, but took a somewhat different view than that expressed above. Specifically, the comment stated that children are most likely to use the central route when they are ego-involved in the subject of persuasion, and that ''ego-involvement generally comes from those subjects which are salient to the groups with which one is aligned - e.g. peers.'' However, the comment also stated that because children would have no real experiences surrounding the initiation of cigarette smoking, they would be likely to engage in peripheral processing, and would rely on credible sources, such as peers. The comment contended,

The reason the elaboration likelihood model is relevant here is that the decision to begin smoking cigarettes does not come out of a set of fixed or habituated experiences personal to the decision maker. For that reason *this decision is likely to be one on which a person is particularly susceptible to the influence of others,* and therefore source credibility becomes key. [Emphasis added].

The agency is not convinced by the comment. This explanation does not address children's responses to tobacco advertisements—it essentially assumes that children are influenced by advertising only insofar as it is filtered through the experience of their peers. This reasoning is both circular and illogical. However, the agency does concur with the comment's view that children typically process tobacco advertising via the peripheral route, that children are particularly susceptible to the influence of others regarding the decision to start smoking or to use smokeless tobacco, and that perceived source credibility plays an important role. FDA maintains that the ''source'' of the persuasive message in tobacco advertising is frequently conveyed by the imagery presented in the advertisement. The same comment expressed this sentiment, stating ''[s]ince the media consumer often does not know the writer or broadcaster personally, the consumer or receiver may attribute source credibility to the media themselves.'' To the extent that characters featured in tobacco advertising, such as Joe Camel, the Marlboro Man or the attractive models or race car heroes typically portrayed in such advertising appear credible and appealing, they are perceived as credible sources, and could influence children regarding the decision to smoke or to use smokeless tobacco products.

2. Advertising and Adults

(2) Several comments from the tobacco industry and the advertising industry stated that cigarette and smokeless tobacco advertising plays an important economic role in tobacco marketing. A comment from the tobacco industry stated that FDA proposed restrictions would: (1) Substantially impair advertising of tobacco to adults; (2) deprive adults of useful information about products and services such as availability, price, and quality; (3) reduce the incentive and ability to market improved products; and (4) deprive adult smokers of the benefits of competition to provide a broad range of choices and to assure that tobacco products are provided at the lowest possible cost. Consequently, the comment said that the 1995 proposed rule would have a far greater adverse impact on advertising to adults than on advertising seen by young people.

One comment from an advertising agency argued that restrictions on the advertising of tobacco products would ''significantly erode the progress made over the past 15 years in increasing the quantity and variety of information readily available to the public.'' This

Advertising Readership,'' *Journal of Applied Psychology*, vol. 36, pp. 207–215, 1952.

[87] Kurnit, P., ''10 Tips From the Top Agency-Exec Explains How Griffin Bacal Scores with Kids,'' *Advertising Age Supplement*, pp. 19–20, February 10, 1992.

[88] Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, p. 3, 1986.

[89] See also, Huang, D. P., D. Burton, H. L'Howe, and D. M. Sosin, ''Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents,'' *Tobacco Control*, vol. 1, pp. 249–255, 1992.

progress, the comment reiterated, has benefited and continues to benefit the public.

Further, several comments argued that unfettered advertising is consistent with our Nation's belief in providing the broadest possible range of information to individuals, so that they can exercise informed judgment in their daily lives. For these reasons, the comment stated, further restrictions on the advertising of legal products would not be in the public interest and should be opposed.

FDA recognizes, as these comments maintained, that imagery and color make advertising appealing to adults, as well as to children, and that advertisers consistently use these elements to make advertisements compelling and attention getting. Moreover, removal of color and imagery will make advertising's role in presenting information to adults more difficult. However, as stated more fully in the preamble to the 1995 proposed rule, FDA has attempted to tailor its advertising restrictions as narrowly as possible consistent with its purpose of reducing young people's attraction to and use of tobacco. Thus, rather than banning all advertising, the proposed regulations retain the informational function of advertising by permitting text-only advertising while removing color and imagery from those advertisements to which young people are unavoidably exposed.

FDA does not believe that these restrictions should dramatically increase search costs for adult smokers and smokeless tobacco users who are actively looking for information on price and new product innovations. Text-only advertising requires a high involvement on the part of the consumer but can realistically be expected to provide sufficient information to carry the message and also provide sufficient appeal to attract current smokers and smokeless tobacco users. Some advertising for low-tar products relies on text-only or text with few pictures.

If the information about product type is important and desired by adult tobacco users, it can and will be provided by text-only advertisements if the industry desires to make the information available. As noted above, advertising for low-tar cigarettes is generally high-involvement advertising at the present and therefore can be expected to survive in a text-only environment. Nonetheless, the agency recognizes that it may be more difficult for advertising, without imagery and color, to attract the attention of current tobacco users. However, the agency has decided that the public health benefits of reducing advertising's ability to create appeal for young people greatly outweighs the tobacco companies' interest in unrestricted advertising to adults.

The position argued by these comments is essentially that industry has the right to communicate freely with its intended audience regardless of the impact its advertising has on the illegal and vulnerable audience of children and adolescents. Other comments counter this comment asserting that it is the Government's obligation to protect children because of their special vulnerabilities, their lack of experience and knowledge, and their limited ability to make appropriate decisions regarding behavior that will have lifelong health consequences. FDA believes its obligation with respect to tobacco products is to safeguard the health and safety of young people to ensure that they do not begin a potentially lifelong addiction to products that cause so much disease and premature death.

C. The Regulations Under the First Amendment

1. Introduction

Under section 520(e) of the act (21 U.S.C. 360j(e)), FDA included a number of proposed conditions in the 1995 proposed rule on how cigarettes and smokeless tobacco could be advertised as part of its proposed restrictions on the sale of these products. The agency tentatively found that these conditions are necessary to reduce the advertising's ability to create demand for these products—that is, the desire to purchase them—among children and adolescents under 18, for whom these products are not safe (60 FR 41314 at 41350). In addition, FDA tentatively found that it was necessary to include an industry-financed education program among these conditions.

In proposing these measures, FDA recognized that they would have to pass muster under the protections of communication extended by the First Amendment to the United States Constitution, in particular, under the protections extended to commercial speech (60 FR 41314 at 41353). Before addressing the commercial speech analysis, however, this section responds to several comments which registered more fundamental complaints under the First Amendment about FDA's proposed approach.

(3) Several comments, which were from the tobacco and advertising industries, found in statements made by FDA evidence of an intent not merely to protect the health of young persons but to ''delegitimize'' lawful adult conduct, to engage in ''viewpoint discrimination,'' and to run ''roughshod'' over the rights of cigarette and smokeless tobacco companies. One comment said that it is outside the realm of permissible exercise of governmental power to suppress speech for the purpose of instilling values that the Federal Government believes are appropriate. This comment also said that the purpose of FDA's rulemaking is to eliminate speech that conflicts with Government messages on smoking and health. The comment noted that FDA's goal is to bring about the demise of smoking as a social custom. However, a comment from a consumer group disagreed, saying instead that FDA's 1995 proposed rule was limited to covering only those activities designed to promote the sale of the product to young people and thus covered only commercial speech.

FDA has carefully considered these comments and has taken the concerns that they expressed into account as it developed this final rule. The agency recognizes that its authority is limited by the act and the Constitution. Thus, it has scrutinized each of the conditions on advertising that it proposed in light of whether the condition advances the purposes of section 520(e) of the act or some other section of the act, and whether the condition is consistent with the First Amendment.

FDA's primary concern is the public health. Because of the potentiality for harmful effects on individuals under 18 from use of cigarettes and smokeless tobacco, FDA is adopting restrictions on advertising among other restrictions on the sale, distribution, and use of these products. These restrictions will mean that it should be more difficult to sell these products to people under age 18, who currently purchase these products in significant numbers.

The agency acknowledges that insofar as these restrictions help reduce the sale of tobacco products to young people, the restrictions will have an adverse effect on the cigarette and smokeless tobacco companies. However, this fact does not mean that FDA is trying to bring about the demise of the tobacco industry. The restrictions that FDA is adopting have been tailored to help reduce tobacco advertising's ability to create an underage market for these products, while leaving open ample avenues for cigarette and smokeless tobacco companies to communicate to current users 18 years of age or older about their products. As explained in detail in

section VI.E. of this document, this is all that the First Amendment requires.

(4) Several comments argued that, in the 1995 proposed rule, FDA had understated the protection that commercial speech is afforded under the First Amendment. These comments pointed out that advertisers and consumers have powerful First Amendment rights to send and receive commercial messages. To support this point, one comment pointed out that the Supreme Court has recognized that the free flow of commercial information is ''indispensable to proper allocation of resources in a free enterprise system.'' (See *Virginia State Bd. of Pharmacy* v. *Virginia Citizen's Consumer Council, Inc.*, 425 U.S. 748, 765 (1976).) The comment also pointed out that the Court went on to say that a ''particular consumer's interest in the free flow of commercial information * * * may be as keen, if not keener by far, than his interest in the day's most urgent political debate'' (*Id*. at 763).

Another comment, however, citing *Ohralik* v. *Ohio State Bar Ass'n.*, 436 U.S. 447 (1978), stated that there are dangers inherent in a free-for-all marketplace, and that, at times, vigilant Government action is needed to protect the public from false, deceptive, or overbearing sales campaigns.

In addition to the comments, the agency has considered the Supreme Court's recent decision in *44 Liquormart, Inc.* v. *Rhode Island*, 116 S.Ct. 1495 (1996), which was handed down after the rulemaking record was closed. The Court ruled unanimously that Rhode Island's ban on all dissemination of price advertising for alcoholic beverages was violative of the First Amendment. No rationale for this judgment commanded a majority of the Court, however. Nonetheless, FDA considered each part of the principal opinion, as well as the concurring opinions, in arriving at the decisions that are set forth in this final rule.

FDA in no way underestimates the protection extended to commercial speech by the First Amendment. FDA recognizes the important societal interests served by this type of speech and has given full consideration to those interests in developing this final rule. Nonetheless, it is also true, as the agency stated in the 1995 proposed rule (60 FR 41314 at 41353 to 41354), that the measure of protection that commercial speech receives is commensurate with its subordinate position in the scale of First Amendment values, and it is subject to modes of regulation that might be impermissible in the realm of noncommercial expression. (See *Florida Bar* v. *Went For It, Inc.*, 115 S.Ct. 2371, 2375 (1995).)

However, in *44 Liquormart, Inc.*, three Justices stated:

> [w]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous review that the First Amendment generally demands.

(116 S.Ct. at 1507)

This statement has no application to the restrictions that FDA is imposing for two reasons. First, FDA is not entirely prohibiting the dissemination of commercial messages about cigarettes and smokeless tobacco. As explained in section VI.E. of this document, it is adopting carefully tailored restrictions on the time, place, and manner in which such messages may be conveyed so that they are not used to undermine the restrictions on access by minors. Second, the restrictions are related to the bargaining process. As explained in section II.C.3. of this document in the discussion of section 520(e) of the act, the access restrictions, and the concomitant restrictions on promotion of these products, derive from the fact that, at least as a matter of law, minors are not competent to use these products.

''The protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation.'' (See *Central Hudson*, 447 U.S. at 563.) FDA has weighed these factors in deciding what restrictions on cigarette and smokeless tobacco advertising can appropriately be included in this final rule.

2. The *Central Hudson* Test

The comments were unanimous in agreeing that any restrictions the agency adopts on commercial speech will be assessed under the test first articulated by the Supreme Court in *Central Hudson*, 447 U.S. at 563–64. This test was originally set out as a four-step analysis in *Central Hudson*; however, in one recent case, *Florida Bar* v. *Went For It, Inc.*, the Supreme Court described the test as having three prongs after a preliminary determination is made, although the matters to be considered remain unchanged:

> Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading* * *. Commercial speech that falls into neither of these categories, * * * may be regulated if the government satisfies a test consisting of three related prongs: first, the government must assert a substantial interest in support of its regulation; second, the government must demonstrate that the restriction on commercial speech directly and materially advances that interest; and third, the regulation must be ''narrowly drawn'' * * *.

(115 S.Ct. at 2376 (citations omitted))

FDA explained in the preamble to the 1995 proposed rule why the restrictions on advertising that it was proposing met each requirement of the *Central Hudson* test (60 FR 41314 at 41354 and 41356). The agency received a number of comments on its analysis—mostly from the tobacco industry, newspaper or magazine associations, and advertisers. These comments argued that FDA's proposed restrictions failed under one or more elements of the *Central Hudson* test. The agency also received comments from a public interest group, which has the protection of commercial speech as one of its interests, and from a coalition of major national health organizations. Both of these comments argued that, in virtually all respects, FDA's proposed restrictions satisfy the *Central Hudson* test.

In the sections that follow, for each of the restrictions on advertising that the agency proposed, FDA will analyze the case law that elucidates the applicable standard, the information presented in comments, and all other available evidence and decide whether that standard is met. However, before the agency does so, it must first consider the preliminary inquiry under *Went For It* and decide whether the First Amendment provides any protection to the advertising that is restricted by this final rule.

3. Is Cigarette and Smokeless Tobacco Advertising Misleading, or Does It Relate to Unlawful Activity?

As stated earlier, the preliminary inquiry under the *Went for It* case is whether the commercial speech is misleading or relates to unlawful activity. FDA did not specifically address this aspect of the *Central Hudson* analysis in its proposal (60 FR 41314 at 41354). Nonetheless, several comments did.

Many of the comments asserted that the targeted speech concerns lawful conduct, and that, therefore, this aspect of the *Central Hudson* analysis is satisfied. One comment noted FDA's silence on this matter and said that there is thus no suggestion that cigarette advertisements propose an illegal transaction or urge youths to begin smoking before it is lawful for them to do so.

Some comments argued, however, that cigarette and smokeless tobacco

advertising is not entitled to First Amendment protection because it is misleading, and it concerns unlawful activity. These comments pointed out that it is unlawful in all 50 States to sell tobacco products to children under the age of 18. The comments said the evidence that FDA assembled in its 1995 proposal suggested that manufacturers of tobacco products are aware that their advertising campaigns induce minors to experiment with tobacco products (citing 60 FR 41314 at 41330–41331), and that much of the promotional efforts of the tobacco industry are geared toward an illegal end—inducing minors to try to break the law by obtaining cigarettes and smokeless tobacco that may not legally be sold or otherwise provided to them.

The comments also argued that governmental entities are entitled to broad discretion when regulating the promotion of legal products or activities that pose dangers to society (citing, e.g., *United States* v. *Edge Broadcasting Co.*, 509 U.S. 418 (1993)). The comments argued that cigarette advertising is designed to persuade minors that any concerns about health hazards are misplaced or overstated, and that their peers are having fun because they smoke.

Contrary positions were taken by several comments. One argued that the fact that the sale of tobacco to minors is illegal under State law does not remove the constitutional protection for advertising to adults an otherwise lawful product (citing *Dunagin* v. *City of Oxford*, 718 F.2d 738, 743 (5th Cir. 1983) (en banc), cert. denied, 467 U.S. 1259 (1984).) A second comment cited the conclusion of a respected researcher that: ''the suggestion that advertising messages are somehow working subliminally to twist children's minds before they are old enough to know better is a complete invention, for which there is no evidence whatever'' (citing McDonald, C., ''Children, Smoking and Advertising: What Does the Research Really Tell Us?,'' 12 *International Journal Of Advertising* 286 (1993)). These comments also argued that given the warnings that must appear in all tobacco advertising, it could not be maintained that tobacco advertising is misleading.

FDA has carefully considered these comments. They raise the fundamental question of whether tobacco advertising is protected by the First Amendment. This question cannot be disposed of based simply on the question of whether such advertising explicitly urges young people to begin purchasing or using tobacco products before it is lawful for them to do so.[90]

The Supreme Court has repeatedly said that commercial speech ''related to'' unlawful activity is not entitled to First Amendment protection. (See *44 Liquormart, Inc.*, 116 S.Ct. at 1505 n.7 (' By contrast, the First Amendment does not protect commercial speech about unlawful activities.''); *Florida Bar* v. *Went For It*, 115 S.Ct. 2376 (''Under *Central Hudson*, the government may freely regulate commercial speech that concerns unlawful activity or is misleading''); *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 69 (1983) (''The State may also prohibit commercial speech related to illegal behavior.''); *Central Hudson*, 447 U.S. at 563–564 (''The government may ban * * * commercial speech related to illegal activity.'' (citations omitted)).) Tobacco advertising is ''related to illegal activity'' in two significant respects and thus, in fact, might not be protected speech.

First, tobacco ads, at least as a legal matter, propose a commercial transaction (see *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 762 (1976); *Pittsburgh Press Co.* v. *Human Relations Com'n*, 413 U.S. 376, 389 (1973)), that is, to sell cigarettes and smokeless tobacco. In proposing these transactions, the advertisers do not differentiate between adult and minor purchasers. Because sales to minors are unlawful in every State,[91] the undifferentiated offer to sell constitutes, at least in part, an unlawful offer to sell. At the very least, these advertisements are clearly perceived by minors as offers or inducements to buy and use these products. Millions of American children and adolescents act on these perceived offers. It is estimated that each year children and adolescents consume between 516 million and 947 million cigarette packages and 26 million containers of smokeless tobacco (60 FR 41314 at 41315). Thus, in a practical sense, cigarette and smokeless tobacco advertising is proposing transactions that are illegal (see *Virginia State Board of Pharmacy* v. *Virginia Citizens Council, Inc.*, 425 U.S. at 772), whether or not that is the advertiser's intent. As such, the protections of the First Amendment might not attach to such advertising because it proposes an illegal transaction. (See *Pittsburgh Press Co.*, 413 U.S. at 389; *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626 638 (1985) (''The States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading, * * *, or that proposes an illegal transaction * * *'' (citations omitted)).)

Second, even if it is assumed, *arguendo*, that cigarette and smokeless tobacco ads are not, for constitutional purposes, literal offers to sell to minors, they nonetheless are ''related to'' an unlawful activity. Whether it is the advertiser's intent or not, as explained in sections VI.D.3. through VI.D.6. of this preamble, cigarette and smokeless tobacco advertising has a powerful appeal to children and adolescents under the age of 18 and through this appeal, by means of the image that it projects, it has an effect on a young person's decision to use, and thus to attempt to purchase, tobacco products. Yet, as stated above, sale of tobacco products to minors is unlawful in all 50 States, and the purchase, possession, or use of tobacco products by minors is unlawful in a majority of States.[92] Thus, the appeal of tobacco advertising to minors is such that this type of advertising can appropriately be viewed as encouraging, and thus being ''related to'', illegal activity. As a result, it is arguable that, without more, FDA would be able to freely restrict such advertising.

Nevertheless, the advertising also relates to lawful activity—the sale of tobacco products to adults. Consequently, FDA may not have unlimited discretion to regulate tobacco advertising. (See *Dunagin* v. *City of Oxford*, 718 F.2d at 743.) At the very least, however, FDA should be afforded discretion to do what it has tried to do in these regulations; that is, to distinguish advertising that ''relates to'' commercial activity that, in substantial respects, is unlawful, the sale of tobacco products to children, from advertising that does not.

Significantly, the Supreme Court was confronted with a situation similar to this in *United States* v. *Edge Broadcasting*. In *Edge*, the Supreme Court upheld a Federal statute that prohibited advertising that ''related to'' unlawful activity (broadcast of lottery advertising by a broadcaster licensed to

[90] As explained more fully below, FDA finds unpersuasive the quote from McDonald because it does not address the means by which cigarette and smokeless tobacco product advertising influences minors' decisions on whether to purchase and use these products. Therefore, the agency turns to the legal issue raised by the comments.

[91] ''State Laws on Tobacco Control—United States, 1995,'' *Morbidity and Mortality Weekly Report (MMWR)*, CDC, DHHS, vol. 44, No. ss–6, pp. 16–17, November 3, 1995.

[92] *Id.*

a State that does not allow lotteries), but not advertising that did not relate to unlawful activity (broadcasting of lottery advertising by a broadcaster licensed to a State that allowed a lottery.)

Edge was recently cited with approval by the plurality opinion in *44 Liquormart Inc.*, 116 S.Ct. at 1511. Justice Stevens (joined by Justices Thomas, Kennedy, and Ginsburg) reasoned that the statute in *Edge* ''was designed to regulate advertising about an activity that had been deemed illegal in the jurisdiction in which the broadcaster was located.'' He contrasted the statute in *Edge* to the statute in *44 Liquormart* which ''targets information about entirely lawful behavior'' (*Id.*). Thus, the Supreme Court has countenanced distinctions in how speech is regulated that are based on whether the underlying conduct to which the speech relates is *entirely lawful* or not. That is exactly the type of distinction that FDA is drawing here.

Thus, a credible argument can be made that advertising of cigarettes and smokeless tobacco, at least to the extent that it is related to sale of these products to children under 18, is not speech protected by the First Amendment, and thus that the regulations that FDA is adopting restricting such advertising are subject only to review under an arbitrary or capricious standard. (See *Florida Bar* v. *Went For it, Inc.*, 115 S.Ct. at 2376.) However, FDA is not relying solely on this analysis. Alternatively, FDA has assumed that a *Central Hudson* test, such as that applied in *Edge*—for products that relate to both lawful and unlawful transactions—would be appropriate here. Therefore, a full analysis of these restrictions under *Central Hudson* follows.

Before proceeding to the *Central Hudson* analysis and considering the comments that bear on it, FDA wants to emphasize that, even if the First Amendment applies to tobacco advertising, the restrictions that the agency is adopting have very limited impact on those attributes of commercial speech that are protected by the First Amendment. In *44 Liquormart, Inc.*, a plurality of the Supreme Court reemphasized that commercial speech is protected solely because of the informational value:

> Advertising, however tasteless and excessive it sometimes may seem, is nonetheless dissemination of information as to *who is producing and selling what product, for what reason, and at what price.* So long as we preserve a predominantly free enterprise economy, the allocation of our resources in large measure will be made through numerous private economic decisions. It is a matter of public interest that those decisions, in the aggregate, be intelligent and well informed. To this end, the free flow of commercial information is indispensable.

116 S.Ct. at 1505 (emphasis added), quoting *Virginia Board of Pharmacy* v. *Virginia Citizens Consumer Council.*

The restrictions that FDA is adopting have virtually no effect on the core informational function of commercial speech as described in *44 Liquormart, Inc.* and *Virginia Board of Pharmacy.* Except for billboards within 1,000 feet of schools and playgrounds, which, as explained below, present special circumstances, FDA is not restricting the ability of a manufacturer, distributor, or retailer to inform the public about what they are selling, why they are selling it, or the price of their products or, for that matter, about the characteristics of their products or about any other aspect of what they sell. FDA's concerns are about the ability of manufacturers to use images, color, and peripheral presentations (such as sponsorship) in their advertising and promotion of their products to create particular appeal for children and adolescents under 18. Thus, FDA has designed the restrictions that it is adopting to ensure that adults can continue to be informed by the information in tobacco advertising while restricting the noninformative aspects of advertising that appeal to children and adolescents under the age of 18. The agency will explain how it has achieved this end in the discussion that follows.

4. Is the Asserted Government Interest Substantial?

Assuming that the *Central Hudson* test applies, ''[t]he State must assert a substantial interest to be achieved by restrictions on commercial speech.'' (See *Central Hudson,* 447 U.S. at 564.) In the 1995 proposed rule, FDA stated that this prong of the *Central Hudson* test was satisfied because the proposed regulations serve the substantial Government interest of protecting the public health. FDA stated that the advertising restrictions will help to reduce the use of cigarettes and smokeless tobacco by those who are ''the most vulnerable to addiction and, perhaps, the least capable of deciding whether to use the products. Decreased use of these products will reduce the risk of tobacco-related illnesses and deaths'' (60 FR 41314 at 41354).

Most of the comments that FDA received on this issue, even some from those who otherwise opposed the agency's proposed restrictions, agreed with the agency that it has a substantial interest in protecting the health of individuals under 18 years of age.

(5) Two comments, however, said that the interest asserted by FDA is insufficient to justify the proposed restrictions on speech. One of those comments said that smoking is a legal and widespread activity, and that there is no congressional policy against smoking. One comment said that while the Government has a substantial interest in ensuring that tobacco products are used by adults only, FDA is not empowered to protect that interest.

FDA strongly disagrees with the latter comments. The Government's interest in the public health, and particularly in the well-being of minors, is well-established. (See *Action for Children's Television* v. *FCC*, 58 F.3d 654, 661 (D.C. Cir. 1995) and 60 FR 41314 at 41354.) In fact, the Supreme Court has found that there is a compelling, not merely a substantial, interest in protecting the physical and psychological well-being of children, *New York* v. *Ferber*, 458 U.S. 747, 756–57 (1982), and that the Government's interest in the well-being of youth and in parents' claim to authority in their own household can justify the regulation of otherwise protected expression, *FCC* v. *Pacifica Foundation*, 438 U.S. 726, 749 (1978). (See also *Denver Area Educational Telecommunications Consortium* v. *FCC*, 64 U.S.L.W. 4706 (in press) (June 28, 1996).)

As the agency has explained in section II.B. and in the 1996 Jurisdictional Determination annexed hereto, cigarettes and smokeless tobacco are drug delivery devices that are subject to regulation as devices under the act. Their use by children and adolescents under 18 presents serious risk to the health of this segment of the population. For example, studies show that the age one begins smoking influences the amount of smoking one will engage in as an adult and will ultimately influence the smoker's risk of tobacco related morbidity and mortality (60 FR 41314 at 41317). In addition, the risk of oral cancer increases with increased exposure to smokeless tobacco products (60 FR 41314 at 41319). Thus, the health of children and adolescents is related to their use of cigarettes and smokeless tobacco.

FDA's compelling interest in the health and well-being of minors supports restrictions on cigarette and smokeless tobacco advertising to ensure

that advertising does not undermine FDA's restrictions on the sale of these products.

One comment said that while FDA's articulated interest in protecting minors from harm clearly is substantial, this interest is not served by FDA's regulations. According to the comment, the only goal served directly by the proposed regulations is that of delegitimatizing smoking. Two comments said that under the guise of protecting adolescents and children, FDA is trying to "'save' all Americans from the 'evils' of smoking." Two comments said that the agency is trying to prevent cigarette advertising from presenting smoking in a positive light. One comment, citing *Carey* v. *Population Services International*, 431 U.S. 678 (1977), said that the Government cannot restrict cigarette advertising because it legitimizes or favorably influences a young person's views toward tobacco products.

FDA finds no merit in these comments. Advertisements for cigarette and smokeless tobacco are not banned by the restrictions that FDA is adopting. For example, the companies are free to use advertising in almost all media that communicates to adults about the price, taste, or joys of using their product, as long as they do so using black-and-white, text-only advertisements, or using imagery and color in publications read primarily by adults. Thus, it is simply not true that manufacturers will be prevented from presenting tobacco use in a positive light or that they will be prevented from conveying truthful, nonmisleading information in almost all media.

These regulations are intended, however, as explained in section VI.E. of this document, to prevent manufacturers from advertising their tobacco products in a way that encourages underage individuals to purchase these products. They are authorized by sections 520(e) and 502(q) of the act and are in no way inconsistent with *Carey* v. *Population Services International*.

Carey involved a challenge to a law that banned all advertisement of contraceptives. The Government argued that advertising contraceptives would legitimize sexual activity of young children. The Supreme Court said that this basis was not a justification for validating suppression of expression protected by the First Amendment (431 U.S. at 701).

Carey is distinguishable from the present situation in several ways. The advertisements in that case stated the availability of products and services that were not only entirely legal but were constitutionally protected because they involved the exercise of a fundamental right (*Id*.). (The Court also struck down other provisions of the law that prohibited distribution of contraceptives to anyone under the age of 16 and by anyone other than a licensed pharmacist.) Cigarettes and smokeless tobacco are neither lawful for all people nor constitutionally protected. The sale of these products to individuals under 18 is unlawful in every State (see also, 42 U.S.C. 300x–26), and possession, purchase, or use of at least some tobacco products by this segment of the population is unlawful in a majority of States.[93] Moreover, there was no credible suggestion in any of these comments that the restrictions on the sale of these products infringe on the exercise of a fundamental right.

The Supreme Court in *Carey* made clear the limited coverage of its holding. (See 431 U.S. at 702, n. 29 ("We do not have before us, and therefore express no views on, state regulation of the time, place, or manner of such commercial advertising based on these or other state interests.").) Thus, given the significant differences in the two situations, *Carey* does not limit FDA's ability to adopt conditions on advertising that are designed to ensure that restrictions on sale to minors are not undermined.

(6) Finally, a group of comments on this first prong of the *Central Hudson* test attacked FDA for being paternalistic. These comments said that a principal theme of commercial speech doctrine is a societal intolerance for Government-enforced ignorance designed to "help" consumers who are not trusted by bureaucrats to evaluate advertising for themselves. One comment said that how to balance short-term gratification against long-term risk is a uniquely personal analysis that is best left to individual autonomy rather than Government censorship. The comment said that people must be trusted to perceive their own best interests without Government intervention in the information flow. These comments take on a particular significance in light of the plurality's statement in *44 Liquormart, Inc*. v. *Rhode Island*, 116 S.Ct. at 1508, that "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."

FDA has no disagreement with these comments with respect to individuals and, in fact, finds these regulations cannot fairly be characterized as paternalistic with respect to that population group. These regulations do not prohibit the inclusion of any information in advertising. They also do not impose the type of ban on accurate commercial information that has characterized the limitations on commercial speech that the Supreme Court has branded as paternalistic. (See, e.g., *44 Liquormart, Inc.*, 116 S.Ct. at 1510; *Virginia Bd of Pharmacy*, 425 U.S. at 769–770.)

The agency acknowledges, however, that in another respect, these regulations are paternalistic. These regulations are specifically aimed at protecting children and adolescents under the age of 18 from the appeal of tobacco advertising. The agency finds however, that for it to be paternalistic with respect to children and adolescents in no way offends the First Amendment or Supreme Court precedent. (See *Denver Area Communications Consortium, Inc*. v. *FCC*, No. 95–124 (U.S. June 28, 1996) *slip op*. at 25.) Nothing in *44 Liquormart, Inc.*, for example, suggests in any way that government may not be paternalistic with respect to children and adolescents under the age of 18.

In fact, the Supreme Court has stated: "* * * [T]he law has generally regarded minors as having a lesser capability for making important decisions." (See *Carey* v. *Population Services International*, 431 U.S. at 693, n. 15.) Given these facts—that most cigarette smokers smoke their first cigarette before 18, that children and adolescents who use tobacco products quickly become addicted to them before they reach the age of 18, that among smokers aged 12 to 17 years, 70 percent regret their decision to smoke, and 66 percent state that they want to quit (60 FR 41314)—the decision to smoke is among the most important that an individual will make. Significantly, all 50 States have prohibited sales of cigarettes to people under 18 years of age. These regulations have been tailored to help ensure that individuals do not make a decision on whether to smoke before they are 18 and have a greater capacity to understand the consequences of their actions, and that they are not influenced to make this decision before that time by advertising. At the same time, FDA has sought to ensure that the restrictions do not burden any more speech than is necessary to accomplish this goal. Thus, FDA's purpose is not inconsistent with law, commercial speech doctrine, or the

[93] *Id*.

country's precepts of individual autonomy.

D. Evidence Supporting FDA's Advertising Restrictions

1. Introduction

Having considered the preliminary inquiry and the first prong of the *Central Hudson* analysis, the agency turns to the heart of this analysis, whether the restrictions on cigarette and smokeless tobacco advertising that FDA is imposing are in proportion to the interest that it is seeking to advance. To meet its burden on this issue, FDA first must show that tobacco advertising plays a concrete role in the decision of minors to smoke, and that each specific restriction on this advertising that it is adopting will contribute to limiting its effects and thus to protecting the health of children and adolescents under the age of 18. The extensive evidence in this proceeding fully supports these judgments.

2. Do the Regulations Directly Advance the Governmental Interest Asserted?

In *Central Hudson*, the Supreme Court said that any limitation on commercial speech that the State imposes ''must be designed carefully to achieve the State's goal'' (447 U.S. at 564). ''* * * [T]he restriction must directly advance the State interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose'' (*Id*.).

The Supreme Court elaborated on what this aspect of the *Central Hudson* test requires in *Edenfield* v. *Fane*, 507 U.S. 761, 770–771 (1993);

It is well-established that ''[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'' * * * This burden is not satisfied by mere speculation or conjecture; rather, a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree * * *. Without this requirement, a state could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.

In *Edenfield*, the Court struck down a Florida ban on in-person solicitation by Certified Public Accountants (CPA's) because the State board failed to demonstrate that the harm it recited was real.

It presents no studies that suggest personal solicitation of prospective business clients by CPAs creates the dangers of fraud, overreaching, or compromised independence that the Board claims to fear. The record does not disclose any anecdotal evidence, either from Florida or another State, that validates the Board's suppositions. (*Id*.)

In *Rubin* v. *Coors*, the Court struck down a section of the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq*.) that prohibited beer labels from displaying alcohol content because the Government failed to demonstrate that this restriction would alleviate the recited harm to a material degree. (See 115 S.Ct. at 1592.) The Court characterized the Government's regulatory scheme as ''irrational'' (*Id*.). See also, Justice Stevens' opinion in *44 Liquormart*, 116 S.Ct. at 1509, 1510. (In striking down Rhode Island's ban on price advertising for failure to demonstrate that the restrictions would advance the State's interest, Stevens, joined by Justices Kennedy, Ginsburg, and Souter, found that while the record ''suggests that the price advertising ban may have some impact on the purchasing patterns of temperate drinkers of modest means * * * no evidence [has been presented] to suggest that its speech prohibition will significantly reduce market-wide consumption.'' Therefore, Stevens stated that ''[s]uch speculation certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends.'')

Thus, under the applicable case law, to adopt the proposed restrictions on cigarette and smokeless tobacco advertising, FDA must find that it can conclude from the available evidence that: (1) Advertising plays a material role in the process by which children and adolescents decide to begin or to continue to use these products; and (2) Limitations on advertising will contribute in a direct and material way to FDA's efforts to ensure that the restrictions it is adopting on the sale and use of tobacco products to minors are not undermined.

Contrary to what some comments asserted, it is not necessary for FDA to establish by empirical evidence that advertising actually causes underage individuals to smoke, or that the restrictions on advertising will directly result in individuals that are under 18 ceasing to use cigarettes or smokeless tobacco. It is not necessary in satisfying this prong of *Central Hudson* for the agency to prove conclusively that the correlation in fact (empirically) exists, or that the steps undertaken will completely solve the problem. (See *United States* v. *Edge Broadcasting Co.*, 509 U.S. 418, 434–35.) Rather, the agency must show that the available evidence, expert opinion, surveys and studies provide sufficient support for the inference that advertising does play a material role in children's tobacco use.

In the 1995 proposed rule, FDA suggested that its judgment as to whether the governmental interest involved was directly advanced by its actions was entitled to some deference. ''The Supreme Court has stated that, when determining whether an action advances the governmental interest, it is willing to defer to the 'common sense judgments' of the regulatory agency as long as they are not unreasonable'' (citing, *Metromedia Inc.* v. *City of San Diego*, 453 U.S. 490, 509 (1981) (60 FR 41314 at 41354)).

Several comments took issue with this suggestion. One comment said that FDA had mischaracterized Supreme Court jurisprudence, and two comments said that courts will defer only to common sense judgments of legislatures.

FDA disagrees with those comments. In *Florida Bar* v. *Went For It, Inc.*, the Supreme Court said that it had permitted ''litigants,'' which it did not limit to State legislatures, to justify speech restrictions by ''studies and anecdotes pertaining to different locales altogether, * * * or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and ''simple common sense * * *'' (115 S.Ct. at 2378). Thus, FDA's reliance on common sense (which, as made clear in section VI.D.3. through VI.D.6. of this document, provides only part of the basis for FDA's findings) is justified.

(7) One comment said that, rather than giving FDA deference, courts review with special care any regulations that suppress commercial speech to pursue a nonspeech-related policy.

FDA disagrees with this comment for two reasons. First, these regulations do not suppress commercial speech. While they limit such speech, they leave open significant means of communication about these products. Second, this comment derives specifically from footnote 9 of *Central Hudson*, 447 U.S. at 566 (''We review with special care regulations that entirely suppress commercial speech in order to pursue a nonspeech-related policy.''). In that case, the Supreme Court found that control of demand for electricity was a speech-related policy (see 447 U.S. at 569). Similarly, the policy that FDA seeks to advance here, control of demand for cigarettes and smokeless tobacco by minors, is a speech-related policy.

(8) Finally, one comment said that FDA claimed deference for its common sense judgments to deflect attention from the lack of a factual basis for the 1995 proposed rule. Two comments, however, stated that FDA has compiled a record on the problem that is more extensive than any that existed in any of the cases in which the Supreme Court upheld restrictions on commercial speech.

In the discussion that follows, FDA reviews the evidence on whether cigarette and smokeless tobacco advertising affects the decision by minors to use these products, and whether the restrictions on advertising that it is imposing will limit the effect to a material degree. This review demonstrates that FDA's judgment on these issues is supported not only by common sense but by studies, anecdotes, history, expert consensus documents, and empirical data. All of this evidence provides support that restrictions on the advertising of these products will directly advance the Government's interest in protecting the health of children and adolescents under 18 years of age.

3. Is There Harm? Does Advertising Affect the Decision by Young People to Use Tobacco Products?

a. *In general.* In the preamble to the 1995 proposed rule, FDA stated that perhaps the most compelling piece of evidence supporting restrictions was that these products were among the most heavily advertised and widely promoted products in America. The agency cited the most recent Federal Trade Commission (FTC) figures of overall expenditures for 1993, that indicated that over $6.1 billion had been spent by the cigarette and smokeless tobacco industries to promote their products in diverse media. These include magazines, newspapers, outdoor advertising, point of purchase, direct mail, in-store, dissemination of nontobacco items with brand identification, and sponsorship of cultural and sporting events.

(9) Several comments from the tobacco industry and the advertising industry criticized FDA's reliance on the immensity of advertising expenditures that show that tobacco products are heavily advertised. The comments claimed that the size of the industry advertising budget is not evidence that it is effective in causing young people to smoke.Conversely, one comment concluded that:

[h]ighly repetitious ad exposure likely leads to judgment biases in both risk and social perceptions, such as assessments of smoking prevalence and the social acceptance experienced by smokers.

The largest psychological association, in its comments, agreed and stated that research indicates that young people are indeed exposed to substantial and unavoidable advertising and promotion,[94] even though they have been banned from radio and television. Referencing numerous studies, this comment stated further that:

there is considerable evidence that young people are exposed to tobacco ads, that those who smoke are especially likely to be aware of cigarette advertising, and that liking of cigarette advertising among young people is predictive of smoking behavior * * *.

The comment continued that increasing one's exposure to advertising and promotions creates persuasion, and that reducing that exposure will impede that process.[95] One study[96] found that even brief exposure to tobacco advertising can cause some young people to have more favorable beliefs about smokers.[97]

FDA did not cite the industry's expenditures to indicate that the size of the industry's advertising budget was, in and of itself, a problem, but rather to show that the very size of the campaign, and the resultant ubiquity and unavoidability of the advertising in all media, created a climate that influences young people's decisions about tobacco use. The ubiquity creates what FDA referred to in the preamble to the proposed rule (60 FR 41314 at 41343), as ''friendly familiarity'' that makes smoking and smokeless tobacco use seem respectable to young people. In its comments, the advertising agency that coined this phrase in the 1960's has protested that FDA used the phrase improperly. However, regardless of the firm's protest, the agency finds that this phrase ''friendly familiarity'' accurately describes the effect of massive marketing that uses a variety of media and saturates potential consumers with information and imagery. Researchers have found that ''the ubiquitous display of messages promoting tobacco use clearly fosters an environment in which experimentation by youth is expected, if not implicitly encouraged.''[98]

b. *Evidence regarding young people's exposure to, recall of, approval of, and response to advertising.* Many studies have demonstrated that young people are aware of, respond favorably to, and are influenced by cigarette advertising. In the preamble to the 1995 proposed rule, FDA presented a number of studies examining young people's exposure to, recall of, approval of, and response to cigarette advertising.[99] Collectively, these studies showed that children who smoke are more likely to correctly identify cigarette advertisements and slogans in which the product names or parts of the slogans have been removed than are children who do not smoke, and that exposure to and approval of cigarette advertising were positively

[94] Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, ''Brand Logo Recognition by Children Aged 3 to 6 years: Mickey Mouse and Old Joe Camel,'' *Journal of the American Medical Association (JAMA)*, vol. 266, pp. 3145–3148, 1991; Mizerski, R., K. Straughn, and J. Feldman, ''The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children,'' presented at Marketing and Public Policy Conference, 1994.

[95] For example, Lavidge, R. J., and G. A. Steiner, ''A Model for Predictive Measurements of Advertising Effectiveness,'' *Journal of Marketing*, vol. 25, pp. 59–62, 1961; McGuire, W. J., ''Persistence of the Resistance to Persuasion Induced by Various Types of Prior Belief Defenses,'' *Journal of Abnormal and Social Psychology*, vol. 64, pp. 241–248, 1962.

[96] Pechmann, C., and S. Ratneshwar, ''The Effects of Antismoking and Cigarette Advertising on Young Adolescents' Perceptions of Peers who Smoke,'' *Journal of Consumer Research*, vol. 21, pp. 236–251, 1994.

[97] See also, Hock, J., P. Gendall, and M. Stockdale, ''Some Effects of Tobacco Sponsorship Advertisements on Young Males,'' *International Journal of Advertising*, vol. 12, pp. 25–35, 1993.

[98] Bonnie, R. J., and B. S. Lynch, ''Time to Up the Ante in the War on Smoking,'' *Issues in Science and Technology*, vol. 11, pp. 33–37, 1994.

[99] Chapman, S., and B. Fitzgerald, ''Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion,'' *American Journal of Public Health*, vol. 72, pp. 491–494, 1982; Aitken, P. P., and D. R. Eadie, ''Reinforcing Effects of Cigarette Advertising on Under-Age Smoking,'' *British Journal of Addiction*, vol. 85, pp. 399–412, 1990; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, ''Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements,'' *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987; Botvin, G. L., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, ''Smoking Behavior of Adolescents Exposed to Cigarette Advertising,'' *Public Health Reports*, vol. 108, pp. 217–224, 1993; Klitzner, M., P. J. Gruenewald, and E. Bamberger, ''Cigarette Advertising and Adolescent Experimentation With Smoking,'' *British Journal of Addiction*, vol. 86, pp. 287–298, 1991; Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, ''Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older,'' *British Journal of Addiction*, vol. 86, pp. 383–390, 1991; O'Connell, D. L., H. M. Alexander, A. J. Dobson, D. M. Lloyd, G. R. Hardes, H. J. Springthorpe, and S. R. Leeder, ''Cigarette Smoking and Drug Use in Schoolchildren: II. Factors Associated With Smoking,'' *International Journal of Epidemiology*, vol. 10, pp. 223–231, 1981; Alexander, H. M., R. Calcott, A. J. Dobson, G. R. Hardes, D. M. Lloyd, D. L. O'Connell, et al., ''Cigarette Smoking and Drug Use in Schoolchildren: IV. Factors Associated With Changes in Smoking Behaviour,'' *International Journal of Epidemiology*, vol. 12, pp. 59–66, 1983.

related to smoking behavior and intentions to smoke.

(10) Several comments from the tobacco industry and advertising groups were critical of these studies. The comments argued that none of the studies demonstrated that recognition of, exposure to, or approval of, cigarette advertising caused the initiation of cigarette smoking; that smoking in fact engendered increased exposure to, approval of and recognition of cigarette advertising; and that the samples were inappropriate and not generalizable. One comment took issue with the way in which smoking transition was defined in the Aitken study cited by the agency.[100] In addition, the same comment questioned the use of self-reported measures of cigarette advertising exposure in several of the studies.

FDA agrees that none of these studies individually is sufficient to: (1) Establish that advertising has an effect of directly causing minors to use tobacco products; (2) determine directionality—that is, did advertising cause the observed effect, or are smokers more observant of advertising (the Klitzner, Aitken, et al., and Alexander studies attempted to control for this effect); or (3) define terms or disprove the influence of peer pressure in smoking behavior.

However, none of these defects is sufficient to render it inappropriate for FDA to use the studies as evidence. The studies, in fact, present useful insight into how advertising affects smoking behavior and when considered with other studies provide sufficient support for the agency's conclusions. For example, one study[101] stated that the results show that part of the process of becoming a smoker is to adopt a preferred brand, which the advertising and tobacco industries concede is affected by advertising. Moreover, these studies clearly indicate that, at a minimum, advertising plays an important role in developing an appealing and memorable image for brands. Finally, FDA recognizes that advertising may not be *the* most important factor in a child's decision to smoke; however, the studies cited by the agency establish that it is a substantial, contributing, and therefore material, factor.

c. *Evidence concerning overestimation of smoking prevalence.* In the preamble to the 1995 proposed rule, FDA cited numerous studies finding that children's misperceptions about the prevalence of smoking are related to smoking initiation and the progression to regular smoking.[102] Further, the evidence indicated that cigarette advertising plays a role in leading young people to overestimate the prevalence of smoking.

(11) Several comments criticized the overestimation of smoking prevalence studies presented by FDA in its 1995 proposed rule. The most common criticism was that the cited studies did not demonstrate a causal relationship between either exposure to advertising or overestimation of smoking prevalence and intentions to smoke. One comment noted that some of the cited studies did not necessarily measure ''overestimation,'' but instead simply measured respondents' perceptions of smoking levels among their peers and adults. Another comment argued that FDA ignored other variables (such as whether or not one's friends smoked) that were predictive of smoking status or intentions to smoke.

It is true that some of the cited studies did not measure ''overestimation'' in the most literal sense but instead measured respondents' perceptions of smoking levels among peers and adults. However, the perceived levels were still uniformly higher among those who smoked than among those who did not. The importance of these studies is the fact that they established differences in perception between smoking and nonsmoking young people about the prevalence, and therefore the acceptability, of smoking.

d. *The effects of selected advertising campaigns that were effective with children.* In the preamble to the 1995 proposed rule, FDA presented evidence about two campaigns that appear to have been particularly effective with children, and a historical analysis of trends in U.S. smoking initiation among 10- to 20-year-olds from 1944 to 1980.[103]

FDA presented several studies finding that the ''Joe Camel'' campaign had a significant impact on underage smoking in the United States,[104] and that a humorous character for Embassy Regal cigarettes named ''Reg'' was appealing to children in the United Kingdom.[105]

FDA also cited a recent study that used data from the National Health Interview Survey to study trends in smoking initiation among 10 to 20 year olds from 1944 through 1980.[106] The study concluded that tobacco marketing campaigns that targeted women resulted in increased smoking uptake in young women and girls, but not in adults generally.[107]

The Joe Camel Campaign—In the preamble to the 1995 proposed rule,

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[100] Aitken, P. P., D. R. Eadie, G. B. Hastings, and A. J. Haywood, ''Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older,'' *British Journal of Addiction*, vol. 86, pp. 383–390, 1991.

[101] Chapman, S., and B. Fitzgerald, ''Brand Preference and Advertising Recall in Adolescent Smokers: Some Implications for Health Promotion,'' *American Journal of Public Health*, vol. 72, pp. 491–494, 1982.

[102] Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, ''Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study,'' *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. A. Johnson, W. B. Hansen, and B. R. Flay, ''Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study,'' *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987; Sussman, S., C. W. Dent, J. Mestel-Rauch, C. A. Johnson, W. B. Hansen, and B. R. Flay, ''Adolescent Nonsmokers, Triers, and Regular Smokers' Estimates of Cigarette Smoking Prevalence: When do Overestimations Occur and by Whom?,'' *Journal of Applied Social Psychology*, vol. 18, pp. 537–551, 1988; 1994 SGR, p. 192–195, citing Burton, et al., The L.A./Finland Study; Sherman, S. J., C. C. Presson, L. Chassin, E. Corty, and R. Olshavsky, ''The False Consensus Effect in Estimates of Smoking Prevalence: Underlying Mechanisms,'' *Personality and Social Psychology Bulletin*, vol. 9, pp. 197–207, 1983; Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, ''Smoking Behavior of Adolescents Exposed to Cigarette Advertising,'' *Public Health Reports*, vol. 108, pp. 217–224, 1993.

[103] Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, B. Rosbrook, D. Shopland, and M. Johnson, ''Does Tobacco Advertising Target Young People to Start Smoking?'' *JAMA*, vol. 266, pp. 3154–3158, 1991; Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, ''Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe Camel,'' *JAMA*, vol. 266, pp. 3145–3148, 1991; Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, ''Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn,'' *British Medical Journal*, vol. 309, pp. 933–937, 1994; Pierce, J. P., L. Lee, and E. A. Gilpin, ''Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising,'' *JAMA*, vol. 271, pp. 608–611, 1991.

[104] Fischer, P. M., M. P. Schwartz, J. W. Richards, A. O. Goldstein, and T. H. Rojas, ''Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel,'' *JAMA*, vol. 266, pp. 3145–3148, 1991; Pierce, J. P., E. Gilpin, D. M. Burns, E. Whalen, E. Rosbrook, D. R. Shopland, and M. Johnson, ''Does Tobacco Advertising Target Young People to Start Smoking?'', *JAMA*, vol. 266, pp. 3154–3158, 1991.

[105] Hastings, G. B., H. Ryan, P. Teer, and A. M. MacKintosh, ''Cigarette Advertising and Children's Smoking: Why Reg was Withdrawn,'' *British Medical Journal*, vol. 309, pp. 933–937, 1994.

[106] Pierce, J. P., L. Lee, and E. A. Gilpin, ''Smoking Initiation by Adolescent Girls, 1944 through 1988: An Association with Targeted Advertising,'' *JAMA*, vol. 271, pp. 608–611, 1994.

[107] *Id.*; See also Pierce, J. P., and E. A. Gilpin, ''A Historical Analysis of Tobacco Marketing and Uptake of Smoking by Youth in the United States: 1890–1977,'' *Health Psychology*, vol. 14, pp. 500–508, 1995. Burns, D. M., L. Lee, J. W. Vaughn, Y. K. Chiu, and D. R. Shopland, ''Rates of Smoking Initiation Among Adolescents and Young Adults, 1907–1981,'' *Tobacco Control*, vol. 4, supp. 1, pp. 52–58, 1995.

FDA described R. J. Reynolds' (RJR) use of the cartoon Joe Camel as the centerpiece of a very successful campaign that sought to revitalize Camel cigarettes. The preamble to the 1995 proposed rule described two sets of studies. One set indicatedthat the campaign was so pervasive and juvenile that children as young as 3 to 6 years old, recognized the Joe Camel character and knew that he sold cigarettes. The other set of studies provided evidence that the campaign had resulted in Camel's share of the adolescent youth market rising from below 4 percent of underage smokers to between 13 and 16 percent in a short period of time (60 FR 41314 at 41333).

This description of the Camel campaign produced over 200 comments from the advertising, tobacco, legal and publications industries, members of legislative bodies, State and local government officials and agencies, health providers and organizations, academics, and the general public. The latter included many anecdotal references to children's positive reactions to the campaign, including comments from parents, teachers, and children themselves. One comment, from a State attorney general, stated that ''in 1993, after reviewing research documenting the extremely powerful effect R. J. Reynolds' 'Cool Joe Camel' ads have on children, I joined with 26 other State Attorneys General in calling'' for a ban on that campaign.

(12) The comments differed radically in assessing the accuracy of FDA's use of Joe Camel as evidence of the effect of a youth-oriented campaign. A number of comments stated that the Joe Camel campaign was neither directed toward children nor effective at reaching them, and that FDA's evidence did not support the agency's position. The comments criticized the studies cited by FDA and referred to other studies that they believed supported their contention that the Joe Camel campaign was not directed toward children. For example, one comment argued there was no evidence to suggest that brand recognition had any influence on smoking initiation. This same comment also complained that the studies relied on by FDA were ungeneralizable and were from medical journals, not marketing journals. Another comment argued that the Pierce study cited by the agency had demonstrated only that Camel and Marlboro were thought to be the most advertised brands across all respondent age groups.[108]

Several comments argued that the finding in the Fischer and Mizerski studies that children recognize Joe Camel did not necessarily indicate that they liked Joe Camel, let alone that they would be more likely to take up cigarette smoking.[109] For example, some comments from the tobacco industry discussed the Mizerski study funded by RJR and criticized FDA's use of it. FDA, as noted above, had cited this study in the 1995 proposed rule to show that 72 percent of 6 year olds and 52 percent of children between the ages of 3 and 6 could identify Joe Camel.[110] This exceeded the recognition rates for Ronald McDonald, a character frequently advertised on television. The comments, however, stated that the results of the study indicated that while recognition of the cartoon trade characters and liking of the associated product each tended to increase with age, for Joe Camel, at every age, children who recognized Joe Camel were more likely to report disliking cigarettes than did children who did not recognize Joe Camel.

Several comments also cited another study by Henke (the Henke Study),[111] which found results suggesting that even though recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes about a product. Although the children in the study were generally able to recognize Joe Camel, 97 percent of the respondents reported that cigarettes were ''bad for you,'' and all but one of the minors stated that cigarettes were for adults. Several comments also mentioned a November 1993 Roper survey of over 1,000 young people between ages 10 and 17.[112] This survey found that 97 percent of those youths who recognized ''Joe Camel'' had negative opinions about smoking.

Finally, these comments also stated that the Joe Camel campaign did not increase the smoking rates of minors. The comments cited to data from CDC's Office of Smoking and Health's (OSH's) study ''1993 Teenage Attitudes and Practices Survey, Public Use Data Tape'' (TAPS II)[113] that show that, contrary to FDA's assertion and citation to data from Monitoring the Future,[114] there has not been an increase in youth smoking rates as a result of the Joe Camel campaign.

Conversely, several comments from professional associations and many from private citizens supported FDA's tentative conclusion that some tobacco advertising campaigns—particularly Joe Camel—are very effective with children. Some comments referred to the same research evidence cited by FDA in the 1995 proposed rule.

It is not the agency's position that the recognition studies provide evidence of the effect of this campaign upon the smoking habits of children. The Henke study found that children age 6 and younger do not smoke and uniformly report that they dislike smoking.[115] However, although young children usually dislike smoking, many of them later do smoke. FDA's point in using the recognition studies was that advertising for Camel cigarettes was so pervasive and appealing to young people that children saw the advertisements and assimilated them even though they were too young to even think about smoking. These studies provide important evidence of the pervasiveness of tobacco advertising.

The Henke study (cited by comments opposed to the 1995 proposed rule), which reported that although recognition of brand advertising symbols increases with age, recognition does not necessarily indicate favorable attitudes toward a product—is subject to

[108] Pierce, J., et al., ''Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California,'' *JAMA*, vol. 266, No. 22, p. 3154–3158, 1991.

[109] Fischer, P. M., et al., ''Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel,'' vol. 266, pp. 3145–3148, 1991; Mizerski, R., ''The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children,'' presented at ''Marketing and Public Policy Conference,'' May 13–14, 1994.

[110] Independent research by Fischer found that 91 percent of 6 year-olds and 30 percent of 3 year-olds recognized Joe Camel. Fischer, P. M., J. W. Schwartz, A. O. Goldstein, and T. H. Rojas, ''Brand Logo Recognition by Children Aged 3 to 6 Years: Mickey Mouse and Old Joe the Camel,'' *JAMA*, vol. 266, pp. 3145–3148, 1991.

[111] Henke, L., ''Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification,'' *Journal of Advertising*, in press.

[112] Roper Starch, ''Advertising Character and Slogan Survey,'' pp. 16–17, November 1993 (conducted for R. J. Reynolds Tobacco Co.).

[113] ''1993 Teenage Attitudes and Practices Survey, Public Use Data Tape,'' CDC, OSH, p. 3, 1993 (unpublished data).

[114] Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Survey, 1975–1993: vol. I: Secondary School Students*, Rockville, MD, DHHS, Public Health Service (PHS), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), NIH Pub. No. 94–3809, 1994.

[115] Henke, L., ''Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification,'' *Journal of Advertising*, in press.

many of the same criticisms as those leveled by the tobacco industry at studies cited by FDA, and in fact contains more serious flaws that suggest that its results should be interpreted with a great deal of caution.

First, the sample employed in this study was both inadequate to test the author's hypotheses, and is nongeneralizable to other populations. There were only 83 participants in the study; this sample is too small to allow for adequate power to test the author's fine-grained hypotheses concerning age. In fact, the inadequate sample size led the author to collapse the participants into three age groups for many analyses, which meant that 3-year olds were placed into the same group as children who were 5-and-a-half years old. In addition, participants all were recruited from middle class neighborhoods in the same ''small coastal town'' in Maine. Racial breakdowns were not presented, but it is likely, given the demographics of upstate Maine, that whites were overrepresented and African-Americans underrepresented. In addition, males were overrepresented. At best, the sample represents the population of 3- to 8-year-old children in that small town in Maine, but it is not even clear that this is the case.

Second, the interview process used to collect data in the study, and even the nature of the interviewers themselves, greatly limit the conclusions that may be drawn from the study. The study used six different interviewers, five of whom were college undergraduates, and one of whom was a child care professional. Each interviewer participated in but a single training session before collecting data. Further, not all of the interviewers were blind to the hypotheses of the study. This is a great concern, considering the very subjective nature of the interview. It was not reported whether who the interviewer was had significant effects on the results of the study (and indeed the sample size is probably too small to permit such an analysis), but it is unlikely that all six interviewers conducted the interviews in precisely the same way or elicited the same types of responses from the participants.

The interview process itself appeared to be highly biased and subjective in nature. It is not surprising that the children overwhelmingly reported that cigarettes were ''bad for you'' and were meant for adults, given that they were being interviewed face-to-face by adult strangers. Any potential differences attributable to recognition of cigarette advertising were probably masked by the intimidating presence of the interviewer. Further, the answers to questions such as ''Do you like this product or not like this product?,'' and ''Is this product good for you or bad for you?'' can depend to a great extent on the manner in which they are asked.

Overall, the small, nonrepresentative sample, the excessive number of questionable interviewers, and the interview process itself all cast serious doubt on the value of this study. Finally, as noted in the previous paragraph, children almost uniformly report that smoking is bad, but many of them will smoke in the future in part due to the appeal created for the product by advertising.

Additional studies—Two additional studies on this issue of recognition were submitted to the docket. The first, an article by Joel S. Dubow, [116] merely commented on several general studies on recall of advertising. The result was that children and especially adolescents remember more about advertising than adults. (FDA agrees with the point that advertising is more memorable to children.) Further, all the advertisements tested, and those that children and adolescents remembered so well, were either on television or presented in a movie theater setting.

Children and adolescents are more visually oriented than adults; they remember what they see on television. However, as noted, commercials for cigarettes are not on television and so the high recognition rates of Joe Camel cannot be accounted for on that basis. Thus, the study begs the same question that is raised by the Mizerski study: Where did those 3 to 6 year olds see the cigarette advertisements they found so memorable?

The answer may be provided by the second recognition study submitted by RJR. One study was conducted by Roper Starch in November 1993 for RJR and tested young people's recognition of advertising characters. The results of that study show that Joe Camel was recognized by 86 percent of all 10 to 17 year olds, in both aided and unaided recall. The characters with greater recognition were all televised characters: the Energizer Bunny, Ronald McDonald, the Keebler Elves, etc. Recognition scores for those characters were in the 97 percent to 100 percent range. Of more interest, 95 percent of those who recognized Joe Camel knew that he sold cigarettes, similar to the product familiarity rates for the other characters. [117]

But perhaps the most interesting answers were those provided by the children who responded that they knew that Joe Camel sold cigarettes. In response to the question, ''[p]lease tell me the ways that you might have seen or heard about this character,'' 51 percent said the information came from a billboard advertisement, 45 percent said from an advertisement in a magazine, 32 percent said from an advertisement in the store, and 22 percent said on a tee shirt. A sizable group said they had seen him on television (42 percent). On the other hand, all the other characters were identified as having been on television (88 percent to 100 percent). Recognition based upon billboard exposure for these other characters was between 6 percent and 13 percent. Most were not recognized as having been on tee shirts.

Clearly, cigarettes are marketed differently than most consumer products; nonetheless, whatever the marketing mix used by the tobacco industry, cigarette advertisements are clearly being seen and assimilated by those too young to be interested in or to have started smoking.

A second type of study, provided evidence of the effect of this campaign on adolescent smoking rates. As noted, one comment disputed that there was a rise in young people's smoking rates that corresponded to the introduction of the Joe Camel campaign. The significance of this argument is that if smoking rates after the introduction of the Joe Camel advertising campaign did not rise, there is little reason to believe that the campaign caused young people to take up smoking. This comment referred to its own analysis of smoking trends, which it stated were derived from TAPS II [118] data and not from the data in Monitoring the Future used by FDA. [119]

FDA has provided a more detailed answer to this comment above. As explained there, the agency finds this comment to be without merit. The Monitoring the Future study is the most consistent source of data available on youth smoking rates. RJR's expert, Dr. J.

[116] Dubow, J. S., ''Advertising Recognition and Recall by Age-Including Teens,'' *Journal of Advertising Research*, pp. 55–60, Sept/Oct 1995.

[117] ''Advertising Character and Slogan Survey,'' pp. 10, 12, 22–23.

[118] ''Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993,'' *MMWR*, CDC, vol. 43, pp. 577–581, Aug 19, 1994.

[119] Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975–1993: Vol. I; Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94–3809, 1994.

Howard Beales, III, has referred to it as ''[t]he most consistent data available'' to track the incidence of teen smoking over time.[120] Moreover, Dr. Beales noted that other Government studies are ''sporadic'' and, by implication, cannot be relied upon to give an accurate picture of overall smoking trends.

The Monitoring the Future Study indicates that from 1987 to 1993, the 30-day smoking rates and daily smoking rates for male high school seniors increased steadily, although with variations in some years.[121] During that same period, Camel's share of the youth market rose from below 4 percent to around 13 percent (60 FR 41314 at 41330).

These data do not absolutely prove that Camel advertising ''caused'' a rise in youth smoking. However, they do provide further evidence that the Joe Camel campaign had an effect on youth smoking rates.

(13) Comments from the tobacco industry maintained that FTC's investigation, which failed to produce ''evidence to support'' FTC action against RJR for the Joe Camel campaign, should have been dispositive of the issue. Therefore, the comments argued, it is inappropriate for FDA to use the campaign as evidence that advertising causes children to start to smoke. The comments maintained that the FTC review included the same studies relied upon by FDA to condemn the Joe Camel campaign.

Comments stated further that Congress has vested jurisdiction in FTC to prosecute unfair and deceptive advertising of tobacco products, and that it has sole jurisdiction in this area. (See Federal Trade Commission Act (the FTC Act) (15 U.S.C. 41).) These comments noted further that FTC has shown its ability to fulfill its responsibilities in this area, citing two recent consent agreements secured by FTC. One was against RJR for advertising that disputed some of the health risks of smoking. (See *In the matter of R. J. Reynolds Tobacco Company*, 113 FTC 344 (1990).) The other was against American Tobacco Company for allegedly misleading statements about tar and nicotine ratings. (See *In the matter of The American Tobacco Company*, Dkt. No. C–3547 (Consent Order, January 31, 1995).)

On the other hand, comments from two national health organizations alleged that the fact FTC concluded it was unable to take action against Joe Camel demonstrates that the FTC Act, as it is currently being interpreted by the Commission, is not sufficient to protect American youth from inappropriate tobacco advertising and that FDA, therefore, needs to take action under its authority.

The industry comments misapprehend FDA's citation to the Joe Camel campaign. As noted above, FDA cited to numerous studies that had been performed by independent researchers on children's recognition of the main character of a youth oriented advertising campaign (60 FR 41314 at 41333). The agency also cited to several documents that it had obtained that indicated that RJR may have intended for its Joe Camel campaign to appeal to and attract young people (60 FR 41314 at 41330). FDA's discussion of the marketing success of the Joe Camel campaign is not intended to suggest that FDA had found or concluded that the Joe Camel campaign violated any law, but that FDA had found in that success—tripling Camel's share of the youth market—support for restricting such activities in the future through rulemaking.

Moreover, FTC did not disagree with FDA's use of the campaign. In its comment to FDA on the 1995 proposed rule, FTC stated, ''This decision [by FTC to close the RJR investigation without issuing a complaint] does not contradict FDA's conclusion.'' FTC continued that its failure to initiate legal action did not ''mean that cigarette and smokeless tobacco advertising, in the aggregate, is not one of a number of factors that 'play[s] an important role in a youth's decision to use tobacco.'''[122]

(14) The other citation to the Joe Camel campaign (60 FR 41314 at 41330) utilized RJR's documents to illustrate the youth focus of one advertising campaign through use of the company's own documents. Some comments received from the tobacco industry (including one from RJR), trade associations, and some individuals disagreed with this use and stated that the Camel campaign was designed to, and did in fact, attract the attention of young adult smokers, aged 18 to 24. These comments stated that the Joe Camel campaign was directed to adult smokers, specifically existing male Marlboro smokers aged 18 to 24. The comments stated that the illustrated character Joe Camel was developed to reposition the brand by stressing images and characteristics, such as the ''Smooth Moves'' image, which appeal to the young adult, particularly male, Marlboro smoker.

Industry comments further stated that the company conducted no market research on nonsmokers, and that the campaign reached adult smokers aged 18 to 24 years. One comment postulated that it is merely the cartoon form of Joe Camel that causes people to mistakenly believe that Joe Camel is child-oriented. It stated further that many adult products are advertised using illustrated characters, such as the Pink Panther for fiberglass insulation, Garfield the Cat for a hotel chain, Mr. Clean for household products, and the Peanuts characters for life insurance. Moreover, RJR stated that it made efforts to ensure that the ad copy and promotional activity for Joe Camel would not appeal to minors. It said that a skateboard promotion proposed by an advertising agency was rejected by the company because it was assumed that skateboarding is disproportionately engaged in by children and adolescents. Similarly, marketing research included 25 to 34 year olds ''to serve as a safety check to make sure that the concept appeal did not skew too young.''

These comments further stated that Joe Camel advertisements were directed to, and reached, the intended market. Examples of publications in which the Joe Camel advertisements were placed are *Cycle World*, *Penthouse*, *Gentleman's Quarterly*, and *Road and Track*. Joe Camel's share of 18 to 24 year olds increased by 6.9 percentage points, from 3.2 in 1986, the year before Joe Camel's inception, to 10.1 by the end of 1994. The comment stated that Camel's and Marlboro's growth came at the expense of other brands. These comments are consistent with the industry's assertion that this is the whole point of cigarette advertising: to encourage current smokers to buy the advertised brand either by switching brands or remaining loyal to their existing brands. (This comment states that because there is no evidence that smoking rates have risen among adolescents, there cannot be a reason to believe that Camel's success among adolescents came from new, as opposed to existing, smokers. See section III.B. of

[120] Beales, J. H., ''Teenage Smoking: Fact and Fiction,'' *The American Enterprise*, vol. 21, March/April 1994.

[121] Johnston, L. D., P. M. O'Malley, and J. G. Bachman, *National Survey Results on Drug Use from the Monitoring the Future Study, 1975–1994, Vol. I: Secondary School Students*, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94–3809, 1995.

[122] FTC analyzed the complaint recommendation before it under its unfairness jurisdiction. An action is unfair if it causes substantial consumer injury, without offsetting benefits to consumers or competition, which consumers cannot reasonably avoid. (*International Harvester*, 194 FTC 949, 1070, 1984.)

this document for a refutation of the industry assertion that smoking rates among adolescents are static.)

In contrast, comments from health organizations and concerned citizens stated that Joe Camel has been successful in attracting underage smokers. These comments further stated the belief that the campaign was intended to attract children, citing the methods of advertising and promotion employed as evidence of its intention to appeal to children. For example, one comment stated: ''* * * T-shirts and caps, like those marketed with 'Joe Camel' are found in disproportionate numbers of children.''

FDA continues to believe that RJR documents do illustrate the creation of and execution of a decidedly youth-oriented campaign.

FDA finds that previously confidential RJR documents provide convincing evidence of the company's intention to attract young smokers and so-called presmokers to its Camel brand. These documents, identified as RJR marketing documents and submitted during the comment period, reflect a company policy that in order to grow and ensure a profitable future, the company must develop new brands that would appeal to and capture a share of the youth market. These young people were described as ''presmokers'' and ''learners'' in RJR marketing language and were identified as being 14 to 18 year olds.

While the documents concerning the Camel campaign (focus group reports, etc.) submitted by RJR to the rulemaking docket do not identify the under-18 group as the company's target, the implication arises from the company-submitted documents that the Camel campaign was the logical outgrowth of the planning and forecasting contained in the heretofore confidential marketing documents.

In a 1972 memo entitled ''Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein,'' the author, Claude Teague Jr., Assistant Director of Research and Development, wrote:

[I]t may be well to consider another aspect of our business; that * * * the factors which induce a presmoker or nonsmoker to become a habituated smoker. * * * He does not start smoking to obtain undefined physiological gratifications or reliefs, and certainly he does not start to smoke to satisfy a nonexistent craving for nicotine. Rather, he appears to start to smoke for purely psychological reasons—to emulate a valued image, to conform, to experiment, to defy, to be daring, to have something to do with his hands, and the like. Only after experiencing smoking for some period of time do the physiological ''satisfactions'' and habituation become apparent and needed. Indeed, the first smoking experiences are often unpleasant until a tolerance for nicotine has been developed. * * * [I]f we are to attract the nonsmoker or presmoker, there is nothing in this type of product that he would currently understand or desire. We have deliberately played down the role of nicotine, hence the nonsmoker has little or no knowledge of what satisfactions it may offer him and no desire to try it. Instead, we somehow must convince him with wholly irrational reasons that he should try smoking, in the hope that he will for himself then discover the real ''satisfactions'' obtainable. [123]

In 1973, the same author reported in another memo, ''Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market,'' his thoughts on how to acquire a portion of the important youth market:

[W]e should simply recognize that many or most of the ''21 and under'' group will inevitably become smokers, and offer them an opportunity to use our brands.Realistically, if our Company is to survive and prosper, over the long-term we must get our share of the youth market. In my opinion this will require new brands tailored to the youth market; I believe it unrealistic to expect that existing brands identified with an over-thirty 'establishment' market can ever become the 'in' products with the youth group. Thus we need new brands designed to be particularly attractive to the young smoker, while ideally at the same time being appealing to all smokers. [124]

Mr. Teague then described the factors he thought must be taken into account in designing a brand that would attract young people:

Several things will go to make up any such new ''youth'' brands, the most important of which may be the image and quality-which are, of course, interrelated. The questions then are: What image? and What quality? Perhaps these questions may best be approached by consideration of factors influencing pre-smokers to try smoking, learn to smoke and become confirmed smokers. * * * For the pre-smoker and ''learner'' the physical effects of smoking are largely unknown, unneeded, or actually quite unpleasant or awkward. The expected or derived psychological effects are largely responsible for influencing the pre-smoker to try smoking, and provide sufficient motivation during the ''learning'' period to keep the ''learner'' period going, despite the physical unpleasantness and awkwardness of the period. * * * [125]

Mr. Teague continues with some reasons why young people smoke and then gives advice on the type of advertising campaign that would appeal to the presmoker group based on these reasons:

A. *Group Identification*—Pre-smokers learn to smoke to identify with and participate in shared experiences of a group of associates. If the majority of one's closest associates smoke cigarettes, then there is strong psychological pressure, particularly on the young person, to identify with the group, follow the crowd, and avoid being out of phase with the group's value system even though, paradoxically the group value system may esteem individuality. This provides a large incentive to begin smoking.

* * * * *

[The brand's] promotion should emphasize togetherness, belonging and group acceptance, while at the same time emphasizing individuality and ''doing ones own thing.''

B. *Stress and Boredom Relief*—The teens and early twenties are periods of intense psychological stress, restlessness and boredom. Many socially awkward situations are encountered. [the documents mentions smoking gives you something to do with your hands—find an ashtray etc.]

C. *Self-Image Enhancement*—The fragile, developing self-image of the young person needs all of the support and enhancement it can get. Smoking may appear to enhance that self-image in a variety of ways. [Values mentioned in the document include adventurousness, adult image.] If one values certain characteristics in specific individuals or types and those persons or types smoke, then if one also smokes he is psychologically a little more like the valued image. This self-image enhancement effect has traditionally been a strong promotional theme for cigarette brands and should continue to be emphasized.

D. *Experimentation*—There is a strong drive in most people, particularly the young, to try new things and experiences. This drive no doubt leads many presmokers to experiment with smoking, simply because it is there and they want to know more about it. A new brand offering something novel and different is likely to attract experimenters, young and old, and if it offers an advantage it is likely to retain those users. [126]

In March 1976 R. J. Reynolds' Research Department created a memo entitled, ''Planning Assumptions and Forecast for the Period 19**–1986 for R. J. Reynolds Tobacco Company.'' Under a heading, The Tobacco Industry and R. J. Reynolds Tobacco Company—subheading E. Products—the memo states:

The present large number of people in the 18–35 year old age group represents the greatest opportunity for long-term cigarette sales growth. Young people will continue to become smokers at or above the present rates during the projection period. The brands which these beginning smokers accept and

[123] Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, pp. 4–5, 1972.

[124] Teague, C., *Research Planning Memorandum on Some Thought About New Brands for Cigarettes for the Youth Market*, p. 1, 1973.

[125] *Id.*, pp. 1–2.

[126] *Id.*, pp. 6–7.

use will become the dominant brands in future years. Evidence now available * * * indicate[s] that the 14 to 18 year old group is an increasing segment of the smoking population. RJR must soon establish a successful new brand in this market if our position in the industry is to be maintained over the long term.
(Emphasis omitted.) [127]

By the mid to late 1980's, RJR was marketing its newly revitalized Camel brand to ''young adults'' 18 to 20 years old. According to an internal memo cited in the *Wall Street Journal*, [128] the business plan for 1990 had a single-minded focus on getting young adults, especially the 18 to 20 year olds, to smoke Camels. The brand was to be refocused on young adult smokers, aged 18 to 24 with a strong emphasis on males 18 to 20. [129]

Documents submitted by RJR in its comment detail its plans for developing and promoting Joe Camel as the spokescharacter for the brand. In language reminiscent of the 1973 Teague memo, RJR reemphasized the importance of the young adult smokers (which RJR nicknamed the ''YAS'')—noting that only 5 percent of smokers start after age 24. [130] The paper noted that 40 percent of the ''virile'' segment have made a brand choice at age 18—a brand to which they will be loyal for years or throughout their smoking career. Thus, although this document describes the YAS as 18 to 24 year olds, the company's interest appears to have been with those younger than 18 who are in the process of selecting their first brand, the 14 to 18 year olds described by Teague.

In addition, the problem, the White Paper emphasized, was that Camel needed a facelift to make it relevant to this YAS group. Research, they noted, indicates that YAS see advertising as ''younger adult oriented'' when it is speaking directly to them. Therefore, advertising needed to be developed to speak to the target audience, to appeal to the ''hot buttons'' of young people such as to ''escape into imagination.'' ''Fantasy to these smokers can mean imagining a place to escape to or an image of yourself that is better than reality.''

The YAS group also relates to excitement and fun, noted the White Paper: ''Younger adults center their lives on having fun in every way possible and at every time possible. Their definition of success is 'enjoying today' which differentiates them from older smokers. Advertising which incorporates an 'exciting', 'fun', 'humorous' theme provides a way for these smokers to 'feel good' about the message.''

By 1988 RJR was testing its new ideas about Camel. It described the results in a *Marketing Research Report, entitled Camel ''Big Idea'' Focus Groups—Round II* dated September 21, 1988, and written by M. R. Bolger. The group was composed of male Marlboro smokers ages 18 to 34. Two groups were men 18 to 20, two groups were 21 to 24, and one group was age 25 to 34 to serve as a ''safety check'' to make sure the concept did not skew too young. Various themes were tested and one, ''Smooth Moves,'' was received best by the younger portion of the target—those that had fewer responsibilities, are single, and go to parties. The focus groups also showed that premiums (nontobacco items) performed best among the younger portion of the group. Older smokers were more discerning and saw the items as being of little value to them. [131]

What resulted from this research was the Joe Camel campaign, an unusually successful effort, particularly with the group that RJR research documents discussed—the 14 to 18 year olds. Thus, RJR appears to have used its research on 18 to 20 year olds to its advantage with the 14 to 18 year old group—a group who shares many of the same interests and ''hot'' buttons of the older group. These internal documents complement those cited in the preamble to the 1995 proposed rule. In the preamble to the 1995 proposed rule, FDA described two letters from RJR sales managers about the placement of YAS [Camel] merchandise. Both letters stated that high school neighborhoods were a likely location for YAS. RJR, in its comments to the proposed rule, stated that those two letters were mistakes. However, these latest documents rebut RJR's comment. The mistake made by the two sales representatives was in speaking too clearly of the company's intention.

''Reg''—The second campaign reviewed by FDA was the ''Reg'' campaign used in the United Kingdom. One comment took issue with FDA's claim that the ''Reg'' campaign was

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[127] An RJR spokesperson referred to these documents and did not dispute their validity. (See Levy, D., ''RJR Memo Targeted Teen Market,'' *USA Today*, p. 1D, October 6, 1995; ''Report: Teen Cigarettes Eyed,'' *AP Online*, October 4, 1995.); *Planning Assumptions and Forecast for the Period 197*–1986 for R.J. Reynolds Tobacco Company*, Research Department, 1976.

[128] Freedman, A. M., and S. L. Huang, ''Reynolds Marketing Strategy Sought to Get Young Adults to Smoke Camels,'' *Wall Street Journal*, p. B10, col. 3, November 2, 1995.

[129] A 1984 strategic research document, authored by Diane Burrows of R. J. Reynolds and entitled ''Younger Adult Smokers: Strategies and Opportunities,'' came to FDA's attention as a result of its inclusion as an exhibit attached to a brief filed by the State of Minnesota and Blue Cross in Ramsey County District Court in litigation involving the seven tobacco companies. The document was also described in numerous press accounts of the event (e.g., Phelps, D., and J. Hodges, ''Suit: Kids were focus of Reynolds strategy. Documents filed in state's lawsuit against the tobacco industry show how R. J. Reynolds targeted young smokers as critical to the industry's future,'' *Star Tribune*, 1A, July 11, 1996; Worklan, P., ''R. J. Reynolds Secret Report Targets Young Adult Market,'' *Chicago Tribune*, N19, July 11, 1996.) Although the agency has not relied on this memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed.

The memo indicates that by 1984, R. J. Reynolds was beginning to conduct research on the concepts detailed above that were developed during the 1970's. The memo describes the problem facing Reynolds at that time of declining market share and then proposed a solution: ''RJR's consistent policy is that smoking is a matter of free, informed, adult choice which the Company does not seek to influence. However, in order to plan our business, we must consider the effects those choices may have on the future of the Industry. Furthermore, if we are to compete effectively, we must recognize the imperative to know and meet the wants of those who are 18 and *have already elected to smoke*, as well as those of older smokers (emphasis added).''

The memo recognizes several important facts: ''The renewal of the market stems almost entirely from 18-year-old smokers. No more than 5% of smokers start after age 24.''Moreover, the memo also recognizes that: ''[t]he brand loyalty of 18-year-old smokers far outweighs any tendency to switch with age. Thus, the annual influx of 18-year-old smokers provides an effortless, momentum to successful 'first brands'.''

These ''first brands'' were identified as those which appeal to the 18-year-old smoker rather than switchers ages 19–24.

The memo identifies additional factors that had to be considered in this calculus: (1) Although 18- to 24-year-olds account for a very small part of market share, this age group represents the future of a brand. Those young, brand loyal smokers who now consume very few cigarettes, will consume more cigarettes with age and generally remain loyal to this first brand, its brand family or to the company; (2) Although young smokers are easier to switch than older smokers, a brand can not rely exclusively on switching younger smokers to produce a lasting brand equity—the major and most important share advantage available to a company is to have a cigarette brand relevant to young people and accepted by them as their ''first brand.''

The reports's recommendation was to research and capitalize on the factors and strategies which have been successful with youth brands of the past. This would require devoting substantial resources to identifying and tracking values, wants, and media effectiveness relevant to younger people. Because of the sensitivity of this young market, the memo continued: ''brand development/management should encompass all aspects of the marketing mix and maintain a long term, single-minded focus to all elements-product, advertising, name, packaging, media, promotion and distribution. (Emphasis omitted)''

This must include, the memo stated, a careful emphasis on the ''imagery and product positives'' relevant to ''younger adults.''

[130] ''White Paper,'' Camel Advertising Development, p. 1, undated.

[131] Bolger, M. R., ''Camel 'Big Idea' Focus Groups—Round II,'' *Marketing Research Report*, September 21, 1988.

particularly effective with British adolescents and argued that the study that FDA relied on was based on unreliable evidence and is not applicable to American adolescents. The comment contended that there was no evidence to show that liking the ''Reg'' character caused children to smoke and argued instead that children who smoked came to like ''Reg.'' The comment also argued that the recognition task, described in the study, was too suggestive and biased, and suggested that the young people were primed and pressured to say they had seen the advertisements during ''games'' that they say took place before the recognition task.

First, this comment is wrong. Games were played during another portion of the study, not the one referenced. The comment confused the quantitative survey with the qualitative. Second, evidence from England about youth smoking habits is no less probative than evidence from the United States, as it provides insights into children's smoking behavior.

Smoking Trends—A few comments were critical of the study of trends in the smoking initiation study, which found a temporal relationship between advertising targeted at women and rising initiation rates among girls and young women.[132] The principal criticisms were that the authors failed to examine the actual advertising campaigns in question, that FDA failed to consider alternative explanations for the study's findings, and that the study's measures were subjective and unreliable.

In response, the agency reiterates that it did not cite to this study, or any one study, as ''proof'' that advertising during this period ''caused'' a rise in smoking initiation. The study was provided as one example of targeted marketing being ''associated'' with increases in cigarette consumption among young people.[133] A logical inference to be drawn from the cumulative effect of such studies is that advertising does play a role in young people's smoking behavior.

e. *Evidence that youth brand choices are related to advertising.* Virtually all of the comments from the tobacco industry claimed that cigarette and smokeless tobacco manufacturers market their products solely to adults. They disputed the findings of studies, cited by FDA in the preamble to the 1995 proposed rule, examining advertising campaigns that had been particularly effective with children. In addition, while the comments acknowledged that younger smokers are the intended targets for some cigarette advertising, they argued that only younger smokers of legal age were targeted.

In the preamble to the 1995 proposed rule, FDA presented a number of studies showing that youth cigarette brand choices are related to advertising.[134] These studies showed that young people smoke many fewer brands than adults, and that their choices are directly related to the amount and kind of advertising. While 86 percent of youths who smoke choose the three most advertised brands,[135] the most commonly smoked cigarettes (39 percent) among adult smokers are brandless (i.e., private label, generics, or plain packaged products).[136] Another study found that children who smoke as few as one cigarette per week can identify a preferred brand.[137]

One comment argued that the CDC study that found that most children smoke the three most advertised brands showed only a correlation between advertising expenditures and brand preferences, and that the data did not even support this correlation consistently. The comment noted that the data on which these findings were based included 18 year olds, who are of legal age to smoke. The comment also contended that the data did not allow a determination of what came first: Changes in advertising expenditures or changes in brand preference (directionality).

The same comment also criticized the study indicating that children who smoke as few as one cigarette per week can identify a preferred brand. In addition to pointing out that the study did not demonstrate a causal relationship and that the sample was not generalizable, the comment argued that:

> * * * *other* research has found that adolescents smoke a smaller number of different brands than do adults, [the researchers] tested only the correlation between adolescent smoking and advertising recognition. [The researcher] did not know which brands the adolescents in this study smoked. [emphasis in original]

Contrary to the comment, these studies are evidence that, when considered together, form a coherent pattern that establishes the role that advertising plays in young people's smoking behavior.

The CDC study[138] provides evidence of young people's smoking choices. Neither the fact that the data included 18-year-olds nor the question of directionality is sufficient to invalidate the study's utility. While the data available for the study contained 18-year-old use, there is little difference between 17- and 18-year-old cigarette use; certainly not enough to invalidate the general finding that underage and 18-year-old smokers choose the three most heavily advertised brands. The issue of directionality of the results is no more important. The results showed that young people chose cigarettes that are heavily advertised, not ones that are cheap or low tar, etc. The CDC study, as noted, did not prove causality—it was not intended to and it did not.

The comment's criticism of the study, which involved children who smoke as few as one cigarette a week, is not correct. The researchers did know the brands that the adolescents in the study smoked. ''Fifty-two percent of all students who had used cigarettes identified a single preferred brand * * *. One brand of cigarettes (Marlboro) accounted for 76% of all preferred brands.'' The study's finding is consistent with every other study of adolescent brand preference: Marlboro is the number one brand choice.

The effect of advertising on brand choice by young people is important. It shows that young people choose the imagery of the two or three most highly advertised brands to smoke, brands that provide specific definitions of a user.

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[132] Pierce, J. P., L. Lee, and E. A. Gilpin, ''Smoking Initiation by Adolescent Girls, 1944 through 1988, An Association with Targeted Advertising,'' *JAMA*, vol. 271, pp. 608–611, 1994.

[133] A more sophisticated example of this type of time series analysis was published by the FTC to show that health claims in food advertising could have a beneficial effect upon people's consumption of high fiber breakfast cereals. (Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling, A Study of the Cereal Market*, Bureau of Economics Staff Report, FTC, August 1989.)

[134] ''Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993,'' *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994; Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, ''Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements,'' *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

[135] ''Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993,'' *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

[136] Teinowitz, I., ''Add RJR to List of Cig Price Cuts,'' *Advertising Age*, pp. 3 and 46, April 26, 1993.

[137] Goldstein, A. O., P. M. Fischer, J. W. Richards, and D. Creten, ''Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements,'' *Journal of Pediatrics*, vol. 110, pp. 488–491, 1987.

[138] ''Current Trends: Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989–1993,'' *MMWR*, CDC, vol. 43, pp. 577–581, August 19, 1994.

The choice permits the user to adopt the image created by the brand.

f. *The Canada advertising case.* A series of comments raises new issues not considered in the preamble to the 1995 proposed rule.

The September 1995 decision of the Supreme Court of Canada on the Canadian Tobacco Products Control Act (TPCA),[139] enacted to regulate tobacco advertising and promotion in Canada, prompted several comments, primarily from the tobacco industry. The TPCA banned all tobacco advertising, restricted the promotion of tobacco products and required packaging to display prominent unattributed health messages and toxic constituent information. As soon as the TPCA was enacted in 1988, the tobacco companies challenged the act as unconstitutional. On September 21, 1995, the Supreme Court of Canada found that Parliament had the criminal law power to legislate regarding the advertising and promotion of tobacco products, but that, based on the record developed in the court below, the restrictions on advertising and promotion violated the tobacco companies' freedom of expression guaranteed to all Canadians. Several of the key sections of the TPCA were struck down by the Canadian Supreme Court. The Canadian court ruled that the government had failed to demonstrate that the restraints regarding advertising, promotion, and labeling were reasonable and justified restrictions on freedom of expression.

The Canadian court also found that the government had failed to demonstrate that less intrusive measures, falling short of a complete restriction on advertising and promotion, would be less effective in protecting young people from inducements to use tobacco products. Further, the Canadian court found that the government had failed to show that unattributed health messages were required to achieve its objective of reducing tobacco consumption. Finally, the Canadian court decided that there was no rational connection between prohibiting a tobacco product trademark on a nontobacco product and the objective of the TPCA. The decision left the advertising and promotion of tobacco products substantially unregulated in Canada.

Because of some similarities between the Canadian federal tobacco control strategy and FDA's proposed regulation, some comments suggested that the opinions of the Canadian court are a basis for rejecting actions and laws targeting lawful tobacco advertising, particularly FDA proposed regulations. Moreover, the comments said that the Canadian court concluded that the proposed prohibition on tobacco advertising could not be sustained because it ''failed the rational connection test'' in that there was no causal connection ''whether based on direct evidence or logic and reason'' justifying the law (100 C.C.C. 3d. 449, Charter of Rights).

In contrast, one comment suggested that the ruling on this case is consistent with FDA's emphasis on reducing image advertising directed towards young people. The comment stated that FDA's focus fits the Canadian court's decision and had the Canadian government restricted image advertising rather than banning all advertising, it would have upheld the regulation.

FDA does not find the decision of the Canadian court to be contrary to its findings. The Canadian court did recognize that image or lifestyle advertising can affect overall consumption. Moreover, contrary to the comment's suggestion, the court specifically recognized that: ''measures * * * to prohibit advertising aimed at children and adolescents * * * would be a reasonable impairment of the right to free expression, given the important objective and the legislative context'' (100 C.C.C. 3d. 449).

Finally, FDA has considered a much larger quantity of evidence than that which was before the Canadian court, including the evidence concerning nontobacco item ownership by young people and the materials received during the comment period. The latter included the heretofore confidential or secret documents from RJR's marketing department and also those concerning the results of RJR's focus groups, which showed that interest in nontobacco items was highest among the young. Thus, FDA considered a much fuller record than that before the Canadian court. Moreover, the comment period provided the agency with additional evidence concerning various proposed provisions. FDA's final rule is thus based on a very complete and full record and its decisions are well justified.

g. *Roberts and Samuelson.* Concerning the effect of advertising on consumption patterns, one study not considered by the court in Canada, but cited by FDA in the preamble to the 1995 proposed rule, was an econometric analysis employed by Roberts and Samuelson[140] to show that advertising can increase the market demand for tobacco products. The study measured the effect on brand share and market size of advertising for low and high-tar cigarettes. The results indicated that advertising for low tar cigarettes did increase overall market size.

The study looked at the question of the effect of advertising not from the viewpoint of the consumer, but from the producer's perspective—how much should a firm invest in advertising in order to maximize its profits. A predicate assumption is that a manufacturer would not invest in advertising if the cost did not produce a return. This study also was conducted by independent economists and appeared in a peer reviewed journal.

Several comments criticized the study as an ''ambitious failure.'' The industry comments criticized the study on the following grounds: The study inappropriately measures the level of advertising in messages and not in expenditures, and the study had inadequacies in some assumptions and in the data and these flaws thus call into question the study's results. Moreover, the comments alleged that misallocation of advertising expenditures may have biased the results. The results of the study show that advertising for low tar cigarettes had a beneficial effect on the overall level of consumption, but that the same effect did not occur for high tar cigarette advertising. The comments noted that young people do not consume low tar cigarettes, and therefore the results are irrelevant to a discussion of youth smoking. Moreover, the comments said that the results are not generalizable to all cigarette advertising. Finally, the comments said that population growth may have accounted for the finding of a relationship between advertising and consumption.

The agency disagrees with the criticisms of this study and finds instead that it is persuasive evidence of the effects of tobacco advertising for low-tar cigarettes on the overall market. In answer to the first criticism, the study used messages instead of expenditures as a measure of advertising in order to increase the accuracy of the analysis. It is the messages actually seen by a consumer, and not the amount spent by the company on advertising, that is more relevant in assessing the effect of advertising. If the cost of advertising

[139] *RJR-MacDonald, Inc.* v. *Canada (Attorney General),* S.Ct. of Canada, 100 C.C.C. 3d 449, Sept. 21, 1995.

[140] Roberts, M. J., and L. Samuelson, ''An Empirical Analysis of Dynamic, Nonprice Competition in an Oligopolistic Industry,'' *Rand Journal of Economics*, vol. 19, pp. 200–220, 1988.

were to go up, and thus firms would have to pay more for fewer messages, we would not expect to find a greater effect on consumers, which was the effect shown by the study.

The second issue, that there were flaws in the study, is similarly not fatal. As noted in section VI.D.4.d. of this document, each study utilizes the best data and methods available at the time. This may not be the perfect study, but its flaws are minor and do not affect its usefulness. Moreover, one major criticism was with the advertising variable and as noted more fully in section VI.D.6.a. of this document data on advertising expenditures are generally considered trade secrets by the companies. Thus, independent researchers have to use whatever data are available, even if they are not perfect. If the industry wanted to ensure more complete studies, it could release old data relevant to advertising expenditures.

Third, the comments complain that the focus of the study, low-tar advertising, limits the applicability of the results. However, the fact that this study found that advertising for low-tar cigarettes increased the market is not a limitation that restricts the results to that one example. The importance of the results is that the study shows that advertising in this oligopolistic industry can affect the market size. The purpose of dividing the market into high- and low-tar advertising was an attempt to isolate the effect of advertising for each of the product classes.

Fourth, the comments expressed concern about the possibility of population growth as an intervening factor. Population growth should not have affected the results as growth would have affected the high-tar market as well as the low-tar market, a consequence that did not occur.

FDA concludes that this study presents excellent evidence of the effect of advertising on consumption patterns and, that it would have provided quite supportive evidence before the Canada court for advertising restrictions.

h. *The African-American youth market.* Referring to the declining African American youth tobacco market, several comments argued that FDA's tentative finding in the preamble to the 1995 proposed rule on the relationship between outdoor cigarette advertising and tobacco consumption by young people is incorrect. Comments said that if cigarette advertising increases the prevalence of smoking among young people, the percentage of African-American young people who smoke should be equivalent to that of whites, because African-American young people see as much or more cigarette advertising than do whites. However, smoking rates for young African-Americans are much lower than for white young people. One comment further indicated that African-American young people's decision to smoke may be more responsive to peer influence and parental and community advice than cigarette advertising.

It is unclear why African-American young people do not use tobacco at the same rate as white young people. It is surely not that their parents smoke less; the smoking rate among African-American adults is 26 percent, almost the same rate as for white adults. [141] Whatever may be the reason (and it is unknown) for the lower smoking rates among youth among that segment of the population, it does not provide sufficient evidence against advertising restrictions when other evidence shows that advertising does affect children's decisions to use tobacco products.

i. *The evidence relating to smokeless tobacco.* A couple of comments argued that FDA had presented insufficient evidence regarding the effect of advertising on the decision to use smokeless tobacco. One joint comment from the smokeless tobacco manufacturers stated:

> The studies cited by the agency regarding cigarette advertisements and smoking are all either highly flawed, biased, or simply do not support the agency's hypothesis. * * * Even more troubling—and from the standpoint of sustaining its legal obligation, a fatal flaw—is the agency's audacity to propose a virtual ban on advertising for smokeless tobacco products without even deigning to build a case.

The comment is correct that there is less evidence available regarding smokeless tobacco advertising practices and smokeless tobacco use. Nevertheless, the record contains sufficient evidence to provide a basis for applying the advertising restrictions in the 1995 proposed rule to smokeless products. In the preamble to the 1995 proposed rule (60 FR 41314 at 41331), reference was made to the remarkably successful regeneration of the smokeless tobacco market by U.S. Tobacco (UST), the leading smokeless tobacco company, in the 1980's. In the 1970's, the segment of the population with the highest use of these products was over age 50, and young men were among the lowest. Fifteen years later, there had been a tenfold increase in the use of smokeless tobacco by young men, whose use became double that of men over 50. The preamble to the 1995 proposed rule attributed that increase to the concerted advertising and marketing efforts of UST.

As detailed more fully in the preamble to the 1995 proposed rule (60 FR 41313 at 41331), officials at UST held a marketing meeting in 1968 where, according to the *Wall Street Journal*, the vice-president for marketing said, ''We must sell the use of tobacco in the mouth and appeal to young people *** we hope to start a fad.'' Another official attending the same meeting was quoted as saying, ''We were looking for new users-younger people who, by reputation, wouldn't try the old products.''

Later, Louis Bantle, the chairman of the board of UST, described the reason that so many young males use smokeless tobacco, ''I think there are a lot of reasons, with one of them being that it is very 'macho;.'' UST's advertising utilized the themes that play well with 'macho' boys—rugged masculine images—and utilized heros to this group—professional athletes. Bantle described the success of this program thus: ''In Texas today, a kid wouldn't dare to go to school, even if he doesn't use the product, without a can in his Levis.''

The UST program also utilized a promotional program that it called ''graduation strategy'':

> UST distributes free samples of low nicotine-delivery brands of moist snuff and instructs its representatives not to distribute free samples of higher nicotine-delivery brands. The low nicotine-delivery brands also have a disproportionate share of advertising relative to their market share. For example, in 1983, Skoal Bandits, a starter brand, accounted for 47 percent of UST's advertising dollars, but accounted for only 2 percent of the market share by weight. In contrast, Copenhagen, the highest nicotine-delivery brand, had only 1 percent of the advertising expenditures, but 50 percent of the market share. This advertising focus is indicative of UST's ''graduation process'' of starting new smokeless tobacco product users on low nicotine-delivery brands and having them graduate to higher nicotine-delivery brands as a method of recruiting new, younger users.
> (60 FR 41314 at 41331)

Therefore, the agency disagrees with the assertion that it has presented no evidence to support restricting smokeless tobacco advertising. In fact, it finds the graduation strategy to be strong evidence of the effectiveness of advertising in targeting young people to become new users and consistent with and supported by the general

[141] ''Cigarette Smoking Among Adults—United States-, 1993,'' *MMWR*, CDC, vol. 43, pp. 925–930, 1994.

discussion, see sections VI.B. and VI.D. of this document.

4. Why Young People Use Tobacco and the Role of Advertising in That Process

(15) Regardless of the evidence cited in section VI.D.3. of this document, many comments argued that children start to smoke and use smokeless tobacco because of influences on them other than advertising, primarily the influence of their friends and peers.

a. *Why young people use tobacco.* One comment cited studies showing that young people who were most likely to be smokers were those who were particularly rebellious or prone to deviant behavior, [142] and said that it was counterintuitive that young people fitting these profiles would want to conform to what advertising portrayed as desirable.

Conversely, many comments said that cigarette advertising, like all advertising portrays highly attractive images. One comment stated that when young people's peers are also smoking, this can serve to personalize the images and make them relevant for their own lives, and cause them to have favorable impressions about their friends who smoke. [143]

One comment argued further that children smoke because they hope to convey a positive self-image. [144] Hence, young people may be particularly vulnerable to being influenced by the attractive images presented in cigarette and smokeless tobacco advertising. [145]

Specifically, the same comment cited numerous studies that indicate that many young people smoke because they hope to convey a positive image. [146] Based on these studies, the comment stated: ''Image or impression management (Schlenker, 1980) has great utility for young people as they struggle for social acceptance and autonomy (citations omitted).''

Finally, the comment described the developmental aspects of adolescents that are relevant to this issue:

With respect to developmental aspects of adolescence, there are two related factors that make adolescents especially vulnerable to being influenced by tobacco advertising. First, adolescents are typically beginning to focus on peer group interactions more than on family interactions (e.g., Brown et al., 1986), which they may likewise value to a far greater extent. Second, tobacco use constitutes a ''temporal trap'' (Messick and McClelland, 1983) in the sense that the peer group benefits of tobacco use are immediate, while the negative consequences in terms of health outcomes are so far into the future that many adolescents, who often see themselves as invulnerable even in the present, would consider them to be irrelevant. Furthermore, the negative social consequences of tobacco use in adulthood (i.e., social stigmatization * * *) are also unimportant to adolescents at the time they are making the decision to use tobacco products. [147]

Stated differently, adolescence is a time of ''identity formation.'' Young people use the attractive imagery of advertising as a ''window into the adult world.'' They are ''susceptible to the images of romance, success, sophistication, popularity, and adventure * * *.'' [148] By adolescence, clothes, possessions, and ''badge products'' such as cigarettes are used to define oneself and to control relations with others. [149]

Support for this view of the role of tobacco advertising also comes from the tobacco industry:

FDA turns a blind eye to the fact that the personal display of products with commercial logo—through dress and other forms of expression—is a form of participation in American popular culture. It is a way to register a group identity to signal one's place in the social fabric.

In addition to these comments, FDA has the words of RJR's research department in a 1973 memo, detailed in section VI.D.3.d. of this document, that chart a course for attracting the young smoker. [150]

On the basis of the evidence cited and reviewed in section VI.D.3. of this document, the agency finds that the suggestion that it is impossible to advertise in a way that would appeal to rebellious nonconformist teenagers is

[142] Chassin, L., C. C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, ''Predicting the Onset of Cigarette Smoking in Adolescents: A Longitudinal Study,'' *Journal of Applied Social Psychology*, vol. 14, pp. 224–243, 1984; Collins, L. M., S. Sussman, J. Mestel Rauch, C. W. Dent, C. J. Johnson, W. B. Hansen, and B. R. Flay, ''Psychosocial Predictors of Young Adolescent Cigarette Smoking: A Sixteen-Month, Three-Wave Longitudinal Study,'' *Journal of Applied Social Psychology*, vol. 17, pp. 554–573, 1987.

[143] Pechmann, C., and S. J. Knight, ''Cigarette Ads, Antismoking Ads and Peers: Why do Underage Youth Smoke Cigarettes?'' *Advances in Consumer Research*, Association for Consumer Research, edited by Corfman, K. P., and J. G. Lynch, eds., Provo, UT, vol. 23, pp. 267–268, 1996.

[144] Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, ''Self-Images and Cigarette Smoking in Adolescence,'' *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. Presson, and S. J. Sherman, ''Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence,'' *Child Development*, pp. 1499–1511, 1982.

[145] *Id.*

[146] Chassin, L., C. Presson, S. J. Sherman, E. Corty, and R. W. Olshavsky, ''Self-Images and Cigarette Smoking in Adolescence,'' *Personality and Social Psychology Bulletin*, vol. 7, pp. 670–676, 1981; Barton, J., L. Chassin, C. C. Presson, and S. J. Sherman, ''Social Image Factors as Motivators of Smoking Initiation in Early and Middle Adolescence,'' *Child Development*, pp. 1499–1511, 1982; Belk, R. W., ''Possessions and the Extended Self,'' *Journal of Consumer Research*, vol. 15, pp. 139–168, 1988; Belk, R. W., R. Mayer, and A. Driscoll, ''Children's Recognition of Consumption Symbolism in Children's Products,'' *Journal of Consumer Research*, vol. 10, pp. 386–397, 1984; Brown, B. B., M. J. Lohr, and E. L. McClenahan, ''Early Adolescents' Perceptions of Peer Pressure,'' vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, ''Social Traps and Temporal Traps,'' *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983; Levy, S. J., ''Meanings in Advertising Stimuli,'' *Advertising and Consumer Psychology*, Praeger, New York, pp. 214–226, 1986; Solomon, M. R., ''The Role of Products as Social Stimuli: A Symbolic Interactionism Perspective,'' *Journal of Consumer Research*, vol. 10, pp. 319–329, 1983.

[147] Brown, B. B., M. J. Lohr, and E. L. McClenhanan, ''Early Adolescents' Perceptions of Peer Pressure,'' *Journal of Early Adolescence*, vol. 6, pp. 139–154, 1986; Messick, P. M., and C. C. McClelland, ''Social Traps and Temporal Traps,'' *Personality and Social Psychology Bulletin*, vol. 9, pp. 105–110, 1983.

[148] Nichter, M., and E. Cartwright, ''Saving the Children for the Tobacco Industry,'' *Medical Anthropology Quarterly*, vol. 5, pp. 236–256, 1991.

[149] Stacey, B. G., ''Economic Socialization in the Pre-Adult Years,'' *British Journal of Social Psychology*, vol. 21, pp. 159–173, 1982.

[150] A July 3, 1974 memo, authored by D. W. Tredennick, of R. J. Reynolds' Marketing Research Department was submitted to the rulemaking docket by the Attorney General of Mississippi in response to the reopening of the rulemaking record (61 FR 11349, March 20, 1996). Although the agency has not relied on the memo as part of the justification for this rule, FDA is citing to it here because it is relevant to the issues discussed. The memo was also reported in the press, see Schwartz, J., ''R. J. Reynolds Marketing Memo Discusses Young Smokers' Brand Image,'' *Washington Post*, A03, April 23, 1996. The memo asked and answered the question: ''What causes smokers to select their first brand of cigarettes?'' The answers developed by Mr. Tredennick echos the concepts discussed above. The memo hypothesized that: ''[t]he causes of initial brand selection *relate directly to the reasons a young person smokes*. The more closely a brand meets the psychological 'support' needs (advertising or otherwise communicated brand or physiological needs (product characteristics), the more likely it is that a given brand will be selected. (Emphasis added)'' One important characteristic was associated with the user ''image'' associated with a brand. ''To some extent young smokers 'wear' their cigarette and it becomes an important part of the 'I' they wish to be, along with their clothing and the way they style their hair.'' The memo also recognized the importance of peer influence on a young person's decisions about smoking and noted that: ''It must also be true that influential young smokers (perhaps relatively few) have made brand selections based on product characteristics or advertising and promotion communication. The fact that two brands, Marlboro and Kool, have such dominant shares among youths suggests the above hypothesis * * *.'' Tredennick noted further that both Marlboro and Kool project imagery that is psychologically important to adolescents—the need for support and strength.

without merit. Tobacco advertising plays directly to the factors that are central to adolescents as they decide whether to use tobacco products. Thus, the available evidence clearly supports a finding that advertising plays an important role in young people's tobacco use.

b. *Determinants of smoking.* Several comments from the advertising and tobacco industries claimed that the econometric studies performed for them by experts found that peers, parents, and siblings have the greatest influence on young peoples' decision to start smoking.

Citing an econometric analysis performed for RJR by Dr. J. H. Beales, on data concerning its Joe Camel advertising campaign, one comment argued that ''minors balance the risks and rewards of smoking to decide whether or not to smoke, just as they would any other consumption decision. The greater an individual minor perceives the net rewards of smoking, the more likely he or she will try smoking. Minors who perceive greater net rewards of smoking are also likely to smoke more intensively.''

The comment further argued that an analysis based upon this theoretical model by Dr. Beales found that neither advertising nor advertising expenditures has an appreciable effect on young people's perceptions of the benefits of smoking and thus would have no indirect effect on teenage smoking decisions. [151] More specifically, the comments stated that the Beales' studies show that advertising expenditures for the particular brands that most teenagers smoke, Marlboro and Camel, do not influence and are not associated with smoking decisions. Moreover, Dr. Beales reported that the results of his studies indicate further that advertising did not have an indirect effect on smoking behavior. Beales concluded that minors who had been exposed to more advertising did not identify the perceived rewards of smoking—''smoking helps when bored,'' ''smoking helps relax,'' ''smoking helps with stress,'' and ''smoking helps in social situations,'' in a greater number than did those minors who reported less exposure. The comment concluded that the failure of the 1993 Beales study to find either direct or indirect effects from advertising on smoking behavior should be conclusive.

FDA does not agree. The 1993 Beales study presents only one analysis of youthful smoking and that analysis is flawed. [152] Dr. Beales appears to have performed tests using an ordered logistic regression model to test for: (1) The effect of advertising on smoking behavior, using advertising expenditures and young people's view of ''most advertised brand'' as measures; and (2) smoking behavior as a function of a number of psychosocial variables and determinants.

First, a logistic model is only as good as the variables used. Thus, if a variable is mispecified or imprecise, the model's predictive capacity will be severely compromised. The variable ''most advertised brand'' appears to be quite imprecise as a measure to capture the effect of advertising. The most that this variable would capture would be the ability of the campaign to be seen and remembered. It would not capture the appeal of the campaign, or the effect of the campaign on consumers, nor could it measure the ability of an advertising campaign to change or create consumer action. In addition, it would not be surprising to find that almost as many nonsmoking young people as young smokers found Camel (or Marlboro) to be the most advertised brands, since those advertising campaigns were quite ubiquitous at the time the data for this study were collected and were, in fact, the most advertised brands. A variable that cannot discriminate between users and nonusers, because all had seen and remembered the advertising, cannot be expected to produce useful predictive results in a regression analysis of why people, particularly young people, smoke.

Second, Dr. Beales attempted to determine whether differences in advertising expenditures would predict smoking behavior. It appears, however, that Dr. Beales did not look at this question longitudinally—that is, he did not look at whether smoking rates varied as a function of advertising expenditures for Camel cigarettes before the Joe Camel campaign and after the campaign started. Instead, he appears to have measured smoking rates as a function of the differences in regional advertising expenditures in California during one time period. It should not be surprising therefore that little if any effect on smoking rates was found: (1) There is no reason to expect to find significant changes in smoking behavior based on small regional variations within one State in advertising expenditures, and (2) optimum expenditures for advertising outlays in any given region would have been determined in advance by an advertising agency and therefore would more likely reflect smoking patterns already in existence. Had he wanted to measure smoking behavior as a function of Camel's advertising, he should have modeled it longitudinally over time. Since the regional advertising expenditures must have been obtained from a RJR data base, Beales clearly had access to other sources of data within the company. He therefore should have been able to acquire advertising expenditures for the Camel brand before the introduction of Joe Camel and advertising expenditures for the period after Joe Camel's appearance. This would have been a better test.

Finally, Dr. Beales performed an analysis to determine the ''true'' determinants of smoking. Dr. Beales' regression analysis utilized a series of psychosocial characteristics and beliefs about smoking. He found that the only factor that failed to produce an association was advertising. First, as noted, there is no reason to believe that ''most advertised brand'' would perform as a useful surrogate for the effects of advertising. Therefore, regardless of the value of the study, it is not good evidence concerning the role of advertising in young people's smoking decision. Second, the analysis indicates what is already known: certain beliefs and life patterns can help predict who may become a smoker. However, it does not measure what effect advertising can have on a young person's perception or beliefs.

Additional concerns about the study are similar to those that the tobacco industry comments raised about studies cited by FDA. The first concern is that several variables used in the model measure the same impact. This redundancy could create a multicollinearity problem (i.e., two or more variables vary together but it is very difficult to determine which variable influences the other). Moreover, the redundancy may have caused irrelevant variables to be included in the regression equation. Both multicollinearity and the inclusion of irrelevant variables can affect the efficiency of the model's estimates. The second concern is that the model used in the study is questionable. The correct model could well have been a double hurdle model, i.e., modeling the decision to smoke first and then modeling the choice of what brand to smoke, second.

[151] Dr. Beales used children's designation of a ''most advertised brand'' as a surrogate for the effect of advertising.

[152] Beales, J. H., ''Advertising and the Determinants of Teenage Smoking Behavior,'' p. 44, 1993.

Finally, there is concern that the data for the impact of advertising expenditures and smoking behavior were incompatible and, thus, may have failed to find a relationship that did in fact exist. The teen smoking prevalence data were from a behavioral study, and the measurement of advertising expenditures was from regional advertising expenditures, undoubtedly maintained by the company. The smoking decision for a teenager may very well not have been influenced by the amount of money spent but by the number of messages he/she receives. The aggregate expenditures for advertising cannot measure the number of messages actually received by an individual teen.

Given the multitude of problems with the design of the study and the choice of variables, the study has limited capability for producing results that can adequately describe advertising effects on smoking behavior. Moreover, this study is but one of many and, whatever its value, it does not overwhelm the evidence that FDA has relied on.

c. *Laugesen and Meads.* In contrast to the Beales' study, FDA had cited a study by Laugesen and Meads, entitled ''Advertising, Price, Income and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets,'' [153] which provided evidence that increases in advertising expenditures had an effect on youth smoking behavior including recruiting new smokers and increasing the market base.

One comment stated that data from supermarkets were unrepresentative, both because of the percentage of sales from supermarkets in New Zealand (presumably not large), and because it is not known what percentage of sales to young people are made at supermarkets. Moreover, many conditions were not accounted for, including possible different pricing structures between retail outlets.

The comments also criticized several major assumptions they claim were made in the study, for example, that young people purchase the less expensive, down market brand. Finally, the comment criticizes the failure to control for other variables (such as rotating health warnings and new advertising restrictions).

The authors themselves responded to some of the concerns expressed. For example, they explained that they specifically chose to collect data from supermarkets because other ''authors with access to full industry data [154] have recommended that the data interval [for supermarket sales] should reflect the inter-purchase time for cigarettes,'' which in New Zealand is a week or less. Moreover, the authors found that supermarket cigarette sales are more consistent than other points of sales. Hence there were fewer fluctuations in the demand data for cigarettes.

Moreover, in response to the second comment, the authors did not assume that young people purchase downmarket cigarettes at a higher rate than the general population, but that people with lower income, which includes young people, purchase these brands more often. But more importantly, the study found that it takes only 2 years of advertising of this downmarket brand to expand the teen market by 4 percent, and this fact was not disputed.

d. *Other comments.* Finally, several comments criticized the quality of the evidence cited by FDA in its preamble to the 1995 proposed rule. One comment stated that FDA has relied too heavily on studies conducted by physicians or others not familiar with the art and science of persuasion. Further, it asserted that most of the evidence cited in support of the regulations had been published in medical journals and not in peer reviewed marketing journals.

However, a review of the evidence presented belies that concern. First, FDA relied on the research and expert opinion of consumer psychologists, business and marketing experts, economists and social science researchers as well as medical experts. Moreover, FDA has relied on two outstanding reports issued in the past few years that specifically addressed the issue of young people's use of tobacco—the 1994 SGR and the IOM Report. Both commented extensively on the role that advertising plays in young people's smoking behavior and use of smokeless tobacco and both recommended strongly that a comprehensive plan to attack the problem of youth tobacco use include stringent advertising restrictions.

Moreover, of the 15 members of the IOM committee, 7 were expert in the fields of behavioral sciences, including psychology, psychiatry and public policy, anthropology, and economics. Similarly, the contributing authors to the 1994 SGR included experts in economics, social research, marketing, and business administration. Finally, the comments submitted include additional empirical evidence, the expert opinion of the American Psychological Association, [155] and the words of the tobacco industry itself, all of which are referred to in this document.

One comment criticized FDA's reliance on the IOM Report and the 1994 SGR as simply presenting ''selective reviews'' of much of the same ''dubious literature'' reviewed by FDA. Another comment stated that FDA had indiscriminately relied on studies cited in the 1994 SGR, none of which, the comment claimed, was capable of determining whether advertising influences children to initiate smoking.

Several comments appeared to place great importance on the fact that both reports acknowledge that the psychosocial and econometric research that they present do not prove that cigarette advertising causes young people to begin smoking or to use smokeless tobacco. The IOM Report stated that, because of the nature of the research, it is not known for certain whether youths already interested in smoking or smokeless tobacco become more attentive to advertisements for these products or whether these advertisements lead youths to become more interested in these products. One comment argued that the ''IOM's recognition of this weakness fatally undermines its own and FDA's arguments on the impact of advertising on smoking behavior.'' Another comment claimed that the IOM Report acknowledges the lack of a causal relationship between advertising and smoking and acknowledges that the very econometric studies it cites are unreliable to determine whether advertising contributes to youth smoking behavior. The comment also stated that FDA misstates IOM's conclusion regarding evidence of a

[153] Laugesen, M., and C. Meads, ''Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets,'' *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

[154] The authors cited this study as an example of one having access to full industry data. Leeflang, P. S. H., and Reuiyl, ''Advertising and Industry Sales: An Empirical Study of the West German Cigarette Market,'' *Journal of Marketing*, vol. 49, p. 97, 1985; Laugesen, M., and C. Meads, ''Advertising, Price, Income, and Publicity Effects on Weekly Cigarette Sales in New Zealand Supermarkets,'' *British Journal of Addiction*, vol. 86, pp. 83–89, 1991.

[155] The American Psychological Association represents 132,000 members and affiliates and is the largest organization of psychologists in the world. Its comment represents the organization's ''research-based recommendations'' and reflects significant input from several relevant divisions including the Division of Personality and Social Psychology, the Division of Society for the Psychological Study of Social Issues, and the Division of Consumer Psychology.

causal relationship between advertising and smoking initiation. Further, several comments cited to a statement in the 1994 SGR that ''no longitudinal study of the direct relationship of cigarette advertising to smoking initiation has been reported in the literature.'' [156] However, these comments failed to include the sentence immediately preceding this quote: ''Considered together, these studies offer a compelling argument for the mediated relationship of cigarette advertising and adolescent smoking.''

Another comment in support of advertising restrictions on tobacco products argued that the multidisciplinary studies cited in the 1994 SGR supported the conclusion that marketing and advertising tobacco products do play a role in tobacco use among young people. The comment suggested that this conclusion is consistent with the 1989 Surgeon General's conclusion that ''the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption.'' [157] Additionally, the comment supported the findings of the 1994 SGR that ''cigarette advertising appears to increase young people's risk of smoking'' by conveying the impression that smoking has social benefits and is far more common than it really is. [158] Moreover, this comment contended that the IOM's conclusions supported FDA's tentative view that image advertising of tobacco products is tremendously appealing to young people.

As noted more fully in section VI.B. of this document, FDA did rely heavily on the two reports, and continues to find the reports persuasive evidence. They represent mainstream scientific consensus and are appropriately entitled to a great deal of deference. The agency notes that, in a different but not entirely unrelated context, that of health claims for food, Congress has said that FDA would have to specifically justify any decision rejecting the conclusions of a report from an authoritative scientific body of the United States. (See section 403(r)(4)(C) of the act (21 U.S.C. 343(r)(4)(C)).) No justification for rejecting the IOM's conclusions exists here.

Finally, the agency, like the 1994 SGR and IOM Report, finds that an adequate basis does exist to conclude that advertising plays a ''mediated relationship'' to adolescent tobacco use. [159] The proper question is not, ''Is advertising the most important cause of youth initiation?'' but rather, ''does FDA have a solid body of evidence establishing that advertising encourages young people's tobacco use such that FDA could rationally restrict that advertising?'' The answer to this question is ''yes.''

5. Has the Agency Met Its Burden?

(16) Several comments from the tobacco and advertising industries criticized the agency for failing to present evidence that conclusively establishes a causal link between advertising and young people's decisions to begin using cigarettes and smokeless tobacco.

FDA disagrees that its burden is to conclusively prove by rigorous empirical studies that advertising causes initial consumption of cigarettes and smokeless tobacco. No single study is capable of doing so. As one comment stated, it would in fact be practically and ethically impossible to conduct such a study. Certainly no study presented by industry or any other party demonstrated that advertising does *not* cause the initial consumption of cigarettes and smokeless tobacco. Indeed, it should be noted that not one study cited by FDA or submitted by industry could conclusively demonstrate that *any* factor actually *caused* children to begin smoking or to use smokeless tobacco. This includes family and peer influences, which the tobacco industry repeatedly cite as the major determinants of youth smoking and smokeless tobacco use. As was suggested by a comment, however, even when a young person's decision to smoke is strongly influenced by a friend or parent, advertising reinforces the decision and makes the young person feel good about the decision and the ''identity'' thereby acquired.

It should also be noted that the apparent focus on the possible causal role of cigarette and smokeless tobacco advertising in young people's *initial* decision to smoke or to use smokeless tobacco is overly narrow. Human behavior cannot be modeled so simplistically. In point of fact, tobacco advertising has an effect on young people's tobacco use behavior if it affects initiation, maintenance, or attempts at quitting.

The evidence that FDA has gathered in this proceeding establishes that cigarette and smokeless tobacco advertising does have such an effect. While not all the evidence in the record supports this conclusion, there is more than adequate evidence, that when considered together, supports a conclusion that advertising, with the knowledge of the industry, does affect the smoking behavior and tobacco use of people under the age of 18. This behavior includes the decision whether to start using cigarettes or smokeless tobacco, whether to continue using or to increase ones consumption, when and where it is proper to use tobacco, and whether to quit. This evidence includes:

Expert opinion—The American Psychological Association provided expert opinion, with specific citation to numerous studies, to show that tobacco advertising plays directly to the factors that are central to children and adolescents and thus plays an important role in their decision to use tobacco. (See section VI.D.4.a. of this document; and 60 FR 41314 at 41329.)

Advertising Theory—Basic advertising and consumer psychology theory, statements from advertising experts, and general consumer testing show that advertising that is multi-media, that uses color, and that employs more pictures, characters, or cartoons as opposed to text is more robust and can be better processed, understood and remembered by children and adolescents, who have less information processing ability than adults. (See section VI.B.1. and VI.B2. of this document.)

Studies and Surveys—Studies show that children are exposed to substantial and unavoidable advertising, that exposure to tobacco advertising leads to favorable beliefs about tobacco use, that advertising plays a role in leading young people to overestimate the prevalence of tobacco use, and that these factors are related to young people's tobacco initiation and use. (See sections VI.D.3.a., VI.D.3.b., and VI.D.3.c. of this document.)

Empirical Studies—Studies conducted on sales data have shown that advertising did increase one segment of the tobacco market (low tar cigarettes), that advertising in New Zealand had the effect of increasing tobacco sales to young people, and that a large multi-country survey showed that advertising tends to increase consumption of tobacco products. (See 60 FR 41314 at 41333 through 41334; sections VI.D.3.g., VI.D.4.c., and VI.D.6.a. of this document)

Anecdotal Evidence, and Various Advertising Campaigns Successful with

[156] 1994 SGR, p. 188.

[157] 1989 SGR, p. 517.

[158] 1994 SGR, p. 195.

[159] *Id.*, p. 188.

Young People—Studies show that the buying behavior of young people is influenced by advertising, that they smoke the most advertised brands, that children ages 3 to 6 can recognize a cartoon character associated with smoking at the same rate as they recognize Ronald McDonald, that various ad campaigns (Camel cigarettes, Reg cigarettes, products designed for women, and smokeless tobacco advertising aimed at new users) that appeared to be targeted to young people did have an effect upon young people's purchases and use of tobacco, and that young people report that they got their information about a tobacco brand from billboards, magazines, in store advertising and on teeshirts (60 FR 41314 at 41329 through 41334; and see sections VI.D.3.d., VI.D.3.e., and VI.D.3.i. of this document).

Industry Statements—Statements in documents created by R. J. Reynolds' researchers, by Philip Morris advertising people, by executives of US Tobacco and by people in and doing work for various Canadian tobacco companies indicate that young people are an important and often crucial segment of the tobacco market.

Consensus Reports—The IOM and 1994 SGR concluded on the basis of an exhaustive review of the evidence that advertising affects young people's perceptions of the pervasiveness, image, and function of smoking, that misperceptions in these areas constitute psychosocial risk factors for the initiation of tobacco use, and thus advertising appears to increase young people's risk of tobacco use.

Consequently, tobacco advertising works in a way that is roughly analogous to the way the Supreme Court described how deceptive advertising works (*FTC* v. *Colgate - Palmolive Co.*, 380 U.S. 374 (1965)). The Supreme Court described how sellers use deceptive practices to break down the resistance of the buying public (*Id*. at 389–90). Here, as the 1994 SGR, the IOM report, and the comment of the American Psychological Association demonstrate, cigarette and smokeless tobacco companies use image and other advertising techniques to appeal to adolescents' need to belong and to appear to be adult, and thereby to break down their resistance to tobacco use. The advertising helps the companies to overcome the fact, as documents for R. J. Reynolds show, that there is no natural craving for nicotine. While the advertising techniques used by the tobacco industry are quite different than those used by the company in the referenced Supreme Court case, they ultimately have the same goal—to induce people, in this case young people, to purchase and use these products.

Thus, the evidence in this proceeding demonstrates that cigarette and smokeless tobacco advertising plays a material role in the decision of children and adolescents under the age of 18 to engage in tobacco use behavior. It therefore establishes that the harm from this advertising is real.

6. The Efficacy of the Restrictions; Empirical Evidence Concerning Advertising Restrictions

The final aspect of the analysis under the second prong of the *Central Hudson* test requires a showing by the agency that the restrictions that it seeks to impose will alleviate the harm to a material degree. FDA finds, based upon a review of all of the evidence and the comments received, that the restrictions will, in fact, meet this test.

(17) Nearly all comments in opposition to advertising restrictions argued that the preponderance of the empirical evidence supported a finding of no effect from advertising on young people. Some comments stated that, consequently, the advertising restrictions are ''unwarranted, unjustified, unnecessary, [and] will not be effective in reducing underage smoking.'' Several comments, representing a variety of interest groups, claimed that the ''best available evidence'' found that ''peer pressure,'' ''peer and family smoking behaviors'' and ''young people's perceptions of the costs and benefits of smoking'' are more important than advertising and promotion in encouraging young people to experiment with cigarettes and smokeless tobacco. [160] Still others claimed that ''being a girl,'' ''living with a single parent,'' ''having relatively less negative views about smoking,'' ''having no intention to stay in full-time education after age 16,'' and ''thinking they might be a smoker in the future,'' are key influencing factors for a young person to start smoking. [161]

The tobacco industry and the advertising industry stated that their advertising is not directed at children and adolescents but to adults who already use tobacco, and thus it is not a proper subject for government regulation. The advertising agency for the largest cigarette brand stated, ''[T]obacco advertising has as its intended audience existing smokers * * * it is not the company's desire that children start to smoke.''

However, one comment questioned this and asked how cigarette advertising that has an impact upon adults can be assumed to leave unaffected a young viewer, smoker or otherwise. The same comment also cited the words of one retired Marlboro ad man: ''I don't know any way of doing this (advertising cigarettes) that doesn't tempt young people to smoke.'' [162]

Many comments from consumer groups, public health organizations and numerous private individuals were supportive of the agency's position that the 1995 proposed rule will reduce underage smoking and use of smokeless tobacco. The comments cited evidence from numerous sources such as government officials, university researchers, and antismoking advocates to demonstrate that restrictions on advertising would be effective.

For example, a comment from a leading psychological association stated that research, common sense, and its expert opinion support that, if image-oriented advertising and promotion are replaced with text-only advertising, it would reduce the advertiser's ability to suggest that tobacco users project a desirable image, e.g., glamour, sexiness or maturity. [163]

FDA has concluded that restrictions on advertising and promotion are necessary to reduce the appeal of tobacco products to young people. Such restrictions will protect the access restrictions that the agency is adopting from being undermined and thereby the health of young people. To be effective,

[160] Beales, J. H., ''Advertising and the Determinants of Teenage Smoking Behavior,'' vol. 44, 1993.

[161] McDonald, C., ''Children, Smoking and Advertising: What Does the Research Really Tell Us?'', *International Journal of Advertising*, vol. 12, pp. 279–287, 1993; Goddard, E., ''Why Children Start Smoking,'' *British Journal of Addiction*, vol. 87, No. 1, pp. 17–25, 1992.

[162] Daniels, D., *Giants, Pygmies and Other Advertising People*, Crain, Chicago, p. 245, 1974.

[163] Cohen, J. B., ''Reconceptualizing Alcohol Advertising Effects: A Consumer Psychology Perspective,'' *The Effects of the Mass Media on the Use and Abuse of Alcohol*, Research Monograph, No. 28, Bethesda, MD, NIH, 1995; Goldberg, M. W., J. Madill-Marshall, G. J. Gorn, J. Liefeld, and H. Vredenburg, ''Two Experiments Assessing the Visual and Semantic Images Associated with Current and Plain (Generic) Cigarette Packaging,'' *Advances in Consumer Research*, edited by Corfman, K. P., and J. G. Lynch, Association for Consumer Research, Provo, UT, vol. 23, 1996; Pollay, R. W., and A. M. Lavack, ''The Targeting of Youths by Cigarette Marketers: Archival Evidence on Trial,'' *Advances in Consumer Research*, Association for Consumer Research, Provo, UT, vol. 20, pp. 266–271, 1993; Richins, M. L., ''Social Comparison and the Idealized Images of Advertising,'' *Journal of Consumer Research*, vol. 18, pp. 71–83, 1991.

these restrictions must be comprehensive, that is, they must apply to the many types of media currently used in a coordinated way to advertise cigarettes and smokeless tobacco.

FDA finds support for the need for comprehensive regulation in the experiences of other countries which have enacted and put into place some form of restrictions on the advertising of tobacco. Some comments discussed the experience in other countries in which tobacco advertising has been banned. These comments indicated that in countries that have enacted restrictions on advertising that were not comprehensive, the industry was able to continue advertising and portraying attractive imagery in media left uncovered by regulations. For example, Canada, Finland, Great Britain, and Australia enacted regulations of tobacco advertising that did not completely ban or restrict all forms of advertising and promotion. In each of those instances, according to the comments, the tobacco industry was able to take advantage of loopholes in the system to continue to advertise to reach their target audience. Thus, in Canada the advertising ban, which did not ban nontobacco items, was accompanied by the increased use of nontobacco items that carried the tobacco brand name as a mechanism for continuing to advertise the tobacco brand and its prior image. In Great Britain, sophisticated colorful advertisements appeared when the use of human figures in tobacco advertising was banned; in Australia, loopholes in sports sponsorship provisions enabled the industry to continue sports advertising.

Another comment detailed numerous other examples of tobacco companies continuing to advertise effectively in spite of a ban or restrictions on advertising. For example, this comment noted that after France banned all cigarette advertising in magazines, Philip Morris set up a travel agency and advertised ''Marlboro Country Travel'' in French magazines (Thus, although there was no longer any ''cigarette advertising,'' Philip Morris was able to continue using its western, cowboy theme in advertisements for a travel agency). The comment noted further that in Europe, advertising for cigarettes was replaced by advertisements, using the same imagery, for Camel and Marlboro sports watches and Camel boots. In Malaysia, cigarette companies set up travel agencies called Marlboro, Kent, and Peter Stuyvesant, clothing stores named Camel, jewelry stores named for Benson and Hedges, luxury car dealerships named More, Salem record stores and Salem and More concert and movie promotions to advertise cigarettes in a country that has banned cigarette advertising. FDA finds that these comments provide strong support for the need for the advertising restrictions to be comprehensive and apply to all advertising media to be effective.

Two aspects of the evidence in this proceeding are particularly persuasive in evidencing that restrictions on advertising will directly advance the agency's goal of protecting the health of children and adolescents under 18. The experience of other countries that have adopted advertising restrictions shows that when those restrictions are enforced, they have resulted in reductions in the level of tobacco use. In addition, the courts themselves have generally found that, as a matter of common sense, reductions in advertising have produced a reduction in demand. While some comments tried to distinguish these cases, FDA finds that they are relevant.

A discussion of each of these aspects of the evidence follows:

a. *International and cross country studies.* FDA did not receive consistent comment on the international studies [164] that it cited in the preamble to the 1995 proposed rule on the relationship between advertising restrictions and consumption.

(18) Several comments stated that advertising restrictions have not affected tobacco product consumption, and further stated that, in fact, tobacco product consumption has increased in most countries with advertising and promotional restrictions.

In contrast, other comments supported the findings of the same studies and stated that the studies support the conclusion that advertising and promotional restrictions can be effective in curbing smoking initiation among young people.

Several comments opposing the 1995 proposed rule maintained that better surveys of the results of advertising restrictions abroad were done in conjunction with the World Health Organization (WHO). The two WHO surveys on the health behavior of schoolchildren in four countries found that smoking among schoolchildren is related to peer smoking behaviors and to the number of smokers in the family. [165] More importantly, the comments said that the survey found ''no systematic differences'' between the smoking behavior of young people in countries where tobacco advertising is completely restricted and in countries where it is not. They asserted that the findings of the WHO survey completely repudiate FDA's assertion that advertising restrictions reduce tobacco consumption among young people. The comments further argued that a followup survey found that the prevalence of smoking among schoolchildren in countries with total tobacco advertising restrictions was actually higher than countries with fewer restrictions. [166]

However, the two surveys cited by these comments did not compare the percentage of young people who smoked before and after the implementation of tobacco advertising restrictions within countries. In order to realistically measure the effect of advertising restrictions, each country must be looked at individually. For example, country A, with a high rate of smoking, cuts its smoking rate in half. This would be considered a major success for country A, but country A still may have a higher smoking rate than country B. Country B may not have instituted any advertising restrictions because its smoking rate has always been low. Thus, comparing the rates of countries A and B would be like comparing apples and oranges.

Studies that have looked at before and after data from individual countries have reported downward trends in smoking rates among young people following advertising restrictions. [167] For example, in Norway the percentage of 15-year old boys and the percentage of 15-year old girls who were daily smokers in 1975, before a restriction on all forms of tobacco advertising and promotion was put in place, was

[164] Smee, C., ''Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing the Evidence,'' Department of Health, Economics, and Operational Research Division, London, 1992; ''Health or Tobacco—An End to Tobacco Advertising and Promotion,'' Toxic Substances Board (TSB), Wellington, New Zealand, May 1989; Laugesen, M., and C. Meads, ''Tobacco Advertising Restriction Price, Income and Tobacco Consumption in OECD Countries, 1960–1986,'' *British Journal of Addiction*, vol. 86, pp. 1343–1354, 1991.

[165] Aaro, L. E., B. Wold, L. Kannas, and M. Rimpela, ''Health Behavior in Schoolchildren: A WHO Cross-National Survey,'' *Health Promotion*, vol. 1, pp. 17–33, May 1986.

[166] Van Reek, J., H. Adriaanse, and L. Aaro, ''Smoking by Schoolchildren in Eleven European Countries,'' *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301–302, 1991.

[167] Bjartveit, K., ''The Effect of an Advertising Ban—Who has the Burden of Proof,'' National Health Screening Service, Norway, 1994; Rimpela, M., L. E. Aaro, and A. H. Rimpela, ''The Effects of Tobacco Sales Promotion on Initiation of Smoking,'' *Scandinavian Journal of Social Medicine*, 1994.

approximately 23 percent and 28 percent, respectively.[168] According to the WHO followup survey, the percentage of 15- to 16-year old boys and the percentage of 15- to 16-year old girls who were daily smokers in 1986–1987 was 16 percent and 17 percent, respectively.[169] This represents success not only with the group that was prohibited from purchasing cigarettes, those younger than 16, but also with a group that could legally purchase cigarettes. These results also appear to indicate that the restrictions did not simply move the onset of smoking to the first legal year of purchase.

Comments from the tobacco industry also relied upon research conducted by J. J. Boddewyn, which has found results contrary to those presented by FDA, to argue that tobacco advertising bans have not been a successful part of tobacco control policy.[170] Boddewyn's research is directly contrary to many of the studies cited by FDA in support of its 1995 proposed rule and is also inconsistent with the best available data on smoking rates from the countries studied.

Boddewyn has used selective data on the total number of cigarettes sold in a particular country as the basis for his analysis and has used it to justify a finding that, in those countries where advertising bans have been introduced, decreases in the total number of cigarettes sold have not followed. Relying solely on the number of cigarettes sold in a country to measure the effects of government restrictions fails to take into account the myriad of influences that can affect cigarette consumption and, thus, will not yield accurate results.

First, the overall number of cigarettes sold in a country may be influenced by factors other than the percentage of the population that smokes. For example, if the population of a country has risen, or if those who remained smokers were the heaviest smokers, the number of cigarettes smoked may not fall even though the percentage of the population that smokes has decreased. Moreover, an analysis based on the number of cigarettes sold would not account for the success advertising restrictions might have had with those not yet addicted to tobacco. The preaddicted group, mostly composed of children, does not smoke as many cigarettes as do older addicted smokers. Therefore, any success in stemming initiation rates would not show up for many years if measured as fewer cigarettes consumed.

Finally, Boddewyn and others have claimed that the experience in Norway, Finland, and Sweden supports the view that advertising restrictions have been ineffective in reducing smoking rates. However, three reports[171] presented at the World Conference of Tobacco and Health in Paris, France in October 1994 support the conclusion that advertising restrictions, if comprehensive and enforced, are effective in helping to reduce the percentage of people who smoke, particularly young people not yet addicted to tobacco.

Bjartveit's report presented the results of the Norwegian experience after the implementation of the 1975 Norway advertising ban. In 1975, Norway banned all advertising of tobacco products and prohibited the sale of tobacco to anyone under the age of 16. Norway also required warnings on packages, an educational program, and, in 1980, a larger excise tax. The results of Norway's actions belie Boddewyn's claims. First, the prevalence of smoking for boys and girls declined between 1975 and 1990. The percentage of daily smokers aged 13 to 15 declined from 15 percent to 9 percent for boys and from 17 percent to less than 10 percent for girls. Per-capita consumption for boys and girls also declined. Between 1975 and 1994, the overall sales of cigarettes and smoking tobacco per person among 15 year olds has declined from over 2,000 grams of tobacco to less than 1,800 grams.

In 1976, Finland banned some forms of tobacco advertising and promotion and increased expenditures for health education. While relatively little data are available on the smoking trends in Finland, one comment reported data that showed the government's actions did have an impact, although the extent has been more uneven than in Norway. Before the advertising restrictions, cigarette consumption was increasing at the rate of 2.2 percent per year. In the decade since the 1975 Finland advertising ban, the rate of increase has been cut in half to a little over 1 percent per year—a meaningful change but not a decline. However, the greatest benefits have been for teenagers. In 1973, 26 percent of 16 to 18 year olds in secondary school smoked. By 1979, 2 years after restrictions went into place, this rate dropped to 14 percent. Since that time, the decrease has continued but has leveled off. In 1973, 19 percent of 14-year old children in Finland smoked. By 1979, 2 years after the ban, only 8 percent of 14-year old children in Finland smoked, a decrease of over 50 percent.

Moreover, a report by Rimpela[172] provided a more complete explanation of the experience that Finland has had with its advertising restrictions. Although the 1978 Finnish Tobacco Act banned cigarette advertisements in youth magazines, it did not eliminate the advertising of product-families or the sponsorship of events. Consequently, the tobacco companies found new means of sales promotion through image advertising in these two venues. The author concluded that a promotional onslaught in these two forums undercut the so-called advertising ban, and the weak implementation of the legislation by health authorities caused the advertising restrictions to be less effective than they might have been with a total ban. The author contrasted these uneven results with the success of Norway's total ban.

The study presents strong evidence for the need for comprehensive advertising restrictions covering all forms of advertising and promotion in order to achieve the best results in reducing youth tobacco use. Finally, the restrictions imposed in Sweden have not been in effect long enough to measure accurately.

i. *The British Health Department Report.* Several comments from the tobacco industry criticized the findings of the British Health Department Report (Smee Report) that advertising increases consumption of tobacco products, and that restrictions on advertising decrease tobacco use beyond what would have occurred in the absence of

[168] Rimpela, M., L. E. Aaro, and A. H. Rimpela, ''The Effects of Tobacco Sales Promotion on Initiation of Smoking,'' *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

[169] Van Reek, J., H. Adriaanse, and L. Aaro, ''Smoking by Schoolchildren in Eleven European Countries,'' *Proceedings of the 7th World Conference on Tobacco and Health*, Duroton, B., and K. Jamrozik, vol. 301, pp. 301–302, 1991.

[170] Boddewyn, J. J., ''Tobacco Advertising Bans and Consumption in 16 Countries,'' International Advertising Association, 1986; Boddewyn, J. J., ''Why do Juveniles Start Smoking?'' Children's Research Unit of London (CRU) Study, 1986; Boddewyn, J. J., ''Cigarette Advertising Bans and Smoking: The Flawed Policy Connection,'' *International Journal of Advertising*, vol. 13, No. 4: pp. 311–332, 1994.

[171] Bjartveit, K., ''The Effect of an Advertising Ban—Who Has the Burden of Proof,'' National Health Screening Service, Oslo, Norway, October 1994; Lund, K., ''Tobacco Advertising and How to Measure Its Effect on Smoking Behavior,'' *Tobacco and Health*, Slama, K., ed., Plenum Press, New York, pp. 199–204, 1995; Rimpela, M., L. E. Aaro, and A. H. Rimpela, ''The Effects of Tobacco Sales Promotion on Initiation of Smoking,'' *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

[172] Rimpela, M., L. E. Aaro, and A. H. Rimpela, ''The Effects of Tobacco Sales Promotion on Initiation of Smoking,'' *Scandinavian Journal of Social Medicine*, vol. 49, pp. 1–23, 1994.

regulation.[173] The Smee Report examined: (1) The relationship between cigarette advertising, (2) the effects of partial and complete advertising bans on tobacco consumption, and (3) the results of cross-national studies. The study focused on countries for which the most complete data exists—Norway, Finland, Canada, New Zealand, and the United Kingdom. One reported result of this analysis was that in all five countries, bans or restrictions on cigarette advertising resulted in an aggregate decrease in cigarette consumption.

(19) The comments argued that the WHO study contradicts the findings of this report regarding Norway, Finland, and Canada, stating that the findings do not indicate that advertising restrictions affect consumption. Several comments stated their belief that the author's (Smee's) ''sweeping and unjustified'' conclusions are based on ''data collected over a short time period'' and on a ''limited and incomplete review of the available evidence''. They also argued that Smee's reliance on existing studies linking advertising and consumption is misplaced. Furthermore, the comments specifically criticized the report's use of several of the reviewed studies, which, they claim, did not apply rigorous statistical analysis. Finally, the comments stated that the author's model made no allowances for the effect of externalities, such as health shocks (the Royal College of Physicians' Report on Smoking in 1962, the Report of the Surgeon General's Panel on Smoking and Lung Cancer in 1964, etc.). All the above comments maintained that the Smee Report should not be relied upon as evidence of the causal relationship between advertising restrictions and teen smoking behavior.

FDA disagrees with the comments' assessment and finds the Smee Report to be unbiased and useful as a comprehensive survey of the literature. Upon examining the specific concerns expressed by the comments in connection with specific country analyses, FDA has found that the criticisms are without merit. For example, the comments stated that the reduction in tobacco consumption found in Norway could be attributed to externalities, such as to enforcement of other provisions of the antitobacco legislation package, e.g., health warnings, health education, and sales restrictions. However, Smee reported that the share of reduction in tobacco consumption attributable to the advertising ban ''is likely to account for the great majority of the effect.'' Another comment expressed concern that Smee, in reporting on the Canadian experience, failed to include income as an independent variable. The comment stated that this could seriously bias the results because real income was falling in Canada at the time the advertising ban went into effect. However, in the initial Smee model, the income variable was included, and it did not explain the variation in tobacco consumption. In the final model, Smee did not include the income variable. However, removing the income variable did not significantly change the estimated coefficient and would not have biased the estimates from the model.

Finally, all econometric studies are subject to limitations. As noted in sections VI.D.4.d. and VI.D.5. of this document, it would require controlled studies to produce better results and it is neither practical nor ethical to conduct such studies. Empirical research is always subject to the criticism that some variables were omitted, or that alternative specifications would yield different results. However, Smee collected many studies, and hence his compilation includes many different specifications of tobacco demand. Thus, although it is difficult to evaluate the causes of variations in each study, an analysis of all the existing studies should yield more generalizable and robust results than those of a single study. The question here is not whether each of the studies has limitations, but to what extent those limitations impair the findings of the overall survey. Smee's study represents the best attempt to date to compile the numerous studies on the effects of advertising restrictions on tobacco use and to provide a coherent analysis. His conclusion was that restrictions on advertising did reduce tobacco use.

A comment in support of the findings of the Smee Report stated that this study was unbiased and performed by a credible organization. The comment argued that advertising restrictions produced the decline in the percentage of young people who smoke in the countries studied. In response to the tobacco industry's claim that the total number of cigarettes consumed continued to rise in several countries, the comment said that ''it takes a number of years for the impact of the fact that fewer people are starting to smoke to show up in overall tobacco consumption data.''

ii. *New Zealand Toxic Substances Board Study*. Several comments gave considerable attention to the New Zealand Government Toxic Substances Board (''TSB'') Study which reviewed the effect of advertising restrictions in 33 countries.[174] The study concluded that there was a correlation between the degree of restrictions imposed in each country and decline in tobacco use.

(20) Comments submitted by those opposing the proposed regulations argued that the study lacked objectivity because of methodological errors, particularly in the collection, sorting and selective use of data. The comments argued that these errors removed all probative value from the study. Moreover, the comments noted that FDA's use of the study illustrates its inconclusive nature. In addition, one comment asserted that the drop-offs in consumption and the number of smokers may be related to events other than legislated restrictions.

One comment argued that several studies cited by FDA in the preamble to the 1995 proposed rule, including Chetwynd and Harrison, do not support the claimed relationship between advertising expenditures and consumption because the studies have flawed data and fundamental methodological errors. For instance, the comment argued that, in the Laugesen study on tobacco consumption in 23 Organization for Economic Cooperation and Development (OECD) countries described below,[175] the qualitative variables used were not relevant to the regression model and biased the results. Additionally, the comment criticized the authors of the study for ignoring contradictory findings.

One comment suggested that the findings in several smaller studies cited by FDA[176] do not indicate that

[173] Smee, C., ''Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing Evidence,'' Department of Health, Economics, and Operational Research Division, London, p. 18, 1992.

[174] ''Health or Tobacco—An End to Tobacco Advertising and Promotion,'' TSB, Wellington, New Zealand, May 1989.

[175] Laugesen, M., and C. Meads, ''Tobacco Advertising Restrictions, Price, Income, and Tobacco Consumption in OECD Countries, 1960–1986,'' *British Journal of Addiction*, vol. 86, pp. 1343–1354, 1991.

[176] Chetwynd, J., P. Coope, R. J. Brodie, and E. Wells, ''Impact of Cigarette Advertising on Aggregate Demand for Cigarettes in New Zealand,'' *British Journal of Addiction*, vol. 83, p. 409–414, 1988; Harrison, R., J. Chetwynd, and R. J. Brodie, ''The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund,'' *British Journal of Addiction*, vol. 84, pp. 1251–1254, 1989; Raferty, J., ''Advertising and Smoking—A Smoldering Debate?'', *British Journal of Addiction*, vol. 84, pp. 1241–1246, 1989.

advertising affects consumption. The comment argued that one of the analyses failed to account for common trends resulting from the diffusion of information about health risks. The comment further stated that Chetwynd used a model in his study that was more likely to indicate correlation than causation. The comment also asserted that the model suffers from poor data and fails to take into account changing social mores. In addition, the comment argued that a comparable study (Boddewyn) has not shown a decrease in cigarette consumption in areas that restrict advertising. [177]

Industry comments uniformly criticized the TSB study. This study was also criticized by the Canadian courts in the course of litigation over the validity of Canada's advertising restrictions, see section VI.D.3.f. of this document. In response, the TSB published a modification of the original study that recognized that mistakes had been made in the initial report. The reissued report was entitled ''A Reply to Tobacco Industry Claims about Health or Tobacco,'' ISBN–0–477–04574–X (hereinafter referred to as the Reply). According to one comment from a public interest group:

> The Reply re-analyzed the data of the impact of advertising in a number of countries based upon criticisms of the original report by the tobacco industry. Even after taking into account the criticisms of the tobacco industry, the New Zealand government found strong empirical evidence of the link between tobacco advertising and tobacco consumption.

In addition to the issuance of the Reply, Laugesen and Meads [178] retested the typology created by the TSB and applied it to 22 OECD countries for a 15-year period. In the preamble to the 1995 proposed rule, FDA referred to the Laugesen study as providing affirmation of the TSB's analysis and conclusions, that, as a group, countries prohibiting tobacco advertising in most or all media experienced more rapid percentage falls in consumption than the group of countries that permitted promotion (60 FR 41314 at 41334).

The industry comments' major criticism of the Laugesen study is that the scale developed by Laugeson is flawed. The comments criticized the amount of weight accorded to different types of advertising restrictions (i.e., TV ban versus warning on package). However, the rating scale accurately reflects the level of restrictions in each country. The steps between the ratings in the scale may be smaller or larger than the comments believe were warranted, but the relative rankings would remain the same regardless.

Finally, several comments found fault with the smaller studies cited by FDA, including ones by Chetwynd and Harrison. Contrary to the comments' assertions, the studies do include the most relevant variables such as price, income and advertising expenditures. A major complaint of the industry regarding studies done abroad is that the advertising expenditures fail to be totally inclusive. However, the solution to that problem lies with the industry in most cases. Advertising expenditures are a closely guarded industry trade secret, [179] which the companies state cannot be released to the public because of their commercial sensitivity. However, the industry could release older relevant data that are no longer sensitive for the purposes of investigation and study. Moreover, researchers who have had access to industry data have not released their data sets for replication by other research groups. [180]

The final study criticized by the industry, performed by Harrison, was written in response to earlier criticism by the industry about the Chetwynd study, and it therefore provided some answers to the comments' concerns. For example, the comments fault Chetwynd for failing to take into account changing social mores. Harrison stated that he retested Chetwynd's model and found that the model was structurally stable through time in the long term. He also found that the long run analyses indicated that the impact of cigarette advertising on consumption may be larger than was suggested in the original work. [181]

After reviewing the studies provided by the comments and reevaluating the studies relied upon in the preamble to the 1995 proposed rule, FDA reaffirms that the statement that it made in the preamble is correct:

> These studies provide insight into the effects of advertising on the general appeal of and demand for cigarettes and smokeless tobacco products. They also provide evidence confirming advertising's effect on consumption and the effectiveness of advertising restrictions on reducing youth smoking.

(60 FR 41314 at 41333)

Based on the foregoing, FDA finds that the international experience provides empirical evidence that restrictions on tobacco advertising, when given appropriate scope and when fully implemented, will reduce cigarette and smokeless tobacco use among children and adolescents under the age of 18. This experience provides strong evidence that the restrictions that FDA is imposing will directly advance its interest in protecting the health of these young people.

b. *Case law considering the effect of advertising and advertising restrictions upon tobacco use by young people.* Virtually every court that has examined the issue has held that there is a direct connection between advertising and demand for the product advertised. For example, in *Central Hudson Gas and Electric*, 447 U.S. at 569, the Supreme Court stated: ''[T]he State's interest in energy conservation is directly advanced by the Commission order at issue here. There is an immediate connection between advertising and demand for electricity.'' See also *Posadas de Puerto Rico* v. *Tourism Co. of Puerto Rico*, 478 U.S. at 341–342. In *United States* v. *Edge Broadcasting Co.*, the Supreme Court carried its position in *Central Hudson* one step further:

> If there is an immediate connection between advertising and demand, and the federal regulation decreases advertising, it stands to reason that the policy of decreasing demand for gambling is correspondingly advanced.

(509 U.S. 434)

Each circuit court that has considered the issue has also concluded that the regulation of advertising is reasonably aimed at reducing demand. (See, *Anheuser-Busch, Inc.* v. *Schmoke*, 63 F.3d 1305. 1314–15 (4th Cir 1995), *vacated and remanded* 64 U.S.L.W. 3333 (May 20, 1996); *Dunagin* v. *City of Oxford, Miss.*, 718 F.2d at 750 (''[W]e hold that sufficient reason exists to believe that advertising and consumption are linked to justify the ban, whether or not 'concrete scientific evidence' exists to that effect.''); and *Oklahoma Telecasters Ass'n* v. *Crisp*, 699 F.2d 490, 501 (10th Cir. 1983), rev'd on other grounds sub.nom. *Capital*

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[177] Boddewyn, J. J., ''Tobacco Advertising Bans and Consumption in 16 Countries,'' International Advertising Association, 1986.

[178] Laugesen, M., and C. Meads, ''Tobacco Advertising Restriction, Price, Income, and Tobacco Consumption in OECD Countries, 1960–1986,'' *British Journal of Addiction*, vol. 86, pp. 1343–1354, 1991.

[179] Even in the United States, only FTC has access to company expenditure data and it is prevented from disclosing information concerning advertising expenditures except at the industry-agglomerated level.

[180] Beales, J. H., ''Advertising and the Determinants of Teenage Smoking Behavior,'' p. 44, 1993.

[181] Harrison, R., J. Chetwynd, and R. J. Brodie, ''The Influence of Advertising on Tobacco Consumption: A Reply to Jackson and Ekelund,'' *British Journal of Addiction*, vol. 84, pp. 1251–1254, 1989.

Cities Cable, Inc. v. *Crisp*, 467 U.S. 691 (1984)).) In *Greater New Orleans Broadcasting Ass'n* v. *United States*, 69 F.3d 1296, 1301 (5th Cir. 1995), the court said:

> They cannot seriously dispute that a prohibition of advertising of casino gambling directly advances the governmental interest in discouraging such gambling and fulfills the [second] *Central Hudson* prong. It is axiomatic that the purpose and effect of advertising is to increase consumer demand.

To counter the weight of this case law, comments that opposed FDA's advertising restrictions made two arguments. First, several comments from the tobacco and advertising industries argued that the agency cannot rely on the assumption of a link between advertising and demand that is embodied in these decisions and, citing the Court's more recent *Coors* decision, contended that the agency's evidentiary record will be held to a higher standard of proof.

However, as one comment correctly noted, the Court in Coors wrote:

> It is assuredly a matter of 'common sense' that a restriction on the advertising of a product characteristic will decrease the extent to which consumers select a product on the basis of that trait.

(115 S.Ct. at 1592) Moreover, in *44 Liquormart, Inc.*, Justice Stevens quoted with apparent approval *Central Hudson's* reliance on the ''immediate connection'' between ''promotional advertising'' and demand (116 S.Ct. at 1506, quoting *Central Hudson* 447 U.S. at 569). Thus, the Supreme Court continues to hold that there is a connection between advertising and demand, and FDA finds no merit to this contention in the contrary argument in the comments.

The second argument that these comments made is that because tobacco products constitute a ''mature product'' whose availability and qualities are widely known to consumers, the purpose and function of cigarette advertising is to build market share and to maintain brand loyalty, not to stimulate demand. FDA considers these comments in depth in the following section of this document.

c. *The function of advertising in the ''mature'' market.* Comments from the industry, advertisers, psychologists, and economists argued that although it may be true that advertising generally serves the function of increasing demand for a product category, that truism does not work for tobacco, which, they claim, is a mature market.

(21) The comments argued that because tobacco is a mature product, advertising serves to reinforce brand loyalty and to induce current smokers to switch brands. They stated that because consumers are already aware of the tobacco category, advertising does not serve to inform potential consumers of the product and to entice them to become a user. One comment likened tobacco to other mature products such as soft drinks, deodorants, antiperspirants, and appliances. Moreover, this comment argued that ''[b]ecause FDA lacks marketing expertise,'' it has been misled by the size of the industry's advertising expenditures and assumed, incorrectly, that this means that the industry is attempting to expand its overall market. Finally, several comments stated that there are no data that clearly prove that advertising and promotion increase demand in the tobacco market.

Other comments took the opposing view and agreed with FDA's assessment that tobacco advertisements make tobacco products more appealing to young people and affects tobacco use among young people. Several comments argued that the market for cigarettes and smokeless tobacco is not mature but is actually very dynamic. In addition to brand switching and brand loyalty, they argued that tobacco marketing generates market expansion. The comment noted that there is substantial movement at the margins with new customers entering the market, and many current customers trying to leave.

FDA agrees with those comments that expressed the view that labeling the tobacco market as a ''mature market'' is a simplistic denotation, which fails to recognize the movement into the market each day of new young smokers often motivated in part by advertising. Even ''mature'' markets must replenish their customer base as older consumers leave the market. In fact, approximately one million new young smokers enter the tobacco market each year. These new smokers are necessary to keep the mature market stable and to prevent decline. There is no evidence to suggest that these new smokers are predestined [182] to enter the market. RJR acknowledged this in one marketing memo,

> ''[I]f we are to attract the nonsmoker or the presmoker, there is nothing in this type of product that he would currently understand or desire. * * * Instead, we somehow must convince him with wholly irrational reasons that he should try smoking.'' [183]

They must be influenced by peers, parents, and advertising, either to join the market or to decline to enter.

The agency finds that regardless of whether marketers and their advertising agencies intentionally target children and adolescents, young people are still affected by advertising. Children are not isolated from tobacco advertising's attractiveness or inducements. There is no ''magic curtain around children and teenagers who seek to learn how to fit into the adult world,'' nor is there any evidence to support a claim that young people are immune from advertising's blandishments. [184]

Comments asserting that tobacco advertising fails to increase consumption for the tobacco market run contrary to the views of one well-known advertising executive who stated:

> I am always amused by the suggestion that advertising, a function that has been shown to increase consumption of virtually every other product, somehow miraculously fails to work for tobacco products. [185]

Further, the view that advertising does not affect consumption is contradicted by industry experience, logic, and evidence. It does not appear credible that the industry spends more than $6 billion annually merely to maintain brand share and to try to switch current smokers; this argument defies common sense. The economics of this argument are strained—five manufacturers control almost 100 percent of the market, and three of these have approximately 90 percent of the market. [186]

The courts have also expressed skepticism about this argument. In *Dunagin* v. *City of Oxford, Miss.*, the advertiser's expert, a professor in sociology who specialized in alcoholism, testified that advertising merely affected brand loyalty and market share, rather than increasing overall consumption or consumption of individual consumers (718 F.2d at 748). The court rejected this argument:

> It is beyond our ability to understand why huge sums of money would be devoted to the promotion of sales of liquor without expected

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[182] Teague, C., *Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market*, 1973.

[183] Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, 1972.

[184] Cohen, J. B., ''Charting a Public Policy for Cigarettes,'' *Marketing and Advertising Regulation: The Federal Trade Commission in the 1990's*, edited by Murphy, P. E., and W. L. Wilkie, University of Notre Dame Press, Notre Dame, IN, pp. 234–254 , 1990.

[185] Foote, E., ''Advertising and Tobacco,'' *JAMA*, vol. 245, pp. 1667–1668, 1981.

[186] Weidner, D., ''RJR Tobacco International Gets New Chief,'' *Winston-Salem Journal*, p. A1, Dec. 8, 1995. (Philip Morris, 45 percent, Reynolds 27 percent.); Antunes, S., ''B & W Harassed Workers,'' *Evening Standard*, p. 47, Nov. 16, 1994. (After Brown & Williamson acquired American Tobacco, it had 18 percent of the market.)

results, or continue without realized results. No doubt competitors want to retain and expand their share of the market, but what businessperson stops short with competitive comparisons? It is total sales, profits, that pay the advertisers and dollars go into advertising only if they produce sales. Money talks: it talks to the young and the old about what counts in the marketplace of our society, and it talks here in support of Mississippi's concern.

(718 F.2d at 749)

The court concluded: ''We simply do not believe that the liquor industry spends a billion dollars a year on advertising solely to acquire an added market share at the expense of competitors'' (718 F.2d at 750). The same reasoning applies here.

(22) One comment discussed the results of a recent study that the comment said had been accepted for publication [187] which found that less than 10 percent of adult smokers switch brands each year, and that only 6.7 percent switch companies. The commentary suggests that this amount of ''real'' brand switching would not justify $6.1 billion, an amount in annual advertising and promotional expenditures.

In addition to logic, there is empirical evidence that advertising can expand demand in a so-called mature market and in fact has done so in the cigarette market before. Smoking rates for teenage girls rose from 8.4 percent in 1968, when major promotional campaigns first targeted women, to 15.3 percent in 1974, by which time other tobacco companies had also begun marketing women's brands. [188] The same phenomenon was captured differently in a recent study [189] that tracked initiation rates for girls and women over a 40-year period. The study found that smoking initiation rates rose for girls under 18 during the period between 1967 and 1973 (women's targeting period), even though initiation rates did not rise for women 18 and older. Finally, as detailed more fully in the preamble to the 1995 proposed rule (60 FR 41314 at 41345), another study looked at the effect of variations in advertising expenditures for low tar cigarettes. Although the advertising did not increase the advertiser's brand share, increased advertising for low tar cigarettes caused the entire market for cigarettes to increase. [190]

The ability of advertising to expand total demand for a particular class of products through market segmentation has also been demonstrated in other markets when the breakfast cereal industry first began making health claims for their products, such as those regarding the cancer-prevention benefits of dietary fiber. The creation of a new segment of the cereal market—healthy cereal—through the use of advertising resulted in an increase in the overall adult cereal market. Advertising caused an increase in aggregate demand by giving consumers a ''new'' product that met their needs, wants, and desires. [191]

Thus, advertising can serve an important role in meeting and expanding desires in the marketplace. It identifies consumers' needs and desires and then matches them with the attributes of particular product categories and brands. Advertising can perform this function through its use of explicit claims or through imagery, code words, or psychosocial cues. And, in doing so, it can both shift demand across the entire product category and create new demand.

Moreover, the industry's mature market categorization assumes that the product category has no outside competitors, i.e., that there is no other product line that competes for the consumers' attentions and dollars. For example, soft drinks are a mature market, but more healthful drinks, such as milk, juices, or even water, can attempt to draw off part of the market. In addition, soft drinks can try to expand their own market share as Coca Cola and later Pepsi did a number of years ago [192] when they promoted cola for breakfast.

Similarly, tobacco has competitors. New users or ''presmokers,'' as one RJR employee refers to them, [193] are faced not only with tobacco imagery but also with antismoking health messages in commercial media and in schools. Current smokers are faced with alternatives to smoking, including over-the-counter and prescription drug advertising for nicotine replacement products and stop-smoking cures. The tobacco market thus has to convince the presmoker or new smoker to switch from the nonuse category promoted by health professionals, public service announcements, and school messages, to tobacco use. Also, it must constantly convince the addicted smoker not to leave the market by use of a competing nicotine-delivery product, a nicotine replacement source, or by other voluntary means.

Finally, even the industry acknowledges that young people are a strategically important audience because brand loyalty often develops during this period of trying cigarettes and becoming a smoker. In 1973, RJR's research and development officer wrote ''Realistically, if our Company is to survive and prosper over the long term, we must get our share of the youth market.'' [194] And, as noted in the preamble of the 1995 proposed rule, these words reflect those uttered by the Canadian sister company of the American tobacco company, Brown and Williamson Tobacco Corp.

> If the last ten years have taught us anything, it is that the industry is dominated by the companies who respond most effectively to the needs of younger smokers. [195]

FDA finds that there is no merit to the industry's claim that because the tobacco market is a mature market, advertising does not stimulate demand but only reallocates the existing market between companies. Not only is the industry's argument overly simplistic, but, as shown, advertising plays an important role in creating new customers, including young people. FDA shares the incredulity expressed by the court in *Dunagin*, 718 F.2d at 750, regarding this argument: ''It is beyond our ability to understand'' why an industry would spend billions a year merely to acquire market share at the expense of its competitors, when it has a much harder job of convincing young people to start a habit that is neither easy to acquire nor pleasant. Consequently, FDA finds that the second prong of *Central Hudson* is satisfied, i.e., the advertising restrictions directly and materially advance the substantial state interest.

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[187] Siegel, M., et al., ''The Extent of Cigarette Brand and Company Switching: Results from the Adult Use-of-Tobacco Survey,'' *American Journal of Preventive Medicine*, vol. 12, No. 1, pp. 14–16, 1996.

[188] Botvin, G. J., C. J. Goldberg, E. M. Botvin, and L. Dusenbury, ''Smoking Behavior of Adolescents Exposed to Cigarette Advertising,'' *Public Health Reports*, vol. 108, pp. 217, 222, 1993.

[189] Pierce J. P., L. Lee, and E. A. Gilpin, ''Smoking Initiation by Adolescent Girls, 1944 through 1988,'' *Journal of the American Medical Association*, vol. 271, No. 8, pp. 608–611, 1994.

[190] Roberts, M. J., and L. Samuelson, ''An Empirical Analysis of Dynamic, Nonprice Oligoplistic Industry,'' *Rand Journal of Economics*, vol. 19, pp. 200–220, 1988.

[191] Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, p. 32, 1989.

[192] Dourado, P., ''Breakfast Cola Takes on America's Coffee Giants,'' *The Independent*, p. 28, April 15, 1990.

[193] Teague, C., *Research Planning Memorandum on Some Thoughts about New Brands of Cigarettes for the Youth Market*, p. 1, 1973.

[194] *Id*.

[195] Overall Marketing Objectives-F88, 1988 Imperial Tobacco Ltd. Marketing Plan, p. 6; 60 FR 41314 at 41331.

E. Provisions of the Final Rule

FDA selected each of the restrictions that it included in the 1995 proposed rule based on its tentative view that the particular restriction is necessary to providing a comprehensive response to the appeal of tobacco advertising to young people. Each proposed restriction was intended to address an aspect of this advertising that contributes to its appeal. The agency tentatively concluded that, together, these restrictions will ensure that advertising is not used to undermine the access restrictions that FDA proposed and thus will help to protect the health of children and adolescents under the age of 18.

In this section of the document, FDA will respond to comments on each element of this comprehensive approach, including comments on whether the regulations are legally supportable. A key question about the agency's approach is whether there is a reasonable fit between the agency's interest and the means that it has chosen to accomplish it; that is, between the agency's interest and the specific restrictions that it proposed. This inquiry involves consideration of the restrictions under the third and final prong of *Central Hudson*.

FDA will first consider comments that raised general concerns about its approach under the third prong of *Central Hudson*. It will then consider comments that raised concerns about specific restrictions under this aspect of *Central Hudson* as part of its discussion of the comments on each restriction.

1. Are FDA's Regulations Narrowly Drawn?

In the preamble to the 1995 proposed rule, FDA stated that the regulations that it was proposing met the final prong of the *Central Hudson* test (60 FR 41314 at 41355). In *Central Hudson,* the Supreme Court stated that the First Amendment mandates that speech restrictions be ''narrowly drawn.'' The Court continued:

> The regulatory technique may extend only as far as the interest it serves. The State cannot regulate speech that poses no danger to the asserted State interest, * * * nor can it completely suppress information when narrower restrictions on expression would serve its interest as well.

(447 U.S. at 565, n.7) FDA pointed out, however, that: ''The Supreme Court has made it clear that this prong does not require a 'least restrictive means test,' but rather that there be a 'reasonable fit' between the government's regulation and the substantial governmental interest sought to be served'' (*Board of Trustees of State University of New York* v. *Fox,* 492 U.S. 469, 480 (1989); (60 FR 41314 at 41355).

(23) This statement by FDA provoked a significant amount of comment. Several comments said that FDA had mischaracterized its burden. These comments argued that *Fox* did not dilute the *Central Hudson* analysis, and that any restriction on commercial speech must be narrowly tailored. One comment pointed out that, in *Rubin* v. *Coors,* the Supreme Court made no mention of reasonable fit. The comment stated that in Rubin v. Coors, the Supreme Court said that *Central Hudson* requires that a valid restriction be no more extensive than necessary to serve the governmental interest (115 S.Ct. at 1591). Finally, one comment said that FDA was arguing that courts have applied a rational basis standard to restrictions on commercial speech, but the comment stated that FDA was wrong because courts have rejected this notion.

In response to these comments, FDA has carefully evaluated the relevant case law. The agency does not agree that it mischaracterized its burden in the 1995 proposed rule.

It is true that in *Rubin* v. *Coors* the Supreme Court found that the challenged statutory provision violated the First Amendment's protection of commercial speech, at least in part, because it was more extensive than necessary (115 S.Ct. at 1594). However, the Court also stated that its inquiry under the last two steps of *Central Hudson* involves ''a consideration of the 'fit' between the legislature's ends and the means chosen to accomplish those ends'' (*Id.* at 1391 (quoting *Posadas De Puerto Rico Associates* v. *Tourism Co. of Puerto Rico,* 478 U.S. at 341); (See also *44 Liquormart, Inc.* v. *Rhode Island,* 116 S.Ct. at 1510 (''As a result, even under the less than strict standard that generally applies in commercial speech cases, the state has failed to establish a reasonable fit between its abridgment of speech and its temperance goal.'')).

Moreover, the Court's statement in *Rubin* v. *Coors* that a restriction on commercial speech must be no broader than necessary, which was cited by a comment, must be read in light of the Court's discussion of this requirement in *Board of Trustees of State University of New York* v. *Fox,* 492 U.S. at 476–481. In *Fox,* the Supreme Court concluded from its consideration of how this phrase has been used in its case law and in the related case law on time, place, and manner restrictions, that what is required, exactly as the agency said in the 1995 proposed rule, is a fit between the Government's ends and the means chosen to accomplish those ends that is not necessarily perfect but reasonable (492 U.S. at 480). The Supreme Court reiterated this point in *Florida Bar* v. *Went For It, Inc.,* 115 S.Ct. at 2380 (citations omitted):

> With respect to this prong, the differences between commercial speech and noncommercial speech are manifest. In *Fox,* we made clear that the ''least restrictive means'' test has no role in the commercial speech context * * * ''What our decisions require,'' instead, ''is a 'fit' between the legislature's ends and the means chosen to accomplish those ends,'' a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served' that employs not necessarily the least restrictive means but * * * a means narrowly tailored to achieve the desired objective.

Thus, FDA did not mischaracterize its burden in the 1995 proposed rule. Moreover, in any event, FDA has narrowly tailored its provisions.

Before turning to the question of whether there is a reasonable fit between FDA's interest in the health of children and the restrictions that FDA proposed on tobacco advertising, the agency wishes to make clear that, contrary to the claim of one comment, it recognizes that courts have not equated the reasonable fit test with rational basis review. (See, e.g., *Florida Bar* v. *Went For It, Inc.*) FDA recognizes that the reasonable fit test requires that the Government goal be substantial, and that the cost of achieving that goal be carefully calculated. (See *Board of Trustees of State University of New York* v. *Fox,* 492 U.S. at 480.) It also recognizes that this test requires that the agency consider whether there are less burdensome alternatives to restrictions on speech.

Having already established that its goal is substantial (see section VI.C.4. of this document), FDA will consider the issues of the costs of the restrictions and alternatives to these restrictions in its analysis of the comments that follows.

(24) Several comments argued that the restrictions on cigarette and smokeless tobacco advertising that FDA proposed are not narrowly tailored. One comment said that the premise of the narrow tailoring requirement is that commercial speech is valuable, and that it may only be restricted when it is necessary to do so. Other comments argued that restrictions on speech must attack only problem speech, and that FDA had failed to prove that this is what the proposed restrictions did. These