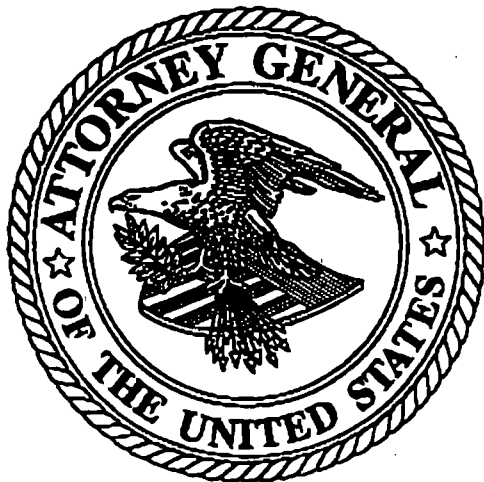


McLain  
3  
Q/A's  
SW



# OFFICE OF THE ATTORNEY GENERAL

## TO

FAX Number 456 - 7431

Name: MARY SMITH

Telephone Number: \_\_\_\_\_

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Building, Room Number, etc. \_\_\_\_\_

Number of Pages Transmitted (including cover sheet)

22

## FROM

FAX Number: \_\_\_\_\_

Name: TOM PERRELLI

Telephone Number: 514 - 2267

Date: \_\_\_\_\_

Building, Room Number, etc. MAIN JUSTICE - ROOM

## COMMENTS

(NOTE: If the receiver did not receive the correct number of pages, please call the transmitter and request retransmission)

The proposed settlement and legislation do not deal expressly with new entrants into the tobacco industry. It appears that new entrants would be treated similar to non-participating manufacturers under Title VI and thus would be subject to advertising and access restrictions, regulatory oversight, and the payment provisions, but would not receive the benefit of any limitations on liability. There are no provisions in the legislation that would prevent new entrants from challenging the constitutionality of the legislation.

Mary —  
Draft answer to  
last question + ack  
latest edit.

Thanks,  
Tom P.

[In general. Add McCain's introductory sentences in each heading (as we have done in sections III-V). Many of the questions and answers do not make sense without them.]

## **I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS**

1. What data does the administration have to substantiate that a ban on outdoor advertising, including stadia and arenas, will reduce smoking and, in particular, youth smoking?

The FDA tobacco rule prohibits outdoor advertising within 1,000 feet of public playgrounds and elementary and secondary schools. All other outdoor advertising is restricted to black text on a white background, devoid of color and imagery. FDA's regulations are based on the agency's finding that children and adolescents spend a great deal of time in areas around schools and playgrounds and these areas, therefore, should be free of tobacco product advertising. All other outdoor advertising should be restricted to text information only, which generally is not as appealing to young people. (See response to II, below.) Data supporting this conclusion are detailed at 61 Fed. Reg. 44501-08.

2. To what extent do you believe such restrictions can be expected to reduce smoking?

FDA's advertising restrictions are based on quantitative and qualitative studies of cigarette advertising that show that a causal relationship exists between tobacco advertising and tobacco use by young people and that stringent advertising restrictions, when combined with a comprehensive program designed to reduce initiation and use among young people, will have a positive effect on reducing smoking rates and youth tobacco use.

FDA's findings regarding the ability of advertising restrictions to reduce youth tobacco use are summarized at 60 Fed. Reg. 41330-34 and 61 Fed. Reg. 44466-500.

3. Does the administration support such a ban. If so, why? If not, why not?

The administration supports appropriate restrictions on outdoor advertising, as evidenced by the FDA tobacco rule (21 C.F.R. 897.30(b)) which prohibits outdoor advertising for cigarettes and smokeless tobacco, including billboards, posters, or placards, from being placed within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary or secondary school. All other outdoor advertising is limited to black text on a white background (21 C.F.R. 897.32(a)).

The prohibition set forth in Section 101(a)(1), however, would prohibit "any form of outdoor tobacco product advertising, including bill boards, posters, or placards." It does not contain the exception for tombstone advertising in certain locations that is included in the FDA regulation. Because that exception ensures that the FDA regulations are appropriately

02/23/88 WED 14:00 FAX  
tailored to serve the government's substantial interest in reducing teenage smoking, Section 101(a)(1)'s broader restriction on all outdoor tobacco advertising raises significant constitutional concerns that are not presented by the FDA regulations.

4. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

As discussed above, the administration's efforts have been focused on supporting the restrictions now codified in FDA regulations. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the outdoor advertising of tobacco products. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

## II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

1. What data does the administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular youth smoking?

FDA's regulations restrict advertising, with certain exceptions, to black text on a white background. ~~No color or imagery is permitted.~~ These restrictions encompass a prohibition of human figures and cartoon characters. ~~The restrictions apply to billboards, publications, in-store advertising, and direct-mail advertisements.~~ FDA's findings in this area are summarized at 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44466-68, 44508-13. FDA's *Federal Register* documents contain specific evidence and summaries of studies. See 60 Fed. Reg. 41333-34 and 61 Fed. Reg. 44475-82. ✓

2. To what extent do you believe such restrictions can be counted on to reduce youth smoking?

See response to I.2., above.

3. What entity would you propose to determine what constitutes a human image or cartoon character?

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

4. What penalty do you believe is appropriate and should accrue for a

**violation of the prohibition on material containing figures determined to be human or cartoon?**

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

**5. Does the administration support this ban? If so, why? If not, why not?**

The administration supports appropriate advertising restrictions, as evidenced by the FDA tobacco rule. Section 101(b) of S. 1414 provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products, which provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in an "adult publication," one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii). The provision's broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present.

In any event, the administration urges the Congress to provide statutory confirmation of the existing authority of the FDA to regulate the use of images in the advertising of tobacco products. This regulatory approach would ensure that the FDA would be authorized, based on existing and future research, to develop necessary and appropriately tailored supplements to its current restrictions, if and when such supplements are needed.

**6. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

As discussed above, the administration's efforts have been focused on the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in discussing how these restrictions will be implemented and the associated penalties, and whether further restrictions are constitutional and otherwise appropriate.

### **III. BAN ON INTERNET ADVERTISING**

The agreement (bill page 16) bans tobacco advertising on the Internet.

**1. Does the administration support such a ban? If so, why? If not, why not?**

- 02/23/88 WED 13:00 FAX
2. How can and should a ban on Internet advertising of cigarettes be enforced?
  3. What, if any, concerns does the administration have regarding the constitutional free speech issues raised by any such ban?
  4. What specific changes, if any, in the legislative language implementing the ban would the administration propose?

In response to Questions III.1 - III.4, the administration believes ~~notes that, insofar as S.1414's proposed complete ban on Internet advertising of tobacco products would be for the purpose of diminishing minors' exposure to such advertising, it would raise significant constitutional concerns, because there might be more narrowly tailored means of achieving such a governmental objective. Cf. Reno v. ACLU, 117 S.Ct. 2329, 2346-48 (1997), interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(e) of S.1414 would impose would raise significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329, 2348 (1997), (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). We would therefore caution the Congress about adopting such a broad measure at this time.~~

V

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This ~~would regulatory approach will ensure that any future regulatory restrictions are targeted at appropriate the right forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focused Internet restriction.~~

V

~~[NOTE: IV and V, below, have been substantially restructured, and slightly altered. Please review in toto.]~~

V

#### IV. BAN ON POINT-OF-SALE ADVERTISING

The agreement (bill page 16) bans point-of-sale tobacco [advertising] except for advertisements which comply with certain restrictions.

1. What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

See responses to I.2. and II.1., above. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising,

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- 02/20/99 WED 10:00 PM
2. How can and should a ban on Internet advertising of cigarettes be enforced?
  3. What, if any, concerns does the administration have regarding the constitutional free speech issues raised by any such ban?
  4. What specific changes, if any, in the legislative language implementing the ban would the administration propose?

In response to Questions III.1 - III.4, the administration believes notes that, insofar as S. 1414 would impose a complete ban Internet advertising for the purpose of diminishing minors' exposure to such advertising, it would raise significant constitutional concerns, because there might be more narrowly tailored means of achieving such a governmental objective. Cf. Reno v. ACLU, 117 S.Ct. 2329, 2346-48 (1997). interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(e) of S. 1414 would impose would raise significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329, 2348 (1997). (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). We would therefore caution the Congress about adopting such a broad measure at this time.

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This ~~would~~ regulatory approach will ensure that any future regulatory restrictions are targeted at appropriate the right forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focused Internet restriction.

[NOTE: IV and V, below, have been substantially restructured, and slightly altered. Please review in toto.]

#### IV. BAN ON POINT-OF-SALE ADVERTISING

The agreement (bill page 16) bans point-of-sale tobacco [advertising] except for advertisements which comply with certain restrictions.

1. What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

See responses to I.2. and II.1., above. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509 - 44510. Point-of-sale advertising

insignificant youth readership, would not have a significant adverse effect on efforts to reduce youth tobacco use]. ~~This change suggested by HHS.~~

4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?
5. Does such a privilege constitute a statutorily granted competitive advantage? If so, why? If not, why not?
6. Does the administration support this grant? If so, why? If not, why not?
7. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.

In response to Questions IV.4 - IV.7, we note that Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point-of-sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed, it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the administration are available to assist the Committee in exploring those concerns.

## V. LIMITATIONS ON POINT-OF-SALE ADVERTISING

The agreement (bill page 17) specifies the size and design of permissible point-of-sale advertising.

1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?

See responses to IV.1. and IV.2, above.

2. Does the administration support this provision? If so, why? If not, why not?
3. If so, what is the justification for statutorily determining a particular size limitation and for the particular size and [design] restrictions proposed?
4. What specific changes in legislative language, if any, does the administration propose? Please provide specifics.

In response to Questions V.2 - V.4, the administration supports appropriate

02/23/88 WED 10:01 FAX  
presents children and adolescents with an enticement at the time when purchase is immediately available.

**2. Does the administration support such a ban? If so, why? If not, why not?**

Section 101(d) of S.1414 would, in general, limit each manufacturer of tobacco products to the display of not more than two separate point-of-sale advertisements in any location at which tobacco products are sold, and would limit each retailer to the display of one point-of-sale advertisement relating to the retailer's own or its wholesaler's contracted retailer or private label brand product. The bill also would require that these point-of-sale advertisements consist only of black letters on a white background, and not be larger than a prescribed size. However, the bill would include a significant exception to these limitations for "adult-only stores and tobacco outlets." Sec. 101(d)(2).

The FDA regulations contain restrictions that are targeted at point-of-sale advertising similar to those proposed in S.1414. They are not quite as broad as those set forth in S.1414 in that there is no numerical limitation and no size limitation. See 21 C.F.R. §§ 897.32, 897.16. Moreover, unlike S.1414, the FDA regulations do not include an exemption for certain manufacturers with a substantial market share.

Under both the FDA regulation and the S.1414 proposal, manufacturers and retailers limited to text-only advertising at the point of sale would not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to minors. Children and adolescents, who are less likely than adults to process print information in a leisurely setting (such as reading a magazine), will find textual material even less appealing in the few moments spent at the retail counter.

The administration supports appropriate restrictions on point-of-sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

**3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?**

The administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations and publications read primarily by adults because ~~there is little reason to believe the evidence then available showed~~ that advertising in locations where children are never present, such as adult-only locations, or are rarely exposed, as is the case with publications with an

✓

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restrictions on point-of-sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions -- such as those limiting the size of point-of-sale advertisements -- are constitutional and otherwise appropriate.

## **VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS**

- 1. Are such agreements currently against federal or state law? If so, is such a provision necessary?**

Ordinarily, under the free market system, retailers are permitted to decide from whom and to whom they will buy and sell, and on what terms. While an agreement of the sort described -- between a manufacturer and a retailer to limit the ability of a competing manufacturer to display advertising on the retailer's premises -- might be anticompetitive under certain circumstances, such agreements are usually not condemned under the federal antitrust laws. The administration has not undertaken a review of state laws to determine whether such an arrangement would violate the law of any state.

- 2. Does the administration support such a provision? If so, why? If not, why not?**

The administration's primary concern is not the relationship of retailers, manufacturers, and distributors between or among one another with respect to advertising. Rather, the administration wants to ensure that point-of-sale advertising and promotional material, whatever their source, consist only of black text on a white background.

- 3. Does the administration support the limitation. If so, why? If not, why not?**

See answer to question 2 above.

- 4. What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.**

See answer to question 2 above.

## **VII. GLAMORIZATION OF TOBACCO**

- 1. What data does the administration possess to indicate whether and to what**

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**extent this provision will reduce smoking, particularly among youth?**

A number of studies (Tye 1990; Terre, Drabman, and Speer 1991; Hazan, Lipton, and Glantz 1994; Thumbs Up! Thumbs Down! 1997) show that depictions of tobacco use in the entertainment media, particularly feature films, are on the increase and exaggerate greatly the actual prevalence of tobacco use in the U.S. population. Research also suggests that adolescents are highly susceptible to pro-smoking messages and images conveyed in entertainment media (Signorielli 1993; Davies 1993; Basil 1997). Focus group research found that young people are able to recall virtually no anti-smoking messages on TV or in the movies, yet they are able quite readily to recall specific movies that portray smoking and to identify actors and actresses who smoke in their entertainment roles (Mermelstein 1997). Deglamorizing tobacco use in the entertainment media can be achieved both by decreasing pro-smoking cues and by increasing anti-smoking cues. A study by researchers at the University of California at Irvine suggests that anti-smoking advertisements before movies can help inoculate young people against the positive images of smoking that appear in movies. Ninth graders who watched the movie "Reality Bites" (in which the cast smokes in about one-third of the scenes) preceded by a California Department of Health Services anti-smoking ad were much less likely to find smoking exciting compared with teens who watched the movie without the counter-advertisement (Pechmann, 1996).

2. **What entity does the administration propose will determine what activity constitutes promoting the image or use of a tobacco product?**
3. **How does the administration envision such a ban will be enforced?**
4. **Does the administration support such limitations?**
5. **What specific changes, if any, in the legislative language would the administration propose? Please provide specifics.**

In response to Questions VII.2 - VII.5, the administration believes that the scope of the restriction on glamorization in S. 1414 is unclear. For example, is the provision intended only to restrict attempts to promote certain brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, then the provision would appear to reach some noncommercial speech, raising significant constitutional concerns. It is also not clear what is meant by the use of the word "promoting." Finally, the phrase "appeals to individuals under 18 years of age" could be subject to challenge on vagueness grounds.

Alternatively, no such constitutional concerns would be raised if Congress enacted legislation that would confirm the authority of the FDA to regulate the advertising of tobacco products through such indirect means as the use of product placement agreements.

## VIII. RESTRICTIONS ON COLOR ADVERTISEMENTS

What data does the administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking particularly youth smoking?

See response to II.1., above.

2. Does the administration believe that the threshold for the restriction of two million readers is the appropriate threshold?

FDA's tobacco rule requires that advertising be restricted to black and white text, except in publications that are read primarily by adults or in adult-only facilities. The text-only requirement is intended to reduce the appeal of cigarettes and smokeless tobacco advertising to young people without unduly affecting the informational messages conveyed to adults. Therefore, FDA proposed in its rulemaking that advertising in so-called "adult" publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people should be nominal. The agency set the definition of adult publication as those whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or those which are read by two million or fewer people under age 18, whichever method results in the lower number of young people. (Magazines with small readership numbers but which appeal to young people may not attract two million young readers but may still be primarily youth oriented; that is, 15 percent or more of their readers are under 18.) In addition, the agency noted that at some point, the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. For example, a magazine with a large total readership base may attract as many as 5 million young people, or more, but those numbers would still not be 15 percent of the magazine's readership. See 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44513-19. ✓

3. How does the administration envision readership demographics being determined?

In its tobacco rulemaking, FDA explained that readership demographics would be determined by measuring the total number of people that read any given copy of a publication. Readership demographics would be measured according to industry standards and, at a minimum, would be based on a nationally projectable survey of people. Two examples of currently available surveys are Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK. FDA also indicated that it would be willing to work with industry on this issue. See 61 Fed. Reg. 44516-19.

4. How would this restriction be enforced?

The restriction would be enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Federal Food, Drug and Cosmetic Act

which provides for the imposition of civil money penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. Does the administration support this restriction? If so, why? If not, why not?

The administration supports the regulation in the FDA rule based upon the findings of the Food and Drug Administration regarding the role and attractiveness of images and color in advertising to young people. See, e.g., 61 Fed. Reg. 44467-68, 44509 (1996).

6. What specific changes, if any, in the legislative language implementing the restriction does the administration propose? Please provide specifics.

As discussed above, the administration supports effective restrictions on the use of color and imagery in tobacco advertising. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the advertising of tobacco products.

#### IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN

1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.

The answers to Parts I-VIII above address the government's authority to impose restrictions on advertising and marketing without the industry's consent. We address here the degree to which "the industry's consent" may affect the constitutional analysis of the advertising restrictions.

We believe that the constitutional analysis of such restrictions might be affected if the industry's adoption of those advertising restrictions that either could not be constitutionally imposed upon the industry, or that exceed the restrictions that are imposed by the FDA regulations, were in some way made contingent upon the industry's willingness to adopt them. For example, we believe that the inclusion of such restrictions in state court consent decrees between states and tobacco manufacturers -- rather than in federal legislation -- would significantly increase the likelihood that the restrictions would be upheld if challenged in the future. However, the inclusion of such restrictions in a federal statute that made adherence to such restrictions a condition of the receipt of certain federal benefits would continue to raise substantial constitutional questions. Such a statute, depending on how it were framed, would be subject to substantial challenge under the unconstitutional conditions doctrine. ✓

## **X WARNING LABELS**

**Does the administration believe that these are appropriate warning labels?**

The administration supports the concept of strengthening warning label statement requirements. Several recent studies (Health Canada 1996; Borland, Cappiello, and Hill 1996; Robinson and Killen 1997) and literature reviews (USDHHS 1994; IOM 1994 ) are available concerning the effectiveness of warning labels in conveying information to consumers. The administration's resources are available to help the Committee evaluate possible improvements to warning label requirements.

**Does the administration possess data suggesting that these warnings will effectively reduce smoking, particularly youth smoking?**

See response to X.1., above.

**What data suggests that the various new warnings will be as or more effective than the current warning requirements?**

See response to X.1., above.

**Does the administration support the provisions authorizing specific new labels? If so, why? If not, why not?**

**What specific changes, if any, in the legislative language implementing this provision would the administration propose? Please provide specifics?**

As stated above, the administration is available to work with the Committee in determining whether changes to the warning statement requirements are appropriate.

## **IX. WARNING LABEL SIZE AND LOCATION REQUIREMENTS**

**What data does the administration have to suggest that these specifications will reduce smoking, particularly youth smoking?**

See response to X.1., above.

**Does the administration support these particular specification? If so, why? If not, why not?**

**Does the administration support the exception provided for flip-top cigarette packages? If so, why? If not, why not?**

What specific changes, if any, in the legislative language to implement these restrictions would the administration propose? Please provide specifics.

The administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

**X.**

### **SMOKELESS TOBACCO ALTERNATIVE LABELS**

What data does the administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?

See response to X.1., above.

Does the administration support the use of these alternative labels?

What changes, if any, to the legislative language implementing this provision would the administration propose? Please provide specifics.

The administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

### **XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS**

1. Does the administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?

Section 114 of the bill ~~would provide the~~ provides FTC with the authority to enforce sections 111 and 112, the provisions relating to warning statement requirements. Section 114 also contains a penalty provision for violations of section 113, the requirement that companies provide ingredient information to the Secretary of HHS pursuant to a new provision of the Federal Food, Drug, and Cosmetic Act, and authorizes the FTC to bring actions to enforce that provision. With respect to sections 111 and 112, section 114 appears to maintain the status quo with respect to warning label enforcement issues. Some other proposed bills would shift that authority to FDA. The administration is available to assist in the Committee in considering these differing approaches. With regard to section 113, which relates to a provision of FDA law, the administration would be pleased to assist the Committee in evaluating whether enforcement authority for the ingredient disclosure

requirements may be more appropriately vested entirely in FDA.

2. What changes in legislative language, if any, does the administration recommend regarding these provisions? Please provide specific language.

As discussed above, the administration would be pleased to assist the Committee in evaluating issues related to the enforcement of advertising, marketing, and labeling restrictions, and in developing modifications, if appropriate, to legislative language.

## **XII. PREEMPTION OF STATE AND LOCAL ACTION**

1. Does the administration support such preemption? If so, why? If not, why not?
2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language?

The administration generally supports the limited preemption of state and local requirements related to the packaging of cigarettes or smokeless tobacco, but does not support the preemption of state and local restrictions on advertising. FDA's current promulgated regulations address advertising. Although the regulations are preemptive, the Federal Food, Drug and Cosmetic Act allows states and localities to apply for waivers to be exempted from federal thresholds. This would allow states and localities to enact or retain existing advertising restrictions that would be more stringent.

The administration is available to work with the Committee with respect to the broader issues of preemption raised by other provisions of the bill. The administration is committed to allowing states and localities the maximum flexibility practicable to develop strong public health policies to prevent and reduce youth tobacco use.

## **XIII. EXEMPTION OF EXPORTS**

1. Does the administration support this exemption? If so, why? If not, why not?

No. As the world's leading exporter of tobacco products, the United States has the obligation to guarantee that its companies will behave responsibly no matter where they do business. There should be no exemptions for policies that would undermine [?] safeguard the health and well being of people anywhere in the world. | ✓

2. What ramifications does this provision have in the area of foreign relations?

Adopting a less stringent policy towards exported tobacco products would send a negative message to the countries where these products are sold -- that the health and well being of their citizens, particularly their children, are less important than the health and well being of Americans.

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

[USER to provide answer.]

#### XIV. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS

1. Does the administration support these provisions? If so, why? If not, why not?

The administration supports access restrictions based upon FDA's findings regarding the ability of persons under 18 to purchase tobacco products in the absence of a photo identification requirement. See, e.g., 61 Fed. Reg. 44437-39 (1996).

2. How does the administration envision that this provision will be enforced, and can it be enforced effectively?

FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing the age and photo ID provisions cooperatively with state and local officials. Because of the enormous number of retailers that sell tobacco, FDA has adopted a cooperative model. By way of comparison, this is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country—by commissioning the services of state and local officials.

In its initial enforcement efforts, FDA contracted with 10 states. Under these contracts, states are conducting between 200 and 330 unannounced retail compliance checks each month over a period of eight months. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to the adolescents. These retailers will be subject to repeat inspections. FDA will seek a fine of \$250 for the second violation and greater fines for subsequent violations. FDA is in the process of contracting with additional states.

FDA anticipates that state and local contracts will provide effective mechanisms to check compliance with other access restrictions, such as the requirement that all transactions

be face-to-face, without the assistance of any electronic device. Commissioned state and local officials will be able to determine compliance with these and similar provisions by visiting facilities, and appropriately documenting observations.

#### **XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES**

1. Does the administration support this prohibition? If so, why? If not, why not?

The administration supports this prohibition based upon FDA's findings regarding the ability of persons under 18 to obtain cigarettes when they are sold in units of less than a full pack. See, e.g., 61 Fed. Reg. 44443, 44445-48.

2. What change in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

The administration does not recommend any changes in the legislative language.

#### **XVI. STATE LICENSURE TO SELL TOBACCO**

1. What data, if any, does the administration have to indicate that licensure will effectively reduce access to tobacco by minors?

Licensure of retailers will give authorities the means of identify those retailers who sell tobacco. States that do not require licensure are having difficulty complying with the Synar amendment, because they have difficulty identifying outlets that sell tobacco products. In addition to providing a list of retailers, the threat of license revocation for noncompliance is extremely motivating to retailers. Furthermore, license fees can be used to cover the cost of enforcement, which is an important determinant of compliance.

2. What entity does the administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?

The administration supports a licensing program that is operated at the state or local levels. The responsible federal agency should have authority to devise a program and set national standards that the participating state and local programs implement.

3. Has the administration developed or formulated the cost of the licensure program? If so, why? If not, why not?

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The administration has not completed work regarding the cost of a licensure program.

4. Does the administration support the licensure program? If so, why? If not, why not? *[Sentences that are bold and in italic still are proposed by DOJ without HHS concurrence.]*

The administration supports an effective licensing program. Federal legislation that calls upon states to establish regulatory programs must be sensitive to federalism concerns. *Section 131 would provide two incentives for states to establish licensing programs for retail distributors of tobacco products. States that establish satisfactory licensing programs (1) would avoid imposition of a federal ban on retail distribution of tobacco products within their borders; and (2) would qualify for block grants under section 502. Congress possesses authority, under principles discussed in New York v. United States, 505 U.S. 144, 173-74 (1992), to "offer States the choice of regulating that activity according to federal standards or having state law pre-empted by federal regulation." Congress also possesses authority, under Spending Clause principles discussed in South Dakota v. Dole, 483 U.S. 203 (1987), to condition the receipt of federal funds by states on their implementation of certain regulatory measures. Accordingly, although the section 131 incentives for state licensing may give rise to constitutional challenges, we believe that they are consistent with the Constitution.*

5. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

The resources of the administration are available to ~~assist~~ work with the Committee in evaluating provisions for a licensing program.

## **XVII. ANTI-TRUST EXEMPTION**

1. Does the administration support such an exemption? If so, why? If not, why not?

The antitrust laws are the most important protector of the free-market economy against anticompetitive actions that would undermine its integrity to the detriment of consumers. Accordingly, exceptions to the antitrust laws should be made only in exceedingly rare instances, when the fundamental free market values underlying the antitrust laws are compellingly overwhelmed by a paramount policy objective; and a proposed exemption must be necessary to permit the paramount policy objective to be pursued. The proponents of an antitrust exemption for the tobacco industry thus face a heavy burden, which they have not yet met.

2. Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?

An antitrust exemption that allowed tobacco firms to set prices jointly could be used by firms to increase prices beyond what is necessary to deter youth smoking and thereby to increase profits at the expense of consumers. It would be very difficult to restrict use of the exemption to its intended purpose, because the tobacco companies would have both the opportunity and the incentive to effect unnecessary price increases and to conceal them under the guise of restrictions on youth smoking. While the resulting collusive price increase would be likely to reduce demand for tobacco products, it would also increase profits for the tobacco companies, at least to the point at which they are collectively charging the "monopoly price." The tobacco companies would thereby be able to use an antitrust exemption to enrich themselves at the expense of those confirmed with smoking habits.

3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.

Before any exemption is considered for enactment, the proponents of the exemption need to meet the burden of demonstrating that this is one of the exceedingly rare instances in which the antitrust laws are incompatible with a clearly paramount policy objective. The administration is extremely skeptical that the proponents of this case will be able to meet that burden.

Even in those rare instances in which that burden is met, any antitrust exemption should be carefully and narrowly crafted to address that objective in the least anticompetitive manner available. If Congress should decide to move forward with consideration of antitrust exemptions for the tobacco industry, the administration would be available to assist in crafting them as narrowly and precisely as possible to achieve their purpose without creating unnecessary anticompetitive effects. ✓

#### **XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY**

[Still have to work this one out.] Whatever the ultimate answer, it should make the following point -- The inclusion of provisions that would enable new entrants to "consent" to restrictions on their advertising would be subject to constitutional review in accord with the principles discussed in our answer to question 9.]

## ADDITIONAL REFERENCES

### VII. GLAMORIZATION

Basil MD. The danger of cigarette "special placements" in film and television. *Health Communication* 1997;9(2):191-198.

Davies J. The impact of the mass media upon the health of early adolescents. *Journal of Health Education* 1993 Supplement:S28-S35.

Mermelstein R. The CDC Tobacco Control Network: understanding factors that influence youth tobacco use. Progress Report October 1995 - September 1997. Chicago, IL: Prevention Research Center, University of Illinois at Chicago.

Pechmann C. Inoculation effect of tobacco counter-advertising. University of California-Irvine, 1997.

Signorielli N. Mass media images and impact on health: a sourcebook. Westport, CT: Greenwood Press, 1993.

Terre L, Drabman R, Speer P. Health-relevant behaviors in media. *Journal of Applied Social Psychology* 1991;21:1303-1319.

Thumbs Up! Thumbs Down! Teens take a look at tobacco use in the movies. American Lung Association of Sacramento-Emigrant Trails, 1997.

Tye JB. Tobacco and youth reporter. Longmeadow, MA: Stop Teenage Addiction to Tobacco, 1990.

### X. WARNING LABELS

Borland R, Cappiello M, Hill D. Impact of the new Australian health warnings on tobacco products. Carlton South, Victoria: Anti-Cancer Council of Victoria, 1996.

Health Canada. Effectiveness of health warning messages. Toronto, Ontario: Tandemar Research Inc., 1996.

Institute of Medicine. Warnings and packaging. Growing up tobacco free: preventing nicotine addiction in children and youths. Washington, DC: National Academy Press, 1994:236-246.

Robinson TN, Killen JD. Do cigarette warning labels reduce smoking? Paradoxical effects among adolescents. *Archives of Pediatric and Adolescent Medicine* 1997;151:267-272.

U.S. Department of Health and Human Services. Warning labels on tobacco products. In Preventing tobacco use among young people: a report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, 1994:257-264.

Food and Drug Administration

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August 11, 1995

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Part V

**Department of  
Health and Human  
Services**

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**Food and Drug Administration**

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21 CFR Part 801, et al.

**Regulations Restricting the Sale and  
Distribution of Cigarettes and Smokeless  
Tobacco Products To Protect Children  
and Adolescents; Proposed Rule  
Analysis Regarding FDA's Jurisdiction  
Over Nicotine-Containing Cigarettes and  
Smokeless Tobacco Products; Notice**

middle, trying and experimenting stages occur when the first cigarette is smoked, often at the urging of a peer, and becomes repeated but irregular. It is important to note that those who experiment often, or begin smoking at an early age, are much more likely to become regular smokers.<sup>113</sup> Therefore, age of initiation is important.

The final stage, nicotine dependence and addiction, is characterized by a physiological need for nicotine. At this stage, the adolescent develops a tolerance for nicotine and can experience withdrawal symptoms (such as dysphoric or depressed mood, insomnia, irritability, frustration or anger, anxiety, and difficulty concentrating) if he or she attempts to quit. However, of those who try to quit, few succeed without help, and there is a high probability of relapse.<sup>114</sup>

In the early stages of smoking, i.e., at initiation, psychosocial factors are decisive, and those factors are most often capitalized on in the themes used in tobacco product advertising. In the final stage, as smoking takes hold, physiological factors (and even health concerns) dominate. A document prepared by Imperial Tobacco Ltd. stated:

At a younger age, taste requirements and satisfaction in a cigarette are thought to play a secondary role to the social requirements. Therefore taste, until a certain nicotine dependence has been developed, is somewhat less important than other things.<sup>115</sup>

Many behavioral and personal characteristics influence an adolescent's decision to use cigarettes or smokeless tobacco products, including: rebelliousness; risk-taking personality; use of other legal or illegal drugs; belief in the perceived utility of smoking (to cope with stress, control weight, or improve one's self-image); low self-esteem or depression; disbelief of or discounting health risks; and poor academic achievement.<sup>116</sup> Cognitive factors specific to children and adolescents also play a role in the early decision to smoke. Children and adolescents often focus on present needs and concerns, and ignore risks that might exist in the future. They exhibit a sense of personal invulnerability that permits them to act as if they were immortal.<sup>117</sup> Tobacco advertising plays on these feelings and exploits these adolescent vulnerabilities. As one report, created for a Canadian cigarette company, stated:

Starters no longer disbelieve the dangers of smoking, but they almost universally assume these risks will not apply to themselves

because they will not become addicted. Once addiction does take place, it becomes necessary for the smoker to make peace with the accepted hazards. This is done by a wide range of rationalizations.<sup>118</sup>

### 3. Industry's Marketing Practices

Industry documents indicate that cigarette manufacturers have conducted extensive research on smoking behavior and attitudes in young people and how advertisements should be made to appeal to young people. Documents from Philip Morris files indicate that the company did, at least on one occasion, conduct research about the smoking habits of young people, questioning people in Iowa, including teen-agers as young as 14.<sup>119</sup> More specifically, research conducted for a Canadian affiliate of one U.S. cigarette firm focused on the need to attract young consumers, stating:

Ads for teenagers must be denoted by a lack of artificiality, and a sense of honesty. Attempts at use of celebrities \*\*\* do not seem to really click. If freedom from pressure and authority can also be communicated, so much the better.<sup>120</sup>

Research conducted by an American cigarette firm, and confirmed by other tobacco companies, revealed another significant behavior: most smokers continue to purchase the brand they smoked when they became regular smokers. Brand loyalty is seen in many consumer products (such as toothpaste, coffee, and automobiles) but is particularly strong for tobacco products. A 1989 "Wall Street Journal" article showed cigarettes as having the highest percentage of brand loyalty among consumers of any consumer product, at 71 percent.<sup>121</sup>

Knowledge about brand loyalty among cigarette smokers, coupled with the fact that most smokers began smoking before the age of 18, may explain why cigarette manufacturers have focused advertising and promotional efforts on younger people. R.J. Reynolds devised what it called a "Young Adult Smokers" ("YAS") program that was apparently designed to appeal specifically to young smokers, 18 to 24 year olds, and more narrowly to 18 to 20 year olds. An element of that program, known as FUBYAS, an acronym for First Usual Brand Young Adult Smokers, captured the concept that a smoker's first regular brand is the brand a smoker will stay with for years. This program featured the use of promotional items, such as hats and tee shirts bearing the Camel brand name, the cartoon Joe Camel, and imagery, that appealed to young people. Although these programs were ostensibly directed at people between the ages of 18 and 24,

company memoranda suggest that the target population included high school students. For example, on January 10, 1990, a manager in Sarasota, Florida, issued a memorandum asking cigarette sales representatives to identify stores:

\* \* \* that are heavily frequented by young adult shoppers. These stores can be in close proximity to colleges [,] high schools or areas where there are a large number of young adults [who] frequent the store.<sup>122</sup>

On May 3, 1990, when the "Wall Street Journal" published this memorandum, the cigarette firm stated that the memorandum was a "mistake" and violated company policy by targeting high schools.<sup>123</sup>

Yet, on April 5, 1990, a manager in Moore, OK, issued a similar memorandum regarding the YAS program asking sales and service representatives to identify what was termed "Retail Young Adult Smoker Retailer Accounts." One criterion for identifying a YAS account included facilities "located across from, adjacent to are [sic] in the general vicinity of the High Schools or College Campus [sic]." <sup>124</sup> This second memorandum suggests that promotions aimed at high school students were part of the company's marketing strategy.

Sales figures suggest that the YAS program was extremely effective. Camel quickly became one of the most popular cigarette brands among people under age 18. Prior to the introduction of the Joe Camel campaign, Camel cigarettes commanded no more than 3 or 4 percent of the youth market. One year into the campaign, the youth share rose to 8.1 percent and by 1991 it was at least 13 percent.<sup>125</sup>

While not all advertising campaigns are so blatantly directed at juveniles, campaigns using more universal themes can be as effective with young people. According to an advertising executive with the advertising agency that created the Marlboro cowboy, "The Marlboro cowboy dispels the myth that in order to attract young people, you've got to show young people." The cowboy theme of independence can be translated into other venues that have appeal for young people and be sold as an appropriate and desirable image. According to John Landry, the Philip Morris executive credited with designing the Marlboro campaign, the Marlboro theme sells because it fits young people's desires. In 1973, Philip Morris sponsored the Marlboro Cup for the first time. Landry recalls that "Secretariat [the winning horse] became a hero to young people. Youth were reaching out for something, and someone they could identify with \* \* \*

'Marlboro Country' fit these desires, this search people were going through." "Something young people could trust." A candid appraisal of the purpose of the Marlboro theme was provided by the marketing director with Philip Morris in Argentina, "Marlboro magic—people using things with [the] Marlboro logo \* \* \* was projected to other products around it and when those kids who were playing with Marlboro merchandise 5 to 10 years ago—when they start smoking they'll smoke Marlboro."<sup>126</sup>

With regard to smokeless tobacco products, the U.S. Tobacco Company (UST) successfully revived a declining market by targeting young people, especially young men, in its promotion and advertising. In 1970, the segment of the population with the highest use of these products was men over age 50, and young males were among the lowest. Fifteen years later, there had been a 10-fold increase in the use of smokeless tobacco products among young males, whose use was double that of men over age 50.<sup>127</sup>

The increased use of smokeless tobacco products by young people was precisely the objective of a marketing strategy of UST set in motion almost 30 years ago. In 1968, officials at UST held a marketing meeting 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."<sup>128</sup> Another official who attended the meeting was quoted as saying, "We were looking for new users—younger people who, by reputation, wouldn't try the old products."<sup>129</sup> When a rival company developed a smokeless tobacco product that 9-year-old children began using, a UST regional sales manager reported to UST's national sales manager that the product was mostly used by children and young adults "from 9 years old and up" and noted that this age was "four or five years earlier than we have reached them in the past."<sup>130</sup>

Responding to a question years later about why so many young males were buying smokeless tobacco, Louis F. Bantle, then chairman of the board of UST said, "I think there are a lot of reasons, with one of them being that it is very 'macho'."<sup>131</sup> Playing to this "macho" perception of smokeless tobacco by young males, advertisements for smokeless tobacco products have traditionally used a rugged, masculine image and have been promoted by well-known professional athletes. UST's successful penetration into the youth market is indicated in a statement by Mr. Bantle: "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'."<sup>132</sup>

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 for recruiting new, younger users.<sup>133</sup>

Tobacco companies deny any youth-directed advertising and promotion activities.<sup>134</sup> Moreover, the industry claims that advertising plays no role in a person's decision to start smoking; that tobacco advertising is designed solely to capture brand share from competitors and maintain product loyalty. The industry further claims that the tobacco market is a "mature" market in which awareness of the product is universal and overall demand is either stable or declining.<sup>135</sup> In a mature market, the industry contends, advertising functions to merely shift customers from one brand to another, but does not act as a stimulus to new customers to enter the market.

One purpose of cigarette advertising may be to encourage or discourage brand switching among current tobacco users. Some experts believe, however, that this same advertising encourages new consumers to begin using these products.<sup>136</sup> Tobacco advertising, promotion, and marketing, on which the industry spends over \$6 billion each year, may serve both purposes largely out of market necessity. Market expansion, in the sense of new customers entering the market, must occur to maintain total tobacco sales and avoid a significant market decline. "[T]he cigarette industry has been artfully maintaining that cigarette advertising has nothing to do with total sales. \* \* \* [T]his is complete and utter nonsense. The industry knows it is nonsense," wrote a former cigarette advertising executive.<sup>137</sup>

Evidence indicates that acquiring a portion of the "starter" market,

overwhelmingly people in their teens, is regarded by the industry as essential to a company's continuing economic viability. One document acquired from Imperial Tobacco Limited (ITL) of Canada, a sister company of the Brown & Williamson Company in the United States, states:

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."<sup>138</sup>

To further this goal, ITL hired a consulting research company to investigate attitudes about smoking among people aged 15 years and older. The purpose of the research, i.e., how best to recruit new smokers, is indicated in the following statement:

It is no exaggeration to suggest that the tobacco industry is under siege. The smoker base is declining, primarily as a function of successful quitting. And the characteristics of new smokers are changing such that the future starting level may be in question.<sup>139</sup>

Similar attitudinal research was done for R.J.R.-MacDonald, Inc., the Canadian subsidiary of R.J. Reynolds.<sup>140</sup> A report entitled YOUTH 1987 closely examined the lifestyles and value systems of "young men and women in the 15-24 age range." The report said the research would:

provide marketers and policymakers with an enriched understanding of the mores and motives of this important emerging adult segment which can be applied to better decision making in regard to products and programs directed at youth.<sup>141</sup>

A similar research objective was described in a 1969 research paper presented to the Philip Morris Board of Directors.<sup>142</sup> The paper stated that one of its objectives was to probe "[w]hy do 70 million Americans \* \* \* smoke despite parental admonition, doctors' warnings, governmental taxes, and health agency propaganda?"<sup>143</sup> The paper continues:

There is general agreement on the answer to the first [question—why does one begin to smoke.] The 16 to 20-year old begins smoking for psychosocial reasons. The act of smoking is symbolic; it signifies adulthood, he smokes to enhance his image in the eyes of his peers.<sup>144</sup>

Cigarette manufacturers are also aware of the difficulties young people encounter when they try to quit smoking. Studies prepared for a Canadian affiliate of a U.S. cigarette company state:

However intriguing smoking was at 11, 12, or 13, by the age of 16 or 17 many regretted their use of cigarettes for health reasons and because they feel unable to stop smoking when they want to.<sup>145</sup>

Another document declares:

[T]he desire to quit seems to come earlier now than before, even prior to the end of high school. In fact, it often seems to take hold as soon as the recent starter admits to himself that he is hooked on smoking. However, the desire to quit, and actually carrying it out, are two quite different things, as the would-be quitter soon learns.<sup>146</sup>

Thus, these documents and reports suggest that cigarette manufacturers know that young people are vital to their markets and that they need to develop advertising and other promotional activities that appeal to young people. They also suggest that cigarette manufacturers know that once those young people become regular smokers, that they, like adult smokers, find quitting smoking to be very difficult, and most young people fail in their attempts to quit.

#### 4. Empirical Research on the Effects of Cigarette Advertising Activities on Young People

The 1994 Surgeon General's Report concluded that "[a] substantial and growing body of scientific literature has reported on young people's awareness of, and attitudes about, cigarette advertising and promotional activities." The report also found that "[c]onsidered together, these studies offer a compelling argument for the mediated relationship of cigarette advertising and adolescent smoking."<sup>147</sup> The Surgeon General's Report and the Institute of Medicine's report<sup>148</sup> find that there is sufficient evidence to conclude that advertising and labeling play a significant and important contributory role in a young person's decision to use cigarettes or smokeless tobacco products.

a. *Studies of advertising recall, approval of advertising, and young people's response to advertising.* Many studies have shown that young people are aware of, respond favorably to, and are influenced by cigarette advertising.<sup>149</sup> Even relatively young children are aware of cigarette advertisements and can recall salient portions. A recent Gallup survey found that 87 percent of adolescents surveyed could recall seeing one or more tobacco advertisements and that half could identify the brand name associated with one of four popular cigarette slogans.<sup>150</sup> One study found that over 34 percent of 12- to 13-year-old California children surveyed could name a brand of cigarettes that was advertised, despite the fact that Federal law bans cigarette and smokeless tobacco product advertising on both radio and television, the usual medium of information for children and adolescents.<sup>151</sup>

Other studies show that children who smoke are more likely to correctly identify cigarette advertisements and slogans in which the product names have been removed than are non-smokers.<sup>152</sup> One study surveyed a group of U.S. high school students and found a positive relationship between smoking level and cigarette advertisement recognition. Regular smokers recognized 61.6 percent of the tobacco advertisements while non-smokers recognized 33.2 percent.<sup>153</sup>

Another study measured cigarette advertising exposure among adolescents by determining which magazines they read and the number of cigarette advertisements in each magazine. The study found that two factors, advertising exposure and whether a friend or friends smoked, were predictive of smoking status or intention to smoke. The authors contended that the findings are consistent with the theory that cigarette advertising successfully represents, through attractive imagery, that smoking is a facilitator for acquiring a desired characteristic or goal.<sup>154</sup>

These studies raised the question of whether smoking causes a person to recognize advertisements or whether a person's exposure to or recognition of advertisements leads to smoking or increases the likelihood that a person will smoke. One study designed specifically to address this issue<sup>155</sup> showed that causality flowed in both directions: experimentation with cigarettes prompted subjects to attend to and retain information from cigarette advertisements (smoking status determined whether the child attended to advertising) and the amount of information retained by each subject from cigarette advertisements predicted the subjects' experimentation with cigarettes (causality).<sup>156</sup>

Another study attempted to address the issue of causality by questioning Glasgow school children at two different times, 1 year apart. The study asked 640 Glasgow children between the ages of 11 and 14 about their intention to smoke and their recognition of cigarette advertising. Children who were more inclined to smoke between the time when the two interviews were conducted tended to be more aware of cigarette advertising at the first interview than children who were less inclined to smoke. The study concluded that cigarette advertising has predisposing, as well as reinforcing, effects on children's attitudes towards smoking and their smoking intentions.<sup>157</sup>

Other studies relating children's misperceptions about the prevalence of smoking to advertising exposure and

smoking status have found that overestimating smoking prevalence appears to be a very strong predictor of smoking initiation and progression to regular smoking.<sup>158</sup> The 1994 Surgeon General's Report found that young people overestimate the prevalence of cigarette smoking<sup>159</sup> and that advertising's pervasiveness plays a role in this misconception. One unpublished study cited in the Surgeon General's Report supports this finding. The study found that children in Los Angeles (where cigarette advertising and promotional campaigns are prevalent) were nearly three times more likely to overestimate the prevalence of peer smoking than were children in Helsinki, Finland (where there has been a total ban on advertising since 1978).<sup>160</sup> Moreover, adolescent smokers are more likely to overestimate the prevalence than adolescent non-smokers.<sup>161</sup> Overestimating smoking prevalence, as well as self-reported exposure to advertising, have both been positively correlated with the intention to smoke.<sup>162</sup>

Additional evidence indicates that children smoke many fewer brands than adults and that their choices, unlike adults, are directly related to the amount and kind of advertising.<sup>163</sup> CDC recently reported that 86 percent of underage smokers who purchase their own cigarettes purchase one of three brands: Marlboro (60 percent), Camel (13.3 percent) and Newport (12.7 percent).<sup>164</sup> These three brands were also the three most heavily advertised brands in 1993.<sup>165</sup> While Marlboro has long been the most popular brand among young people, Camel's share of the youth market increased from around 3 percent to 13.3 percent as a result of the invigorated Joe Camel campaign.

Adult preferences, on the other hand, are more dispersed. The three most commonly purchased brands among all smokers (as measured by market share) accounted for only 35 percent of the overall market share. (Camel had approximately 4 percent of the market and its market share did not change as a result of the Joe Camel advertising.) Furthermore, the most popular "brand" of cigarette among adult smokers was no brand at all: 39 percent of all cigarettes sold in the first quarter of 1993 were from the "price value market" which includes private label, generics, and plain-packaged products.<sup>166</sup> These brands typically rely on little or no advertising and little or no imagery on their packaging.

These studies present evidence that advertising plays a significant role in children's smoking behavior. There are, in addition, individual case studies that

illustrate the profound effect that certain cigarette advertising campaigns can have on the youth market.

b. *The effect of selected advertising campaigns, which were effective with children.* Two American studies and one British study analyzed alleged youth-oriented campaigns to determine what effect they had on the underage market. One U.S. study examined the effect on the youth market of R.J. Reynolds' advertising campaign for Camel brand cigarettes. In the mid 1980's, R.J. Reynolds sought to revitalize its Camel brand cigarettes. It gave its symbol, the Camel, a new, more hip personality. It transformed the symbol into "Joe Camel," an anthropomorphic "spokescamel." The campaign featured Joe as a humorous figure in history, as an advisor to young adults with "smooth moves" and eventually as one of a gang of hip camels ("the hard pack" band and the gang at the watering hole bar). The study analyzed 1990 data from the California Tobacco Survey which consisted of a telephone survey of 24,296 adults and 5,040 children under the age of 18. The study found that teenagers were twice as likely as adults to identify Camel cigarettes as one of the two most advertised brands.<sup>167</sup>

One study explored the power of the Joe Camel campaign to penetrate the youth market. The study found that children as young as 3 years old could identify Joe Camel as a symbol for smoking. This recognition ranged from 30 percent of 3 year olds, to 91 percent of 6 year olds. In fact, the recognition rates for Joe Camel surpassed the rates for certain children's products, cereals, computers, and network television symbols.<sup>168</sup> A similar study funded by R.J. Reynolds found that 72 percent of 6 year olds and 52 percent of children between the ages of 3 and 6 could identify Joe Camel. These rates exceeded the recognition rates for Ronald McDonald, which were 62 percent of the 6 year olds and 51 percent of children between the ages of 3 and 6.<sup>169</sup> The higher recognition rates for Joe Camel are remarkable because, unlike Ronald McDonald who appears in television commercials during children's viewing hours, Federal law prohibits cigarette advertisements on television.

Data collected by researchers for the State of California found that in 1990, 23.1 percent of the under age 18 market in California purchased Camel as their brand. This represented a 230 percent increase over its pre-"Joe Camel" 1986 rate. The same growth rate did not occur for adults.<sup>170</sup> Nationally, Camel had less than 3 percent of the youth market before the brand was repositioned in

1988 and Joe Camel was introduced.<sup>171</sup> By 1989, Camel's share of the youth market had risen to 8.1 percent,<sup>172</sup> and by 1992, 13 to 16 percent.<sup>173</sup> During this same period, Camel's share of the adult market barely moved from its 4 percent level.<sup>174</sup>

The other American study used data from the National Health Interview Survey to study trends in smoking initiation among 10- to 20-year-olds from 1944 through 1980. The study found that initiation rates for 18- to 20-year-old women peaked in the early 1960's and steadily declined thereafter. Initiation rates for girls under 18, however, increased abruptly around 1967. This was the same period when brands specifically intended for women were introduced and heavily advertised. The initiation rate was particularly steep for women who did not attend college. The initiation rate for girls under the age of 18 peaked in 1973—about the same time that sales for these brands (Virginia Slims, Silva Thins, and Eve) peaked. Between 1967 and 1973, smoking initiation rates increased around 110 percent for 12-year-old girls, 55 percent for 13-year-olds, 70 percent for 14-year-olds, 75 percent for 15-year-olds, 55 percent for 16-year-olds, and 35 percent for 17-year-olds.<sup>175</sup>

In contrast, initiation rates for men declined from 1944 to 1949 and did not decline again until the middle to late 1960's. Initiation rates for boys under 16 showed little change during the entire study period. The study concluded that advertising for women's brands during this period was positively associated with increased smoking uptake in girls under 18 years of age.<sup>176</sup>

The British study looked at a campaign featuring a flippant and humorous character named "Reg." The study found that 91 percent of 11- to 15-year-olds recognized the ads, compared with 52 percent of 33- to 55-year-olds. Teenagers who liked the advertisements were more likely to smoke. In fact, it was one of the two brands that most children smoked. During the period in which Reg was advertised, smoking by 11- to 15-year-olds in northern England increased from 8 percent to 10 percent, but the rate for this same age group in southern England, where the advertisements did not appear, remained stable at 7 percent.<sup>177</sup> The government, pursuant to the industry's voluntary code, later requested that the company discontinue the advertising campaign because of its disproportionate appeal to children.

These studies provide compelling evidence that promotional campaigns can be extremely effective with young people.

c. *Direct quantitative studies.* There are many direct quantitative studies of the relationship between advertising and tobacco use and of the effects of advertising restrictions and bans on consumption. 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 effects on consumption and the effectiveness of advertising restrictions on reducing youth smoking.

A large, multinational study commissioned by the New Zealand Government examined consumption trends in 33 countries between 1970 and 1986.<sup>178</sup> Controlling for income, price, and health education, the study found that the greater a government's degree of control over tobacco promotion, the greater the annual average fall in tobacco consumption and in the rate of decrease of smoking among young people.<sup>179</sup> One of the report's most relevant conclusions was that, among the 18 countries with data on youth smoking, there is evidence of a relationship between stringent government restrictions on tobacco promotion and reduced uptake of smoking among young people. The report concluded that there appeared to be a greater decrease in smoking uptake in those countries with the most stringent measures compared with those countries where advertising had not been affected.<sup>180</sup>

Other studies that have looked at populations in general provide evidence that restrictions can have an important effect on total consumption and provide inferential evidence of similar positive effects on youth smoking. One such study conducted by the Chief Economic Advisor of the Department of Health of the Government of Great Britain found that advertising tends to increase consumption of tobacco products and that restrictions on advertising tend to decrease tobacco use beyond what would have occurred in the absence of regulation.<sup>181</sup> After performing an in-depth analysis of data from the four countries (Norway, Finland, Canada, and New Zealand) which had varying degrees of tobacco advertising restrictions and for which data exist, the study concluded that restrictions, including bans on some forms of advertising or on all advertising, resulted in an overall decrease in consumption. The study suggests that Norway's restrictions on all advertising, sponsorship, and indirect advertising produces a 9 to 16 percent reduction in consumption over the long run.<sup>182</sup> Finland's ban on advertising and

restrictions on other nonadvertising measures reduced cigarette smoking by 6.7 percent.<sup>183</sup>

Canada's Tobacco Products Control Act, which became effective on January 1, 1989, banned most print advertising, restricted sponsorship, and forbade indirect advertising (e.g., use of trade names on non-tobacco items). Although advertising restrictions often take time to be fully effective, the study found that in only 2 years following the institution of government regulation, consumption was reduced 2.8 percent more than would have been expected had there been no advertising restrictions.<sup>184</sup>

Another study looked at tobacco consumption per adult in the 22 countries of the Organization for Economic Cooperation and Development between 1960 and 1986.<sup>185</sup> The report reaffirmed the New Zealand Board's conclusion 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 which permitted promotion.<sup>186</sup>

Other studies try to measure the effect that advertising has on the general level of consumption in a country. Advertising can have an increased effect on consumption, even in those countries where the smoking rate has been falling. The analyses are able to determine whether consumption would have fallen at a greater rate but for the advertising, and ascribe that difference (the slowed rate of decline) to advertising.

One New Zealand study provides evidence that changes in advertising expenditures can have an effect on youth smoking behavior. The study analyzed the total sales of cigarettes sold by New Zealand supermarkets over a 42 week period. The study design included advertising that had recently been modified to contain newly-mandated, strong, varied disease warnings that occupied 15 percent of the advertisement. Moreover, no human form could be displayed in the advertising except a hand and forearm, and one color apart from black was usually used. The results indicated that advertising for upscale brands of cigarettes did not raise cigarette consumption, but that consumption of an inexpensive brand with a heavy youth appeal did increase with increased advertising. Moreover, the study found that the advertising for the new, inexpensive brand had the additional effect of recruiting young smokers and increasing the market base.<sup>187</sup>

Studies that assessed the response of large population groups to changes in advertising generally confirm a finding that advertising has a positive effect on consumption. The most recent comprehensive analysis of existing studies on the effect of advertising expenditures on consumption rates was done in the English study, discussed above. Among other things, the study looked at the effect of yearly fluctuations in advertising expenditures within several countries, but principally within the United States and United Kingdom. The result was that the "preponderance of positive results points to the conclusion that advertising does have a positive effect on consumption."<sup>188</sup> Individual, smaller studies<sup>189</sup> have examined the same question and confirmed a finding of effect of advertising on consumption.<sup>190</sup>

#### 5. Summary of Evidence

The agency concludes that the preponderance of quantitative and qualitative studies of cigarette advertising suggests: (1) A causal relationship between advertising and youth smoking behavior, and (2) a positive effect of stringent advertising measures on smoking rates and on youth smoking. Moreover, industry statements indicate the importance of the youth market segment to the industry's continued success. Actions taken by industry members to attract young smokers have also resulted in attracting children and adolescents. Finally, examples of specific campaigns directed at young people support the hypothesis that cigarette advertising and promotion play an important role in encouraging young people to start smoking, to sustain their smoking habit, and to increase consumption. Therefore, the agency finds that stringent restrictions on advertising are essential if smoking by adolescents is to be reduced.

#### 6. Proposed Subpart D—Labeling and Advertising

a. *General overview.* Proposed subpart D would establish regulations on the labeling and advertising of cigarettes and smokeless tobacco products. Proposed subpart D consists of four sections. Proposed § 897.30 would establish the scope of permissible forms of labeling and advertising; Proposed § 897.32 would set forth the format and content requirements. Proposed § 897.34(a) would prohibit the sale and distribution of non-tobacco items and services that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristics; proposed § 897.34(b)

would prohibit proof of purchase gifts and games of chance and contests; and § 897.34(c) would prohibit sponsorship of events that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristics. Proposed § 897.36 would address false and misleading labeling and advertising. These sections are discussed more fully below.

The proposed rule would establish different labeling and advertising requirements for cigarettes and smokeless tobacco products. These differences result from different Federal preemption provisions contained in the two Federal laws requiring warning labels on those products. Briefly, FDA believes that the Cigarette Act only preempts FDA's authority to require additional statements about smoking and health on cigarette packages, while the Smokeless Act prohibits FDA from requiring additional information about health and tobacco use in advertising as well as on the package of smokeless tobacco products. For a more complete discussion, see section IV.C. below.

b. *Proposed § 897.30—permissible forms of labeling and advertising.* Proposed § 897.30 would set forth the permissible forms of labeling and advertising for cigarettes and smokeless tobacco products. Labeling and advertising are used throughout this subpart to include all commercial uses of the brand name of a product (alone or in conjunction with other words), logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product. However, labeling and advertising would exclude package labels, which would be covered under proposed subpart C. In brief, § 897.30(a) of the proposed rule would define permissible outlets for labeling and advertising as newspapers, magazines, periodicals, billboards, posters, placards, entries and teams in sponsored events, promotional materials, audio and/or video formats, and delivered at the point of sale. Proposed § 897.30(b) would prohibit outdoor advertising of tobacco products from appearing outside of buildings within 1,000 feet of an elementary or secondary school or playground. These are places where children and adolescents spend a great deal of time and should therefore be free of advertising for these products. The agency believes that this a reasonable restriction and notes that the cigarette industry's voluntary "Cigarette Advertising and Promotion Code," revised in 1990, contains a similar

provision concerning schools and playgrounds.

These labeling and advertising requirements are an effort to control the proliferation of promotional messages that attract young people. As discussed above, advertising and promotion can play a significant role in young people's smoking behavior. The agency finds that restricting the permissible forms of media would help prevent young people from starting to use cigarettes and smokeless tobacco products and becoming addicted to those products. Proposed § 897.30 (a) would describe the range of known labeling and advertising media currently used by cigarette and smokeless tobacco product companies.

It is important to note that the proposal would not affect any other limitations on labeling or advertising, such as the radio and television advertising bans placed on cigarette and smokeless tobacco product advertising (the Cigarette Act, 15 U.S.C. 1331, 1334 and the Smokeless Act, 15 U.S.C. 4401, 4402(f)) nor any other actions taken by Federal agencies (e.g., FTC's "Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986," 16 CFR Part 307 (1994)).

c. *Proposed § 897.32—format and content requirements for labeling and advertising.* Proposed § 897.32 would describe the format and content requirements for cigarette and smokeless tobacco product labeling and advertising. This section would establish requirements in three principal areas: text-only format, the product's established name, and a brief statement of the risks of using cigarettes.

i. *Text-only advertising.* The agency considered various options available to control advertising's influence on young people, from a full ban on all advertising and promotion, to restrictions on advertising and promotional practices that children actually view. FDA's proposed rule would address the need to eliminate advertising's influence on young people and, at the same time, preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products. Therefore, the agency agrees with the IOM's recommendation that advertising and labeling should appear in text-only format because this format would reduce the attraction and appeal that cigarette and smokeless tobacco product advertising have for young people. Recognizing that it is difficult to draw the line between advertising that should be restricted or regulated and advertising that does not pose an unreasonable risk of influencing

young people, the agency requests comment on the appropriateness of the proposed regulations and whether other alternatives would be more appropriate or effective.

Under proposed § 897.32(a), cigarette and smokeless tobacco product labeling and advertising, as described in § 897.30 (a), and (b), would be required to use black text on a white background and nothing else. This text-only requirement is intended to reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 without affecting the informational message conveyed to adults.

However, FDA believes that advertising in publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people would be nominal. Therefore, advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposes to define such publications as those: (a) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or (b) that is read by two million or fewer people under age 18, whichever method results in the lower number of young people. The readership of a publication is the total number of people that read any given copy of that publication. It should be measured according to industry standards and at a minimum by asking a nationally projectable survey of people what publications they read or looked at during any given time. A reader is one who said that he/she read the last issue of a publication. Prior to disseminating advertising containing images and colors, it would be the company's obligation to establish that the publication meets the criteria for a primarily adult readership.

The concept of text-only advertising requirements is not new. The cigarette industry has employed text-only advertisements in the past, particularly when it sought to inform or educate consumers about company policies or important issues. See, e.g., "In the Matter of R.J. Reynolds Tobacco Co.," 111 F.T.C. 539 (D. 9206) (1988) (a text-only advertisement that disputed that cigarette smoking was related to coronary heart disease); "Washington Post," October 18, 1994, at p. A11; "Washington Post," October 20, 1994, at p. A17; "Time," 144(19): 42(1994) (Philip Morris text-only advertisement which discussed environmental tobacco smoke); "Tobacco Control and Marketing: Hearings Before the Subcommittee on Health and the

Environment of the House Committee on Energy and Commerce," R.J. Reynolds, to the Honorable Edolphus Towns (Reynolds' text-only advertisement about youth smoking).

Several studies show how strongly images appeal to young people. Photographs, pictures, cartoons, and other graphics allow the advertiser to encode its sales message in a way that makes the advertisement more compelling and memorable.<sup>191</sup> Imagery ties the products to a positive visual image that can be used consistently in all advertising media as well as on the product package itself.<sup>192</sup>

Adding visual images to a text advertisement can produce greater recall and a more positive product rating.<sup>193</sup> Not surprisingly, studies have shown 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.<sup>194</sup>

One study examined 243 seventh and eighth grade students in Chicago to determine the appeal (likability) of different types of cigarette advertising. The study compared a Joe Camel advertisement, an advertisement with a model, and a text-only advertisement. The results indicated that adolescents found advertisements containing pictures and cartoons to be significantly more appealing than advertisements with human models; advertisements with any imagery were more appealing than text-only advertisements. These results are particularly compelling because a study by the Advertising Research Foundation found that an advertisement's "likability" is the best predictor of product sales.<sup>195</sup>

In arriving at its proposal, FDA considered other options, including banning all advertising or restricting the type of imagery used.<sup>196</sup> FDA believes that the evidence detailed above would justify a ban on all or most advertising and promotion of tobacco products. The studies cited and industry statements and actions already discussed in this proposal indicate the positive effect that advertising can have on young people's smoking behavior, while other studies establish that bans on cigarette advertising can help reduce overall consumption and youth initiation. Given the extremely grave health consequences of a lifetime of smoking, actions taken that would help achieve a lower initiation rate among young people would be authorized as a matter of law and justified as a matter of public health policy.

Moreover, young people are currently exposed to billions of dollars worth of tobacco advertising and promotion that

use attractive imagery and do not rely on objective product claims. The industry's claims that this advertising exists solely to maintain brand loyalty or induce smokers to switch. However, as noted previously, tobacco advertising and promotion appear to have a more profound effect on brand choices by young people (86 percent of young people smoke the three most advertised brands) than on adults, whose choice is more often based on price (39 percent of the market is comprised of generic and discount products.) Furthermore, brand loyalty runs higher for cigarettes than for any other product. Thus, significant expenditures would not appear to be necessary to retain loyal consumers and would appear to be excessive and wasteful if they are expended merely to get people to switch brands.

While a total ban on advertising, therefore, would likely be justified, FDA believes that limiting advertisements and labeling to which children are exposed to a text-only format is less burdensome and would effectively reduce the appeal of tobacco products to children and adolescents. Further, while some have suggested prohibiting only youth-oriented images, the agency has been unable to define the subset of advertising and labeling directed to young people based upon the media selected or the location of the advertising. For example, billboards are always visible to young people, and there are few, if any, publications that children and adolescents cannot see. Thus, the proposed text-only requirement would offer the most protection for children and adolescents while still enabling informative advertising to reach persons aged 18 and older. Given the complexities of this subject, however, FDA invites comment on other potential methods that may exist for curtailing advertising's appeal to young people.

*ii. Non-tobacco items and sponsorship.* Proposed § 897.34(a) would prohibit the sale or distribution of all non-tobacco items that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic. As noted above, advertising expenditures have risen dramatically in the past two decades, and the distribution of the marketing expenditures represents a major shift in marketing trends. In 1970, the amounts spent on traditional advertising represented 82 percent of total spending, but, by 1991, this figure had fallen to approximately 17 percent.<sup>197</sup> The remaining funds devoted to marketing cigarettes are spent on a variety of promotional activities designed to assure

advantageous placement of products in retail outlets, get products into a prospective consumer's hand through the use of coupons and samples, and provide gifts, contests, and other non-tobacco items and gifts to create special appeal and reduce real price.<sup>198</sup>

Proposed § 897.34(a) would pertain to non-tobacco items and services (other than cigarettes or smokeless tobacco products) that the tobacco companies market, license, distribute, or sell. Manufacturers often provide branded, non-tobacco items as an inducement to purchase cigarettes or generate purchases through the use of proof-of-purchase coupons. Both R.J. Reynolds and Philip Morris utilize this popular technique by providing either a coupon with each package (Camel cash) or indicating that each package was worth a number of credits towards a purchase (Marlboro miles). Each company also printed glossy catalogues with items and gifts that could be purchased using "cash" or credits. Either method creates an incentive to purchase the tobacco product by reducing the product's real price; the consumer gets the product and the non-tobacco "gift."

The IOM found that this form of advertising is particularly effective with young people.<sup>199</sup> Young people have relatively little disposable income, so promotions are appealing because they represent a means of "getting something for nothing." In many cases, the items—tee shirts, caps, and sporting goods—are particularly attractive to young people. Some items, when used or worn by young people, also create a new advertising medium—the "walking billboard"—which can come into schools or other locations where advertising is usually prohibited. A 1992 Gallup survey found that about half of adolescent smokers and one quarter of non-smokers owned at least one of these items.<sup>200</sup> Similar data were reported for a group of ninth graders from New York State. Among these ninth-graders, 48 percent of occasional smokers and 28 percent of non-smokers reported owning branded clothing.<sup>201</sup>

A recent report found that tobacco companies spent \$600 million on programs that provide promotional items in exchange for proofs-of-purchase (usually by catalogue). Although the tobacco industry states that these items are meant for individuals over the age of 20, many teens report participating in promotional activities, with participation ranging from 25.6 percent of 12- to 13-year-olds and 42.7 percent of 16- to 17-year-olds owning a promotional item. The report found that 68.2 percent of current smokers

participated, and 28.4 percent of non-smokers participated. The report concluded that there is an association between participating in promotions and a person's susceptibility to tobacco use. It also noted that participation in promotions has the same ability to predict susceptibility to tobacco use as does use by a household member.<sup>202</sup> These proposed provisions would eliminate these items and therefore would prevent young people from wearing such items and becoming "walking advertisements."<sup>203</sup>

Proposed § 897.34(b) would prohibit all proof of purchase sales or gifts of non-tobacco items as well as all contests, lotteries, or games of chance that are linked to the purchase of, or in consideration for the purchase of, a tobacco product. Because contests and lotteries are usually conducted through the mail, the agency has not been able to devise regulations that would reduce a young person's access to contests or lotteries.

Proposed 897.34(c) would also prohibit a sponsored event from being identified with a cigarette or smokeless tobacco product brand name or any other brand identifying characteristic. Entries and teams in sponsored events are to be treated as labeling under § 897.30 and § 897.32 and would be required to be in text-only, black and white format. Any other athletic, musical, artistic, or other social or cultural event would be permitted to be sponsored in the name of the tobacco company. However, the event would not be permitted to include any brand name (alone or in conjunction with any other words), logo, symbols, motto, selling message, or any other indicia of product identification similar or identical to those used for any brand of cigarettes or smokeless tobacco products. The corporation in whose name the sponsorship would be permitted, would be required to have been in existence on January 1, 1995. This latter provision is intended to prevent manufacturers from circumventing this restriction by incorporating separately each brand that they manufacture for use in sponsorship.

Sponsorship by cigarette and smokeless tobacco companies associates tobacco use with exciting, glamorous, or fun events, such as car racing and rodeos. It provides an opportunity for what sponsorship experts call "embedded advertising"<sup>204</sup> that actively creates a "friendly familiarity" between tobacco and sports enthusiasts, many of whom are children and adolescents. Those watching a sponsored event, including children and adolescents, repeatedly see the sponsor's brand or

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**DRAFT 2-23-98 6P.M.**

**I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS**

- 1. What data does the administration have to substantiate that a ban on outdoor advertising, including stadia and arenas, will reduce smoking and, in particular, youth smoking?**

The FDA tobacco rule prohibits outdoor advertising within 1,000 feet of public playgrounds and elementary and secondary schools. All other outdoor advertising is restricted to black text on a white background, devoid of color and imagery. FDA's regulations are based on the agency's finding that children and adolescents spend a great deal of time in areas around schools and playgrounds and these areas, therefore, should be free of tobacco product advertising. All other outdoor advertising should be restricted to text information only, which generally is not appealing to young people. (See response to II, below.) Data supporting this conclusion are detailed at 61 Fed. Reg. 44501-08. *✓ these*

- 2. To what extent do you believe such restrictions can be expected to reduce smoking?**

FDA's advertising restrictions are based on quantitative and qualitative studies of cigarette advertising that show that a causal relationship exists between tobacco advertising and tobacco use by young people and that stringent advertising restrictions, when combined with a comprehensive program designed to reduce initiation and use among young people, will have a positive effect on reducing smoking rates and youth tobacco use.

FDA's findings regarding the ability of advertising restrictions to reduce youth tobacco use are summarized at 60 Fed. Reg. 41330-34 and 61 Fed. Reg. 44466-500. *✓ these*

- 3. Does the administration support such a ban. If so, why? If not, why not?**

The administration supports appropriate restrictions on outdoor advertising, as evidenced by the FDA tobacco rule (21 C.F.R. 897.30(b)) which prohibits outdoor advertising for cigarettes and smokeless tobacco, including billboards, posters, or placards, from being placed within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary or secondary school. All other outdoor advertising is limited to black text on a white background (21 C.F.R. 897.32(a)).

The prohibition set forth in Section 101(a)(1), however, would prohibit "any form of outdoor tobacco product advertising, including bill boards, posters, or placards." It does not contain the exception for tombstone advertising in certain locations that is included in the FDA regulation. Because that exception ensures that the FDA regulations are appropriately tailored to

serve the government's substantial interest in reducing teenage smoking, Section 101(a)(1)'s broader restriction on all outdoor tobacco advertising raises significant constitutional concerns that are not presented by the FDA regulations.

- 4. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

As discussed above, the administration's efforts have been focused on supporting the restrictions now codified in FDA regulations. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the outdoor advertising of tobacco products. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate. 

## **II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING**

- 1. What data does the administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular youth smoking?**

FDA's regulations restrict advertising, with certain exceptions, to black text on a white background. No color or imagery is permitted. These restrictions encompass a prohibition of human figures and cartoon characters. The restrictions apply to billboards, publications, in-store advertising, and direct mail advertisements. FDA's findings in this area are summarized at 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44466-68, 44508-13. FDA's *Federal Register* documents contain specific evidence and summaries of studies. See 60 Fed. Reg. 41333-34 and 61 Fed. Reg. 44475-82. ✓

- 2. To what extent do you believe such restrictions can be counted on to reduce youth smoking?**

See response to I.2., above.

- 3. What entity would you propose to determine what constitutes a human image or cartoon character?**

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

- 4. What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures determined to be human or cartoon?**

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

- 5. Does the administration support this ban? If so, why? If not, why not?**

The administration supports appropriate advertising restrictions, as evidenced by the FDA tobacco rule. Section 101(b) of S. 1414 provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products, which provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in an "adult publication," one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii). The provision's broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present.

In any event, the administration urges the Congress to provide statutory confirmation of the existing authority of the FDA to regulate the use of images in the advertising of tobacco products. This regulatory approach would ensure that the FDA would be authorized, based on existing and future research, to develop necessary and appropriately tailored supplements to its current restrictions, if and when such supplements are needed.

- 6. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

As discussed above, the administration's efforts have been focused on the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in discussing how these restrictions will be implemented and the associated penalties, and whether further restrictions are constitutional and otherwise appropriate. ✓

### **III. BAN ON INTERNET ADVERTISING**

- 1. Does the administration support such a ban? If so, why? If not, why not?**

2. **How can and should a ban on Internet advertising of cigarettes be enforced?**
3. **What, if any, concerns does the administration have regarding the constitutional free speech issues raised by any such ban?**
4. **What specific changes, if any, in the legislative language implementing the ban would the administration propose?**

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In response to III.1 - III.4, the administration believes that, because there may be more narrowly tailored means of achieving the government's underlying interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(c) of S.1414 would impose would raises significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329,2348 (1997) (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). We would therefore caution the Congress about adopting such a broad measure at this time.

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This regulatory approach will ensure that any future restrictions are targeted at the right forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focussed Internet restriction. *UP*

#### IV. BAN ON POINT-OF-SALE ADVERTISING

1. **What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?**

See responses to I.2. and II.1., above, regarding FDA's proposal restricting point-of-sale advertising. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509 - 44510. Point-of-sale advertising presents the child with an enticement at the time when purchase is immediately available.

Manufacturers and retailers limited to text-only advertising at point of sale will not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to young people. Children and adolescents, who are less willing than adults to process print information in a leisurely setting (such as reading a

magazine), will find textual material even less appealing in the few moments spent at the retail counter.

**2. Does the administration support such a ban? If so, why? If not, why not?**

The administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

**3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?**

The administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations and publications read primarily by adults because the evidence then available showed that advertising in locations where children are never present, such as adult-only locations, or are rarely exposed, as is the case with publications with an insignificant youth readership, would not have a significant adverse effect on efforts to reduce youth tobacco use.

**4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?**

**5. Does such a privilege constitute a statutorily granted competitive advantage? If so, why? If not, why not?**

**6. Does the administration support this grant? If so, why? If not, why not?**

**7. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

Section 101(d) would impose a general prohibition on the use of what is termed "point-of-sale advertising" of tobacco products but would include a significant exception for "adult-only stores and tobacco outlets." Sec. 101(d)(2). The FDA regulations contain restrictions that are targeted at point-of-sale advertising, however, they are not as broad as those set forth in S.1414 primarily because they do not prohibit tombstone advertising. See 21 C.F.R. §§ 897.32, 897.16. The resources of the administration are available to assist the Committee in crafting restrictions on point-of-sale advertising that avoid any significant constitutional concerns that the restrictions on point-of-sale advertising in S.1414 would raise.

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Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point of sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed, it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the administration are available to assist the Committee in exploring those concerns.

**V. LIMITATIONS ON POINT-OF-SALE ADVERTISING**

- 1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?**

See response to IV.1., above.

- 2. Does the administration support this provision? If so, why? If not, why not?**

The administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

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*Is this enough?*

**VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS**

- 1. Are such agreements currently against federal or state law? If so, is such a provision necessary?**

Ordinarily, under the free market system, retailers are permitted to decide from whom and to whom they will buy and sell, and on what terms. While an agreement of the sort described -- between a manufacturer and a retailer to limit the ability of a competing manufacturer to display advertising on the retailer's premises -- might be anticompetitive under certain circumstances, such agreements are usually not condemned under the federal antitrust laws. The administration has not undertaken a review of state laws to determine whether such an arrangement would violate the law of any state.

- 2. Does the administration support such a provision? If so, why? If not, why not?**

The administration's primary concern is not the relationship of retailers, manufacturers, and distributors between or among one another with respect to advertising. Rather, the

## **DRAFT 2-23-98 6P.M.**

administration wants to ensure that point-of-sale advertising and promotional material, whatever their source, consist only of black text on a white background.

3. **Does the administration support the limitation. If so, why? If not, why not?**

See answer to question 2 above.

4. **What specific changes, if any, in the legislative language implement the ban would the administration propose? Please provide specifics.**

See answer to question 2 above.

## **VII. GLAMORIZATION OF TOBACCO**

1. **What data does the administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?**

A number of studies (Tye 1990; Terre, Drabman, and Speer 1991; Hazan, Lipton, and Glantz 1994; Thumbs Up! Thumbs Down! 1997) show that depictions of tobacco use in the entertainment media, particularly feature films, are on the increase and exaggerate greatly the actual prevalence of tobacco use in the U.S. population. Research also suggests that adolescents are highly susceptible to pro-smoking messages and images conveyed in entertainment media (Signorielli 1993; Davies 1993; Basil 1997). Focus group research found that young people are able to recall virtually no anti-smoking messages on TV or in the movies, yet they are able quite readily to recall specific movies that portray smoking and to identify actors and actresses who smoke in their entertainment roles (Mermelstein 1997). Deglamorizing tobacco use in the entertainment media can be achieved both by decreasing pro-smoking cues and by increasing anti-smoking cues. A study by researchers at the University of California at Irvine suggests that anti-smoking ads before movies can help inoculate young people against the positive images of smoking that appear in movies. Ninth graders who watched the movie "Reality Bites" (in which the cast smokes in about one-third of the scenes) preceded by a California Department of Health Services anti-smoking ad were much less likely to find smoking exciting compared with teens who watched the movie without the counter-advertisement (Pechmann, 1996).

2. **What entity does the administration propose will determine what activity constitutes promoting the image or use of a tobacco product?**
3. **How does the administration envision such a ban will be enforced?**

4. **Does the administration support such limitations?**
5. **What specific changes, if any, in the legislative language would the administration propose? Please provide specifics.**

In response to Questions VII.2 - VII.5, the administration believes that the scope of the restriction on glamorization in S. 1414 is unclear. For example, is the provision intended only to restrict attempts to promote certain brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, then the provision would appear to reach some noncommercial speech, raising significant constitutional concerns. It is also not clear what is meant by the use of the word "promoting." Finally, the phrase "appeals to individuals under 18 years of age" could be subject to challenge on vagueness grounds.

Alternatively, no such constitutional concerns would be raised if Congress enacted legislation that would confirm the authority of the FDA to regulate the advertising of tobacco products through such indirect means as the use of product placement agreements.

## VIII. RESTRICTIONS ON COLOR ADVERTISEMENTS

1. **What data does the administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking particularly youth smoking?**

See response to II.1., above.

2. **Does the administration believe that the threshold for the restriction of two million readers is the appropriate threshold?**

FDA's tobacco rule requires that advertising be restricted to black and white text, except in publications that are read primarily by adults or in adult-only facilities. The text-only requirement is intended to reduce the appeal of cigarettes and smokeless tobacco advertising on young people without unduly affecting the informational messages conveyed to adults. Therefore, FDA proposed in its rulemaking that advertising in publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people should be nominal. The agency set the definition of adult publication as those whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or those which are read by two million or fewer people under age 18, whichever method results in the lower number of young people. (Magazines with small readership numbers but which appeal to young people may not attract two million young readers but may still be primarily youth oriented; that is, 15 percent or more of their readers are under 18.) In addition, the agency noted that at some point, the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless

of the percentage of the readership. For example, a magazine with a large total readership base may attract as many as 5 million young people, or more, but those numbers would still not be 15 percent of the magazine's readership. See 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44513-19.

**3. How does the administration envision readership demographics being determined?**

In its tobacco rulemaking, FDA explained that readership demographics would be determined by measuring the total number of people that read any given copy of a publication. Readership demographics would be measured according to industry standards and, at a minimum, would be based on a nationally projectable survey of people. Two examples of currently available surveys are Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK. FDA also indicated that it would be willing to work with industry on this issue. See 61 Fed. Reg. 44516-19. on

**4. How would this restriction be enforced?**

The restriction would be enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Federal Food, Drug and Cosmetic Act which provides for the imposition of civil money penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a). on

**5. Does the administration support this restriction? If so, why? If not, why not?**

The administration supports the regulation in the FDA rule based upon the findings of the Food and Drug Administration regarding the role and attractiveness of images and color in advertising to young people. See, e.g., 61 Fed. Reg. 44467-68, 44509 (1996). ✓

**6. What specific changes, if any, in the legislative language implementing the restriction does the administration propose? Please provide specifics.**

As discussed above, the administration supports effective restrictions on the use of color and imagery in tobacco advertising. The administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the advertising of tobacco products.

**IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN**

**1. Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.**

## **DRAFT 2-23-98 6P.M.**

The answers to Parts I-VIII above address the government's authority to impose restrictions on advertising and marketing without the industry's consent. We address here the degree to which "the industry's consent" may affect the constitutional analysis of the advertising restrictions.

We believe that the constitutional analysis of such restrictions might be affected if the industry's adoption of those advertising restrictions that either could not be constitutionally imposed upon the industry, or that exceed the restrictions that are imposed by the FDA regulations, were in some way made contingent upon the industry's willingness to adopt them. For example, we believe that the inclusion of such restrictions in state court consent decrees between states and tobacco manufacturers -- rather than in federal legislation -- would significantly increase the likelihood that the restrictions would be upheld if challenged in the future. However, the inclusion of such restrictions in a federal statute that made adherence to such restrictions a condition of the receipt of certain federal benefits would continue to raise substantial constitutional questions. Such a statute, depending on how it were framed, would be subject to substantial challenge under the unconstitutional conditions doctrine. 7

## **X WARNING LABELS**

### **1. Does the administration believe that these are appropriate warning labels?**

The administration supports the concept of strengthening warning label statement requirements. Several recent studies (Health Canada 1996; Borland, Cappiello, and Hill 1996; Robinson and Killen 1997) and literature reviews (USDHHS 1994; IOM 1994 ) are available concerning the effectiveness of warning labels in conveying information to consumers. The administration's resources are available to help the Committee evaluate possible improvements to warning label requirements.

### **2. Does the administration possess data suggesting that these warnings will effectively reduce smoking, particularly youth smoking?**

See response to X.1., above.

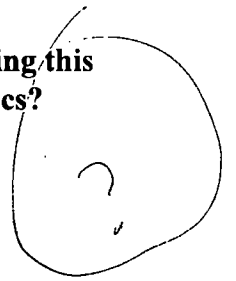
### **3. What data suggests that the various new warnings will be as or more effective than the current warning requirements?**

See response to X.1., above.

### **4. Does the administration support the provisions authorizing specific new labels? If so, why? If not, why not?**

5. **What specific changes, if any, in the legislative language implementing this provision would the administration propose? Please provide specifics?**

As stated above, the administration is available to work with the Committee in determining whether changes to the warning statement requirements are appropriate.



#### **IX. WARNING LABEL SIZE AND LOCATION REQUIREMENTS**

1. **What data does the administration have to suggest that these specifications will reduce smoking, particularly youth smoking?**

See response to X.1., above.

2. **Does the administration support these particular specification? If so, why? If not, why not?**
3. **Does the administration support the exception provided for flip-top cigarette packages? If so, why? If not, why not?**
4. **What specific changes, if any, in the legislative language to implement these restrictions would the administration propose? Please provide specifics.**

The administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

#### **X. SMOKELESS TOBACCO ALTERNATIVE LABELS**

1. **What data does the administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?**

See response to X.1., above.

2. **Does the administration support the use of these alternative labels?**
3. **What changes, if any, to the legislative language implementing this provision would the administration propose? Please provide specifics.**

The administration, as discussed above, has focused its efforts on supporting the

## **DRAFT 2-23-98 6P.M.**

restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are appropriate.

### **XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS**

- 1. Does the administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?**

Section 114 of the bill provides FTC with the authority to enforce sections 111 and 112, the provisions relating to warning statement requirements. Section 114 also contains a penalty provision for violations of section 113, the requirement that companies provide ingredient information to the Secretary of HHS pursuant to a new provision of the Federal Food, Drug, and Cosmetic Act, and authorizes the FTC to bring actions to enforce that provision. With respect to sections 111 and 112, section 114 appears to maintain the status quo with respect to warning label enforcement issues. Some other proposed bills would shift that authority to FDA. The administration is available to assist in the Committee in considering these differing approaches. With regard to section 113, which relates to a provision of FDA law, the administration would be pleased to assist the Committee in evaluating whether enforcement authority for the ingredient disclosure requirements may be more appropriately vested entirely in FDA.

- 2. What changes in legislative language, if any, does the administration recommend regarding these provisions? Please provide specific language.**

As discussed above, the administration would be pleased to assist the Committee in evaluating issues related to the enforcement of advertising, marketing, and labeling restrictions, and in developing modifications, if appropriate, to legislative language.

### **XII. PREEMPTION OF STATE AND LOCAL ACTION**

- 1. Does the administration support such preemption? If so, why? If not, why not?**
- 2. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specific language?**

The administration generally supports the limited preemption of state and local requirements related to the packaging of cigarettes or smokeless tobacco, but does not support the preemption of state and local restrictions on advertising. FDA's current regulations address advertising. Although the regulations are preemptive, the Federal Food, Drug and Cosmetic Act

**DRAFT 2-23-98 6P.M.**

allows states and localities to apply for waivers to be exempted from federal thresholds. This would allow states and localities to enact or retain existing advertising restrictions that would be more stringent.

The administration is available to work with the Committee with respect to the broader issues of preemption raised by other provisions of the bill. The administration is committed to allowing states and localities the maximum flexibility practicable to develop strong public health policies to prevent and reduce youth tobacco use.

### **XIII. EXEMPTION OF EXPORTS**

**1. Does the administration support this exemption? If so, why? If not, why not?**

No. As the world's leading exporter of tobacco products, the United States has the obligation to guarantee that its companies will behave responsibly no matter where they do business. There should be no exemptions for policies that would safeguard the health and well being of people anywhere in the world.

**2. What ramifications does this provision have in the area of foreign relations?**

Adopting a less stringent policy towards exported tobacco products would send a negative message to the countries where these products are sold -- that the health and well being of their citizens, particularly their children, are less important than the health and well being of Americans.

**3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

**Proposed response:** The provision should be revised as follows:

- "It shall be unlawful for any domestic concern or any officer, director, employee, or agent of such concern to make use of the mails or any means or instrumentality of interstate commerce to contribute, either directly or through a foreign subsidiary, joint venture, affiliate, or licensee to--  
  
    "(1) the sale or distribution of tobacco products in a foreign country to children; or  
    "(2) the advertising or promotion of tobacco products in a foreign country in a manner that appeals to children.
- "It shall be unlawful for any domestic concern or any officer, director, employee, or agent

of such concern either directly or through a foreign subsidiary, joint venture, affiliate, or licensee, to make use of the mails or any means or instrumentality of interstate commerce to cause or contribute to the export from the United States any tobacco product the package of which does not contain a warning label that--

“(1) is in the primary language of the country in which the tobacco product is sold or distributed to consumers; and

“(2) except for the requirement of paragraph (1)--

“(A) complies with Federal requirements for labeling of similar tobacco products manufactured, imported, or packaged for sale or distribution in the United States; or

“(B) complies with the labeling requirements of the foreign country in which the product is sold or distributed to consumers and which the labeling requirements the Secretary of Health and Human Services determines are substantially similar to Federal requirements and are adequately enforced by such country.”

#### **XIV. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS**

**1. Does the administration support these provisions? If so, why? If not, why not?**

The administration supports access restrictions based upon FDA's findings regarding the ability of persons under 18 to purchase tobacco products in the absence of a photo identification requirement. See, e.g., 61 Fed. Reg. 44437-39 (1996).

**2. How does the administration envision that this provision will be enforced, and can it be enforced effectively?**

FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing the age and photo ID provisions cooperatively with state and local officials. Because of the enormous number of retailers that sell tobacco, FDA has adopted a cooperative model. By way of comparison, this is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country—by commissioning the services of state and local officials.

In its initial enforcement efforts, FDA contracted with 10 states. Under these contracts, states are conducting between 200 and 330 unannounced retail compliance checks each month over a period of eight months. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to the adolescents. These retailers will be subject to repeat inspections. FDA will seek a fine of \$250 for the second violation and greater fines for subsequent violations. FDA is in the process of contracting with additional states.

FDA anticipates that state and local contracts will provide effective mechanisms to check compliance with other access restrictions, such as the requirement that all transactions be face-to-face, without the assistance of any electronic device. Commissioned state and local officials will be able to determine compliance with these and similar provisions by visiting facilities, and appropriately documenting observations.

## **XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES**

- 1. Does the administration support this prohibition? If so, why? If not, why not?**

The administration supports this prohibition based upon FDA's findings regarding the ability of persons under 18 to obtain cigarettes when they are sold in units of less than a full pack. See, e.g., 61 Fed. Reg. 44443, 44445-48.

- 2. What change in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

The administration does not recommend any changes in the legislative language.

## **XVI. STATE LICENSURE TO SELL TOBACCO**

- 1. What data, if any, does the administration have to indicate that licensure will effectively reduce access to tobacco by minors?**

Licensure of retailers will give authorities the means of identify those retailers who sell tobacco. States that do not require licensure are having difficulty complying with the Synar amendment, because they have difficulty identifying outlets that sell tobacco products. In addition to providing a list of retailers, the threat of license revocation for noncompliance is extremely motivating to retailers. Furthermore, license fees can be used to cover the cost of enforcement, which is an important determinant of compliance.

- 2. What entity does the administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?**

The administration supports a licensing program that is operated at the state or local levels. The responsible federal agency should have authority to devise a program and set national standards that the participating state and local programs implement.

3. **Has the administration developed or formulated the cost of the licensure program? If so, why? If not, why not?**

The administration has not completed work regarding the cost of a licensure program.

4. **Does the administration support the licensure program? If so, why? If not, why not? *[Sentences that are bold and in italic still are proposed by DOJ without HHS concurrence.]***

The administration supports an effective licensing program. Federal legislation that calls upon states to establish regulatory programs must be sensitive to federalism concerns. *Section 131 would provide two incentives for states to establish licensing programs for retail distributors of tobacco products. States that establish satisfactory licensing programs (1) would avoid imposition of a federal ban on retail distribution of tobacco products within their borders; and (2) would qualify for block grants under section 502. Congress possesses authority, under principles discussed in New York v. United States, 505 U.S. 144, 173-74 (1992), to "offer States the choice of regulating that activity according to federal standards or having state law pre-empted by federal regulation." Congress also possesses authority, under Spending Clause principles discussed in South Dakota v. Dole, 483 U.S. 203 (1987), to condition the receipt of federal funds by states on their implementation of certain regulatory measures. Accordingly, although the section 131 incentives for state licensing may give rise to constitutional challenges, we believe that they are consistent with the Constitution.*

5. **What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

The resources of the administration are available to work with the Committee in evaluating provisions for a licensing program.



## **XVII. ANTI-TRUST EXEMPTION**

1. **Does the administration support such an exemption? If so, why? If not, why not?**

The antitrust laws are the most important protector of the free-market economy against anticompetitive actions that would undermine its integrity to the detriment of consumers. Accordingly, exceptions to the antitrust laws should be made only in exceedingly rare instances, when the fundamental free market values underlying the antitrust laws are compellingly overwhelmed by a paramount policy objective; and a proposed exemption must be necessary to permit the paramount policy objective to be pursued. The proponents of an antitrust exemption

for the tobacco industry thus face a heavy burden, which they have not yet met.

**2. Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?**

An antitrust exemption that allowed tobacco firms to set prices jointly could be used by firms to increase prices beyond what is necessary to deter youth smoking and thereby to increase profits at the expense of consumers. It would be very difficult to restrict use of the exemption to its intended purpose, because the tobacco companies would have both the opportunity and the incentive to effect unnecessary price increases and to conceal them under the guise of restrictions on youth smoking. While the resulting collusive price increase would be likely to reduce demand for tobacco products, it would also increase profits for the tobacco companies, at least to the point at which they are collectively charging the "monopoly price." The tobacco companies would thereby be able to use an antitrust exemption to enrich themselves at the expense of those confirmed with smoking habits.

**3. What changes in legislative language, if any, does the administration recommend regarding this provision? Please provide specifics.**

Before any exemption is considered for enactment, the proponents of the exemption need to meet the burden of demonstrating that this is one of the exceedingly rare instances in which the antitrust laws are incompatible with a clearly paramount policy objective. The administration is extremely skeptical that the proponents of this case will be able to meet that burden.

Even in those rare instances in which that burden is met, any antitrust exemption should be carefully and narrowly crafted to address that objective in the least anticompetitive manner available. If Congress should decide to move forward with consideration of antitrust exemptions for the tobacco industry, the administration would assist in crafting them as narrowly and precisely as possible to achieve their purpose without creating unnecessary anticompetitive effects.

**XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY**

**[Still have to work this one out.]** Whatever the ultimate answer, it should make the following point -- The inclusion of provisions that would enable new entrants to "consent" to restrictions on their advertising would be subject to constitutional review in accord with the principles discussed in our answer to question 9.]

**ADDITIONAL REFERENCES**

**VII. GLAMORIZATION**

Basil MD. The danger of cigarette "special placements" in film and television. *Health Communication* 1997;9(2):191-198.

Davies J. The impact of the mass media upon the health of early adolescents. *Journal of Health Education* 1993 Supplement:S28-S35.

Mermelstein R. The CDC Tobacco Control Network: understanding factors that influence youth tobacco use. Progress Report October 1995 - September 1997. Chicago, IL: Prevention Research Center, University of Illinois at Chicago.

Pechmann C. Inoculation effect of tobacco counter-advertising. University of California-Irvine, 1997.

Signorielli N. Mass media images and impact on health: a sourcebook. Westport, CT: Greenwood Press, 1993.

Terre L, Drabman R, Speer P. Health-relevant behaviors in media. *Journal of Applied Social Psychology* 1991;21:1303-1319.

Thumbs Up! Thumbs Down! Teens take a look at tobacco use in the movies. American Lung Association of Sacramento-Emigrant Trails, 1997.

Tye JB. Tobacco and youth reporter. Longmeadow, MA: Stop Teenage Addiction to Tobacco, 1990.

**X. WARNING LABELS**

Borland R, Cappiello M, Hill D. Impact of the new Australian health warnings on tobacco products. Carlton South, Victoria: Anti-Cancer Council of Victoria, 1996.

Health Canada. Effectiveness of health warning messages. Toronto, Ontario: Tandemar Research Inc., 1996.

Institute of Medicine. Warnings and packaging. Growing up tobacco free: preventing nicotine addiction in children and youths. Washington, DC: National Academy Press, 1994:236-246.

Robinson TN, Killen JD. Do cigarette warning labels reduce smoking? Paradoxical effects

**DRAFT 2-23-98 6P.M.**

among adolescents. Archives of Pediatric and Adolescent Medicine 1997;151:267-272.

U.S. Department of Health and Human Services. Warning labels on tobacco products. In Preventing tobacco use among young people: a report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, 1994:257-264.



U. S. Department of Justice  
Office of the Attorney General

McGinn  
Q & A's  
EW

Washington, D.C. 20530

DATE: February 26, 1998

TO: Mary Smith

Telephone No. ( )        -        Fax No. ( ) 456 - 7431

FROM: Thomas J. Perrelli  
Assistant to the Attorney General

Telephone No. (202) 514 - 2267 Fax No. (202) 514 - 1724

TRANSMISSION CONTAINS 27 SHEETS INCLUDING THIS COVERSHEET

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SPECIAL NOTE(S) \_\_\_\_\_

WARNING: Many fax machines produce copies on thermal paper. The image produced is highly unstable and will deteriorate significantly in a few years. It should be copied on a plain paper copier prior to filing as a record.

Elena, Mary, Cynthia --

Here are DOJ's edits to the McCain draft. They consist of a line-edited draft and a separate re-draft of questions 3 through 5. Here is a quick summary of the important changes:

- 1) Question II -- we've removed two sentences because we are concerned that we have improperly described the FDA's regulations.
- 2) Question III -- we have rewritten the Internet ban answer to preserve the argument that there is an Internet ban currently in place under 15 U.S.C. § 1335. A red-lined version of the changes has been provided.
- 3) Question IV -- we have restructured the answer and made some important changes. A new version has been provided.
- 4) Question V -- some minor editing. A new version has been provided.
- 5) Question XVI -- we've provided an alternative formulation to the answer to Question XVI.4 on licensing. We would be happy with either answer, and HHS might prefer the shorter formulation.

Give me a call after you've had a chance to look at the changes.

Tom Perrelli  
514-2267

DAJ Rewrite of III-V

### III. BAN ON INTERNET ADVERTISING

The agreement (bill page 16) bans tobacco advertising on the Internet.

1. Does the administration support such a ban? If so, why? If not, why not?
2. How can and should a ban on Internet advertising of cigarettes be enforced?
3. What, if any, concerns does the administration have regarding the constitutional free speech issues raised by any such ban?
4. What specific changes, if any, in the legislative language implementing the ban would the administration propose?

In response to III.1 - III.4, the Administration believes notes that, insofar as S.1414's proposed complete ban on Internet advertising of tobacco products would be for the purpose of diminishing minors' exposure to such advertising, it would raise significant constitutional concerns, because there might ~~may~~ be more narrowly tailored means of achieving such a governmental objective. Cf. Reno v. ACLU, 117 S.Ct. 2329, 2346-48 (1997) (discussing less restrictive alternatives to a ban on Internet transmission of indecency in a manner available to minors). ~~interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(e) of S.1414 would impose would raise significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329, 2348 (1997), (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). While we would applaud a voluntary limit of this kind, we therefore caution the Congress about adopting such a broad measure at this time.~~

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This ~~would regulatory approach will~~ ensure that any future ~~regulatory~~ restrictions are targeted at ~~appropriate the right~~ forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focused Internet restriction.

[NOTE: IV and V, below, have been substantially restructured, and slightly altered. Please review in toto.]

### IV. BAN ON POINT-OF-SALE ADVERTISING

**The agreement (bill page 16) bans point-of-sale tobacco [advertising] except for advertisements which comply with certain restrictions.**

- 1. What data does the administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?**

See responses to I.2. and II.1., above. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509 - 44510. Point-of-sale advertising presents children and adolescents with an enticement at the time when purchase is immediately available.

- 2. Does the administration support such a ban? If so, why? If not, why not?**

Section 101(d) of S.1414 would, in general, limit each manufacturer of tobacco products to the display of not more than two separate point-of-sale advertisements in any location at which tobacco products are sold, and would limit each retailer to the display of one point-of-sale advertisement relating to the retailer's own or its wholesaler's contracted retailer or private label brand product. The bill also would require that these point-of-sale advertisements consist only of black letters on a white background, and not be larger than a prescribed size. However, the bill would include a significant exception to these limitations for "adult-only stores and tobacco outlets." Sec. 101(d)(2).

The FDA regulations contain restrictions that are targeted at point-of-sale advertising similar to those proposed in S.1414. They are not quite as broad as those set forth in S.1414 in that there is no numerical limitation and no size limitation. See 21 C.F.R. §§ 897.32, 897.16. Moreover, unlike S.1414, the FDA regulations do not include an exemption for certain manufacturers with a substantial market share.

Under both the FDA regulation and the S.1414 proposal, manufacturers and retailers limited to text-only advertising at the point of sale would not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to minors. Children and adolescents, who are less likely than adults to process print information in a leisurely setting (such as reading a magazine), will find textual material even less appealing in the few moments spent at the retail counter.

The administration supports appropriate restrictions on point-of-sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

**3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?**

The administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations because there is little reason to believe that advertising in such locations would have a significant adverse effect on efforts to reduce youth tobacco use.

- 4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?**
- 5. Does such a privilege constitute a statutorily granted competitive advantage? If so, why? If not, why not?**
- 6. Does the administration support this grant? If so, why? If not, why not?**
- 7. What specific changes, if any, in the legislative language implementing the ban would the administration propose? Please provide specifics.**

In response to IV.4 - IV.7, the Administration notes that Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point-of-sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed, it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the administration are available to assist the Committee in exploring those concerns.

## **V. LIMITATIONS ON POINT-OF-SALE ADVERTISING**

The agreement (bill page 17) specifies the size and design of permissible point-of-sale advertising.

- 1. What data does the administration possess to suggest that such limitations will reduce smoking, particularly among youth?**

See responses to IV.1. and IV.2, above.

- 2. Does the administration support this provision? If so, why? If not, why not?**
- 3. If so, what is the justification for statutorily determining a particular size limitation and for the particular size and [design] restrictions proposed?.**

**4. What specific changes in legislative language, if any, does the administration propose? Please provide specifics..**

In response to V.2 - V.4, the administration supports appropriate restrictions on point-of-sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the administration are available to assist the Committee in determining whether further restrictions -- such as those limiting the size of point-of-sale advertisements -- are constitutional and otherwise appropriate.

Draft 2/25/98 -- 1:15 pm

January 26, 1998

Dear Mr. Chairman:

The Clinton Administration looks forward to working with you and others in Congress to develop comprehensive, bipartisan legislation that will reduce teen tobacco use. In addition to the enclosed responses to your questions, we are prepared to provide the appropriate staff to give the Committee the technical assistance you request. We also are providing you with a number of resource documents cited below that we hope will be of assistance as you work to develop comprehensive legislation to protect our nation's children from tobacco related disease and death.

As you know, the President has called on Congress to enact comprehensive legislation that raises the price of cigarettes by up to \$1.50 a pack over the next ten years, expressly confirms the FDA's gives the FDA full authority to regulate tobacco products, gets tobacco companies out of the business of marketing to children, furthers public health research and goals, and protects tobacco farmers and their communities. A piecemeal approach will not meet our overriding goal, which is to drastically reduce teen smoking.

As part of such a comprehensive effort, the Administration has long recognized the importance of restricting the advertising and marketing of tobacco products to young people's access to young people. Two recent studies underscore what we have said before -- that tobacco advertising aimed at young people is a significant factor in their decision to start smoking. Comprehensive tobacco legislation, especially if combined with even further voluntary agreements to restrict advertising, is an opportunity for Congress to reaffirm FDA's efforts in this area.

Many of the provisions included in S.1414 would codify the comprehensive regulations on nicotine-containing tobacco products that the FDA adopted in its final Tobacco Rule issued August 28, 1996. The FDA restrictions were carefully crafted on the basis of a multi-year investigation, and resulted from the analysis of myriad studies and research on the effects of advertising, specifically tobacco advertising, on young people and the consideration and analysis of more than 700,000 comments submitted in response to the proposed FDA rule. As you know, the Administration believes strongly that the FDA has jurisdiction and authority to issue such advertising restrictions and that comprehensive tobacco legislation should provide express statutory confirmation of this power.

The Administration also believes, as the Department of Justice has explained at length in the FDA litigation, that the FDA's regulations that restrict the advertising of tobacco products are consistent with the First Amendment, under the currently controlling framework for First Amendment review of restrictions on advertising, set out by the Supreme Court in Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980), and subsequent cases. The FDA restrictions would, if implemented, substantially advance the Government's wholly legitimate and compelling interest in curtailing minors' demand for and use of tobacco products by reducing minors' exposure to tobacco product advertising. Moreover, the FDA's regulations are tailored to serve this objective. For these reasons, we believe the advertising restrictions in S.1414 that track the FDA regulations are constitutional.

Other restrictions contained in S.1414 give rise to constitutional concerns that are not presented by the FDA regulations, such as whether such restrictions would be sufficiently tailored to serve the governmental interest in reducing teenage smoking. The enclosed responses detail these concerns. Such limits on advertising nonetheless may be extremely valuable in reducing youth smoking and protecting the public health, and the Administration once again challenges the tobacco industry to adopt them voluntarily.

To assist the committee in developing legislation regulating tobacco products, including legislation restricting the advertising of tobacco products, we have provided with this response copies of the two documents <sup>that</sup> detail the analysis and findings on which the FDA regulations are based: the FDA's proposed rule and preamble published in 60 Fed. Reg. 41314 (August 11, 1994); and the FDA's final rule and preamble published in 61 Fed. Reg. 44396 (August 28, 1996). Our answers to your questions include citations to these documents where appropriate. In addition, the FDA's administrative record contains the studies described in those documents as well as public comments received by the agency. That record is contained on 5 CD's, which are also provided with this response.

We hope this material is helpful and we look forward to providing you and the members of the Committee with any additional assistance that may be needed.

Sincerely,

Enclosure

In general: Add McCah's introductory sentences in each heading (as we have done in sections III - V). Many of the Q+A do not make sense without them. ✓

DRAFT 2-25-98 3:30 P.M.

# **I. BAN ON OUTDOOR ADVERTISING, INCLUDING IN STADIA AND ARENAS**

1. What data does the Administration have to substantiate that a ban on outdoor advertising, including stadia and arenas, will reduce smoking and, in particular, youth smoking?

The FDA tobacco rule prohibits outdoor advertising within 1,000 feet of public playgrounds and elementary and secondary schools. All other outdoor advertising is restricted to black text on a white background, devoid of color and imagery. FDA's regulations are based on the agency's finding that children and adolescents spend a great deal of time in areas around schools and playgrounds and these areas, therefore, should be free of tobacco product advertising. All other outdoor advertising should be restricted to text information only, which generally is not appealing to young people. (See response to question II, below.) Data supporting this conclusion are detailed at 61 Fed. Reg. 44501-08. ✓

2. To what extent do you believe such restrictions can be expected to reduce smoking?

FDA's advertising restrictions are based on quantitative and qualitative studies of cigarette advertising that show that a causal relationship exists between tobacco advertising and tobacco use by young people and that stringent advertising restrictions, when combined with a comprehensive program designed to reduce initiation and use among young people, will have a positive effect on reducing smoking rates and youth tobacco use.

FDA's findings regarding the ability of advertising restrictions to reduce youth tobacco use are summarized at 60 Fed. Reg. 41330-34 and 61 Fed. Reg. 44466-500.

3. Does the Administration support such a ban. If so, why? If not, why not?

The Administration supports appropriate restrictions on outdoor advertising, as evidenced by the FDA tobacco rule (21 C.F.R. 897.30(b)) which prohibits outdoor advertising for cigarettes and smokeless tobacco, including billboards, posters, or placards, from being placed within 1,000 feet of the perimeter of any public playground or playground area in a public park, elementary or secondary school. All other outdoor advertising is limited to black text on a white background (21 C.F.R. 897.32(a)).

The prohibition set forth in Section 101(a)(1), however, would prohibit "any form of outdoor tobacco product advertising, including bill boards, posters, or placards." It does not contain the exception for tombstone advertising in certain locations that is included in the FDA regulation. Because that exception ensures that the FDA regulations are appropriately tailored to

DRAFT 2-25-98 3:30 P.M.

serve the government's substantial interest in reducing teenage smoking, Section 101(a)(1)'s broader restriction on all outdoor tobacco advertising raises significant constitutional concerns that are not presented by the FDA regulations. We believe, however, that voluntary limits of this kind would be of significant value to the public health. ✓ ✓

4. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.

As discussed above, the Administration's efforts have been focused on supporting the restrictions now codified in FDA regulations. The Administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the outdoor advertising of tobacco products. The resources of the Administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

## II. BAN ON HUMAN FIGURES AND CARTOON FIGURES IN ADVERTISING

1. What data does the Administration have to substantiate that barring the use of human figures and cartoon advertising will reduce smoking, in particular youth smoking?

FDA's regulations restrict advertising, with certain exceptions, to black text on a white background. ~~No color or imagery is permitted.~~ These restrictions encompass a prohibition of human figures and cartoon characters. ~~The restrictions apply to billboards, publications, in-store advertising, and direct-mail advertisements.~~ FDA's findings in this area are summarized at 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44466-68, 44508-13. FDA's *Federal Register* documents contain specific evidence and summaries of studies. See 60 Fed. Reg. 41333-34 and 61 Fed. Reg. 44475-82. A new study, published in the February 18th edition of *The Journal of the American Medical Association (JAMA)*, found that tobacco industry advertising and promotional activities influence teens to start smoking and that 34 percent of teen smoking could be attributed to tobacco promotional activities. ✓ ✓

2. To what extent do you believe such restrictions can be counted on to reduce youth smoking?

See response to L2., above.

3. What entity would you propose to determine what constitutes a human image or cartoon character?

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug

**DRAFT 2-25-98 3:30 P.M.**

Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

4. What penalty do you believe is appropriate and should accrue for a violation of the prohibition on material containing figures determined to be human or cartoon?

Under the FDA's regulations, the requirement that tobacco advertisements under most circumstances use black text on a white background is enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Food, Drug, Cosmetic Act. That Act provides for the imposition of civil penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

5. Does the Administration support this ban? If so, why? If not, why not?

The Administration supports appropriate advertising restrictions, as evidenced by the FDA tobacco rule. The Administration also supports enactment of legislation confirming the existing authority of the FDA to regulate the use of images in the advertising of tobacco products. This regulatory approach would ensure that the FDA would be authorized, based on existing and future research, to develop necessary and appropriately tailored supplements to its current restrictions, if and when such supplements are needed.

Section 101(b) of S. 1414 provides that "[n]o manufacturer, distributor, or retailer may use a human image or a cartoon character or cartoon-type character in its advertising, labeling, or promotional material with respect to a tobacco product." This restriction would go beyond the FDA regulation restricting the use of images in the advertising of tobacco products, which provides that, in general, tobacco advertising must take the form of tombstone advertising but permits images to be used without restriction in an "adult publication," one whose readership is at least 85 percent adult and includes less than two million children. 21 C.F.R. § 897.32(a)(2)(i)-(ii). The provision's broader restriction on the use of images in the advertising of tobacco products would raise significant constitutional concerns that the FDA regulation does not present. We believe a voluntary industrywide ban would be of significant value to the public health.

6. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.

As discussed above, the Administration's efforts have been focused on the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in discussing how these restrictions will be implemented and the associated penalties, and whether further restrictions are constitutional and otherwise appropriate.

**DRAFT 2-25-98 3:30 P.M.**

### **III. BAN ON INTERNET ADVERTISING**

1. Does the Administration support such a ban? If so, why? If not, why not?
2. How can and should a ban on Internet advertising of cigarettes be enforced?
3. What, if any, concerns does the Administration have regarding the constitutional free speech issues raised by any such ban?
4. What specific changes, if any, in the legislative language implementing the ban would the Administration propose?

In response to III.1 - III.4, the Administration believes that, because there may be more narrowly tailored means of achieving the government's underlying interest in restricting the advertising of tobacco products on the Internet, the categorical prohibition that Section 101(c) of S.1414 would impose raises significant constitutional concerns. See Reno v. ACLU, 117 S.Ct. 2329, 2348 (1997) (explaining that compelled tagging schemes are obvious less restrictive alternative to banning Internet transmission of content harmful to minors). While we would applaud a voluntary limit of this kind, we therefore caution the Congress about adopting such a broad measure at this time.

In order to ensure that the government retains necessary flexibility to regulate the advertising of tobacco products on the Internet, we recommend that the Congress provide express statutory confirmation of the FDA's existing authority to regulate such advertising. This regulatory approach will ensure that any future restrictions are targeted at the right forms of Internet advertising and are fashioned in a manner that is appropriately sensitive to First Amendment concerns. Alternatively, we are prepared to work with Congress to fashion a more narrowly focussed Internet restriction.

### **IV. BAN ON POINT-OF-SALE ADVERTISING**

1. What data does the Administration have to substantiate that a ban on point-of-sale advertising would reduce smoking, in particular, youth smoking?

See responses to I.2. and II.1., above, regarding FDA's proposal restricting point-of-sale advertising. In its tobacco rulemaking, FDA found that young people get their information and product imagery from all types of advertising, including at the point of sale. See 61 Fed. Reg. 44509 - 44510. Point-of-sale advertising presents the child with an enticement at the time when purchase is immediately available.

**DRAFT 2-25-98 3:30 P.M.**

Manufacturers and retailers limited to text-only advertising at point of sale will not be prohibited from promoting products at retail. Adult consumers looking for price and product information will be able to find that information even without imagery and colors, which are particularly attractive to children. While text-only advertising can still be effective with adults, it will have less allure and be less appealing to young people. Children and adolescents, who are less willing than adults to process print information in a leisurely setting (such as reading a magazine), will find textual material even less appealing in the few moments spent at the retail counter.

- 2. Does the Administration support such a ban? If so, why? If not, why not?**

The Administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA tobacco rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

- 3. Is the exemption of point-of-sale advertisement for adult stores and tobacco outlets appropriate?**

The Administration's focus has been on preventing children and adolescents from using tobacco products. Restrictions on the advertising that makes these products appealing to young people is a vital component of these efforts. FDA's regulations exempt adult-only locations and publications read primarily by adults because the evidence then available showed that advertising in locations where children are never present, such as adult-only locations, or are rarely exposed, as is the case with publications with an insignificant youth readership, would not have a significant adverse effect on efforts to reduce youth tobacco use.

- 4. Is it appropriate to grant companies with greater cigarette market share additional point-of-sale advertising rights? If so, why? If not, why not?**
- 5. Does such a privilege constitute a statutorily granted competitive advantage? If so, why? If not, why not?**
- 6. Does the Administration support this grant? If so, why? If not, why not?**
- 7. What specific changes, if any, in the legislative language implementing the ban would the Administration propose? Please provide specifics.**

Section 101(d) would impose a general prohibition on the use of what is termed "point-of-sale advertising" of tobacco products but would include a significant exception for "adult-only stores and tobacco outlets." Sec. 101(d)(2). The FDA regulations contain restrictions that are

**DRAFT 2-25-98 3:30 P.M.**

targeted at point-of-sale advertising, however, they are not as broad as those set forth in S.1414 primarily because they do not prohibit tombstone advertising. See 21 C.F.R. §§ 897.32, 897.16. The resources of the Administration are available to assist the Committee in crafting restrictions on point-of-sale advertising that avoid any significant constitutional concerns that the restrictions on point-of-sale advertising in S.1414 would raise.

Section 101(d)'s exception permitting manufacturers with a greater market share to engage in more point of sale advertising than their competitors appears inconsistent with the government's asserted interest in restricting such advertising. Granting manufacturers point-of-sale advertising opportunities consonant with market share is unrelated to the objective of reducing youth tobacco use; indeed, it may run counter to that goal. Moreover, the proposal presents constitutional and anti-competitive concerns that should be addressed. The resources of the Administration are available to assist the Committee in exploring those concerns.

**V. LIMITATIONS ON POINT-OF-SALE ADVERTISING**

1. What data does the Administration possess to suggest that such limitations will reduce smoking, particularly among youth?

See response to IV.1., above.

2. Does the Administration support this provision? If so, why? If not, why not?

The Administration supports appropriate restrictions on point of sale advertising, as evidenced by the FDA Tobacco Rule. As discussed above, its efforts have been focused on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are constitutional and otherwise appropriate.

**VI. BAN ON ADVERTISING RESTRICTION AGREEMENTS**

1. Are such agreements currently against federal or state law? If so, is such a provision necessary?

Ordinarily, under the free market system, retailers are permitted to decide from whom and to whom they will buy and sell, and on what terms. While an agreement of the sort described -- between a manufacturer and a retailer to limit the ability of a competing manufacturer to display advertising on the retailer's premises -- might be anticompetitive under certain circumstances, such agreements are usually not condemned under the federal antitrust laws. The Administration has not undertaken a review of state laws to determine whether such an arrangement would violate the law of any state.

DRAFT 2-25-98 3:30 P.M.

2. Does the Administration support such a provision? If so, why? If not, why not?

The Administration's primary concern is not the relationship of retailers, manufacturers, and distributors between or among one another with respect to advertising. Rather, the Administration wants to ensure that point-of-sale advertising and promotional material, whatever their source, consist only of black text on a white background. *except in adult-only facilities*

3. Does the Administration support the limitation. If so, why? If not, why not?

See answer to question 2 above.

4. What specific changes, if any, in the legislative language implement the ban would the Administration propose? Please provide specifics.

See answer to question 2 above.

## VII. GLAMORIZATION OF TOBACCO

1. What data does the Administration possess to indicate whether and to what extent this provision will reduce smoking, particularly among youth?

A number of studies (Tye 1990; Terre, Drabman, and Speer 1991; Hazan, Lipton, and Glantz 1994; Thumbs Up! Thumbs Down! 1997) show that depictions of tobacco use in the entertainment media, particularly feature films, are on the increase and exaggerate greatly the actual prevalence of tobacco use in the U.S. population. Research also suggests that adolescents are highly susceptible to pro-smoking messages and images conveyed in entertainment media (Signorielli 1993; Davies 1993; Basil 1997). Focus group research found that young people are able to recall virtually no anti-smoking messages on TV or in the movies, yet they are able quite readily to recall specific movies that portray smoking and to identify actors and actresses who smoke in their entertainment roles (Mermelstein 1997). Deglamorizing tobacco use in the entertainment media can be achieved both by decreasing pro-smoking cues and by increasing anti-smoking cues. A study by researchers at the University of California at Irvine suggests that anti-smoking ads before movies can help inoculate young people against the positive images of smoking that appear in movies. Ninth graders who watched the movie "Reality Bites" (in which the cast smokes in about one-third of the scenes) preceded by a California Department of Health Services anti-smoking ad were much less likely to find smoking exciting compared with teens who watched the movie without the counter-advertisement (Pechmann, 1996).

*advertisements*

**DRAFT 2-25-98 3:30 P.M.**

2. What entity does the Administration propose will determine what activity constitutes promoting the image or use of a tobacco product?
3. How does the Administration envision such a ban will be enforced?
4. Does the Administration support such limitations?
5. What specific changes, if any, in the legislative language would the Administration propose? Please provide specifics.

In response to Questions VII.2 - VII.5, the Administration believes that the scope of the restriction on glamorization in S. 1414 is unclear. For example, is the provision intended only to restrict attempts to promote certain brand names of tobacco products or is it intended to restrict the promotion of smoking generally? If the latter were the case, then the provision would appear to reach some noncommercial speech, raising significant constitutional concerns. It is also not clear what is meant by the use of the word "promoting." Finally, the phrase "appeals to individuals under 18 years of age" could be subject to challenge on vagueness grounds.

Alternatively, no such constitutional concerns would be raised if Congress enacted legislation that would confirm the authority of the FDA to regulate the advertising of tobacco products through such indirect means as the use of product placement agreements.

**VIII. RESTRICTIONS ON COLOR ADVERTISEMENTS**

1. What data does the Administration have to substantiate that a ban on color ads, except in publications with limited youth readership, will reduce smoking particularly youth smoking?

See response to II.1., above.

2. Does the Administration believe that the threshold for the restriction of two million readers is the appropriate threshold?

So-called "adult"

FDA's tobacco rule requires that advertising be restricted to black and white text, except in publications that are read primarily by adults or in adult-only facilities. The text-only requirement is intended to reduce the appeal of cigarettes and smokeless tobacco advertising on young people without unduly affecting the informational messages conveyed to adults. Therefore, FDA proposed in its rulemaking that advertising in publications that are read primarily by adults should be allowed to use imagery and color because the effect of such advertising on young people should be nominal. The agency set the definition of adult publication as those whose readers age 18 or older constitute 85 percent or more of the publication's total readership, or those which are read by two million or fewer people under age

**DRAFT 2-25-98 3:30 P.M.**

18, whichever method results in the lower number of young people. (Magazines with small readership numbers but which appeal to young people may not attract two million young readers but may still be primarily youth oriented; that is, 15 percent or more of their readers are under 18.) In addition, the agency noted that at some point, the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. For example, a magazine with a large total readership base may attract as many as 5 million young people, or more, but those numbers would still not be 15 percent of the magazine's readership. See 60 Fed. Reg. 41335-36 and 61 Fed. Reg. 44513-19.

**3. How does the Administration envision readership demographics being determined?**

In its tobacco rulemaking, FDA explained that readership demographics would be determined by measuring the total number of people that read any given copy of a publication. Readership demographics would be measured according to industry standards and, at a minimum, would be based on a nationally projectable survey of people. Two examples of currently available surveys are Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK. FDA also indicated that it would be willing to work with industry on this issue. See 61 Fed. Reg. 44516-19.

**4. How would this restriction be enforced?**

The restriction would be enforced by the Food and Drug Administration and the Department of Justice under the provisions of the Federal Food, Drug and Cosmetic Act which provides for the imposition of civil money penalties, 21 U.S.C. § 333(f), injunctive relief, 21 U.S.C. § 332, and/or criminal prosecution, 21 U.S.C. § 333(a).

**5. Does the Administration support this restriction? If so, why? If not, why not?**

The Administration supports the regulation in the FDA rule based upon the findings of the Food and Drug Administration regarding the role and attractiveness of images and color in advertising to young people. See, e.g., 61 Fed. Reg. 44467-68, 44509 (1996).

**6. What specific changes, if any, in the legislative language implementing the restriction does the Administration propose? Please provide specifics.**

As discussed above, the Administration supports effective restrictions on the use of color and imagery in tobacco advertising. The Administration urges Congress to provide statutory confirmation of the existing authority of the FDA to regulate the advertising of tobacco products.

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DRAFT 2-25-98 3:30 P.M.

## **IX. GENERAL QUESTION REGARDING MARKETING/ADVERTISING BAN**

1. **Can the marketing and advertising restrictions envisioned in the settlement be constitutionally imposed, with or without the industry's consent? Please discuss.**

The answers to Parts I-VIII above address the government's authority to impose restrictions on advertising and marketing without the industry's consent. As noted, we believe that certain of those restrictions raise significant constitutional concerns. We address here the degree to which "the industry's consent" may affect the constitutional analysis of the advertising restrictions.

Voluntary commitments to restrict advertising are of course constitutional. For this reason, we believe that the inclusion of such restrictions in state court consent decrees between states and tobacco manufacturers — rather than in federal legislation — would significantly increase the likelihood that the restrictions would be upheld if challenged in the future. However, the inclusion of such restrictions in a federal statute that made adherence to such restrictions a condition of the receipt of certain federal benefits would continue to raise substantial constitutional questions. Such a statute, depending on how it were framed, could be subject to substantial challenge under the unconstitutional conditions doctrine. The resources of the Administration are available to assist the Committee in crafting legislation designed to minimize this potential problem.

## **X. WARNING LABELS**

1. **Does the Administration believe that these are appropriate warning labels?**

The Administration supports the concept of strengthening warning label statement requirements. Several recent studies (Health Canada 1996; Borland, Cappiello, and Hill 1996; Robinson and Killen 1997) and literature reviews (USDHHS 1994; IOM 1994) are available concerning the effectiveness of warning labels in conveying information to consumers. The Administration's resources are available to help the Committee evaluate possible improvements to warning label requirements.

2. **Does the Administration possess data suggesting that these warnings will effectively reduce smoking, particularly youth smoking?**

See response to X.1., above.

DRAFT 2-25-98 3:30 P.M.

3. What data suggests that the various new warnings will be as or more effective than the current warning requirements?

See response to X.1., above.

4. Does the Administration support the provisions authorizing specific new labels? If so, why? If not, why not?
5. What specific changes, if any, in the legislative language implementing this provision would the Administration propose? Please provide specifics?

As stated above, the Administration is available to work with the Committee in determining whether changes to the warning statement requirements are appropriate.

**IX.**

**WARNING LABEL SIZE AND LOCATION REQUIREMENTS**

1. What data does the Administration have to suggest that these specifications will reduce smoking, particularly youth smoking?

See response to X.1., above.

2. Does the Administration support these particular specification? If so, why? If not, why not?
3. Does the Administration support the exception provided for flip-top cigarette packages? If so, why? If not, why not?
4. What specific changes, if any, in the legislative language to implement these restrictions would the Administration propose? Please provide specifics.

The Administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are appropriate.

*anyone notice that  
there's two IX's?*

DRAFT 2-25-98 3:30 P.M.

X

## SMOKELESS TOBACCO ALTERNATIVE LABELS

1. What data does the Administration have to suggest that the various new warning labels will effectively reduce the use of smokeless tobacco, particularly among youth?

See response to X.1., above.

2. Does the Administration support the use of these alternative labels?
3. What changes, if any, to the legislative language implementing this provision would the Administration propose? Please provide specifics.

The Administration, as discussed above, has focused its efforts on supporting the restrictions now codified in FDA regulations. The resources of the Administration are available to assist the Committee in determining whether further restrictions are appropriate.

## XI. ENFORCEMENT OF ADVERTISING, MARKETING AND LABELING RESTRICTIONS

1. Does the Administration support the enforcement provisions regarding advertising, marketing and labeling? If so why? If not, why not?

Section 114 of the bill <sup>would provide</sup> provides the FTC with the authority to enforce sections 111 and 112, the provisions relating to warning statement requirements. Section 114 also contains a penalty provision for violations of section 113, the requirement that companies provide ingredient information to the Secretary of HHS pursuant to a new provision of the Federal Food, Drug, and Cosmetic Act, and authorizes the FTC to bring actions to enforce that provision. With respect to sections 111 and 112, section 114 appears to maintain the status quo with respect to warning label enforcement issues. Some other proposed bills would shift that authority to FDA. The Administration is available to assist in the Committee in considering these differing approaches. With regard to section 113, which relates to a provision of FDA law, the Administration would be pleased to assist the Committee in evaluating whether enforcement authority for the ingredient disclosure requirements may be more appropriately vested entirely in FDA.

2. What changes in legislative language, if any, does the Administration recommend regarding these provisions? Please provide specific language.

As discussed above, the Administration would be pleased to assist the Committee in evaluating issues related to the enforcement of advertising, marketing, and labeling restrictions, and in developing modifications, if appropriate, to legislative language.

DRAFT 2-25-98 3:30 P.M.

## **XII. PREEMPTION OF STATE AND LOCAL ACTION**

1. Does the Administration support such preemption? If so, why? If not, why not?
2. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specific language?

The Administration generally supports the limited preemption of state and local requirements related to the packaging of cigarettes or smokeless tobacco, but does not support the preemption of state and local restrictions on advertising. FDA's ~~current~~ regulations address advertising. Although the regulations are preemptive, the Federal Food, Drug and Cosmetic Act allows states and localities to apply for waivers to be exempted from federal thresholds. This would allow states and localities to enact or retain existing advertising restrictions that would be more stringent. recently promulgated ✓

The Administration is available to work with the Committee with respect to the broader issues of preemption raised by other provisions of the bill. The Administration is committed to allowing states and localities the maximum flexibility practicable to develop strong public health policies to prevent and reduce youth tobacco use.

## **XIII. EXEMPTION OF EXPORTS**

1. Does the Administration support this exemption? If so, why? If not, why not?

The Administration strongly believes that comprehensive tobacco legislation should strengthen international efforts to control tobacco. The President indicated his support for this effort in his statement of September 17, 1997. This month the Administration also issued guidance to American posts abroad encouraging them to assist and promote tobacco-control efforts in host countries. The Administration looks forward to working with the Committee on this issue.

2. What ramifications does this provision have in the area of foreign relations?

See response to XIII.1. above.

**DRAFT 2-25-98 3:30 P.M.**

3. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

See response to XIII.1. above.

#### **XIV. RESTRICTIONS ON ACCESS TO TOBACCO PRODUCTS**

1. Does the Administration support these provisions? If so, why? If not, why not?

The Administration supports access restrictions based upon FDA's findings regarding the ability of persons under 18 to purchase tobacco products in the absence of a photo identification requirement. See, e.g., 61 Fed. Reg. 44437-39 (1996).

2. How does the Administration envision that this provision will be enforced, and can it be enforced effectively?

FDA currently is enforcing aspects of its restrictions on youth access to tobacco products embodied in the FDA tobacco rule (21 C.F.R. §§ 897.14, 897.16). FDA is enforcing the age and photo ID provisions cooperatively with state and local officials. Because of the enormous number of retailers that sell tobacco, FDA has adopted a cooperative model. By way of comparison, this is how FDA regulations are enforced for dairy farm and retail food inspections in communities across the country—by commissioning the services of state and local officials.

In its initial enforcement efforts, FDA contracted with 10 states. Under these contracts, states are conducting between 200 and 330 unannounced retail compliance checks each month over a period of eight months. Information about the compliance checks is sent to FDA, which issues a warning for the first violation to retailers found selling to the adolescents. These retailers will be subject to repeat inspections. FDA will seek a fine of \$250 for the second violation and greater fines for subsequent violations. FDA is in the process of contracting with additional states.

FDA anticipates that state and local contracts will provide effective mechanisms to check compliance with other access restrictions, such as the requirement that all transactions be face-to-face, without the assistance of any electronic device. Commissioned state and local officials will be able to determine compliance with these and similar provisions by visiting facilities, and appropriately documenting observations.

**DRAFT 2-25-98 3:30 P.M.**

**XV. PROHIBITION ON SALE OF LESS THAN A FULL PACK OF CIGARETTES**

1. **Does the Administration support this prohibition? If so, why? If not, why not?**

The Administration supports this prohibition based upon FDA's findings regarding the ability of persons under 18 to obtain cigarettes when they are sold in units of less than a full pack. See, e.g., 61 Fed. Reg. 44443, 44445-48.

2. **What change in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.**

The Administration does not recommend any changes in the legislative language.

**XVI. STATE LICENSURE TO SELL TOBACCO**

1. **What data, if any, does the Administration have to indicate that licensure will effectively reduce access to tobacco by minors?**

Licensure of retailers will give authorities the means of identify those retailers who sell tobacco. States that do not require licensure are having difficulty complying with the Synar amendment, because they have difficulty identifying outlets that sell tobacco products. In addition to providing a list of retailers, the threat of license revocation for noncompliance is extremely motivating to retailers. Furthermore, license fees can be used to cover the cost of enforcement, which is an important determinant of compliance.

2. **What entity does the Administration envision would enforce the licensure requirement if a state should be unable or unwilling to implement the licensure program?**

The Administration supports a licensing program that primarily operates at the state or local levels. The Administration is available to work with the Committee on issues concerning the relationship of such programs to federal standards or registration activities.

3. **Has the Administration developed or formulated the cost of the licensure program? If so, why? If not, why not?**

The Administration has not completed work regarding the cost of a licensure program.

DRAFT 2-25-98 3:30 P.M.

4. Does the Administration support the licensure program? If so, why? If not, why not?

The Administration supports an effective licensing program. Federal legislation that calls upon states to establish regulatory programs must be sensitive to federalism concerns. Section 131 would provide two incentives for states to establish licensing programs for retail distributors of tobacco products. States that establish satisfactory licensing programs (1) would avoid imposition of a federal ban on retail distribution of tobacco products within their borders; and (2) would qualify for block grants under section 502. Congress possesses authority, under principles discussed in New York v. United States, 505 U.S. 144, 173-74 (1992), to "offer States the choice of regulating that activity according to federal standards or having state law pre-empted by federal regulation." Congress also possesses authority, under Spending Clause principles discussed in South Dakota v. Dole, 483 U.S. 203 (1987), to condition the receipt of federal funds by states on their implementation of certain regulatory measures. Accordingly, although the section 131 incentives for state licensing may give rise to constitutional challenges, we believe that they are consistent with the Constitution.

5. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

The resources of the Administration are available to <sup>assist</sup> work with the Committee in evaluating provisions for a licensing program. ✓

## XVII. ANTI-TRUST EXEMPTION

1. Does the Administration support such an exemption? If so, why? If not, why not?

The antitrust laws are the most important protector of the free-market economy against anticompetitive actions that would undermine its integrity to the detriment of consumers. Accordingly, exceptions to the antitrust laws should be made only in rare instances, when the fundamental free market values underlying the antitrust laws are overwhelmed by a paramount policy objective; and a proposed exemption must be necessary to permit the paramount policy objective to be pursued. The proponents of broad antitrust exemptions -- for example, an exemption that allowed companies to set prices jointly -- have not yet met this heavy burden.

2. Could such an exemption be used to set prices beyond those necessary to deter youth smoking, but to increase profits for the industry?

An antitrust exemption that allowed tobacco firms to set prices jointly could be used by firms to increase prices beyond what is necessary <sup>to assist in</sup> to deter youth smoking and thereby to increase <sup>detering</sup> profits.

LANGUAGE  
[ALTERNATIVE CONSTRUCTION] THAT <sup>16</sup> WOULD PRESENT GREATER FLEXIBILITY  
FOR FUTURE DISCUSSIONS. DELETE ALL FOLLOWING "... CONCERNS." AND INSERT  
"THE ADMINISTRATION WOULD BE HAPPY TO WORK WITH THE COMMITTEE"

**DRAFT 2-25-98 3:30 P.M.**

profits at the expense of consumers. It would be very difficult to restrict use of the exemption to its intended purpose, because the tobacco companies would have both the opportunity and the incentive to effect unnecessary price increases and to conceal them under the guise of restrictions on youth smoking. While the resulting collusive price increase would be likely to reduce demand for tobacco products, it would also increase profits for the tobacco companies, at least to the point at which they are collectively charging the "monopoly price." The tobacco companies would thereby be able to use an antitrust exemption to enrich themselves at the expense of those confirmed with smoking habits.

3. What changes in legislative language, if any, does the Administration recommend regarding this provision? Please provide specifics.

Before any exemption is considered for enactment, the proponents of the exemption need to meet the burden of demonstrating that this is one of the rare instances in which the antitrust laws are incompatible with a clearly paramount policy objective. The Administration is extremely skeptical that the proponents of this case will be able to meet that burden, except perhaps to support agreements to restrict advertising to children.

Even in those rare instances in which that burden is met, any antitrust exemption should be carefully and narrowly crafted to address that objective in the least anticompetitive manner available. If Congress should decide to move forward with consideration of antitrust exemptions for the tobacco industry, the Administration would assist in crafting them as narrowly and precisely as possible to achieve their purpose without creating unnecessary anticompetitive effects.

be available to

## **XVIII. APPLICABILITY TO NEW ENTRANTS IN TOBACCO INDUSTRY**

1. Under the agreement, and the implementing legislation, what is the assurance that new entrants into the tobacco industry will comply with the statute and any related consent agreements not to challenge the legality of the agreement implementation legislation?

The proposed settlement and legislation do not deal expressly with new entrants into the tobacco industry. It appears that new entrants would be treated similar to non-participating manufacturers under Title VI and thus would be subject to advertising and access restrictions, regulatory oversight, and the payment provisions, but would not receive the benefit of any limitations on liability. There are no provisions in the legislation that would prevent new entrants from challenging the constitutionality of the legislation.

DRAFT 2-25-98 3:30 P.M.

## ADDITIONAL REFERENCES

### VII. GLAMORIZATION

Basil MD. The danger of cigarette "special placements" in film and television. *Health Communication* 1997;9(2):191-198.

Davies J. The impact of the mass media upon the health of early adolescents. *Journal of Health Education* 1993 Supplement:S28-S35.

Mermelstein R. The CDC Tobacco Control Network: understanding factors that influence youth tobacco use. Progress Report October 1995 - September 1997. Chicago, IL: Prevention Research Center, University of Illinois at Chicago.

Pechmann C. Inoculation effect of tobacco counter-advertising. University of California-Irvine, 1997.

Signorielli N. Mass media images and impact on health: a sourcebook. Westport, CT: Greenwood Press, 1993.

Terre L, Drabman R, Spect P. Health-relevant behaviors in media. *Journal of Applied Social Psychology* 1991;21:1303-1319.

Thumbs Up! Thumbs Down! Teens take a look at tobacco use in the movies. American Lung Association of Sacramento-Emigrant Trails, 1997.

Tye JB. Tobacco and youth reporter. Longmeadow, MA: Stop Teenage Addiction to Tobacco, 1990.

### X. WARNING LABELS

Borland R, Cappiello M, Hill D. Impact of the new Australian health warnings on tobacco products. Carlton South, Victoria: Anti-Cancer Council of Victoria, 1996.

Health Canada. Effectiveness of health warning messages. Toronto, Ontario: Tandem Research Inc., 1996.

Institute of Medicine. Warnings and packaging. Growing up tobacco free: preventing nicotine addiction in children and youths. Washington, DC: National Academy Press, 1994:236-246.

Robinson TN, Killen JD. Do cigarette warning labels reduce smoking? Paradoxical effects among adolescents. *Archives of Pediatric and Adolescent Medicine* 1997;151:267-272.

**DRAFT 2-25-98 3:30 P.M.**

**U.S. Department of Health and Human Services. Warning labels on tobacco products. In Preventing tobacco use among young people: a report of the Surgeon General. Atlanta, GA: Centers for Disease Control and Prevention, 1994:257-264.**

# Federal Register

Wednesday  
August 28, 1996

*John  
McLain  
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SW*

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## Part II

### Department of Health and Human Services

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#### Food and Drug Administration

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21 CFR Part 801, et al.  
Regulations Restricting the Sale and  
Distribution of Cigarettes and Smokeless  
Tobacco to Protect Children and  
Adolescents; Final Rule

either acting on its own or on the basis of information supplied to it, that one of its items does not comply with the regulations. Knowing that the item does not comply with the requirements in part 897, the manufacturer is then obligated to remove the violative item. Notice of an opportunity for a hearing or other due process considerations associated with recalls under section 518 of the act (21 U.S.C. 360h) are inapplicable because the manufacturer, rather than the government, would be the principal party during this process, using information it has to act on its own items. In any case, section 518 of the act applies to the recall of a device, not its advertising.

FDA fully expects manufacturers to comply with § 897.12. For example, if the manufacturer provided advertising that used colors and photographs, contrary to § 897.32, which requires black and white text only, the manufacturer is deemed to know that the advertising does not comply with § 897.32 and should remove that advertising. In this situation, where the manufacturer's advertising clearly does not comply with the regulations, requiring FDA to provide notice and an opportunity for a hearing (as the comment would apparently require) would simply waste FDA's and the manufacturer's resources.

FDA will take regulatory action against manufacturers who fail to comply with this provision or any other applicable provision. The nature of the regulatory action will depend, in large part, on the violation, but could range from issuance of a warning letter, to an injunction under section 302 of the act (21 U.S.C. 332), the imposition of civil penalties, criminal fines, and/or imprisonment under section 303 of the act (21 U.S.C. 333), and seizures under section 304 of the act (21 U.S.C. 334).

## 2. Visual Inspections by a Manufacturer's Representative at Each Point of Sale

Proposed § 897.12(b) would have required a manufacturer's representatives to visually inspect each point of sale that they visit during the normal course of business to ensure that cigarettes and smokeless tobacco are "labeled, advertised, and distributed in accordance with this part." The preamble to the 1995 proposed rule indicated that manufacturers keep extremely detailed records about each retailer and that some records noted whether the retailer should be visited weekly, biweekly, etc. and noted the types of displays in the retailer's

establishment (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also stated that this provision would not impose a new responsibility or burden on companies that did not visit retailers as part of their ordinary business practice and, for those manufacturers that would be expected to comply, estimated that these visual inspections would take no more than 2 to 3 minutes per visit (60 FR 41314 at 41323 and 41365). Based on the comments received in response to this proposal, the agency has deleted § 897.12(b) from the final rule.

(30) Several comments opposed proposed § 897.12(b). One comment argued that proposed § 897.12(b) is unconstitutional because it would hold manufacturers vicariously liable for the acts of others in violation of the Due Process Clause, and would violate Article I, Section 8 of the Constitution, which implicitly reserves to States the authority to raise militias. One comment asserted that the number of manufacturers' representatives varies among manufacturers and that there are too many retail establishments for those representatives to inspect. The comment added that any inspection would require more than 3 minutes to be effective, so that conducting inspections at each retailer would be labor intensive and costly. Another comment, notwithstanding the statement in the preamble to the 1995 proposed rule that the provision applied only to those firms that visit retailers in the ordinary course of business, asserted that its entire staff would be too small to visit all the retailers that it services. A small number of comments added that such responsibilities would, in effect, constitute a hidden "tax" on manufacturers.

Other comments, many submitted by sales representatives, objected to proposed § 897.12(b), stating that the representatives have no power over a retailer's actions and cannot take any adverse action, such as discontinuing supplies, to retailers who sell cigarettes and smokeless tobacco to young people. Some comments explained that, even if a sales representative could ask a distributor to stop supplying certain retailers, the retailer could simply switch distributors and continue to obtain products. Other comments argued that the responsibility to prevent sales to young people rests solely with the retailer.

In contrast, several comments supported proposed § 897.12(b) because sales representatives frequently visit retailers or because manufacturers

deliver materials, such as self-service displays and promotional materials, to retailers. One comment even suggested amending the rule to require manufacturers to enter into contracts with retailers and distributors to comply with FDA regulations and to state that failure to comply would result in termination of the retailer's or distributor's ability to obtain the manufacturer's cigarettes or smokeless tobacco.

After consideration of the comments, the agency has removed § 897.12(b). FDA intends to examine this matter further and to develop a guidance describing how manufacturers may be able to assist retailers to comply with this subpart. Possible options might include methods suggested by the comments, such as contractual agreements between retailers and manufacturers including provisions on compliance and the consequences of noncompliance.

## D. Additional Responsibilities of Retailers (§ 897.14)

Proposed § 897.14 would have established additional responsibilities for retailers, stating that "[i]n addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes and smokeless tobacco to any person (other than a distributor or retailer)" comply with specific, listed requirements.

FDA, on its own initiative, has amended § 897.14 to delete the parenthetical text referring to a distributor or retailer because the evidence does not establish that retailers sell these products to such parties, and if a retailer did sell these products to a distributor or retailer, the retailer would be acting as a "distributor" as defined in § 897.3(c).

FDA, also on its own initiative, has amended § 897.14 to add a new paragraph (a) stating that, as one of the listed requirements, "[n]o retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age" and has renumbered proposed § 897.14(a) through (c) accordingly. The new paragraph codifies a concept that was present throughout the 1995 proposed rule, namely that retailers are not to sell cigarettes or smokeless tobacco to young people under 18 years of age.

## 1. Use of Photographic Identification to Verify Age

Under proposed § 897.14(a) (now renumbered as § 897.14(b)), each retailer, or an employee of the retailer,

would have been required to verify, by means of photographic identification containing the bearer's date of birth, that no person purchasing or intending to purchase cigarettes or smokeless tobacco is younger than 18 years of age.

The preamble to the 1995 proposed rule explained that studies indicate that young people who purchase cigarettes and smokeless tobacco from stores are often not asked to verify their age. For example, one study found that 67 percent of young people, whose mean age was 15 years, were asked no questions when they attempted to purchase cigarettes. In some cases, retail clerks even encouraged purchases by young people, suggesting less expensive brands or offering to make up the difference if he or she lacked sufficient funds (60 FR 41314 at 41323). The preamble to the 1995 proposed rule also noted that requiring proof of age to purchase cigarettes and smokeless tobacco could reduce cigarette and smokeless tobacco use among young people (60 FR 41314 at 41323). Consequently, the 1995 proposed rule would have required retailers to verify that persons who intend to purchase cigarettes or smokeless tobacco are legally entitled to do so.

The preamble to the 1995 proposed rule also indicated that a driver's license or college identification card would be acceptable forms of photographic identification, but the agency invited comment on whether the final rule should contain more specific requirements on the types of identification (60 FR 41314 at 41323).

FDA received many comments supporting a proof of age requirement. These comments came from law enforcement entities, drug abuse prevention groups, health care professionals, medical societies, public health organizations, and even some adult smokers who agreed that a proof of age requirement will reduce young people's access to cigarettes and smokeless tobacco. One comment from a coalition of State attorneys general said there "are many teenagers who look much older than they are, who can obtain tobacco products quite easily. When they are required to show age verification, they will not be mistaken for an older age. Therefore, they will not be permitted to acquire tobacco products." Another comment from a State public health department reported that, based on data analyzed from the State's own experience, illegal tobacco purchases occur less than 5 percent of the time when the retailer checks a photographic identification card to

verify age, as opposed to a 95 percent illegal sales rate when no photographic identification card is checked.

In response to comments and changes to § 897.16 regarding mail order and vending machine sales and self-service displays in facilities that are inaccessible to children and adolescents, the final rule excepts the proof of age requirement under these limited circumstances.

(31) Several comments objected to making retailers responsible for their employees' actions. These comments asserted that an employee's failure to verify a potential purchaser's age or an employee's error should not subject the retailer to any regulatory action. A few comments faulted the 1995 proposed rule for not holding sales clerks responsible or argued that the rule would be ineffective because it would not alter a sales clerk's behavior.

In contrast, many comments supported the requirements that hold retailers responsible for preventing illegal sales. Indeed, one comment suggested that there should be "significant penalty[ies] for sales to persons under 18, including the loss of the opportunity to sell tobacco \* \* \*". Another comment stated that the rule should contain penalties for illegal tobacco sales.

The agency declines to amend the rule to relieve retailers from responsibility. Retailers, in general, are responsible for the acts of their employees. (See *United States v. Park*, 421 U.S. 658, 672 (1975).) Relieving retailers from responsibility for their employees' actions would only invite abuse because retailers could continue to sell products to young people and, if caught making such sales, could blame their employees without suffering any adverse consequences themselves. To reflect its position that retailers are generally responsible for their employees' actions, FDA has amended § 897.14 to remove all references to "an employee of the retailer." Thus, § 897.14 now refers to a "retailer" and makes no distinction for the retailer's employees.

As for the comment claiming the rule contains no penalties for illegal tobacco sales, the agency believes that the comment misunderstands how the rule will operate. In general, FDA regulations implement and interpret the agency's statutory obligations under the act, including various criminal and civil penalties. Thus, a regulation need not specify what penalties are attached to a violation because the act provides this information.

FDA has, however, amended proposed § 897.14(a) (now renumbered as § 897.14(b)) to state that, "[e]xcept as otherwise provided in § 897.16(c)(2)(i) and in paragraph (a)(2) of this section," a retailer shall ensure compliance with the prohibition against sales to persons under 18 by verifying the purchaser's age. FDA made this amendment to correspond with the prohibition, in § 897.14(a), against sales to persons under 18 and because, as discussed in greater detail below, the final rule permits sales from vending machines and self-service merchandisers that are inaccessible to young people and permits mail-order sales. These modes of sale are either secure from access by young people (by requiring age verification upon entrance to the facility) or not used by them. The exception for paragraph (a)(2) complements another change to § 897.14 (discussed in greater detail below) to not require proof of age from persons over the age of 26.

FDA has also amended § 897.14(b) to delete the words "intending to purchase." The requirement that retailers verify the age of persons "purchasing the product" sufficiently accomplishes the provision's goal of reducing illegal sales.

(32) Several comments supported the use of identification cards to verify the purchaser's age. Some comments, responding to a question in the preamble to the 1995 proposed rule asking whether the rule should specify the types of identification that would comply with a proof-of-age requirement, advocated using identification cards, passports, or other official documents establishing the bearer's age issued by States, the Federal Government, or foreign governments. One comment recommended that States develop a uniform coding system for identification cards to permit retailers to read or to scan identification cards quickly to verify a purchaser's age. Other comments advised against the use of college or school identification cards; the comments noted that colleges and schools have little incentive to design their identification cards to be sufficiently tamper-proof.

In contrast, one comment stated that the agency should not ask for comment on the type of identification card to require, arguing that the "degree of micromanagement implied by the Agency's invitation for such comment underscores the inappropriateness of federal action in this area."

FDA recognizes the comments' concern. However, the final rule does

not require a uniform coding system or a Federal, State, or local government identification card.

(33) FDA received several comments that addressed when a retailer should inspect a purchaser's photographic identification card. One comment interpreted the provision as requiring retailers to inspect visually the photographic identification card of every purchaser, and said that this would be unreasonable. The same comment contended that retailers and their employees should be required to demand proof of age only from prospective purchasers who do not appear to be over 18; this was the standard employed in Everett, WA, which was cited in the preamble to the 1995 proposed rule.

In contrast, other comments supported age verification for all tobacco sales. Some comments from retailers indicated that some retailers check identification cards for all tobacco sales, while many comments submitted by retailers stated that they check identification cards to verify the age of purchasers who appear to be "underage." Other comments suggested that the regulation require visual inspection of photographic identification cards for purchasers who appear to be younger than 21, 25, 26, or 30 years of age. Such a requirement appeared to be independently selected to ensure that the purchaser met the age requirement in the particular jurisdiction.

Contrary to the comment that interpreted the rule as requiring proof of age in all transactions, the 1995 proposed rule would have given retailers some flexibility in deciding when to demand proof of age. The preamble to the 1995 proposed rule cited studies and reports demonstrating that few retailers request proof of age from young people attempting to purchase cigarettes or smokeless tobacco (60 FR 41314 at 41323). Consequently, proposed § 897.14(a) (now renumbered as § 897.14(b)) would have required retailers to verify that prospective purchasers are of legal age, and the preamble to the 1995 proposed rule suggested that retailers request proof of age from anyone who does not appear to be at least 26 years old (60 FR 41314 at 41323). This suggestion was similar to a recommendation made in a report by 26 State attorneys general. The agency anticipated, for example, that requiring proof of age from a senior citizen would be unnecessary, but strongly recommended requiring proof

of age from an individual who appears youthful.

However, due to concerns that, despite the language in the preamble to the 1995 proposed rule, the rule would require age verification in all cases, the agency has amended the rule to except from the age verification requirement individuals who are over 26 years old. The agency declines to amend the rule to require age verification if the purchaser appears to be 21, 25, 26, or 30 years old. Determining a person's age by his or her physical appearance alone is a subjective determination, and so requiring age verification if a person "looked" like he or she was a particular age would be difficult to administer and to enforce. By requiring age verification if a purchaser is 26 years old or younger, regardless of his or her appearance, the retailer foregoes age verification at its own risk.

The agency notes that using the higher age of 26 as the threshold for requiring proof of age should increase the likelihood that illegal sales to young people will not occur. Using a lower age, such as 18 (which is used in some States) or 21, as the threshold for requiring proof of age may enable some young people to purchase cigarettes and smokeless tobacco, and, as a result, cause a retailer to be in violation of this subpart.

(34) Many comments, particularly comments from retailers, supported the requirement for age verification but added that the requirement should be voluntary. Others said that State law or regulations requiring age verification are adequate, and that, as a result, FDA regulation is unnecessary. Other comments claimed FDA regulation would add "red tape and paperwork" that would not reduce young people's access to cigarettes and smokeless tobacco and would instead "come at great cost to taxpayers."

On the other hand, State attorneys general and other State and local enforcement authorities commented that the Federal regulations requiring age verification by inspection of photographic identification card will complement and enhance their enforcement abilities.

FDA declines to delete an age verification requirement from the rule. The preamble to the 1995 proposed rule cited studies and reports to show that young people are often able to purchase cigarettes and smokeless tobacco without showing proof of age (60 FR 41314 at 41323). In one case, the young people were able to purchase cigarettes even when they admitted that they were

under the legal age (60 FR 41314 at 41323). These studies and reports suggest that the final rule must require retailers to demand proof of age because voluntary efforts are ineffective.

As for deferring to State laws and regulations, FDA believes that State efforts to require proof of age, and retailer compliance with such efforts, should increase and become more effective due to section 1926 of the PHS Act. This provision requires States to enact and to enforce laws prohibiting manufacturers, retailers, or distributors of tobacco products from selling or distributing such products to persons under age 18 in order to receive substance abuse prevention and treatment block grants. However, State laws may differ, and so the final rule requires retailers to verify the age of purchasers. This will establish a uniform, national requirement regarding proof of age and is consistent with the assertion of Federal authority over these products under the act.

(35) Many comments pointed out that there is no penalty for parents who allow underage children to smoke.

FDA believes that the vast majority of adults and parents do not purchase tobacco products for young people. Parental actions are also beyond the scope of FDA's authority. However, it should be noted that parental consent to a young person's purchase of cigarettes and smokeless tobacco cannot override the requirements in § 897.14(a) prohibiting sales to anyone under 18 and in § 897.14(b) that each purchase is subject to age verification. Thus, under this rule, a retailer must refuse to sell cigarettes or smokeless tobacco to any young person who claims that he or she has "permission" to purchase such products for himself or herself or for an adult.

(36) One comment contended that the photographic identification card requirement is invalid because it exceeds FDA's authority under section 520(e) of the act because it does not purport to provide reasonable assurance of the safety and effectiveness of cigarettes.

FDA disagrees with the comment. Section 520(e) of the act authorizes the agency to establish, by regulation, conditions restricting the sale, distribution, or use of a device if, because of the device's potentiality for harmful effect or the collateral measures necessary to its use, the agency determines that there cannot be a reasonable assurance of the device's safety or effectiveness. A photographic identification card requirement is a

condition of sale for these products and a collateral measure that is necessary to the requirement that the products are not sold to anyone under the age of 18.

(37) One comment contended that proposed § 897.14(a) (now renumbered as § 897.14(b)) is precluded by section 1926 of the PHS Act. The comment stated that this law established Congress' intent to allow States to enact necessary programs to keep tobacco products out of the hands of young people as a condition for receiving block grant funding. According to the comment, there is no single best approach, and the FDA proposal prevents States from emulating the successful approach used in Woodridge, IL. The comment stated that FDA may not preempt State laws without making a showing of clear and manifest congressional intent to authorize its preemption of those State laws.

The agency disagrees with the comment. The preemption issues related to this rule (as well as the rule's relationship to the regulations issued by the Substance Abuse and Mental Health Services Administration (SAMHSA) implementing section 1926 of the PHS Act regarding the sale and distribution of tobacco products to individuals under the age of 18 (the SAMHSA rule) are discussed in great detail in section X. of this document.

## 2. Minimum Age

Proposed § 897.14(a) (now renumbered as § 897.14(b)), would have required retailers to verify that persons buying cigarettes or smokeless tobacco were not younger than 18 years of age. FDA received many comments supporting a Federal minimum age to purchase cigarettes and smokeless tobacco. Some comments suggested that enforcement of this provision would be as effective as advertising limitations in controlling underage smoking. In supporting the proposal, comments noted that while most teenage smokers do not plan to be smokers 5 years after they begin smoking, less than 10 percent of teenagers are able to quit within 5 years of starting. Moreover, like their adult counterparts, 70 percent of high school seniors who smoke would like to stop smoking completely. Some comments noted that the average age at which teenage smokers first tried their first cigarette is 13 or 14 years, and by age 18, many teens are smoking daily and smoking at a rate very near the adult rate. Health-care professionals (nurses, physicians, dentists, public health officials, etc.) as a group were very

supportive of a Federal minimum age limit of at least 18.

(38) A major American medical association suggested amending § 897.14(a) (now renumbered as § 897.14(b)) to raise the minimum age of sale to 21. It noted that one State, Pennsylvania, has set 21 as the minimum age for the purchase of cigarettes, and argued that prior to enactment of the national standard of age 21 for alcohol purchase, many States had laws that allowed purchase at age 18, but subsequently changed to 21 without hardship.

Other comments advocated raising the minimum age to 19 years. Several comments explained that many high school students are 18 years old; thus, if FDA increased the minimum age to 19 years, it would be less likely that an underage high school student would be able to purchase or obtain cigarettes or smokeless tobacco, because raising the age to 19 would eliminate from the high school environment peers who are legally able to obtain nicotine-containing tobacco products. In addition, the agency received a considerable number of comments from students, teachers, and even adult smokers, urging the agency to raise the legal age to purchase cigarettes to 21, to be consistent with the legal age to purchase alcohol. Indeed, many comments assumed that the legal age was already 21 and urged the agency to retain this age limit.

In contrast, other comments supporting 18 as the minimum age for purchasing cigarettes and smokeless tobacco argued that, because most States already established 18 as the minimum age, FDA regulations did not need to establish a minimum age. A few comments, mostly from young people, asked FDA to lower the legal age for purchasing cigarettes to below 18 years of age.

In order to make its decision on the appropriate minimum age, the agency weighed a variety of factors including evidence on the onset of nicotine addiction and the history underlying the age of majority. FDA's goal is to prevent underage use of tobacco in order to preclude as many new cases of nicotine addiction as possible. The agency considered minimum ages from 18 to 21, because individuals are generally viewed as reaching adulthood in this age range. The agency faced the question: At which age in this range are most individuals able to make an informed decision to begin using a product that the overwhelming majority of individuals will not be able to stop

using, even though using the product is likely to lead to severe disability and premature death?

The agency began by reviewing key data sources on the onset and course of nicotine addiction. The National Household Surveys on Drug Abuse sought to determine the age when individuals first tried a cigarette and the age when individuals first started smoking daily—an important measure of the progression toward addiction. The survey asked questions of 30 to 39 year olds who had ever smoked daily. The average age of first trying a cigarette was 14.5 years.<sup>41</sup> Eighty-two percent had tried a cigarette before 18, 89 percent before 19, 91 percent before 20, and 98 percent before 25.<sup>42</sup> Daily smoking began slightly later. Fifty-three percent began smoking daily before 18, 71 percent before 19, 77 percent before 20, and 95 percent before 25.<sup>43</sup>

The agency reviewed the history underlying the theory of majority and the concept of adults making informed choices. Majority is defined in Black's Law Dictionary as "the age at which, by law, a person is capable of being legally responsible for all his or her acts \* \* \*, and is entitled to the management of his or her own affairs and to the enjoyment of civic rights. \* \* \*"<sup>44</sup> The 26th Amendment to the United States Constitution provides those 18 years and above with the right to vote. Prior to the adoption of the 26th Amendment in 1971, the age of majority in almost every State was 21. Each State has the power to set its own age of majority and since enactment of the 26th Amendment most States have lowered the age of majority from 21 to 18.

The agency reviewed the reasons why Congress chose 18 as the appropriate age to vote. According to a Senate report on lowering the voter age, the 21 year age was believed to be derived by historical accident. Eighteen-year olds bore many adult citizens' responsibilities such as the ability to marry and raise a family, and serve in the military. A lower voting age was seen as benefiting society by bringing into the American political system the idealism, concern, and energy of young people. (See "Lowering the Voting Age to 18," S. Rept. 92-96, 92d Cong., 1st sess., p. 5, March 8, 1971.)

While the justifications do not necessarily support establishing a minimum age of 18 for tobacco

<sup>41</sup> 1994 SGR, p. 67.

<sup>42</sup> *Id.*, p. 65.

<sup>43</sup> *Id.*

<sup>44</sup> Black's Law Dictionary, edited by M. A. Black, West Publishing Co., St. Paul, MN, p. 955, 1990.

products, the agency declines to raise the minimum age for several reasons. First, as stated in the preamble to the 1995 proposed rule, all States prohibit the sale of tobacco products to persons under the age of 18; currently only four States prohibit cigarette sales to persons over 18 (60 FR 41314 at 41315). Consequently, setting a national minimum age of 18 is consistent with most States. Second, selecting 18 as the minimum age is consistent with the age Congress established under section 1926 of the PHS Act, which conditions a State's receipt of substance abuse grants on State laws to prohibit any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual under the age of 18.

FDA also declines to amend the rule to eliminate a Federal minimum age and instead rely on existing State laws. Establishing 18 as the national minimum age will strengthen State and local enforcement, as discussed earlier.

FDA also declines to amend the rule to reduce the minimum age. Reducing the minimum age would undermine existing State laws and the rule's effectiveness because it would, in essence, circumvent statutory and regulatory protections by letting more young people purchase these products. Reducing the minimum age would also be contrary to the evidence cited in the preamble to the 1995 proposed rule, which shows that half of adults start smoking daily before age 18.

FDA does plan to monitor closely the incidence of new cases of nicotine addiction. If the evidence indicates that the number of new cases of nicotine addiction does not significantly decline, consistent with the agency's stated goal of a 50 percent reduction, but rather are merely delayed a year or two, FDA will consider whether increasing the minimum age for purchase of nicotine-containing tobacco products would further the goal of the rule.

### 3. Restrictions Against "Impersonal" Modes of Sale

Proposed § 897.14(b) (now renumbered as § 897.14(c)) would have required the retailer or an employee of the retailer to provide cigarettes or smokeless tobacco to a purchaser "without the assistance of any electronic or mechanical device (such as a vending machine or remote-operated machine)." The preamble to the 1995 proposed rule stated that this provision would have the practical effect of making access to cigarettes and smokeless tobacco more difficult for

young people (60 FR 41314 at 41324). In response to comments, the agency has amended § 897.14(c) to allow for the use of certain impersonal modes of sale, such as vending machines and self service displays (merchandisers only), in facilities which are inaccessible to individuals under the age of 18 at any time. Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because retailers are generally responsible for their employees' actions and has revised the text to correspond more closely with § 897.16(c).

(39) Several comments objected to proposed § 897.14(b). One comment asserted that proposed § 897.14(b) (now renumbered as § 897.14(c)) was unjustified, and arbitrary and capricious because it would apply to locations where young people are not permitted to enter and, in places where they can enter, would be unnecessary if retailers required proof of age from prospective cigarette and smokeless tobacco purchasers. The comment stated that less restrictive alternatives, such as increased supervision over self-service displays, exist. The comment further argued that FDA lacked support for this provision, stating that, regardless of how tobacco products are sold over-the-counter, the key party in the transaction is the cashier. According to the comment, requiring retail clerks to comply with applicable minimum age laws should be sufficient to prevent illegal sales to young people, thereby making the proposed provision unnecessary. The comment, therefore, stated that the evidence did not support a rule that would preclude State and local governments from relying on "less drastic controls."

In contrast, many comments agreed that this provision would reduce a young person's access to cigarettes and smokeless tobacco because it would require potential purchasers to interact with retailers or would discourage young people from purchasing these products because they would have to interact with a retailer and provide proof of age. One comment stated that the regulations establish a code of conduct for merchants, ensuring that they take practical steps to prevent illegal sales of tobacco products to young people. One comment stated that face-to-face transactions are the only way to assure that identification of under-age customers is checked.

FDA disagrees, in part, with the comments that oppose this provision. FDA declines to amend the rule to rely

on alternative measures such as increased supervision of displays or proof of age alone. The preamble to the 1995 proposed rule cited reports and studies showing that young people can easily use impersonal modes of sale despite restrictions on their placement or the installation of devices to prevent illegal sales. For example, for self-service displays, the Institute of Medicine (IOM) Report *Growing Up Tobacco-Free, Preventing Nicotine Addiction in Children and Youths* (1994) referred to surveys in two communities that found over 40 percent of daily smokers in grade school shoplifted cigarettes (60 FR 41314 at 41325). For vending machines, the preamble to the 1995 proposed rule cited several studies and reports showing that young people were able to purchase cigarettes—despite laws restricting the placement of those machines, or requiring the machines to have a locking device to prevent sales to young people (60 FR 41314 at 41324 through 41325).

FDA also found that relying solely on retailers to verify the purchaser's age had limited effect on reducing young people's access to cigarettes and smokeless tobacco; retail clerks rarely asked young people to verify their age or even assisted in completing a purchase. Some retail sectors also suffered from high employee turnover rates that undermined the effectiveness of retailer programs to prevent illegal sales (60 FR 41314 at 41323). Consequently, the agency believes that the most effective approach towards reducing young people's access to cigarettes and smokeless tobacco is a sufficiently comprehensive set of access restrictions to prohibit most impersonal modes of sale; require retailers to verify the consumer's age, and make young people's access to these products more difficult.

The agency also reminds parties that these products are restricted devices because of their potentiality for harmful effect. The final rule contains restrictions that the agency believes are necessary in order to reduce the number of children and adolescents who use and become addicted to these products. Relying solely on retail clerks to verify age, increasing supervision over displays, or deferring to other less restrictive alternatives would not, in comparison to the rule's comprehensive approach, be sufficient to achieve that goal.

With respect to locations that are entirely inaccessible to young people, however, the agency has amended

§ 897.16 to permit certain modes of sale, such as vending machines and self-service displays (merchandisers only), in facilities where young people are not present, or permitted to enter, at any time. These modes of sale do not involve hand-to-hand transactions between the retailer and the purchaser. Consequently, FDA has made a corresponding amendment to § 897.14(c) to require retailers to personally provide cigarettes or smokeless tobacco to purchasers "[e]xcept as otherwise provided in § 897.16(c)(2)(ii) and revised the text to correspond more closely with the language in § 897.16(c)(1)." The amendments to § 897.16 are discussed in greater detail below.

(40) A few comments questioned the need for proposed § 897.14(b) (now renumbered as § 897.14(c)). These comments said that the rule would not prompt retailers to verify a prospective purchaser's age because retailers who sell cigarettes and smokeless tobacco to minors are already in violation of State laws.

FDA disagrees with the comments' assertion. FDA's enforcement authority and the range of sanctions under the act should give retailers additional incentives to verify proof of age. Hence, FDA believes that the weight of Federal law and these regulations will prompt retailers to pay more attention to the consumer's age. By way of analogy, the United States enjoys a very high rate of compliance with prescription drug restrictions in part because a violation of the prescription requirement is actionable under Federal law. Similarly, section 1926 of the PHS Act gives States, as a condition for receiving a block grant for the prevention and treatment of substance abuse, further incentive to ensure that illegal tobacco sales to young people do not occur and that the illegal sales rate steadily decreases from 50 percent in fiscal year 1994 (or fiscal year 1995 for some States) to 20 percent 4 years later. States must also conduct annually a reasonable number of random, unannounced inspections to ensure compliance with State law (see 61 FR 1492 at 1508, January 19, 1996). Section 1926 of the PHS Act and its implementing regulations should also prompt States to devote more attention to compliance efforts to prevent illegal sales to young people and, through the requirement for random, unannounced inspections, make retailers more aware of the need to verify the consumer's age.

#### 4. Restrictions Against the Sale of Individual Cigarettes

Proposed § 897.14(c) (now renumbered as § 897.14(d)) would have prohibited the retailer or an employee of the retailer from breaking or otherwise opening any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco that is smaller than the quantity in the unopened product. In response to comments and for other reasons discussed below, the agency has amended § 897.14(d) to prohibit retailers from breaking or otherwise opening "any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in the minimum cigarette package size defined in § 897.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use." Additionally, as stated in section IV.D.1. of this document, FDA has deleted the reference to "an employee of the retailer" because the retailer is generally responsible for its employee's actions.

(41) Several comments opposed proposed § 897.14(c) (now renumbered as § 897.14(d)) in conjunction with proposed § 897.10 (which would establish general responsibilities for manufacturers, distributors, and retailers). The comments said it would be unreasonable to expect retailers to inspect all packages to assure compliance with minimum package requirement, as well as other requirements, and yet retailers would face significant penalties if they failed to comply. Other comments asked whether retailers would be held liable for opening shipping packages consisting of individual cigarette packages or cartons and selling the individual packages or cartons.

The comments misinterpreted the proposed provision. Section 897.14(d) does not require retailers to police minimum package requirements, but rather expressly states that the retailer shall not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarettes or smokeless tobacco that is smaller than the quantity in the unopened package. The confusion may have stemmed from the definition of "package." Section 897.3(f) defines "package" as a "pack, box, carton, or other container \* \* \* in which

cigarettes or smokeless tobacco are offered for sale, sold, or otherwise distributed to consumers." The provision, therefore, focuses on two distinct actions: (1) The retailer breaks or opens a cigarette package or smokeless tobacco product; and (2) the retailer sells or distributes a portion of the cigarette package or smokeless tobacco product to a consumer.

A literal reading of proposed §§ 897.3(f) and 897.14(d) together would prohibit a retailer from opening a carton of cigarettes to sell a single package of 20 cigarettes. The agency did not intend to prohibit retailers from opening shipped quantities or bundles of cigarette packages or cartons or smokeless tobacco in order to break that shipment down into ordinary packages, cartons, or other standard product units. The agency has amended § 897.14(d), to eliminate this unintended effect. The new language clarifies that retailers may open shipping boxes or cigarette cartons to sell a pack of cigarettes or a smokeless tobacco package. Additionally, FDA has modified the introduction to § 897.14(d), changing "the retailer shall not" break or open any cigarette or smokeless tobacco package to "no retailer may" break or open any package. This change is intended to simplify the text and does not alter a retailer's obligations under § 897.14(d).

(42) One comment from a company opposed a restriction on the sale of single cigarettes because it had made a substantial investment developing a vending machine that would sell single cigarettes that complied with applicable labeling and tax laws. The comment added that its machines are located in areas that are frequented by or limited to adults and that there is a market for adults who wish to smoke only occasionally.

The restriction against the sale of single cigarettes pertained to single cigarettes that are removed from cigarette packages or cartons and sold on an individual basis. Thus, the product described by the comment, a prepackaged single cigarette that complies with all applicable labeling and tax laws, does not appear to correspond to what is commonly known as a "loose." As for selling a packaged single cigarette in a vending machine, the final rule permits vending machines to be used in certain locations that are entirely inaccessible to young people. This comment, and corresponding amendments to the rule, are discussed in greater detail in section IV.E.4.a. of this document.

(43) A small number of comments opposed any restriction on the sale of single cigarettes, stating that such a restriction would make purchases by adults more difficult or could actually work to the detriment of adults who are trying to reduce their cigarette consumption by purchasing single cigarettes.

Most comments, however, supported a prohibition against the sale of single cigarettes. In general, they agreed that eliminating single cigarettes would make cigarette purchases more expensive for young people and, as a result, less likely. A number of State attorneys general stated that this provision, in conjunction with others, would assist States in enforcing compliance with State laws. A few comments noted reports of single cigarette sales occurring within their State or jurisdiction; one stated that "the problem of loosies is a very old story within the inner city," while another even claimed seeing young people wait in line for free samples of single cigarettes.

The agency declines to amend the rule to exclude single cigarettes. The preamble to the 1995 proposed rule cited evidence that a significant number of retailers are willing to sell single cigarettes to young people and are sometimes more inclined to sell single cigarettes to young people than to adults (60 FR 41314 at 41324). The comments supporting the rule reinforce the notion that single cigarettes appeal to young people.

While FDA is sensitive to the fact that adults who wish to quit smoking may wish to purchase single cigarettes to reduce smoking, on balance, the agency believes that the benefits of eliminating single cigarette sales to young people outweighs any possible detriment to adults.

##### 5. Additional Comments

(44) Several comments suggested that FDA license retailers and impose fines or other sanctions on retailers who sell cigarettes and smokeless tobacco to young people.

The agency declines to amend the rule to create a licensing system. FDA notes that SAMHSA confronted similar comments when it proposed rules to implement section 1926 of the PHS Act and elected not to require a licensing system (61 FR 1492 at 1495). The preamble to the SAMHSA rule indicated that States could use a licensing system to identify retail outlets and enforce State laws, with licensure fees and civil penalties funding the States' random,

unannounced inspections and covering administrative and enforcement costs (61 FR 1492 at 1495). FDA concurs with the SAMHSA analysis and, because licensure would be a State matter, will refrain from establishing a licensing system for retailers.

As for fines and other sanctions, no amendment to the rule is necessary. The act already establishes fines and other sanctions for parties who violate the act. For example, any restricted device that is sold, distributed, or used in violation of regulations for that restricted device is misbranded under section 502(q) of the act (21 U.S.C. 352(q)), and section 301(a) of the act prohibits the introduction or delivery for introduction into interstate commerce of a misbranded device. (Section 709 of the act creates a presumption that all devices are in interstate commerce and section 304 allows seizure of adulterated or misbranded devices even in the absence of interstate commerce.) Among other things, section 301(b) of the act prohibits the misbranding of a device in interstate commerce, while section 301(c) of the act prohibits the receipt in interstate commerce of any misbranded device. Additionally, any person who violates section 301 of the act is subject to injunctions under section 302 of the act and civil penalties, fines and imprisonment under section 303 of the act, while section 304 of the act authorizes seizure actions against misbranded devices themselves without any need for proof of interstate commerce.

(45) One comment argued that retailers should be required to keep cigarette products from public view.

FDA declines to amend the rule as suggested by the comment. The agency believes that concealing these products from view would not significantly enhance the restrictions against access by young people and would instead unduly impair an adult's ability to determine what products and brands a retailer is selling as well as the retailer's ability to sell those products.

(46) One comment stated that § 897.14 can only be enforced by routine compliance checks using underage agents. The comment suggested that FDA negotiate with States to receive information on violations of State laws and to use that information against retailers who fail to comply with § 897.14.

FDA intends to cooperate with State governments to curtail illegal sales of cigarettes and smokeless tobacco to young people. Additionally, as stated earlier in this document, FDA is

authorized to commission State officials to perform certain functions on behalf of the agency. FDA may consider commissioning State officials, where appropriate, if commissioned State officials would help ensure compliance with these regulations.

(47) One comment would amend § 897.14 to refer to "purchasing" and "obtaining" cigarettes or smokeless tobacco. The comment said this would prevent young people from attempting to obtain cigarettes or smokeless tobacco from retailers by claiming to act with a parent's permission or on behalf of a parent or adult.

The agency declines to amend the rule as suggested by the comment. As written, § 897.14 prohibits retailers from selling cigarettes or smokeless tobacco to anyone under 18 and also requires retailers to verify the purchaser's age. These provisions do not make any distinction or exception as to whether the person purchasing the products claims to be purchasing the products for an adult. In other words, even if a young person claimed to have a parent's permission or to be purchasing these products for an adult, § 897.14(a) still prohibits retailers from selling cigarettes or smokeless tobacco to that young person, and § 897.14(b) requires the retailer to verify the purchaser's age.

(48) As mentioned earlier in the discussion for § 897.10, FDA has amended the final rule to create a new § 897.14(e) to require each retailer to remove or bring into compliance all self-service displays, advertising, labeling, and other items at the retailer's establishment if those items do not comply with the requirements under this part. This amendment became necessary because comments from manufacturers and retailers claimed that retailers owned the self-service displays or that, once the manufacturer's representative gives an item to a retailer, the item becomes the retailer's property. Consequently, § 897.14(e) requires retailers to remove or otherwise bring into compliance items at the retailer's establishment if those items do not comply with this subpart. This provision essentially gives retailers three options with respect to an item that violates the requirements in this rule: (1) If the item belongs to a manufacturer, the retailer could ask the manufacturer to remove the item, consistent with the manufacturer's obligations under § 897.12; (2) the retailer could convert the item to another use or alter the item to make it comply with the regulations; or (3) the retailer could remove the item.

*E. Conditions of Manufacture, Sale, and Distribution (§ 897.16)***1. Restrictions on Nontobacco Trade Names on Tobacco Products**

Proposed § 897.16 would have established several important restrictions or conditions on the sale of cigarettes and smokeless tobacco. Proposed § 897.16(a) would have prohibited the use of a trade or brand name for a nontobacco product as the trade or brand name for a tobacco product "except for tobacco products on which a trade or brand name of nontobacco product was in use on January 1, 1995." For example, Harley Davidson cigarettes would be "grandfathered" under this provision. The preamble to the 1995 proposed rule stated that the provision would be necessary to prevent the industry from circumventing the purpose behind the rule (60 FR 41314 at 41324) by benefitting from the promotion of the nontobacco items in ways that appeal to young people. FDA noted, however, that several cigarette brands already used trade names that are normally associated with nontobacco products and would exempt those brands from § 897.16. The final regulation remains essentially the same, but clarifies the agency's intent by amending the language to limit the exception to those product names "whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995."

(49) FDA received few comments on this provision. The comments asserted that the 1995 proposed rule would effect takings compensable under the Fifth Amendment.

The agency disagrees with these comments. The final rule does not violate the Fifth Amendment. This issue is discussed in greater detail in section XI of this document.

(50) Several comments on the use of nontobacco trade names on tobacco products would delete proposed § 897.16(a), arguing that the provision will have no effect on cigarette or smokeless tobacco use by young people, and that businesses should be free to decide how to advertise or sell their products. One comment challenged the agency's authority to regulate nontobacco trade names, stating that the act only permits the agency to take action against names that are false and misleading. According to this comment, a nontobacco trade name that appeals to young people does not become subject to the act. The comment further charged

that FDA has no evidence to support a conclusion that a tobacco product bearing a nontobacco trade name would be especially appealing to young people; the comment explained that the brands mentioned by FDA in the preamble to the 1995 proposed rule—Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes—either have very small market shares or are not sold in the United States.

In contrast, one comment said § 897.16(a) is "essential to avoid the same problems that occur with 'image' advertising." The comment explained that tobacco manufacturers have used nontobacco trade names on tobacco products to give the tobacco products an "instant image."

The point of this provision, like the restrictions on advertising, is to ensure that the restrictions on sale and distribution to children and adolescents are not undermined by how the product is presented to the public. As detailed in subpart D of part 897, FDA is restricting the way cigarette and smokeless tobacco are advertised in order to eliminate those elements that resonate most strongly with the needs of those under 18 to establish an appropriate image and to create a sense of acceptance and belonging. The use of nontobacco trade names has particular appeal in the former regard. If a firm could use a popular nontobacco product trade name and put it on a tobacco product, the firm could attempt to exploit the imagery or consumer identification attached to the nontobacco product to make the tobacco appeal to young people.

For example, young people might purchase a particular nontobacco product that they perceive as symbolizing the adult sophistication or sex appeal of its users; they might also be inclined to purchase cigarettes bearing the same trade name if they perceive that the cigarettes will enhance their lifestyles in the same manner. Section 897.16(a), therefore, eliminates a potential loophole in the advertising and labeling provisions.

FDA also disagrees with the comment challenging FDA's authority. Section 897.16(a) is authorized under section 520(e) of the act which permits FDA to restrict, by regulation, the sale, distribution, or use of certain devices. Prohibiting firms from adopting nontobacco product names that appeal to young people is a restriction on the product's "sale." The comment's suggestion that FDA cannot rely on section 502(a) of the act reveals a misunderstanding of FDA's position.

FDA predicated its action on section 520(e) of the act and therefore it is not necessary to address the relevance of section 502(a).

FDA is not persuaded that small market shares for cigarette products bearing nontobacco trade names undermines the need for § 897.16(a). The preamble to the 1995 proposed rule demonstrated that young people use the most heavily advertised brands and that they can purchase cigarettes and smokeless tobacco easily (60 FR 41314 at 41323 through 41326, and 41332). The brands cited in the preamble, Harley-Davidson, Cartier, and Yves St. Laurent's Ritz, are not among the most heavily advertised brands, and, according to the comment, two (Cartier and Ritz) are not sold in the United States. Thus, there is no reason to expect these brands to be especially appealing to or purchased by young people in the United States today. However, if the other provisions in this rule are effective, some manufacturers might try altering their advertising or marketing strategy in order to generate product appeal; § 897.16(a) thus eliminates this potentially significant avenue for making a product appeal to young people.

(51) A few comments noted that the provision did not elaborate on what constitutes a "trade or brand name for a nontobacco product." One comment interpreted the terms as including any nontobacco product trade name used anywhere in the world and, as a result, argued that the provision would impose an impossible burden on manufacturers to conduct trademark searches. The comment added that manufacturers would not be able to conduct trade or brand names searches with certainty (because the 1995 proposed rule did not confine itself to registered trademarks) and manufacturers would be subject to regulatory action even if they unknowingly used a trade or brand name for a nontobacco product.

In contrast, another comment noted that a brand name directory published by the Tobacco Merchants Association of the United States lists numerous brand names for both nontobacco and tobacco products. The comment suggested that there are a greater number of cigarette products whose brand names were the same as brand names for nontobacco products than the three brands that FDA identified in the preamble to the 1995 proposed rule. The comment suggested that FDA amend the rule to limit eligible brand name "tie-ins" to those relating to both tobacco products and to nontobacco products

sold in the United States as of January 1, 1995.

FDA agrees, in part, with the comments. It would be unreasonable for the regulation to encompass all possible nontobacco product trade names, regardless of their nationality or whether the trade name was a registered trademark. Neither FDA nor manufacturers would be able to ensure that a name was not used elsewhere. FDA intended that proposed § 897.16(a) would apply to trade names in use in the United States, and that the exception for nontobacco product trade names would apply only to product trade names that were in use on both tobacco and nontobacco products as of January 1, 1995. Consequently, to clarify the rule, FDA has amended § 897.16(a) to restrict manufacturers to use of those product names that were used on both nontobacco and tobacco products in the United States as of January 1, 1995.

(52) One comment would amend § 897.16(a) to state that, in addition to being on the market as of January 1, 1995, the cigarette brand had to have generated sales of at least 500 million cigarettes or 500 million grams of cigarette or smokeless tobacco in 1994. The comment explained that this amendment would eliminate a "loophole" because a product with "nominal sales volume could open up large marketing holes for all sorts of product names."

FDA declines to amend the provision as suggested by the comment. The final rule, as amended, prohibits manufacturers from using a nontobacco product trade or brand name as the trade or brand name for a cigarette or smokeless tobacco product. The sole exception is for tobacco products whose trade or brand name was on both nontobacco and tobacco products sold in the United States as of January 1, 1995. FDA will construe this exception narrowly such that the trade or brand name on the nontobacco product must be the same. For example, if the trade name for a nontobacco product was "Old Time Country Store," a cigarette product called "Old Time" would not qualify for the exception because the name is not identical to that for the nontobacco product.

(53) FDA, on its own initiative, has amended § 897.16(a) to replace the word "may" with "shall." This amendment is intended to reinforce the notion that, except as otherwise provided in § 897.16(a), manufacturers are prohibited from using a trade or brand name of a nontobacco product as the

trade or brand name for a cigarette or smokeless tobacco product.

## 2. Minimum Package Size

Proposed § 897.16(b) would have made 20 cigarettes the minimum package size for cigarettes. The preamble to the 1995 proposed rule explained that FDA selected 20 as the minimum number of cigarettes because most cigarette packs in the United States contain 20 cigarettes and that establishing a minimum package size would preclude firms from manufacturing so-called "kiddie packs." The preamble to the 1995 proposed rule explained that "kiddie packs" usually contain a small number of cigarettes, are easier to conceal, and are less expensive than full-sized packs. The preamble to the 1995 proposed rule also noted that, based on studies or reports in other countries, significant numbers of children purchase "kiddie packs" (60 FR 41314 at 41324). Thus, by establishing a minimum package size, the 1995 proposed rule would have essentially eliminated the manufacture, distribution, and sale of "kiddie packs." The final rule provides a narrow exception to the minimum package size in response to a comment on vending machines that sell certain packaged, single cigarettes.

(54) Several comments opposed creating any minimum package size. A minority disputed that the rule would be effective, stating that young people will get cigarettes anyway or will simply begin purchasing full-sized packs. One comment, submitted on behalf of specialty tobacco companies, suggested exempting specialty tobacco products from the rule. The comment explained that many specialty tobacco products are produced in package sizes smaller than 20 cigarettes, ranging from 8 to 18 cigarettes, but that young people do not purchase specialty tobacco products. Consequently, the comment sought an exemption for specialty tobacco products or for products with a very small market share. One comment asserted that small package sizes reduce smoking by adults while another comment would amend the rule to lower the minimum size to 10 cigarettes; neither comment offered any evidence to support their assertions.

In contrast, many comments supported proposed § 897.16(b). The comments indicated that eliminating "kiddie packs" is "essential to protect youth" and described "kiddie packs" as an "obvious come-on that would appeal to kids." Other comments said the provision would reduce underage

purchases because children would not be able to afford full-sized packs as easily or as quickly as they might afford "kiddie packs."

The final rule retains 20 cigarettes as the minimum package size. The agency disagrees that this provision will be ineffective. The provisions in this subpart are designed to: (1) Make young people's access to cigarettes and smokeless tobacco more difficult by restricting specific modes of access to these products that young people use, and (2) make purchases by young people more difficult (by requiring proof of age, and other methods) and more expensive (by eliminating free samples and "kiddie packs").

Additionally, while some tobacco products, specifically the specialty tobacco products, may have been sold in smaller sizes, the benefits of eliminating "kiddie packs," namely eliminating a product size that is relatively inexpensive and appealing to young people, outweigh any inconvenience to adults.

FDA also declines to create an exemption based on market share or claims that young people do not use a particular type of cigarette; such exemptions would not treat manufacturers equally, would depart from FDA's traditional approach of regulating devices as a class (see section IV.B. of this document), and would be impractical because a firm's compliance with the rule could vary depending on fluctuations in market share and use by young people. Moreover, even a small percentage of a market, such as 1 or 2 percent, could translate into a large number of Americans; for example, 2 percent of the approximately 50 million Americans who smoke would represent 1 million people. Two percent of the approximately 3 million children under age 18 who are regular smokers would represent 60,000 young people.

Furthermore, FDA declines to make 10 cigarettes the minimum package size. The comment did not offer any justification for the lower figure, and the agency believes that a smaller package size would be counterproductive because a 10-cigarette minimum size would be tantamount to making a "kiddie pack" the minimum package size for cigarettes.

(55) One comment supported the provision, but suggested that FDA amend the rule to prevent the development of "mini" cigarettes or "short smokes." The comment said such products contain less tobacco so that they can be sold at a lower price.

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.<sup>45</sup> 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

<sup>45</sup> 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."<sup>46</sup>

(59) The same comment challenged a study by Hill.<sup>47</sup> 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."<sup>48</sup>

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."<sup>49</sup> 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.<sup>50</sup> 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.

<sup>46</sup> *Id.*, p. 19s.

<sup>47</sup> 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.

<sup>48</sup> *Id.*, p. 128.

<sup>49</sup> *Id.*, p. 126.

<sup>50</sup> "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 machines are permitted at all, they should be permitted only in locations to which minors may not be admitted.<sup>51</sup>

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."<sup>52</sup> 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.

Furthermore, 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

<sup>52</sup> "Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors," Battelle, prepared for the CDC, OSH, p. 17, April 1994.

<sup>51</sup> IOM Report, p. 214.

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.<sup>76</sup>

#### 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

<sup>76</sup>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.

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 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 the 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

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.<sup>77</sup>

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.<sup>78</sup>

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.<sup>79</sup>

<sup>77</sup> 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.

<sup>78</sup> 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.

<sup>79</sup> "Philip Morris Keeps Smoking—Campbell Sees Growth for Tobacco Unit in Declining Industry," *Advertising Age*, p. 20, Nov. 19, 1990.

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.<sup>80</sup> 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.<sup>81</sup> 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.<sup>82</sup> Moreover, the

importance of color in advertising becomes more salient when it is considered that most consumer behavior occurs in conditions of "low involvement."<sup>83</sup> 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*<sup>84</sup> 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.<sup>85</sup>

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.<sup>86</sup>

Categories," *Journal of Marketing Research*, vol. 17, pp. 294-306, 1980.

<sup>83</sup> 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.

<sup>84</sup> Short, D., "The Colour of Money," *The European*, p. 21, April 10, 1996.

<sup>85</sup> Id. Brant was commenting on Pepsi's decision to change its brand color to blue.

<sup>86</sup> 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

Continued

<sup>80</sup> 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.

<sup>81</sup> 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.

<sup>82</sup> Hanssens, D., and B. Weitz, "The Effectiveness of Industrial Print Advertisements Across Product

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.<sup>87</sup>

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."<sup>88</sup> 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.<sup>89</sup>

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.

<sup>87</sup> 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.

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

<sup>89</sup> 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 Citizens' 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.<sup>90</sup>

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,<sup>91</sup> 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.<sup>92</sup> 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

<sup>90</sup> 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.

<sup>91</sup> "State Laws on Tobacco Control—United States, 1995," *Morbidity and Mortality Weekly Report (MMWR)*, CDC, DHHS, vol. 44, No. 38-6, pp. 16-17, November 3, 1995.

<sup>92</sup> *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 delegitimizing 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.<sup>2</sup> 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.<sup>3</sup> 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."

<sup>3</sup> *Id.*

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

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,<sup>94</sup> 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.<sup>95</sup> One study<sup>96</sup> found that even brief exposure to tobacco advertising can cause some young people to have more favorable beliefs about smokers.<sup>97</sup>

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."<sup>98</sup>

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.<sup>99</sup> 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

<sup>94</sup> 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.

<sup>95</sup> 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; Altken, P. P., and D. R. Eadie, "Reinforcing Effects of Cigarette Advertising on Under-Age Smoking," *British Journal of Addict*, 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 Addict*, vol. 86, pp. 287-298, 1991; Altken, 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 Addict*, vol. 86, pp. 383-391, 1991; O'Connell, D. L., H. M. Alexander, A. J. Dobson, D. M. Lloyd, G. R. Hards, 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. Hards, 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.

<sup>96</sup> 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.

<sup>97</sup> 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.

<sup>98</sup> 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.

<sup>99</sup> 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.

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.<sup>100</sup> 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<sup>101</sup> 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.<sup>102</sup> 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.<sup>103</sup>

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

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.<sup>106</sup> 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.<sup>107</sup>

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

<sup>103</sup> 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, 1994.

<sup>104</sup> 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; 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.

<sup>105</sup> 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.

<sup>106</sup> 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.

<sup>107</sup> *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.

<sup>100</sup> 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.

<sup>101</sup> 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.

<sup>102</sup> 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, Tiers, 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. 192-185, 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.

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 indicated that 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.<sup>108</sup>

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.<sup>109</sup> 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.<sup>110</sup> 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),<sup>111</sup> 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.<sup>112</sup> 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)<sup>113</sup> that show that, contrary to FDA's assertion and citation to data from Monitoring the Future,<sup>114</sup> 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.<sup>115</sup> 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

<sup>108</sup> 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.

<sup>109</sup> 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.

<sup>110</sup> Independent research by Fischer found that 61 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.

<sup>111</sup> Henke, L., "Young Children's Perceptions of Cigarette Brand Advertising Symbols: Awareness, Affect and Target Market Identification," *Journal of Advertising*, in press.

<sup>112</sup> Roper Starch, "Advertising Character and Slogan Survey," pp. 16-17, November 1993 (conducted for R. J. Reynolds Tobacco Co.).

<sup>113</sup> "1993 Teenage Attitudes and Practices Survey, Public Use Data Tape," CDC, OSH, p. 3, 1993 (unpublished data).

<sup>114</sup> 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.

<sup>115</sup> 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,<sup>118</sup> 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.<sup>117</sup>

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<sup>119</sup> data and not from the data in Monitoring the Future used by FDA.<sup>119</sup>

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.

<sup>117</sup> "Advertising Character and Slogan Survey," pp. 10, 12, 22-23.

<sup>118</sup> "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.

<sup>119</sup> Dubow, J. S., "Advertising Recognition and Recall by Age-Including Teens," *Journal of Advertising Research*, pp. 55-60, Sept/Oct 1995.

<sup>120</sup> 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.<sup>120</sup> 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.<sup>121</sup> 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.'" <sup>122</sup>

(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 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

<sup>120</sup> Beales, J. H., "Teenage Smoking: Fact and Fiction," *The American Enterprise*, vol. 21, March/April 1994.

<sup>121</sup> 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. 1: Secondary School Students, DHHS, PHS, NIH, NIDA, NIH Pub. No. 94-3809, 1995.

<sup>122</sup> 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.<sup>123</sup>

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.<sup>124</sup>

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. \* \* \*<sup>125</sup>

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.<sup>126</sup>

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

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

<sup>124</sup> Teague, C., *Research Planning Memorandum on Some Thought About New Brands for Cigarettes for the Youth Market*, p. 1, 1973.

<sup>125</sup> *Id.*, pp. 1–2.

<sup>126</sup> *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.)<sup>127</sup>

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*,<sup>128</sup> 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.<sup>129</sup>

<sup>127</sup> 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 1977-1986 for R.J. Reynolds Tobacco Company*, Research Department, 1976.

<sup>128</sup> 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.

<sup>129</sup> 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'."

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.<sup>130</sup> 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."

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' 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."

<sup>130</sup> "White Paper," Camel Advertising Development, p. 1, undated.

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.<sup>131</sup>

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

<sup>131</sup> 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.<sup>132</sup> 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.<sup>133</sup> 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.<sup>134</sup> 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,<sup>135</sup> the most commonly smoked cigarettes (39 percent) among adult smokers are brandless (i.e., private label, generics, or plain packaged products).<sup>136</sup> Another study found that children who smoke as few as one cigarette per week can identify a preferred brand.<sup>137</sup>

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).

<sup>134</sup> "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.

<sup>135</sup> "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.

<sup>136</sup> Teinowitz, L., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3 and 46, April 26, 1993.

<sup>137</sup> 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.

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<sup>138</sup> 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.

<sup>138</sup> "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.

<sup>132</sup> 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.

<sup>133</sup> 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.)

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),<sup>139</sup> 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<sup>140</sup> 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

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

<sup>140</sup> 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.<sup>141</sup> 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.

1. *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 heroes 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—

<sup>141</sup> "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,<sup>142</sup> 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.<sup>143</sup>

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

Specifically, the same comment cited numerous studies that indicate that many young people smoke because they

hope to convey a positive image.<sup>146</sup> 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.<sup>147</sup>

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 \* \* \*"<sup>148</sup> By adolescence, clothes, possessions, and "badge products" such as cigarettes are used to define oneself and to control relations with others.<sup>149</sup>

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.<sup>150</sup>

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

<sup>148</sup> Nichter, M., and E. Cartwright, "Saving the Children for the Tobacco Industry," *Medical Anthropology Quarterly*, vol. 5, pp. 236-256, 1981.

<sup>149</sup> Stacey, B. G., "Economic Socialization in the Pre-Adult Years," *British Journal of Social Psychology*, vol. 21, pp. 159-173, 1982.

<sup>150</sup> 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 echo 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 T 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.

<sup>142</sup> 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.

<sup>143</sup> 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.

<sup>144</sup> 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.

<sup>145</sup> *Id.*

<sup>146</sup> 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. McClelland, "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 Sociology*, 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.

<sup>147</sup> Brown, B. B., M. J. Lohr, and E. L. McClelland, "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.

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.<sup>151</sup> 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.<sup>152</sup> 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 misspecified 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.

<sup>151</sup> Dr. Beales used children's designation of a "most advertised brand" as a surrogate for the effect of advertising.

<sup>152</sup> 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,"<sup>153</sup> 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<sup>154</sup> 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,<sup>155</sup> 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

<sup>153</sup> 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.

<sup>154</sup> The authors cited this study as an example of one having access to full industry data. Leeflang, P. S. H., and Reuyl, "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.

<sup>155</sup> 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."<sup>156</sup> 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."<sup>157</sup> 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.<sup>158</sup> 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.<sup>159</sup> 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.B.2. 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**

<sup>156</sup> 1994 SGR, p. 188.

<sup>157</sup> 1989 SGR, p. 517.

<sup>158</sup> 1994 SGR, p. 185.

<sup>159</sup> *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.f. 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.<sup>160</sup> 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.<sup>161</sup>

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."<sup>162</sup>

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.<sup>163</sup>

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,

<sup>162</sup> Daniels, D., *Giants, Pygmies and Other Advertising People*, Crain, Chicago, p. 245, 1974.

<sup>163</sup> 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.

<sup>160</sup> Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," vol. 44, 1993.

<sup>161</sup> 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.

the 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<sup>164</sup> 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.<sup>165</sup> 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.<sup>166</sup>

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.<sup>167</sup> 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

<sup>164</sup> 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.

<sup>165</sup> 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.

<sup>167</sup> 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.

<sup>166</sup> Smees, 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.

approximately 23 percent and 28 percent, respectively.<sup>168</sup> 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.<sup>169</sup> 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.<sup>170</sup> 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<sup>171</sup> 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<sup>172</sup> 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 (Smea 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

<sup>168</sup> 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.

<sup>169</sup> 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.

<sup>170</sup> 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.

<sup>171</sup> 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.

<sup>172</sup> 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.<sup>173</sup> 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.<sup>174</sup> 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,<sup>175</sup> 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<sup>176</sup> do not indicate that

<sup>174</sup> "Health or Tobacco—An End to Tobacco Advertising and Promotion," TSB, Wellington, New Zealand, May 1989.

<sup>175</sup> 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.

<sup>176</sup> 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.

<sup>173</sup> 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.

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.<sup>177</sup>

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<sup>178</sup> 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 Laugesen 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,<sup>179</sup> 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.<sup>180</sup>

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.<sup>181</sup>

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*

<sup>177</sup> Boddewyn, J. J., "Tobacco Advertising Bans and Consumption in 16 Countries," International Advertising Association, 1986.

<sup>178</sup> 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.

<sup>179</sup> 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.

<sup>180</sup> Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

<sup>181</sup> 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<sup>182</sup> 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."<sup>183</sup>

<sup>182</sup> Teague, C., *Research Planning Memorandum on Some Thought about New Brands of Cigarettes for the Youth Market*, 1973.

<sup>183</sup> Teague, C., *Research Planning Memorandum on the Nature of the Tobacco Business and the Crucial Role of Nicotine Therein*, 1972.

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.<sup>184</sup>

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.<sup>185</sup>

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 them have approximately 90 percent of the market.<sup>186</sup>

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

<sup>184</sup> 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.

<sup>185</sup> Foote, E., "Advertising and Tobacco," *JAMA*, vol. 245, pp. 1667-1668, 1981.

<sup>186</sup> Weldner, 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<sup>187</sup> 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.<sup>188</sup> The same phenomenon was captured differently in a recent study<sup>189</sup> 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.<sup>190</sup>

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.<sup>191</sup>

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<sup>192</sup> when they promoted cola for breakfast.

Similarly, tobacco has competitors. New users or "presmokers," as one RJR employee refers to them,<sup>193</sup> 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."<sup>194</sup> 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.<sup>195</sup>

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.

<sup>187</sup> 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.

<sup>188</sup> 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.

<sup>189</sup> 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.

<sup>190</sup> Roberts, M. J., and L. Samuelson, "An Empirical Analysis of Dynamic, Nonprice Oligopolistic Industry," *Rand Journal of Economics*, vol. 19, pp. 200-220, 1988.

<sup>191</sup> Ippolito, P., and A. Mathios, *Health Claims in Advertising and Labeling: A Study of the Cereal Market*, p. 32, 1989.

<sup>192</sup> Dourado, P., "Breakfast Cola Takes on America's Coffee Giants," *The Independent*, p. 28, April 15, 1990.

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

<sup>194</sup> *Id.*

<sup>195</sup> 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

comments stated that FDA's proposed restrictions are more extensive than necessary to achieve the agency's asserted interest, particularly because the agency had failed to show that the advertising restrictions will have any effect on underage smoking. Some comments argued that the restrictions that FDA proposed were tantamount to a ban because they will prevent the advertiser's message from reaching consumers.

Other comments disagreed. These comments said that FDA's proposed action is narrowly tailored. They argued that FDA had steered clear of imposing a categorical ban on tobacco advertising, or even broad prophylactic rules. One comment said that tailored prohibitions, instead of all-out bans, are important signposts indicating a measured response.

FDA disagrees with the comments that claimed that the restrictions were not narrowly tailored. The agency recognizes, as the Supreme Court said in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985), that it has the burden of distinguishing the harmless from the harmful. FDA has met this burden.

The restrictions that FDA is adopting are not like those in *Central Hudson*, which, even though the Public Service Commission's interest was limited to energy conservation, reached all promotional advertising, regardless of the impact of the touted service on energy use. (See 447 U.S. at 570.) Rather, FDA's restrictions are carefully crafted to focus on those media and aspects of advertising that children are routinely exposed to and that the available evidence shows has the greatest effect on youngsters, while leaving the informational aspects of advertising largely untouched. FDA is not banning outdoor advertising; it is restricting it so that it does not unavoidably confront children when they play. It is not banning print advertising. It is restricting the use of images and color, which are particularly appealing to children, in publications that have a large number of young readers under the age of 18 and in other forms of advertising to which children are routinely exposed but permitting unrestricted advertising in adult publications and adult venues. It is restricting cigarette and smokeless tobacco companies' use of brand names and product identifications in sponsored events, but again in a way that reflects the agency's concern about children and adolescents under the age of 18. That is, it is permitting companies

to sponsor in the corporate name in order to engender good will, but preventing them from using the brand specific attractive imagery that is influential with young people. Finally, it is prohibiting the use of branded promotional items because it is the young who find particular value in these items. In each of these respects, the agency has gone no further than it has found, based on the evidence, is necessary to meet its ends. (See *Dunagin v. City of Oxford, Miss.*, 718 F.2d at 751.)

Under the restrictions that FDA is adopting, firms will remain free to disseminate advertising that performs all the informational functions that are protected by the First Amendment. They will be able to disseminate information on what they are selling, for what reason, and at what price. (See *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748, 765 (1976); *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977).) Thus, the situation here is analogous to that in *Friedman v. Rogers*, 440 U.S. 1 (1979), where the Supreme Court found that a restriction on the use of optometrical trade names had only an incidental effect on the content of commercial speech. The Court said that "the factual information associated with trade names may be communicated freely and explicitly to the public" (440 U.S. at 16). So, here, any information that firms wish to communicate to adults may still be communicated by use of words. Indeed, the tobacco industry has used text-only advertising successfully in the past.<sup>196</sup>

It may be true, as some of the comments state and as the agency recognized above, that it will be more difficult for adult consumers to find cigarette and smokeless tobacco advertising without images and color, but willingness to search for information is one of the things that adults will do when they need information about price, quality, or product performance. Moreover, as discussed above, adult tobacco users are particularly interested in information on price, "safer" cigarettes, and new products, information that can be freely conveyed under FDA's regulations.

(25) The effect of the proposed restrictions on cigarette and smokeless tobacco product manufacturers' ability to communicate with adults was the subject of a number of comments. These comments argued that the proposed

restrictions would not only preclude speech that may be perceived by young people, it would preclude speech that would be received by adults. The restrictions, these comments asserted, would deprive adults, who are legally entitled to smoke, of their right to the free flow of relevant commercial information. Other comments, relying on several cases, said that the First Amendment does not countenance wholesale censorship of speech for adults under the guise of protecting children. Many comments, for example, quoted a statement from *Butler v. State of Michigan*, 352 U.S. 380, 383 (1957) ("Surely, this is to burn the house to roast the pig.") in support of this point. One comment said that FDA's purpose of reducing tobacco use by minors cannot support massive censorship between tobacco advertisers and adults.

One comment, however, argued that FDA's proposed restrictions are narrowly tailored to the specific types of advertising that are most effective with children. This comment said that these restrictions permit companies to continue marketing practices that do not appeal to children.

FDA has considered the concerns expressed in the comments. First, FDA does not agree that its interest is limited. As discussed above, the agency's interest is compelling. Nonetheless, the agency has tried very hard to tailor the restrictions on advertising in this final rule to focus them in order to limit the appeal of advertising to the young and ensure that the restrictions on access to cigarettes and smokeless tobacco will not be undermined, while at the same time, minimizing their effect on adults. Given this approach, FDA's restrictions differ significantly from those struck down in *Butler v. State of Michigan*, where the Court overturned conviction of a bookseller for selling a book to adults that contained some portions that might be objectionable to young people. In that case, the Supreme Court stated:

We have before us legislation not reasonably restricted to the evil with which it is said to deal. The incidence of this enactment is to reduce the adult population of Michigan to only what is fit for children. (352 U.S. at 383)

This statement clearly does not describe the situation under the restrictions FDA is adopting. Except for limits on images and colors, the restrictions that FDA is adopting do not limit what cigarette and smokeless tobacco manufacturers, distributors, or retailers may say. As stated above, they are free to put into words any nondeceptive message that they would have communicated by color or image.

<sup>196</sup> As discussed more fully elsewhere, advertising for low-tar products is generally more reliant on text than on imagery.

FDA's restrictions, as one comment stated, restrict only those advertising techniques that have the most appeal. Thus, contrary to the situation in *Butler v. Michigan*, these restrictions are reasonably restricted to the harms they are intended to address.

Nor are the restrictions that FDA is imposing like the one struck down in *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60 (1983), which was cited by several comments. In that case, a Federal statute prohibited the mailing of unsolicited advertisements for contraceptives. The Postal Service sought to justify this restriction as aiding parents' efforts to discuss birth control with their children. While the Court found this interest to be substantial, it found the restriction to be more extensive than the Constitution permits (463 U.S. at 73). The Supreme Court struck down the restrictions, stating: "The level of discourse reaching the mailbox simply cannot be limited to that which would be suitable for a sandbox" (*Id.* at 74). It is in this respect that FDA's restrictions differ from those in *Bolger*. While FDA may limit the type of color or imagery, or the use of noncommunicative media, i.e., hats, FDA's restrictions do not limit the types of information that can be disseminated, except within 1,000 feet of schools and playgrounds.

(26) Other comments cited *Sable Communications v. FCC*, 492 U.S. 115 (1989), in which the Supreme Court struck down an outright ban on indecent as well as obscene interstate commercial telephone messages. This case is not relevant here because FDA is not imposing an outright ban on cigarette and smokeless tobacco advertising,<sup>197</sup> and because in contrast to Congress's failure to make findings that would justify the ban in *Sable*, FDA is fully explaining the basis for each of the restrictions that it is adopting here.

Other comments cited *Erznoznik v. City of Jacksonville*, 422 U.S. 205 (1975), in which the Supreme Court struck down an ordinance that, to protect minors, made it illegal to exhibit a motion picture visible from public streets in which female buttocks and bare breasts were shown. In doing so,

the Supreme Court stated that: "Speech \* \* \* cannot be suppressed solely to protect the young from ideas or images that a legislative body thinks unsuitable for them" (422 U.S. at 213).

Again, however, FDA is imposing restrictions on the manner and, to a limited extent, places in which cigarettes and smokeless tobacco are advertised, not content restrictions. Moreover, FDA is restricting commercial speech, which, as stated in section VI.C.1. of this document, is subject to a subordinate position in the scale of First Amendment values to the noncommercial expressions involved in *Erznoznik*. Thus, this case has no application here.

(27) Finally, a few comments cited *Project 80's, Inc. v. City of Pocatello*, 942 F.2d 635 (9th Cir. 1991), a case in which the U.S. Court of Appeals for the Ninth Circuit struck down ordinances that prohibited door-to-door solicitation because they restricted both wanted and unwanted solicitations. (See 942 F.2d at 638-639.) The municipalities sought to defend these ordinances on the grounds that they did not prohibit in-home sales. However, the court said that residents who wanted to receive unwanted solicitors had to post a "Solicitors Welcome" sign, and that the Government's imposition of affirmative obligations on the residents' First Amendment rights to receive speech is not permissible (*Id.* at 639).

Presumably, the comments cited this case as evidence that FDA's restrictions on tobacco advertising sweep too broadly because they affect the rights of both minors and adults to receive speech. Again, however, the case is distinguishable. Under FDA's restrictions, adults will be able to continue to receive tobacco advertising without any obligation to take any affirmative steps. They will have to look a little harder because, to advance FDA's interest in protecting the health of minors, advertisements will generally not have images or color, and such advertising will not be around schools or playgrounds. However, the advertising should otherwise continue to be available in newspapers, magazines, and billboards and appear unrestricted in adult publications and venues. There is no indication in *Project '80, Inc. v. City of Pocatello*, that the Ninth Circuit would find in such restrictions an undue burden under the First Amendment.

This review of the case law shows that FDA's effort to tailor the restrictions that it is adopting for cigarette and smokeless tobacco advertising that

clearly distinguishes them from the governmental efforts to protect minors that have been struck down as sweeping too broadly and as impinging on the rights of adults. Under FDA's restrictions, there will still be a free flow of information to adults and not massive censorship as some comments allege. Thus, these comments do not provide a basis to conclude that FDA's restrictions fail the third prong of the *Central Hudson* test.

(28) Several comments pointed out that the Supreme Court has stated on several occasions that regulations that disregard numerous and obvious less restrictive and more precise means of achieving the government's asserted objectives are not narrowly tailored. These comments suggested that there are several less restrictive alternatives to the restrictions on advertising that FDA had proposed. One alternative pointed to by the comments was better enforcement of laws prohibiting sales to minors. The comments pointed out that Congress passed legislation as part of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act of 1992, that prohibits DHHS from providing block grants for the prevention and treatment of substance abuse unless the State prohibits the sale and distribution of tobacco products to persons under 18. The comments said that FDA should give this new law a chance to work before imposing restrictions on speech, particularly in light of the fact that DHHS itself said in its 1995 proposed rule to implement this new law that "[e]liminating virtually all sales [of tobacco products] to minors does not even present particularly difficult enforcement problems" (see 58 FR 45156 at 45165, August 26, 1993).

The other alternative, according to the comments, that exists to the restrictions is an educational campaign that is sponsored either by the Government or that is provided through voluntary counter speech by the tobacco industry.

The agency recognizes that the various opinions by the Justices in 44 *Liquormart* reiterate the need to consider nonspeech restrictions. Justice Stevens, speaking for himself and Justices Kennedy, Ginsburg, and Souter stated that the legislature "cannot satisfy the requirement that its restriction on speech be no more extensive than necessary," given that alternative forms of regulation, such as taxation or limits on purchases that did not involve restrictions on speech, could achieve the goal of promoting temperance as well as, or better, than,

<sup>197</sup> The Court specifically distinguished *FCC v. Pacifica Foundation*, 438 U.S. 726 (1978), because that case did not involve a total ban on broadcasting indecent material. The Court pointed out that the FCC rule in that case sought to channel the indecent material to times of the day when children most likely would not be exposed to it (*Sable Communications v. FCC*, 492 U.S. at 127). FDA's intention here is to impose a similar type of focused and tailored restriction on tobacco advertising to limit the appeal of such advertising to children.

its ban. Moreover, Justice O'Connor in a concurrence, joined by the Chief Justice, and Justices Souter and Breyer stated:

The availability of less burdensome alternatives to reach the stated goal signals that the fit between the legislature's ends and the means chosen to accomplish those ends may be too imprecise to withstand First Amendment scrutiny. (116 S.Ct. at 1521)

(29) One comment, however, argued that, for two reasons, there is no plausible claim that FDA has disregarded reasonable alternatives. First, the comment pointed out that the Federal Government has engaged in an incremental effort for 30 years to strike the appropriate balance in regulating the sale of tobacco products. This effort was successful in bringing down overall smoking rates, but youth smoking rates remained stable during the 1980's and have recently begun to rise. Because previous measures have failed, the comment said, it was now appropriate for FDA to take stricter action to reduce the use of tobacco products by minors. Second, the comment noted that a lack of narrow tailoring often manifests itself in a restraint that is either grossly underinclusive or overinclusive. The comment said that FDA had been neither here.

In *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2380, the Supreme Court made clear that the question whether a restriction on commercial speech is reasonably well-tailored turns, at least in part, on the existence of "numerous and obvious less burdensome alternatives to restrictions on commercial speech \* \* \*." (See 115 S.Ct. at 2380 (citing *Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 418 n.13 (1993)).) FDA has considered the alternatives suggested by the comments and finds that none of them is an appropriate alternative to the restrictions that FDA is adopting.

First, the Government has engaged in a 30-year effort to eliminate young people's access to and use of tobacco products. The industry, through its voluntary code and various education programs, has professed to be part of the solution. However, tobacco can be easily obtained by young people (between 516 million and 947 million packs of cigarettes sold illegally per year to children (1992-1993) (60 FR 41314 at 41315)). Moreover, although adult smoking rates have declined dramatically since the publication of the first Surgeon General's Report in 1964 (from over 42.4 percent in 1965 to 25 percent in 1993) (60 FR 41314 at 41317), young people's smoking rates failed to decline during the decade of the 1980's

and began to rise in 1991. Between 1991 and 1995, the proportion of 8th and 10th graders who reported smoking in the 30 days before the survey had risen by one-third, to about 19 percent and 28 percent, respectively. Smoking among high school seniors had increased by more than one-fifth since 1992, with 33.5 percent saying that they had smoked in the 30 days before the survey.<sup>198</sup> Thus, past efforts involving age restrictions and warning messages on packages and advertising have not been sufficient to reduce the demand for tobacco by young people. The restrictions on advertising are designed to affect the demand.

Second, the agency proposed a sufficiently comprehensive set of regulatory restrictions to address the problem of tobacco use by young people, to wit: (1) Provisions that restrict and prevent sales of tobacco products to young people; (2) provisions that reduce the appeal of tobacco products for young people that is created by advertising and promotions; and (3) a program to provide educational messages for young people to help them resist tobacco use. Thus, the agency has not relied solely on regulations that have an impact upon the speech of the tobacco industry but has included provisions to address the activity itself.

Third, while it is true that better enforcement of laws restricting sales to minors is complementary to FDA's approach, it does not eliminate the need for this action. As DHHS recognized in its final rule implementing the ADAMHA Reorganization Act of 1992, DHHS's action under that statute and FDA's regulations both address the need to reduce minors' access to tobacco products. FDA's action, however, in addition to reducing access, attempts, through the restrictions on advertising, to reduce "the powerful appeal of tobacco products to children and adolescents" (61 FR 1492, January 19, 1996).<sup>199</sup>

<sup>198</sup> "Teen Smoking, Marijuana Use Increase Sharply, Study Shows; HHS Sees Alarming 'Culturewide' Change in Progress," *The Washington Times*, p. A2, December 16, 1995; quoting from "Results from the 1995 Monitoring the Future Survey," National Institute on Drug Abuse Briefing for Donna E. Shalala, Ph.D., Secretary of Health and Human Services, December 13, 1995.

<sup>199</sup> It is true that in its August 25, 1993, proposal (58 FR 45156), DHHS stated, as the comments say, that eliminating virtually all sales to minors does not present particularly difficult enforcement problems. This statement did not imply, however, that achieving this goal would be easy, nor did it reflect consideration of what ancillary measures would be useful to help to achieve this goal. It was,

Advertising, as explained in sections VI.B. and VI.D. of this document, plays a role in the decision of children and adolescents to use cigarettes and smokeless tobacco. As long as advertising continues to play that role, young people will be motivated to obtain access to tobacco products and to attempt to circumvent any access restrictions. Thus, the restrictions on speech are necessary to prevent advertising from undermining FDA's proposed restrictions on access. First, the agency notes that the voluntary educational campaigns conducted by tobacco companies have not been effective in reducing underage tobacco use. This fact is evidenced by the increase in prevalence of tobacco use among young people. (See, e.g., 60 FR 41314 at 41315.) Second, the agency finds that any educational campaign is likely to be undermined if the young people to whom it is aimed continue to be the target of advertising that fosters the perception that experimentation with tobacco by young people is expected and accepted.

The U.S. Court of Appeals for the Fifth Circuit considered a suggestion similar to that of an educational campaign in *Dunagin v. City of Oxford, Miss.* and found it not to be an alternative to restrictions on advertising:

We do not believe that a less restrictive time, place, and manner restriction, such as a disclaimer warning of the dangers of alcohol, would be effective. The state's concern is not that the public is unaware of the dangers of alcohol \* \* \*. The concern instead is that advertising will unduly promote alcohol consumption despite known dangers. (See 718 F.2d at 751; see also *Posadas de Puerto Rico Ass'n v. Tourism Co. of Puerto Rico*, 478 U.S. at 344.) This is exactly FDA's concern about the effect of advertising on underage tobacco use, and why an educational campaign, which may complement advertising restrictions, is not an alternative to them.

Thus, the agency concludes that there are no less burdensome alternatives to restrictions on advertising. In this respect, this proceeding is distinguishable from that considered in *Rubin v. Coors*, which was cited by a number of the comments. In *Rubin v. Coors*, the Supreme Court pointed to the fact that the respondent cited several options that could advance the Government's asserted interest in a manner less intrusive to respondent's First Amendment rights than the

rather, a statement of DHHS' view that this goal could be achieved.

statutory provision the Government had adopted (115 S.Ct. at 1593).<sup>200</sup> Here, as in section VI.E. of this document, there are none believed to be nearly as effective.

In *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430 (1993), the Supreme Court said that "the requirement of narrow-tailoring is met if 'the \* \* \* regulation promotes a substantial Government interest that would be achieved less effectively absent the regulation,' provided that it did not burden substantially more speech than necessary to further the government's legitimate interests."

FDA's restrictions on cigarette and smokeless tobacco advertising clearly meet this test. FDA's restrictions directly and materially advance its compelling interest in the health of children and adolescents under the age of 18. The discussion of the lack of less restrictive alternatives demonstrates that the agency's goals would be achieved less effectively in the absence of these restrictions. Finally, as the discussion on narrow tailoring and in the review of the comments on each of the regulations on advertising that follows makes clear, FDA is restricting only those aspects of advertising that have particular appeal to the young. Thus, the agency has crafted the advertising provisions with specificity to allow unrestricted advertising in those venues that are not seen by or used by children and adolescents. Accordingly, publications with adult readership and adult establishments may have unlimited print advertising. Moreover, companies are free to offer nontobacco items and events in their corporate names or unbranded. Companies, thus, can reward adult usage by providing these incentives but may not do so in a format (with brand identification and imagery) which is appealing to young people.

However, the agency has been unable to determine additional areas for unrestricted advertising. Thus, other than adult establishments, such as bars, there are no areas at other retail establishments that are not visible to young people. Billboards are ubiquitous and accessible to all ages. Nontobacco items can be restricted to dissemination to adults, but they would still serve as walking billboards. Finally, there are no adult only sponsored events—children are at the events or watching them on

television. As described more fully in section VI.E.8. of this document, in the case of auto racing, attendance by young people is on the rise.

## 2. Section 897.30(a)—Permissible Forms of Labeling and Advertising

Proposed § 897.30(a) would have established the scope of permissible forms of labeling and advertising for cigarettes and smokeless tobacco. Proposed § 897.30(a)(1) would have defined permissible forms of advertising as newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution); billboards, posters, placards; and nonpoint of sale promotional material (including direct mail). Proposed § 897.30(a)(2) would have defined permissible forms of labeling as point of sale promotional material; audio and/or video formats delivered at a point of sale; and entries and teams in sponsored events.

In response to the comments, FDA has revised § 897.30(a) so that it no longer distinguishes between advertising and labeling, deletes teams and entries as permissible advertising, describes the procedure that FDA will follow when it is informed by advertisers of their intent to advertise in a medium not listed in the regulation.

In addition, the first sentence of § 897.30(a), which states that this subpart does not apply to cigarette or smokeless tobacco product package labels, has been redesignated as § 897.30(c).

(30) Several comments were received addressing the issue of permissible advertising outlets. Comments from the tobacco and advertising industries opposed the 1995 proposed rule. These comments criticized the 1995 proposed rule for not defining the term "advertising" and called the 1995 proposed rule unprecedented in the scope of its limitations on the forms of media, a violation of the First Amendment, a violation of the Administrative Procedure Act (APA), and beyond FDA's statutory authority. Supporters of the 1995 proposed rule, including health and public interest groups, stated that it is a reasonable measure given the effect of advertising on children and that it provides manufacturers with a wide variety of means for communicating with their customers. Some supporting comments urged that the prohibition of certain media, such as the Internet, be stated explicitly.

Several comments from the tobacco industry expressed concern that FDA did not define the term "advertising"

"because § 897.30(a)(1) would limit the media in which cigarettes may be 'advertised,' the definition of 'advertising' as used by FDA is crucial; yet the term is not defined in the proposed regulations."

Moreover, they expressed concern that the definition was so sweeping that it could literally "include reports to shareholders or potential shareholders; communications among manufacturers, wholesalers, distributors, and retailers; or even communications to the news media insofar as they might be deemed a 'commercial use.'"

Other comments requested that the agency clarify the definition to ban product placements in movies and commercials shown in movie theaters. Several comments stated that § 897.30 should be extended to include tobacco product packages to reduce the means of a child expressing affinity with the image associated with a particular brand. One comment recommended tombstone packaging without an identifiable logo.

The agency carefully considered whether it should attempt to define the term "advertising" more explicitly than it did. "Advertising" as a term is constantly evolving, as new media and new techniques of marketing emerge. Although its boundaries are understood (and were provided in the preamble to the 1995 proposed rule), there is no one accepted definition. FTC is the Federal agency with general responsibility for regulating most consumer advertising. Yet neither FTC nor any of its rules define the general term "advertising." The agency agrees with the approach taken by FTC and continues to believe that the term "advertising" should not be defined any more specifically. Thus, FDA finds that the description of advertising in the preamble to the 1995 proposed rule is appropriate.

Labeling and advertising are used throughout this subpart to include all commercial uses of the brand name of a product (alone or in conjunction with other words), logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product. However, labeling and advertising would exclude package labels, which would be covered under proposed subpart C. (60 FR 41314 at 41334)

The agency also agrees with comments that state that it must provide some context for the application of so open ended a definition. For example, comments contended that "commercial use" could be interpreted to include such items as trade advertising (communication between

<sup>200</sup> One alternative that the respondents in *Rubin v. Coors* advanced was prohibiting marketing efforts emphasizing high alcohol strength (115 S.Ct. at 1593.) What FDA is doing here is analogous to that alternative. It is restricting marketing efforts that have particular appeal to the young.

manufacturers, wholesalers, distributors, and retailers), shareholder reports, and possibly even communications with the news media. This was not FDA's intent. This rule is a consumer based regulation; it is not the intention of FDA to include purely business related communications. Thus, noncommercial uses would not be affected. These would include such uses as unpaid press statements, signs on factories noting locations, business cards, and stockholder reports. While many of these uses would be ordinary and necessary business expenses, they would not be commercial uses in the context of the rule's restrictions on tobacco advertising affecting minors' tobacco use.

Furthermore, the preamble to the 1995 proposed rule explained that the agency intends to permit advertising with imagery and color in publications that are read primarily by adults. For that reason, under § 897.32(a), advertisements in publications (whether periodic or limited distribution) with primarily adult readership are not restricted to a text-only format. Trade advertising in trade press publications and trade show publications, trade catalogs, price sheets, and other publications for wholesalers, distributors, and retailers that will not be seen by consumers, including minors, are unaffected by the rule.

Also, the agency does not believe that the term "advertising" needs to be defined to clarify what is not a permissible advertising outlet. The 1995 proposed rule clearly specifies what advertising outlets are included within the regulation's coverage. However, the agency has been persuaded to make more clear its procedures for new or uncovered media. These procedures are described in this section.

The agency does not agree with comments that the rule needs to be clarified regarding infomercials or advertorials (program length commercials). Television infomercials are not allowed under the statutory broadcast ban, and magazine advertorials would be treated like any other magazine advertising. The agency recognizes that commercial advertising messages (videos) shown in a movie theater are not addressed by the 1995 proposed rule. If this becomes a desired medium, the companies would need to notify FDA 30 days prior to using a new medium. Finally, product placements in movies, music videos, and television, if not placed at the expense of a tobacco manufacturer, distributor, or retailer, would not be affected by this rule. The

agency does not intend to regulate a film producer's artistic expression—i.e., what the producer chooses to display in movies.

The agency has decided not to include restrictions on tobacco product packaging. The agency has attempted to narrowly tailor this rule and therefore has not included packaging restrictions at this time.

(31) Several comments from the advertising industry expressed concern that the wording of § 897.30(a)(1) would ban all advertising for tobacco products that is not expressly permitted. If so, the comment states, the rule would be arbitrary and capricious because the agency did not present evidence that these unnamed advertising techniques influence young people. Another comment pointed out that the channels available to tobacco companies for communicating with adults already have been severely restricted by Congress' ban on television and radio advertising.

In contrast, comments from organizations of health professionals and a public interest group supported the scope of permissible advertising. One specific comment stated that, "The media listed in § 897.30 provide manufacturers with a wide variety of means for communicating with their customers."

The agency has determined that the scope of the permissible outlets for tobacco advertising in the 1995 proposed rule is reasonable. The permissible forms are the known current forums for tobacco labeling and advertising and account for the vast majority of advertising expenditures. While the format of much of current tobacco advertising is being restricted to a text-only format, almost all of the current media outlets being used for tobacco advertising will still be permissible. Legal users will continue to be able to receive information about cigarettes and smokeless tobacco, in a text-only format in most cases, in virtually all the same media currently used for tobacco advertising. Moreover, if an advertiser intends to use a new media outlet not included in the list of permissible advertising, its responsibility is to notify FDA and provide the agency with information about the media and the extent to which the advertising is seen by young people. FDA will review any submission and make a determination whether provisions of the final regulation provide sufficient information for the advertiser to know how to disseminate its advertising or whether the

regulations need to be amended. Advertising in any new media will be subject to the text-only format requirement if it is a medium used by young people. Therefore, FDA has created a new § 897.30(a)(2) to reflect this new process.

The agency believes this approach is reasonable and is fully consistent with its statutory authority and with the First Amendment. In *Central Hudson Gas & Electric Co.*, 447 U.S. at 571, n.13, the Supreme Court suggested that the Public Service Commission might consider a system of previewing advertising campaigns to ensure that they will not defeat conservation policy. The Court pointed out that "commercial speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it" (*Id.*). Given the agency's significant interest in ensuring that the restrictions on access that it is imposing are not undermined, FDA finds that the requirement that firms consult with it before using a new advertising medium is a limited means of regulating commercial expression that is likely to vindicate FDA's public health interests. This approach will not prohibit the tobacco industry from advertising in new media but will protect young people by giving the agency an opportunity to review the problems presented by a new media and to design new regulations or adapt current ones.

(32) One comment from a public interest group concerned with electronic media urged FDA to explicitly prohibit tobacco advertising over the Internet, Worldwide Web, and other on-line services and interactive media. The comment stated that children and adolescents are increasingly using on-line services with up to 4 million Americans under age 18 using, or with access to, on-line services. The comment stated further that the interactive nature of the on-line services gives advertisements numerous advantages over traditional print advertisements. The comment emphasized that a ban on tobacco advertising over these media is necessary because the text-only format would not be as effective in reducing the appeal of tobacco advertising to minors given the interactive nature of these media.

One comment from an organization of health professionals stated that one tobacco company advertises its mail-order business through a Web site on the Internet and offers links to other tobacco-related sites. The comment wondered why this type of advertisement was not banned by FCC

since the Internet operates over telephone lines; a form of electronic media that is regulated by FCC and from which cigarette advertising is banned.

A few comments dealt with on-line advertising and recommended that the rule should limit format to black text on a plain background, require advertisers to demonstrate that significant numbers of children do not access ad sites, require use of any available blocking technology, and define "conspicuous" and "prominent" as they pertain to interactive media.

Some of these comments have suggested that advertising of tobacco products in on-line media should be banned under the Federal Cigarette Labeling and Advertising Act's (the Cigarette Act) (15 U.S.C. 1331) and the Comprehensive Smokeless Tobacco Health Education Act of 1996's (the Smokeless Act) (15 U.S.C. 4401) prohibition of advertising on any media subject to the jurisdiction of FCC. The agency leaves the issue of jurisdiction and the applicability of the broadcast ban to the Department of Justice, which has the appropriate jurisdiction over the Cigarette Act, and to FTC, which has along with the Department of Justice jurisdiction over the Smokeless Act. Were these agencies not to take action and were, tobacco advertising to continue in on-line media, then FDA is available to meet with advertisers regarding their responsibility under the final rule.

The agency recognizes the growing importance and use of on-line media and the Internet for communications of all sorts, including tobacco sales and advertising. On-line media are not included within the list of permissible outlets for tobacco advertising because the agency does not have sufficient information on the technology to include regulations in the final rule. However, advertisers interested in advertising on the Internet should notify the agency, after the rule is final, and provide the agency with sufficient information about use by young people so that the agency can make a proper determination. This notification is for discussion purposes only, and is not in any way intended to imply, or create a need for, prior approval.

The agency recognizes the concern expressed by one comment that a text-only format, without additional requirements, may not be as effective in protecting young people from on-line advertising as it would be for print advertising because of the interactive nature of on-line media. The agency would consider the unique qualities of

on-line media and the Internet in evaluating any requests to use these media. Any other statement about specific requirements for this new media or any other media would constitute speculation at this point.<sup>201</sup>

Section 897.30(a)(1) provides a comprehensive listing of the permissible forms of advertising and labeling. The evidence that FDA has gathered in this proceeding establishes the need for and importance of such a comprehensive listing. In addition to the general evidence and support provided by expert opinion, advertising theory, studies and surveys, empirical studies, anecdotal evidence, industry statements, and two consensus reports (the IOM Report and the 1994 SGR) described in section VI.D.5. of this document, FDA has found specific support for a comprehensive listing in:

**Empirical Studies**—Various economic and econometric studies of international and cross-country data show that restrictions on advertising and promotional activities can result in a decline in tobacco use (see section VI.D.6.a. of this document).

**Country Experience**—The experience of countries, such as Norway and Finland, shows that comprehensive advertising restrictions can positively affect the smoking rates of young people over time (see section VI.D.6.a. of this document).

**Advertising Theory**—Each separate advertising media plays a critical role in shaping young people's beliefs about tobacco use, and ultimately their use of tobacco products (see sections VI.D.3.a. through VI.D.3.e. of this document). Therefore, regulation of advertising must address each type of media. As will be described in the following sections of the regulation, the restrictions on each media are necessary to reduce the appeal of tobacco for young people and to prevent unrestricted tobacco advertising from undermining the regulation's access provisions. Moreover, as international experience indicates (see section VI.D.6. of this document), when regulations that are not comprehensive are implemented, tobacco money can migrate to unregulated advertising venues (e.g., if publications are prohibited, money expended on sponsorship will increase) and can undermine the force of the regulation. Thus, in order to be effective,

restrictions must be as comprehensive as possible.

Based on all of the foregoing, FDA concludes that the comprehensive listing of permissible advertising in § 897.30(a)(1) will directly and materially advance the agency's efforts to reduce consumption of tobacco products by children and adolescents under the age of 18.

### 3. Section 897.30(b)—Billboards

The agency proposed in § 897.30(b) to prohibit outdoor advertising, including but not limited to billboards, posters, or placards, placed within 1,000 feet of any public playground or playground in a public park, elementary school, or secondary school. FDA proposed this provision because these are places where children and adolescents spend a great deal of time and should therefore be free of advertising for these products. The agency tentatively concluded that this was a reasonable restriction and noted that the cigarette industry's voluntary "Cigarette Advertising and Promotion Code," (the Code) revised in 1990, contains a similar provision concerning schools and playgrounds (60 FR 41314 at 41334 through 41335).

(33) FDA received over 2,500 comments concerning this part of the 1995 proposed rule. Comments opposing this measure pointed out that the tobacco industry has established a voluntary code similar to the proposed provision with which advertisers already comply, and that therefore, there is no reason to make this measure mandatory. These comments also stated that outdoor advertising does not target children and adolescents, and that parents, siblings, and friends have a much greater influence than billboards and posters on a young person's desire to start smoking. Further, they stated that there is no evidence that this measure would reduce any teenager's desire to smoke.

Most comments supported this provision, stating that children and adolescents should not be subjected to visual images promoting tobacco use around those areas where they attend school or play. The comments argued that children and adolescents want to be like the attractive models in the advertising, and, thus, the advertisements directly influence them to start using tobacco.

In the Federal Register of March 20, 1996 (61 FR 11349), the agency reopened the comment period for the August 1995 proposed rule to place on the public record a memorandum that provided further explanation of the

<sup>201</sup> In addition to the substantive changes, the following changes in language have been made: (1) Deletion of "only" in § 897.30(a)(1); (2) substitution of (a)(2) for (b) in 897.30; and (3) deletion of "and" before "in point of sale" in § 897.30(a)(1).

agency's proposal to ban outdoor advertising within 1,000 feet of schools and playgrounds. The document provided an additional 30 days in which to comment on this new information. The memorandum stated that the agency was aware of the industry's voluntary 500-foot ban on advertising from schools and playgrounds but also that it was cognizant, based on the experience of its employees, that billboards can loom large in the sight of children and adolescents at that distance and thus would be able to capture their attention. The agency also noted that 1,000 feet is about 3 blocks and that signage kept that far away from schools and playgrounds would not loom as large, if it would be visible at all. Moreover, the 1,000 feet will protect children as they travel to and from these locations.

In response to the comments, FDA has modified the provision to clarify the coverage of the provision. Thus, the final rule states that the 1,000-foot area is to be measured from the perimeter of the playground or school. Moreover, a definition of playground is included as well as an indication that the relevant area of a playground in a larger public park is limited to the play area itself. Section 897.30(b) reads:

No outdoor advertising for cigarettes or smokeless tobacco, including billboards, posters, or placards, may be placed within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., a public park with equipment such as swings and seesaws, baseball diamonds, or basketball courts), elementary school, or secondary school.

(34) Several comments asked FDA to define what is meant by the term "playground." The comments stated that the term could be construed to include literally any place of outdoor recreation where children may play (i.e., a paved parking lot, a tennis court, or a city park), even places used primarily by persons 18 years of age or older. One of the comments noted that the industry code refers to "children's playgrounds" (i.e., playgrounds designed primarily for use by children), but that § 897.30(b) refers to "any playground."

Some comments suggested that the term "playground" should include the playgrounds of city parks, recreation facilities, theme parks (e.g., Disneyland), and national parks.

The agency agrees that it needs to clarify what is meant by the term "playground." A typical dictionary definition of "playground" states that it is: (1) An outdoor area set aside for recreation and play, especially one having equipment such as seesaws and

swings; or (2) a field or area of unrestricted activity. The intent of the proposal was not to preclude outdoor advertising within 1,000 feet of any area that would fall under this broad definition, but to preclude cigarette and smokeless tobacco advertising around those areas where children and adolescents are likely to spend a lot of time. Clearly, areas around schools with equipment such as swings and seesaws are areas where children are likely to play. Public parks for family recreational purposes with play equipment, and facilities for activities such as baseball or basketball are also areas where children and adolescents are likely to be present for hours at a time.

However, private enterprises, such as theme parks and recreational facilities, are not necessarily intended only for children and adolescents. Those that are, may require the presence of an adult for entry. There are usually entrance fees or required purchases for use of these areas. In addition, children and adolescents may not be present in these areas on any regular basis (e.g., an annual visit to a theme park). Therefore, the agency will not include these areas in the regulation. Moreover, because all outdoor advertising must be in black and white text, the agency sees no need to extend the prohibition beyond elementary and secondary schools and public playgrounds at this time.

The concern expressed that a decision by private parties to build a playground could destroy the value of a billboard sign should no longer exist. Because the agency is limiting its definition of playground to those publicly owned playgrounds, any interested party could object to the establishment of the playground.

FDA is modifying § 897.30(b) to state that outdoor advertising is prohibited within 1,000 feet of the perimeter of any public playground or playground area in a public park (e.g., areas with equipment such as swings and seesaws, baseball diamonds, basketball courts), elementary school or secondary school. The agency concludes that this modification in § 897.30(b) is adequate to clarify the term "playground," and that a more specific definition for "playground" is not necessary at this time.

The agency notes that the definition makes clear that, when an area is set aside for a playground within a public park, the 1,000 feet is measured from the perimeter of the play area and not from the larger park.

(35) Several comments contended that the regulation should specify that the 1,000-foot rule should be measured from the perimeter of the property to avoid confusion. One comment asked that the provision be more clear as to what types of schools would be included within the definition.

The agency agrees with the first comment. The intent of the 1995 proposed rule was that the distance would be measured from the perimeter of the school or playground. Any other measurement could defeat the purpose of the regulation. For example, measuring from the edge of a building or from the center of a playground could allow outdoor advertising to be placed closer to the perimeter where children may be assembled or playing. In addition, for large schools or playgrounds, the outdoor advertising could feasibly be near the perimeter of the school or playground if the distance is measured from somewhere other than the perimeter. Therefore, to clarify the intent of the provision, FDA is modifying § 897.30(b) to state that no outdoor advertising may be placed within 1,000 feet of the perimeter of any playground, elementary school, or secondary school.

However, the agency does not believe that it needs to provide a definition of elementary and secondary schools, as those terms, as commonly used, include all such schools (kindergarten through 12th grade) whether public, private, or parochial.

(36) One comment stated that the tobacco industry Code of Advertising Practices (the Code) applies to outdoor advertising on billboards, and that § 897.30(b) applies to all outdoor signage, including signage on the exterior of retail establishments that sell tobacco, and conceivably even to advertising on buses, taxis, and other vehicles that might venture within the 1,000-foot zone.

Another comment stated that FDA should consider regulations that eliminate tobacco advertising via traveling vans and trailers because trailers and vans are mobile billboards and can be strategically placed to gain maximum exposure among young people.

FDA agrees that § 897.30(b) applies to more forms of advertising media than does the tobacco industry code (i.e., all outdoor advertising, not just billboards). FDA's regulation restricts all outdoor advertising of tobacco products, including, but not limited to, billboards, posters, and placards. However, the intent and purpose of § 897.30(b) is not

to prohibit signage on taxis and buses that are not located in, but may pass through, the school or play zone. Such signage is usually temporary or transient and does not present the same concern of a permanent sign.

(37) Several comments questioned the factual basis for the proposed ban on outdoor advertising of cigarettes and smokeless tobacco within 1,000 feet of schools and playgrounds and stated that "employee" experience is not a sufficient basis. One comment argued that FDA should give little weight to employee experience in light of the fact that cigarette manufacturers submitted expert testimony that children and adolescents pay relatively little attention to billboard advertising at any distance. In addition, some comments argued that FDA's analysis related solely to billboards, and that it had presented no evidence or analysis justifying a ban on store signage. Finally, several comments stated that the agency failed to take into account the "visibility" of the outdoor advertising. These comments suggested that any regulation must take into account whether obstructions exist (e.g., trees, winding roads, signage placed facing away from the prohibited area).

The agency disagrees that it has not provided an adequate basis for its proposed regulation. In addition to the analysis provided by the agency in its March 20, 1996, Federal Register document, the agency received two comments during the comment period with evidence regarding this issue. A professor of biophysics and optometry stated that he believed that there was a rational and quantitative basis for deciding on a given distance if that distance was to be based on the visibility of words on a billboard. Specifically, he stated that children and adolescents typically have 20/15 visual acuity. Therefore, it is possible, using a mathematical formula using a right-angled triangle and the definition of the tangent trigonometric function to compute the distance at which words are visible. He computed the distances from which it would be possible to see both words 1 foot high and 2 feet high. In addition, he computed the distances for a "normal" visual acuity of 20/20. If one were to average these numbers, the result would be approximately 1,200 feet, which could be rounded to 1,000 feet.

Table 1a.

|              | 1-foot high letters | 2-foot high letters |
|--------------|---------------------|---------------------|
| 20/15 vision | 917 feet            | 1,833 feet          |
| 20/20 vision | 687.8 feet          | 1,376               |

(38) Another comment reminded the agency that two separate laws passed by Congress had provided for a 1,000-foot zone around schools as a means to protect youngsters from dangerous and unsafe behavior. The Controlled Substances Act (21 U.S.C. 860) provides additional penalties for anyone distributing or manufacturing drugs within 1,000 feet of schools, playgrounds, and universities, and 18 U.S.C. 922 prohibited possession of a firearm within 1,000 feet of schools.<sup>202</sup> Moreover, the comment contained scores of pictures of advertising billboards and signs within 500 and 1,000 feet of school and playgrounds as well as statements by children indicating that the signs are ubiquitous and attractive. The pictures and statements may only be anecdotal evidence of the proliferation of tobacco advertising near schools and playgrounds, but the number of children who provided pictures in such a short period of time indicates that the problem of advertising in proximity to schools and playgrounds is not isolated.

Moreover, the agency also disagrees that it has no basis for including other outdoor signage, including signs on stores, in the regulation. The agency provided evidence in the administrative record and comments refer to evidence,<sup>203</sup> which showed that in a test area, those stores within 1,000 feet of schools had a significantly greater percentage of windows covered with tobacco signs than those further away. Moreover, the two RJR memoranda by sales representatives, described in section VI.D.3.d. of this document, mention the importance of supplying stores near high schools with "young adult" material.

This provides sufficient support for the agency's concern with signage on stores near schools. Young people are more likely to frequent stores near schools, especially older adolescents,

and these venues should therefore be free of advertising for tobacco products.

The agency also finds that it cannot address the comments' concerns with obstructions. It would not be possible to qualify a regulation to account for the fact that trees may obstruct a sign when they are in full bloom but not in winter, or that children may be able to see signage as streets wind or that face away from the school or playground as they walk to and from school. The line that the agency has drawn is narrowly tailored (see *Board of Trustees of State University of New York v. Fox* 492 U.S. at 480) and consistent with how a standard needs to be crafted for it to be enforceable.

Finally, FDA finds that the expert testimony referred to in the industry comment that indicates that young people do not pay attention to billboards is contradicted by other evidence in the record. The Roper Starch study mentioned in section VI.D.3.d. of this document, submitted by RJR, reported that 51 percent of 10 to 17 year olds surveyed reported that they had seen or heard of Joe Camel from a billboard advertisement. For this reason, FDA is not accepting the suggestion in the comment.

(39) A number of comments from the tobacco and outdoor advertising industries stated that the tobacco industry had adopted a code in 1990, which encouraged all billboard companies to establish and manage a program to prohibit alcohol and tobacco advertisements within 500 feet of places of worship and primary and secondary schools. They noted that over 16,000 billboards nationwide have been voluntarily identified as "off limits" for these categories of advertising. As a consequence, the comments asserted that Government action is unnecessary.

One of the comments stated that the fact that members of an industry have elected to submit to a code of advertising practices does not make it reasonable for the government to impose mandatory advertising restrictions backed by criminal sanctions. It stated that private parties may voluntarily take actions that the Constitution forbids the Government to mandate. The comment argued that few industries would risk any self-regulation if their decision to do so might establish a predicate for even greater Federal regulation.

Conversely, several comments raised concerns about the voluntary code and cited numerous examples of violations that continued after the sponsors and the billboard companies had been informed of the violations. One

<sup>202</sup> Although this statute was overturned in *United States v. Lopez*, 115 S.Ct. 1624 (1995), as inappropriate under the Commerce Clause, the congressional determination that 1,000 feet was an appropriate distance was not disturbed.

<sup>203</sup> Rogers, T., E. C. Teighey, E. M. Tencott, J. L. Butler, and L. Welner, "Community Mobilization to Reduce Point-of-Purchase Advertising of Tobacco," *Health Education Quarterly*, 1995, in press.

comment stated that a survey found that in California tobacco advertising is more prevalent at stores within 1,000 feet of schools than at stores farther from schools. The comment asserted that statewide findings also revealed that there is more exterior store advertising in areas where at least 30 percent of the neighborhood is 18 years old or younger, and that the advertisements are placed near the candy or at a child's eye view (3 feet or below).

The agency is aware that the Code of Advertising Practices has not been uniformly observed, as several comments pointed out. Moreover, the industry code is significantly less inclusive than the proposed regulation as it covers only billboard advertising and not other forms of outdoor advertising such as posters and placards. These other forms are likely to be placed near retail establishments and in some cases, according to comments, have appeared on school fences. The agency finds that all outdoor advertising must be included in the regulation in order to provide comprehensive coverage. There is little difference between a billboard and a large poster to a child. Both are advertisements, and both are visible, so that children see them as they go to and from school and play.

In addition, the Code prohibits outdoor advertising only within 500 feet of schools, an area only a block or a block and a half from the school (there are 10 to 12 city blocks to a mile). One block will not provide sufficient protection as it would not cover the areas where many children congregate with their friends. Moreover, a child's vision does not stop at one block from school. A prohibition of 1,000 feet will ensure the absence of signs for 2 to 3 blocks from a school or playground which can be seen from these locations where children spend a significant amount of time each day. (Several comments stated that FDA had misused its math to calculate block distances in its March 20, 1996, Federal Register document (61 FR 11349).) If the misstatement caused any confusion, the agency regrets it but does not believe that the one-half block difference undermined the rationale.)

(40) One series of comments supported FDA's 1995 proposal, stating that the restriction on billboards near schools should not be compromised, nor the distance reduced.

A number of comments argued that the proposed regulation did not go far enough. One comment recommended excluding outdoor tobacco advertising

from neighborhoods where children live. Another comment stated the belief that the ban on billboards should be at least double the proposed 1,000 feet from schools, while others argued that outdoor advertising should be prohibited completely.

These comments stressed the importance of billboards and other outdoor advertising in creating cigarette brand awareness among children. For example, one comment discussed the results of a survey conducted for *Advertising Age*, which showed that 46 percent of children 8 to 13 years old said they most often saw cigarette advertising on billboards, outpacing magazines. It stated that 34 percent of children 14 to 18 years old cited billboards as the predominant advertising medium for tobacco products.<sup>204</sup> The comment stated further that all billboards, regardless of placement, are seen by significant numbers of children, therefore, it clearly makes sense that, as a means to protect children from tobacco advertising, such advertisements should be prohibited from billboards and other outdoor advertisements. The comment emphasized its point by quoting from the billboard industry's own marketing material ("Outdoor: It's not a medium, it's a large"), "You can't zap it. You can't ignore it \* \* \* It asks little time, but leaves a long impression." The comment stated that the same publication notes, "Outdoor is right up there. Day and night. Lurking. Waiting for another ambush."

One tobacco company presented evidence of the effectiveness of billboards in bringing tobacco advertising to children. RJR, in its comment on the 1995 proposed rule, as stated in section VI.D.3.d. of this document, attached a study conducted for it to test children's recognition of advertising characters and slogans (Roper Starch study). This study involved 1,117 children 10 to 17 years of age, with 86 percent of them recognizing Joe Camel using aided and unaided recall. When asked where they had seen Joe Camel, 51 percent said on billboards.<sup>205</sup> That amount of recall shows that billboards represent a very effective advertising medium and belies the industry's assertion that billboards are not an effective source of advertising information for children.

<sup>204</sup> Levin, G., "Poll Shows Camel Ads are Effective With Kids; Preteens Best Recognize Brand," *Advertising Age*, p. 12, April 27, 1992.

<sup>205</sup> "Advertising Character and Slogan Survey," pp. 10, 22.

Finally, one comment from a public interest group warned that, the more complex a rule is, the more difficult enforcement becomes. It stated that spacing limitations, such as the proposed 1,000-foot zone around schools, begs a series of questions, for example: How is that distance measured, from what point to what point. It stated that these questions would make it virtually impossible for citizens to play an active role in enforcing this rule. The comment stated that without citizen participation, billboard control is extremely difficult, and that this situation has, in fact, contributed to the industry's disregard for local and State billboard control laws.

The agency finds that the comments, as well as the evidence spelled out in the 1995 proposal, have provided ample support to establish that outdoor advertising has a significant impact on children and adolescents. While the comments have presented significant evidence in support of a ban on all outdoor advertising, the agency is not convinced that a ban or a restriction on tobacco advertising of more than 1,000 feet would be appropriate. As discussed elsewhere in this document, the agency is requiring that all permissible outdoor advertising be in a black and white, text-only, format. Therefore, some of the concerns raised by the comments requesting a complete ban on outdoor tobacco advertising or of expanding the ban are addressed by that provision. Moreover, the agency's regulations are an attempt to balance the rights of adults to receive information about a legal product with its desire to protect children from the unavoidable appeal of advertising. Thus, although the line could be drawn elsewhere, the agency finds that the 1,000 feet limitation should ensure adequate protection from visible advertising where children spend a significant amount of time but will permit adults to get information.

(41) One comment stated that FDA's action violated the APA because the agency offered no evidence in support of its claim that children spend a great deal of time in areas as far as 1,000 feet from the places specified in § 897.30(b). It added that the justification for text-only advertising undercuts FDA's justification for its 1,000-foot ban.

Another comment stated that although tobacco product advertising is disseminated through a broad spectrum of media, outdoor advertising is the only such medium that is subject to additional specific prohibitions under the 1995 proposed rule beyond the

prohibitions applicable to all tobacco product advertising. It stated that the record does not contain evidence that would establish either that these prohibited outdoor advertising signs are viewed more often by minors than other advertising media, or that outdoor advertising in general has a greater impact on minors than other media. There is nothing, the comments argued, that indicates that the mandatory content restrictions and affirmative disclosure requirements imposed by the proposal would be less effective in outdoor advertising of tobacco products than when such an advertisement is placed in a rock and roll magazine, or in an exempt publication with 1 million adolescent readers.

One of the comments stated that because the text-only requirement itself is intended to render the advertising unattractive to young people, the additional "protection" offered by the 1,000-foot rule would be wholly gratuitous.

Several comments argued that there is no proof that this additional area of ban will reduce any teenager's desire to use tobacco: a desire that has withstood the ban of TV and radio advertisements and a massive educational program. The comment stated that the 1,000-foot rule seems particularly gratuitous in view of the fact that it would ban advertising that FDA, by virtue of its proposed text-only requirement, already has stripped of the features FDA deems make it appealing to young people.

FDA disagrees with these comments. The agency's bases for the text-only requirement for billboards and for the 1,000-foot ban are reasonable and supportable, and they are not in conflict. The text-only format requirement will reduce the appeal of cigarette and smokeless tobacco product advertising to persons younger than 18 years of age without affecting the information conveyed to adults (60 FR 41314 at 41335). It is an attempt to narrowly tailor the restriction by balancing the need to restrict advertising's appeal to children with the preservation of the informational function of advertising for adults.

The prohibition on outdoor advertising within 1,000 feet of schools and playgrounds is designed to address a different problem. The concern is not the appeal of the advertising. If the problem were only appeal, the 1,000-foot restriction would not be necessary because the text-only requirement would eliminate this concern. The concern is the nature of billboards themselves. Billboards near schools and

playgrounds ensure that children are exposed to their messages for a prolonged period of time. As the Supreme Court recognized in *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934), billboards are seen without the exercise of choice or volition, and viewers have the message thrust upon them by all the arts and devices that skill can produce. This is particularly true of billboards that are readily visible (i.e., within 1,000 feet) when children play or study at a playground or school, places where by design children spend a lot of time, or when children walk to and from a school or playground. Confronted daily and unavoidably with the advertised message, even in text-only, a child gets a sense of familiarity, normalcy and acceptability of the message and the product that is advertised.

(42) Several comments stated that placing a circle with a radius of 1,000 feet drawn from the perimeter of each school and playground would establish a "forbidden zone" that would be at least 2,000 feet in diameter (i.e., over one-third of a mile). They stated that in many communities, this would be tantamount to a de facto ban, for there would be virtually no outdoor location that could escape the rule's prohibition.

Several comments pointed out that even if advertisers wanted to disseminate advertisements on billboards that complied with the FDA proposal, there would be virtually no locations where such outdoor advertising signs could be located in some cities. They submitted results of computer assisted surveys of nine cities showing the areas where outdoor advertising of tobacco products would be allowed under the 1995 proposal. The survey showed that outdoor tobacco advertising would be prohibited in 94 percent and 78 percent of the respective land mass of Manhattan and Boston under the proposal. The comment stated that this range approximates the high and low percentages that could be anticipated in other metropolitan areas in the United States. Moreover, when it correlated the data collected from the study and other data regarding the actual location of billboards, the comment found that, even under the most expansive view, not a single billboard in Manhattan (including the commercial corridor of Times Square), and no more than 24 actual billboard locations in the entire city of Boston, would be permitted to display tobacco advertisements.

The comment stated further that even if the rule permits a few locations where tobacco advertising would be allowed in

a given municipality, there is no commercial utility in a limited number of outdoor advertising signs where the location of the advertisement is dictated by the 1,000-foot rule, rather than by market demographics and vehicle circulation. According to the comments, these latter factors are what actually control billboard placement. It concluded that, as a practical matter, FDA's proposed outdoor advertising restrictions would eliminate billboards as a medium for tobacco advertising even in those jurisdictions where a small number of such signs theoretically would be available.

FDA has carefully considered the possibility that its restrictions effectively outlaw outdoor advertising in most urban areas. The agency has concluded, however, that if this situation comes to pass, it would be a consequence of the density of population in cities. FDA's intent in adopting § 897.30(b) is to restrict the accessible and intrusive communication of information about cigarettes and smokeless tobacco to children and adolescents at school and at play. It was not to provide for distances that would have the effect of banning outdoor signs from urban areas. By limiting the restriction to 1,000 feet, FDA has tried to make it no more extensive than necessary to achieve its intended end. FDA has considered the cost of its restriction but concludes that a narrower restriction would not adequately advance its purpose of protecting young people from unavoidable advertising in settings in which they are essentially a captive audience.

The 1,000-foot restriction on outdoor advertising will serve to remove what has been shown is an effective means for tobacco companies to communicate with young people in a direct and unavoidable manner. Eliminating such billboards will thus mean eliminating a means by which the industry has influenced young people to engage in tobacco use behavior. Therefore, the agency concludes that § 897.30(b) is a necessary part of its effort to reduce underage use of tobacco products.

Several comments from the tobacco industry and from retailers pointed out that § 897.30(b) would prevent retail establishments within the 1,000-foot zone from informing potential customers that tobacco (or particular brands thereof) are available for purchase therein and at what prices. These comments stated that this restriction not only would hurt the retailers but would increase, in turn, the

search costs for adult smokers. The comments stated that retailers in the small slivers of a city in which outdoor advertising would continue to be permitted would be afforded an unfair competitive advantage.

One comment added that convenience stores located within 1,000 feet of a school or playground would not even be able to put a small black on white placard on top of a gas pump that merely indicates the price of tobacco, but that a billboard across the street and located a little over 1,000 feet away from the same school or playground could carry the brand name of a tobacco product in black letters as tall as the store's front door. The comment urged FDA to recognize this distinction.

The agency acknowledges that some retailers may be prohibited from placing advertising concerning tobacco products on or around their retail establishments, while others, perhaps just across the street, can. Any minimum distance that the agency establishes will preclude some retailers from outdoor advertising at their retail establishments but not others. However, FDA has determined that it is necessary to keep outdoor advertising away from areas where children are likely to congregate daily.

FDA notes that the Supreme Court cases that have considered restrictions on speech have recognized that such restrictions may not be perfectly tailored, see, e.g., *Board of Trustees of State University of NY v. Fox*, 492 U.S. at 479. Thus, while in a few instances there may be inequities created by the line FDA has drawn, because there is a reasonable fit, as explained in section VI.E.1. of this document, between FDA's ends and the restrictions that it is adopting, these minor problems do not doom FDA's rule (*Id.* at 480).

FDA's prohibition on signage on stores within 1,000 feet of schools and playgrounds will advance the agency's interest in protecting the health of children. Several of the studies submitted with comments showed that there is more signage in and around stores near schools and playgrounds than in stores generally. The ban on outdoor advertising within 1,000 feet of schools and playgrounds will ensure that signage near schools will be removed and thus minimize any sense of familiarity that would develop.

Thus, even though the agency has carefully considered these comments, it concludes that it is appropriate to establish a minimum distance from schools and playgrounds within which all outdoor advertising is prohibited.

(43) A number of comments argued that the prohibition on tobacco billboards within 1,000 feet of schools violates the Commerce Clause as recently interpreted by the Supreme Court in *United States v. Lopez*, 115 S.Ct. 1624 (1995). In *Lopez*, the Supreme Court held that Congress lacked the power under the Commerce Clause to criminalize the possession of a gun within 1,000 feet of a school. One comment argued that the Congress's commerce power only permits it to regulate, for example, the interstate transit of advertisements, but that once the advertisement is within a state, it is private property and not subject to regulation under the Commerce Clause.

The agency disagrees. Under the Commerce Clause, Congress may "regulate those activities having a substantial relation to interstate commerce, \* \* \*, i.e., those activities that substantially affect interstate commerce." (See *Lopez*, 115 S.Ct. at 1629-30 (citation omitted).) As the Supreme Court noted in *Lopez*, "the possession of a gun in a local school zone is in no sense an economic activity that might, through repetition elsewhere, substantially affect any sort of interstate commerce" (*Id.* at 1634; see also *id.* at 1640 (Kennedy, J., concurring)). As all advertising is inherently commercial in that it proposes a sale, the placement of tobacco billboards in a local school zone is economic activity that does substantially affect interstate commerce because it affects the demand for tobacco and smokeless tobacco. That the advertisements are private property after transportation in interstate commerce does not alter this analysis. Indeed, "[a]ctivities conducted within State lines do not by this fact alone escape the sweep of the Commerce Clause. Interstate commerce may be dependent upon them." (See *United States v. Rock Royal Co-op., Inc.*, 307 U.S. 533, 569 (1939); see also *Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942) (holding that, under Commerce Clause, Congress could control farmer's production of wheat for home consumption because cumulative effect of such consumption by many farmers might alter supply and demand in interstate wheat market).) As such, regulation of the placement of billboards advertising tobacco products does not violate the Commerce Clause. 206

<sup>206</sup> Moreover, cigarettes and smokeless tobacco products are nicotine delivery devices. Congress plainly provided for medical devices to be federally regulated as indicated by the provision allowing seizure of devices without proof of interstate

(44) A number of comments argued that § 897.30(b) would violate the First Amendment. These comments argued that, given the requirement for black text-only on a white background, the restriction on billboards within 1,000 feet of schools and playgrounds would not directly and materially advance a substantial government interest. The comments also argued that the billboard restriction could not be considered to be narrowly tailored. One comment from a public interest group, however, argued that FDA's proposal is fully constitutional because it is much more limited than the restrictions on billboards upheld in *Penn Advertising v. Mayor and City Council of Baltimore*, 63 F.3d 1318 (4th Cir. 1995) vacated, remanded 64 U.S.L.W. 3868 (U.S. July 1, 1996), and *Metromedia, Inc. v. San Diego*, 453 U.S. 490 (1981). The comment pointed out that in *Metromedia, Inc.*, the Supreme Court held that the City's interest in traffic safety and aesthetics were sufficient to justify a ban on commercial outdoor advertising (453 U.S. at 551, n. 23). Here, the comment said, the interest that FDA has asserted is more weighty.

FDA disagrees with the comments that argued that § 897.30(b) violates the First Amendment. As explained, this restriction does advance FDA's interest beyond what is accomplished by the text-only restriction. As explained in sections VI.B. and VI.D. of this document, the regular exposure of children to tobacco advertising, even in text-only form, builds a sense of familiarity and acceptability that, reports and studies say, contributes materially to the decisions of young people to experiment with and use tobacco products. Thus restrictions that eliminate such exposure will eliminate one factor that contributes to the process by which children and adolescents decide to smoke or use smokeless tobacco and, consequently, will directly advance FDA's interest.

Moreover, the restriction that FDA is adopting is narrowly tailored to advance its interest. FDA's concern is with the advertising that can be seen from schools and playgrounds, the place at which children and adolescents spend a significant amount of time each day. Three blocks or 1,000 feet is about the distance at which signs are readily visible. Thus, FDA has restricted outdoor advertising within this distance of schools and playgrounds.

shipment (section 304 of the act) (21 U.S.C. 334)) and by a presumption that devices are in interstate commerce (section 709 of the act) (21 U.S.C. 379)).

The result of FDA's restriction is that children will not be confronted with tobacco advertising as they study and play and thus there will be a corresponding reduction in the ability of tobacco advertisers to create the impression of acceptance and familiarity that is influential with youngsters. Consequently, there is a reasonable fit between FDA's interest in protecting the health of children and the restriction on outdoor advertising that it is adopting (see *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. at 416; *Board of Trustees of State University of New York v. Fox*, 492 U.S. at 480).

Thus, FDA concludes that, in fashioning the restriction on billboards, it has fully met its obligations under the First Amendment.

In summary, FDA finds that § 897.30(b) will contribute in a direct and material way to reducing underage tobacco use. The evidence establishes that billboards are one of the most effective forms of advertising for young people, and that their elimination near schools and playgrounds will directly and materially advance FDA's goals.

**Studies**—A Roper Starch survey submitted by R. J. Reynolds found that billboards were the most mentioned source of information about Joe Camel for children (see section V.D.3.d. of this document), and a study conducted for *Advertising Age* (April 27, 1992) discussed in this section showed that 46 percent of children 8 to 13 and 34 percent of children 14 to 18 said that billboards are a predominant form of advertising for tobacco.

**Advertising Theory**—Billboards near schools and playgrounds give the child a sense of familiarity, normalcy, and acceptability of the message on the product. Therefore, regulation of the format and even the location of some billboards and other outdoor signs within 1,000 feet of a school or playground, is essential. As discussed in this section, comments submitted in this rulemaking include photographs that evidence the intrusive effect of billboards and signage around schools and playgrounds.

**Evidence of Children's Visual Range**—Data provided by a professor of biophysics and optometry, detailed in this section, support a finding that 1,000 feet is an appropriate distance to remove signage that would be visible and readable to students.

**Congressional Finding**—As detailed in this section, Congress mandated a 1,000 foot drug free zone around schools and playgrounds (Controlled Substances Act (21 U.S.C. 860)) as an appropriate

area in which to protect young people from drug dealing near schools and playgrounds.

Finally, the agency has tailored the ban as narrowly as possible by defining playgrounds narrowly and, as noted above, by restricting the area of the ban to that consistent with children's visual range.

#### 4. Section 897.32(a)—Text-Only Format

Under proposed § 897.32(a), cigarette and smokeless tobacco product labeling and advertising, as described in § 897.30(a) and (b), would be required to use black text on a white background and nothing else. The agency tentatively concluded that this text-only requirement would reduce the appeal of cigarette and smokeless tobacco product labeling and advertising to persons younger than 18 years of age and preserve advertising's informative aspects—that is, to provide useful information to consumers legally able to purchase these products.

In response to comments, the agency has decided to permit another exception to the requirement that all permissible advertising appear in text-only. Thus, it has created an exception for advertising in adult facilities that meet the criteria of § 897.16(c)(2)(ii) provided the advertising is affixed to the wall or fixture in the facility and is not visible from outside the facility. FDA has added this provision, as paragraph (a)(1) of § 897.32 and renumbered the exception for adult publications as § 897.32(a)(2)(i) and (a)(2)(ii).

Several comments suggested that FDA should provide an appropriate definition of "text-only" for permissible audio and video advertising, specifically static black text on a white background with no music or sounds. Therefore, proposed § 897.32 has been revised in consideration of comments received. A new § 897.32(b) has been added to provide guidance for audio/video advertising. Proposed § 897.32(b) has been redesignated as (c), and proposed § 897.32(c) and (d) have been eliminated. New § 897.32(b) has been added to provide explicit format requirements for one form of permissible advertising that had been left out of the proposed regulation.<sup>207</sup>

<sup>207</sup> In addition to the substantive changes made to § 897.32, the following changes in language have been made: (1) Addition of "Except as provided." \* \* \* section," to § 897.32(a); (2) addition of "any" to § 897.32(a); (3) amended language in § 897.32(a)(2) starting with "any publication" and ending with "an adult publication" and, in the last sentence, "an adult publication,"; (4) two changes to § 897.32(a)(2)(i) "younger than 18 years of age"

Many comments were received specifically addressing the text-only proposal. That children and adolescents should not use tobacco products was the one point of agreement among them. However, many comments from adult smokers and nonsmokers, retailers, tobacco farmers, elected officials, and the tobacco, advertising, newspaper, and magazine industries strongly objected to the text-only requirement. Their major objections were that: (1) Cigarette advertising does not cause young people to start smoking; (2) the proposed advertising restrictions would violate the First Amendment; and (3) the restrictions would have the effect of a virtual ban on cigarette advertising. Some comments expressed the concern or suspicion that FDA was using this proposal, ostensibly directed at minors, as a pretext to try to ban cigarette advertising generally.

In contrast, nearly three-quarters of the comments—mostly from parents, teenagers, public health officials, teachers, doctors, public interest groups, medical organizations, and some individuals in the advertising business—supported the proposal for text-only advertisements. The major reason presented for their support was the need to eliminate the appeal for tobacco that the advertising creates among children and adolescents. Some supporters urged even stronger action such as a total ban on all tobacco advertising. Some comments expressed the opinion that even though the proposed regulations may also affect adults, any resulting reductions in smoking by adults would not necessarily be bad.

(45) A number of comments questioned the validity of the evidence cited by FDA as support for the proposal. Many of these comments came from groups representing the tobacco, advertising, and publishing industries. These comments argued that there is no evidence that advertising with color and images encourages use of tobacco by minors or that advertising converts nonsmokers or nonchewers into smokers or chewers. Moreover, these other comments argued that there is no evidence that limiting advertisements to text-only is essential to reduce youth smoking and that there is no evidence that black and white text will reduce underage smoking.

In contrast, a number of supportive comments stated that the evidence cited by FDA, as well as studies published

and "15 percent or less"; and (5) deletion of "labeling" from § 897.32(c).

since the proposal, demonstrate the special susceptibility of children and adolescents to pictures, cartoons, photographs, other graphic images and colors.

Specifically, many comments observed that the appearance of Joe Camel in traditional advertising forums (magazines, billboards) attracts children and adolescents. One child wrote that his father gave him two sports magazines. "There were eight smoking ads in them \* \* \* the last one had two pictures of Joe Camel smoking. This can attract kids to start smoking."

Studies cited in the preamble to the 1995 proposed rule and in section IV.B. of this document, demonstrate the impact that images and colors, cartoons, and pictures and other graphic material have on children and adolescents. This does not mean that the same characteristics of advertising do not appeal to or affect adults. However, the effect of these techniques on children and adolescents is magnified because of their usual level of involvement in advertising as in everything else.<sup>208</sup> As detailed more fully in section VI.B. of this document, children and adolescents respond to stimuli that interest them, and that provides them with information that is important. Young people do not have the information processing skills that adults possess, and as a result more often than not, the information that is relevant to them comes in the form of images and colors rather than with a lot of words. This fact provides an explanation why 86 percent of children and adolescents smoke the three most heavily advertised brands (all are promoted with attractive imagery), even though they are generally price sensitive.<sup>209</sup> Adults buy generic products for price reasons or low tar brands for health concerns.<sup>210</sup> Advertising's colorful images are not as relevant to them as cost. Given these factors, FDA finds that the text-only requirement will significantly reduce the appeal of cigarette and smokeless tobacco advertising to young people and reduce its influence on them.

(46) Many comments, especially from the magazine, newspaper, advertising,

and tobacco industries, stated that the proposal will operate as a virtual ban on most types of cigarette and smokeless tobacco advertisements. These comments argued that the text-only format requirement will eliminate tobacco companies' ability to attract the attention of potential customers and to convey brand messages and will render advertising invisible to adults.

Therefore, tobacco advertisers would be far less likely to advertise in the text-only format. Also, not having a clear standard for when the text-only requirement applies (see also definition of adult publication) will cause tobacco advertisers to avoid more publications than may be necessary to ensure that they do not violate the rule. Many of these comments also argued that advertising would become ineffective. One comment said that advertising that passes unnoticed amounts to no advertising at all. This comment also asserted that, as a result of the text-only proposal, no viable alternative channels of communication would exist.

Comments from the tobacco and advertising industry suggested that the advertising industry would suffer revenue, profit, and job losses as a result of the text-only format; employees involved in graphics arts would especially be affected; and suppliers providing services and products to advertising agencies would also be adversely affected.

A number of comments supporting the proposal recommended a total ban on all tobacco advertising. Many comments stated that a ban on all tobacco advertising and marketing would be reasonable because the tobacco industry will use any available loopholes to market tobacco products and will test any partial ban.

Tobacco companies will be able to continue advertising in most of the same forums in a text-only format. Advertising with colors, pictures, and graphics will still be allowed in adult publications. Tobacco advertisers will still be able to convey information to adults about taste, price, and product development using text-only advertising. Many current advertisements for low tar cigarettes rely heavily on text formats.

The agency is not limiting fonts, font styles, or size of type because it believes that the tobacco industry and its advertising firms can use their creativity with a variety of print formats to produce text-only advertising that will effectively communicate their messages, including brand messages, to adults. However, the agency is also convinced

that print advertising, no matter how creative, will not be able to provide the attractive imagery that young people look for in advertising to explain the importance of a product to them, e.g., what to wear, whom to hang out with, how to look cool (see discussion of the importance of color and imagery in the introduction to this section).

Moreover, although the restriction to text-only advertisements may tend to solidify market position, it will not give any one company new competitive advantage over another since all companies must play by the same rule. Thus, the economic impact of the rule on the advertising business will be mitigated by a shifting of resources to create new advertising in compliance with the rule and to advertising for other businesses (see section XV. of this document entitled "Analysis of Impacts" for more information).

The agency does not support a total ban on all tobacco advertising as was suggested by a number of comments. The agency has been able to tailor the restrictions that it is adopting, by requirements such as the text-only advertisements requirement, to eliminate the appeal of tobacco advertising for children and adolescents while still allowing a means for companies to communicate with adult tobacco users. The use of text-only will mean that there can be continued advertising that is less likely to attract young people but that can convey information to adults.

(47) Several comments stated that limiting point of sale advertising to text-only would effectively ban point of sale advertising and impair retailers' ability to market tobacco products to adult customers.

Many comments noted the places one sees (and placement of) Joe Camel at point of sale, the nature of the items on which his image appears, and his ubiquitousness in and around stores, as evidence of the intent of at least one tobacco company to try to attract young people. A physician commented that he recently was returning from an evening [of] helping to care for [a] patient who was dying of emphysema [a lung ailment caused by cigarette smoking]. I decided to stop at a convenience store \* \* \* I was confronted with no less than 14 advertisements for cigarettes. From the Camel Joe sign beckoning in the parking lot \* \* \* a customer is bombarded with ads urging them to buy cigarettes.

Another comment stated that "advertisements on convenience store doors are placed well below adult eye-level and features such popular advertising cartoons as Joe and

<sup>208</sup> One such study tested the effect of different forms of advertising on children and found that they preferred pictures to text-only. (See Huang, P. 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.)

<sup>209</sup> "Changes in the Cigarette Brand Preferences of Adolescent Smokers—United States, 1989-1993," in *MMWR*, CDC, DHHS, vol. 43, pp. 577-581, 1994.

<sup>210</sup> Teinowitz, L., "Add RJR to List of Cig Price Cuts," *Advertising Age*, pp. 3, 46, April 26, 1993.

Josephine Camel. It seems counter-intuitive to assume that such advertising is intended for adults." Another comment stated, "Tobacco companies say they do not want to entice our children to smoke, then why are Joe Camel ads above the candy counters?" One comment noted that at a major retailer near the commenter's neighborhood, Joe Camel posters are right behind an exhibit of pogs, a popular children's collectible toy.

Manufacturers and retailers are not prohibited from promoting tobacco products at the retail level. Adult consumers looking for price and product information about cigarettes and smokeless tobacco will be able to find that information by searching even without the images to attract them. Text-only point of sale advertising, like magazines or billboards, will be effective in communicating this information. Thus, FDA is not banning point of sale advertising.

While text-only point of sale advertising can be effective with adults, it will have less allure and be less appealing to children and adolescents. Children and adolescents, who are less willing to process print information in a leisurely setting (such as reading a magazine), will not find textual material appealing in the momentary time setting of a retail purchase.

(48) A comment from an advertising industry association stated that:

"...FDA's prohibition on all direct mail promotion of tobacco products except for 'tombstone' messages... is even more onerous than that imposed on publications, since at least some publications will be permitted to carry non-tombstone advertising. The disparate treatment of direct mail exposes the real purpose of the FDA to censor messages to adults, because that medium by definition can be addressed to a specific audience, i.e., adults, with little risk of inadvertent viewing by minors.

This comment also noted that this form of direct advertising is not insignificant to the industry and given the small likelihood of youth access to it, should not be severely restricted. The comment noted that total industry spending on direct mail advertising was \$33 million in 1993.

Some comments from mail-order firms noted that the text-only requirement would adversely affect catalogs for tobacco and related products, making them less appealing and less effective for marketing to adult smokers. One comment from the owner of a small (55 employees) tobacco products manufacturing business said the text-only requirement for its catalog, along with several other aspects of the

1995 proposed rule, would destroy his business:

It offends me as a good American running a clean, honest business that a cadre of bureaucrats in Washington, DC would propose a rule that could ruin my life's work. FDA has given no more thought to the impact on my business than I might give to swatting a mosquito.

A supportive comment stated that the tobacco industry has made increasing use of direct mail promotions, including contests, questionnaires, coupons, offers, and even birthday cards. It stated that no company can be certain its mailing lists do not include minors. In a 1993 survey of 12 to 17 year olds, 7.6 percent indicated they had received mail personally addressed to them from a tobacco company. This could project out to 1.6 million persons aged 12 to 17. This comment noted that a major tobacco company sent free packs of cigarettes to people on its mailing list as a holiday present "from the Camel family" and has not changed its practice despite the fact that as many as 1.6 million 12 to 17 year olds could be on tobacco company mailing lists.

Direct mail is a high involvement medium, that is, it requires the recipient to study the text in order to get the central message. In those circumstances, text-only can be effective with recipients who have an interest in the offer. There is less of a need to attract a consumer's attention with a direct mail promotion, including a catalog, than with a point of sale or magazine advertisement. A consumer opening a direct mail promotion he/she is interested in is in a high-involvement mode and is prepared to read the enclosed material and catalog. Although the material may be more easily ignored, current tobacco users who want to buy by direct mail can get the information from textual material.

Mailings in text-only to current customers and to other adult smokers are permitted under the rule. On the other hand, if a direct mail promotion or catalog is seen by a child, the text-only format would make it much less appealing and less interesting. This is especially important since there is evidence that as many as 1.6 million children aged 12 to 17 receive direct mail tobacco promotions. Thus, text-only direct mail is important to accomplish the purpose of this rulemaking. Moreover, contrary to being censorship, as some comments stated, the text-only format for direct mail will allow advertisers to send adults an encyclopedia of information about any aspect of smoking or tobacco products

while protecting children from the effects of advertising.

Although direct mail catalog advertising will be less interesting, sales should only be minimally affected. As the final rule does not include a prohibition on mail-order sales, the only restriction will be the text-only format. In addition, this should be less of an impediment than a total ban to small mail order company owners such as the commenter.

This compromise represents the agency's attempt to narrowly tailor its rule. Based on comments received from the industry, most mail-order customers purchase tobacco products for price, convenience, and uniqueness and to stockpile a long term supply. The agency believes that creative and effective advertising for adults can be designed in the text-only format for catalogs, especially for catalogs targeted to consumers purchasing tobacco products for these reasons. Therefore, FDA is not exempting direct mail promotion of tobacco products from the text-only requirement.

(49) One comment suggested that FDA create an exception for direct mail similar to that for publications. The comment said that direct marketers can target mailings so that children and adolescents are protected to, at the very least, the same degree that the regulations provide for the publishing industry.

FDA has considered this request but finds that it cannot grant it. The agency based the threshold for publications on the ground that publications with youth readership of less than 15 percent are not of interest to young people and thus would be unlikely to be read by them. The same cannot be said of direct mail advertisements that come addressed with the child's name on it. (As explained in this section, surveys show that a significant portion of tobacco direct mail advertising is sent directly to individuals under the age of 18.) The appearance of the child's name in the address will cause the child to look at the advertisement and thus will cause the message to be thrust on the child in a manner similar to messages on billboards or point of purchase (see *Packer Corp. v. Utah*, 285 U.S. 105, 110 (1934)). Thus, direct mail advertising is more similar in nature to billboards and point of purchase advertising than are publications. Consequently, as with the former types of advertising, FDA has concluded that to reduce the appeal of direct mail advertising to those youngsters who view it, it is appropriate

to require that this type of advertising be in the text-only format.

(50) A few comments said that in the same way the agency attempted to carve out an exception for publications with primarily adult readers, it should permit a similar exception for advertising in bars, clubs, etc., with customers over 21 years of age.

The agency agrees with these comments. The agency recognizes the need to precisely tailor its regulations and thus, has created an exception for advertising in adult only (18 years of age and older) facilities permitted to sell tobacco products from vending machines and self-service under § 897.16(c)(2)(ii). These facilities, which are required to ensure that no one under the age of 18 is present, or permitted to enter, the facility at any time, may display permissible advertising, i.e., with color and imagery, provided that the advertising is not visible from outside the facility and is affixed to a wall or fixture within the facility. These conditions will ensure that the advertising does not become a surrogate for outdoor advertising and is not carried from the facility.

(51) The agency received some comments from opponents and supporters of the 1995 proposed rule that stated that this provision might be counterproductive and result in increased demand for cigarettes and smokeless tobacco by minors. One comment from an association of advertising agencies stated that a reduction in spending on cigarette advertising, resulting from the proposal, could make cigarettes less expensive and increase demand for these products. In contrast, another comment from a tobacco company stated that reduced competition due to the text-only restrictions could lead to price increases for some brands which would harm the adult purchasers of those brands.

Some comments stated that the health warnings in cigarette advertising would become less effective in the proposed text-only format. This consequence could result in fewer people giving up smoking because of information in the health warnings. Some comments argued that the text-only format might actually attract more attention from minors because these advertisements would be so different from most advertising.

The agency finds that, on balance, the evidence does not support a conclusion that the text-only requirement will be counterproductive. This finding is based in part on the contradictory comments regarding the price of cigarettes. Some

comments from the advertising industry argued that tobacco companies would use the savings from doing less advertising to reduce the price of cigarettes, which would increase demand especially among young people who are price sensitive. Other comments from the tobacco industry argued that the requirement would reduce competition, which could lead to higher prices for adult consumers. This conflict points out the speculative, and therefore unconvincing, nature of the claims that the restrictions will be counterproductive.

Also, despite concerns expressed by the tobacco industry and others that the text-only format would make the Surgeon General's health warning less effective, there is evidence from the focus groups conducted by the agency that this warning is not very effective with young people now.<sup>211</sup> The text-only format will not interfere with the ability of the Surgeon General's warning to warn adults of the health hazards of smoking. This format will, however, reduce the appeal to young people that advertising creates and therefore will lessen the need for the warning for young people.

The agency has considered the concern of some comments that the text-only format will be so unlike most advertising that young people will be attracted to it. Whatever attraction the novelty has for young people, the agency has concluded that it should be less than the attraction of the current imagery in tobacco advertising.

(52) A number of comments, especially from the tobacco industry, expressed concern about the 1995 proposed rule's adverse impact on competition. Many comments stated that advertising is critical to competition, brand choice, and product innovation. Comments from the tobacco industry stated that the primary purposes of its advertising are to promote brand competition and to maintain brand loyalty. Many of these comments argued that the text-only format would stamp out competition and freeze market shares. Some comments also stated that the 1995 proposed rule would serve as a barrier to new and improved products and product innovation, especially to products like lower tar cigarettes.

Although all firms will be subject to the same rules, some firms may still gain an advantage by dominant market position or by being more creative in their text-only advertising or more

effective in their placement of advertising. Tobacco companies will still be able to advertise in virtually all the same forums they use now, but companies may gain competitive advantages by developing new marketing techniques aimed at adults that are within the rules. All industries have to adapt to changing competitive circumstances, whether caused by government regulations, demanded by the public, self-imposed as in professional sports, affected by international competition and changing technologies, or in reaction to changes in consumer preferences. Creative companies can succeed by adapting better than their competitors within the new framework.

Additionally, these advertising restrictions could make it more difficult for a new competitive tobacco company to be formed and to enter the market. But, there are much greater barriers to entry for a new firm in terms of the nature of the tobacco business, capital requirements, and the existing large firms already in the business. Nevertheless, to the extent that the regulations do produce anticompetitive effects, these are outweighed by the public health benefits of the rule.

Finally, information on new products and on product innovations need not be "stamped out." This kind of information can be conveyed in the text-only format. One example of a new product that the tobacco industry claims might not have been developed if this rule had been in effect is the low tar cigarette. Yet advertising for low tar brands tends to use much more text than regular brands because the information is factual and specific. Therefore, the agency continues to find the text-only requirement to be an appropriately tailored remedy.

(53) Comments offered differing views on the function of advertising. Some stated that imagery is necessary to attract and hold the attention of adult smokers in order to convey useful information about the product and to effectively differentiate brands, while others saw images as being too appealing to children. These latter comments argued that FDA's rule is seeking to regulate only the presentation of the advertising that attracts children (the imagery), not its content.

One small business owner said the proposed ban on imagery would make established advertising logos with pictures worthless, not just for the major tobacco companies but also for small firms in tobacco related businesses. Others stated that the 1995 proposed

<sup>211</sup> Focus group report in administrative record, December 1, 1995, 60 FR 61670.

rule is not strong enough. One comment said that FDA is mistaken in asserting that the black and white text format removes imagery and emotive content from the advertisement. It said that the regulation should also limit the type styles, font sizes, and shapes of borders and letters.

The agency continues to believe that it has created an appropriately tailored remedy. The tobacco and advertising industries argue that FDA's ban on imagery and color is overinclusive and not narrowly tailored. FDA disagrees, however. The restriction on the use of images and color preserves informational advertising because of its utility to adults while eliminating the aspects of advertising that are most attractive to young people. The agency is regulating only the manner in which advertising is presented, not the information contained in it. Also, the agency is allowing imagery in advertising in adult publications.

There is undoubtedly an impact on businesses that have established logos, pictures, and other graphics associated with their businesses or products. However, all businesses are subject to the same requirements, and thus no one business should receive any competitive advantage.

The agency does not agree with comments recommending restrictions on type styles, fonts, etc. Such a restriction on advertising is, given the currently available evidence, more restrictive than necessary. Text-only advertising should be sufficient to reduce the appeal of advertising based on imagery to children and adolescents, however creatively the text is displayed. The agency concludes that the elimination of imagery and color directly and materially advances its interest in protecting the health of young people by making tobacco advertising much less appealing to them and, therefore, it makes it less likely that they will be influenced to use tobacco products.

(54) Several comments requested that FDA provide specific regulation for audio and video formats. Specifically, the comments requested that audio be confined to a text-only format appropriate for audio (words) unaccompanied by music or sound and that video be limited to black text on a white background only. Restrictions, such as these, the comments continued, would apply the spirit of the text-only format to these media. Finally, one comment expressed the concern that without these restrictions, tobacco companies might create and disseminate

music tapes, similar to one distributed by RJR with music by "The Hard Pack." This would, the comment stated, provide aural imagery for young people.

The agency agrees that it should provide more specific guidance for permissible audio and video media and that this guidance should be a logical application of the text-only requirement. Therefore, the agency has amended § 897.32 to add a new paragraph (b), which requires text-only black and white text in video advertising, which should be static, and text-only, no music, in audio advertisements.

(55) Several comments challenged FDA's proposal to limit most advertising to the use of the text-only, black print on white background format on the grounds that this limitation would violate the First Amendment. These comments relied most heavily on three cases: *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), in which the Supreme Court struck down a restriction on the use of pictures in attorney advertising; *Shapero v. Kentucky Bar Association*, 486 U.S. 466 (1988), in which the Supreme Court held that the State may not restrict lawyer solicitations to those least likely to be read by the recipient; and *In re R. M. J.*, 455 U.S. 191 (1984), a case in which the Court struck down a requirement that lawyers use a fixed format in their advertising. One comment, however, argued that FDA's restriction is fully consistent with the First Amendment.

In *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. at 647, the Supreme Court said that "the burden is on the State to present a substantial governmental interest justifying the restriction \* \* \* and to demonstrate that the restriction vindicates that interest through [narrowly tailored] means."<sup>212</sup> FDA will apply this test here.

As explained in section VI.C.4. of this document, FDA has not merely a substantial, but a compelling, interest in the health of minors. It is this interest that led it to propose the restriction on the use of images and color in cigarette and smokeless tobacco advertising.

Several comments argued, however, that the restriction on images and color do not further FDA's interest. These comments argued that there is no evidence that the use of color and

images in advertising increases tobacco use among young people.

FDA has fully addressed this assertion. The available evidence demonstrates that pictures and colors have particular appeal to children and adolescents under 18 years of age, and that they are more important to underage individuals than other aspects of the advertisement.<sup>213</sup> Young people pay attention to peripheral cues in an advertisement, such as the models that appear in them, color, and scenery, and it is these components that tobacco advertisers use to create the images that are so important to people under the age of 18. Thus, the restriction on images and colors will have a particular effect on the appeal of advertisements to young people and make these advertisements a significantly less effective means of communicating to this group.

(56) Several comments also argued that FDA's restriction on the use of colors and images is not narrowly tailored, pointing to the fact that the agency proposed to eliminate the use of all visual images and graphic designs in cigarette and smokeless tobacco advertisements.

These comments misinterpret the rule. FDA has not restricted all use of color and images. FDA has provided that these mechanisms may continue to be used in publications with primarily adult readership and in adult-only establishments. The agency has endeavored to restrict as little speech as possible. FDA has found, however, that it could not limit the appeal of cigarette and smokeless tobacco advertising to the young if it did not restrict the use of image and color.

Each of the cases relied upon by the comments is fundamentally distinguishable from the current situation. In each of these cases, the body seeking to restrict the advertising in question failed to present any evidence that the restriction was addressing an actual harm (see *Zauderer*, 471 U.S. at 648-649; *Shapero*, 486 U.S. at 479-80; (see also *Florida Bar v. Went For It, Inc.*, 115 S.Ct. at 2378 ("Finally, the State in *Shapero* assembled no evidence attempting to demonstrate any actual harm caused by targeted direct mail.")); *In re R. M. J.*, 455 U.S. at 206). Here, in contrast, the record fully establishes the reality of the harm, and that FDA's interest will be directly and materially advanced by the

<sup>212</sup> *Zauderer* actually states " \* \* \* through the least restrictive available means." However, in *Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 478-481, the Court clarified this phrase as requiring narrowly tailored means.

<sup>213</sup> See, e.g., Petty, R. E., and J. T. Cacioppo, *Communication and Persuasion: Central and Peripheral Routes to Attitude Change*, Springer-Verlag, New York, 1986.

restriction on colors and images. For these reasons, FDA finds no merit to these comments.

In summary, FDA finds that the evidence amassed during this investigation and provided by comments provides ample support for its requirement that all forms of advertising that children see and are exposed to can have an effect upon their attitudes about tobacco use.

The empirical studies and surveys, expert opinion, anecdotal evidence, industry statements, and consensus report described in section VI.D.5. of this document implicate advertising as an important source of information for young people's attitudes about, and use of, tobacco products. This evidence shows that any regulation that hopes to be successful must be comprehensive and include some type of restriction upon all forms of advertising and promotions. FDA's regulation provides restrictions that will contribute directly and materially to that end but that are tailored as narrowly as possible. Except in the limited case of outdoor advertising within 1,000 feet of schools, no informational advertising will be disturbed. However, those aspects of advertising that have particular appeal to young people will be banned.

**Color and Imagery**—Color and imagery are necessary ingredients for advertising in conditions of "low involvement," such as occurs when skimming a magazine or seeing a billboard (see sections VI.B.1.b. and VI.B.1 c. of this document).

FDA's restriction will eliminate the color and imagery but will permit information to be communicated. This requirement is as important for in-store advertising, billboards, and direct mail, as it is for traditional publications. As discussed in this section, young people get their information and product imagery from all these sources: (1) Point of sale advertising confronts young people when they go to make a purchase. The imagery is as large as life and presents the child with an enticement at the time when purchase is immediately available. It can as effectively impart information to adults with words. (2) Direct mail can frequently wind up in the hands of a young person or be addressed personally to the child or adolescent. One study found that 7.6 percent of children 12 to 17 years questioned had received mail personally addressed to them from a tobacco company (1.6 million teens).

**Billboards**—Billboards provide a major source of information about

tobacco for young people. One study published in *Advertising Age* (April 27, 1992), found that 46 percent of children 8 to 13 years old and 34 percent of children 14 to 18 cited billboards as the predominant advertising medium for tobacco products (see section VI.E.3. of this document). The Starch Survey conducted for R.J. Reynolds found that 51 percent of children 10 to 17 who recognized Joe Camel as a tobacco mascot, reported seeing him on billboards (see section VI.D.3.d. of this document).

**Cross-Country and International Studies**—Studies described evidence that regulations that are stringent and comprehensive will have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones (see section VI.D.6.a. of this document). The text-only requirement, while not as stringent as a ban, will accomplish its purpose while preserving the informational function of advertising.

Finally, the regulation is narrowly tailored. It permits adult publications and adult locations to display advertising with images and colors. The agency has attempted to define these venues with as much precision as possible but recognizes that there may be some difficulties in application. It, therefore, has made it clear that it will work with the industry to try to establish as clear rules as possible. In-store, outdoor, and direct mail advertising do not lend themselves to such tailoring. Nonetheless, the agency is confident that adults seeking information about products can be adequately informed at time of purchase or by mail order catalogue using text-only.

#### 5. Section 897.32(a)—Definition of "Adult Publication"

The preamble to the 1995 proposed rule explained that the agency was interested in permitting advertising in publications that are read primarily by adults to continue to use imagery and color. For that reason, under proposed § 897.32(a), advertisements in publications with primarily adult readership would not be restricted to a text-only format. The agency proposed to define such publications as those: (1) Whose readers age 18 or older constitute 85 percent or more of the publication's total readership,<sup>214</sup> or (2) that are read

by fewer than 2 million people under the age of 18, whichever method ensures the fewest young readers. The agency defined the readership of a publication as the total number of people that read any given copy of that publication and stated in the preamble that it should be measured according to industry standards and, at a minimum, by asking a nationally projectable survey of people what publications they read or looked at during any given time. The preamble to the 1995 proposed rule noted that a reader is one who said that he or she read the last issue of a publication. The 1995 proposed rule provided that before disseminating advertising containing images and colors, it would be the company's obligation to establish that the publication meets the criteria for a primarily adult readership.

Numerous comments were received by the agency regarding the exception from the text-only requirement for adult publications and the definition of an adult publication. Comments from the newspaper, magazine, and advertising industries were particularly critical of the readership thresholds chosen for the definition of an adult publication and were especially concerned about whether there would be any reliable and practical way to determine readership levels for most publications. Many comments from individuals who supported the text-only requirement saw this exception as a possible loophole for the tobacco industry to escape the text-only restrictions.

In a notice published in the *Federal Register* of March 20, 1996 (61 FR 11349), the agency reopened the comment period to place on the public record a memorandum that provided further explanation of the agency's proposal to exempt publications with primarily adult readership from the text-only requirement. The document provided an additional 30 days to comment on this new information. The memorandum stated that the agency had selected the 85 percent per 2-million threshold based on the public perception that certain magazines are likely to be of interest to young people under the age of 18. The agency extrapolated from the readership percentages for those publications to the proposed threshold levels. Data supporting this line had been placed in the administrative record for the proposed rule (vol. 105, document 1550) and additional readership data was

<sup>214</sup> This portion of the definition was edited in the final rule to make the two provisions parallel. Thus, § 897.32(a)(2)(i) now reads, "whose readers younger than 18 years of age constitute 15 percent

or less of the total readership as measured by competent and reliable survey evidence."

provided during the comment period. The agency noted additionally that at some point the number of underage readers is so great that the publication can no longer be considered to be of no interest to those under 18, regardless of the percentage of the readership. The agency selected 2,000,000 as that level.<sup>215</sup>

(57) Some comments objected to the proposed readership thresholds, calling them arbitrary and stating that FDA provided no basis, no rational justification, and no evidence for them. One tobacco industry comment stated that it used an FTC methodology based on readership and the number of pages of advertising to conclude that magazines with greater readership by minors tend to have less cigarette advertising than other publications.

Some comments also objected to the 2 million minor readers threshold because it would subject some adult-oriented magazines to the tombstone format even though their percentage of minor readers is very low. One comment cited the following examples and readership figures: *People Magazine* (3,020,000 minors: 7.8 percent of all readers) and *Better Homes and Gardens* (2,042,000 minors: 5.5 percent of all readers); *Time* (1,972,000 minors: 7.66 percent of all readers) and *Newsweek* (1,911,000 minors: 8.01 percent of all readers) are also close to the threshold. In addition, some comments suggested that FDA's explanation that 2,000,000 is a large number is not adequate basis for regulation.

Some comments stated that the proposed thresholds were unfair to the up to 85 percent, or more in some cases, of a publication's readers who were adults. "Such a regulation is inconsistent with the principle that the government may not 'reduce the adult population \* \* \* to reading only what is fit for children.'"

In contrast, comments supporting the proposal stated that just because the line (i.e., thresholds) could be drawn differently was not important as long as FDA can rationally explain why it drew the line where it did. One comment suggested that FDA should require the text-only format in the 10 most read magazines by young people in addition to the present proposal. Some comments recommended requiring the text-only format for advertisements in all publications.

One comment stated that no tobacco advertising, even text-only, should be

allowed whatsoever in publications with youth readership, and adult publications should have text-only tobacco advertisements. This comment also said that the agency should monitor this exception to ensure that tobacco companies don't increase advertising in national adult publications that are widely read by the entire family including children and adolescents and to be wary of tobacco companies creating their own adult publications saturated with tobacco advertising.

Other comments supporting the proposal stated that some degree of overinclusiveness is acceptable and expected because of the difficulties in fine-tuning any regulation. Other comments saw any exception for any publications as a potential loophole that could be used by tobacco companies to continue using imagery in advertising. They said that experience in other countries with tobacco advertising restrictions showed that "the tobacco industry used all of its creativity to manipulate the system to take advantage of whatever opportunities were still available to reach their target audience, particularly young, impressionable individuals."

The comments received, especially from the magazine and newspaper industries, made clear that both defining an adult publication and determining whether a particular publication meets the definition are difficult issues. However, while these comments were helpful in pointing out the difficulty of defining an adult publication, they did not offer any realistic alternative definition in terms of a readership-by-minors threshold. Because of the concern about tobacco use by children and adolescents, which was voiced by virtually all comments pro or con, the agency believes it has sufficient evidence to justify a text-only requirement. However, the agency's concern is with advertising that affects minors and with tailoring the restrictions in this final rule to burden as little speech as possible. Therefore, FDA concludes that an exception from the text-only requirement for publications that are read primarily by adults is still reasonable and feasible.

The agency has decided to retain the exception for adult publications and to retain the readership thresholds in this final rule. The 15 percent young readers threshold is reasonable based on readership data submitted with comments. The 15 percent threshold would require text-only advertising in the following sports and racing magazines: *Sports Illustrated* (18

percent), *Car and Driver* (18.3 percent), *Motor Trend* (22.1), and *Road & Track* (20.6 percent) and in the following general circulation magazines: *Rolling Stone* (18.5 percent), *Vogue* (18 percent), *Mademoiselle* (19.7 percent), and *Glamour* (17.1 percent).<sup>216</sup> The agency's judgment is based on common public perception that these are the types of magazines that young people under the age of 18 will find of interest and read. Thus, based on public perceptions and inductively given the nature of the magazines involved, FDA finds a 15 percent cut-off to be appropriate.

The 2 million number is justified based upon the agency's concern for young people. The agency finds that at some point, the number of underage readers is so great that the magazine can no longer be considered to not be of interest to children and adolescents under 18 years of age. This threshold would require text-only advertising in a publication like *People*, where the percentage of readers who are minors is only 7.8 percent, but where the number of readers under 18 years of age is 3,020,000. Publications like *Time*, *Newsweek*, *Family Circle*, and *Popular Mechanics*, however, would not be subject to the text-only format under either threshold; based on how these publications are affected, FDA concludes that, on balance, the thresholds are reasonable.<sup>217</sup> The agency's concern is not with the "intended" audience of the publication because there is no magic curtain between the interests of young adults and adolescents. The agency's concern is to protect children from the appeal of advertising that they cannot avoid. Fifteen percent youth readership or 2 million young readers narrowly addresses this concern.

The agency does not agree with comments that the rule should be made more restrictive by, for example, allowing only text-only advertising in adult publications and no advertising at all in other publications. The text-only format will reduce the appeal of tobacco advertising to young people while allowing communication of important information to adults. The agency will continue to monitor the effect on young people of text-only advertising as well as the exception created for adult publications and will consider taking any additional action that is appropriate.

<sup>215</sup> See section XV. of this document, Analysis of Impacts, for a discussion of publications that would be affected.

<sup>216</sup> Barents Group, LLC, citing Publishers Information Bureau and Mediarnark Research, Inc., pp. 53-54.

<sup>217</sup> *Id.*

Finally, the agency finds no basis to the comments' concern that the regulations will reduce the reading level of adults to those of children. The agency has crafted the exception for adult publications specifically to minimize the effect of the regulations on adults. Moreover, text-only, or the absence of color and imagery, will have significantly less impact on adults than on young people. As discussed more fully in the introduction to this section, adults generally have more capacity to engage in high involvement search than do young people. Furthermore, full information will be available to them in the text format. The First Amendment demands no more.

(58) Several comments recognized that FDA made the March 20, 1996, Federal Register document and the associated data in the record publicly available to meet its obligation under the APA to provide interested parties with an opportunity to comment meaningfully on the proposed rule. These comments stated, however, that one of the memoranda, dated March 11, 1996, placed on the public record by the Federal Register document makes clear that FDA had readership numbers in mind when it developed the proposal, but that the agency had failed to disclose those numbers to the public. The comments said that these numbers are neither reflected in the memorandum added to the record in the March 20, 1996, Federal Register document nor the administrative record that FDA has made publicly available. The comments said that the memorandum in question refers to readership numbers that were in comments submitted by the tobacco industry, and thus these numbers could not have been the numbers that FDA considered in developing its proposal. The comments said that FDA's failure to disclose this information rendered the proceeding arbitrary and capricious.

These comments are in error. FDA placed the information that it relied upon in developing the tentative 15-percent threshold on public display at approximately the time that it published the proposed rule. The data appear at pages 95T030074-75 of the administrative record (vol. 105, number 1550). (The numbers are similar but not identical to those supplied by the industry.) As one comment pointed out, in *Connecticut Light & Power Co. v. Nuclear Reg Com'n.*, 673 F.2d 525, 530 (D.C. Cir.), cert. denied 459 U.S. 835 (1982), the United States Court of Appeals for the District of Columbia Circuit stated, "In order to allow for

useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." The agency fully complied with this expectation by including the data that it had reviewed in the material that it made publicly available. Thus, the agency finds the claims in the comments summarized here to be without any basis in fact.

(59) Several comments asserted that the memorandum added to the record in the March 20, 1996, Federal Register document did not provide a reasoned explanation for the threshold that FDA had proposed. Several comments argued that there is no principle in, or discernible from, the memorandum that leads to the choice of 15 percent, as opposed to 49 percent, as the ceiling for the percentage of underage readers a publication could have and still be considered primarily adult. One comment said that FDA's reasoning was circular. Other comments said that FDA had pointed to no facts in the March 20, 1996, Federal Register document or the attendant memorandum that supports its judgment. These comments stated that FDA merely applied an arbitrarily chosen 15 percent figure to readership data and concluded that it had hit the right number. Some comments questioned why a publication with 84 percent adult readership was problematic, while a publication with 86 percent adult readership was not. Of all the comments that criticized FDA's proposed threshold, only one provided any alternative. This comment cited the tobacco industry's voluntary Cigarette Advertising and Promotion Code, Advertising 1(a), which prohibits advertising in publications directed primarily to those under 21 years of age.

In contrast to the foregoing comments, which were from the tobacco and advertising industries, a comment from a coalition of groups concerned about smoking and health stated that the agency's tentative judgment was unbiased, reasonable, and narrowly tailored to meet FDA's stated goal of limiting the specific forms of advertising that have the greatest impact on children to those publications that do not have a regular heavy readership of children.

FDA has carefully reviewed these comments. Based on this review, FDA first considered whether its March 20, 1996, Federal Register document and the memorandum added to the record under that notice had adequately

explained the basis for the proposed threshold.

The legislative history of the APA states that agency notice must be sufficient to fairly apprise interested parties of the issues involved, so that they may present responsive data or arguments thereto (S. Doc. 248, 79th Cong., 2d sess. 200 (1946)). The notice must disclose in detail the thinking that has animated the form of the proposed rule and the data on which that rule is based. (See *Home Box Office, Inc. v. FCC*, 567 F.2d 9 (D.C. Cir. 1977).) In *Connecticut Light & Power v. Nuclear Reg. Com'n.*, 673 F.2d at 530, the court held that a notice of proposed rulemaking should provide an accurate picture of the agency's reasoning, so that interested persons may comment meaningfully on the proposed rule.

The March 20, 1996, Federal Register document and the associated data in the record clearly meet this standard. As stated in this section, FDA made clear that its tentative judgment was based on a review of available data (from Simons Market Research) on the readership profiles of various publications. By dividing the publications based on whether, in the FDA employees' experience, the publications were publicly perceived as being of interest to minors or not and then examining readership information on each publication, FDA employees found that the publications that were viewed as being of interest to young people had readerships that included individuals under the age of 18 at a level of 15 percent or higher. FDA also found that the information on additional publications that it received during the comment period produced results that were consistent with the pattern that emerged from its initial review.<sup>218</sup>

Thus, FDA's reasoning is not circular. FDA based the threshold on its tentative finding, from the work that its employees had done, that the publications viewed as of interest to young people had readerships that were more than 15 percent under 18. Significantly, while the comments of the tobacco and advertising industry disagreed with the basis for the proposed threshold in various ways, none presented any data showing that publications with a youth readership of 15 percent or more are not viewed by consumers as of interest to young people.

It is important to keep in mind that the purpose of the threshold is to ensure

<sup>218</sup> See memorandum of March 11, 1996, added to the administrative record in the March 20, 1996, Federal Register.

that no more speech than necessary is burdened by FDA's restriction on advertising. Given that FDA wants to ensure that its restriction is as narrowly tailored as possible, in response to the criticisms in the comments, FDA considered whether there was a more appropriate basis on which to craft the restriction. Unfortunately, the comments criticizing the proposal were not helpful. The only suggested alternative to the proposed threshold that they put forward was the provision in the Code. This provision is inadequate on its face, however, because it is based on a minimum age of 21, rather than 18, which is the minimum provided in the laws of all the States and section 1926 of the PHS Act. Moreover, the comment that suggested this alternative gave no indication of how the age group to which a publication is primarily directed would be determined.

As a matter of common sense, FDA focused on the percentage of readers under the age of 18 in the general population and on comparing that percentage to the percentage of readers under 18 years of age for a particular publication. Certain conclusions can logically be drawn on the basis of such a comparison. If the percentage of young readers of a publication is greater than the percentage of young people in the general population, the publication can be viewed as having particular appeal to young readers. A publication with a youth readership percentage that is approximately equal to the percentage of young people in the general population can be viewed as one of general appeal, including appeal to young readers. A publication with a lower percentage of young readers than in the general population, however, would obviously be one of limited appeal to young people, and thus one that could appropriately be considered of interest primarily to adults.

Given the logic of this approach, FDA turned to the U.S. census. What the agency found is that young people between the ages of 5 and 17 constitute approximately 15 percent of the U.S. population.<sup>219</sup> Since this percentage is the same as the one that FDA used in developing the proposal, this approach fully supports the approach that FDA proposed. (Although 5 and 6 year olds may not be reading magazines, utilizing this age group builds in a margin for error.) It ratifies the judgments that FDA

employees made in arriving at the proposed threshold.

Some may assert that it is mere coincidence that the two approaches produce the same result. FDA disagrees. The congruence of the two approaches, the FDA employee anecdotal search and the use of the census data, is attributable to the basic validity of the premise underlying FDA's initial approach. Magazines have reputations as to the audiences to which they appeal, and those reputations are generally earned based on the nature of their contents. Thus, contrary to the assertions in some of the comments, the 15 percent threshold is well-supported and appropriate.

As for the question as to why a publication with 84 percent adult readership would be problematic, while a publication with 86 percent adult readership would not, the agency turns to the case law on narrow tailoring, which is, as stated in section V.E. of this document, what this exercise is about. In *Board of Trustees of State University of N.Y. v. Fox*, the Supreme Court stated:

In sum, while we have insisted that "the free flow of commercial information is valuable enough to justify would-be regulators the costs of distinguishing \* \* \* the harmless from the harmful," \* \* \* we have not gone so far as to impose upon them the burden of demonstrating that the distinguishment is 100% complete, or that the manner of restriction is absolutely the least severe that will achieve the desired end. What our decisions require is a "fit between the legislature's ends and the means to accomplish those ends," \* \* \* —a fit that is not necessarily perfect but reasonable \* \* \* (492 U.S. at 480 (citations omitted))

FDA has done its best to distinguish publications that are likely to be read by children and adolescents from those that are not. FDA finds that, if its restriction on advertising is to be meaningful, it must be based on a line that is enforceable. While only 2 percentage points separate a publication with 84 percent adult readership from one with 86 percent (although those 2 percentage points can mean a difference of tens of thousands of youngsters), the underrepresentation of underage readers in the readership of the latter publication establishes its limited appeal to young readers, and thus that it is less likely to be read by them.

For the foregoing reasons, FDA is adopting the 15-percent threshold.

(60) Comments from an association of magazine publishers and others expressed a number of concerns about the adequacy of current data for determining whether a publication met

the definition of an adult publication. Some comments said that current data and methodology to determine youth readership, while adequate for marketing purposes, are totally inadequate to justify their use as measuring devices for the imposition of criminal or civil liability on the exercise of First Amendment rights. These comments noted that the vast majority of magazines do not subscribe to either adult or youth surveys. Two comments stated that only about 2 percent of all magazines participate in the two major adult audience surveys. One comment stated that participation in the youth readership surveys, Simmons's STARS and MediaMark Research Inc.'s (MRI's) TEENMARK, is even more limited, just over one-half of one percent of all magazines.

One comment noted that to comply with the 1995 proposed rule, publications must identify readers of all ages but that current audience measurement systems do not provide this comprehensive coverage especially for readers younger than 12 years of age. Another comment noted that since the survey organizations do not survey individuals on college campuses, in the armed services, or in institutional settings, adult readership would be underestimated. Several comments noted the difficulty in determining readership data for any one issue of a magazine. Another comment noted that multi-issue advertisements would be a problem for publications right around the threshold if the publication crosses back and forth.

Several comments noted that the survey organizations would have to make substantial methodological changes to the surveys to meet the 1995 proposed rule's standard. One comment said that some problems would include adding magazines to the surveys, and dealing with unreliable results. Another comment asked who would decide the research design for the surveys since different research methodologies could be competent and reliable yet result in different conclusions. Another comment said that it could be prohibitively expensive to increase audience samples to create a legally enforceable standard, and that changes to audience measurement procedures could undermine the usefulness of the surveys for their designed marketing information purpose.

One supporting comment from an association of addiction specialists stated that "the agency should require the industry to monitor with surveys of ad recall (correlated with tobacco use

<sup>219</sup> U.S. Bureau of the Census, Population Paper Listing 21, 1994.

and intention to use patterns) among the population under age 18 years to help the agency understand the extent to which image-based messages continue to reach the young."

One comment pointed out that it would be virtually impossible to determine a legally enforceable standard for the 15 percent youth readership threshold since there is substantial variation in audience estimates between survey organizations and over time. Several comments noted that FDA's definition of a reader is not consistent with the definition used by Simmons and MRI.

Some comments suggested that a more realistic measure of who reads a publication would be who subscribes to it. Other comments opposed this alternative stating that the key criteria should be regular readership, not paid subscribers. One comment said that "[t]his alteration of the proposed exemption would destroy the intent and purpose of the advertising limitation."

Several comments said that the proposal would violate due process by punishing publishers or advertisers who are unable to determine whether their conduct violates the law because the survey data are not sufficiently comprehensive and reliable. Several comments, including one from an association of newspaper publishers, expressed concern about who would determine readership. One comment asked whether a newspaper would be subject to criminal liability based on readership data it supplies, and whether the responsibility for ascertaining whether a publication qualifies as an adult publication would be on those running the advertisements.

The agency recognizes the limitations of current readership data and the difficulties of using current readership surveys to meet the requirements of this rule. However, the agency concludes that the exception from the text-only format for adult publications is feasible as well as reasonable. First of all, the burden of proof for determining youth readership is placed by the rule on the tobacco company doing the advertising, not on the publication or the advertising agency. Under § 897.32(a)(2), the tobacco company will need to be able to demonstrate that a publication in which it is running an advertisement with images and colors meets the definition of an adult publication. Therefore, only the tobacco company will be subject to any penalties for improperly placing advertisements, even if it used data provided by the publication as part of its determination.

Second, either of the two methodologies can be used to measure readership. In addition, the agency has modified § 897.32(a)(1) and (a)(2) to make clear that any other competent and reliable private sector survey evidence may be used. A tobacco company may use one of the two major customary and reasonable readership surveys (such as MRI and Simmons). The agency does not believe that there is only one acceptable methodology. The agency is willing to accept the standard methodology currently used by MRI and Simmons as evidence. Moreover, the agency is willing to use the age range of 12 to 17, which appears to be the current standard for defining youth, in determining youth readership.

If a particular publication is not currently covered by one of the major surveys, it is the tobacco company's responsibility to develop the readership data necessary to justify a decision to advertise in that publication. The company could request a survey by one of the major survey firms, or it could develop an acceptable alternative. In either case, the agency will be available to work with the company. The company will always have the alternative to advertise in any publication in the text-only format.

The agency also acknowledges the difficulty in determining the youth readership for any particular issue of a publication. Thus, data from a survey for the most recent issues of a publication can serve as proof of readership for comparable upcoming issues unless a particular upcoming issue is being targeted at younger readers. The survey schedule used by the major survey organizations would be acceptable to the agency. A tobacco company could utilize a more frequent survey schedule if it believed the readership had changed in its favor. A rolling average of a certain number of issues could be used, for example, to determine youth readership. The problem of multi-issue contracts for advertising could be solved by a survey for a comparable period of time (e.g., winter months) preceding the contract.

The agency is willing to accept the definitions of a reader that are customarily used by the major survey organizations. The agency does not agree that using subscribers to a publication in lieu of readers is a better measure. Many children who read a publication will not be listed as subscribers (for example, *Sports Illustrated* has a youth readership of 18 to 20 percent but a youth subscriber rate

of only 6.5 or 7 percent).<sup>220</sup> Also, adults are more likely to subscribe for their families, thereby creating an underestimation of youth exposure.

(61) Several comments assumed that the purpose of the March 20, 1996, Federal Register document was to justify the restriction on advertising format that the agency had proposed for other than adult-oriented publications. These comments argued that explaining how the agency arrived at the 15 percent and 2 million readership thresholds does not approach the factual justification necessary to restrict First Amendment freedoms.

Other comments asserted that FDA's assumption that certain magazines were of interest to those under 18, as the starting point in arriving at the 15 percent threshold, shows that the limits were content based. These comments argued that basing restrictions on content violated the First Amendment.

The comments misunderstood FDA's purpose in proposing, and in adopting, the 15 percent and 2 million under 18 readership thresholds and of the memoranda added to the public record in the March 20, 1996, Federal Register document that indicated how the agency tentatively arrived at those thresholds. As discussed in section VI.D. of this document, the evidence in this proceeding establishes the effect of cigarette and smokeless tobacco advertising on those under 18 years of age. This evidence fully justifies FDA's decision to restrict the advertising for these products.

However, in imposing such a restriction on commercial speech, FDA has an obligation to ensure that the restriction is no more broad than necessary to serve the agency's substantial interests (*Board of Trustees of State University of N.Y. v. Fox*, 492 U.S. at 476). The purpose of the memorandum was to document FDA's efforts to tailor the restriction to ensure that it did not restrict advertising in those publications that were not likely to be read by children or adolescents and thus were not likely to have an effect on the group that FDA is trying to protect. Consequently, contrary to the claims of the first group of comments, the agency's goal in the memorandum was not to justify a restriction on First Amendment freedoms but to explain how it sought to ensure, and why its tentative decision was that, the limits it proposed to place on the coverage of the

<sup>220</sup> Interview on "The News Hour With Jim Lehrer," Public Broadcasting Systems, May 16, 1996.

restriction are reasonable (see *Id.* at 480).

On the other hand, other comments that opposed FDA's proposed restriction on format said that the threshold would have different impacts on similar publications. One comment provided the following examples of publications that would be considered "youth oriented" or primarily adult under the 15 percent threshold (the comment argued that the effects of the 2 million readership threshold were not relevant to the rationality of the 15 percent threshold):

Table 1b.—Examples of Publications

| Youth Oriented Publications | Primarily Adult Oriented Publications |
|-----------------------------|---------------------------------------|
| Popular Science .....       | Popular Mechanics                     |
| Soap Opera Weekly .....     | Soap Opera Digest                     |
| Outdoor Life .....          | Field and Stream                      |
| Cable Guide .....           | TV Guide                              |
| Mademoiselle .....          | Cosmopolitan                          |

The positions taken by these comments makes clear that the thresholds were not content based. If the thresholds were content based, then publications that have similar content would be subject to the same restriction. They are not. The reason they are not is that FDA's goal in arriving at the thresholds was to ensure that cigarette and smokeless tobacco advertisements that are likely to be seen by children and adolescents are the kinds of advertisements that are likely to appeal to them. The agency's only way of judging the likelihood that an advertisement that appears in a publication will be seen by those under the age of 18 is by considering the readership profile of that publication. Thus, the agency has tailored the threshold to either reflect the percentage of readership that are under 18 years of age or to ensure that publications with an extensive youth readership are covered.

The comments that complained about the differing impact of FDA's threshold on similar publications, given the purpose of the threshold, serve to underline its significance. The information submitted by the comments shows that there are significant differences in the readership of similar publications and thus in the likelihood that the material contained in these publications will be seen by young people. The treatment of publications under the agency's restriction reflects the latter fact, not the former.

*Popular Science* magazine has a readership that is 6 percent more

youthful than *Popular Mechanics*; *Soap Opera Weekly* has a 3 percent more youthful readership than *Soap Opera Digest*; and there is a 9 percent bigger youth audience for *Outdoor Life* than for *Field and Stream*. These differences are not minor or meaningless and demonstrate that, although the 15 percent threshold is not perfect, it will serve, as it was designed to, protect those under 18. *TV Guide* and *Cosmopolitan* are not excluded although, as mass distribution magazines the percentage of young readers is less than 15 percent, because they attract over 2 million young readers—a number of young people too large to ignore.<sup>221</sup>

(62) Many comments, especially from the magazine and newspaper industries, expressed concerns about the impact of this proposal on their way of doing business. One comment stated that the proposed text-only format would provide financial disincentives for magazines and newspapers to attract young readers, especially if the publication were near the borderline of being required to use the text-only format. This comment suggested that the provision would affect editorial and content decisions regarding young readers.

Some comments noted that newspapers have been struggling to attract young readers raised on television, but that success in doing this might cause the loss of significant tobacco advertising revenue. One newspaper industry association comment stated that the rule would discourage newspaper programs promoting youth reading and literacy. Some comments stated that the loss of advertising revenue could cause publications to decrease content and increase prices. Some comments thought the result of these effects of the rule would be losses in jobs in the newspaper and magazine industries.

The agency is not sure what impact the exception for adult publications will have on incentives for magazines and newspapers to attract young readers, on editorial content, and on youth literacy programs. The comments that raised these issues mostly speculated about these effects and did not provide any data as to how many of the thousands of newspapers and magazines in the United States carry tobacco advertising, or on what portion of their total advertising revenue comes from tobacco companies. Many business factors affect

a publication's decisions regarding its target audience and editorial content, and these are likely to change for a variety of reasons. Those publications affected by this regulation will have to adjust just as they would if a major advertiser reduced its advertising. Under the rule, all publications could still accept text-only advertising. The cigarette and smokeless tobacco industries are capable of designing their advertising to be attractive to adult readers (see section VI.E.4. of this document). Thus, it seems as likely that the effects of the rule in these areas will be minimal and will be far outweighed by the overall benefits of reducing youth smoking. The effect of the rule on prices and jobs in the magazine and newspaper industries is addressed in the section on the economic impact of the rule.

(63) Several comments argued that FDA's restrictions on the format of advertising, and the standard that it proposed for deciding whether a publication has a predominantly adult readership, interfere with the rights of newspapers and magazines to decide what to print. One comment said that some publications will not want to give up revenue from tobacco advertising. Therefore, the comment continued, these publications will base decisions about editorial content on how appealing a particular story would be to readers under the age of 18. Because of the impact of the restrictions on editorial content, the comment concluded, they should be subject to strict scrutiny rather than the more limited scrutiny given to commercial speech.

FDA finds no merit to this argument. A similar argument was made in *Pittsburgh Press Co. v. Pittsburgh Com'n on Human Relations*, 413 U.S. 376 (1973). The newspaper company in that case, which involved a First Amendment challenge to a municipal ordinance that prohibited a newspaper from carrying gender-designated advertising for nonexempt job opportunities, argued that the focus of the case must be on the exercise of editorial judgment by the newspaper rather than on the commercial nature of the ads in question.

The Supreme Court rejected this argument. The Court said that under some circumstances, at least, a newspaper's editorial judgments in connection with an advertisement take on the character of the advertisement. In those cases, "[t]he scope of the newspaper's First Amendment protection may be affected by the content of the advertisement"

<sup>221</sup> Baronts Group, LLC, citing Publishing Information Bureau and Mediamark Research, Inc., pp. 53-54.

(*Pittsburgh Press Co.*, 413 U.S. at 386). The Court said that, at least under some circumstances, a commercial advertisement remains commercial in the hands of the media (*Id.* at 387). The Court found that nothing about the decision to accept a commercial advertisement for placement in a gender-designated column lifts the newspaper's actions from the category of commercial speech. The Court said that the ad was in practical effect a commercial statement (*Id.* at 387-88; see also *United States v. Hunter*, 459 F.2d 205, 212 (4th Cir. 1972) ("But it has been held that a newspaper will not be insulated from the otherwise valid regulation of economic activity merely because it also engages in constitutionally protected dissemination of ideas"))).

Here, the question that is raised is whether or not a publication will decide to put itself in a position of being able to accept an advertisement that is particularly appealing to individuals under 18 years of age or not. Nothing about this judgment distinguishes it from the commercial speech itself. Because nothing about FDA's restrictions would prevent the publication from carrying a cigarette or smokeless tobacco advertisement no matter what judgment the publication makes, essentially the editorial judgment comes down to the question of what will be the format of the advertisement that it will carry. This judgment clearly comes within the category of commercial speech, and FDA has fully justified its regulation of commercial speech under the *Central Hudson* test.

#### 6. Advertising—§ 897.32 Requirements for Disclosure of Important Information

a. *Established name and intended use*—§ 897.32(c). Proposed § 897.32(b) (now renumbered as § 897.32(c)) provided that each manufacturer, distributor, and retailer (of tobacco and smokeless tobacco) advertising or causing to be advertised, disseminating or causing to be disseminated, advertising, but not labeling, permitted under § 897.30(a), shall include, as provided in section 502(r) of the act, the product's established name and a statement of its intended use as follows: "Tobacco—A Nicotine Delivery Device," "Cigarette Tobacco—A Nicotine-Delivery Device," or "Loose Leaf Chewing Tobacco," "Plug Chewing Tobacco," "Twist Chewing Tobacco," "Moist Snuff" or "Dry Snuff," whichever is appropriate for the

product, followed by the words "A Nicotine-Delivery Device."

The preamble to the 1995 proposed rule explained that section 502(r)(1) of the act requires, for any restricted device, that all advertising or other descriptive printed material contain a true statement of the device's established name. Under section 502(r)(2) of the act, a restricted device is misbranded unless all advertising contains "a brief statement of the intended uses of the device." The agency explained in the preamble to the 1995 proposed rule that it is necessary to require that the product's established name and intended uses be placed on all advertising, under section 520(e) of the act, as a measure that affirmatively identifies the products to persons reading the advertising (the other brief statement requirements under section 502(r)(2) of the act are discussed in section IV.E.6.b. of this document).

The agency did not receive any comments on the "established name" provision and has thus codified the provision in the final rule as § 897.32(c). The agency has modified the "intended use" provision in this final rule to require that cigarette and smokeless tobacco advertising contain the statement "A Nicotine-Delivery Device for Persons 18 or Older." For clarity, the agency has referenced subpart D generally rather than § 897.30(a) specifically. As stated in the 1995 proposed rule, the established name requirement applies to both tobacco and smokeless tobacco.

(64) Several comments opposed the proposed "intended use" provision. One tobacco industry comment stated that FDA's proposal is not authorized under section 502(r) of the act because: (1) The "intended use" of tobacco products is for smoking taste and pleasure, not a "nicotine delivery device;" (2) the "intended use" provision of the act does not require that manufacturers list all information related to all purposes for which a drug is intended; and (3) FDA is not free to prescribe an "intended use" of its own invention. The comment also argued that FDA's statement, which communicates only that a cigarette yields nicotine, is not a statement of "intended use" and is of no value to consumers who obtain more complete nicotine information that cigarette manufacturers already provide in advertising.

The agency disagrees with the comments stating that it is not free to prescribe an intended use. As discussed in this section, the agency is required by

section 502(r)(2) of the act to require a brief statement of intended use for all restricted devices.

Additionally, it is within FDA's primary jurisdiction and expertise to determine a device's intended use. FDA has decades of experience evaluating the intended uses of FDA-regulated products, including restricted devices, prescription and over-the-counter drugs, biological products, and dietary supplements through its review and approval process for those products.

As described in the 1996 Jurisdictional Determination annexed hereto, the available evidence demonstrates that manufacturers intend to affect the structure and function of the body by delivering pharmacologically active doses of nicotine to the consumer. Although the agency proposed that the intended use include the language "Nicotine Delivery Device," the agency has determined, based on the comments received, that a more accurate statement of the intended use would provide more value to consumers. Because cigarettes and smokeless tobacco products can legally be sold only to those persons 18 years of age and older, the agency believes the intended use statement should reflect the target population for which the product is intended. Often, the intended use statement for a drug or device includes the patient population by whom the product may be used. Accordingly, the intended use statement has been revised to require the following language on all advertisements for cigarette and smokeless tobacco: "A Nicotine-Delivery Device For Persons 18 or Older."

b. *Section 897.32(d) Brief statement.* Proposed § 897.32(c) and (d) would have required that each manufacturer, distributor, and retailer of cigarettes include in all advertising, but not labeling, a brief statement, printed in black text on a white background that was readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning. Because the Smokeless Act preempts other statements about tobacco use and health in advertising, the 1995 proposed rule stated that the provision only applied to cigarettes (and not smokeless tobacco). The 1995 proposed rule provided one brief statement as an example ("ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING") (60 FR 41314 at 41338). The agency requested comment on what other information should be included in the brief statements concerning relevant