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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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, and 897

[Docket No. 95N–0253]

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing new regulations governing the sale and distribution of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents in order to address the serious public health problems caused by the use of and addiction to these products. The proposed rule would reduce children's and adolescents' easy access to cigarettes and smokeless tobacco as well as significantly decrease the amount of positive imagery that makes these products so appealing to them. The proposed rule would not restrict the use of tobacco products by adults.

Specifically, the proposed rule would establish 18 years of age as the Federal minimum age of purchase and would prohibit cigarette vending machines, free samples, mail-order sales, and self-service displays. It would also require that retailers comply with certain conditions regarding sales of tobacco, especially verification that the purchaser is at least 18 years of age before a tobacco sale is made. Finally, the proposed rule would limit advertising and labeling to which children and adolescents are exposed to a text-only format; ban the sale or distribution of branded non-tobacco items such as hats and tee shirts; restrict sponsorship of events to the corporate name only; and require manufacturers to establish and maintain a national public education campaign aimed at children and adolescents to counter the pervasive imagery and reduce the appeal created by decades of pro-tobacco messages and thus to help reduce young people's use of tobacco products.

The objective of the proposed rule is to meet the goal of the report ''Healthy People 2000'' by reducing roughly by half children's and adolescents' use of tobacco products. If this objective is not met within seven years of the date of publication of the final rule, the agency will take additional measures to help achieve the reduction in the use of tobacco products by young people. FDA is requesting comment regarding the type of additional measures that would be most effective.

DATES: Written comments and recommendations by November 9, 1995.

ADDRESSES: Submit written comments and recommendations to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

Approximately 50 million Americans currently smoke cigarettes and another 6 million use smokeless tobacco products.[1] These tobacco products are responsible for more than 400,000 deaths each year due to cancer, respiratory illnesses, heart disease, and other health problems.[2] Cigarettes kill more Americans each year than acquired immune deficiency syndrome (AIDS), alcohol, car accidents, murders, suicides, illegal drugs, and fires combined.[3] On average, smokers who die from a disease caused by smoking lose 12 to 15 years of life because of tobacco use.[4]

In a separate document,[5] FDA is addressing the issue of its jurisdiction over nicotine-containing cigarettes and smokeless tobacco products. The results of an extensive investigation and comprehensive legal analysis support a finding at this time that the nicotine in these products is a drug and that these products are nicotine-delivery devices within the meaning of the Federal Food, Drug, and Cosmetic Act (the act). FDA proposes to regulate cigarettes and smokeless tobacco products by employing its restricted device authority, which affords the most appropriate and flexible mechanism for regulating the sale, distribution, and use of these products.

The primary objective of the proposed rule is to reduce the death and disease caused by tobacco products. Rather than banning tobacco products for the millions of Americans who are currently addicted to them, this regulation focuses on preventing future generations from developing an addiction to nicotine-containing tobacco products. In addition, the scientific evidence strongly suggests that nicotine addiction begins when most tobacco users are teenagers or younger and, thus, is a pediatric disease. Therefore, reducing the number of young people who regularly start to use tobacco products will help to prevent future generations of individuals from becoming addicted to nicotine.

The goal of the proposed rule is to help the country achieve one of the objectives of ''Healthy People 2000,'' which is to reduce the number of children and adolescents who use tobacco products by roughly one half by the year 2000. The agency has modified the goal to include a different measurement tool and established 7 years after publication of the final rule as the goal's endpoint. ''Healthy People 2000'' discussed national health promotion and disease prevention objectives in this country. It was facilitated by the Institute of Medicine of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments.[6]

To determine the most appropriate regulatory measures, the agency reviewed the current patterns of use of tobacco products. According to the 1994 Surgeon General's Report, ''Preventing Tobacco Use Among Young People: A Report of the Surgeon General'' (the 1994 Surgeon General's Report), more than 3 million American adolescents currently smoke cigarettes and an additional 1 million adolescent males use smokeless tobacco.[7] Every day, another 3,000 young people become regular smokers.[8] U.S. data suggest that anyone who does not begin smoking in childhood or adolescence is unlikely to ever begin.[9] Eighty-two percent of adults who ever smoked had their first cigarette before age 18, and more than half of them had already become regular smokers by that age.[10] Moreover, the younger one begins to smoke, the more likely one is to become a heavy smoker.[11]

Many young tobacco users become addicted to nicotine, a chemical substance in tobacco. Although they believe that they will not become addicted to nicotine or become long-term users of tobacco products, they often find themselves unable to quit smoking.[12] In fact, among smokers aged 12–17 years, 70 percent already regret their decision to smoke and 66 percent state that they want to quit.[13] Those who are able to quit experience relapse rates and withdrawal symptoms similar to those reported in adults.[14]

Long-term addiction to nicotine can result in serious chronic diseases and premature death. An adolescent whose cigarette use continues into adulthood increases his or her risk of dying from

cancer, cardiovascular disease, or lung disease.[15] In addition, smokeless tobacco use has been linked to oral cancer and other adverse effects.[16]

Although most segments of the American adult population have decreased their use of cigarettes, the prevalence of smoking by young people has failed to decline for more than a decade. Recently, smoking among young people has begun to rise.[17] Between 1991 and 1994, the prevalence of smoking by eighth graders increased 30 percent, from 14.3 percent to 18.6 percent. Among 10th grade students, it increased from 20.8 percent to 25.4 percent and for 12th grade students, it rose from 28.3 percent to 31.2 percent.[18] Between 1985 and 1994, smoking among college freshmen increased from 9 percent to 12.5 percent.[19]

Millions of American children and adolescents can easily buy or obtain cigarettes and smokeless tobacco products. The large number of young people who use these products is especially noteworthy because all States prohibit the sale of tobacco products to persons under the age of 18, and a few States prohibit cigarette sales to persons under the ages of 19 or 21.[20] These State laws, however, are rarely enforced. 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 products.[21]

In addition to easy access to tobacco products, advertising and promotional activities can influence a young person's decision to smoke or use smokeless tobacco products. Tobacco products are among the most heavily advertised products in the United States.[22] In 1993, the tobacco industry spent a total of $6.2 billion on the advertising, promotion, and marketing of cigarettes and smokeless tobacco. Of that number, 31 percent ($1.9 billion) was spent on advertising and promotional activities; 26 percent ($1.6 billion) was given to retailers in the form of cash allowances or retailer items to facilitate and enhance the sale of tobacco products, and finally, 43 percent ($2.6 billion) was in the form of financial incentives (e.g. coupons, cents off, buy one/get one free, free samples) to consumers.[23]

Tobacco product brand names, logos, and advertising messages are pervasive, appearing on billboards, on buses and trains, in magazines and newspapers, and on clothing and other goods. These ubiquitous images and messages convey to young people that tobacco use is desirable, socially acceptable, safe, healthy, and prevalent in society. One study found that 30 percent of 3 years olds and 91 percent of six year olds associate the ''Joe Camel'' cartoon figure with cigarettes.[24] Studies also show that most young people buy the most heavily advertised cigarette brands, whereas many adults buy generic or ''value category'' cigarette brands, which have little or no image advertising.[25]

In proposing this regulation, FDA examined many domestic and foreign tobacco control statutes, regulations, and legislation, as well as numerous studies and reports. FDA also reviewed recommendations from various public health organizations, including the World Health Organization, the Office of the Surgeon General, the Centers for Disease Control and Prevention (CDC), the National Cancer Institute (NCI), and the Institute of Medicine (IOM). Two reports, the 1994 Surgeon General Report and the 1994 IOM Report ''Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths,'' were especially helpful and informative.

The agency has examined many options for reducing tobacco use by children and adolescents, and believes that an effective program must address the following two areas: (1) Restrictions on cigarette and smokeless tobacco sales that will make these products less accessible to young people; and (2) restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people along with requirements for a manufacturer-funded national education campaign aimed at those under 18 years of age to help reduce the products' appeal to these young people. A brief description of the major provisions of the proposed rule follows.

A. Sale and Distribution

The proposed rule would restrict the sale of cigarettes and smokeless tobacco products to individuals age 18 and older. This age restriction is based on the fact that most adult smokers became regular smokers before age 18.

The proposed rule would require retailers to verify the age of persons who wish to buy cigarettes or smokeless tobacco products and would eliminate ''impersonal'' methods of sale that do not readily allow age verification, such as mail orders, self-service displays, and vending machines.

The proposed rule would make each manufacturer, distributor, and retailer of tobacco products responsible for complying with the proposed restrictions. Manufacturers would be required to remove all manufacturer-supplied or manufacturer-owned self-service displays, advertising, labeling, and other items that do not conform to the requirements in the proposed rule.

The proposed rule would prohibit the distribution of free samples and would allow the exchange of coupons and other non-cash certificates only by individuals 18 or older and only in face-to-face transactions. Currently, young people, including children in elementary school, are often able to obtain free samples despite industry-imposed age restrictions on such distributions.

The proposed rule would also prohibit the sale of single cigarettes (''loosies'') and ''kiddie packs (less than 20 to a pack) which, due to their relatively low price and easy concealment, have been shown to be particularly appealing to children and adolescents.

Further, the proposed rule would prohibit manufacturers from using a trade name or brand name of a non-tobacco product for a cigarette or smokeless tobacco product. This will prevent a manufacturer from transferring the images, good will, and appeal of a popular non-tobacco product to a tobacco product.

B. Labeling, Advertising and Educational Programs

Advertising that reaches children would be in black and white, text-only format. Studies indicate that children and adolescents are very receptive to images and cartoons and less attentive to texts. However, the proposed rule would not affect advertising in publications with primarily adult readership—imagery and color would continue to be permitted in such publications. Finally, outdoor advertising of tobacco products located within 1,000 feet of schools and playgrounds would be banned. Consequently, the proposed rule would help reduce the appeal of advertising to children and adolescents without affecting informational messages conveyed to adults.

The proposed rule would prohibit the sale or distribution of brand identifiable non- tobacco items and services, proof-of-purchase sales, games and contests, and sponsorship of events in the brand name, as well as advertising for these items, services, and events.

The proposed rule would require manufacturers to establish and maintain a national educational campaign in order to counter the pervasive imagery and reduce the appeal created by decades of pro-tobacco messages and, thus, help reduce young people's use of tobacco products. Evidence exists that mass media antismoking campaigns conducted nationally between 1967 and 1970, and more recently, in Vermont and California, have had a sustained

effect on preventing teens from starting to smoke and on significantly reducing per capita cigarette consumption.

C. Healthy People 2000 Objective

Seven years after publication of the final rule, the agency would determine whether additional restrictions on tobacco products are required by using outcome-based objectives modeled on the ''Healthy People 2000'' report. One of the goals for tobacco use established by that report is to reduce by roughly one half the percentage of young people using tobacco products by the year 2000. If this objective is not met within the time specified by the rule, FDA would take additional measures to help achieve the reduction in young people's use of tobacco products. The proposed rule requests comment on which additional measures should be adopted.

The agency intends to adopt one or more additional provisions only if the continued use of cigarettes and smokeless tobacco products by children and adolescents indicates that the goal of reducing tobacco use by young people by roughly half had not been met.

The remainder of this discussion of the proposed rule (hereinafter ''preamble'') is organized as follows: Chapter II examines the use of cigarettes and smokeless tobacco products by children and adolescents, and the health consequences of using nicotine-containing tobacco products; Chapter III describes the provisions of the proposed rule and provides the rationale for each of the requirements; Chapter IV reviews the legal authority for these specific requirements, and Chapters V through VIII provide analyses required by the Paperwork Reduction Act of 1980, various Executive Orders, as well as provides analyses of various economic and environmental impacts.

References

1. Substance Abuse and Mental Health Services Administration, ''National Household Survey on Drug Abuse: Population Estimate 1993,'' Rockville, MD: Department of Health and Human Services, Public Health Service, Substances Abuse and Mental Health Services Administration, Office of Applied Studies, DHHS Pub. No. (SMA) 94–3017, 1994, pp. 89, 95; ''Cigarette Smoking Among Adults—United States, 1993,'' in ''Morbidity and Mortality Weekly Report (MMWR),'' CDC, Department of Health and Human Services (DHHS), vol. 43, No. 50, pp. 925–930, 1994; ''Use of Smokeless Tobacco Among Adults—United States, 1991,'' in ''MMWR,'' CDC, DDS, vol. 42, pp. 263–266, 1993; Unpublished data from the 1992 Youth Risk Behavior Survey, National Health Interview Supplement, CDC.

2. ''Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990,'' in ''MMWR,'' CDC, DHHS, vol. 42, no. 33, pp. 645–649 (1993).

3. IOM, p. 3. Collectively, AIDS, alcohol, car accidents, murders, suicides, illegal drugs and fire combined cause nearly 251,000 deaths a year.

4. ''Cigarette Smoking—Attributable Mortality and Years of Potential Life Lost—United States, 1990, in ''MMWR,'' CDC, DHHS, vol. 42, no. 33, pp. 645–649, 1993; Peto, R., et al., ''Mortality from Tobacco in Developed Countries: Indirect Estimation from National Vital Statistics,'' *The Lancet,* vol. 339, pp. 1268–1278, 1992.

5. ''Nicotine In Cigarettes and Smokeless Tobacco Products is a Drug and These Products are Nicotine-Delivery Devices Under the Federal Food, Drug, and Cosmetic Act,'' FDA, DHHS, August, 1995.

6. DHHS, ''Healthy People 2000, ''U.S. Department of Health and Human Services, Public Health Service, Intro. pp. 1–8, September 1990.

7. DHHS, ''Preventing Tobacco Use Among Young People: A Report of the Surgeon General,'' Atlanta, Georgia: DHHS, PHS, CDC, NCCDPHP, OSH, 1994 pp. 5 (hereinafter cited as ''1994 SGR'').

8. IOM Report p. 8.

9. 1994 SGR, pp. 5, 58, 65–67.

10. 1994 SGR, p. 65.

11. Taioli, E., E.L. Wynder, ''Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood,'' *The New England Journal of Medicine,* vol. 325, No. 13 pp. 968–969, 1991; and L.G. Escobedo, et al., ''Sports Participation, Age of Smoking Initiation, and the Risk of Smoking Among U.S. High School Students,'' *Journal of the American Medical Association,* vol. 269, No. 11, pp. 1391–1395, 1993.

12. IOM Report, pp. 51–52.

13. The George H. Gallup International Institute. ''Teenage Attitudes and Behavior Concerning Tobacco,'' at p. 54, September 1992.

14. Reasons for Tobacco Use and Symptoms of Nicotine Withdrawal Among Adolescent and Young Adult Tobacco Users—United States, 1993,'' in ''Morbidity and Mortality Weekly Report,'' CDC, DHHS, vol. 43, No. 41, pp. 745–750, 1994; 1994 SGR, p. 78.

15. McGinnis, J.M., and W.H. Foege, ''Actual Causes of Death in the United States,'' *Journal of the American Medical Association,* vol. 270, No. 18, pp. 2207–2212, 1993; see generally DHHS, ''Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General.'' DHHS, PHS, CDC, NCCDPHP, OSH. DHHS Publication No. (CDC) 89–8411, p. 5, 1989 (hereinafter cited as ''1989 SGR''); DHHS, ''The Health Consequences of Smoking Chronic Obstructive Lung Disease: A Report of the Surgeon General, ''DHHS, PHS, OSH, 1984 (hereinafter cited as ''1984 SGR''); DHHS, ''The Health Consequences of Smoking: Cardiovascular Disease, A Report of the Surgeon General,'' Public Health Service, OSH, DHHS, p. 76, 1983; DHHS, ''The Health Consequences of Smoking—Cancer—A Report of the Surgeon General,'' DHHS, PHS, OSH, p. 8, 1982 (hereinafter cited as ''1982 SGR'').

16. 1994 SGR, p. 39; DHHS, ''The Health Consequences of Using Smokeless Tobacco: A Report of the Advisory Committee to the Surgeon General,'' p. 32–47, Bethesda, Md., DHHS, PHS, NIH Publication No. 86–2874, April, 1986 (hereinafter cited as ''1986 SGR'').

17. ''Cigarette Smoking Among Adults—United States 1991, ''in ''MMWR,'' CDC, DHHS, Vol. 42, no. 12, pp. 230–233, 1993; 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, Volume I: Secondary School Students,'' Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, National Institute on Drug Abuse, NIH Pub. No. 94–3809, pp. 9, 19, 1994; The University of Michigan, News and Information Service, July 20, 1995, ''Smoking rates climb among American teenagers, who find smoking increasingly acceptable and seriously underestimate the risks.'' Table 1.

18. 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, Volume I: Secondary School Students,'' Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institute of Health, National Institute on Drug Abuse, NIH Pub. No. 94–3809, 1994; The University of Michigan, News and Information Service, July 20, 1995, ''Smoking rates climb among American teenagers, who find smoking increasingly acceptable and seriously underestimate the risks.'' Table 1.

19. ''Washington Post,'' January 9, 1995, at p. A5, col. 3 (describing findings from a survey of approximately 238,000 freshman conducted by the UCLA Higher Education Research Institute) and UCLA, Health Education Research Institute, ''The American Freshman: National Norms for Fall 1994.

20. Coalition on Smoking OR Health, ''State Legislated Actions on Tobacco Issues,'' at Appendix G, 1993.

21. DiFranza, J.R., and J.B. Tye, ''Who Profits From Tobacco Sales to Children?'' *Journal of the American Medical Association,* vol. 263, No. 20, pp. 2784–2787, 1990; Cummings, K.M., T. Pechacek, and D. Shopland, ''The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State,'' *American Journal of Public Health,* vol. 84, No. 2, pp. 300–302, 1994 (conservative estimates of cigarette use by teenagers in 1991 have teenagers smoking 516 million packs of cigarettes and spending $962 million (of which the industry gained a profit of $190 million); an estimated 255 million packs were sold illegally to minors).

22. 1994 SGR, p. 160.

23. Federal Trade Commission, ''Report to Congress for 1993, Pursuant to the Federal Cigarette Labeling and Advertising Act,'' Table 3D (1995) and Federal Trade Commission, ''Report to Congress, Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986,'' Table 4D (1995).

24. Pierce, J.P., et al., ''Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California,'' *Journal of the American Medical Association,* vol. 266, No. 22, pp. 3154–3158, 1991; See also Fischer, P.M. et al., ''Brand Logo Recognition

by Children Aged 3 to 6 Years, Mickey Mouse and Old Joe Camel,'' *Journal of the American Medical Association,* vol. 266, No. 22, pp. 3145–3148, 1991.

25. ''Changes in Cigarette Brand Preference of Adolescent Smokers, United States, 1989–1993,'' in ''MMWR,'' DHHS, CDC, vol. 42, No. 32, pp. 577–581, 1994; Teinowitz, I., ''Add RJR to List of Cigarette Price Cuts,'' *Advertising Age,* pp. 3, 46, April 26, 1993.

II. Cigarette and Smokeless Tobacco Product Use Among Children and Adolescents

Each year, the cigarette industry loses about 1.7 million customers in the United States; about 400,000 die from diseases caused by their smoking and another 1.3 million quit smoking.[1] To offset the sales lost to smokers who die or quit smoking, cigarette manufacturers rely on young people as the primary source of new customers. Each day, approximately 3,000 young people become regular smokers,[2] serving as the industry's major domestic source of replacement smokers.

A. Epidemiology of Tobacco Use Among Children and Adolescents

In 1965, the year following the first Surgeon General's Report [3] describing the relationship between smoking and diseases such as lung cancer, chronic bronchitis, and emphysema, 42.4 percent of the overall adult population in the United States smoked.[4] By 1990, the prevalence of smoking in the United States had declined to 25.5 percent.[5] The greatest reduction in adult smoking occurred from 1987 to 1990, when the prevalence of smoking declined by 1.1 percentage point annually, twice the rate of decline during the preceding 20 years.[6] The prevalence of smoking among adults leveled off at 25.6 percent in 1991 and was 26.5 percent in 1992. This change was due to a change in the definition of current smokers, rather than an increase in prevalence. The new definition incorporates some day (i.e., less than daily, occasional, or infrequent) smoking.[7] The estimate for 1992 with the old definition was 25.6 percent—the same as in 1991. In 1993, under the new definition, prevalence was 25.0 percent.[8]

The long-term downward trend in adult smoking contrasts with the trends in smoking among young people. The Institute of Medicine noted that the number of high school seniors who have smoked in the last 30 days remained ''basically unchanged since 1980,'' at approximately 30 percent, and further reported that 16.7 percent of 8th grade students were current smokers (that is, had smoked within the past 30 days), and 8.3 percent smoked daily.[9] The prevalence of cigarette smoking in recent years among 8th and 10th grade students has risen significantly and provides cause for great concern. For example, among 8th grade students, 14.3 percent in 1991 and 18.6 percent in 1994 were current smokers; among 10th grade students, 20.8 percent in 1991 and 25.4 percent in 1994 were current smokers.[10]

The 1994 Surgeon General's Report reviewed several different surveys and found that the estimated percentage of adolescents who have ever smoked cigarettes ranged from approximately 42 percent (as reported by the 1991 National Household Survey on Drug Abuse) to 70 percent (as reported by the 1991 Youth Risk Behavior Survey).[11] The 1994 Surgeon General's Report also found that 28 percent of high school seniors were current smokers.[12] (The most recent data reported by the Monitoring the Future Project indicates that in 1994 the number of high school seniors who were current smokers had risen to 31.2 percent.)[13] Further, the 1994 Surgeon General's Report states that seven to 13 percent of adolescents were frequent or heavy smokers, consuming at least one-half pack daily or smoking 20 days or more of the 30 days in a survey period.[14]

Approximately 3 million children under the age of 18 are daily smokers.[15] One study found that children between the ages of 8 and 11 who are daily smokers consume an average of 4 cigarettes daily, and those who are between the ages of 12 and 17 average nearly 14 cigarettes daily. The study also estimated that adolescents consume an estimated 947 million packs of cigarettes and 26 million containers of smokeless tobacco annually and account for annual tobacco sales of $1.26 billion.[16] Another study estimates that teenagers in 1991 smoked 516 million packs of cigarettes and spent $962 million purchasing them.[17] As stated previously, these figures are especially significant given that all States prohibit the sale of tobacco to persons under the age of 18 (with some States prohibiting sales to persons under the age of 19 and one State, Pennsylvania, prohibiting cigarette sales to persons under the age of 21).[18] Unfortunately, few States successfully enforce their laws restricting tobacco sales to minors.[19]

Studies have also suggested that the age one begins smoking can greatly influence 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. Those who started smoking by early adolescence were more likely to be heavy smokers than those who began smoking as adults.[20] Another study found that high school students who smoked their first cigarette during childhood smoked more often and in greater amount than those who first tried smoking during adolescence.[21]

The escalating use of smokeless tobacco products by underage persons presents an additional and growing public health problem. Smokeless tobacco products include chewing tobacco and snuff and are also known as ''spit tobacco'' or ''spitting tobacco.'' In 1970, the prevalence of snuff use among males was lowest in those 17 to 19 years of age and the highest use was by men aged 50 or more. By 1985, a dramatic shift had occurred, and males between 16 and 19 were twice as likely to use snuff as men aged 50 and over.[22] An estimated 3 million users of smokeless tobacco products were under the age of 21 in 1986,[23] when Congress enacted the Comprehensive Smokeless Tobacco Health Education Act (the Smokeless Act) (15 U.S.C. 4401). The Smokeless Act required the Secretary of Health and Human Services (the Secretary) to inform the public of the health dangers associated with smokeless tobacco use, required warning labels on packages, banned advertising on electronic media subject to the Federal Communications Commission's jurisdiction (such as television and radio), and encouraged States to make 18 years the minimum age for purchasing smokeless tobacco products. Despite the Smokeless Act and State laws prohibiting sales to minors, a high percentage of persons under the age of 18 use smokeless tobacco products. For example:

- 1991 school-based surveys estimated that 10.7 percent of U.S. high school seniors and 19.2 percent of male 9th to 12th grade students use smokeless tobacco.[24]
- A 1992 national household-based survey of U.S. children found that 11.9 percent of males 12–17 years of age were using smokeless tobacco.[25]
- Among high school seniors who had ever tried smokeless tobacco, 73 percent did so by the ninth grade.[26]

In some parts of the United States the rates are especially high. According to the 1990–91 Youth Risk Behavior Survey, the smokeless tobacco product use rates among males in grades 9 through 12 were as high as 34 percent in Tennessee, 33 percent in Montana, 32 percent in Colorado, and 31 percent in Alabama and Wyoming.[27]

Native American youth are especially vulnerable to smokeless tobacco product use. The rates for both males and females are extremely high, ranging from 24 percent to 64 percent, and at rates that, in some areas, are 10 times higher than those for non-Native

Americans.[28] Studies also suggest that Native Americans begin using smokeless tobacco products at much earlier ages than non-Native Americans. A 1986 survey at the Rosebud Sioux Reservation in South Dakota revealed that 21 percent of kindergarten children used smokeless tobacco products,[29] and a survey of Native Americans in the state of Washington indicated that 33 percent of former users and 57 percent of current users started using smokeless tobacco products before the age of 10.[30]

The recent and very large increase in the use of smokeless tobacco products by young people and the addictive nature of these products has persuaded the agency that these products must be included in any regulatory approach that is designed to help prevent future generations of young people from becoming addicted to nicotine-containing tobacco products.

B. The Health Effects Associated With Cigarettes and Smokeless Tobacco Products

Over 400,000 Americans die each year from smoking-related illnesses. This equates to more than one of every five deaths in the United States.[31] If an adolescent's tobacco use continues for a lifetime, there is a 50 percent chance that the person will die prematurely as a direct result of smoking.'' [32] Moreover, the earlier a young person's smoking habit begins, the more likely he or she will become a heavy smoker and therefore suffer a greater risk of smoking related diseases.[33] Smoking is responsible for about 30 percent of all cancer deaths,[34] including 87 percent of all lung cancer deaths; 82 percent of deaths from chronic obstructive pulmonary disease (COPD); [35] 21 percent of deaths from coronary heart disease; [36] and 18 percent of deaths from stroke.[37] Further, a causal relationship exists between cigarette smoking and cancers of the larynx, mouth, esophagus, and bladder; and atherosclerotic peripheral vascular disease, cerebrovascular disease (stroke), and low-birth weight babies.[38] Cigarette smoking is also a probable cause of infertility and peptic ulcer disease and contributes to, or is associated with, cancers of the pancreas, kidney, cervix, and stomach.[39]

Much of the following brief discussion is abstracted from several Surgeon General's reports. The Surgeon General's reports summarize thousands of peer-reviewed scientific studies and are themselves peer-reviewed and subjected to significant scientific scrutiny.

1. Health Effects of Cigarette Smoking

Epidemiologic studies provide overwhelming evidence that smoking causes lung cancer.[40] The risk of getting lung cancer may be more than 20 times greater for heavy smokers than nonsmokers.[41] The relationship between smoking and lung cancer is due to the numerous carcinogens in cigarette smoke.[42] Cigarette smoking caused an estimated 117,000 deaths from lung cancer in 1990.[43]

The risk of getting lung cancer increases with the number of cigarettes smoked and the duration of smoking, and decreases after cessation of smoking.[44] Starting smoking at an earlier age increases the potential years of smoking and increases the risk of lung cancer.[45] Studies have shown that lung cancer mortality is highest among adults who began smoking before the age of 15.[46]

Cigarette smoking also causes cancer of the larynx, mouth, and esophagus.[47] According to current estimates, 82 percent of laryngeal cancers are due to smoking and about 80 percent of the 10,200 deaths from esophageal cancer in 1993 can be attributed to smoking.[48] The risk of oral cancer among current smokers ranges from 2.0 to 18.1 times the risk in people who have never smoked and can be reduced more than 50 percent after quitting.[49] The risk of esophageal cancer among current smokers ranges from 1.7 to 6.4 times the risk in people who have never smoked and can also be reduced by about 50 percent after quitting.[50]

Epidemiologic studies demonstrate that cigarette smoking contributes to the development of pancreatic cancer.[51] The reason for this relationship is unclear, but may be due to carcinogens or metabolites present in the bile or blood.[52] In 1985, the proportion of pancreatic cancer deaths in the United States attributable to smoking was estimated to be 29 percent in men and 34 percent in women.[53]

Cigarette smoking accounts for an estimated 30 to 40 percent of all bladder cancers and is a contributing factor for kidney cancer.[54] The increased risk of kidney and bladder cancer may be related to the number of cigarettes smoked per day, and the risk decreases following smoking cessation.[55]

Smoking appears to be a contributing factor for cancer of the cervix. The association between cigarette smoking and cervical cancer persists after control is made for risk factors, such as age at first intercourse and the number of sexual partners, that predispose a woman to developing sexually-transmitted diseases. The inclusion of these risk factors, however, may not completely rule out confounding by sexually-transmitted diseases. However, the findings that components of tobacco smoke can be found in the cervical mucus of smokers, that the mucus of smokers is mutagenic, and that former smokers have a lower risk of getting cervical cancer than current smokers are consistent with the hypothesis that smoking is a contributing cause of cervical cancer.[56]

The 1982 Surgeon General's Report concluded that stomach cancer is associated with cigarette smoking.[57] Studies show a slight increase in mortality from stomach cancer in smokers compared with nonsmokers.[58]

Smoking is a leading cause of heart disease. The 1964 Surgeon General's Report noted that male cigarette smokers had higher death rates from coronary heart disease than nonsmokers.[59] Subsequent reports have concluded that cigarette smoking contributes to the risk of heart attacks, chest pain, and even sudden death.[60] Overall, smokers have a 70 percent greater death rate from coronary heart disease than nonsmokers.[61]

Ischemic heart disease resulting from cigarette smoking claimed nearly 99,000 lives in 1990.[62] One study estimates that 30 to 40 percent of all coronary heart disease deaths are attributable to smoking.[63] Smokers between the ages of 40 and 64, who smoked more than one pack a day, were shown to have a risk of coronary heart disease that is 3.2 times higher than people who do not smoke.[64]

Several processes that are likely to contribute to heart attacks are influenced or caused by smoking: atherosclerosis, thrombosis, coronary artery spasm, cardiac arrhythmia, and reduced capacity of the blood to deliver oxygen. The nicotine and carbon monoxide in cigarette smoke are believed to be responsible for heart disease, but other components, such as cadmium, nitric oxide, hydrogen cyanide, and carbon disulfide, have also been implicated.[65] Female smokers who also use oral contraceptives increase their risk of heart attacks tenfold.[66]

Smoking also increases a person's risk of atherosclerotic peripheral vascular disease, especially if the smoker is diabetic.[67] Complications of this disease include decreased blood delivery to the peripheral tissues, gangrene, and ultimately loss of the affected limb. Smoking cessation is the most important intervention in the management of peripheral vascular disease.[68]

Smoking is a cause of stroke.[69] Stroke is the third leading cause of death in the United States.[70] The association of

smoking with stroke is believed to be mediated by the mechanisms responsible for atherosclerosis (narrowing and hardening of the arteries), thrombosis, and decreased cerebral blood flow in smokers.[71] Female smokers who use oral contraceptives are at an increased risk of having a stroke.[72]

Cigarette smoking is the leading cause of chronic obstructive pulmonary disease (COPD) in the United States. Approximately 84 percent of the COPD deaths in men and 79 percent of the COPD deaths in women are attributable to cigarette smoking.[73] The risk of death from COPD may depend on how many cigarettes a person smokes daily, how deeply the person inhales, and the age when the person began smoking.[74] The number of cigarettes smoked per day is a strong indicator for the presence of the principal symptoms of chronic respiratory illness, including chronic cough, phlegm production, wheezing, and shortness of breath.[75]

Smoking's effects on lung structure and function appear within a few years after cigarette smoking begins.[76] Children who smoke suffer from respiratory illnesses more than children who do not smoke. Adolescents who smoke may experience inflammatory changes in the lung, reduced lung growth, and may not achieve normal lung function as an adult.[77]

Cigarette smoking is a probable cause of peptic ulcer disease.[78] Peptic ulcer disease is more likely to occur in smokers than in nonsmokers, and the disease is less likely to heal, and more likely to cause death in smokers than nonsmokers.[79] Quitting smoking reduces the chances of getting peptic ulcer disease and is an important component of effective peptic ulcer treatment.[80]

Studies also show that women who smoke have reduced fertility.[81] One study showed that smokers were 3.4 times more likely than nonsmokers to take more than 1 year to conceive.[82]

Smoking's severe detrimental effects during pregnancy are well documented.[83] Women who smoke are twice as likely to have low birth weight infants as women who do not smoke.[84] Smoking also causes intrauterine growth retardation of the fetus.[85] Mothers who smoke also have increased rates of premature delivery.[86]

Smoking may lead to premature infant death. Babies of mothers who smoke are more likely to die than babies born to nonsmoking mothers.[87] A recent meta-analysis reported that use of tobacco products by pregnant women results in 19,000 to 141,000 miscarriages per year, and 3,100 to 7,000 infant deaths per year. In addition, the meta-analysis attributed approximately two-thirds of deaths from sudden infant death syndrome to maternal smoking during pregnancy.[88] By another estimate, if all pregnant women stopped smoking, there would be 4,000 fewer infant deaths per year in the United States.[89]

2. Health Effects of Smokeless Tobacco Products

Smokeless tobacco use can cause oral cancer.[90] The risk of oral cancer increases with increased exposure to smokeless tobacco products, particularly in those areas of the mouth where smokeless tobacco products are used.[91] The risk of cheek and gum cancers is nearly 50 times greater in long-term snuff users than in nonusers.[92] Snuff and chewing tobacco contain potent carcinogens, including nitrosamines, polynuclear aromatic hydrocarbons, and radioactive polonium.[93]

Smokeless tobacco use can cause oral leukoplakia, a precancerous lesion of the soft tissue that consists of a white patch or plaque that cannot be scraped off.[94] One study of 117 high school students who were smokeless tobacco users revealed that nearly 50 percent of these students had oral tissue alterations.[95] There is a 5 percent chance that oral leukoplakias will transform into malignancies in 5 years.[96] The leukoplakia appears to decrease or resolve upon cessation of smokeless tobacco use.[97]

Smokeless tobacco use causes oral cancer and oral leukoplakia and may be associated with an increased risk of cancer of the esophagus. Smokeless tobacco use has been implicated in cancers of the gum, mouth, pharynx, and larynx. Snuff use also causes gum recession and is associated with discoloration of teeth and fillings, dental caries, and abrasion of the teeth.[98]

References

1. IOM Report, p. 115; ''Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost—United States, 1990,'' in ''MMWR,'' CDC, DHHS, vol. 42, pp. 645–649, 1993, reprinted in *Chronic Disease and Health Promotion Adapted from MMWR Tobacco Topics 1990–1993*, pp. 77–81; McGinnis, J.M., and W.H. Foege, ''Actual Causes of Death in the United States,'' *Journal of the American Medical Association*, vol. 270, No. 18, pp. 2207–2212, November 10, 1993; Pierce, J.P., et al., ''Trends in Cigarette Smoking in the United States, Projections to the Year 2000,'' *Journal of the American Medical Association*, vol. 261, No. 1, pp. 61–65, 1989.

2. Pierce, J.P., et al., ''Trends in Cigarette Smoking in the United States, Projections to the Year 2000,'' *Journal of the American Medical Association*, vol. 261, No. 1, pp. 65–65, 1989.

3. U.S. Department of Health, Education and Welfare, ''Smoking and Health, Report of the Advisory Committee to the Surgeon General of the Public Health Service,'' HEW, PHS, 1964 (hereinafter cited as ''1964 SGR'').

4. National Center for Health Statistics, Health United States 1993. Hyattsville, MD: DHHS, PHS, DHHS Pub. No. (PHS) 94–1232, 1994.

5. ''Cigarette Smoking Among Adults-United States, 1990,'' in ''MMWR,'' CDC, DHHS, Vol. 41, No. 50, pp. 354–355, 361–362 (1992).

6. *id*.; IOM Report, p. 7.

7. ''Cigarette Smoking Among Adults—United States, 1992, and Changes in the Definition of Current Cigarette Smoking,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 19, p. 342–6, 1994.

8. ''Cigarette Smoking Among Adults—United States, 1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 50, pp. 925–930, 1994.

9. 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, Volume 1—Secondary School Students,'' Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Institute on Drug Abuse, NIH Pub. No. 94–3409, pp. 9, 79, 1994.

10. *Id*., p. 9; The University of Michigan, News and Information Services, July 20, 1995, ''Smoking rates climb among American teen-agers, who find smoking increasingly acceptable and seriously underestimate the risks,'' Table 1.

11. 199 SGR, p. 59.

12. *Id*.; p. 58.

13. The University of Michigan, News and Information Service, July 20, 1995, ''Smoking rates climb among American teen-agers, who find smoking increasingly acceptable and seriously underestimate the risk,'' Table 1.

14. 1994 SGR, pp. 58–62.

15. DiFranza, J.R. and J.B. Tye, ''Who Profits Tobacco Sales to Children?'' *Journal of the American Medical Association*, vol. 263, No. 20, pp. 2784–2787, 1990.

16. *Id*., pp. 2785–2786.

17. Cummings, K.M., T. Pechacek, and D. Shopland, ''The Illegal Sale of Cigarettes to U.S. Minors: Estimates by State,'' *American Journal of Public Health*, vol. 84, No. 2, pp. 300–302, 1994.

18. Coalition on Smoking OR Health, ''State Legislated Actions on Tobacco Issues,'' p. i, 1993. (Federal law requires States to ban the sale or distribution of tobacco products to anyone under the age of 18 by October 1, 1994, in order to receive certain funds (42 U.S.C. 300x–26)).

19. ''Youth Access to Tobacco,'' DHHS, Office of the Inspector General, Publication, No. OEI–02–91–00880, pp. 5–8, December 1992; Kusserow, R.P., ''Youth Access to Cigarettes,'' DHHS, Office of the Inspector General, Publication No. OEI–02–90–02310, pp. 3–5, May 1990.

20. Taioli, E., and E.L. Wynder, ''Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood,'' *The New England Journal of Medicine*, vol. 325, No. 13, pp. 968–969, 1991.

21. Escobedo, L.G., S.E. Marcus, D. Holtzman, and G.A. Giovino, ''Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among U.S. High School Students,'' *Journal of the American Medical Association,* vol. 269, No. 11, pp. 1391–1395, March 17, 1993.

22. ''Spit Tobacco and Youth,'' Office of Inspector General, DHHS, p. 3, December 1992.

23. Connolly, G.N., et al., ''The Reemergence of Smokeless Tobacco,'' *The New England Journal of Medicine,* vol. 314, No. 16, pp. 1020–1027, April 17, 1986.

24. Kann, L., et al., ''Results from the National School-Based 1991 Youth Risk Behavior Survey and Progress Toward Achieving Related Health Objectives for the Nation,'' *Public Health Reports,* vol. 108, (Supp. 1), pp. 47–54, 1993.

25. Division of Adolescent and School Health, unpublished data from the 1992 Youth Risk Behavior Survey'' supplement to the National Health Interview Survey, CDC.

26. 1994 SGR, p. 101.

27. ''Spit Tobacco and Youth,'' Office of Inspector General, p. 3, December 1992 (citing the Youth Risk Behavior Survey).

28. ''Prevalence of Oral Lesions and Smokeless Tobacco Use in Northern Plains Indians,'' in ''MMWR,'' DHHS, CDC, vol. 37, No. 39, pp. 608–611, October 7, 1988; See also Schinke, S.P., and R.F. Schilling, ''Pacific Northwest Native American Youth and Smokeless Tobacco Use,'' *International Journal of the Addictions,* vol. 22, No. 9, pp. 881–884, 1987 (a survey of 144 adolescent Native Americans in Washington State and Alaska showed that 34 percent of adolescent females and approximately 43 percent of adolescent males (mean age: 12.3 years) used smokeless tobacco weekly); Schinke, S.P., et al., ''Smokeless Tobacco Use Among Native American Adolescents'' (letter to the editor), *The England Journal of Medicine,* vol. 314, No. 16, pp. 1051–1052, April 17, 1986 (a survey of 254 Native American adolescents in Washington State (mean age: 13.8 years) showed that 24 percent used smokeless tobacco weekly); Hall, R.L., and D. Dexter, ''Smokeless Tobacco Use and Attitudes Toward Smokeless Tobacco Among Native Americans and Other Adolescents in the Northwest,'' *American Journal of Public Health,* vol. 78, No. 12, pp. 1586–1588, December 1988 (a survey of 1,180 sixth, ninth, and eleventh graders in the State of Washington showed that 34 percent of male Native Americans and 24 percent of female Native Americans were current users of smokeless tobacco products).

29. ''Prevalence of Oral Lesions and Smokeless Tobacco Use in Northern Plains Indians,'' in ''MMWR,'' CDC, DHHS, vol. 37, No. 39, p. 609, October 7, 1988.

30. Hall, R.L. and D. Dexter, ''Smokeless Tobacco Use and Attitudes Toward Smokeless Tobacco Among Native Americans and Other Adolescents in the Northwest,'' *American Journal of Public Health,* vol. 78, No. 12, p. 1587, December 1988.

31. McGinnis, J.M., and W.H. Foege, ''Actual Causes of Death in the United States,'' *Journal of the American Medical Association,* vol. 270, No. 18, pp. 2207–2212, November 10, 1993.

32. Peto, et. al., ''Mortality From Smoking in Developing Countries, 1950–2000. Indirect Estimates from National Vital Statistics,'' Oxford, England: Oxford University Press, p. A10, 1994.

33. Taioli, E. and E.L. Wynder, ''Effect of the Age at Which Smoking Begins on Frequency of Smoking in Adulthood,'' *The New England Journal of Medicine,* vol. 325, No. 13, pp. 968–969, 1991; and Escobedo, L.G., et al. ''Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among U.S. High School Students, *Journal of the American Medical Association,* vol. 269, No. 11, pp. 1391–1395, 1993.

34. 1989 SGR, p. 97.

35. Id., p. 157.

36. Id., p. 97.

37. *Id.,* p. 157.

38. *Id.,* pp. 98–99; 1990 SGR, p. 10.

39. 1989 SGR, pp. 98–99.

40. See generally 1964 Surgeon General's Report.

41. 1989 SGR, pp. 44–48.

42. See 1964 Surgeon General's Report; 1989 SGR, p. 43, *see,* DHHS, ''The Health Benefits of Smoking Cessation. A Report of the Surgeon General 1990,'' DHHS, PHS, CDC, OSH, DHHS Publication No. (CDC) 90–8416, p. 107, 1990 (hereinafter cited as ''1990 SGR'').

43. ''Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost-United States, 1990,'' in *MMWR,* CDC, DHHS, vol. 42, no. 33, pp. 645–649 (1993).

44. 1990 SGR, p. 107.

45. 1994 SGR, p. 29; Escobedo, L.G., et al., ''Sports Participation, Age at Smoking Initiation, and the Risk of Smoking Among U.S. High School Students,'' *The Journal of the American Medical Association,* vol. 269, no. 11, pp. 1391–1395, 1993.

46. 1989 SGR, p. 45.

47. 1989 SGR, p. 56; Blot, W.J., et al., ''Smoking and Drinking in Relation to Oral and Pharyngeal Cancer,'' *Cancer Research,* vol. 48, pp. 3282–3287, 1988; Schottenfeld, D., ''Epidemiology of Cancer of the Esophagus,'' *Seminars in Oncology,* vol. 11, No. 2, pp. 92–100, 1984; Elwood, J.M., et al., ''Alcohol, Smoking, Social and Occupational Factors in the Aetiology of Cancer of the Oral Cavity, Pharynx and Larynx,'' *International Journal of Cancer,* vol. 34, pp. 603–612, 1984.

48. Bartecchi, C.E., T.D. MacKenzie, and R.W. Schrier, ''The Human Cost of Tobacco Use,'' *The New England Journal of Medicine,* vol. 330, No. 13, pp. 907–912, 1994. (p. 909)

49. 1990 SGR, pp. 147, 151.

50. *Id.,* p. 152.

51. 1989 SGR, pp. 56–57; Gordis, L., and E.B. Gold, ''Epidemiology of Pancreatic Cancer,'' *World Journal of Surgery,* vol. 8, pp. 808–821, 1984.

52. 1989 SGR, p. 57.

53. 1990 SGR, p. 155.

54. 1989 SGR, p. 56.

55. *Id.;* McLaughlin, J.K., et al., ''A Population-Based Case-Control Study of Renal Cell Carcinoma,'' *Journal of the National Cancer Institute,* vol. 72, No. 2, pp. 275–284, 1984; Hartge, P., et al., ''Changing Cigarette Habits and Bladder Cancer Risk: A Case-Control Study,'' *Journal of the National Cancer Institute,* vol. 78, No. 6, pp. 1119–1125, 1987.

56. 1989 SGR, p. 58; 1990 SGR, pp. 10, 166

57. 1982 SGR, p. 8.

58. 1989 SGR, p. 57.

59. U.S. Department of Health, Education, and Welfare, ''Smoking and Health Report of the Advisory Committee to the Surgeon General of the Public Health Service,'' HEW, PHS, p. 38, 1964 (hereinafter cited as ''1964 SGR'').

60. Bartecchi, C.E., T.D. MacKenzie, and R.W. Schrier, ''The Human Cost of Tobacco Use,'' *The New England Journal of Medicine,* vol. 330, No. 13, pp. 907–912, March 31, 1994, citing ''Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost-United States, 1990,'' in *MMWR,* CDC, DHHS, vol 42, no. 33 (1993).

61. 1990 SGR, p. 198.

62. Bartecchi, C.E., T.D. MacKenzie, and R.W. Schrier, ''The Human Cost of Tobacco Use,'' *The New England Journal of Medicine,* vol. 330, No. 13, pp. 907–912, March 31, 1994, citing ''Cigarette Smoking-Attributable Mortality and Years of Potential Life Lost-United States, 1990,'' in *MMWR,* CDC, DHHS, vol 42, no. 33 (1993).

63. Fielding, J.E., ''Smoking: Health Effects and Control,'' in ''Public Health and Preventive Medicine,'' Appleton & Lange, p. 716, 1992.

64. 1983 SGR, p. 76.

65. 1990 SGR, p. 191.

66. 1989 SGR, p. 197.

67. *Id.,* p. 63; 1990 SGR, p. 243; Hughson, W.G., J.I. Mann, and A. Garrod, ''Intermittent Claudication: Prevalence and Risk Factors,'' *British Medical Journal,* vol. 1, pp. 1379–1381, 1978.

68. 1990 SGR, pp. 243–244; 1989 SGR, p. 63.

69. 1989 SGR, pp. 61–63. Wolf, P.A., et al., ''Cigarette Smoking as a Risk Factor for Stroke, The Framingham Study,'' *Journal of the American Medical Association,* vol. 259, No. 7, pp. 1025–1029, February 19, 1988; Abbott, R.D., et al., ''Risk of Stroke in Male Cigarette Smokers,'' *The New England Journal of Medicine,* vol. 315, No. 12, pp. 717–720, September 18, 1986; Colditz, G.A., et al., ''Cigarette Smoking and Risk of Stroke in Middle-Aged Women,'' *The New England Journal of Medicine,* vol. 318, No. 15, pp. 937–941, April 14, 1988.

70. 1989 SGR, p. 61.

71. 1989 SGR, pp. 61–63.

72. ''Labeling Guidance Text for Combination Oral Contraceptives Prescribing Information (PI) Physician Labeling,'' FDA, CDER, p. 7, August 1994.

73. 1989 SGR, p. 156; Fielding, J.E., ''Smoking: Health Effects and Control,'' in ''Public Health and Preventive Medicine,'' Appleton and Lange, p. 723, 1992.

74. Lebowitz, M.D. and B. Burrows, ''Quantitative Relationships Between Cigarette Smoking and Chronic Productive Cough,'' *International Journal of Epidemiology,* vol. 6, No. 2, pp. 107–113, 1977; Dean, G. et al., ''Factors related to respiratory and cardiovascular symptoms in the United Kingdom,'' *Journal of Epidemiology and Community Health,* vol. 32, no. 2, pp. 86–96, 1978; Higgins, M.W., J.B. Keller, and H.L. Metzner, ''Smoking, Socioeconomic Status, and Chronic Respiratory Disease,'' *American Review of*

Respiratory Disease, vol. 116, pp. 403–409, 1977; Higenbottam, T., et al., ''Lung Function and Symptoms of Cigarette Smokers Related to Tar Yield and Number of Cigarettes Smoked,'' *The Lancet,* pp. 409–412, February 23, 1980; Schenker, M.B., J.M. Samet, and F.E. Speizer, ''Effect of Cigarette Tar Content and Smoking Habits on Respiratory Symptoms in Women,'' *American Review of Respiratory Disease,* vol. 125, No. 6, pp. 684–690, June 1982.

75. 1994 SGR, p. 16.

76. *Id.,* p. 16–17; Bates, D.V., ''Effects of Smoking and Environmental Pollutants,'' in ''Respiratory Function in Disease,'' pp. 152–155, W.B. Saunders Company, 1989. Holland, W.W. and A. Elliott, ''Cigarette Smoking, Respiratory Symptoms, and Anti-Smoking Propaganda,'' *The Lancet,* pp. 41–43, January 6, 1968; Seely, J.E., E. Zuskin, and A. Bouhuys, ''Cigarette Smoking: Objective Evidence for Lung Damage in Teen-Agers,'' *Science,* vol. 172, pp. 741–743, May 14, 1971; Rush, D., ''Respiratory Symptoms in a Group of American Secondary School Students: The Overwhelming Association with Cigarette Smoking,'' *International Journal of Epidemiology,* vol. 3, No. 2, pp. 153–165, 1974; Bewley, B.R., T. Halil, and A.H. Snaith, ''Smoking by Primary Schoolchildren Prevalence and Associated Respiratory Symptoms,'' *Brit. J. prev. Soc. Med.,* vol. 27, pp. 150–153, 1973; Bewley, B.R., and J.M. Bland, ''Smoking and Respiratory Symptoms in Two Groups of Schoolchildren,'' *Preventive Medicine,* vol. 5, pp. 63–69, 1976.

77. 1994 SGR, p. 29; Tager, I.B., et al., ''The Natural History of Forced Expiratory Volumes: Effect of Cigarette Smoking and Respiratory Symptoms,'' *American Review of Respiratory Disease,* vol. 138, No. 4, pp. 837–849, October 1988; Tager, I.B., et al., ''Effect of Cigarette Smoking on the Pulmonary Function of Children and Adolescents,'' *American Review of Respiratory Disease, vol. 131, No. 5, pp. 752–759, May 1985.*

78. 1989 SGR, p. 76; Lane, M.R., and S.P. Lee, ''Recurrence of Duodenal Ulcer After Medical Treatment,'' *The Lancet,* pp. 1147–1149, May 21, 1988; Korman, M.G., et al., ''Influence of Cigarette Smoking on Healing and Relapse in Duodenal Ulcer Disease,'' *Gastroenterology,* vol. 85, No. 4, 871–874, 1983.

79. 1989 SGR, p. 76; Sontag, S., et al., ''Cimetidine, Cigarette Smoking, and Recurrence of Duodenal Ulcer,'' *The New England Journal of Medicine,* vol. 311, No. 11, pp. 689–693, September 13, 1984.

80. *Id.*

81. Baird, D.C. and A.J. Wilcox, ''Cigarette Smoking Associated With Delayed Conception,'' *Journal of the American Medical Association,* vol. 253, No. 20, pp. 2979–2983, May 24/31, 1985.

82. *Id.*

83. See generally, Surgeon General's Reports for the followings years: DHHS, ''The Health Consequences of Smoking for Women, A Report of the Surgeon General,'' DHHS, CDC, pp. v, vii, viii, 192, 1980 (hereinafter cited as ''1980 SGR''); 1989 SGR, pp. 100, 197; 1990 SGR, pp. i, viii, 11, 12, 371, 372, 373, 378, 381, 382, 387, 389, 410; Schramm, W., ''Smoking and Pregnancy Outcome,'' *Missouri Medicine,* vol. 77, No. 10, pp. 619–629, October 1980.

84. 1980 SGR, p. 192; Fielding, J.E., ''Smoking: Health Effects and Control,'' in ''Public Health and Preventive Medicine,'' Appleton and Lange, p. 725, 1992.

85. 1989 SGR, p. 72; Ounsted, M., V.A. Moar, and A. Scott, ''Risk Factors Associated With Small-for-Dates and Large-for-Dates Infants,'' *British Journal of Obstetrics and Gynecology,* vol. 92, No. 1, pp. 226–232, March 1985; Shiono, P.H., M.A. Klebanoff, and GG. Rhoads, ''Smoking and Drinking During Pregnancey—Their Effects on Preterm Birth,'' *Journal of the American Medical Association,* vol. 225, No. 1, pp. 82–84, 1986.

86. 1990 SGR, p. 386; Andrews, J., and J.M. McGarry, ''A Community Study of Smoking in Pregnancy,'' *The Journal of Obstetrics and Gynecology of the British Commonwealth,* vol. 79, No. 12, pp. 1057–1073, December 1972; Alameda County Low Birth Weight Study Group, ''Cigarette Smoking and the Risk of Low Birth Weight: A Comparison in Black and White Women,'' *Epidemiology,* vol. 1, No. 3, pp. 201–205, May 1990; van den Berg, B.J. and F.W. Oechsli, ''Prematurity,'' in ''Perinatal Epidemiology,'' Oxford University Press, p. 77, 1984; Meyer, M.B. B.S. Jonas, and J.A. Tonascia, ''Perinatal Events Associated with Maternal Smoking During Pregnancy,'' *The American Journal of Epidemiology,* vol. 103, No. 5, pp. 454–476, 1976.

87. 1989 SGR, p. 73.

88 DiFranza, J.R., and R.A. Lew, ''Effect of Maternal Cigarette Smoking on Pregnancy Complications and Sudden Infant Death Syndrome,'' *Journal of Family Practice,* vol. 40, No. 4, pp. 1–10, April 1995.

89. 1989 SGR. p. 73.

90. 1994 SGR, p. 39; 1986 SGR, pp. 33–47.

91. 1986 SGR, p. 44.

92. 1986 SGR, p. 40; Winn, D.M., et al., ''Snuff Dipping and Oral Cancer Among Women in the Southern United States,'' *The New England Journal of Medicine,* vol. 304, No. 13, pp. 745–749, March 26, 1981.

93. 1986 SGR, pp. 58–69.

94. 1994 SGR, p. 39; WHO Collaborating Centre for Oral Precancerous Lesions, ''Definition of Leukoplakia and Related Lesions: An Aid to Studies on Oral Precancer,'' *Oral Surgery, Oral Medicine Oral Pathology,* vol. 46, No. 4, pp. 518–539, October 1978.

95. Greer, R.O., and T.C. Poulson, ''Oral Tissue Alterations Associated With the Use of Smokeless Tobacco by Teen-Agers,'' *Oral Surgery, Oral Medicine, Oral Pathology,* vol. 56, No. 3, pp. 275–284, September 1983.

96. 1994 SGR. p. 39.

97. *Id.*

98. *Id.,* pp. 39–40; see generally 1986 SGR.

III. Description of the Proposed Rule

The proposed rule would create a new part 897 of Title 21 of the Code of Federal Regulations governing the labeling, advertising, sale, and distribution of cigarettes and smokeless tobacco. The Commissioner has proposed that nicotine-containing cigarettes and smokeless tobacco products be regulated as restricted devices within the meaning of section 520(e) of the act (21 U.S.C. 360j(e)). The regulations are being proposed pursuant to the authority of section 520(e) of the act, which authorizes the agency to regulate the sale, distribution, and use of certain devices. Certain of the provisions in the regulation are also being proposed pursuant to the authority of sections 201, 502, 510, 701, and 704 of the act.

In brief, the proposed rule is intended to support current State laws regarding sales to minors by reducing the appeal of cigarettes and smokeless tobacco to, and limiting access by, persons under 18 years of age. The overall goal of the proposed rule is to decrease the rates of death and disease caused by tobacco products by substantially reducing the number of young people who begin using cigarettes or smokeless tobacco products.

The proposed rule consists of five subparts. Subpart A, General Provisions, would set forth scope and purpose provisions and provide definitions. Subpart B, Sale and Distribution to Persons Under 18 Years of Age, would describe the responsibilities of manufacturers, distributors, and retailers concerning the manufacture, sale, and distribution of cigarettes and smokeless tobacco products. Subpart C, Labels and Educational Messages, would require each manufacturer to establish and maintain a national public educational program, including major reliance on television messages, in order to combat the pervasive imagery and appeal created by decades of pro-tobacco messages, and, thus, to discourage young people from using cigarettes and smokeless tobacco products. Subpart D, Labeling and Advertising, would limit advertising and labeling to which children and adolescents are exposed to a text-only format; ban the sale or distribution of branded non-tobacco items such as hats and tee shirts; and restrict sponsorship of events to the corporate name only. Finally Subpart E, Miscellaneous Requirements, would describe the records and reports that must be submitted to FDA or made available for inspection, discuss the rule's relationship to State and local laws or requirements, and require one or more additional measures to be taken if the prevalence of tobacco use is not significantly reduced within seven years of the publication of the final rule.

A. Subpart A—General Provisions

Subpart A would contain three provisions that describe the rule's scope and purpose and provide definitions that apply throughout part 897.

1. Section 897.1—Scope

Proposed § 897.1(a) would state that part 897 is intended to establish conditions under which nicotine-containing cigarettes and smokeless tobacco products may be sold, distributed, or used. The proposed rule would not apply to pipe tobacco or to cigars because the agency does not currently have sufficient evidence that these products are drug delivery devices under the act. FDA has focused its investigation of its authority over tobacco products on cigarettes and smokeless tobacco products, and not on pipe tobacco or cigars, because young people predominantly use cigarettes and smokeless tobacco products. Proposed § 897.1(b) would note that all references to regulatory sections in the Code of Federal Regulations are to Title 21 unless otherwise noted.

2. Section 897.2—Purpose

Proposed 897.2(a) would state that part 897 is intended to help prevent persons younger than 18 years of age from becoming addicted to nicotine, thereby avoiding the life-threatening consequences often associated with tobacco use. The proposed rule would accomplish this goal by reducing the appeal of and access to cigarettes and smokeless tobacco products by persons under 18 years of age; it would preserve access to cigarettes and smokeless tobacco products by persons 18 years of age and older. Proposed § 897.2(b) would add that the provisions are intended to provide important information about product use to users and potential users.

3. Section 897.3—Definitions

Proposed 897.3 would establish definitions of terms used in the proposed rule, such as ''cigarette'' (897.3(a)) and ''distributor'' (897.3(c)). In drafting the definitions, FDA examined existing definitions in Federal laws and regulations and paid special attention to existing definitions in other FDA regulations. These definitions are contained in the proposed codified language.

Proposed 897.3(e) contains the definition of ''nicotine,''which is based, in part, on the chemical name and formula for nicotine in the ''Merck Index''(10th Edition). The agency also notes that, while the proposed rule defines ''cigarette,'' in part, as a product that ''contains or delivers nicotine,'' it is aware that some companies are trying to develop chemical substances that are pharmacologically active or are as addictive as nicotine or that would be used to enhance nicotine's pharmacological qualities. The agency's investigation has focused primarily on cigarettes and smokeless tobacco products that contain nicotine, and FDA would therefore consider a cigarette-like product that contains a pharmacologically active or addictive substance in place of nicotine to be a ''new'' drug delivery device that would be outside the scope of this regulation. To be legally marketed, such a product would require premarket approval.

B. Subpart B—Sale and Distribution to Persons Under 18 Years of Age

Subpart B would establish certain conditions or requirements for the sale and distribution of cigarettes and smokeless tobacco pursuant to section 520(e) of the act. These provisions are intended to reduce access to cigarettes and smokeless tobacco products by children and adolescents. Studies show that it is easy for most young people to obtain tobacco products. The University of Michigan Monitoring the Future Study in 1993 reported that 75 percent of 8th graders and nearly 90 percent of 10th graders said it would be fairly easy or very easy to get cigarettes.[1] According to a 1990 survey of 9th graders, 67 percent of current smokers said they usually buy their own cigarettes.[2] Further, interviews conducted by the Department of Health and Human Services' (DHHS) Office of the Inspector General in 1986 found that 94 percent of junior and high school students said that ''it was either never or only rarely difficult'' to buy smokeless tobacco products.[3]

Most children and adolescents who smoke purchase their own cigarettes. A 1991 study showed that an estimated 516 million packs are consumed by young people every year; almost half of these packs are sold to minors.[4] The 1994 Surgeon General's Report examined 13 studies of over-the-counter sales and determined that approximately 67 percent of minors are able to purchase tobacco illegally. Moreover, successful cigarette purchases by children and adolescents averaged 88 percent in studies of vending machines.[5]

A significant percentage of young people can also easily purchase smokeless tobacco products directly from retailers. Studies examining smokeless tobacco product purchases by young people suggest that direct successful underage purchases range from 30 percent (for junior high school students) to 62 percent (for senior high school students).[6] Interviews conducted by the DHHS' Office of the Inspector General in 1986 found that 90 percent of smokeless tobacco users in junior and senior high schools said they purchased their own smokeless tobacco products.[7]

Youth access restrictions have been found to be effective in reducing illegal sales and some studies have demonstrated that efforts to reduce access have led to a decrease in tobacco use by young people. In Woodridge, IL, for example, a comprehensive community intervention involving retailer licensing, regular compliance checks, and penalties for merchant violations significantly reduced illegal sales from 70 percent to less than 5 percent almost 2 years later. Further, rates of experimentation and regular smoking dropped by more than 50 percent among seventh and eighth graders.[8]

In contrast, attempts to reduce sales to young people by relying exclusively on educational programs for retailers were not nearly as effective. For example, one study found that minors were able to buy cigarettes in 73 percent of stores receiving informational packages on preventing illegal sales to minors.[9] After a comprehensive retailer education program was conducted, illegal sales to minors decreased to 68 percent of stores. However, after citations were issued to violative establishments, over-the-counter illegal sales dropped to 31 percent.[10]

The proposed rule would prohibit the sale and distribution of cigarettes and smokeless tobacco products to individuals younger than 18. This restriction parallels the age restrictions established by almost all States. Moreover, it is based on the fact that most people who become regular smokers do so at a young age. For instance, the IOM reported that the average age when people become ''daily'' smokers is 17.7 years.[11] According to the National Household Surveys on Drug Abuse (1991), 53 percent of people who ever smoked became regular smokers by the time they were 18 years old.[12] Further, 82 percent of those who had ever smoked daily first tried a cigarette before the age of 18.[13]

Available data documenting the course of a young person's ability to quit smoking after initiating smoking support the need for an age restriction. A study tracking students from grades 6 to 12 in six Minnesota communities noted a ''striking pattern'' that:

> * * * once students become weekly smokers, they are unlikely to give up cigarettes. Of the students who were current smokers, an increasing percentage remained smokers over the years of follow-up; they were either unable or unwilling to quit smoking. Of the self-reported quitters, 13% to

46% returned to weekly smoking by the next year's measurement period.[14]

The study found that ''students who smoke are increasingly unlikely to quit as they get older.'' [15]

Effectively prohibiting sales to people younger than 18 years of age will therefore help reduce the number of adolescents and youths who become daily smokers. FDA also selected the age limit of 18 to be consistent with the 1992 Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) Reorganization Act [16] that conditions receipt of substance abuse grants on States adopting laws prohibiting the sale and distribution of cigarette and smokeless tobacco products to minors under age 18, and because the majority of States have set 18 as the age of purchase of these products.

1. Section 897.10—General Responsibilities of Manufacturers, Distributors, and Retailers

Proposed 897.10 would describe the general responsibilities of manufacturers, distributors, and retailers, and would make manufacturers, distributors, and retailers responsible for ensuring that the cigarettes and smokeless tobacco products they manufacture, label, advertise, package, sell, distribute, or otherwise hold for sale comply with all the applicable regulations under proposed Part 897.

2. Section 897.12—Additional Responsibilities of Manufacturers

Proposed 897.12 would provide that, in addition to its other responsibilities, each manufacturer would be responsible for removing all self-service displays, violative advertising, labeling, and other manufacturer- or distributor-supplied items from each point of sale. Proposed § 897.12(b) would require each manufacturer to monitor, through visual inspection on each visit to a point of sale (carried out in the normal course of the manufacturer's business), to assure the proper labeling, advertising, and distribution of its products. This provision would not create a new responsibility or burden for companies (typically the smaller ones) who do not visit retail locations as part of their usual business practice. The obligation to inspect exists only for those companies (typically the larger ones) for whom visits are part of their usual business practice.

Further, because there are detailed contracts between the larger cigarette manufacturers and retailers, proposed 897.12 should not impose a significant burden on these manufacturers. For example, a Non-Self-Service Carton Shelf Plan for the R.J. Reynolds Tobacco Co. specified that '' [t]he height of the top shelf cannot exceed 72 inches and must have a height capacity of seven cartons * * *'' and that the cigarette display or shelves ''* * * must be in total view of the consumer * * *'' and ''* * * may not be placed more than 10 feet from point-of-purchase.'' [17] Another plan, titled ''R.J. Reynolds Tobacco USA Savings Center Display Plan,'' created six different pay scales for retailers; the retailers would receive more money if they sold a large volume of cigarettes. Under this plan, R.J. Reynolds would also provide a ''merchandiser'' to display its products, and the retailer would agree to stock the ''designated RJR shelf rows'' ''no less than five cartons high,'' and not alter the shelves or reduce the amount allocated to R.J. Reynolds products.[18] In both plans, the retailer also agreed to permit R.J. Reynolds representatives to ''plan-o-gram, adjust, and divide its allocated space as deemed necessary'' and to ''make reasonable audits of performance and to inspect and rotate R.J.R's products in stores under contract.'' [19]

Former sales representatives and managers interviewed by FDA stated that manufacturers keep extremely detailed records about each retailer. Some records noted whether the retailer should be visited weekly, biweekly, monthly, etc.; other entries included the types of displays in the retailer's establishment. At least one company also gave portable computers to its representatives; the data entered into these computers were downloaded nightly and sent to company headquarters. These detailed contracts and records demonstrate that the manufacturers are heavily involved in establishing and maintaining retailers' displays and that the proposed rule's requirements that each manufacturer be responsible for removing violative advertising, labeling, and self-service displays, and for performing a visual inspection on each subsequent business call are both feasible and reasonable.

3. Section 897.14—Additional Responsibilities of Retailers

Proposed 897.14 would establish additional responsibilities for retailers. Proposed 897.14(a) would require the retailer or the retailer's employees to verify that people who intend to purchase cigarettes or smokeless tobacco products are legally entitled to do so. Verification would be by direct visual inspection of each prospective purchaser and, if necessary, would include the use of a photographic identification card with a birth date. Examples of documents that would be acceptable are a driver's license or a college identification card. The proposal would require an identification card with a picture and a birth date because such identification cards are more reliable than other forms of identification. FDA invites comment on whether the final rule should contain more specific requirements concerning the types of identification that would comply with this provision.

The agency has found strong support for the additional retailer responsibilities that this section would impose. According to a recent report endorsed by 26 State attorneys general, industry training films and programs used by retailers regarding tobacco sales had little or no impact on preventing illegal sales to minors and, in some retail sectors, high employee turnover rates complicated training efforts. Moreover, determining a young customer's age through visual examination alone proved to be difficult. Thus, the attorneys general recommended requiring proof of age of anyone who does not appear to be at least 26 years old.[20]

Additionally, studies indicate that minors who are able to purchase cigarettes and other tobacco products from stores are rarely asked to verify their age. For example, in one study, 67 percent of minors (mean age: 15 years) were asked no questions when they attempted to purchase cigarettes.[21] Store cashiers tried discouraging the minors from buying cigarettes in only 7 percent of the spot checks conducted by the authors. In 14 percent of the cases, the cashiers actually ''encouraged the minor's purchase by offering matches, suggesting a cheaper brand, or offering to make up the difference if the minor was 'short on cash'.'' [22]

In another report, five minors between the ages of 13 and 16 were sent to various locations to buy cigarettes. Despite signs at some locations that prohibited entry by persons under the age of 21, the minors were able to buy cigarettes, even when they admitted they were under 21. For smokeless tobacco products, studies show that half of the stores examined were willing to sell smokeless tobacco products to minors.[23] In contrast, in Everett, WA, where a local ordinance required proof of age if the prospective buyer did not appear to be of legal age to purchase cigarettes, over 60 percent of students between the ages of 14 and 17 reported being asked for proof of age when they attempted to buy cigarettes, and tobacco use, among 14 to 17-year-olds, declined from 25.3 percent to 19.7 percent overall.[24]

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

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

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

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

a. *Restrictions on product names.* Proposed 897.16(a) would prohibit prospectively the use of a trade or brand name for a non-tobacco product as the trade or brand name for a cigarette or smokeless tobacco product. The agency is aware of three brands of cigarettes that have used this strategy: Harley-Davidson, Cartier, and Yves St. Laurent's Ritz cigarettes. In the final rule, the agency intends to exempt those brands that already use the trade or brand name of a non-tobacco product.

This provision would complement the requirements in proposed subpart D (regarding labeling and advertising) that would reduce the appeal of cigarettes and smokeless tobacco products to people younger than 18. FDA believes that this provision is necessary to prevent manufacturers from circumventing the purpose of this proposed rule. As discussed elsewhere, the imagery associated with tobacco products is an important factor in why young people smoke. This provision would prevent tobacco manufacturers from capitalizing on the imagery of other consumer products by using the brand name of those products for tobacco products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the mail-order card to verify, for example, that he/she is 21. The agency concludes that proposed § 897.16(c) would significantly reduce access to cigarettes and smokeless tobacco products by persons younger than 18. The ban of mail-order sales is recommended by the IOM [67] and Philip Morris recently announced that it would discontinue mail-order sales in order to reduce access to young people.[68]

d. *Free samples.* Proposed § 897.16(d) would prohibit manufacturers, distributors, and retailers from distributing free samples of tobacco products. The agency is proposing this restriction because many young people, including elementary school children, receive free samples.[69] Free samples are often distributed at ''mass intercept locations'' such as street corners and shopping malls, and events such as music festivals, rock concerts, and baseball games. They have been distributed at zoos, at bars and restaurants where entertainers perform and promote the product, and through the mail.[70] Free samples give young people a ''risk-free and cost-free way to satisfy their curiosity'' about tobacco products and, when distributed at cultural or social events, may increase social pressure on young people to accept and use the free samples.[71]

For smokeless tobacco products, distribution of free samples to young people has been a foundation of the growth strategy of the UST (makers of Skoal, Copenhagen, Happy Days, and other smokeless tobacco products).[72] In 1992 and 1993, the smokeless tobacco industry spent nearly $16 million annually on the distribution of free samples. The industry's largest expenditure in 1993 was on coupons and retail value-added articles to encourage trial use ($32 million).[73]

Despite industry-imposed age restrictions on the distribution of samples, underage persons are able to obtain samples either by lying about their age or by enlisting older friends and relatives to obtain samples for them.[74] The lure of free samples can also be quite attractive; one advertising campaign offering a sample pack of Skoal Bandits reportedly generated 400,000 responses in a 3-month period.[75]

Even elementary school children are able to obtain free cigarette samples easily. One survey examined five schools in Chicago and a sample of students at DePaul University. Four percent of the elementary school students reported receiving free samples of cigarettes themselves. Nearly half of the elementary and high school students and one-quarter of the college students ''* * * reported having seen free cigarettes given to children and adolescents.'' [76] In another survey, one-third of approximately 500 New Jersey high school students who were current or former smokers reported receiving free cigarette samples before the age of 16.[77]

The distribution of free samples to minors occurs despite the industry's voluntary code against distributing cigarettes to persons under the age of 21. The recent IOM report noted several problems with the industry's voluntary code, stating that ''distribution to minors appears to be nearly inevitable.'' [78] While the voluntary code instructs employees distributing samples to ask for identification and ask other questions if they suspect a potential recipient to be under age, distribution of samples to minors occurs anyway because the samplers are often placed in crowded places and constrained by time:

> There is a significant time constraint in asking for proof of age from all young-looking individuals who solicit samples, not to mention the time required for the myriad of other questions which samplers are instructed to ask. Samplers are often surrounded on all sides by those soliciting samples and a dozen or more outstretched arms waiting (or grabbing) for samples * * * those passing out samples are usually quite young themselves. These youthful distributors may lack the psychological wherewithal to request proof of age and refuse solicitations from those in their own peer group.[79]

Consequently, the ineffectiveness of the industry's voluntary code and the fact that State laws that ban or restrict the distribution of free samples are rarely enforced led IOM to recommend prohibiting distribution of free samples in public places and through the mail.[80] The National Cancer Institute reached a similar conclusion in 1991, and stated, ''The offer of free cigarettes and smokeless tobacco products is reminiscent of the drug pusher who gives the first sample free to get his customer hooked.'' [81] The proposed rule is consistent with IOM's and NCI's recommendations.

C. Subpart C—Labels and Educational Programs

Proposed subpart C would provide the established name for cigarettes and smokeless tobacco products that is required by sections 502 of the act. In addition, it would require that cigarette and smokeless tobacco manufacturers fund a national program including educational messages in order to undo the effects of young people's near constant exposure to pro-tobacco messages and, thus, to discourage young people from using cigarettes and smokeless tobacco products, pursuant to sections 201, 502, and 520(e) of the act.

1. Section 897.24—Established Names for Cigarettes and Smokeless Tobacco Products

Proposed § 897.24 would provide the ''established name'' for cigarettes, cigarette tobacco, and smokeless tobacco products. This provision is intended to implement section 502(e)(2) of the act, which states that a device shall be deemed misbranded if its label fails to display the established name for the device ''in type at least half as large as that used thereon for any proprietary name or designation for such device.'' Section 502(e)(4) of the act, in turn, explains that the ''established name'' for a device is the applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), the official title in a compendium if the device is recognized in an official compendium but has no official name, or ''any common or usual name of such device.''

In this case, no official names have been designated under section 508 of the act, and no compendium provides an established name for these products. Consequently, proposed § 897.24 would consider ''cigarettes,'' ''cigarette tobacco,'' and the common or usual names for smokeless tobacco products (such as ''moist snuff'' or ''loose leaf chewing tobacco'') as established names.

2. Section 897.29–Educational Programs Concerning Cigarettes and Smokeless Tobacco Products

The Surgeon General's 1994 Report suggested that ''a nationwide, well-funded antismoking campaign could effectively counter the effects of cigarette advertising in its currently permitted media forms.'' [82] IOM also recommended that ''counter-tobacco advertisements should be intensified to reverse the image appeal of pro-tobacco messages, especially those that appeal to children and youths.'' [83]

FDA's proposal is consistent with the Surgeon General's and IOM's findings. Proposed 897.29 would require each manufacturer to establish and maintain a national public educational program, including major reliance on television messages, to combat the effects of the pervasive and positive imagery that has for decades helped to foster a youth market for tobacco products.

FDA based proposed 897.29, in part, on historical experience. From July 1, 1967 to December 31, 1970, the Federal Communications Commission, as part of

the ''Fairness Doctrine,'' required broadcasters to provide a significant amount of time for antismoking messages on television and radio. Thus, one antismoking message appeared for every three or four industry-sponsored, prosmoking advertisements. This amounted to approximately $75 million (in 1970 dollars) in commercial air time for antismoking messages annually, until a ban on prosmoking advertisements on television and radio became effective on January 1, 1971. Thus, for several years, the American public was exposed to both pro- and antismoking messages.

During this time, per capita cigarette consumption declined 7 percent, from 4,280 in 1967 to 3,985 in 1970. Most of the 7 percent decline (6.2 percent) was attributable to the anti-smoking messages.[84] This was the first time since the early 1930's that per capita consumption declined consecutively for 3 years and was one of the largest declines ever recorded. Additionally, a study of nearly 7,000 adolescents found that adolescent smoking rates declined during this period.[85] The greatest decline occurred in the first year that the antismoking messages appeared. A 1972 econometric analysis confirmed that the antismoking messages had up to a 5.6 times greater effect on cigarette consumption than promotional cigarette advertising.[86] When the antismoking messages ended on television and radio (due to the Federally-mandated ban on advertising on television and radio, thereby ending the application of the Fairness Doctrine), per capita cigarette consumption began to rise.

A similar experience occurred in Greece during the late 1970's.[87] In an effort to reduce cigarette consumption, the Greek government launched an antismoking campaign and, in 1978, banned cigarette advertising on television and radio. In 1979, the Greek Government intensified its antismoking effort by adding television and radio counter-advertising as well as a community-based print education campaign. This enhanced campaign lasted 2 years but was discontinued following a change in government, with the ban on television and radio advertising remaining. Evaluation of this experience revealed that, during the counter-advertising phase, the annual increase in per capita tobacco consumption dropped to zero, compared to the pre-campaign advertising ban rate of 6 percent increase in consumption. When the campaign ended, the annual rate of increase in tobacco consumption quickly increased to earlier levels. This experience suggests that intensive health education and counter-advertising campaigns can be effective.

There have been numerous research and demonstration projects evaluating the effectiveness of counter-advertising and mass-media smoking cessation programs.[88] As the research designs have evolved, more has been learned about which types of programs are effective and under what conditions. Most recently, well-evaluated studies of programs in Vermont, California, and elsewhere suggest that mass-media and counter-advertising campaigns can have a sustained effect on both preventing teens from starting to smoke and in helping smokers quit.

In Vermont, researchers tested the effect of mass-media and school health education programs.[89] Students exposed to both school and media interventions were 35 percent less likely to have smoked in the past week than students exposed only to the school program, and this preventive effect persisted for at least 2 years following the completion of the intervention program. The decrease occurred even in students who were considered to be at slightly higher risk of becoming smokers because of demographic considerations (lower family income).

There have been similar results in helping smokers interested in quitting. In California, the Department of Health Services has been conducting a $26 million multi-year media campaign to prevent teens from starting to smoke and help adult smokers quit. In a preliminary study of the campaign's effectiveness, researchers found that the state media campaign ''had a negative impact on cigarette consumption, while industry advertising had a positive impact on cigarette consumption.'' The authors concluded that ''[t]his suggests, as one would expect, that increasing state media expenditures and decreasing industry advertising are both effective ways to deter smoking.'' [90] According to a recent evaluation, the media campaign's advertisements directly influenced 7 percent (33,000) of Californians who quit smoking in 1990 to 1991, and contributed to the quitting of another 173,000.[91] The California media program has also resulted in high levels of awareness among young people,[92] and may have contributed to stopping the rise in teen smoking that had been occurring in California prior to the campaign.[93]

FDA has proposed general criteria in the codified language. The following describes one set of requirements for such a program that the agency is considering requiring in a final rule. FDA is soliciting comments on whether the described program would accomplish the goal of creating an effective national program that would correct and combat the effects of the pervasive positive imagery in advertising and, thus, help reduce young people's use of tobacco products or whether additional or different requirements would be preferable. The program would be national in scope and could require that the companies purchase certain times and places on television programming (referred to in the industry as a ''buy''). For example, a television buy could: (1) Devote at least 80 percent of its resources to television messages, both on network and on cable television, during prime time hours (between the hours of 8 p.m. and 11 p.m.), early fringe time (between the hours of 4 p.m. and 6 p.m.), and access time (time that is allocated to local broadcasting stations); (2) be directed to persons between the ages of 12 and 17 years; and (3) be national in scope. Moreover, the buy could include advertising time in at least 50 percent of television programs rated by a national rating service as being in the top 20 for persons between the ages of 12 and 17 and corresponding to the demographic profile of underage tobacco users by gender, racial, and ethnic characteristics, and the remaining percentage in programs with either high concentration or high coverage to young people. The buy could ensure that the manufacturer reach an average of 70 to 90 percent of all persons between the ages of 12 and 17 years five to seven times per 4-week period. (The 4-week period is often referred to as a ''flight.'') Such requirements would help to ensure that the educational messages reach large numbers of young people and are consistent with the way in which advertising is typically purchased. In addition, to ensure that the messages change over time and remain novel and of interest to young people, each message could be limited in use so that each message would be presented no more than 15 times per quarter to the top two-fifths (referred to as top two quintiles) of television viewers between the ages of 12 and 17 and who watch the most television.

The industry members could select from a variety of messages maintained by FDA. FDA could collect and maintain a file of messages developed by states with active tobacco control programs (such as California and Massachusetts), from voluntary health organizations (as was done by broadcasters during the Fairness Doctrine period), and from other appropriate sources, including messages developed and submitted by the tobacco

companies. FDA could determine which messages would be appropriate in consultation with other entities and offices within the Department of Health and Human Services, such as CDC's Office on Smoking and Health; with other federal agencies with expertise in consumer behavior and marketing, such as the Federal Trade Commission; and with consultants and contractors who are expert in communications theory and practice. FDA, in consultation with other federal agencies and other experts, could review the messages to ensure that their language and imagery are effective with 12- to 17-year olds. Each message would be evaluated to determine if it were designed to influence those beliefs and attitudes of 12- to 17- year olds that are most likely to affect the initial decision to smoke (or to start using smokeless tobacco products), the decision to continue smoking (or continue to use smokeless tobacco products), and/or the decision to quit. Examples of appropriate messages include those addressing addiction, weight control, effective ways to refuse a cigarette and other social influences that are related to youth smoking.

Moreover, an appropriate educational program could require each manufacturer to submit, on a quarterly basis, analyses of every television buy by time period on network television (referred to as ''day part''), cable, and other media, prepared and executed by the party or parties responsible for the advertising. This requirement could fulfill the manufacturer's responsibility to report on the effectiveness of the program.

In addition, each manufacturer could conduct tracking studies of persons between the ages of 12 and 17. This would enable the manufacturers to determine how effective their educational programs and buys were. The studies could be performed twice per year and would need to meet recognized industry standards for tracking studies, such as measuring recall and recognition of the televised messages. These studies could be given to FDA, which could review the results of the industry's testing in consultation with other experts as needed, in order to help the agency refine its selection criteria for messages.

Finally, the remaining 20 percent of the messages could be placed in other media, with emphasis on radio and outdoor advertising. Consideration should be given to ensuring that these messages appear in media that are heavily used by young people.

Under proposed § 897.29, each manufacturer would devote an amount of money to the corrective educational program proportionate to its share of the total advertising and promotional expenditures of the cigarette and smokeless tobacco industry. Thus, a company whose expenditures equal 40 percent of total industry expenditures would be required to allocate an amount equal to 40 percent of the total monies required. The agency calculated the amount of money that would be allocated to the initial corrective educational program by looking at the period of time when the Fairness Doctrine was in effect. It was estimated that, at that time, approximately $75 million a year in air time was provided by broadcasters for anti-smoking messages, which translates to $290 million in 1994 dollars. In order to ensure an effective program, the agency is proposing that approximately half that amount, or $150 million a year, be allocated initially. Under this proposal, the agency could determine each manufacturer's proportionate share of the overall advertising and promotional expenditures of the cigarette or smokeless tobacco industry by referring to the most recent figures reported to the FTC under the Cigarette Act or the Smokeless Act. This provision is intended to ensure that the corrective educational programs are adequately funded in proportion to each manufacturer's overall reported advertising and promotion expenses.

D. Subpart D—Labeling and Advertising

1. Introduction

Proposed subpart D would establish certain requirements for cigarette and smokeless tobacco product labeling (excluding product labels) and advertising pursuant to sections 520(e), 502(q), and 502(r) of the act. The proposal would apply similar requirements to labeling and advertising in print media because both are used 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. Therefore, FDA has decided to place the labeling provisions with the advertising requirements rather than place the labeling provisions with those pertaining to product labels.

Regulating cigarette and smokeless tobacco product labeling and advertising is essential to decrease young people's use of tobacco products. Proposed subpart D would preserve the informational component of labeling and advertising while decreasing their appeal to children and adolescents.

Briefly, the proposed regulations would require that advertising in any publication with a youth readership of more than 15 percent (youth being defined as under 18) or more than 2 million children and adolescents under 18 be limited to a text-only format in black and white. Advertising in any publication that is read primarily by adults would be permitted to continue to use imagery and color. Pursuant to section 502(r), the proposed regulations would require that cigarette advertising contain a statement of the product's established name, intended use, and a brief statement regarding relevant warnings, precautions, side effects, and contradictions. In addition, brand identifiable non-tobacco items, such as hats and tee shirts, and brand identifiable sponsorship of events, such as the Virginia Slims Tennis Tournament or a sponsored event using a tobacco product logo or symbol, would be prohibited.

Section 201(m) of the act (21 U.S.C. 321(m)) defines ''labeling'' as ''all labels and other written, printed, or graphic matter'' that are on an article or its containers or wrappers, or ''accompanying such article.'' In interpreting the phrase ''accompanying such article,'' the Supreme Court has held that it is not necessary for the labeling to physically accompany the product (see *Kordel* v. *United States*, 338 U.S. 345, 350 (1948)). Thus, labeling includes traditional promotional items, such as booklets, calendars, movies, etc., and also less obvious types of labeling, such as clocks, coffee mugs, desktop toys, and even tee shirts.[94] FDA would, therefore, consider non-tobacco items distributed by cigarette and smokeless tobacco companies with the product's brand name or product identification printed on them (e.g., tee shirts, hats, pens, golf tees) to be ''labeling,'' and these would be prohibited.

Subpart D is based, in part, on the recommendations of major U.S. and world health organizations and on current efforts by other countries to reduce tobacco use. These organizations and countries support advertising restrictions as an essential part of any comprehensive program to reduce or eliminate smoking by young people. The American Medical Association, American Heart Association, American Cancer Society, American Lung Association, American Academy of Family Physicians, the World Health Assembly, and the World Health Organization have recommended restrictions on advertising and promotion including a total ban of all promotional and advertising activities.[95]

Additionally, the recent IOM report recommended that, to ensure that one clear message about the health risks of tobacco use is disseminated, the government should see to it that the ''contradictory message [minimizing the risk] now conveyed by the tobacco industry''is stopped.[96] The report recommended many restrictions that are similar to those in the proposed rule. For example, the report recommended that advertising either be banned entirely or restricted to a text-only format.[97] The IOM said that such an approach would ''eliminate all the images that imply that tobacco use is beneficial and make it attractive, and that encourage young people to use tobacco products.'' [98]

The proposed labeling and advertising regulations are also based upon numerous studies and reports. The first and most compelling piece of evidence supporting restrictions on cigarette and smokeless tobacco product labeling, advertising, and promotion is that these products are among the most heavily advertised products in America. Between 1970 (1 year before Federal law prohibited cigarette advertisements on television and radio) and 1993, cigarette advertising and promotional expenditures increased from $361 million to $6 billion, a 1,562 percent increase.[99] These messages were disseminated in print media, on billboards, at point of sale, by direct mail, on specialty items (hats, tee shirts, lighters), at concerts and sporting events, in direct mail solicitations, as sponsorships on television, and in other media. FDA is concerned that the amount of advertising, its attractive imagery, and the fact that it appears in so many forums, overwhelms the government's health messages.

Advertising and promotion of smokeless tobacco products, although a much smaller market than cigarettes, also increased over the years. The largest increase in advertising expenditures for smokeless tobacco products occurred for moist snuff. U.S.Tobacco (UST), the market leader in moist snuff, increased its television advertising expenditures from $800,000 in 1972 to $4.6 million in 1984,[100] an increase of 485 percent. By 1993, total advertising and promotional expenditures for smokeless tobacco products exceeded $119 million. This increase was largely attributable to the advertising of moist snuff ($71.4 million).[101] This increase in expenditures corresponds to the growth of the moist snuff portion of the smokeless tobacco market, from 36 million pounds in 1986 to 50 million pounds in 1993. All other segments of the smokeless tobacco market declined during that period.[102]

In addition to spending large amounts on advertising, the cigarette and smokeless tobacco product industries have disseminated a variety of advertising and promotional messages that have had an enormous impact upon young people's attitudes towards smoking. In summarizing its analysis of the industry's advertising practices, IOM stated:

> The images typically associated with advertising and promotion convey the message that tobacco use is a desirable, socially approved, safe and healthful, and widely practiced behavior among young adults, whom children and youths want to emulate. As a result, tobacco advertising and promotion undoubtedly contribute to the multiple and convergent psychosocial influences that lead children and youths to begin using these products and become addicted to them.[103]

The pervasiveness and magnitude of the labeling and advertising for these products create an atmosphere of ''friendly familiarity'' [104] that affects and shapes a young person's views towards tobacco products. Thus, FDA's decision to propose stringent regulations for labeling and advertising is based upon compelling evidence that advertising and labeling play an important role in shaping a young person's attitude towards, and willingness to experiment with, cigarettes and smokeless tobacco products.

2. Advertising, Labeling, and Adolescents

Products may be advertised and promoted for their symbolic or fanciful attributes. Advertising utilizing this technique tries to convey that consumption of the product will enhance the user's self image [105] or image in the community. Consumers purchasing products for these symbolic attributes hope to acquire the image as well as the product itself.[106] This psychosocial consumer phenomenon is particularly descriptive of adolescent consumer behavior. As one consumer psychologist remarked:

> [adolescence] create[s] a lot of uncertainty about the self, and the need to belong and to find one's unique identity as a person becomes extremely important. At this age, choices of activities, friends, and ''looks''often are crucial to social acceptance. Teens actively search for cues from their peers and from advertising for the ''right''way to look and behave.* * * Teens use products to express their identities, to explore the world and their new-found freedoms in it, and also to rebel against the authority of their parents and other socializing agents. Consumers in this age sub-culture have a number of needs, including experimentation, belonging, independence, responsibility, and approval from others. Product usage is a significant medium to express these needs.[107]

For example, adolescent males often use ''such 'macho' products as cars, clothing, and cologne to bolster developing and fragile masculine self-concepts.'' [108]

Adolescents view cigarettes as a symbol to be used in helping to create a desired self image and to communicate that image to others. Cigarette advertising reinforces this symbolism and links smoking to success, social acceptance, sophistication, and a desirable lifestyle. The rugged and masculine Marlboro Man conveying, in the words of the Chief Executive Officer and President of Philip Morris, ''elements of adventure, freedom, being in charge of your own destiny,'' [109] and the cool Joe Camel, giving humorous dating tips, provide imagery that adolescents can accept as identifying badges. Not surprisingly, these brands are among the most popular with young people. One Canadian tobacco company described its ''masculine''targeting in these words:

> Since 1971, [the company's] marketing strategy has been to position [a cigarette brand] as a ''masculine trademark for young males.'' It has been our belief that lifestyle imagery conveying a feeling of independence/freedom should be used to trigger the desire for individuality usually felt by maturing young males.[110]

Advertising for cigarette brands targeted to women have proven successful in attracting young female smokers. One study correlated trends in rising smoking initiation rates among girls with the introduction of several brands targeted at women. Some of these campaigns utilized themes thought to be appealing to women (e.g. liberation and feminism, images of slimness and sophistication). The advertising campaigns preceded a rapid increase in smoking initiation rates among girls under 18 that was not accompanied by any increase in smoking rates for women, boys, or men.

Thus, advertising can play an important role in a youth's decision to use tobacco. Many researchers, including those within the cigarette industry, have advanced a stage-based model of smoking uptake.[111] The first, preparatory stage is when a child or adolescent starts forming his or her attitudes and beliefs about smoking, and sees smoking as a coping mechanism, as a badge of maturity, as a way to enter a new peer group, or as a means to display independence.[112] During this stage, pervasive advertising imagery that glamorizes tobacco use may be an important factor in shaping beliefs. The

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.[113] 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.[114]

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.[115]

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.[116] 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.[117] 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.[118]

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.[119] 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.[120]

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.[121]

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.[122]

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.[123]

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*].'' [124] 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.[125]

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.'' [126]

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.[127]

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.'' [128] 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.'' [129] 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.'' [130]

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'.'' [131] 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'.'' [132]

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.[133]

Tobacco companies deny any youth-directed advertising and promotion activities.[134] 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.[135] 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.[136] 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.[137]

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.''[138]

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.[139]

Similar attitudinal research was done for R.J.R.-MacDonald, Inc., the Canadian subsidiary of R.J. Reynolds.[140] 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.[141]

A similar research objective was described in a 1969 research paper presented to the Philip Morris Board of Directors.[142] 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?'' [143] 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.[144]

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.[145]

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.[146]

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.'' [147] The Surgeon General's Report and the Institute of Medicine's report [148] 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.[149] 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.[150] 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.[151]

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.[152] 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.[153]

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.[154]

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 [155] 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).[156]

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.[157]

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.[158] The 1994 Surgeon General's Report found that young people overestimate the prevalence of cigarette smoking [159] 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).[160] Moreover, adolescent smokers are more likely to overestimate the prevalence than adolescent non-smokers.[161] Overestimating smoking prevalence, as well as self-reported exposure to advertising, have both been positively correlated with the intention to smoke.[162]

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.[163] 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).[164] These three brands were also the three most heavily advertised brands in 1993.[165] 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.[166] 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.[167]

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.[168] 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.[169] 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.[170] Nationally, Camel had less than 3 percent of the youth market before the brand was repositioned in 1988 and Joe Camel was introduced.[171] By 1989, Camel's share of the youth market had risen to 8.1 percent,[172] and by 1992, 13 to 16 percent.[173] During this same period, Camel's share of the adult market barely moved from its 4 percent level.[174]

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.[175]

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.[176]

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-years-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.[177] 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.[178] 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.[179] 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.[180]

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.[181] 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.[182] Finland's ban on advertising and

restrictions on other nonadvertising measures reduced cigarette smoking by 6.7 percent.[183]

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.[184]

Another study looked at tobacco consumption per adult in the 22 countries of the Organization for Economic Cooperation and Development between 1960 and 1986.[185] 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.[186]

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.[187]

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.'' [188] Individual, smaller studies [189] have examined the same question and confirmed a finding of effect of advertising on consumption.[190]

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.[191] 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.[192]

Adding visual images to a text advertisement can produce greater recall and a more positive product rating.[193] 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.[194]

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.[195]

In arriving at its proposal, FDA considered other options, including banning all advertising or restricting the type of imagery used.[196] 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.[197] 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.[198]

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.[199] 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.[200] 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.[201]

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.[202] These proposed provisions would eliminate these items and therefore would prevent young people from wearing such items and becoming ''walking advertisements.'' [203]

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''[204] 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

corporate name linked with an event they enjoy. For example, sponsoring a race car, motorcycle, or boat enables manufacturers to place cigarette brand names and logos on the vehicles and drivers' uniforms; by sponsoring the event itself, the manufacturers may also place cigarette brand names and logos on the event and on official's clothing.

IEG, the leading source in the United States for sponsorship information and consulting services, is also the only company that tracks and analyzes sponsorship of sporting and other events and causes. It publishes the IEG Sponsorship Report, an international biweekly newsletter on sponsorship, as well as an industry report titled, ''IEG's Complete Guide to Sponsorship: Everything you need to know about sports, arts, event, entertainment and cause marketing.''[205] In this primer for companies considering sponsorship, it defines sponsorship as ''a cash and/or in-kind fee paid to a property (typically in sports, arts, entertainment, or causes) in return for access to the exploitable commercial potential associated with that property.''[206] According to the IEG, ''[s]ponsorship, the fastest growing form of marketing, is unregulated in the U.S.''[207] In North America, total sponsorship grew from $850 million in 1985 to more than $4.2 billion in 1994 and is done by thousands of companies.[208] The IEG further notes that for the cost of a 30-second spot on the Super Bowl telecast, a company can sponsor a NASCAR Winston Cup car and receive more than 30 hours of television coverage.[209]

The report states that companies can link sponsorship directly to product usage or sales.[210] The Chairman and CEO of R.J. Reynolds summed up the underlying purpose of sponsorship for his company by saying, ''We made it clear from the day we announced our sponsorship of the Grand National Division that we were in the business of selling cigarettes, not the racing business.''[211]

The cigarette [212] and smokeless tobacco industry [213] has been involved in sponsorships for many years and was at one time one of the dominant sponsors of events. More recently other industries have become increasingly involved in sponsoring events and causes and today the packaged goods, retail, and financial service industries are the leading sponsors of events. Although the tobacco industry accounts for only 4 percent of all sponsored events,[214] FDA has concluded that sponsored events are a significant part of the successful marketing of tobacco products and that sponsorship should be regulated under this proposal.

Companies often choose to sponsor events in order to heighten their visibility, shape consumer attitudes, communicate commitment to a particular lifestyle, and to drive sales.[215] The IEG reports that sponsorship offers several advantages over traditional advertising. According to the IEG, sponsorship is generally more effective in ''establishing qualitative attributes, such as shaping consumers' image of a brand, increasing favorability ratings and generating awareness.''[216] IEG also states that companies with huge advertising budgets and high consumer awareness (such as tobacco companies), ''are looking to the event to have a rub-off effect on their image and ultimately their sales.''[217] One marketing executive of a company that sponsors professional beach volleyball said, ''Consumer attitudes are the hardest thing to change * * * the more our brand is part of events that are part of a consumer's lifestyle, the more we can affect his or her attitude toward the product.''[218]

Image compatibility is listed by IEG as the number one factor in determining which events to sponsor. IEG encourages companies to consider whether the event offers the imagery it is trying to establish and whether it depicts a lifestyle with which the company wants to be associated.[219] A senior Philip Morris executive explained how the sponsorship of racing car events by Marlboro is consistent with the cowboy imagery associated with Marlboro: ''We perceive Formula One and Indy car racing as adding, if you will, a modern-day dimension to the Marlboro Man. The image of Marlboro is very rugged, individualistic, heroic. And so is this style of auto racing. From an image standpoint, the fit is good.''[220]

The tobacco industry's sponsorship of events also can lead to associations (often referred to as ''tie-ins'') with youth-oriented items that extend the imagery. A sponsored event ''can bring excitement, color, and uniqueness to a [point-of-purchase] display and can be merchandised weeks or months in advance.'' [221] For example, auto racing's popularity with children led one toy manufacturer to sponsor a Sprint car team in the 1991 ''World of Outlaw'' series, sponsored principally by UST. The toy company made toy racing cars with Marlboro and Camel decals. Another toy company made toy cars with Copenhagen and Skoal decals; Copenhagen and Skoal are the two major smokeless tobacco product brands for UST.[222] Additionally, ''Inside Winston Cup Racing Sports Club Magazine'' reportedly included a page called Kids Korner with puzzles and games for children.[223]

Sponsorship's impact can be measured by the amount of ''free'' advertising that appears on television. The amount and financial value of television exposure gained by a firm can be substantial. According to one study, Marlboro cigarette's sponsorship of a Championship Auto Racing Team in the 1989 season gave Marlboro nearly 3 ½ hours of television exposure and 146 mentions of the brand name. This exposure had a value of $8.4 million. In the Indianapolis 500, Marlboro received more than $2.6 million in advertising exposure. In the Marlboro Grand Prix, race officials wore Marlboro Grand Prix shirts and caps, and the Marlboro logo or name appeared 5,933 times during the broadcast.[224]

Another study used the ''Sponsor's Report'' to estimate the value of all product exposure for most U.S. auto races. In 1992, 354 motorsport broadcasts were measured. These programs had a total viewing audience of 915 million people, of whom 64 million were children and adolescents. Exposure value for all sponsors was $830 million. Tobacco products accounted for 8.2 percent ($68 million) of the total. The impact of sponsoring televised events such as these automobile races is perhaps most apparent when one realizes that over 10 million people attended these events, while 90 times that number viewed them on television.[225]

Sponsorship's effectiveness also can be measured by a change in consumer awareness of or attitudes toward a product or company. Evidence regarding sponsorship's impact on young people is somewhat limited, but reports indicate that cigarette manufacturers' sponsorship of sporting events can lead young people to associate brand names with certain life styles or activities or can affect their purchasing decisions.

One study of children in Glasgow found that one-third of the 10- and 11-year-old children surveyed correctly matched cigarette brands to the sports that their manufacturers sponsored. Many children between the ages of 6 and 17 surveyed could specify a brand and the sponsored sport or game, and nearly half of the children associated a life style or image (such as ''excitement'' and ''fast racing cars'') to cigarette brands, even when the cigarette advertisement made no reference to the sport.[226] Another study also found an increase in awareness of the sponsored brands and concluded that even fairly brief exposure to tobacco-sponsored sports on TV may increase considerably

the levels of brand awareness as long as it is linked to well-publicized images.[227]

In Australia, the percentages of children in four different States between the ages of 12 and 14 who smoked were similar. However, their cigarette brand purchases mirrored the brands that had sponsored sporting events in their respective States. For example, more than 44 percent of children in New South Wales and Queensland smoke Winfield, the sponsor of the Queensland Rugby League, whereas, in South Australia, about 44 percent of children smoke Escort, which sponsors the South Australia's Australian Rules Escort Cup. This study demonstrates the effectiveness of sports sponsorship in influencing children's choice of cigarettes.[228]

Finally, a study was conducted in which approximately 100 boys in a secondary school were shown a 15-minute videotape containing an advertisement promoting a cigarette company's sponsorship of a sporting event while another 100 boys were shown the same video with an advertisement of a non-tobacco company's sponsorship of a sporting event. Exposure to the advertisement for the tobacco-sponsored event did not significantly change the boys' general attitudes to smoking. However, non-smoking students who saw the tobacco sponsorship advertisement had a significantly higher level of agreement with the statement that ''smoking doesn't harm people if they play sports'' than did nonsmokers who were not exposed to this advertisement. According to the study's authors: ''Our study suggests that advertising of sponsorships reinforces existing behaviors, and has the potential to increase the rate at which young males smoke by negating the ill-effects associated with smoking. We also conclude that these promotions do affect those under the age of 18 by creating associations with events, teams or personalities with whom they identify.'' [229]

The proposed rule is intended to break the link between tobacco company-sponsored events and use of tobacco. These provisions are intended to reduce the so-called ''friendly familiarity'' that sponsorships and items generate among young people.

iii. *Established name and intended use.* Proposed § 897.32(b) would require each piece of advertising for cigarettes, cigarette tobacco, or smokeless tobacco products, permitted under § 897.30(a), to state the product's established name and give a statement of its intended use. 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 * * * printed prominently and in type at least half as large as that used for any trade or brand name thereof.'' The agency has determined that the established names for these products are the common and usual names: ''cigarettes,'' ''cigarette tobacco,'' ''loose leaf chewing tobacco,'' ''plug chewing tobacco,'' ''twist chewing tobacco, ''moist snuff,'' and ''dry snuff.'' (These names would be codified at proposed § 897.24.)

The product's established name would be followed by the words, ''a Nicotine-Delivery Device.'' 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 finds 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 which affirmatively identifies the products to persons reading the advertising.

iv. *The brief statement.* Under proposed § 897.32(c), cigarette advertising (permitted under § 897.30(a)) would contain information regarding relevant warnings, precautions, side effects, and contraindications. This brief statement is required under section 502(r)(2) of the act. Section 502(r)(2) does not require that labeling contain a brief statement and the agency does not intend to place such a requirement on labeling (e.g., vehicles, entries or teams in sponsored events). Because of the products' serious ''potentiality for harmful effect,'' the proposal would specify the text of the brief statement. This would ensure that all advertisements contain the same, required information in a manner that is consistent, readable, clear and conspicuous, and not misleading to the reader.

FDA is generally responsible for approving information in the brief statement to ensure that the appropriate risks and benefits are communicated. In this case, the risks associated with cigarettes are much greater than those for any other consumer product on the market, and hundreds of different cigarette brands exist. The proposed rule, therefore, would provide, as an example, the following text for one of the brief statements to ensure that important information is communicated in an informative manner to young people and that the information is consistent for all cigarette brands:

''ABOUT 1 OUT OF 3 KIDS WHO BECOME SMOKERS WILL DIE FROM THEIR SMOKING.''

FDA will include in the final rule the exact language for any and all brief statements to ensure that this important information is conveyed accurately and effectively. In addition, the agency requests comment on what other information should be included in the brief statements concerning relevant warnings, precautions, side effects, and contraindications.

Support for the proposed brief statement comes from the European Union''s report on the labeling of tobacco products. The report states that ''[t]he warnings which are perceived as being the most credible are, in general, those which draw attention to the risk of death, the risk of illness and to the addiction caused by smoking. Credibility is reinforced when the message is felt to apply personally to the reader or which describes a risk which may be felt by the reader to concern them personally.'' [230]

During the comment period for this proposed rule, FDA intends to perform extensive focus group testing on the proposed brief statement[s]. The testing will evaluate the content and various formats for the brief statement[s] to determine if the warnings are communicated effectively. The agency will base the design, the format and content of the brief statement[s] on the results of this testing and the comments received to the proposed rule.

FDA is not proposing that advertising list cigarette ingredients, but FDA is aware that several surveys and studies show that cigarette users would like to know more about the ingredients in, or the chemical constituents of, smoke delivered by cigarettes. In a survey of 2,345 adults, 93 percent agreed that tobacco companies should be required to list additives on package labels the way food and drug companies are required to list ingredients.[231] Those surveyed believed that in order to inform consumers about the risks involved in smoking, more comprehensive information about cigarette ingredients and combustion by-products should be provided to the consumer.

Section 502(r)(2) of the act (21 U.S.C. 352(r)(2)) states that ''in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health,'' a restricted device shall be misbranded unless its advertising and other descriptive printed matter include ''a full description of the components of

such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued * * * after an opportunity for a hearing.'' However, the Cigarette Act and the Smokeless Act both require submissions of reports or lists of ingredients to the Secretary (see 15 U.S.C. 1335a and 4403) that must be kept confidential. The agency tentatively concludes that these provisions may preclude FDA from requiring components or ingredients to be listed in all advertising and other printed matter. Therefore, FDA has decided, at this time, not to require a description of components or ingredients, but invites comment on whether it should initiate proceedings to determine whether the agency should require a listing of the component parts or ingredients of these restricted devices and the impact of the Cigarette Act's and the Smokeless Act's provisions on the agency's authority.

IOM recently recommended that a ''regulatory agency should take steps to inform consumers about the meaning of statements regarding tar and nicotine yields.'' [232] Some manufacturers voluntarily disclose the quantities of tar and nicotine, as determined by the FTC method, in their labeling or advertising, and one Surgeon General's warning states, ''Cigarette Smoke Contains Carbon Monoxide.''

Consumers are aware that cigarettes produce tar and carbon monoxide and that they contain nicotine. Most consumers, however, do not understand the FTC rating numbers or the health implications of each constituent.[233] The proposed rule would not explain the FTC ratings because of the controversy surrounding the FTC method for determining tar, nicotine, and carbon monoxide.

In December 1994, a conference was held under the auspices of an Ad Hoc Committee of the President's Cancer Panel (the Ad Hoc Committee) to consider the continuing usefulness of the FTC method. Although the full report is not yet available, the Ad Hoc Committee's relevant conclusions were:

> The smoking of cigarettes with lower machine-measured yields has a small effect in reducing the risk of cancer caused by smoking, no effect on the risk of cardiovascular diseases, and an uncertain effect on the risk of pulmonary disease. * * *
>
> The FTC test protocol does not accurately reflect actual human smoking, which is not standardized, but is characterized by wide variations.

The Ad Hoc Committee recommended, among other things, that: (1) The FTC protocol be changed to produce a range of tar, nicotine, and carbon monoxide ratings for each brand to better reflect the intensity with which each cigarette can be smoked; and (2) the range of ratings for each brand should be communicated to consumers. The Ad Hoc Committee recognized that designing the new test and determining how to convey the information to consumers would require the involvement of many agencies, including the National Institutes of Health, FDA, and CDC, and would also take time. The Ad Hoc Committee recommended against measuring other smoke constituents, but suggested that smokers be informed of ''other hazardous smoke constituents'' in packages and in advertising.

The FTC is considering whether and how to implement these recommendations. Until that occurs, FDA will not propose any requirements concerning tar, nicotine, and carbon monoxide ratings, but the agency requests comment on whether it should implement one of the recommendations of the Ad Hoc Committee by proposing to require manufacturers to provide information about these substances through a package insert and/or to provide information about nicotine in labeling and advertising.

In considering the design of the warning, FDA notes that research indicates that novel formats for warnings are most likely to capture the viewer's attention.[234] The FTC reported in 1981 on the noticeability of messages inside a rectangle, octagon, circle and arrow, and enlarged rectangle.[235] The report concluded that the circle and arrow and octagon were noticed and recalled more often. Recall of the message in the circle and arrow was 64 percent, whereas recall of the same message in a rectangle (the shape used in current cigarette advertising) was only 28 percent.[236] Other studies describe the importance that format has in conveying the information and ensuring that it is sufficiently processed.[237] Factors such as print size, color, contrast, graphic design, positioning (e.g. at the top of each page of advertising), shape, spacing, font style, and highlighting are all important considerations for effectively communicating information, particularly to young people.

In addition, FDA notes that several studies have demonstrated that rotating messages assists in maintaining their noticeability. FTC concluded, in its 1981 investigation of cigarette advertising practices, that a ''rotational warning system would provide sufficient repetition of each message to contribute to long term recall of that message, while decreasing the likelihood that any one message would become so familiar and so overexposed that its effectiveness would 'wear out.''' [238] The report concluded that quarterly rotated messages would assist in maintaining the novelty of the message, thus enhancing noticeability.[239] Additionally, the report concluded that shorter messages which are rotated are specific and concrete and are more easily converted into mental images. These messages are recalled more readily.[240]

The Centre for Behavioural Research on Cancer in Australia described a process of ''habituation'' that occurs with warnings and health messages. Under this process, a person's response to a warning or health message declines as that person increases his or her exposure to the warning or health message.[241] It found that habituation is greater as the frequency of exposure increases and is reduced if exposure to the stimulus is stopped for a period of time,[242] as can be the case if the messages are dissimilar and rotated.

The proposed regulation requires that the brief statement be readable, clear, conspicuous, prominent, and contiguous to the current Surgeon General's warning. FDA requests comments on the text and design of the brief statements, particularly in its ability to reach young people, and/or whether and what design specifications should be established. Specifically, it requests comment on how best to insure that the statement will be clear, conspicuous, and prominently displayed.

d. *False or misleading labeling and advertising.* Proposed § 897.36 would declare the labeling or advertising of cigarettes and smokeless tobacco products to be false or misleading if the labeling or advertisement contains ''any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made for the product.'' This provision would implement section 201(n) of the act, which states that labeling or advertising may be misleading based on ''representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article,'' and section 502(q)(1) of the act, which declares a restricted device to be misbranded if ''its advertising is false or misleading in any particular.'' FDA emphasizes that

proposed § 897.36 is meant to be illustrative rather than exhaustive. There may be other ways in which labeling or advertising would be ''false or misleading.'' For example, advertising or labeling that stated that a study showed that smoking can cure emphysema would be false and misleading.

The agency's regulations concerning prescription drug advertising provide great specificity as to what constitutes violative advertising, 21 CFR part 202. The agency has decided that this same degree of specificity is not practical in the case of a widely used consumer product. Tobacco advertising contains an unlimited variety of claims that make categorization difficult. Therefore, the agency has tentatively concluded that it will provide general guidance for the types of advertising claims that will be considered violative, rather than to attempt to identify every possible type of false and misleading claim.

E. Subpart E—Miscellaneous Requirements

Proposed subpart E would consist of three provisions. These provisions would provide record and report requirements, describe the rule's relationship to state and local laws, and require additional measures if the prevalence of tobacco use is not dramatically reduced within seven years of the date the final rule is published.

1. Section 897.40—Records and Reports

Proposed § 897.40 would address reports and records. In brief, proposed § 897.40(a) would require each manufacturer to submit to FDA copies of all labels and labeling, and a representative sample of its advertising for enforcement purposes. The proposal would also permit a manufacturer to submit a representative sample of its labels if they would be similar for multiple packages or products. Proposed § 897.40(a) would direct manufacturers to send information and reports to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20857, with each section plainly marked, i.e., ''Labels,'' or ''Labeling and Advertising,'' whichever is appropriate.

This provision is the minimum required by section 510(j) of the act (21 U.S.C. 360(j)), which requires submission to FDA of labels, labeling, and a representative sample of advertising for restricted devices. As explained elsewhere in this document, the agency intends to regulate cigarettes and smokeless tobacco products as restricted devices rather than as drug products, but will assign all of such products to the Center for Drug Evaluation and Research (CDER). Thus, proposed § 897.40(a) reflects the statutory requirement in section 510(j) and would direct copies of labels to the Documents and Records Section in CDER. Proposed § 897.40(b) would authorize FDA employees to inspect records, particularly for purposes of review, copying, or any other use related to the enforcement of the act. This requirement is similar to the inspection authority under the medical device tracking regulations at 21 CFR 821.50 and implements the agency's inspection authority contained in section 704 of the act.

2. Section 897.42—State and Local Requirements

Proposed § 897.42 would address preemption of State and local requirements. Section 521(a) of the act (21 U.S.C. 360k(a)) states that:

* * * no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this Act to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

Proposed § 897.42(a) would require manufacturers, distributors, and retailers to comply with any more stringent State or local requirements relating to the sale, distribution, labeling, or advertising of cigarettes and smokeless tobacco products provided that the State or local requirement does not conflict with FDA regulations. These more stringent state requirements would, therefore, be part of the regulatory scheme and would not be preempted. For example, the proposal would not preempt a State law raising the minimum age for purchasing cigarettes to 21 or prohibiting cigarette or smokeless tobacco product advertisements on billboards located near schools.

FDA is aware that many States and local governments have enacted innovative and effective laws and regulations pertaining to cigarettes and smokeless tobacco products, and the agency encourages future activity in these areas. Moreover, because the proposed rule addresses only the sale, distribution, labeling, and advertising of cigarettes and smokeless tobacco products, State and local requirements in other areas are not affected. For example, the proposal clearly would not preempt State laws regarding licensing, taxes, or smoking in public areas.

If a State or local government is uncertain whether section 521(a) of the act preempts a particular law or regulation, proposed § 897.42(b) would permit the State or local government to easily and expeditiously request and receive an advisory opinion from FDA. Regulations governing applications for exemptions from Federal preemption of State and local requirements applicable to devices can be found at 21 CFR part 808.

FDA is aware of several recent court decisions construing section 521 of the act to preempt certain common law tort actions with respect to medical device products. FDA does not believe that section 521 should be read to give any preemptive effect to these proposed regulatory requirements over tort actions with respect to tobacco products. FDA specifically invites comment on this issue.

3. Additional Regulatory Measures

FDA is also proposing that additional provisions aimed at further reducing the appeal of tobacco advertising and thus discouraging young people from using cigarettes or smokeless tobacco products be required if, seven years from the date the final rule is published, FDA finds that the percentage of young people under the age of 18 who smoke, or the percentage of young men who use smokeless tobacco, has not decreased roughly by 50 percent. This goal could be measured using data of national tobacco use rates of children and adolescents. One method would be:

1. For cigarette manufacturers, the percentage of daily cigarette smokers among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program such as the Monitoring the Future Project (MTFP) for both the reference (1994) and target years (seven years from the date of the publication of the final rule); or

2. For smokeless tobacco product manufacturers, the percentage of male regular smokeless tobacco product users (any use in the past 30 days) among 12th graders is at least 50 percent less than it was in 1994 as measured by an objective, scientifically valid, and generally accepted program for both the reference (1994) and target years (seven years from the date of the publication of the final rule) and the percentage of female regular smokeless tobacco product users among 12th graders is no greater than it was in 1994 as measured in both the reference (1994) and target years.

The Institute for Social Research at the University of Michigan collects and maintains the data from the MTFP. The

project is funded through the National Institute on Drug Abuse. The survey utilizes both a cross-sectional and a longitudinal design, with self-administered surveys in a sample of selected schools. Data for daily smoking by 12th graders have been collected annually since 1976. Smokeless data for any use within past 30 days are available for the years 1986 to 1989 and 1992 to 1994 for 12th graders. (Twelfth graders are a suitable surrogate for the upper age of the prohibited smoking age because twelth graders are 17–18 years old.) The MTFP is one of the more consistent and complete data sets available on young people and provides a stable and reliable basis for measuring the proposed reductions. FDA is requesting comment on the appropriateness of using this data set, including whether the methodology used by MTFP is appropriate for this purpose or on whether other measures would be more reliable and enforceable.

FDA derived its outcome-based objectives from the ''Healthy People 2000'' objectives. ''Healthy People 2000'' discusses national health promotion and disease prevention objectives in this country. This report was facilitated by IOM of the National Academy of Sciences, with the help of the U.S. Public Health Service, and included almost 300 national membership organizations and all State health departments. The report was the product of eight regional hearings and testimony from more than 750 individuals and organizations. Contributors included the CDC, the National Institutes of Health, the American Academy of Pediatrics, the American Heart Association, the American Medical Association, the American Cancer Society, the American Lung Association, the Blue Cross and Blue Shield Association, the American College of Physicians, and the Federation of American Societies for Experimental Biology.

Recognizing that reducing cigarette smoking by youth is an important national priority, the ''Healthy People 2000'' report established a basic goal for the year 2000 to reduce by half the initiation of cigarette smoking by children and youth and to reduce by 39.4 and 55.1 percent the use of smokeless tobacco by young men.

The ''Healthy People 2000'' objectives for cigarettes required the smoking prevalence among young people (ages 20 to 24) to be cut in half in 13 years—from 30 percent in 1987 to 15 percent by the year 2000. The proposed regulation takes as its premise the type of outcome established in ''Healthy People 2000.'' However, because the time frame is different, the proposed regulation would use data as it measures actual usage by high school seniors, a group closer in age to the relevant age group. The prevalence of daily cigarette smoking among high school seniors was 19.4 percent in 1994. Calculating from 1994, daily smoking prevalence among high school seniors must be reduced by half to 9.7 percent seven years after date of the final publication of the rule. Any major changes in the methodology of this survey would require a reassessment of the objective in light of the influences of the changes on the survey's prevalence estimates.

The ''Healthy People 2000'' smokeless tobacco goals are to reduce use in 12- to 17-year-old males by 39.4 percent in 12 years—from 6.6 percent in 1988 to 4.0 percent in the year 2000 and for 18- to 24-year-old males by 55.1 percent—from 8.9 percent in 1987 to 4.0 percent by the year 2000. The proposed rule also modifies the ''Health People 2000'' goal reflecting the different time frame. The objectives also will use data for the nation's high school seniors to monitor progress in reducing the prevalence of smokeless tobacco use. Since high school seniors are 17- to 18-years-old, the percent reduction for high school seniors should be about midway between that required for males 12- to 17-years-old (i.e., 39.4 percent) and 18- to 24-years-old (i.e., 55.1 percent). Thus, a 50 percent reduction would be required to be in compliance with this proposed regulation. Smokeless tobacco use rates (once in 30 days) for senior high school boys was 20.3 percent in 1994. Therefore, the goal would be 10.2 percent. (Failure to reach these objectives would justify the imposition of additional regulatory requirements on the sale, distribution, and use of cigarettes and smokeless tobacco products. Recognizing that smokeless tobacco use by young girls is not extensive (2.6 percent in 1994), the agency believes that an additional goal might be considered—that smokeless tobacco use by young females not increase. This goal would help prevent the development of a new market for smokeless tobacco products.

While the agency finds that the proposed rule is a comprehensive approach that should prove effective in regulating these products, it recognizes that additional measures might be necessary because many different factors may affect a young person's decision to start smoking or use smokeless tobacco products. Additionally, the tobacco industry has shown its ability to find new outlets for promoting its products when restrictions are imposed; for example, within a relatively short period of time after the federally imposed electronic media ban became effective, the cigarette industry redirected the funds spent on television and radio advertising to traditional print and outdoor media. Over time, more nontraditional forms of advertising emerged, including using non-tobacco items (e.g., tee shirts and hats) that served as ''walking billboards,'' placing products in movies, creating massive lists of smokers to target by direct mail, publishing magazines with articles as well as advertising, creating ''friendly familiarity'' and good will for tobacco products by sponsoring sporting and artistic events and by having its sponsored events appear on television (in spite of the television advertising ban).[243] In addition, in Canada, the cigarette companies evaded a ban on sponsorship in the name of a brand variety (but not in the company's corporate name), by creating corporate identities for relevant brands. These new corporations could then legally sponsor events.[244]

Therefore, to guard against this possibility, and to provide for an additional incentive for the companies to take appropriate actions, the agency is proposing that one or more additional measures would be imposed in the event that the outcome-base objectives provided in proposed § 897.44 are not achieved.

At the time a final rule is published, FDA intends to propose specific additional measures. The agency invites public comment on what regulatory measures(s) should be considered. The agency reiterates that additional measures would become operational only if the outcome-based objectives are not achieved.

Finally, the agency requests comment on what would be the appropriate schedule for implementing the provisions of the final rule. It is likely that the final rule would contain some provisions that could not be complied with immediately following the date that the final rule becomes effective. FDA is seeking comment on, and information about, such matters as size of inventories, manufacturing practices, retooling, useful life of equipment, and other similar business considerations. The agency will take the information provided on these issues into account when it established the implementation schedule for the final rule.

F. Other Amendments

The proposed rule would also make two minor amendments to existing regulations. The proposal would exempt cigarettes and smokeless tobacco

products from the Statement of Identity requirements for over-the-counter devices at 21 CFR 801.61 and from the reporting requirements at 21 CFR parts 803 and 804. Section 801.61 stems, in part, from the Fair Packaging and Labeling Act, and Tobacco products are exempt from the statute's requirements. Therefore, the proposed rule would exempt cigarettes and smokeless tobacco products for 21 CFR 801.61.

Parts 803 and 804 pertain to the reporting of deaths, serious injuries, and malfunctions associated with devices. FDA is proposing to exempt cigarettes and smokeless tobacco products from these reporting requirements because the adverse health effects attributable to cigarettes and smokeless tobacco products are extensive and well-documented, and the agency sees little benefit in requiring manufacturers and distributors of these products to report such information to FDA.

References

1. Institute of Medicine, ''Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths,'' p. 201, 1994 (hereinafter cited as ''IOM Report'').
2. *Id*.
3. DHHS, ''Preventing Tobacco Use Among Young People: A Report of the Surgeon General,'' Atlanta, Georgia: DHHS, PHS, CDC NCCDPHP, OSH, p. 141, 1994 (hereinafter cited as ''1994 SGR'').
4. Cummings, K.M., T. Pechacek, and D. Shopland, ''The Illegal Sale of Cigarettes to U.S. Minors' Estimates by State,'' *American Journal of Public Health*, vol. 84, No. 2, pp. 300–302, 1994.
5. 1994 SGR, p. 249.
6. *Id*. p. 141.
7. *Id*.
8. Jason, L.A., et al., ''Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors,'' *Journal of the American Medical Association*, vol. 266, No. 22, pp. 3159–3161, December 11, 1991.
9.Feighery, E., D.G. Altman, and G. Shaffer, ''The Effects of Combining Education and Enforcement to Reduce Tobacco Sales to Minors,'' *Journal of the American Medical Association*, vol. 266, No. 22, pp. 3168–3171, December 11, 1991.
10. *Id*.
11. IOM Report, p. 199.
12. 1994 SGR, p. 65, Table 7.
13. *Id*.
14. Kelder, S.H., et al., ''Longitudinal Tracking of Adolescent Smoking, Physical Activity, and Food Choice Behaviors,'' *American Journal of Public Health*, vol. 84, No. 7, pp. 1124, 1994.
15. *Id.*, p. 1123.
16. Section 1926(b)(1) PHSA.
17. R.J. Reynolds Tobacco Company, ''Non-Self-Service Carton Shelf Plan, NSS–2.''
18. R.J. Reynolds Tobacco USA Savings Center Display Plan.
19. *Id*.
20. ''No Sale: Youth Tobacco and Responsible Retailing,'' Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.
21. Erickson, A.D., et al., ''A Baseline Assessment of Cigarette Sales to Minors in San Diego, California,'' *Journal of Community Health*, Vol. 18, No. 4, pp. 213–224, 1993.
22. *Id.*, p. 220.
23. 1994 SGR, p. 141.
24. Hinds, M.W., ''Impact of a Local Ordinance Banning Tobacco Sales to Minors,'' *Public Health Reports*, vol. 107. No. 3, pp. 355–358, 1992.
25. Klonoff, E.A., et al. ''The Problem and Sociocultural Context of Single-Cigarette Sales,'' *Journal of the American Medical Association*, vol. 271, No. 8, pp. 618–620, 1994.
26. Archibald, C., ''Sale of Individual Cigarettes: A New Development,'' Letters to the Editor, *Pediatrics*, vol. 91, No. 4, p. 851, 1993.
27. IOM Report, pp. 215–216.
28. *Id.*, p. 216.
29. ''No Sale: Youth, Tobacco and Responsible Retailing,'' Findings and Recommendations of a Working Group of State Attorneys General, pp. 29–30, December 1994.
30. Lewit, E.M., D. Coate, and M. Grossman, ''The Effects of Government Regulation on Teenage Smoking,'' *Journal of Law and Economics*, vol. XXIV, No. 3, pp. 545–569, 1981; Warner, K.E., ''Smoking and Health Implications of a Change in the Federal Cigarette Excise Tax,'' *Journal of the American Medical Association*, vol. 225, No. 8, pp. 1028–1030, 1986; Harris, J.E. ''The 1983 Increase in the Federal Cigarette Excise Tax.'' in ''Tax Policy and the Economy,'' vol. 1, MIT Press, 1987.
31. Photocopy of Newport Cigarette pack containing 10 cigarettes; ''USA Today,'' November 22, 1994, at p. B1, col. 4.
32. Wilson, D.H., et al., ''15s: 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*, vol. XI, No. 1, pp. 16S–20S, 1987.
33. ''Students and Tobacco,'' The 1990 Nova Scotia Council on Smoking and Health Survey, Final Report, March 1991.
34. Hill, D.J., et al., ''Tobacco and Alcohol Use Among Australian Secondary Schoolchildren 1987,'' *Medical Journal of Australia*, Vol. 152, pp. 124–130, 1990.
35. Battelle, ''Design of Inspection Surveys for Vendor Compliance with Restrictions on Tobacco Sales to Minors,'' prepared for the CDC, OSH, pp. 14, 18, April 1994.
36. ''Strategies to Control Tobacco Use in the United States: A Blueprint for Public Health Action in the 1990's,'' National Cancer Institute, NIH Publication No. 92–3316, p. 235, October 1991.
37. Altman, D.G., el at., ''Reducing the Illegal Sale of Cigarettes to Minors,'' *Journal of the American Medical Association*, vol. 261, No. 1, pp.80–83, 1989.
38. Forster, J.L., M. Hourigan, and P. McGovern, ''Availability of Cigarettes to Underage Youth in Three Communities,'' *Preventive Medicine*, vol. 21, pp. 320–328, 1992.
39. ''Strategies to Control Tobacco Use in the United States: A Blueprint for Pubic Health Action in the 1990's, '' National Cancer Institute, NIH Publication No. 92–3316, p. 235, October 1991.
40. 1994 SGR, p. 249.
41. Response Research, Inc., ''Study of Teenage Cigarette Smoking and Purchase Behavior,'' for the National Automatic Merchandising Association, Chicago, p. 23, June/July 1989.
42. Forster, J.L., M. Hourigan, and S. Kelder, ''Locking Devices on Cigarette Vending Machines: Evaluation of a City Ordinance,'' *American Journal of Public Health*, vol. 82, No. 9, pp. 1217–1219 (Table 1), 1992.
43. *Id.*, p. 1219 (Table 2).
44. *Id*.
45. ''Minors' Access to Cigarette Vending Machines—Texas,'' in ''MMWR,'' DHHS, CDC, vol. 43, No. 34, pp. 625–627, 1994.
46. Cismoski, J. And M. Sheridan, ''Availability of cigarettes to Under-Age Youth in Fond du Lac, Wisconsin,'' *Wisconsin Medical Journal*, vol. 92, No. 11, pp. 626–630, 1993.
47. Forster, J.L., M. Hourigan, and P. McGovern, ''Availability of Cigarettes to Underage Youth in Three Communities,'' *Preventive Medicine*, vol. 21, pp. 320–328, 1992; ''Cigarette Vending Machines Sell Cigarettes to Children, 11–15 Years Old, 100% of the Time,'' Smokefree Educational Services, Inc., October 1990; Memorandum from Sgt. Tony Pearsall, City of Valleys Police Department to Chief Galvin, City of Valleys Police Department, ''Minors Purchasing Cigarettes from Vending Machines at Local Bars,'' December, 1990; Mead, R., ''Teen Access to Cigarettes in Green Bay, Wisconsin,'' *Wisconsin Medical Journal*, pp. 23–24, January 1993; Kotz, K., ''An Evaluation of the Minnesota State Law to Restrict Youth Access to Tobacco,'' presented to APHA 121st Annual Meeting, San Francisco, CA, October 24–28, 1993; ''Springfield Teen Tobacco Purchase Survey,'' Stop Teenage Addiction to Tobacco (STAT), 1993; ''Cigarette Vending Machine Purchases Easy For Springfield Youth,'' Stop Teenage Addiction to Tobacco (STAT), June 11, 1993.
48. ''Cigarette Vending Fact Sheet,'' National Automatic Merchandising Association, 1993.
49. Cummings, K.M. et al., ''Where teenagers get their cigarettes: a survey of the purchasing habits of 13–16 year olds in 12 US communities,'' *Tobacco Control*, vol. 1, pp. 264–267, 1992.
50. *Id*.
51. IOM Report, pp. 212–213.
52. IOM Report, pp. 212–215.
53. ''Model Sale of Tobacco Products to Minors Control Act,'' A Model Law Recommended for Adoption by States or Localities to Prevent the Sale of Tobacco Products to Minors, U.S. Department of Health and Human Services, May 24, 1990.
54. ''No Sale: Youth, Tobacco and Responsible Retailing,'' Findings and Recommendations of a Working Group of State Attorneys General, pp. 31–32, 1994.
55. ''Youth Access to Cigarettes,'' DHHS, Office of the Inspector General, Publication No. OEI–02–90–02310, pp. 8–9, May 1990.

56. ''Census of the Industry Issue,'' *Vending Times,* p. 42, 1994.
57. *Id.,* ''Cigarette Vending Fact Sheet,'' National Automatic Merchandising Association, 1993, ''State of the Industry Report,'' *Automatic Merchandiser,* p. A10, August 1994. Calculations from these reports indicate sales per machine, per day, ranging from $9.41 to $12.56.
58. *Id.*
59. *Id.*
60. ''Census of the Industry Issue,'' *Vending Times,* p. 9, 1994.
61. Statement of Richard W. Funk, on behalf of National Automatic Merchandising Association before the House Subcommittee on Transportation and Hazardous Materials of the Energy and Commerce Committee, Serial No. 101–85, p. 242, July 25, 1993; ''Cigarette Vending Fact Sheet,'' National Automatic Merchandising Association, 1993.
62. ''Census of the Industry Issue,'' *Vending Times,* p. 42, 1994.
63. ''Cigarette Vending Fact Sheet,'' National Automatic Merchandising Association, 1993.
64. IOM Report, pp. 214–215.
65. *Id.,* p. 215. See also Comerford, A.M. and J. Slade, ''Selling Cigarettes: A Salesman's Perspective,'' supported in part by Institute of Medicine, National Academy of Sciences project, pp. 5–6, July 25, 1994 (self-service displays are an important source of tobacco products for minors; shoplifting is common, but the ''tobacco industry encourages self-service sales strategies by citing studies and supporting in-store tests which are targeted at demonstrating that profits from increased sales outweigh losses due to pilferage increases''); ''No Sale: Youth, Tobacco and Responsible Retailing,'' Findings and Recommendations of a Working Group of State Attorneys General, p. 29, December 1994 (advocating behind the counter sales to reduce shoplifting by minors and to decrease purchases by very young buyers from clerks).
66. Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vender-Assisted Tobacco Sales,'' North Bay Health Resources Center, Petaluma, CA, November 3, 1994.
67. IOM Report, pp. 225–226.
68. Hwang, S.L., ''Philip Morris Cos. Unveils Plan Aimed At Curbing Cigarette Smoking by Minors,'' *Wall Street Journal,* A3, col. 2, June 28, 1995.
69. U.S. Department of Health and Human Services, ''Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General,'' U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, DHHS Publication No. (CDC) 89–8411, p. 597, 1989 (hereinafter cited as ''1989 SGR'').
70. Davis, R.M., and L.A. Jason, ''The Distribution of Free Cigarette Samples to Minors,'' *American Journal of Preventive Medicine,* vol. 4, No. 1, pp. 21–26, 1988; See also *Sales Merchandiser,* R.J. Reynolds Tobacco Co. Sales Dept., p. 8, July–August 1982 (describing how RJR sales personnel are ''[a]lways on the lookout for special opportunities'' and how free samples were provided at events in North Carolina and Tennessee; the article implies that over 10,000 people saw the ''Work Horse tobacco Spitting Contest'' and received a sample of ''Work Horse'' chewing tobacco).
71. IOM Report, p. 216; See also 1994 SGR, p. 186; Davis, R.M., And L.A. Jason, ''The Distribution of Free Cigarette Samples to Minors,'' *American Journal of Preventive Medicine,* vol. 4, No. 1, pp. 21–26, 1988.
72. ''Strategies to Control Tobacco Use in the United States: A Blueprint for Public Health Action in the 1990's,'' National Cancer Institute, NIH Publication No. 92–3316, p. 236, October 1991.
73. ''Federal Trade Commission Report to Congress Pursuant to the Comprehensive Smokeless Tobacco health Education Act of 1986,'' 1995, p. 24.
74. ''Wall Street Journal,'' October 26, 1994, at p. A14, col. 5.
75. ''The New York Times,'' January 13, 1984, at p. D4, col. 5.
76. Davis, R.M., and L.A. Jason, ''The Distribution of Free Cigarette Samples to Minors,'' *American Journal of Preventive Medicine,* vol. 4, No. 1, pp. 21–26, 1988.
77. 1989 SGR, p. 597.
78. IOM Report, p. 216.
79. Davis, R.M., and L.A. Jason, ''The Distribution of Free Cigarette Samples to Minors,'' *American Journal of Preventive Medicine,* vol. 4, No. 1, pp. 21–26, 1988; See also DHHS, Office of the Inspector General, ''Spit Tobacco and Youth,'' p. 12, December 1992 (stating that either age is rarely verified before a young person receives a free sample or that industry procedures to verify age are ineffective); Ecenbarger, W., ''America's New Merchants of Death,'' *Reader's Digest,* vol. 142, No. 852, pp. 50–57, 1993 (describing how, in foreign countries, free samples of American cigarettes are distributed outside high schools and at video arcades).
80. IOM Report, pp. 216–217.
81. ''Strategies to Control tobacco Use in the United States: A Blueprint for Public Health Action in the 1990's,'' National Cancer Institute, NIH Publication No. 92–3316, p. 238, October 1991.
82. 1994 SGR, p. 188; IOM Report, p. 83.
83. IOM Report, p. 97.
84. See Simonich, W.L., ''Government Antismoking Policies,'' Peter Lang Publishing Inc., 1991.
85. Lewit, E.M., D. Coate, and M. Grossman, ''The Effects of Government Regulation on Teenage Smoking,'' *Journal of Law and Economics,* vol. XXIV, No. 3, pp. 545–573, 1981.
86. Hamilton, J.L., ''The Demand for Cigarettes: Advertising, the Health Scare, and the Cigarette Advertising Ban,'' *Rev Econ Stat,* vol. 54, p. 406, 1972.
87. Doxiadis, S.A., D.V. Trihopoulos, and H.D. Phylactou, ''Impact of a Nationwide Anti-Smoking Campaign,'' *The Lancet,* pp. 712–713, 1985.
88. Flay, B.R., ''Mass Media and Smoking Cessation: A Critical Review,'' *American Journal of Public Health,* vol. 77, pp. 153–160, 1987.
89. Flynn, B.S., et al., ''Prevention of Cigarette Smoking Through Mass Media Intervention and School Programs,'' *American Journal of Public Health,* vol. 82, pp. 827–834, 1992; Flynn, B.S., et al., ''Mass Media and School Interventions for Cigarette Smoking Prevention: Effects Two Years After Completion,'' *American Journal of Public Health,* vol. 84, pp. 1148–1150, 1994.
90. Hu, T.W., et al., ''The State Antismoking Campaign and the Industry Response: The Effects of Advertising on Cigarette Consumption in California,'' *AEA Papers and Proceedings,* vol. 85, no. 2, p. 89, May 1995.
91. Popham, W.J. et al., ''Do Anti-Smoking Media Campaigns Help Smokers Quit?'' *Public Health Reports,* vol. 108, pp. 510–513, 1993.
92. Popham, W.J., et al., ''Effectiveness of the California 1990–1991 Tobacco Education Media Campaign,'' *Am J Prev Med,* 1994 (in press).
93. Pierce, J.P., et al., ''Tobacco Use in California, An Evaluation of the Tobacco Control Program, 1989–1993,'' University of California, San Diego, La Jolla, CA, 1994.
94. Adams, D.G., ''FDA Regulation of Promotion of Drugs: A Legal Primer,'' *Drug Information Journal,* vol. 23, pp. 626, 1989.
95. ''American Academy of Family Physicians Urges Greater Regulation of Tobacco,'' 1994–1995 Compendium of AAFP Positions of Selected Health Issues, Washington, DC, 1995; ''Resolution WHA 31.56,'' The Thirty-first World Health Assembly, May 1976; Letter from Thomas P. Houston, M.D., American Medical Association, to Sharon Natanblut, Food and Drug Administration, August 2, 1995; World Health Organization, *It Can Be Done,* p. 33, 1990; Forty-Third World Health Assembly, ''Tobacco or Health,'' WHA 43.16, May 17, 1990; Coalition on Smoking or Health, Endorses Call for Ban on Tobacco Advertising and Promotion, June 9, 1986.
96. IOM Report, p. 131.
97. *Id.,* p. 132.
98. *Id.*
99. ''Report to Congress for 1993, Pursuant to the Federal Cigarette Labeling and Advertising Act,'' Federal Trade Commission, Table 3 and 3D, 1995.
100. Ernster, V.L., ''Advertising and Promotion of Smokeless Tobacco Products,'' DHHS, PHS, NIH, NCI, No. 8, p. 87, 1989.
101. ''Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986,'' pp. 25–35, 1995.
102. *Id.,* pp. 28–35.
103. IOM Report, p. 131.
104. ''Friendly familiarity'' is a phrase coined by Leo Burnett, one of the original ad executives who worked on the Marlboro account. Multiple exposures, he noted, creates a friendly familiarity that helps build confidence in a brand. Burnett, Leo *Communications of an Advertising Man,* Chicago: Leo Burnett Co., p. 217, 1961, cited in affidavit of Richard W. Pollay in support of the city's motion for a preliminary injunction, *Sterling Doubleday Enterprises, L.P. v. New York and Philip Morris.* Supreme Court of the State of New York, County of Queens, p. 7, n. 12, June 3, 1994.
105. Solomon, M., ''The Role of Products as Social Stimuli: A Symbolic Interactionism

Perspective,'' *Journal of Consumer Research*, vol. 10, pp. 319–329, 1983.

106. *Id.*; See also, Olsen, J., and J. Peter, ''Consumer Behavior and Marketing Strategy,'' 3rd edition, 1993; Sirgy, M.J., ''Self-Concept in Consumer Behavior: A Critical Review,'' *Journal of Consumer Research*, vol. 9, pp. 287–289, 1982.

107. Solomon, M.R., ''Consumer Behavior, Buying, Having, and Being,'' Allyn and Bacon, p. 448, 1992. See also, IOM Report, p. 119; Tye, J.B., K.E. Warner, and S.A. Glantz, ''Tobacco advertising and consumption. Evidence of a Causal Relationship,'' *Journal of Public Health Policy*, vol. 8, No. 4, pp. 492–508, Winter 1987; Cohen, J.B., ''Effect of Cigarette Advertising on Consumer Behavior,'' University of Florida, p. 33, 1990.

108. Solomon, M., ''The Role of Products as Social Stimuli: A Symbolic Interactionism Perspective,'' *Journal of Consumer Research*, vol. 10, p. 325, 1983.

109. 1994 SGR, p. 177, quoting from R.W. Murray, Philip Morris' President and CEO.

110. ''Foreward to F'85, Marketing Plans for Players'' Imperial Tobacco Document No. 197, p. 1.

111. Cohen, J.B., ''Effects of Cigarette Advertising on Consumer Behavior,'' University of Florida, p. 32, 1990 (citing Jarvik, M.E., ''The Role of Nicotine on the Smoking Habit,'' in ''Learning Mechanisms and Smoking,'' Aldine, 1970; Dunn, W.L. Jr., ''Smoking Behavior: Motives and Incentives,'' V.H. Winston & Sons, pp. 102–103, 1973; Leventhal, H., and P.D. Cleary, ''The Smoking Problem: A Review of the Research and Theory in Behavioral Risk Modification,'' *Psychological Bulletin*, vol. 88, No. 2, pp. 370–405, 1980).

112. *Id.*

113. Chassin, L., et al., ''The Natural History of Cigarette Smoking: Predicting Young-Adult Smoking Outcomes From Adolescent Smoking Patterns,'' *Health Psychology*, vol. 9, No. 6, pp. 701–716, 1990.

114. 1994 SGR, p. 124 (citing Flay, B.R., ''Youth Tobacco Use: Risks, Patterns, and Control,'' in ''Nicotine Addiction: Principles and Management,'' Oxford University Press, 1993); ''Diagnostic and Statistical Manual of Mental Disorders,'' American Psychiatric Association, 4th rev. ed., p. 244, 1994.

115. Imperial Tobacco Document No. 89: Research Brief for Player's Filter, p. 2; (Imperial Tobacco Ltd. and R.J. Reynolds-MacDonald Inc. v. Le Procurer General du Canada, Quebec Superior Court, 1990).

116. See generally, 1994 SGR, pp. 133–137, 141–145 and studies cited therein.

117. Cohen, J.B., ''Effects of Cigarette Advertising on Consumer Behavior,'' University of Florida, p. 34, 1990.

118. ''Project Plus/Minus,'' Kwechansky Marketing Research, Inc., Report for Imperial Tobacco Limited, Study Highlights, p. 1, May 7, 1982 (cited in Pollay, R., ''The Functions and Management of Cigarette Advertising,'' Rapport, July 27, 1989).

119. Hilts, P.J., and G. Collins, ''Documents Disclose Philip Morris Studied Nicotine's Effect on Body,'' *New York Times*, June 8, 1995, pp. A1, D6.

120. Kwechansky Marketing Research, Inc., ''Project 16,'' p. 97, October 18, 1977.

121. ''Wall Street Journal,'' October 19, 1989, at p. B1.

122. Memorandum from J.P. McMahon, Division Manager, RJR Sales Company, to Sales Reps, January 10, 1990.

123. ''Wall Street Journal,'' May 3, 1990, at p. B1, col. 3.

124. Memorandum from R.G. Warlick, Division Manager, RJR Sales Company, to All Area Sales Representatives, Sales Representatives, and Chain Service Representatives, April 5, 1990.

125. 1994 SGR, pp. 70–71; 1978 NHIS reported that 2 percent of 18–19 year old smokers smoked Camels; Adult Use of Tobacco Survey (1986) 17–18 year olds—2.7 percent, (unpublished data); ''Teenage Attitudes and Practices Survey,'' U.S. Public Health Service and U.S. Department of Education, 1989, reported in ''Changes in the Cigarette Brand Preference of Adolescent Smokers, U.S. 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, pp. 577–581, 1994.

126. John Benson worked on the Marlboro account for 30 years at the Leo Burnett advertising agency. This quote and the two other that follow are from a Marlboro oral history project on file at the Archives Center, National Museum of American History, Smithsonian Institution, Washington, D.C. The other quotes are from John Landry, who worked at Philip Morris for 30 years as a brand manager and senior vice president (vice president for marketing), and Rafael Arguelles, who was manager and marketing director of Massalin Particulares, an Argentinian tobacco company acquired by Philip Morris in 1964.

127. See IOM Report, p. 58; ''Spit Tobacco and Youth,'' Office of Inspector General, December 1992, p. 3.

128. Freedman, A., ''How a Tobacco Giant Doctors Snuff Brands to Boost Their 'Kick,' '' *Wall Street Journal*, October 26, 1994, at p. A14.

129. *Id.*

130. *Id.*

131. Blum, A., ''Using athletes to push tobacco to children/Snuff-dippin' cancer-lipped man,'' *New York State Journal of Medicine*, vol. 83, p. 1367, 1983.

132. Mintz, M., ''Marketing Tobacco to Children,'' *The Nation*, vol. 252, No. 17, p. 577 (May 6, 1991).

133. Connolly, G.N., ''Statement of the Coalition on Smoking or Health Before the House Energy and Commerce Committee, Subcommittee on Health and the Environment, November 29, 1994'' amended December 5, 1994. See also ''Wall Street Journal,'' October 26, 1994, at p. A1, col. 6 (describing different types of smokeless tobacco products and how underage users perceive them); and at p. A14, col. 1 (describing advertising campaigns by UST).

134. ''Is the Youth Market Fair Game,'' *Advertising Age*, pp. M–16–17, January 31, 1983.

135. See generally, ''Tobacco Issues (Part 2)'' ''Hearings Before the House Committee on Energy & Commerce,'' 101st Congress, Serial No. 101–126, 1989, 302–308 (testimony of S. Ward); 1994 SGR, p. 174; IOM Report, p. 115.

136. 1994 SGR, pp. 166–70, 173–77, 188–95; IOM Report 116–24; Foote, E., ''Advertising and Tobacco,'' *Journal of the American Medical Association*, vol. 245, No. 16, pp. 1667–68, 1981.

137. Foote, E., ''Advertising and Tobacco,'' *Journal of the American Medical Association*, vol. 245, No. 16, p. 1668, 1981.

138. Overall Marketing Objectives-F88, 1988 Imperial Tobacco Ltd. Marketing Plan, p.6.

139. The Creative Research Group Limited, ''Project Viking, Volume I: A Behavioral Model of Smoking,'' Foreword, February–March, 1986.

140. ''Youth 1987,'' The Creative Research Group Limited, for RJR Macdonald Inc., Foreword, June 8, 1987.

141. *Id.*

142. Wakeham H. ''Smoker Psychology Research,'' presented to the Philip Morris Board of Directors on November 26, 1969.

143. *Id.*, p. 2.

144. *Id.* p. 8.

145. ''Project 16,'' Kwechansky Marketing Research Inc., for Imperial Tobacco, Ltd., at p. vi, October 18, 1977.

146. ''Project Plus/Minus,'' Kwechansky Marketing Research Inc., for Imperial Tobacco, Ltd., at p. 1, May 7, 1982.

147. 1994 SGR, p. 188.

148. IOM Report, p. 131.

149. IOM Report, pp. 123–124; 1994 SGR, pp. 188–192; Tye, J.B., K.E. Warner, and S.A. Glantz, ''Tobacco Advertising and Consumption: Evidence of a Causal Relationship,'' *Journal of Public Health Policy*, vol. 8, pp. 492–508, Winter 1987; Pierce, J.P., et. al., ''Tobacco Use in California, An Evaluation of the Tobacco Control Program, 1989–1993,'' A Report to the California Department of Health Services, University of California, San Diego, p. 85, 1994.

150. ''Teen-Age Attitudes and Behavior Concerning Tobacco—Report of the Findings,'' The George H. Gallup International Institute, Princeton, N.J., p. 18, September 1992.

151. Pierce, J.P., et al., ''Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California,'' *Journal of the American Medical Association*, vol. 266, No. 22, pp. 3154–3158, 1991.

152. 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, No. 5, pp. 491–494, 1982; Aitken, P.P., and D.R. Eadie, ''Reinforcing Effects of Cigarette Advertising on Under-Age Smoking,'' *British Journal of Addiction*, vol. 85, pp. 399–412, 1990.

153. Goldstein, A.O., et al., ''Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements,'' *Journal of Pediatrics*, vol. 110, No. 3, pp. 488–491, 1987.

154. Botvin, G.J., et al., ''Smoking Behavior of Adolescents Exposed to Cigarette Advertising,'' *Public Health Reports*, vol. 108, No. 2 pp. 217–224, 1993.

155. Klitzner, M., P.J. Gruenewald, and E. Bamberger, ''Cigarette Advertising and Adolescent Experimentation with Smoking,'' *British Journal of Addiction*, vol. 86, pp. 287–298, 1991.

156. *Id.*

157. Aitken, P.P., et al., ''Predisposing Effects of Cigarette Advertising on Children's Intentions to Smoke When Older,'' *British Journal of Addiction,* vol. 86, pp. 383–390, 1991. See also, O'Connell, D.L., et al., ''Cigarette Smoking and Drug Use in Schoolchildren. II Factors Associated with Smoking,'' *International Journal of Epidemiology,* vol. 10, No. 3, pp. 223–231, 1981; 1994 SGR, p. 189, (citing Alexander, H.M., et al., ''Cigarette Smoking and Drug Use in Schoolchildren: IV—Factors Associated with Changes in Smoking Behavior,'' *International Journal of Epidemiology,* vol. 12, No. 1, pp. 59–65, 1983).

158. Chassin, L., et al., ''Predicting the Onset of Cigarette Smoking in Adolescents; A Longitudinal Study,''*Journal of Applied Social Psychology,* vol. 14, No. 3, pp. 224–243, 1984; Collins, L.M., et al., ''Psychosocial Predictors of Young Adolescent Cigarette Smoking: a Sixteen-Month, Three-Wave, Longitudinal Study,'' *Journal of Applied Social Psychology,* vol. 17, No. 6 pp. 554–573, 1987; Sussman, S., et al, ''Adolescent Nonsmokers, Triers and Regular Smokers' Estimates of Cigarette Smoking Prevalence: When Do Overestimations Occur and by Whom?'' *Journal of Applied Social Psychology,* vol. 18, No. 7, pp. 537–551, 1988.

159. 1994 SGR, p. 192; Chassin, L., et al., ''Predicting the Onset of Cigarette Smoking in Adolescents; a Longitudinal Study,'' *Journal of Applied Social Psychology,* vol. 14, No. 3, pp. 224–243, 1984.

160. 1994 SGR. pp. 192–193.

161. Sherman, S.J., et al., ''The False Consensus Effect in Estimates of Smoking Prevalence, Underlying Mechanisms,'' *Personality and Social Psychology Bulletin* vol. 9, No. 2, pp. 197–207, 1983.

162. See Botvin, G., et al., ''Smoking Behavior of Adolescents Exposed to Cigarette Advertising,'' *Public Health Reports,* vol. 108, No. 2, pp. 217–224, 1993; Sherman, S.J., et al., ''The False Consensus Effect in Estimates of Smoking Prevalence: Underlying Mechanisms,'' *Personality and Social Psychology Bulletin,* vol. 9, No. 2, pp. 197–207, 1983.

163. ''Changes in the Cigarette Brand Preferences of Adolescent Smokers-United States, 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, pp. 577–581, 1994. See also Goldstein, A.O., et al., ''Relationship Between High School Student Smoking and Recognition of Cigarette Advertisements,'' *The Journal of Pediatrics,* vol. 110, No. 3, pp. 488–491, 1987.

164. ''Changes in the Cigarette Brand Preferences of Adolescent Smokers-United States, 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, pp. 577–581, 1994.

165. *Id.*

166. Teinowitz, I., ''Add RJR to List of Cigarette Price Cuts,'' *Advertising Age,* pp. 3, 46, April 26, 1993.

167. Pierce, J., et al., ''Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California,'' *Journal of the American Medical Association,* vol. 266, No. 22, p. 3145–3148, 1991.

168. Fischer, P.M., et al., ''Brand Logo Recognition by Children Aged 3 to 6 Years. Mickey Mouse and Old Joe the Camel,'' *Journal of the American Medical Association,* vol. 266, No. 22, pp. 3145–3148, 1991.

169. Mizerski, R., ''The Relationship Between Cartoon Trade Character Recognition and Product Category Attitude in Young Children,'' presented at ''Marketing & Public Policy Conference,'' May 13–14, 1994.

170. Pierce, J., et al., ''Does Tobacco Advertising Target Young People to Start Smoking? Evidence from California,'' *Journal of the American Medical Association,* vol. 266, No. 22, pp. 605–611, 1994. Pierce's study was the first to identify the effect Camel advertising had on the youth market. His study, however, was limited to California. There is no comparable data for others states. The California data confirms the national findings reports by Gallup.

171. 1994 SGR, p. 70 citing 1978 NHIS (18–19 year olds) stating that 2 percent of current smokers used Camel.

172. ''Teenage Attitudes and Practices Survey,'' U.S. Public Health Service and U.S. Department of Education, 1989 cited in ''Changes in the Cigarette Brand Preferences of Adolescent Smokers-United States, 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, pp. 557–581, 1994.

173. ''Teenage Attitudes and Behavior Concerning Tobacco—Report of the Findings,'' The George H. Gallup International Institute, Princeton, NJ, p. 64, September 1992; ''Changes in the Cigarette Brand Preference of Adolescent Smokers, U.S. 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, p. 580, 1994.

174. ''Changes in the Cigarette Brand Preference of Adolescent Smokers, U.S. 1989–1993,'' in ''MMWR,'' CDC, DHHS, vol. 43, No. 32, pp. 577–581, 1994.

175. Pierce, J., L. Lee, and E.R. Gilpin, ''Smoking Initiation by Adolescent Girls, 1944 Through 1988,'' *Journal of the American Medical Association,* vol. 271, No. 8, pp. 608–611, 1994.

176. *Id.*

177. Hastings, G.B., et al., ''Cigarette Advertising and Children's Smoking: Why Reg Was Withdrawn,'' *British Medical Journal,* vol. 309, pp. 933–937, 1994.

178. ''Health or Tobacco—An End to Tobacco Advertising and Promotion,'' Toxic Substances Board Wellington, New Zealand, May 1989.

179. *Id.* at pp. xx, xxiv.

180. Highlights of the report's other findings are:

- Tobacco advertising bans for health reasons are, on average, accompanied by falls in tobacco consumption four times faster than in partial ban countries.
- In countries where tobacco has been promoted virtually unrestricted in all media, consumption has markedly increased (+1.7 percent per year).
- In countries where advertising has been totally banned or severely restricted, the percentage of young people who smoke has decreased more rapidly than in countries where tobacco promotion has been less restricted.
- When the results of this study of promotion/consumption trends in 33 countries between 1970 and 1986 are put alongside the evidence from econometrics studies * * * it seems more likely than not that, other factors remaining unchanged, the elimination of tobacco promotion *causes* a reduction in tobacco consumption and smoking prevalence to a level below what it would have been otherwise.
- Tobacco consumption increases when tobacco promotion is permitted and real price is allowed to fall; consumption declines markedly when promotion is totally banned and prices [are] raised *Id.,* pp. xxiii, xxiv, 76. See also IOM Report, p. 125.

181. Smee, C., ''Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing the Evidence,'' Department of Health, Economics, and Operational Research Division, London, 1992 p. 22, (Draft).

182. *Id.,* p. 18.

183. *Id.*

184. *Id.,* pp. 19–20.

185. 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.

186. *Id.,* p. 1344.

187. 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.

188. Smee C., ''Effect of Tobacco Advertising on Tobacco Consumption—A Discussion Document Reviewing the Evidence,'' Department of Health, Economics, and Operational Research Division, London, 1992, p.16 (Draft).

189. One study looked at the effect of variations in advertising expenditures for low-tar cigarettes. The study found that increased advertising expenditures for low tar cigarettes did not increase the advertiser's brand share, but instead benefitted all cigarette manufacturers by increasing overall cigarette consumption. Roberts, M.J., and L. Samuelson, ''An Empirical Analysis of Dynamic, Nonprice Oligopolistic Industry,'' *Rand J Econ,* vol. 19, No. 2, pp. 200–220, 1988.

190. A study of the complete New Zealand market found that there was a positive relationship between cigarette consumption and cigarette advertising over the period 1973–1985 in New Zealand; for every one percent change in advertising, there was a .07 percent change in consumption. Moreover the effect lasted for a year after change in advertising. Chetwynd, J., et al., ''Impact of Cigarette Advertising on Aggregate Demand for Cigarettes in New Zealand,'' *British Journal of Addiction,* vol. 83, pp. 409–414, 1988. The New Zealand Toxic Substances Board reanalyzed the data and confirmed the conclusion that variations in advertising expenditures did have an effect upon consumption but found that advertising might have a greater effect on consumption than the earlier study. Harrison R., J. Chetwynd, and R.J. Brodie, ''The Influence of Advertising on Tobacco Consumption: A Reply to Jackson & Ekelund,'' *British Journal of Addiction,,* vol. 84, pp. 1251–1254, 1989; Raftery, J., ''Advertising and Smoking—A Smoldering Debate, *British Journal of Addiction*'', vol 84, pp. 1241–1246, 1989.

Not all studies show a decrease in cigarette consumption in areas that ban advertising. For example, one study asserts that advertising bans have not been followed by significant changes in tobacco consumption. Boddewyn, J.J., ''Tobacco Advertising Bans and Consumption in 16 Countries,'' International Advertising Association, 1986.

191. Hendon, D.W., ''How Mechanical Factors Affect Ad Perception,'' *Journal of Advertising Research,* vol. 13, No. 4, pp. 39–45, 1973.

192. Callcott, M.F., and P.A. Alvey, ''Toons Sell . . . and Sometimes They Don't.'' An Advertising Spokes-Character Typology and Exploratory Study,'' Proceedings of the 1991 Conference of the American Academy of Advertising, pp. 44–52, 1991.

193. Rossiter, J. and L. Percy, ''Attitude Change Through Visual Imagery in Advertising,'' *Journal of Advertising,* vol. 9, No. 2, pp. 10–16, 1980; Lutz, K., and R. Lutz, ''Effect of Interactive Imagery on Learning: Application to Advertising,'' *Journal of Applied Psychology,* vol. 62, No. 4, pp. 493–498, 1977; Rossiter, J. and L. Percy, ''Visual Imaging Ability As a Mediator of Advertising Response'' in ''Advances in Consumer Research,'' vol. 5, Association for Consumer Research, p. 621–629, 1978.

194. Rossiter, J., ''Visual and Verbal Memory in Children's Product Information Utilization'' in ''Advances in Consumer Research,'' vol. 3, Association for Consumer Research, p. 523–527, 1976 (children use non-verbal, visually stored information differently than adults).

195. Huang, P., et al., ''Black-White Differences in Appeal of Cigarette Advertisements Among Adolescents,'' *Tobacco Control,* vol. 1, No. 4, pp. 249–255, 1992.

196. FDA recognizes that requiring text-only advertising is not a total panacea and that not all advertising containing cartoons or figures will be popular with young people (e.g., popular cartoon characters advertising life insurance or home insulation). Some advertisements that contain only words will be attractive (e.g., the words ''win free tickets'' to a concert or event). However, the agency finds that the effect of imagery is powerful and that the proposal represents the best approach regarding labeling and advertising that appeal to young people.

197. IOM Report, pp. 107–108.

198. *Id.*

199. *Id.,* p. 108.

200. ''Teen-Age Attitudes and Behavior Concerning Tobacco—Report of the Findings,'' The George H. Gallup International Institute, Princeton, N.J., pp. 17, 59, September 1992.

201. ''Survey of Alcohol, Tobacco and Drug Use Among Ninth Grade Students in Erie County, 1992,'' Roswell Park Cancer Institute, Buffalo, N.Y., p. 26, 1993.

202. Slade, J., D. Altman, and R. Coeytaux, ''Teenagers Participate in Tobacco Promotions'' Presented at the 9th World Conference on Tobacco and Health, October 10–14, 1994.

203. IOM Report, p. 110.

204. ''IEG's Complete Guide to Sponsorship: Everything you need to know about sports, arts, events, entertainment, and cause marketing,'' IEG Inc., Chicago, IL., p. 5, 1995 (hereinafter cited as ''IEG Guide'').

205. IEG Guide.

206. *Id.,* p. ii.

207. *Id.,* p. 33.

208. *Id.,* pp. 2–3.

209. *Id.,* p. 10.

211. Chapman, S., ''The Dying Trade,'' International Organization of Consumers Unions, The Hague, The Netherlands, p. 53, September 1985.

212. ''Federal Trade Commission Report to Congress For 1993, Pursuant to the Federal Cigarette Labeling and Advertising Act,'' Federal Trade Commission, 1995.

213. ''Federal Trade Commisison Report to Congress for 1993, Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986,'' Federal Trade Commission, 1995.

214. IEG Guide, p. 14.

215. *Id.,* pp. 10–12.

216. *Id.,* p. 40.

217. *Id.,* p. 10.

218. *Id.*

219. *Id.,* p. 15.

220. 1994 SGR, p. 179 (citing *Business of Racing,* p. 5A, 1989.)

221. IEG Guide, p. 11.

222. Blum, A., ''Sounding Board, The Marlboro Grand Prix: Circumvention of the Television Ban on Tobacco Advertising,'' *The New England Journal of Medicine,* vol. 324, No. 13, pp. 915–916, March 28, 1991.

223. *Id.,* p. 916.

224. *Id.,* pp. 914, 916.

225. Slade, J., ''Tobacco Product Advertising During Motorsports Broadcasts: A Quantitative Assessment,'' presentation at 9th World Conference on Tobacco and Health, October 10–14, 1994.

226. Aitken, P.P., D.S. Leathar, and S.I. Squair, ''Children's Awareness of Cigarette Brand Sponsorship of Sports and Games in the UK,'' *Health Education Research, Theory and Practice,* vol. 1, No. 3, pp. 203–211, 1986.

227. Ledworth, F., ''Does Tobacco Sports Sponsorship on Television Act as Advertising to Children,'' *Health Education Journal,* vol. 43, no. 4, 1984.

228. Memorandum from Gray, N., (Anti-Cancer Council of Victoria), to All Members of the Federal Parliament, December 15, 1989.

229. Hoek, J., P. Gendall, and M. Stockdale, ''Some Effects of Tobacco Sponsorship Advertisements on Young Males,'' *International Journal of Advertising,* vol. 12, No. 1, January 1993.

230. ''The Labelling of Tobacco Products in the European Union,'' European Bureau for Action on Smoking Prevention, p. 5, 1993.

231. Strouse, R., and J. Hall, ''Robert Wood Johnson Foundation Youth Access Survey: Results of a National Household Survey to Assess Public Attitudes About Policy Alternatives for Limiting Minor's Access to Tobacco Products,'' p. 42, December 1994.

232. IOM Report, P. 249.

233. Gori, G., ''Cigarette Classification as a Consumer Message,'' *Regulatory Toxicology & Pharmacology,* vol. 12, pp. 253–262, 1990.

234. Cohen, J.B., and T.K. Srull, ''Information Processing Issues Involved in the Communication and Retrieval of Cigarette Warning Information,'' Center for Consumer Research, University of Florida, p. 12, November 1980.

235. Myers, M.L. et al., Public Version of the Federal Trade Commission, ''Staff Report on the Cigarette Advertising Investigation,'' pp. 5–17 and 5–19, May 1981.

236. *Id.*

237. Biehal, G. and D. Chakravarti, ''Information-Presentation Format and Learning Goals as Determinants of Consumers' Memory Retrieval and Choice Processes,'' *Journal of Consumer Research,* vol. 8, pp. 431–441, March 1982; Beltramini, R. ''Perceived Believability of Warning Label Information Presented in Cigarette Advertising,'' *Journal of Advertising,* pp. 26–32, 1988; Bettman, J.R., J.W. Payne, and R. Staelin, ''Cognitive Considerations in Designing Effective Labels for Presenting Risk Information,'' *Journal of Public Policy & Marketing,* vol. 5, pp. 1–28, 1986.

238. Myers, M.L. et al., Public Version of the Federal Trade Commission, ''Staff Report on the Cigarette Advertising Investigation,'' pp. 5–31 and 5–32, May 1981.

239. *Id. p. 5–32.*

240. *Id.*

241. ''Health Warnings and Contents Labelling on Tobacco Products,'' Centre for Behavioural Research in Cancer, p. 42, 1992.

242. *Id.*

243. ''Wall Street Journal,'' December 27, 1994, at p. B5.

244. Sweanor, D.T., ''Measures Adopted by the Tobacco Industry to Circumvent Canada's Tobacco Products Control Act,'' p. 3, August 1994.

IV. Legal Authority

A. Regulation of Nicotine-Containing Tobacco Products

As more fully described in ''Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine-Delivery Devices Under The Federal Food, Drug, And Cosmetic Act,'' the Food and Drug Administration has conducted an extensive investigation and comprehensive legal analysis. The results of that inquiry support a finding at this time that the nicotine in cigarettes and smokeless tobacco products is a drug within the meaning of the act because it is intended to affect the structure or function of the body and it achieves its intended effects through chemical action within the human body. Based on the evidence now before the agency, cigarettes and smokeless tobacco products are drug delivery systems whose purpose is to deliver nicotine to the body in a manner in which it can be most readily absorbed by the consumer and, hence, are devices.

Thus, these products are combination products within the meaning of 21 U.S.C. 353 (g) and 21 CFR 3.2(e) that the agency has the discretion to regulate using drug authorities, device authorities, or a combination of both

authorities. The agency proposes to make these products subject to regulation pursuant to the act's device authorities. The remainder of this discussion explains the regulatory framework for combination products; why nicotine-containing cigarettes, loose tobacco, and smokeless tobacco products are drug/device combination products; and why the agency can exercise its discretion to regulate them only under the act's device provisions. Finally, this section discusses a number of other legal issues raised by the provisions of the proposed rule.

1. The Federal Food, Drug, and Cosmetic Act and Combination Products

As part of the Medical Device Amendments of 1976, Congress established, for the first time, a premarket approval mechanism for certain devices. Congress also expanded the act's device definition to expressly include items such as implements, machines, implants, and in vitro reagents. ''Device'' was defined as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure of any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Pub. L. No. 94–295 (1976).

The act was amended by the Safe Medical Devices Act of 1990, among other reasons, to recognize and provide for the regulation of products that constitute a combination of a drug, device, or biological product (21 U.S.C. 353(g)). The Safe Medical Devices Act also modified the act's drug and device definitions to conform them to the new section regarding primary jurisdiction over combination products. (See S. Rep. 101–513). Among these modifications is that the definition of ''drug'' no longer excludes devices or their components, thereby eliminating the notion that ''drug'' and ''device'' are mutually exclusive terms.

In light of the act's public health protection purposes, the agency has consistently construed the device definition broadly, and courts have upheld this interpretation. *United States* v. *An Undetermined Number of Unlabeled Cases*, 21 F.3rd 1026, 1028 (10th Cir. 1994); *United States* v. *22 Rectangular Devices*, 714 F. Supp. 1159, 1162 n.7 (listing additional examples), 1164–65 (D. Utah 1989); see, e.g., *United States* v. *23, More or Less, Articles, etc.* 192 F.2d 308, 309 (2d Cir. 1951) (phonograph records used in treating insomnia).

Because the act's definition of device is a statutory term of art, it encompasses a very wide assortment of items. Obvious examples of devices are simple medical implements such as thermometers or tongue depressors and more complicated electronic products such as X-ray machines or cardiac pacemakers. Less obvious examples of devices include in vitro reagents and other products used for diagnostic purposes, such as culture media made from snake venom (21 CFR 864.8100, 864.8950) and animal and human sera (21 CFR 864.2800). FDA also regulates many organic substances as devices. For example, a simple plant product that consists of nothing more than coagulated tree sap, gutta percha, which is used to fill the root canal in a tooth, is a device (21 CFR 872.3850). All of these articles are devices because they are instruments, apparatuses, implements, machines, contrivances, implants, in vitro reagents, or another similar or related article with uses or effects encompassed by the act. Therefore, understanding what can properly be regarded as a device for purposes of the act requires a statutory, not a lay, understanding of the term. The following discussion identifies the parts of cigarettes, loose cigarette tobacco, and smokeless tobacco that are devices, and explains why these products are drug delivery systems.

2. Cigarettes, Smokeless Tobacco Products, and Loose Tobacco Are Drug Delivery Systems

Because drugs cannot be administered in pure chemical form, drug delivery systems are designed and used to deliver drugs into the body's circulatory system or to specific target sites in the body at predetermined, controlled rates.[1] FDA considers articles such as instruments, machines, contrivances, implants, or other similar or related articles, whose primary purpose is the delivery of a drug, and that are distributed with a drug product to be drug delivery systems. Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health, Section VII.A.1.(b) (October 31, 1991). These articles are often called ''pre-filled delivery systems.'' Examples of these combination products include contrivances containing drugs, such as pre-filled syringes, transdermal patches, and metered-dose inhalers. *Id*. CDER has primary jurisdiction over the regulation of such products, and has the authority to use drug provisions, device provisions, or a combination of drug and device provisions to regulate particular drug delivery systems. *Id*.

Cigarettes and smokeless tobacco products function like drug delivery systems in that they contain a drug, nicotine; are used to deliver the drug to the site at which the drug will be absorbed into the body, the mouth or lungs; and after the drug has been delivered, the delivery system, the cigarette butt or smokeless tobacco material, depleted of nicotine, remains and must be discarded. Only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body. The subsections below explain in greater detail why these products are drug delivery systems.

a. *Cigarettes.* Cigarettes are drug delivery systems consisting of a drug, nicotine, and device components that include the tobacco itself, the paper the tobacco is rolled in and, in the case of filter cigarettes, the filter. A cigarette is analogous to a metered-dose inhaler, an instrument that converts a drug into an aerosolized form for inhalation and delivery to the lungs for absorption into the bloodstream.

Although lighting a cigarette appears to be a simple action, there is, in fact, a complex process taking place within the cigarette. A cigarette consists of carefully blended and treated nicotine-containing rolled tobacco. The blended and treated tobacco is wrapped in paper that is precisely treated so that the entire tobacco rod burns in a controlled manner. Attached to the tobacco rod (in 95 percent of U.S. cigarettes) is a filter with many possible design features, including vents and chambers. The primary purpose of parts of the cigarette, and the cigarette itself, a consciously engineered and, in the industry's own words, ''highly-engineered''[2] product, is to effectuate the delivery of a carefully controlled amount of the nicotine to a site in the human body where it can be absorbed. The drug, nicotine, is generally contained within the treated rolled tobacco. The delivery system, the nicotine-containing cigarette, must be lit to have its intended effect on the structure or function of the body and, once lit and used, is discarded.

In this manner, an average American cigarette yields approximately 1.0 mg of nicotine, although the smoker can adjust

this yield by the manner in which the cigarette is smoked, e.g., by puffing more or less frequently, by inhaling more or less deeply, or by covering, with the fingers holding the cigarette or the lips, the vent holes that may be part of the filter.

As discussed in ''Nicotine In Cigarettes And Smokeless Tobacco Products Is A Drug And These Products Are Nicotine-Delivery Devices Under The Federal Food, Drug, And Cosmetic Act,'' there is significant evidence now before the agency that the manufacturers of cigarettes intend, as a primary purpose of these products, to deliver the drug nicotine to consumers. That evidence supports a finding at this time that part of a cigarette, the nicotine, is a drug under the act. However, as described above, cigarettes are not simply packaged nicotine. Rather, they are carefully engineered, complex products that are designed to deliver a controlled amount of nicotine to the consumer using such device components as the tobacco, the paper, and the filter.

Nicotine-containing loose cigarette tobacco is used by smokers who roll their own cigarettes usually with paper made for that purpose. The evidence before the agency supports a finding at this time that the processed loose cigarette tobacco product is a device for the same reasons that the tobacco in factory-made cigarettes to be a device: it contains within it the drug intended to be consumed and is not dependent upon being metabolized for the achievement of its principal intended purpose, i.e., the delivery of nicotine, and must be lit and burned in order for the nicotine to be released in a form in which it can be absorbed by the body.

b. *Smokeless Tobacco Products.* Four principal kinds of smokeless tobacco are manufactured in the United States: loose leaf, plug, twist or roll, and oral snuff. Loose leaf chewing tobacco consists of tobacco leaves that have been heavily treated with licorice and sugars. Plug tobacco is made from tobacco that is immersed in a mixture of licorice and sugar and then pressed into a plug. Twist tobacco is produced from leaves that are flavored and twisted to resemble a rope. Oral snuff is available in both dry and moist varieties. Dry snuff consists of powdered tobacco that contains flavor and aroma additives. Moist snuff is fine particles of tobacco that hold considerable moisture; many types are made with a variety of flavorings such as wintergreen or mint.[3] Chewing tobacco and snuff are treated by the manufacturer to achieve an alkaline pH that facilitates absorption of nicotine.[4]

Smokeless tobacco products function like temporary implants or infusion devices that deliver a controlled amount of nicotine to the cheek and gum tissue for absorption into the bloodstream. The device element of smokeless tobacco products is the tobacco, which contains the drug nicotine and delivers the nicotine to the cheek and gum tissue for absorption into the body, but is not intended to be consumed. Instead, in normal use, most of the tobacco is extruded from the mouth after absorption of the nicotine. This extrudable portion of the product does not achieve its primary intended purpose through chemical action in the mouth, but allows nicotine to be extracted from the tobacco by the user's saliva and: (a) mechanically holds the nicotine in a form that is palatable, thereby allowing sufficient time for absorption of nicotine through the cheek and gum tissue; and (b) delivers chemical agents, primarily alkalines, to increase the pH within the oral cavity, to affect the rate of absorption of nicotine through the cheek and gum tissue.

3. FDA May Exercise Its Discretion to Regulate Cigarettes and Smokeless Tobacco Products Under the Device Provisions of the Act

As explained above, the agency's factual and legal inquiry supports a finding at this time that nicotine-containing cigarettes and smokeless tobacco products are drug/device combination products, namely, drug delivery devices. Under the combination product authority of section 503 of the act, FDA must designate a component of FDA to regulate combination products based on a determination of the product's ''primary mode of action.'' In the case of cigarettes and smokeless tobacco, the primary mode of action is that of a drug, due to the nicotine, and, therefore, primary jurisdiction over these products belongs in CDER. CDER's primary jurisdiction over cigarettes and smokeless tobacco is not determinative, however, of which provisions of the act apply. Rather, the agency has the discretion to regulate these drug delivery systems using drug authorities, device authorities, or a combination of both authorities. (See 21 CFR 3.2(e)(1994); 56 FR 58754 at 58754 and 58755 (November 21, 1991); Intercenter Agreement, Section VII.A.1.(b).) It is within FDA's discretionary power to determine which, if any, of the available regulatory authorities it will employ in the regulation of a product. See *Heckler* v. *Chaney*, 470 U.S. 821 (1985).

In determining which statutory authority to apply to these products, FDA has carefully considered the regulatory schemes for human drug products and devices, as well as the differing effects of these regulatory schemes on the millions of Americans who use these products. If FDA were to regulate cigarettes, cigarette tobacco, and smokeless tobacco under the drug authorities of the act, the new drug provisions would be applied, and each nicotine-containing cigarette, cigarette tobacco, and smokeless tobacco product would either have to: (a) be shown to be not a ''new drug'' because it is generally recognized as safe and effective (21 U.S.C. 321(p)); or (b) be the subject of an approved new drug application containing, among other things, adequate tests of the safety and substantial evidence of the effectiveness of the product. (See 21 U.S.C. 355.) In light of the accumulated data on the adverse health effects of tobacco, neither of these outcomes can be viewed as a realistic possibility in currently marketed products. The products would be unapproved new drugs, and as such, FDA could require their removal from the market. (See 21 U.S.C. 331(d), 355(a).)

The agency does not believe that their sudden and total withdrawal from the market would provide the best means of protecting the public health. The nicotine in tobacco products is highly addictive and is the principal reason adults continue to use tobacco products in the face of clear evidence of harm. Major recent studies reveal that the vast majority of the Nation's more than 50 million cigarette and smokeless tobacco users are addicted to the nicotine in these products. Surveys also show that while as many as 70 percent of current smokers would like to quit, only a tiny percentage are able to quit permanently. Studies on smokeless tobacco users show a similar pattern of persistent attempts to quit with extremely low success rates.[5]

Because of the high addiction rates and the difficulties smokers experience when they attempt to quit, there may be adverse health consequences for many individuals if the products were to be withdrawn suddenly from the marketplace. Our current health care system and available pharmaceuticals may not be able to provide adequate or sufficiently safe treatment for such a precipitous withdrawal. Moreover, banning all tobacco products may not achieve the primary health objective addressed in this regulation, i.e. reducing the number of children and adolescents who become addicted to these products. Given the long,

widespread use of these products in this country, it is not unreasonable to assume that a black market and/or smuggling would develop to supply addicted users with the products they require. The products that would be available through a black market could very well be more dangerous (e.g., cigarettes containing more tar or nicotine, or more toxic additives) than products currently on the market. Thus, FDA believes that a ban on all tobacco products would not eliminate smoking and would not be in the best interest of the public health at this time.

Given the dangerous health consequences of the continued use of cigarettes and smokeless tobacco products, however, the agency believes that some strong action is necessary to protect the public health. As explained in the next section, FDA has chosen to regulate these combination products using the Act's device provisions, rather than the drug provisions, because application of the device authorities would allow the continued marketing of the affected products under certain prescribed conditions established under notice and comment rulemaking procedures.

As discussed above, the primary jurisdiction over these combination products within FDA lies in CDER. This designation is appropriate because of CDER's expertise in pharmacology and drug delivery; addiction, the disease associated with tobacco use; and the regulation of pre-filled drug delivery systems. CDER, however, has the authority to use drug provisions, device provisions, or a combination of drug and device provisions in regulating these products.

4. Regulation of Cigarettes and Smokeless Tobacco Under the Device Authorities

As currently marketed, cigarettes and smokeless tobacco products are not safe and effective. Chronic use of tobacco products causes disease and premature death in a significant proportion of users.

Both the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 were designed to provide an array of regulatory tools that could provide reasonable assurance of the safety and effectiveness of devices. Since tobacco products are plainly not safe, one regulatory tool available under the statute is to ban the products, making their sale illegal. The legal basis for such a ban would be that tobacco products present an unreasonable and substantial risk of illness or injury. See section 516 of the act. Because of the addictiveness of tobacco products, however, tobacco products present special problems not ordinarily associated with devices. As discussed in the preceding section, in the case of cigarettes and smokeless tobacco products, a ban would not be in the best interest of the public health.

While premarket approval of a device has generally been regarded as the regulatory control that provides the greatest assurance of safety and effectiveness, on occasion the agency has chosen not to use premarket approval for critical devices that potentially raise significant safety and efficacy issues. For example, the agency has announced that it will no longer enforce premarket approval requirements for heart valve allografts. See the **Federal Register** of October 14, 1994 (59 FR 52078). FDA took this action after concluding that other regulatory controls would be more appropriate than premarket approval to provide reasonable assurance of the safety and effectiveness of these products. See also *Heckler* v. *Chaney*, 470 U.S. 821 (1985) (upholding agency's decision not to enforce premarket approval requirements for use of prescription drugs for lethal injection).

The Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990 provide the agency with considerable flexibility in identifying the most appropriate scheme for regulating products. These device provisions authorize the agency to use the regulatory tools that most appropriately protect the public from unsafe or ineffective devices. Moreover, these device provisions permit the agency to tailor the regulatory controls authorized under the statute to address the specific risks associated with individual devices. The following tools, among others, may be used to help provide reasonable assurance of safety and effectiveness for individual devices: special controls (section 514 of the act); premarket approval (section 515 of the act); product development protocols (section 515 of the act); notification and recall (section 518 of the act); device tracking (section 519(e) of the act); custom devices (section 520(b) of the act); restrictions on sale, distribution, and use (section 520(e) of the act); and postmarketing surveillance (section 522 of the act). Where the public cannot be appropriately protected from a hazardous device using the tools on which the agency might otherwise rely for a device posing a substantial risk, FDA has discretion to employ other, more appropriate regulatory controls provided by the Medical Device Amendments of 1976 and the Safe Medical Devices Act of 1990.

In the situation presented by widespread addiction to cigarettes and smokeless tobacco, where restrictions on supply would not be effective, the goals of the statute can best be achieved by preventing future users from becoming addicted to tobacco products. Restrictions on the sale and distribution of cigarettes and smokeless tobacco products to young people, as well as restrictions on advertising that fosters appeal and creates a demand for tobacco products among young people, are therefore the appropriate tools to attain the goal of reasonable assurance of safety and effectiveness for cigarettes and smokeless tobacco products, even if the goal can only be reached over one or more generations.[6]

The agency believes that the measures proposed in this regulation will reduce the exposure of children and adolescents to the health risks associated with tobacco use; will greatly reduce the number of individuals who are now, or may in the future become, addicted to nicotine in these products; and, from an epidemiological perspective, the combined effects of the proposed measures will, under the unique circumstances of these products, provide the most reasonable assurance of their safety.

The Medical Device Amendments provide authority to restrict the sale and distribution of products, like tobacco, for which there cannot otherwise be reasonable assurance of safety and effectiveness. Section 520(e) of the act, which authorizes FDA to restrict the sale and distribution of certain devices, provides regulatory tools that would enable FDA to achieve the goal of reducing demand for tobacco products. Therefore, FDA is proposing to declare cigarettes and smokeless tobacco products ''restricted devices'' and to impose restrictions on the underage sale and distribution of these tobacco products, pursuant to section 520(e) of the act.

5. Restricted Device Authority Under Section 520 of the Act

Section 520(e)(1)(B) of the act authorizes FDA to issue regulations restricting the sale, distribution, or use of a device:

> if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness.

Because of the potentiality for harmful effects from cigarettes and smokeless tobacco products, there cannot be reasonable assurance of the safety and effectiveness of these products short of

additional restrictions designed to prevent new users from becoming addicted to nicotine-containing tobacco products and to provide information to current users on how to quit.

As discussed earlier in this document, cigarettes and smokeless tobacco products have substantial ''potentiality for harmful effect'' because they are both addictive and pose a significant risk to the health of users. The most effective way to provide reasonable assurance of the safety and effectiveness of tobacco products is to prevent future generations from using and becoming addicted to these products in the first instance, and as explained elsewhere in this document, tobacco use is typically initiated during childhood and adolescence. The mean average age when people become daily smokers is 17.7 years of age.[7] Moreover, those who start smoking in childhood are more likely to become heavier smokers than those who start smoking in adolescence, and those who start as adolescents are more likely to become heavier smokers than those who start as adults. Thus, the age at which an individual starts smoking is an important factor that influences the intensity of that person's smoking as an adult, and consequently his or her ultimate health risks. These facts are echoed in one of the major conclusions of the 1994 Surgeon General's Report: ''Nearly all first use of tobacco occurs before high school graduation; this finding suggests that if adolescents can be kept tobacco-free, most will never start using tobacco.''[8]

The proposed restrictions on sale and distribution of tobacco products are therefore designed to substantially reduce the number of children and adolescents who become addicted to tobacco. The proposed regulations would restrict young people's access to tobacco (see proposed §§ 897.12, 897.14, and 897.16), decrease the allure of the advertising and promotion of these products (see proposed §§ 897.30, 897.32, 897.34, and 897.36), and provide educational messages aimed at young people to combat pervasive pro-tobacco messages and thus to help them resist tobacco use (see proposed § 897.29).

Access. Although State and local laws impose certain restrictions on the access of young people to tobacco, over a million children and adolescents continue to become regular tobacco users each year. Unless additional measures are imposed to substantially reduce this number, cigarettes and smokeless tobacco will continue to cause disease and death in each subsequent generation. Thus, without additional restrictions designed to eliminate or substantially reduce the initiation of cigarettes and smokeless tobacco use by children and adolescents, there cannot be reasonable assurance of the safety of these products.

Advertising. For the many reasons described in this document, advertising plays a role in influencing a young person's decision to purchase and use these products. This advertising is particularly attractive to persons under the age of 18. Sections 502 (q) and (r) of the act give the agency specific authority over the advertising of restricted devices to ensure that it is truthful, nonmisleading, and contains important information about the risks associated with the use of the product. Thus, section 502(q) of the act declares misbranded any restricted device whose advertising is ''false or misleading in any particular'' (see proposed § 897.36) and section 502(r) requires that ''all advertisements and other descriptive printed matter'' associated with a restricted device must contain certain specified information, including a brief statement of ''relevant warnings, precautions, side effects, and contraindications'' (see proposed § 897.32).

In addition, the agency has proposed restrictions on the sale of these products, specifically to prohibit all sales to those under the age of 18. Advertising with attractive imagery, brand identifiable non-tobacco items, and sponsorship of events are appealing to young people under age 18 and are effective in influencing their decision to use tobacco products. The advertising techniques that would be prohibited by the proposed rule encourage an unauthorized use of these products and thus cause them to be misbranded.

Most importantly, FDA also has been granted broad authority in section 520(e) of the act, under which the agency may place restrictions on the sale, the distribution, or the use of certain devices where the potentiality for harm makes these restrictions necessary. The broad sweep of this language implies authority to regulate many aspects of the commercialization of a restricted device. FDA is interpreting this section to authorize restrictions on the product's distribution, its offering for sale (including inducements to sale), the sale itself, and the consumer's use (including the product's misuse). This reading of section 520(e) of the act is required if the agency is to have the ability to regulate restricted devices effectively and avoid having its efforts undercut. For example, the agency is proposing to prohibit the sale of tobacco products to those under age 18. If a manufacturer advertises its tobacco products in such a way that it has the effect of encouraging underage individuals to purchase these products, the restriction on the sale of the product would be significantly undermined. In such a case, section 520(e) of the act provides the agency the additional authority to curtail the advertising practices that threaten the effectiveness of its sale restrictions.

Just as restrictions must be placed on young people's access to tobacco products in order to limit their ability to purchase these products, it is equally important to place restrictions on the marketing practices (including advertising and promotion) of the tobacco industry. Certain advertising and promotional practices of the tobacco industry play a significant and important contributory role in a young person's decision to use cigarettes and smokeless tobacco products.

As detailed more fully in Chapter III, subpart D, individual studies illustrate the profound effect that certain tobacco campaigns have had upon the youth market. Moreover, studies have indicated that comprehensive restrictions on advertising can help reduce children's demand for these products.

Restrictions on advertising are necessary in order to reduce the demand for tobacco products by young people and therefore their desire to purchase these products. Accordingly, placing restrictions on certain marketing and advertising practices of the tobacco industry is necessary to restrict the ''sale, distribution, or use'' of these products.

Information and Educational Messages. FDA has determined that an educational program about cigarettes and smokeless tobacco products is a restriction that is necessary because of the ''potentiality for harmful effect'' of these products. As discussed above, it is necessary to impose restrictions to discourage children and adolescents from using and becoming addicted to these products and to provide important health information to those who are currently addicted to these products to allow them to decrease or cease their use of these products. The brief statements that would be mandated by the proposed rule will be designed to provide some information for current users, but are not specifically addressed to, nor narrowly targeted to, the adolescent nonuser. Consequently, given the effect of the pervasive and long standing pro-tobacco messages on young people, FDA is proposing an educational campaign, national in scope

and specifically directed to adolescent nonusers. The goal of this effort is to combat the attractive imagery fostered by decades of tobacco advertising, in order to reduce the number of individuals, especially children and adolescents, who will become addicted to the nicotine in these products.

In addition, company-financed educational messages are not an uncommon remedy. FDA has imposed a similar educational requirement for hearing aids, which are also regulated as restricted devices under section 520(e) of the act. The agency requires that a User Instructional Brochure be distributed to each prospective hearing aid user. In addition to providing directions for the safe and effective use of this product, this brochure describes the adverse reactions, side effects, warnings, and limitations associated with the hearing aid. It also encourages prospective users to seek medical evaluation by a licensed physician before purchasing the product. The agency requires that specified user information be provided to educate consumers about the risks of other FDA-regulated products such as Shiley heart valves, silicone breast implants, and certain childhood immunizations.

Finally, FDA regulations provide specific language for certain disclosures in prescription and over-the-counter drug labeling, see ''Pregnancy—Nursing Warning'' for aspirin and aspirin-containing products, 21 CFR 201.63; ''Disclosure of Drug Efficacy Study Evaluations in Labeling, and Advertising,'' 21 CFR 201.200; warning concerning ''Isoproterenol Inhalation Preparations,'' 21 CFR 201.305; and warning concerning ''Drugs with Thyroid Hormone Activity,'' 21 CFR 201.316.

Unlike the users of other restricted devices, however, the youthful potential users of tobacco products are not easily identified. Because tobacco products and tobacco advertising are distributed so widely, and have been so effective at creating positive images of tobacco use, educational information cannot realistically be specifically targeted to those particular individuals susceptible to taking up smoking. Therefore, the most effective way to reach the target audience is to mandate a widespread educational campaign as described in § 897.29 of the proposed rule.

The proposed provision on educational messages is also authorized, in addition to section 520(e) of the act, under sections 502(a), 502(q), and 201(n) of the act (21 U.S.C. 352(a), 352(q), and 321(n)). Sections 502 (a) and (q) of the act state that a device shall be deemed to be misbranded if either its labeling or advertising is false or misleading in any particular. Section 201(n) of the act directs FDA, in determining whether the labeling or advertising of an article is misleading, to examine the representations made or suggested in the labeling or advertising as well as ''the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article * * *.'' The proposed educational message requirement is consistent with these statutory provisions because it is intended to help ensure that cigarette and smokeless tobacco product advertising and labeling is not false or misleading and to counteract the appeal of these products previously created by advertising, thereby providing important, material information regarding the consequences of cigarette or smokeless tobacco product use by young people in a manner that is appropriate for that age group. FDA's interpretation of sections 502(a)′ and 201(n) of the act and its authority to require the dissemination of information to persons who use human drug products has been upheld in federal court. (See *Pharmaceutical Manufacturers Association* v. **Food and Drug Administration,** 484 F.Supp. 1179 (D.Del.), *aff'd*, 634 F.2d 106 (3rd Cir. 1980) (per curiam) (upholding FDA's authority to require mandatory patient package inserts)).

Finally, although the Cigarette and Smokeless Tobacco Acts [9] prohibit advertising for cigarettes and smokeless tobacco in specified communications media, including television and radio, they do not prohibit all discussions of cigarettes and smokeless tobacco on television. Specifically, they do not prevent broadcasters from airing public service announcements regarding the dangers of tobacco use and they likewise would not prohibit tobacco manufacturers from purchasing air time to broadcast government mandated and approved educational messages to young people to encourage them not to smoke or use smokeless tobacco.

Although the required messages would concern smoking and smokeless tobacco use, they do not constitute ''advertising'' within the meaning of those acts. The U.S. Court of Appeals for the District of Columbia in *Public Citizen* v. *FTC*, 869 F. 2d 1541 (D.C. Cir. 1989), gave a common sense definition of the word ''advertising'' in its recent interpretation of the Smokeless Act:

> Our understanding of the common meaning of the term ''advertising,'' consistent with that contained in Webster's Third New Int'l Dictionary (1976), is that it involves any action to ''call public attention to a [a product] * * * so as to arouse a desire to buy.'' At the most basic level this is surely what smokeless tobacco companies are doing when they splash their brand logos and selling messages across T-shirts and other promotional items.

Id. at 1554 (modifications in original). Government approved messages that seek to discourage young people from using tobacco are intended to have the opposite effect of advertising as defined in *Public Citizen* and, therefore, do not constitute advertising.

Information for current smokers. FDA has carefully tailored these restrictions to aspects of the sale and distribution of tobacco products that create a demand for these products among children and adolescents and that permit their continued access to tobacco products despite State and local laws against sale to young people. The most effective regulatory tool available to FDA to help current smokers stop using tobacco products is to require that information be provided through advertising. FDA is therefore proposing to require a brief statement in cigarette advertising giving the health risks of tobacco use. (See § 897.32(c)).

6. Conclusion

Without the restrictions contained in this proposed rule designed to prevent future generations from becoming addicted to tobacco products, there cannot be reasonable assurance of the safety and effectiveness of cigarettes and smokeless tobacco products. FDA seeks the most rational regulatory structure for cigarettes, cigarette tobacco, and smokeless tobacco products permitted under the act to achieve an important public health goal, and simultaneously, to avoid what might be widely regarded as an unwanted and ultimately unsuccessful result.

The agency's comprehensive investigation and legal analysis support a finding at this time that cigarettes, cigarette tobacco, and smokeless tobacco are subject to regulation on the basis of their nicotine content and intended use. Each of these products employs a device component to achieve its effect on the body, and therefore each is a drug/device combination product. As such, FDA may, in its discretion, regulate them using the act's device provisions.

The device provisions permit the continued marketing of the affected products under certain prescribed conditions designed to substantially reduce the number of young people who become addicted to tobacco products and thereby to break the cycle of

addiction and disease fostered by tobacco products.

References

1. Smolen V.F., and L. Ball, eds., ''Controlled Drug Bioavailability,'' John Wiley & Sons, New York, vol. 1, p. 3; id. vol. 3, preface at p. xi, 1984.
2. FDA Docket No. 94P–0069/CPI, 94P–0077/CPI, Response of R.J. Reynolds Tobacco Company to the Petitions Filed by Action on Smoking and Health and the Coalition on Smoking OR Health, p. 78, November 2, 1994.
3. Institute of Medicine, ''Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths,'' pp. 60–61, 1994.
4. Benowitz, N., ''Nicotine and Smokeless Tobacco,'' *CA–A Cancer Journal for Clinicians,* vol. 38, No. 4, pp. 244–247, 1988.
5. Severson, H.H., ''Enough Snuff: St Cessation from the Behaviorial Clinical, and Public Health Perspectives,'' in ''Smokeless Tobacco or Health, An International Perspective,'' Smoking and Tobacco Control Monograph 2, DHHS, PHS, NIH, NIH Publication No. 93–3461, pp. 281–282; Glover, E.D., ''Conducting Smokeless Tobacco Cessation Clinics,'' *American Journal of Public Health,* vol. 76, No. 2, p. 207, 1986; Hatsukami, D., R. Nelson, and J. Jensen ''Smokeless Tobacco: Current Status and Future Directions, *British Journal of Addiction,* vol. 86, pp. 559–563, 1991; Glover, E.D. and P.N. Glover, ''Smokeless Tobacco Cessation and Nicotine Reduction Therapy,'' in ''Smokeless Tobacco or Health, An International Perspective, Smoking and Tobacco Control,'' Monograph 2, DHHS, PHS, NIH, NIH Publication No. 93–3461, pp. 291–295; Ary, D.V., et al., ''An In-Depth Analysis of Male Adolescent Smokeless Tobacco Users: Interview with Users and Their Fathers,'' *Journal of Behavioral Medicine,* vol. 12, pp. 449–467, 1989.
6. The Medical Device Amendments also provide authority to remedy unsafe products by forcing corrections in their design. See sections 514 and 518 of the Act. FDA has determined, however, that there are insufficient data available at this time to permit the conclusion that modifications in cigarettes and smokeless tobacco products would make them safe or even substantially safer.
7. 1994 SGR, p. 67.
8. 1994 SGR, p. 5.
9. 15 U.S.C. 1335 and 15 U.S.C. 4402(f).

B. Other Requirements

As explained above, FDA is proposing to regulate cigarettes and smokeless tobacco products as devices and, in accordance with section 520(e) of the act, is proposing to restrict their sale, distribution, and use. As devices, the products would also be subject to various pre-existing requirements in the statute and the regulations. These regulations include the general labeling requirements for devices at 21 CFR part 801 (excluding § 801.62); establishment registration and device listing requirements at 21 CFR part 807; and good manufacturing practice requirements at 21 CFR part 820.

Under section 502(q)(2) of the act, a restricted device that is sold, distributed, or used in violation of regulations prescribed under section 520(e) of the act shall be deemed to be misbranded. Therefore, nicotine-containing cigarettes and smokeless tobacco products that are marketed in violation of the proposed rule would be regarded by FDA as misbranded. It is already the case under the laws of all 50 States that retailers are liable when a sale of cigarettes or smokeless tobacco products is made to an underage individual. Perhaps the most significant effect of the proposed rule with regard to potential legal liability is that manufacturers, as well as retailers and distributors, could be held responsible for violations of the regulations. As with other violative manufacturer activities under the act, such a finding could result in various sanctions, including: fines, injunctions, civil money penalties, product seizure, and prosecution.

C. Preemption Under the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act

Although sections 502(q), 502(r), and 520(e) of the act give FDA authority to regulate the sale, distribution, and use of a restricted device and to impose certain requirements on all advertisements and other descriptive printed matter, both the Cigarette Act and the Smokeless Act contain provisions that limit the exercise of Federal, State, and local authorities. The agency has reviewed its statutory authority in light of these two statutes and concludes that neither the Cigarette Act nor the Smokeless Act preclude FDA from regulating these products or enacting each of the provisions in the proposed regulation.

1. The Cigarette Act

The Cigarette Act requires, among other things, specific warning notices on cigarette packages and advertisements. The Cigarette Act contains express language regarding other Federal and State regulation:

> (a) No statement relating to smoking and health, other than the statement required by [15 U.S.C. 1333], shall be required on any cigarette package.
>
> (b) No requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.

15 U.S.C. 1334. The proposed rule takes into account the Federal preemption provision of the Cigarette Act and is consistent with this statutory prohibition.

The preemption provision of the Cigarette Act regarding advertising and promotion applies only to State action. Hence, because the proposed rule would impose Federal, not State, requirements, the proposed rule's labeling and advertising requirements are permissible under 15 U.S.C. 1334(b).

In addition to being permissible under the Cigarette Act, the proposed rule would actually further Congressional intent to protect cigarette packages from diverse, nonuniform, and confusing cigarette labeling and advertising regulations. The proposal would require inclusion of certain information in cigarette advertisements, and these requirements would apply to cigarettes sold and distributed throughout the United States. Under this scheme, States could not impose ''diverse, nonuniform, and confusing'' labeling or advertising requirements, Cigarette Act, Public Law 89–92, as amended by Public Law 91–222 (April 1, 1970) and Public Law 93–109 (September 21, 1973); 15 U.S.C. 1331 (1973).

Two recent cases support the interpretation that the Cigarette Act does not establish an absolute prohibition against Federal action. In *Cipollone* v. *Liggett Group, Inc.*, the Supreme Court considered whether the Cigarette Act preempted an action by an individual against a cigarette manufacturer for breach of express warranty that cigarettes ''did not present any significant health consequences,'' failure to warn consumers about health hazards, fraudulent misrepresentation of health hazards to consumers, and conspiracy to ''deprive the public of medical and scientific information about smoking.'' 112 S. Ct. 2608, 2613–14 (1992). The Court examined the preemption provision in the Cigarette Act and the amendments contained in the Public Health Cigarette Smoking Act and stated that,

> When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a ''reliable indicium of congressional intent with respect to state authority,'' * * * ''there is no need to infer congressional intent to pre-empt state laws from the substantive provisions'' of the legislation * * * Congress'' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.

Id. at 2618 (citations omitted) (emphasis added).

The Court found that the preemption provisions ''merely prohibited state and federal rulemaking bodies from mandating particular cautionary statements on cigarette labels'' and held that the preemption provisions did not constitute an absolute prohibition against all Federal and State action. *Id.*

The Supreme Court in *Freightliner Corp.* v. *Myrick,* 115 S. Ct. 1483 (1995) clarified its language in *Cipollone.* The Court stated ''[t]he fact that an express definition of the preemptive reach of a statute ''implies''—*i.e.,* supports a reasonable inference—that Congress did not intend to pre-empt other matters does not mean that the express clause entirely forecloses any possibility of implied preemption.'' *Id.* at 1488 (emphasis added.) The Court noted that it would still be appropriate to conduct the proper analysis to determine if preemption should be implied. Having said that, the Court stated that such an analysis had been done in *Cipollone.* Finally, the Court found no implied preemption in *Freightliner* even in the absence of federal regulation.

The California Supreme Court, in *Mangini* v. *R.J. Reynolds Tobacco Co.,* 875 P.2d 73 (Cal. en banc), *cert. denied,* 115 S.Ct. 577 (1994), considered whether the Cigarette Act precluded an action under California law for engaging in an ''unlawful, unfair, or fraudulent business act or practice'' by using ''unfair, deceptive, untrue, or misleading advertising.'' The petitioner claimed that R.J. Reynolds had illegally targeted minors in its Joe Camel advertising campaign. R.J. Reynolds asserted that its cigarettes were properly labeled and, therefore, that California could not impose any regulation regarding cigarette advertising if the regulation were based on smoking and health. It added that a prohibition against selling cigarettes to minors was based on underlying health concerns and that only the Federal Government could prevent advertisements that urge minors to smoke. The California Supreme Court applied the analysis in *Cipollone* and held that, while the petitioner's action would prohibit cigarette advertising directed at minors, the underlying legal duty for the petitioner's action was not based on smoking and health. The California Supreme Court held that, ''The predicate duty is to not engage in unfair competition by advertising illegal conduct or encouraging others to violate the law.'' *Id.* at 80. As for the argument that allowing state law claims to proceed would violate congressional policy favoring a comprehensive Federal program for cigarette labeling and advertising, the court disagreed, stating,

> State law prohibitions against advertisements targeting minors do not require Reynolds to adopt any particular label or advertisement ''with respect to any relationship between smoking and health;'' rather, they forbid any advertisements soliciting unlawful purchases by minors. The prohibitions do not create '' 'diverse, nonuniform, and confusing'' standards. Unlike state law obligations concerning the warning necessary to render a product 'reasonably safe,' state law proscriptions'' against advertisements targeting minors 'rely on a single, uniform standard:'' ' do not target minors.

Id. at 80 (quoting 112 S.Ct. at 2624). Consequently, the court held that,

> It is now asserted that plaintiff's effort to tread upon Tobacco Road is blocked by the nicotine wall of congressional preemption. The federal statute does not support such a view. Congress left the states free to exercise their police power to protect minors from advertising that encourages them to violate the law. Plaintiff may proceed under that aegis.

Id. at 83. The Supreme Court later denied R.J. Reynolds' petition for a writ of *certiorari.* See 115 S.Ct. 577 (1994). Although *Mangini* concerned preemption of State action, the California Supreme Court's decision and the U.S. Supreme Court's denial of *certiorari* indicate a judicial intent not to extend the Cigarette Act's preemption provisions beyond its literal terms. Thus, restrictions on cigarette companies allegedly targeting children are not restrictions based on ''smoking and health.'' See also *Banzhaf* v. *Federal Communication Commission,* 405 F.2d 1082, 1089 (D.C. Cir. 1968), *cert. denied,* 396 U.S. 842 (1969) (preemption provision of the 1965 Cigarette Act did not bar the Federal Communication Commission from requiring radio and television stations to broadcast anti smoking messages: ''Nothing in the Act indicates that Congress had any intent at all with respect to other types of regulation by other agencies—much less that it specifically meant to foreclose all such regulation.'' (footnote omitted))

Applying these cases to FDA's proposed rule, the agency believes that the proposed requirement for a brief statement about smoking and health is not preempted.

2. The Smokeless Act

For smokeless tobacco products, the Smokeless Act states in part:

> (a) Federal action
>
> No statement relating to the use of smokeless tobacco products and health, other than the statements required by [this title,] shall be required by any Federal agency to appear on any package or in any advertisement (unless the advertisement is an outdoor billboard advertisement) of a smokeless tobacco product.

15 U.S.C. 4406(a). The proposal would not require any messages in advertising because the Smokeless Act's preemption provision is broader than the preemption provision in the Cigarette Act and preempts any Federal (as well as State) action mandating health/safety messages in advertising.

Thus, given these statutory restrictions and court precedent, FDA has determined that neither the Cigarette Act nor the Smokeless Act preempts any aspect of the proposed rule.

D. Constitutional Issues—Regulation of Speech and the First Amendment

The proposed rule's restrictions on commercial speech are consistent with the First Amendment's protection of freedom of expression. The Supreme Court distinguishes between commercial speech and other forms of speech with respect to First Amendment rights. Traditionally, commercial speech was not granted any protection under the Constitution. More recently, the Supreme Court has granted commercial speech limited constitutional protection. See *Ohralik* v. *Ohio State Bar Ass'n,* 436 U.S. 447, 456, *reh'g denied,* 439 U.S. 883 (1978); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.,* 425 U.S. 748 (1976); *Bigelow* v. *Virginia,* 421 U.S. 809, 818 (1975). The Supreme Court, in *Edenfield* v. *Fane,* 113 S. Ct. 1792 (1993), stated:

> [c]ommercial speech [ ] is ''linked inextricably'' with the commercial arrangement that it proposes, * * * so the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself. * * * For this reason, laws restricting commercial speech, unlike laws burdening other forms of protected expression, need only be tailored in a reasonable manner to serve a substantial state interest in order to survive First Amendment scrutiny.

Id. at 1798 (citations omitted).

It is undisputed that the ''Constitution * * * affords a lesser protection to commercial speech than to other constitutionally guaranteed expression.'' *United States and Federal Communication Commission* v. *Edge Broadcasting Co.,* 113 S.Ct. 2696, 2703 (1993) (citations omitted). Accord, *City of Cincinnati* v. *Discovery Network, Inc.,* 113 S.Ct. 1505, 1513 (1993); *Board of Trustees of the State University of New York* v. *Fox,* 492 U.S. 469, 475, *mot. denied,* 493 U.S. 887 (1989); *Central Hudson Gas and Electric Corp.* v. *Public*

Service Commission, 447 U.S. 557, 563 (1980); *Ohralik,* 436 U.S. at 455–56. Therefore, although commercial speech is protected, the government has latitude to regulate commercial speech in ways it could not regulate other forms of expression. *Friedman* v. *Rogers,* 440 U.S. 1, 10 n.9 (1979) (''When dealing with restrictions on commercial speech we frame our decisions narrowly, ''allowing modes of regulation [of commercial speech] that might otherwise be impermissible in the realm of noncommercial expression.'' (citation omitted).

In *Central Hudson Gas & Electric Corp.* v. *Public Service Commission of New York,* the Supreme Court established a four-prong test to determine whether restrictions on commercial speech are unconstitutional. The first prong states that for commercial speech to come within the protection of the First Amendment the speech must concern lawful activity. The other prongs relevant to an analysis of restrictions on commercial speech are:

(2) The government interest that is asserted to justify the proposed limitation must be substantial;

(3) The proposed limitation must directly advance the government's interest; and

(4) The proposed limitation should be no more extensive than is necessary to serve that interest.

Central Hudson, 447 U.S. 557, 566 (1980).

Since *Central Hudson,* the Supreme Court has taken a permissive view of the government's regulation of commercial speech and has upheld several restrictions on commercial speech. FDA believes that the proposed restrictions on the labeling and advertising of cigarettes and smokeless tobacco products, and the requirement that manufacturers fund and disseminate a media-based educational campaign, also would withstand any First Amendment challenge.

The *Central Hudson* analysis begins with the second prong. The proposed rule meets the requirements of the second prong because it serves the substantial government interest of protecting the public health. The Supreme Court has held that the government's ''interest in the health, safety, and welfare of its citizens constitutes a 'substantial' governmental interest.'' *Posadas de Puerto Rico Associates* v. *Tourism Company of Puerto Rico,* 478 U.S. 328, 341 (1986) (Court upheld restrictions on advertising of casino gambling to residents of Puerto Rico). Accord, *Fox,* 492 U.S. 469 (1989); *Metromedia Inc.* v. *City of San Diego,* 453 U.S. 490, 507–08 (1981). *National Council for Improved Health* v. *Shalala,* Memorandum Decision and Order, Civil No. 94–C–5090 (June 30, 1995) (U.S. District Court for the district of Utah rejected claim that FDA's regulation of dietary supplements violated First Amendment protection.) In this instance, the proposed rule's labeling and advertising restrictions and mandated educational campaign would reduce the use of cigarettes and smokeless tobacco products by those young individuals 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. The proposed rule, therefore, reflects a substantial government interest in public health.

The proposed rule also meets the third prong of the *Central Hudson* test by directly advancing the government's substantial interest. 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. *Metromedia,* 453 U.S. at 509 (''We likewise hesitate to disagree with the accumulated, common-sense judgments of local lawmakers and of the many reviewing courts that billboards are real and substantial hazards to traffic safety.'')

The agency's proposed restrictions on advertising and labeling are based on its review of the evidence that shows that advertising plays an important role in young people's decisions to use tobacco products. Such evidence, consisting of numerous published studies, reports, and recommendations by the industry, health professionals, consumer groups, and public health organizations, demonstrates how advertising and labeling may make young people more receptive to using cigarettes and smokeless tobacco products and how the regulatory approach proposed by FDA may reduce the potential harm to young people. See *Florida Bar* v. *Went for It,* 63 U.S.L.W. 4644 (1995) (anecdotal record sufficient to meet third prong of *Central Hudson*). The Supreme Court has specifically deferred to the government's conclusion that advertising increases consumption of a product. In *Edge,* the Court stated:

> Within the bounds of the general protection provided by the Constitution to commercial speech, we allow room for legislative judgments. Here, as in *Posadas de Puerto Rico,* the Government obviously legislated on the premise that the advertising of gambling serves to increase the demand for the advertised product. Congress clearly was entitled to determine that broadcast of promotional advertising of lotteries undermines North Carolina's policy against gambling, even if the North Carolina audience is not wholly unaware of the lottery's existence. Congress has, for example, altogether banned the broadcast advertising of cigarettes, even though it could hardly have believed that this regulation would keep the public wholly ignorant of the availability of cigarettes.

Edge, 113 S.Ct. at 2707 (citations omitted). Accord, *Posadas,* 478 U.S. at 341–42 (Puerto Rican legislature's belief that advertising of casino gambling aimed at Puerto Rican residents would increase demand for it was a reasonable one); *Dunagin* v. *City of Oxford, Miss.,* 718 F.2d 738, 748 n.8 (5th Cir. 1983) (''whether there is a correlation between advertising and consumption is a legislative and not an adjudicative fact question''), *cert. denied,* 467 U.S. 1259 (1984).

The proposed rule's requirement that the manufacturers provide funds for a media-based educational campaign is similarly supported by ample evidence that such educational campaigns have been very effective in reducing initiation and prevalence of tobacco use by young people. The proposed rule directly addresses the serious public health problem caused by tobacco use by young people in a manner that ''will in fact alleviate [the harm] to a material degree.'' *Edenfield,* 113 S.Ct. at 1800.

Unlike the advertising restrictions (text-only format, ban on promotional items, and restrictions on sponsorship), which would help reduce the appeal of future advertising to young people, the proposed education campaign is necessary to address the widespread misconceptions about tobacco use among young people that have in part been created by the ubiquitous advertising and promotional practices of the tobacco industry. For example, the industry currently spends nearly $2 billion creating appealing imagery and sponsoring and advertising events that associate their products with lifestyles that are attractive and popular with young people.

The amount of advertising, the variety of its format (e.g. advertisements, on hats, at concerts, on televised sponsored events), and the appeal of its messages compete effectively with the health messages of the government and health authorities. One consequence is that many young people believe that tobacco products are an important part of growing up and being ''cool.'' Another consequence is that young people remain ignorant of the strength of the

addiction to tobacco products and the relevance to them of the long-term health risks. In the short run, the educational messages would help counter these information deficits and, in the long run, they would provide young people with appropriate information to help them resist tobacco use.

The agency gathered enough evidence regarding the association between promotion and use of cigarettes and smokeless tobacco products and the efficacy of an appropriately designed educational campaign to tentatively conclude that the proposed rule's restrictions on commercial speech would alter young people's smoking behavior. Therefore, the restrictions can be said to ''directly advance'' the legitimate government goal of decreasing the use of these harmful products. (For a discussion of the evidence, see the discussion pertaining to proposed Subpart D, ''Labeling and Advertising.'')

Finally, the proposed rule meets the fourth prong of the *Central Hudson* test, which the Court has modified to require that the governmental regulation of commercial speech not be over broad. 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. *Fox*, 492 U.S. at 4774–4780. The Supreme Court stated:

> What our decisions require 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, as we have put it in other contexts discussed above, a means narrowly tailored to achieve the desired objective. Within those bounds we leave it to governmental decisionmakers to judge what manner of regulation may best be employed.

Id. at 480 (citations omitted) (emphasis added). Accord, *Edenfield*, 113 S.Ct. at 1798 (''[L]aws restricting commercial speech, unlike laws burdening other forms of protected expression, need only be tailored in a reasonable manner to serve a substantial state interest in order to survive First Amendment scrutiny.''); *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) (''[W]e hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.'')

This holding is consistent with the Supreme Court's earlier decisions regarding the overbreadth doctrine. The Supreme Court has held that the overbreadth doctrine—which permits an attack on a statute on the basis that it might be applied unconstitutionally in circumstances other than those before a court—applies weakly, or not at all, to commercial speech.

> Since advertising is linked to commercial well-being, it seems unlikely that such speech is particularly susceptible to being crushed by overbroad regulation. Moreover, concerns for uncertainty in determining the scope of protection are reduced; the advertiser seeks to disseminate information about a product or service that he provides, and presumably he can determine more readily than others whether his speech is truthful and protected.

Bates v. *State Bar of Arizona*, 433 U.S. 350, 381 (citations omitted), reh'g denied 434 U.S. 881 (1977).

As with the third prong, the Supreme Court has expressed a willingness to defer this determination to the regulating body. Since *Fox*, the courts have applied the ''reasonable fit'' standard to uphold the regulation of commercial speech. See *Edge*, 113 S.Ct. at 2705 (upholding restrictions on the broadcast of lottery advertisements); *South-Suburban Housing Center* v. *Greater South Suburban Bd. of Realtors*, 935 F.2d 868, 892 (7th Cir. 1991) (upholding restrictions on the mailing of solicitations to people who had registered with the municipality their desire not to receive them, as ''reasonable fit'' with the desire to protect residential privacy), *cert. denied*. 502 U.S. 1074, 112 S.Ct. 971 (1992); *Puerto Rico Tele-Com, Inc.* v. *Ocasio Rodriguez*, 747 F.Supp. 836, 845 (D.P.R. 1990) (upholding a cease and desist order by the Puerto Rico Department of Consumer Affairs (DACO) prohibiting a long-distance phone carrier from using a price study in a deceitful or misleading way as ''a reasonable 'fit' between DACO's orders against plaintiff and its mandate to protect consumers''); *Central American Refugee Center* v. *City of Glen Cove*, 753 F.Supp. 437, 440 (E.D.N.Y. 1990) (upholding ordinance prohibiting solicitation of employment from a vehicle or by a pedestrian on a public street as a ''reasonable fit'' with the governmental interest in protecting vehicle passengers and people crossing the street). Moreover, the Court has granted greater leeway and upheld reasonable regulations of commercial speech with regard to socially harmful activities. *Edge*, 113 S.Ct. 2696 (upholding Federal prohibition of lottery advertising on radio in non lottery State); *Posadas de Puerto Rico Associates*, 478 U.S. 328 (1986) (upholding ban of advertising of casino gambling directed to Puerto Rican citizens); *Capital Broadcasting Co.* v. *Mitchell*, 333 F.Supp. 582 (D.D.C. 1971), affd. mem, 405 U.S. 1000 (1972) (upholding broadcast ad ban on cigarette advertising); nothing in *Rubin* v. *Coors Brewing Company*, 63 U.S.L.W. 4319 (April 19, 1995) is to the contrary (statutory prohibition against statements of alcohol content of beer on labels or in advertising failed completely to advance the governmental interest asserted of preventing ''strength wars'' among brewers).

The agency believes that, because it could have banned the sale or distribution of the product, or banned certain of the marketing and promotional practices of the tobacco industry, the lesser steps of regulating labeling and advertising and requiring manufacturers to fund a government approved educational campaign are reasonable. As the Supreme Court has stated:

> [I]t is precisely *because* the government could have enacted a wholesale prohibition of the underlying conduct that it is permissible for the government to take the less intrusive step of allowing the conduct, but reducing the demand through restrictions on advertising.

Posadas, 478 U.S. at 346 (emphasis in original). More specifically, the Court stated:

> Legislative regulation of products or activities deemed harmful, such as cigarettes, alcoholic beverages, and prostitution, has varied from outright prohibition on the one hand. * * * to legalization of the product or activity with restrictions on stimulation of demand on the other hand. * * * To rule out the latter, intermediate kind of response would require more than we find in the First Amendment.

Id. at 346–347 (citations omitted). This analysis applies not only to the restrictions on the type of advertising permitted (text-only), but also the requirement that the manufacturers fund and disseminate a government approved educational campaign. The Supreme Court has stated that the government may dictate the form of, and information in, commercial speech. *Virginia Pharmacy*, 425 U.S. at 771 n.24 (''They may also make it appropriate to require that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.''); *In re R.M.J.*, 455 U.S. 191, 201 (1982) (''warning or disclaimer might be appropriately required* * *in order to dissipate the

possibility of consumer confusion or deception''); *Bates*, 433 U.S. at 384.

As noted above, on several occasions the agency has imposed similar educational requirements—e.g., user instructional brochures—in order to reduce consumer confusion or to prevent the misuse of a device. In those circumstances, the agency has required that the company use agency approved language. Courts have approved of similar ''corrective'' or ''coerced'' speech ordered by other federal agencies. See *Warner-Lambert Co.* v. *FTC*, 562 F.2d 749 (D.C. Cir. 1977), *cert. denied*, 435 U.S. 950 (1978) (corrective advertising is appropriate where company has engaged in a long history of deceptive advertising and the misperceptions continue even in the absence of current advertising); *United States* v. *Frame*, 885 F.2d 1119 (3rd Cir. 1989) (court upheld legislation that required beef producers, including those who objected, to pay an assessment to fund pro-beef commercials written and disseminated by a quasi-government board), *cert. denied*, 493 U.S. 1094 (1990).

In conclusion, the agency believes that the evidence would support a ban on all advertising and, therefore, that the more limited restrictions imposed by this proposed rule are reasonable as proportionate to the agency's desired goal—to reduce tobacco-related illnesses and deaths by helping to prevent young people from becoming addicted to the nicotine in cigarettes and smokeless tobacco products. The requirements proposed here serve to prevent distribution of these products to young people, to reduce the effectiveness of advertising and promotion on young people, and to ensure that an appropriate educational campaign is aimed at young people. Thus, the means chosen are a reasonable fit to the substantial interest and, consequently, pass the final prong of the *Central Hudson* test.

V. Paperwork Reduction Act of 1980

The proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. The title, description, and respondent description of the information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents.

Description: The proposed rule would collect information from manufacturers and retailers of cigarettes and smokeless tobacco products. The proposed rule would require such persons to: use established names for cigarettes and smokeless tobacco products; establish and maintain educational programs; observe certain format and content requirements for labeling and advertising; and submit labels, labeling, and advertising to FDA.

Description of Respondents: Businesses.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

CFR Section	Annual No. of responses	Annual frequency	Average burden per response	Annual burden hours
897.24	1,000	1	40 hours	40,000
897.29	1,000	1	1,000 hours	1 million
897.32	200,000	1	20 minutes	66,667
897.40	200,000	1	20 minutes	66,667
Total				1,173,334

The agency has submitted a copy of the proposed rule to OMB for its review of these information collections. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden. Comments should be sent to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, rm. 3208, New Executive Office, Washington, DC 20503, Attn: Desk Officer for FDA.

VI. Executive Orders

A. Executive Order 12606: The Family

Executive Order 12606 directs Federal agencies to determine whether policies and regulations may have a significant impact on family formation, maintenance, and general well-being. FDA has analyzed this proposed rule in accordance with Executive Order 12606, and has determined that it has no potential negative impact on family formation, maintenance, and general well-being.

FDA has determined that this rule will not affect the stability of the family, and particularly, the marital commitment. It will not have any significant impact on family earnings.

The proposed rule would not impede the parental authority and rights in the education, nurture, and supervision of children. Rather, the proposed rule would, if finalized, help the significant majority of American families that seek to discourage their children from using cigarettes and smokeless tobacco products. The pervasive promotion and easy availability of these products, despite existing laws in all 50 States prohibiting their sale to children, severely hinder the individual family from carrying out this function by itself.

Section 1(g) of Executive Order 12606 requires that FDA assess the proposed rule in light of the message, if any, it sends to young people ''concerning the relationship between their behavior, their personal responsibility, and the norms of our society.'' The proposed rule would, if finalized, help reduce the conflict between the anti-smoking messages issued by Federal and State authorities and the pro-tobacco messages seen in advertising. This would enable young people to understand how prevalent tobacco use is in society and also appreciate how their decisions regarding cigarette and smokeless tobacco use can affect their health.

Although Executive Order 12606 does not require that individuals or organizations be permitted to participate in proposed rulemaking proceedings, FDA expressly requests all such interested parties to submit comments and suggestions regarding this rule's effect on the family.

B. Executive Order 12612: Federalism

Executive Order 12612 requires Federal agencies to carefully examine regulatory actions to determine if they would have a significant effect on federalism. Using the criteria and principles set forth in the order, FDA has considered the proposed rule's impact on the States, on their relationship with the Federal Government, and on the distribution of power and responsibilities among the various levels of government. FDA concludes that this proposal is consistent with the principles set forth in Executive Order 12612.

Executive Order 12612 states that agencies formulating and implementing policies are to be guided by certain federalism principles. Section 2 of Executive Order 12612 enumerates fundamental federalism principles. Section 3 states that, in addition to these fundamental principles, executive departments and agencies shall adhere, to the extent permitted by law, to certain listed criteria when formulating and implementing policies that have federalism implications. Section 4 lists special requirements for preemption.

Executive Order 12612 recognizes that Federal action limiting the discretion of State and local governments is appropriate ''where constitutional authority for the action is clear and certain and the national activity is necessitated by the presence of a problem of national scope'' (section 3(b)). The constitutional basis for FDA's authority to regulate drugs and devices is well established.

Moreover, in developing the provisions of this proposed rule, the agency carefully considered the provisions of the proposed rule implementing section 1926 of the Public Health Service Act, the Substance Abuse Prevention and Treatment block grant program. As a condition of receipt of such grants, a State must have in place a law that prohibits the sale or distribution of any tobacco product to individuals under age 18 and enforce the law in a manner that can reasonably be expected to reduce the extent to which tobacco products are available to individuals under the age of 18. The statute prescribes random, unannounced inspections, but otherwise allows the States considerable flexibility in designing their enforcement programs. By imposing the explicit obligations on manufacturers, distributors, and retailers to control access by children and adolescents to nicotine-containing cigarettes and smokeless tobacco products, the FDA proposals will help States achieve their goals under their substance abuse programs. FDA therefore believes that the two programs complement each other.

The proposed rule would establish uniform minimum standards with respect to the labeling, advertising, sale, and distribution of nicotine-containing cigarettes, cigarette tobacco, and smokeless tobacco products. The proposed rule would expressly provide, however, that these regulations do not preempt State and local laws, regulations, and ordinances that establish higher standards with respect to these products, or affect these products in areas not covered by the proposed rule, e.g., environmental smoke.

The proposed regulation of nicotine-containing cigarettes, cigarette tobacco, and smokeless tobacco is narrowly drawn. First, it focuses on reducing methods of promotion that are either expressly designed to appeal to American youths, or that are designed without regard to their appeal to American youths. Second, it focuses on reducing the easy access of these nicotine containing products by American youths.

The agency concludes that the policy proposed in this document: Has been assessed in light of the principles, criteria, and requirements in Executive Order 12612; is not inconsistent with that Order; will assist States in fulfilling their obligation under the Substance Abuse Prevention and Treatment block grant program; will not impose additional costs or burdens on the States; and will not affect the States' ability to discharge traditional State governmental functions.

Section 4 of Executive Order 12612 states that an executive department or agency proposing to act through rulemaking to preempt State law is to provide all affected States notice and opportunity for appropriate participation in the proceedings. As required by the Executive Order, States have, through this notice of proposed rulemaking, an opportunity to participate in the proceedings (section 4(e)). Consistent with Executive Order 12612, FDA requests information and comments from interested parties, including but not limited to State and local authorities, on these issues of federalism.

C. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights

Executive Order 12630 directs Federal agencies to ''be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning and carrying out governmental actions so that they do not result in the imposition of unanticipated or undue additional burdens on the public fisc.'' Section 3(a). Section 3(c) of the order states that actions taken to protect the public health and safety ''should be undertaken only in response to real and substantial threats to public health and safety, be designed to advance significantly the health and safety purpose, and be no greater than is necessary to achieve the health and safety purpose.'' Additionally, section 4(d) requires, as a prerequisite to any proposed action regulating private property use for the protection of public health and safety, each agency to: (1) Clearly identify the public health or safety risk created by the private property use that is the subject of the proposed action; (2) establish that the proposed action substantially advances the purpose of protecting the public health and safety against the identified risk; (3) establish, to the extent possible, that the restrictions imposed on private property are not disproportionate to the extent to which the use contributes to the overall risk; and (4) estimate, to the extent possible, the potential cost to the government should a court later determine that the action constitutes a taking.

The agency has considered whether the proposed rule would result in a ''taking'' of private property. The proposed rule would, if finalized, restrict outdoor advertising from being placed within 1,000 feet of any elementary or secondary school or playground, eliminate cigarette vending machines and self-service displays, ban all brand identifiable non-tobacco items, such as hats and tee shirts, prohibit the use of a trade name of a non-tobacco item for any tobacco product, and require established names and a brief statement on labels, labeling, and/or advertising. In addition, the proposed rule would require that all sponsored events be carried out only in the corporate name. While these requirements might affect private property, they do not constitute ''takings.''

In determining whether a governmental action has resulted in a ''taking,'' recent court decisions have

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. Environmental Impact

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

VIII. Analysis of Impacts

A. Introduction and Summary

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

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

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

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

costs (mostly for educational programs). In addition, they would face significant advertising restrictions. Retailers would pay $11 million in one-time costs and $52 million in annual costs. On an annualized basis, using a 3 percent discount rate over 15 years, costs for these initial requirements total about $230 million (also about $230 million at a 7 percent discount rate). Achieving the ''Healthy People 2000'' goals, however, could demand still further efforts by tobacco manufacturers to restrict youth access to tobacco products. Moreover, FDA plans to propose additional requirements that would become effective only if these goals were not met.

TABLE 1—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES
[Undiscounted lives and life-years; 3% discount rate for monetary values]

Fraction of teenage cohort deterred	Fewer adult smokers**	Lives saved	Life-years saved	Medical savings	Morbidity-related productivity savings	Mortality-related willingness-to-pay		Total benefits	
						Life-years saved	Lives saved	Low	High
	(No.)	(No.)	(No.)	($bils.)	($bils.)	($bils.)	($bils.)	($bils.)	($bils.)
1/2*	250,000	60,200	905,300	2.6	0.9	24.6	39.7	28.1	43.2
1/3	167,000	40,100	603,600	1.8	0.6	16.4	26.4	18.8	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.9	15.9	11.4	17.4
1/10	50,000	12,000	181,100	0.5	0.2	4.9	7.9	5.6	8.6
1/20	25,000	6,000	90,500	0.3	0.1	2.5	4.0	2.9	4.3

*Estimate used in analysis.
**Assumes 50% of adolescents who are deterred from smoking refrain as adults.

TABLE 2—INDUSTRY COSTS FOR CORE PROVISIONS
[$mils.]

Requirements by sector*	One-time costs	Annual operating costs	Total annualized costs**
Tobacco Manufacturers	15–28	175	177
Visual Inspections		24	24
Training		1	1
Label Changes	4–17		1
Self-Service Ban	11		1
Educational Programs		150	150
Retail Establishments	11	52	53
Training		10	10
I.D. Checks		28	28
Self-Service Ban	11	14	15
TOTAL	26–39	227	230

*Advertising restrictions are considered under distributional effects.
**Sum of one-time costs annualized over 15 years at 3 percent and annual operating costs.

Consumers would incur costs to the extent that they lose positive utility received from the imagery embodied in product advertising campaigns. Consumers would also lose the convenience offered by the use of cigarette vending machines. Costs for these compliance activities were based on the agency's best estimate of the resources that would be needed to establish effective programs for decreasing the incidence of lifelong addictions to nicotine-containing cigarettes and smokeless tobacco products.

In addition to the costs described above, the proposal would create distributional and transitional effects. While the overall impact of these changes on the national economy would be small, because dollars not spent on tobacco-related expenditures would be spent on other goods or services, several individual industries would be affected. Tobacco manufacturers and suppliers would face increasingly smaller sales, because reduced tobacco consumption by youth would lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues would be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent, substantially mitigating the costs associated with any resource dislocation. Also, if State excise tax rates on tobacco products remain at current levels, State tax revenues would decrease slowly over time, falling by $252 million by the tenth year.

Tobacco manufacturers spent $6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent would be substantially altered to reflect the various ''text only'' restrictions or other prohibitions. If tobacco advertising outlays declined, various service agencies and communications media (including suppliers of retail counter and other display space) would need to attract replacement sponsors. Similarly, vending machine operators would need to find substitute products to replace that portion of their revenue that is currently derived from the sale of cigarettes. Many of these adjustments would occur quickly (e.g., TV networks reportedly recouped advertising revenues within 1 year of the 1971 ban), but others could create short-term disruptions as businesses moved to replace lost product lines.

In sum, FDA finds that compliance with this proposed rule would impose some economic costs on the tobacco industry and short-term costs on several other industry sectors. With regard to small businesses, most impacts would

be small or transitory. For a small retail convenience store not currently complying with this proposal, the additional first year costs could reach $320. For those convenience stores that already check customer identification, these costs fall to $35. Moreover, the proposed rule would not produce significant economic problems at the national level, as the gradual displacement in tobacco-oriented sectors would be largely offset by increased output in other areas. Thus, pursuant to the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation would greatly exceed the compliance costs that it would impose on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current proposal is the least burdensome alternative that would meet the ''Healthy People 2000'' goals.

B. Statement of Need for Proposed Action

The need for action stems from the agency's determination to ameliorate the enormous toll on the public health that is directly attributable to the consumption by adolescents of cigarettes and smokeless tobacco products. According to the nation's most knowledgeable health experts, tobacco use is the most important preventable cause of morbidity and premature mortality in the United States, accounting each year for over 400,000 deaths (approximately 20 percent of all deaths). Moreover, these morbidity and mortality burdens do not spare middle aged adults—with the average smoking-related death responsible for the loss of up to 15 life-years.[1]

In its guidelines for the preparation of Economic Impact Analyses, OMB asks that Federal regulatory agencies determine whether a market failure exists and if so, whether that market failure could be resolved by measures other than new Federal regulation. The basis for this request derives from standard economic welfare theory, which by assuming that each individual is the best judge of his/her own welfare, concludes that perfectly competitive private markets provide the most efficient use of societal resources. Accordingly, the lack of perfectly competitive private markets (market failure) is frequently used to justify the need for government intervention. Common causes of such market failures include monopoly power, inadequate information, and market externalities or spillover effects.

While FDA believes that various elements of market failure are relevant to the problem of teenage tobacco addiction, the agency also believes that the proposed regulatory action could be justified even in the absence of a traditional market failure. As noted above, the implications of the market failure logic are rooted in a basic premise of the standard economic welfare model—that each individual is the best judge of his/her own welfare. However, FDA is convinced that this principle does not apply to children and adolescents. Even steadfast defenders of individual choice acknowledge the difficulty of applying the ''market failure'' criterion to non adults. Littlechild, for example, adds a footnote to the title of his chapter on ''Smoking and Market Failure'' [2] to note that ''[t]he economic analysis of market failure deals with choice by adults.'' FDA finds this statement consistent with its view that even if many children make rational choices,[3] the agency's regulatory determinations must reflect the societal conviction that children under the age of legal consent cannot be assumed to act in their own best interest.[4]

In particular, FDA finds that the imagery used in industry advertising and promotional programs obscures adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. The preceding sections of this preamble describe numerous studies on the shortcomings of the risk perceptions held by children. Although most youngsters acknowledge the existence of tobacco-related health risks, the abridged time horizons of youth make them exceptionally vulnerable to the powerful imagery advanced through targeted industry advertising and promotional campaigns. In effect, these conditions constitute an implicit market failure that has not been adequately remedied by government action.

Moreover, the agency does not view these results as inconsistent with the growing economic literature based on the Becker and Murphy models of ''rational addiction.'' [5] Although several empirical studies have demonstrated that, for the general population, cigarette consumption is ''rationally addictive'' in the sense that current consumption is affected by both past and future consumption,[6] Chaloupka notes that this ''rationality'' does not hold for younger or less educated persons, for whom past but not future consumption maintains a significant effect on current consumption. He concludes, ''[t]he strong effects of past consumption and weak effects of future consumption among younger or less educated individuals support the a priori expectation that these groups behave myopically.'' [7]

A further market failure would exist if the use of tobacco imposed external or spillover costs on nonusers. Many studies have attempted to calculate the societal costs of smoking, but few have addressed these externalities. The most detailed research on whether smokers pay their own way is the 1991 study by Manning, et al., ''The Cost of Poor Health Habits,'' [8] which develops estimates of the present value of the lifetime external costs attributable to smoking. This study examines differences in costs of collectively financed programs for smokers and nonsmokers, while simultaneously controlling for other personal characteristics that could affect these costs (e.g., age, sex, income, education, and other health habits, etc.). The authors found that nonsmokers subsidize smokers' medical care, but smokers (who die at earlier ages) subsidize nonsmokers' pensions. On balance, they calculated that before accounting for excise taxes, smoking creates net external costs of about $0.15 per pack of cigarettes in 1986 dollars ($0.33 per pack adjusted to 1995 dollars by the medical services price index.) While acknowledging that these estimates ignored external costs associated with lives lost due to passive smoking, perinatal deaths due to smoking during pregnancy, and deaths and injuries caused by smoking- related fires, the authors concluded that there is no net externality, because the sum of all smoking-related externalities is probably less than the added payments imposed on smokers through current Federal and State cigarette excise taxes. A Congressional Research Service report to Congress examined estimates of the potential magnitude of the omitted costs and concurred with this finding.[9]

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the proposed regulation include the costs that would be avoided by eliminating the adverse health effects associated with the consumption of tobacco products. Most research on the costs of smoking-related illness has concentrated on the medical costs and productivity losses associated with the prevalence of death and illness in a given year. These prevalence-based studies typically measure three components: (1) The contribution of smoking to annual levels of illness and death, (2) the direct costs of providing extra medical care, and (3) the indirect

costs, or earnings foregone due to smoking-related illness or death.[10]

In a recent statement, the U.S. Office of Technology Assessment (OTA) declared that ''the greatest 'costs' of smoking are immeasurable insofar as they are related to dying prematurely and living with debilitating smoking-related chronic illness with attendant poor quality of life.'' Nonetheless, OTA calculated that in 1990 the national cost of smoking-related illness and death amounted to $68 billion and included $20.8 billion in direct health care costs, $6.9 billion in indirect morbidity costs, and $40.3 billion in lost future earnings from premature death.[11] More recently, the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at $50 billion.[12] Unfortunately, these prevalence-based studies do not answer many of the most important questions related to changes in regulatory policy, because they present the aggregate cost of smoking-related illness in a single year, rather than the lifetime cost of illness for an individual smoker. As noted in the 1992 Report of the Surgeon General, most prevalence-based studies fail to consider issues concerning ''the economic impact of decreased prevalence of cigarette smoking, the length of time before economic effects are realized, the economic benefits of not smoking, and a comparison of the lifetime illness costs of smokers with those of nonsmokers.'' [13] In effect, although these studies are designed to measure the smoking-related draw on societal resources, they are not well-suited for analyzing the consequences of regulatory-induced changes in smoking behavior.

2. FDA's Methodology

An alternative methodology, termed incidence-based research, compares the lifetime survival probabilities and expenditure patterns for smokers and nonsmokers. As this approach models the individual life-cycle consequences of tobacco consumption, FDA has relied on these incidence-based studies to value the beneficial effects of the proposed rule over the lifetime of each new cohort of potential smokers. The methodology incorporates the following steps:

- A projection of the extent to which the rule would reduce the incidence, or the annual number of new adolescent users of tobacco products
- A projection of the extent to which the reduced rates of adolescent tobacco consumption would translate to reduced rates of lifetime tobacco consumption
- A projection of the extent to which the reduced rates of lifetime tobacco consumption would decrease the number of premature deaths and lost life-years
- An exploration of various means of estimating the monetary value of the expected health improvements.

The annual benefits of the proposed regulation are measured as the present value of the lifetime benefits gained by those youngsters, who in the absence of the proposed regulation, would have become new smokers.

3. Reduced Incidence of New Young Tobacco Users

Each year, an estimated 1 million youngsters become new smokers. The proposed regulation targets this group by restricting youth access to tobacco products and by limiting advertising activities that affect adolescents. Several communities have demonstrated that access restrictions are extremely effective when vigorously applied. Woodridge, IL, for example, achieved a compliance rate of over 95 percent. Moreover, 2 years after that law was enacted, a survey of 12 to 14 year-old students indicated that overall smoking rates were down by over 50 percent (over ⅔ for regular smokers).[14]

The proposed advertising and promotional restrictions would augment these efforts to limit the attraction of tobacco products to underage consumers. As discussed in detail in the preamble above, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, the majority of the relevant research indicates that advertising restrictions would reduce consumer demand. For example, according to the 1989 report of the Surgeon General, ''The most comprehensive review of both the direct and indirect mechanisms concluded that the collective empirical, experiential, and logical evidence makes it more likely than not that advertising and promotional activities do stimulate cigarette consumption.'' [15] Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the UK Department of Health determined that, ''the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption.'' [16]

In Northern California, 24 cities and unincorporated areas in 5 counties adopted local youth tobacco access ordinances that prohibit self-service merchandising and point-of-sale tobacco promotional products in retail stores. Survey measures of the impact of these ordinances by the Stop Tobacco Access for Minor Project (STAMP) found that, on average, tobacco sales to minors dropped 40 percent to 80 percent.[17]

In the August 26, 1993, **Federal Register**, the Substance Abuse and Mental Health Services Administration (SAMHSA) proposed a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. FDA strongly supports the basic objectives of this program, but believes that their full achievement would demand a broad arsenal of controls; including industry programs to complement and fortify the new State inspectional programs, together with restrictions on industry advertising and promotions to counter the influence of ongoing marketing activities. While quantitative estimates of the effectiveness of these activities cannot be made with certainty, FDA believes that, if aggressively implemented and supported by both industry and public sector entities, comprehensive programs designed to discourage youthful tobacco consumption could reasonably achieve the ''Healthy People 2000'' goal of halting the onset of smoking for at least half, or 500,000, of the 1,000,000 youngsters who presently start to smoke each year.

The agency acknowledges the imposing size of the required effort and understands that the performance goals may not be fully attainable if the affected industry sectors choose to ignore the new incentives established by the proposed regulation. After all, the industry's long- term profits hinge on attracting new customers. Nonetheless, FDA is confident that the combined effect of the proposed restrictions on advertising and promotion, prohibition of self-service tobacco products (including vending machines), new labeling information and educational programs, and age verification obligations for retailers would significantly diminish the allure as well as the access to tobacco products by youth. Moreover, if the performance goals are not met 7 years after the effective date of the final rule, additional requirements would enhance the effectiveness of these activities. Thus, this study projects regulatory benefits on the presumption that the ''Healthy People 2000'' goals would be met, but also presents results for effectiveness levels that are considerably smaller.

4. Reduced Rate of Lifetime Tobacco Use

As part of its regulatory proposal, SAMHSA assumed that its new monitoring program would significantly reduce the amount of underage

smoking, but its methodology did not project these reduced smoking rates into adult years. SAMHSA acknowledged the conservative nature of its estimate and noted the likelihood that the majority of the cost savings would accrue over long time spans, ''as each cohort of non-smoking youth ages into non-smoking adults.'' Nevertheless, SAMHSA did not quantify these lifetime benefits, ''because there are so many uncertainties as to future outcomes.'' While agreeing that long term benefit projections are uncertain, FDA is convinced that estimates based on valid assumptions can provide reasonable approximations of future cost savings.

The major beneficiaries of the proposed rule are those individuals who would otherwise become addicted to tobacco early in life, but who are unlikely to start using tobacco products as an adult. Evidence from SAMHSA suggests that this percentage will be high as most smokers become daily cigarette smokers before the age of 18. The 1994 Surgeon General's Report indicates that 82 percent of persons (aged 30 to 39) who ever smoked daily began to smoke before the age of 18. That report concludes that ''if adolescents can be kept tobacco-free, most will never start using tobacco.'' FDA agrees with that assessment, but notes that the above percentage may not reflect the ultimate demand for tobacco consumption that may occur if adolescent access is effectively limited. Thus, to account for this possibility, FDA conservatively assumed that this proposed regulation would prevent the use of tobacco as an adult for only one half of the estimated 500,000 youngsters who would be deterred from starting to smoke each year. Accordingly, FDA has calculated the annual benefits of the proposed rule from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult.

5. Lives Saved

FDA calculated the number of smoking-related deaths that would be averted by the 250,000 lifetime nonsmokers (who in the absence of the proposed regulation would be smokers) from age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate were derived from the American Cancer Society's Cancer Prevention Study II, as shown in Table 3.

TABLE 3—PROBABILITY OF SURVIVAL BY AGE, SEX, AND SMOKING STATUS

[Probabilities of a 17-Year-Old Surviving to Age Shown]

Age (years)	Male neversmokers	Male all smokers	Female neversmokers	Female all smokers
35	1	1	1	1
45	0.986	0.966	0.988	0.984
55	0.951	0.893	0.962	0.939
65	0.867	0.733	0.901	0.831
75	0.689	0.466	0.760	0.630
85	0.336	0.159	0.453	0.289

Source: Thomas Hodgson, ''Cigarette Smoking and Lifetime Medical Expenditures,'' ''The Milbank Quarterly,'' vol. 70, no. 1, 1992, p. 91. Based on data from the American Cancer Society's Cancer Prevention Study II.

FDA initially compared the probability of death for smokers versus nonsmokers within each 10-year period. Differences in the probabilities of death were then multiplied by the number of smokers remaining at the start of each 10-year period. Excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. Because these data do not account for potentially confounding variables, such as alcohol consumption, or other lifestyle differences, FDA adjusted the mortality estimate to 24 percent to reflect findings by Manning et al.[18] that such nontobacco lifestyle factors may account for 13 percent of excess medical care expenditures. FDA recognizes that this 24 percent mortality estimate may be too low. For example, Peto, et al. found that about half of all adolescents who continue to smoke regularly will eventually die from smoking-related disease.[19] Moreover, CDC projects that up to 1 in 3 adolescent smokers may die prematurely. Nevertheless, for this analysis, FDA relied on the probabilities shown in Table 3, corrected by the 13 percent lifestyle influence adjustment, to project that achieving the ''Healthy People 2000'' performance goal would prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.[20]

The economic assessment of health-related variables requires discounting the value of future events to make them commensurate with the value of present events. For this analysis, a 3 percent discount rate was used to calculate the present value of the projections. (Most health-related cost-effectiveness studies use rates of from 3 to 5 percent. FDA presents summary estimates below for rates of both 3 and 7 percent.) On the assumption that it would be 20 years before each year's cohort of new adults reached the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that, on a present value basis, the proposed rule would save 15,863 lives per year.

6. Life-Years Saved

The number of life-years that would be saved by preventing each year's cohort of 250,000 adolescents from acquiring a smoking addiction was calculated from the same age-specific survival differences between smokers and non-smokers. In each 10-year life span, the number of years lived for each cohort of persons who would have been smokers but who were deterred was compared to the number of years that would have been lived by that same cohort if they had been smokers. The difference between these two measures is the life-years saved for that 10-year period.[21] Deducting the 13 percent lifestyle adjustment indicates that over the full lifetime of each cohort, the proposed regulation would gain an estimated 905,000 life-years, or about 15 years per life saved. On a discounted basis, the proposed rule would save an estimated 211,391 life-years annually.

7. Monetized Benefits of Reduced Tobacco Use

There is no fully appropriate means of assigning a dollar figure to represent the attendant benefits of averting thousands of tobacco-induced illnesses and fatalities. However, to quantify important components of the expected economic gains, FDA has developed estimates of the value of the reduced medical costs and the increased worker productivity that would result from

fewer tobacco-related illnesses. In addition, since productivity measures do not adequately value the avoidance of premature death, FDA has adopted a willingness-to-pay approach to value the benefits of reduced tobacco-related fatalities.

8. Reduced Medical Costs

On average, at any given age, smokers incur higher medical costs than nonsmokers. However, nonsmokers live longer and therefore continue to incur medical costs over more years. Several analysts have reported conflicting estimates of the net outcome of these factors, but the most recent research is the incidence-based study by Hodgson,[22] who found that lifetime medical costs for male smokers were 32 percent higher than for male neversmokers and lifetime medical costs for female smokers were 24 percent higher than for female neversmokers. Hodgson determined that the present value of the lifetime excess costs were about $9,400 in 1990 dollars (future costs discounted at 3 percent).[23] As noted earlier, the incidence-based study by Manning et al., implies that about 13 percent of the excess medical costs are attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index (CPI) for medical care raises the present value of Hodgson's excess medical cost per new smoker to $10,590 in 1994 dollars. Thus, those 1,000,000 young people under the age of 18, who currently become new smokers each year, are responsible for excess lifetime medical costs measured at a present value of $10.6 billion (1,000,000 x $10,590). Since FDA projects that the proposed regulation would prevent 250,000 of these individuals from smoking as adults, the medical cost savings attributable to the proposed regulation is estimated at $2.6 billion per year.

9. Reduced Morbidity Costs

An important cost of tobacco-related illness is the value of the economic output that is lost while individuals are unable to work. Thus, any future reduction in such lost work days contributes to the economic benefits of the proposed regulation. Several studies have calculated prevalence-based estimates of U.S. productivity losses due to smoking-related morbidity, but FDA knows of no incidence-based estimates. Hodgson, however, has shown that in certain situations, incidence measures can be derived from available prevalence measures. For example, he demonstrates that in a steady-state model, the only difference between prevalence and incidence-based costs are due to discounting.[24] Consequently, FDA has adopted Hodgson's method to develop a rough approximation of incidence-based costs from an available prevalence-based estimate of morbidity costs.

Rice et al.[25] found that lost wages due to tobacco-related work absences in the United States amounted to $9.3 billion in 1984. This equates to $12.3 billion in 1994 dollars when adjusted by the percentage change in average employee earnings since 1984. Although FDA does not have a precise estimate of the life-cycle timing of these morbidity effects, the relevant latency periods would certainly be shorter than for mortality effects. Thus, to account for the deferred manifestation of smoking-related morbidity effects, FDA assumed that they would occur over a time horizon equal to 80 percent of that previously measured for mortality effects. Further, because the long-term decline in smoking prevalence has exceeded the growth in population, the estimated incidence-based costs were reduced by another 20 percent. At a 3 percent discount rate, this methodology implies that the incidence-based cost of smoking-related morbidity, or the present value of the future costs to one year's cohort of 1,000,000 new smokers, is about $3.5 billion. Based on FDA's estimate that the proposed regulation would prevent 250,000 youths per year from smoking as adults, the estimated annual benefits from reduced morbidity amount to about $879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Unfortunately, the specific willingness-to-pay of smokers is unknown, because institutional arrangements in the markets for medical care obscure direct measurement techniques.[26] Nevertheless, many studies have examined the public's willingness-to-pay to avoid other kinds of life-threatening risks, especially workplace and transportation hazards. An EPA-supported study[27] found that most empirical results support a range of $1.6 to $8.5 million (in 1986 dollars) per statistical life saved, which translates to $2.2 to $11.6 million in 1994 dollars. However, the uncertainty surrounding such estimates is substantial. Moreover, Viscusi has shown that smokers, on average, may be willing to accept greater risks than nonsmokers. For example, smokers may accept about one-half the average compensation paid to face on-the-job-injury risks.[28] FDA therefore has conservatively used $2.5 million per statistical life, which is towards the low end of the research findings, to estimate society's willingness-to-pay to avert a fatal smoking-related illness. Thus, the annual benefits of avoiding the discounted number of 15,863 premature fatalities would be $39.7 billion.

An alternative method of measuring willingness-to-pay is to calculate a value for each life-year saved. This approach, which is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age, is the traditional means of assessing the cost-effectiveness of medical interventions. Nevertheless, there have been few attempts to determine the appropriate value of a life-year saved. OMB suggests several approaches, including annualizing with an appropriate discount rate the estimated value of a statistical life over the average expected life-years remaining. For example, at a 3 percent discount rate, a $2.5 million value per statistical life for an individual with 35 years of remaining life-expectancy translates to about $116,500 per life year. Since the proposed regulation would save 211,391 discounted life-years annually, this approach yields annual benefits of $24.6 billion. FDA notes that this approach does not attribute any value to lost consumer utility from tobacco product consumption and solicits public comment on this methodology.

11. Reduced Fire Costs

Every year lighted tobacco products are responsible for starting fires which cause millions of dollars in property damage and thousands of casualties. In 1992, fires started by lighted tobacco products caused 1,075 deaths and $318 million in direct property damage.[29] A reduction in the number of smokers, and the coinciding number of cigarettes smoked, would result in a drop in the number of fires over the years. If the number of fires fell by the same percentage as the expected reduction in cigarette sales, this would imply present value savings due to fewer fires of $203 million for the value of lives saved and $24 million for the value of averted property damage, totaling $227 million annually over a 40-year period. Moreover, these estimates do not include costs for nonfatal injuries or for providing temporary housing.

12. Summary of Benefits

The discussion above demonstrates the formidable magnitude of plausible estimates of the economic benefits available from smoking reduction efforts. As described, FDA forecasts

annual net medical cost savings of $2.6 billion and annual morbidity-related productivity savings of $900 million. From a willingness-to-pay perspective, the annual benefits of reduced tobacco-related disease mortality range from $24.6 to $39.7 billion. As a result, the value of the annual disease-related benefits of achieving the ''Healthy People 2000'' goal is projected to range from $28.1 to $43.2 billion. (Following Hodgson, this analysis uses a 3 percent discount rate. A 7 percent rate reduces these benefits to a range of $9.1 to $10.4 billion.) These totals do not include the benefits expected from fewer fires (over $200 million annually), reduced passive smoking, or decreased use of smokeless tobacco products. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates would still yield impressive results. Table 1 above summarized the disease-related health benefits and illustrates that youth deterrence rates as small as 1/20, which would prevent the adult addiction of at least 25,000 of each year's cohort of 1,000,000 new adolescent smokers, would provide annual benefit values measured in the billions of dollars. Moreover, the higher risk estimates suggested by Peto, et al. could significantly increase these values.

D. Regulatory Costs

OMB guidelines for Regulatory Impact Analysis direct that agency cost estimates reflect the opportunity costs of the proposed alternative (i.e., the value of the benefits foregone as a consequence of that alternative.)[30] According to these guidelines, estimates should include ''private-sector compliance costs, government administrative costs, and costs of reallocating workers displaced as a result of the regulation * * * Such costs may include the value (opportunity cost) of benefits foregone, losses in consumers' or producers'' surpluses, discomfort or inconvenience, and loss of time.''[31] Accordingly, FDA finds that the proposed rule would impose new burdens on the manufacturers of tobacco products and less stringent requirements on retailers of tobacco products. In addition, certain other industry sectors would experience lost sales and employment, but these effects would be largely offset by gains to other sectors, as discussed in section VIII.E. of this document.

A critical variable underlying several of the cost estimates is the number of retail outlets that sell tobacco products. According to the Retail Trade Census, a total of 2.4 million retail trade establishments operated in 1987. Unfortunately, the Retail Trade Census publishes product line data for only the 1.5 million retail establishments with payroll. Of these, about 275,000 report sales for the broad merchandise line of ''Cigars, cigarettes, and tobacco.'' FDA does not know how many of the nonpayroll outlets sell tobacco products. There were about 215,000 nonpayroll outlets among the most likely establishment types (grocery stores, service stations, drug stores, liquor stores, drinking places, general merchandise, and eating places.) If all of these nonpayroll stores sold tobacco products (an unreasonably high estimate considering that only 34 percent of those with payroll reported sales of tobacco merchandise), the total number of retail establishments selling over-the-counter tobacco products would be 275,000 + 215,000, or 490,000. Moreover, these data may overstate the number of outlets operating at any one time, because they represent the number of establishments in business at any time during the year and outlet turnover is significant. The figure may be understated, however, if a substantial number of nonpayroll stores that sell tobacco products are classified among other establishment types.

Alternatively, New Jersey issued about 18,300 retail cigarette sales licenses in 1988, but the census estimate for the number of retail establishments with payroll selling tobacco products in that state was only about 6,000. This implies that over twice as many nonpayroll outlets sell tobacco products as outlets with payrolls. If the New Jersey licensing data, which imply about 2.4 cigarette licenses per 1,000 population, were extrapolated to the United States, they project to about 600,000 such outlets nationwide. However, this estimate also may overstate the current number of establishments selling tobacco products at any one time, because of the high failure rate among small businesses obtaining licenses (i.e. more licenses issued than establishments surviving).

Neither the census nor the New Jersey data account for those outlets that may convert cigarette vending machine sales to over-the-counter sales once vending machines are banned as proposed in this regulation. Industry estimates of the number of cigarette vending machines in operation in 1993 vary from 182,000[32] to 480,000[33]. FDA does not know how many of these operations would convert to over-the-counter sales, but for this study, the agency has assumed that about 100,000 establishments would initiate new over-the-counter operations to replace lost vending machine sales. Thus, FDA estimates that a maximum of about 700,000 retail outlets would continue to sell tobacco products.

1. Costs to Manufacturers

a. *Core requirements.* Under the proposed regulation, manufacturers of tobacco products would incur compliance costs for the following requirements: visual inspections of retail outlets, training manufacturers' representatives, changing package labels, assisting self-service bans, and financing consumer education programs.

b. *Visual inspections.* The manufacturer is responsible for removing all items that do not comply with the requirements of this proposal and for visually inspecting each retail establishment during any visit to such establishment, to ensure that the products are appropriately labeled, advertised, and sold, or distributed. Thus, manufacturer inspections would be required during every business visit to a tobacco-selling outlet by a manufacturer's representative. As manufacturers' representatives routinely visit most retail outlets selling their products, the proposed requirement would provide a periodic scrutiny of retail tobacco operations without imposing additional travel costs. FDA cannot project these costs precisely, as the intensity of the audit would vary with the characteristics of the retail operation, but the agency believes that most manufacturers' representatives would need little incremental time to conduct routine audits. On average, FDA estimates that each audit would be accomplished by a relatively quick assessment that would take no more than 2 to 3 minutes. The assumption of an additional 3 minutes per visit implies a total of 30 minutes a day for a manufacturer's representative who may visit an average of 10 outlets daily. At a labor cost of $25 per hour, the annual cost of the additional one-half hour spent daily on monitoring would be $3,250 per employee.

FDA does not know how many manufacturers' representatives currently make sales calls on tobacco product retailers, but preliminary results from the 1992 U.S. Census of Manufacturers indicate that cigarette manufacturers employ about 7,300 nonproduction workers. Thus, if all nonproduction workers were engaged in retail sales, the industry monitoring costs would approach $24 million per year ($3,250 × 7,300). However, many nonproduction employees serve in management or clerical positions. Moreover, the above cost estimate fails to account for the likely relationship between the total time needed for a manufacturers'

representative to visit a retail outlet and the type of promotional activities permitted. For instance, the ban on self-service displays may cause manufacturers' representatives to spend less time conducting display inspections. Thus, FDA suspects that the above cost estimate may be high.

c. *Training.* Each manufacturer's representative would have to receive training on the requirements of the regulation and the new monitoring responsibilities of their position. FDA estimates that this training could be accomplished in about 8 hours. Thus, assuming that the 7,300 estimate for the number of manufacturers' representatives adequately accounts for normal employee turnover, the annual training costs would total about $1 million.

d. *Label changes.* The proposed regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA has estimated the compliance costs for printing new labels in the event that new labels would be needed.

Approximately 933 varieties of cigarettes are currently produced in the United States.[34] FDA does not have information on the number of smokeless tobacco varieties, but has assumed that the total number of cigarette and smokeless tobacco varieties is 1,000. FDA also assumes that most varieties of cigarettes are packaged in both single packs and cartons, but that each variety of smokeless tobacco is packaged in only one type of package. Consequently, the total number of labels was calculated as: 933 cigarette varieties × 2 package types per variety (individual packs and cartons) + 67 smokeless tobacco varieties = 1,933 package types.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach used information compiled by The Research Triangle Institute (RTI) in its report to FDA on the cost of changing food labels.[35] RTI reported a cost of about $700 for a 1-color change in a lithographic printing process. FDA multiplied this figure by 4 to account for a 2 color change on the actual warning labels and an additional 2 colors for modifications to the existing label to make room for the warning label. This calculation yielded incremental printing costs of about $2,800 per label, or $5,412,400 for all 1,933 varieties of affected tobacco products. Adjusting this figure downward by RTI's methodology to account for the current frequency of label redesign predicts that the total one-time cost of completing these label changes within a 1-year compliance period would be approximately $4 million.

The second approach was to use cost information provided in the regulatory impact analysis of a roughly comparable Canadian regulation.[36] The Canadian Government estimated a cost of $30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are sold in two sizes and about 20 percent are also sold in flip top packages.[37] Canadian labels, however, are typically printed using a gravure method; which, according to RTI, is about 3.5 times as expensive as the lithography process used in the United States. Adjusting the Canadian estimate upward, to account for the larger number of cigarette and smokeless tobacco varieties; and downward, for the smaller number of packages per variety and the smaller cost of the lithography printing process, provides a $17 million estimate for the total cost of these label changes.

e. *Self-service ban.* The proposed regulation would ban the use of self-service displays by requiring vendors to physically provide the regulated tobacco product to all purchasers. An estimated one-time cost of $22.5 million for effecting this change is derived below in section VIII.D.3. Although any new behind-the-counter shelving or locking cases must be located at the retail level, the prevailing business practice is for tobacco manufacturers' sales representatives to assist and even pay for this equipment.[38] Since FDA cannot know if manufacturers would continue this practice, this study assumes that manufacturers and retailers would share these costs equally by apportioning $11 million to each.

f. *Educational program.* The proposed regulation requires manufacturers of both cigarettes and smokeless tobacco products to fund consumer educational programs. FDA estimates that the requirements of this provision equate to a total cost of about $150 million annually for cigarette and smokeless tobacco product manufacturers.

g. *Restricted advertising/promotion.* The determination of the industry costs attributable to the proposed restrictions on tobacco product advertising is complex. While there is no doubt that individual companies realize enhanced goodwill asset values from advertising programs, the industry has long held that advertising prompts brand-switching, but does not increase aggregate sales. Of course, if this were true, advertising would be unprofitable from the standpoint of the industry as a whole and reduced levels would increase rather than decrease aggregate industry profits. FDA does not accept industry's stated views on this issue, particularly with respect to the impact of advertising and promotional programs on youth. Nevertheless, FDA does not consider it appropriate to count as a societal cost the *voluntary* reduction in the consumption of tobacco products that would result from reduced advertising outlays. Although industry sales would fall, consumer dollars no longer used on tobacco products would be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales and profits would not be societal costs, but rather distributional effects, as discussed below under that heading. Moreover, as shown in that section, any short-term frictional or relocation impacts would be significantly moderated by the gradual phase-in of the economic effects. As there are different views regarding the appropriate methodology for assessing these advertising consequences, FDA asks for public comment on the correct approach.

h. *Producer surplus.* Although voluntary decreases in the sale of tobacco products would not impose substantial long-term societal costs, mandatory restraints on the access of consumers to desired products would imply economic costs. Economists typically measure inefficiencies attributable to product bans by calculating lost ''producers' surplus,'' which is a technical term for describing the difference between the amount a producer is paid for each unit of a good and the minimum amount the producer would accept to supply each unit, or the area between the price and supply curve. Data from Cummings et al. indicate that youngsters under the age of 18 consume 318 million packs of cigarettes per year, leading to industry profits of $117 million.[39] On the assumption that the proposed regulation would reduce teenage smoking by one-half, these profits would fall by about $58 million. However, since most of this profit is derived from illegal sales to youths, FDA has not counted this figure as a societal cost.

2. Outcome-Based Activities

FDA plans to propose additional requirements that would become effective only if the rule's outcome-based objectives are not met. To avoid these consequences, manufacturers may decide it is in their best interest to initiate or to increase their support of programs that discourage underage purchasing of tobacco products.

Alternative activities. Tobacco manufacturers may decide to actively support the achievement of the

''Healthy People 2000'' goals in order to avoid the need to comply with any optional provisions. For example, the industry could work to reduce the prevalence of underage tobacco use by contributing either financial or staffing resources to local civic or public programs, by developing and disseminating effective educational materials, or by establishing its own surveillance programs. FDA does not know which of these activities, if any, the industry might support; but the cost of such activities could be substantially less than the cost of complying with an optional provision of the outcome-based objective. For example, if the cost of a retail surveillance visit were $25, an industry program to monitor selling procedures in all 700,000 retail outlets twice a year would cost $35 million. SAMHSA estimated that the establishment and implementation of effective State-administered retail surveillance systems would cost about $30 million annually.

3. Costs to Retail Outlets

SAMHSA recognized that retail businesses would bear new costs for duties such as training staff, posting signs, and checking for compliance. It believed the largest component of these costs would be for the ''time spent in instructing sales clerks that they must avoid selling to minors and in dealing with occasional lapses.'' SAMHSA projected these costs at roughly $100 per year per establishment, or $100 million for an estimated 1 million establishments. SAMHSA noted, however, that ''effective training may already be in place in a third or more of all businesses.'' [40] FDA has developed its own estimates of the costs likely to be incurred by the retail sector for additional employee time or other expenses and finds that they do not differ substantially from the SAMHSA estimate.

Training. SAMHSA reports that the average retail store has 12 employees, which implies a total of 8.4 million (12 × 700,000) affected retail employees. Assuming retail employee compensation of $15,410 annually,[41] providing instructions for 15 minutes per employee amounts to about $16 million per year. Adopting the SAMHSA finding that one-third of the retail outlets are already conducting some training lowers this cost to $10 million.

I.D. checks. Retail establishments would bear additional costs if they must check the identification of purchasers, because many establishments do not currently conduct such checks. The burden imposed would vary with the flow of business in any particular outlet. In some instances, the additional workload might compel the hiring of additional employees. At other times, the age verification would cause little productive time loss, or the establishment would shift some of the cost to customers through an increase in the average amount of time customers wait in line to make purchases. For this analysis, FDA has assumed that the affected establishments would bear all of the costs imposed by this requirement. Based on data from the 1994 Surgeon General's Report [42] on the tobacco consumption of cigarette smokers 5 to 6 years after high school, and national data on the annual per capita consumption of smokeless tobacco,[43] FDA estimates that consumers aged 18 to 26 purchase 2.4 billion tobacco products a year. Since FDA does not know how many of these purchases are for multiple items, the agency has conservatively assumed that the number of consumer transactions is about 2.2 billion. The time needed to conduct identification checks for these transactions would vary, but if 75 percent of the transactions were extended by 10 seconds and the average value of employee time was $15,410,[44] the added time cost would amount to 2.1 cents per purchase, or $35 million per year. Assuming current compliance at 20 percent reduces the incremental costs to $28 million. Tobacco transactions involving underage smokers were excluded from this calculation, based on the assumption that they would decline dramatically once compliance with the regulation was achieved.

Self-service ban. The proposed ban on self-service displays would affect a number of retail stores, although shoplifting concerns have already caused many establishments to place tobacco products in areas not directly accessible to customers. Retailers that have discontinued self-service displays have typically modified their stores by either: (1) Placing tobacco products on shelving located directly behind or near all checkout lines, (2) placing tobacco products behind one or two checkout lines only, similar to the ''cash only'' or ''less than 10 items'' lines commonly found in supermarkets, (3) dispensing tobacco products from a controlled area of the store, where store employees typically conduct other administrative or customer-service tasks, or (4) installing a signaling system, whereby assigned store clerks bring requested tobacco products to individual checkout stations. Each store's physical configuration determines the most cost-effective approach, but at least one regional survey found that retail outlets readily complied with comparable local ordinances without architectural remodeling or substantial refitting of checkout counters or store aisles.[45]

Certain retail outlets that sell large volumes of cigarettes by the carton would bear the greatest burden from this proposed provision, because the physical size of cartons may preclude their placement in close proximity to a cashier. Most cigarette cartons are sold in the 56,000 largest retail outlets, including 23,000 supermarkets,[46] 12,800 general merchandise outlets, and 20,200 chain drug stores.[47] If three-quarters of these outlets spent an average of $300 each for labor and materials to accomplish this relocation, the one-time cost would be about $12.6 million. The remaining 645,000 smaller retail establishments would typically need to do much less, since small packages can almost always be stored adjacent to or directly above a cashier. Most outlets already keep the majority of cigarette packs in such restricted areas, although most smokeless tobacco products may have to be relocated. FDA has assumed that 50 percent of these smaller outlets would take 2 hours, and 25 percent would take 4 hours to complete any necessary relocation of stock. At an estimated $7.70 labor cost per hour, this adds a one-time cost of $9.9 million, for a total of about $22.5 million. As noted above under the ''Cost to Manufacturers'' section, manufacturers often pay partially or even completely for behind-the-counter shelving or locking cases for use in retail establishments. Thus, FDA assumed that this $22.5 million one-time cost would be shared equally by manufacturers and retail outlets.

The required reconfiguration of tobacco displays may also impose added labor costs for each purchase transaction, especially for those outlets that adopt signaling-type systems or that move inventory to areas located further from employee workstations. To estimate any additional labor costs, FDA has assumed that the ban on self-service tobacco displays would require 10 seconds of additional labor time for 75 percent of all retail transactions involving cartons of cigarettes. Based on an estimated 900 million retail transactions for cigarette cartons and an annual employee compensation of $15,410,[48] this added labor cost projects to about $14 million per year. This estimate understates actual costs if the required changes have a greater than expected adverse affect on labor productivity, but overstates actual costs if current compliance exceeds 25

percent. Also, some of the added costs would be offset by reductions in product pilferage. Since FDA does not know the relative magnitude of these potentially offsetting factors, the agency has retained the $14 million figure as its best preliminary estimate of the labor costs that would be imposed by the self-service ban.

In total, FDA projects that the retail sector would incur one-time costs of about $11 million and annual costs of about $52 million. As shown above in Table 2, the sum of the one-time costs imposed on the manufacturing and retail sectors for the initial provisions would range from about $26 to $39 million, whereas the total annual costs would be about $227 million. For these provisions, the sum of these annualized one-time costs (15 years at 3 percent discount rate) and annual operating costs yield about $230 million per year (also about $230 million at 7 percent discount rate).

4. Costs to Consumers

a. *Advertising restrictions.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. According to the Bureau of Economics of the FTC, the benefits of advertising derive from:

> * * * its role in increasing the flow and reducing the cost of information to consumers * * * First, advertising provides information about product characteristics that enables consumers to make better choices among available goods * * * Second, theoretical arguments and empirical studies indicate that advertising increases new entry and price competition and hence reduces market power and prices in at least some industries * * * Third, advertising facilitates the development of brand reputations. A reputation, in turn, gives a firm an incentive to provide products that are of consistently high quality, that live up to claims that are made for them, and that satisfy consumers.[49]

FDA has considered each of these issues in turn. While agreeing that certain forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that the proposed tobacco product advertising restrictions would impose few significant societal costs. As discussed in the preamble above, the proposed regulation does not prohibit factual, written advertising. Thus, the proposed rule would not impede the dissemination of important information to consumers. While imagery and promotional activities may be important determinants of consumer perceptions and sales, they typically provide little meaningful information on essential distinctions among competing tobacco products. The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, is less obvious, as various empirical studies have reached conflicting conclusions. Nevertheless, from FDA's perspective, even if advertising restrictions led to higher prices, this result would discourage tobacco consumption and thereby enhance the public health. Finally, FTC's third point, which emphasizes the positive aspects of advertising in supporting brand reputations, is more relevant for long-lived items, such as consumer durables, where purchases are infrequent or personal experience is inadequate. Advertising is less likely to play a key role in assuring high quality levels for tobacco products, where consumer search costs are low and a brand's reputation for quality is tested by consumers every day. For these products, high quality would remain a prerequisite of commercial success irrespective of advertising strategies.

Other analysts suggest still other potential attributes of product advertising. For example, according to F.M. Scherer, author of a widely read text on industrial organization:

> Advertising is art, and some of it is good art, with cultural or entertainment value in its own right. In addition, it can be argued that consumers derive pleasure from the image advertising imparts to products, above and beyond the satisfaction flowing in some organic sense from the physical attributes of the products. There is no simple case in logic for distinguishing between the utility people obtain from what they think they are getting and what they actually receive. As Galbraith observed, ''The New York housewife who was forced to do without Macy's advertising would have a sense of loss second only to that from doing without Macy's.'' [50]

Similarly, Becker and Murphy have argued that advertisements should be considered ''goods'' if people are willing to pay for them and as ''bads'' if people must be paid to accept them.[51] They explain that, in general, the more easily the advertisements can be ignored, the more likely it is that the ads themselves provide utility to consumers. Newspaper and magazine advertisements, for example, must provide positive consumer utility or they would be ignored by readers. The proposed rule would allow such advertisements to continue, some in their current form, others in a text-only format. (In fact, industry outlays for newspaper and magazine advertisements have dropped dramatically over the years, currently constituting only about 5 percent of the industry's total advertising and promotion budget.) Conversely, the extraordinary growth in industry advertising and promotion has been in areas that are typically bundled with other products, or placed in prominent public settings that are difficult to ignore. Thus, there is considerable question about the contribution of these programs to consumer utility.

b. *Consumer surplus.* Consumer surplus is a concept that represents the amount by which the utility or enjoyment associated with a product exceeds the price charged for the product. Since it reflects the difference between the price the consumer would be willing to pay and the actual market price, it is used by economists to measure welfare losses imposed by consumer product bans. However, FDA's proposed rule imposes no access restrictions on adults, who would be free to consume tobacco products if they so desired. Thus, FDA has not included any value for lost consumer surplus in its estimate of societal costs.

c. *Inconvenience.* Some adult consumers would be inconvenienced by the unavailability of cigarette vending machines. FDA believes that over time, most smokers would adjust their purchasing patterns to reflect this circumstance. However, the agency has not attempted to quantify the degree of this disutility and asks public comment on its potential cost.

E. Distribution and Transitional Effects

The proposed regulation would impose a variety of sector-specific distributive effects. Those sectors affiliated with tobacco and tobacco products would lose sales revenues and these losses would grow over time. On the other hand, nontobacco related industries would gain sales, because dollars not spent on tobacco would be spent on other commodities.

1. Tobacco Industry

For its calculation of regulatory benefits, FDA estimated that implementation of the proposed regulation would reduce the cigarette consumption of underage smokers by one-half. As discussed above, based on data presented in Cummings et al., FDA estimates that teenage smokers under the age of 18 consumed about 318 million packs of cigarettes in 1991. If the proposed regulation cuts these sales by one-half, the resulting annual drop in industry revenue would be $143 million (assuming manufacturer share of 50 percent of retail price, or 90 cents per pack.) Moreover, FDA has assumed that at least one-half of those 500,000 teenagers who would be deterred from starting to smoke each year would refrain from smoking as adults,

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

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

2. Vending Machine Operators

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

3. Advertising Sector

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

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

4. Retail Outlets

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

5. Other Private Sectors

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

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

6. State Tax Revenues

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

F. Small Business Impacts

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

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

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

[Establishments with Payroll Only]

Establishment type	Tobacco sales		% of total sales	
	($ mils)	(%)	Establishments handling tobacco	All establishments
All	23,231	100	5.0	1.6
Food Stores	13,057	56	5.0	4.3
Service Stations	4,280	18	6.5	4.2
Drug and Proprietary	2,152	9	5.1	4.0
General Merchandise	1,470	6	2.1	0.8
Liquor Stores	706	3	7.2	3.8
Eating and Drinking	182	1	2.4	0.1

Source: 1987 Census of Retail Trade, Merchandise Line Sales.

To illustrate the effects of this proposal on a typical small retail store, FDA separately estimated the likely compliance costs for an average-sized convenience store that sells 300 packages of tobacco products daily, of which about 50 might be purchased by young adults aged 18 to 26. Based on the cost assumptions described above, the outlet's first year costs would total about $320, with the largest single cost, $285, the labor cost for checking identification. For those stores that already verify the age of young customers of tobacco products, the additional costs fall to $35. This estimate does not account for the possible reduction in promotional allowances, although these allowances might fall following a ban on self-service marketing. Alternatively, as noted above, manufacturers would continue to compete for the best shelf space for their products, perhaps even

more so if they find that ''text only'' advertising erodes the stimulus effect of point-of-purchase advertising. Thus, the proposed advertising restrictions could enhance the share of the industry's advertising and promotion budget that is directed towards promotional allowances in retail outlets.

G. Alternatives

One alternative considered by the agency was a far more prescriptive monitoring requirement for tobacco manufacturers. Under this rule, each manufacturer of tobacco products would have been required to adopt a system for monitoring the sales and distributions of retail establishments. These monitoring systems were to: (1) Include signed written agreements with each retailer, (2) contain adequate organizational structure and personnel to monitor the labeling, advertising, and sale of tobacco products at each retail distribution point, and (3) establish, implement, and maintain procedures for receiving and investigating reports regarding any improper labeling, advertising, or distribution. The additional costs for this monitoring was estimated at about $85 million per year. FDA rejected this alternative, because it decided that the industry might employ its resources more efficiently if permitted to choose among alternative compliance modes. It is possible, however, that the industry might implement certain features of this approach in order to avoid the optional performance-based provision that would become effective if the ''Healthy People 2000'' goals were not met.

A second alternative considered by the agency was to require package inserts containing educational information in cigarette and smokeless tobacco products. FDA had incomplete date to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, preliminarily projected one-time costs of about $490 million and annual operating costs of about $54 million. FDA did not select this alternative as the agency was not certain that the benefits of this provision would justify the large compliance costs.

FDA also considered setting the permissible age for purchase at 19 rather than 18, because many 18-year-old adolescents are still in high school, where they can easily purchase tobacco products for classmates. This alternative would have added costs of about $34 million annually, mostly due to lost producer profits. The proposed regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become regular smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

The agency also considered restricting rather than prohibiting sales from vending machines. However, as stated in the preamble above, studies indicated that measures such as placing locks on vending machines or restricting their placement failed to prevent young people from purchasing cigarettes from vending machines.

References

1. Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, April 28, 1994, pp. 1–2.

2. Littlechild, S.C., ''Smoking and Market Failure,'' in ''Smoking and Society: Toward a More Balanced Assessment,'' R.D. Tollison, editor, Lexington Books, p. 271, 1986.

3. Viscusi, W.K., ''Smoking: Making the Risky Decision,'' Oxford University Press, 1992; see also Beales, J.H., ''Teenage Smoking: Fact and Fiction,'' *The American Enterprise,* pp. 20–25, March/April 1994.

4. Goodin, R.E., ''No Smoking: The Ethical Issues,'' University of Chicago Press, pp. 30–32, 1989.

5. Becker, G.S., and K.M. Murphy, ''A Theory of Rational Addiction,'' *Journal of Political Economy,* vol. 96, No. 4, pp. 675–700, 1988.

6. Becker, G.S., M. Grossman, and K.M. Murphy, ''An Empirical Analysis of Cigarette Addiction,'' *The American Economic Review,* vol. 84, No. 3, pp. 396–418, June 1994; Chaloupka, F., ''Rational Addictive Behavior and Cigarette Smoking,'' *Journal of Political Economy,* vol. 99, No. 4, pp. 722–742, 1991; Keeler, T.E., et al., ''Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence,'' *Journal of Health Economics,* vol. 12, pp. 1–18, 1993.

7. Chaloupka, F., ''Rational Addictive Behavior and Cigarette Smoking,'' *Journal of Political Economy,* vol. 99, No. 4, pp. 740, 1991.

8. Manning, W.G., et al., ''The Costs of Poor Health Habits, A Rand Study,'' Harvard University Press, Cambridge, 1991.

9. Gravelle, J.G., and D. Zimmerman, ''CRS Report for Congress: Cigarette Taxes to Fund Health Care Reform: An Economic Analysis,'' Congressional Research Service, p. 1, March 8, 1994.

10. See the 1992 Report of the Surgeon General, pp. 105–112, for a full summary of these methodologies and findings.

11. Statement of Clyde Behney and Maria Hewitt on Smoking-Related Deaths and Financial Costs: Office of Technology Assessment Estimates for 1990 Before the Senate Finance Committee, April 28, 1994, p. 2.

12. ''Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993,'' in ''MMWR,'' CDC, DHHS, vol 43, No. 26, July 8, 1994, pp. 469–472.

13. 1992 SGR, p. 111.

14. Jason, L.A., et al., ''Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors,'' *The Journal of the American Medical Association,* vol 266, No. 22, December 11, 1991, p. 3159.

15. U.S. Department of Health and Human Services, ''Reducing the Health Consequences of Smoking: 25 Years of Progress,'' A Report of the Surgeon General, U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, DHHS publication No. (CDC) 89–8411, p. 517, 1989.

16. Economics and Operational Research Division, Department of Health, ''Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence,'' p. 22, October 1992.

17. Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Petaluma, California, p. 4, November 3, 1994.

18. Manning, W.G., et al., ''The Costs of Poor Health Habits, A Rand Study,'' Harvard University Press, Cambridge, 1991.

19. Peto et al., ''Mortality from Smoking in Developing Countries, 1950–2000,'' Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

20. Assumes new non-smokers are 50 percent male and 50 percent female.

21. For each 10-year age interval, the number of life-years is calculated as the number of people in each cohort (250,000) times the probability of surviving until the end of that age interval times 10 years of life, plus the number expected to die in that interval times an assumed 5 years of life.

22. Hodgson, T.A., ''Cigarette Smoking and Lifetime Medical Expenditures,'' *The Milbank Quarterly,* vol. 70, No. 1, p. 91, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

23. *id.,* p. 97 (Using the average of the male and female totals).

24. Hodgson, T.A., ''Annual Costs of Illness Versus Lifetime Costs of Illness and Implications of Structural Change,'' *Drug Information Journal,* vol. 22, No. 3, p. 329, 1988.

25. Rice, D.P., et al., ''The Economic Costs of the Health Effects of Smoking, 1984,'' *The Milbank Quarterly,* vol. 64, No. 4, p. 526, 1986.

26. Schelling, T.C., ''Economics and Cigarettes,'' *Preventive Medicine,* vol. 15, pp. 549–560, 1986.

27. Fisher, A., L.G. Chestnut, and D.M. Violette, ''The Value of Reducing Risks of Death: A Note on New Evidence,'' *Journal of Policy Analysis and Management,* vol. 8, No. 1, pp. 88–100, 1989.

28. Viscusi, W.K., ''Fatal Tradeoffs: Public and Private Responsibilities for Risk,'' Oxford University Press, p. 24, 1992.

29. Miller, A.L., ''The U.S. Smoking-Material Fire Problem Through 1992: The Role of Lighted Tobacco Products in Fire,'' National Fire Protection Association, p.2, 1994.

30. ''Appendix V: Regulatory Impact Analysis Guidance,'' in ''Regulatory Program of the United States Government,'' Office of Management and Budget, pp. 663–666, April 1, 1990–March 31, 1991.
31. *Id.*, p. 663.
32. ''1994 State of the Industry Report,'' in *Automatic Merchandiser,* August 1994, p. A8.
33. ''Census of the Industry Issue,'' in *Vending Times,* August 1994.
34. ''Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes,'' Federal Trade Commission, 1994.
35. French, M.T., et al., ''Compliance Costs of Food Labeling Regulations,'' Final Report, RTI Project Number 233U–3972–02 DFR, January 1991.
36. Department of National Health and Welfare, ''Tobacco Products Control Regulations, amendment,'' *Canada Gazette, Part II,* vol. 127, No. 16, pp. 3277–3294, August 11, 1993.
37. Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.
38. Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring only Vendor Assisted Tobacco Sales,'' North Bay Health Resources Center, Petaluma, California, p. 5, November 3, 1994.
39. Cumings, K. M., T. Pechacek, and D. Shopland, ''The Legal Sale of Cigarettes to U.S. Minors: Estimates by State,'' *American Journal of Public Health,* vol. 84, No. 2, February 1994, p. 301, (Derived by substracting sales to 18-year-olds from the reported 516 million packs consumed).
40. 58 FR 45156, 45159–45160 (August 26, 1993).
41. ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, p. II–10, October 1992
42. 1194 SGR, p. 85.
43. U.S. Department of Commerce, ''Statistical Abstract of the United States 1993,'' 113 edition, 1993, p. 137; Department of Health and Human Services, Office of Inspector General, ''Spit Tobacco and Youth'' Additional Analysis, June 1993.
44. ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, P. II–10, October 1992.
45. Kropp, R. ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Welfare Merchandising and Requiring only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Pentaluma, California, p. 5, November 3, 1994.
46. U.S. Department of Commerce, ''Statistical Abstract of the United States 1994,'' 114th edition, no. 1284, 1994, p. 787.
47. National Association of Chain Drug Stores, ''Prescription Drug Marketplace Simulation Mode; User's Guide,'' Appendix B, 1992.
48. ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, p. II–10, October 1992.
49. Recommendations of the Staff of the Federal Trade Commission, ''Omnibus Petition for Regulation of Unfair and Deceptive Alcoholic Beverage Advertising and Marketing Practices,'' Appendix A, pp. 3–4, March 1985.
50. Scherer, F.M. ''Industrial Market Structure and Economic Performance,'' 2nd Edition, Rand McNally College Publishing Co., Chicago, p. 380, 1980.
51. Becker, G.S. and K.M. Murphy, ''A Simple Theory of Advertising as a Good or Bad,'' *Quarterly Journal of Economics,* vol. 108, p. 941, November 1993.
52. ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, October 1992, p. ES–3.
53. Vending Times, ''Census of the Industry Issue,'' 1994, p. 42.
54. Automatic Merchandiser, ''State of the Industry Report,'' p. A8, August, 1994.
55. Wolfson, A. ''Canada's Ad Ban Puts Cigarettes Out of Sight,'' *The Courier-Journal,* pp. A1,–A4, August 1, 1994.
56. Teinowitz, I., ''First Smoke, Then Fire'', *Advertising Age,* p. 30, Spring 1995.
57. Endicott, R.C., ''Top Advertisers Rebound, Spending to $36 Billion,'' *Advertising Age,* vol. 64, No. 41, p. 1, September 29, 1993.
58. 56 FR 11661, (March 20, 1991).
59. Expert Panel Report, ''When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products,'' Prepared at the request of Health Canada, p. 140, March 1995.
60. ''An Advertising Supplement'' *Advertising Age,* p. 2, September 26, 1994.
61. Kropp, R., ''A Position Paper on Reducing Tobacco Sales to Minors by Prohibiting the Sale of Tobacco Products by Means of Self-Service Merchandising and Requiring Only Vendor-Assisted Tobacco Sales,'' North Bay Health Resources Center, Petaluma, California, p. 2, November 3, 1994.
62. ''The Economic Impact of the Tobacco Industry on the United States in 1990,'' Price Waterhouse, October 1992.
63. Gray, H.P., and I. Walter, ''The Economic Contribution of the Tobacco Industry,'' in ''Smoking and Society: Toward a More Balanced Assessment'', R.D. Tollison, editor, Lexington Books, p. 248, 1986.
64. The Tobacco Institute, ''The Tax Burden on Tobacco,'' vol. 28, 1993, p. 4.
65. U.S. Department of Commerce, ''Statistical Abstract of the United States 1994,'' 114th edition, no. 464, 1994, p. 298.
66. ''1994 State of the Industry Report,'' in *Automatic Merchandiser,* August 1994, p. A2.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 804

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 897

Cigarettes, Smokeless tobacco, Labeling, Advertising, Sale and Distribution, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 801, 803, and 804 be amended and that a new part 897 be added as follows:

Note: The part number for part 897 as proposed at 60 FR 32417 will be changed by the agency in a future issue of the **Federal Register**.

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 507, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374).

2. Section 801.61 is amended by adding a new paragraph (d) to read as follows:

§ 801.61 Statement of identity.

* * * * *

(d) This provision does not apply to cigarettes or to smokeless tobacco products as defined in part 897 of this chapter.

PART 803—MEDICAL DEVICE REPORTING

3. The authority citation for 21 CFR part 803 continues to read as follows:

Authority: Secs. 502, 510, 519, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 371, 374).

4. Section 803.1 is amended by adding a new paragraph (d) to read as follows:

§ 803.1 Scope.

* * * * *

(d) This part does not apply to cigarettes or to smokeless tobacco products as defined in part 897 of this chapter.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

5. The authority citation for 21 CFR part 804 continues to read as follows:

Authority: Secs. 502, 510, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 360, 360i, 360j, 371, 374.

6. Section 804.1 is amended by adding a new paragraph (c) to read as follows:

§ 804.1 Scope.

* * * * *

(c) This part does not apply to distributors of cigarettes or smokeless tobacco products as defined in part 897 of this chapter.

7. New part 897 is added to read as follows:

PART 897—CIGARETTES AND SMOKELESS TOBACCO PRODUCTS

Subpart A—General Provisions

Subpart B—Sale and Distribution to Persons Under 18 Years of Age

Subpart C—Labels and Educational Programs

Subpart D—Labeling and Advertising

Subpart E—Miscellaneous Requirements

Authority: Secs. 502, 510, 520, 701, 704 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 352, 360, 360j, 371, 374).

Subpart A—General Provisions

§ 897.1 Scope.

(a) This part is intended to establish the conditions under which cigarettes and smokeless tobacco products that contain or deliver nicotine, because of their potential for harmful effect, shall be sold, distributed, or used under the restricted device provisions of the Federal Food, Drug, and Cosmetic Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of Title 21, unless otherwise noted.

§ 897.2 Purpose.

The purpose of this part is to establish conditions for the sale, distribution, and use of cigarettes and smokeless tobacco products in order to:

(a) Reduce the number of people under 18 years of age who become addicted to nicotine, thus avoiding the life-threatening consequences associated with tobacco use; and

(b) Provide important information regarding the use of these products to users and potential users.

§ 897.3 Definitions.

(a) *Cigarette* means any product (including components, accessories, or parts) which contains or delivers nicotine, is intended to be burned under ordinary conditions of use, and consists of:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco;

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (a)(1) of this section; or

(3) Any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco described by paragraphs (a)(1) or (a)(2) of this section) and as to which 1,000 units weigh not more than 3 pounds.

(b) *Cigarett tobacco* means any loose tobacco that contains or delivers nicotine and is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements pertaining to cigarettes shall also apply to cigarette tobacco.

(c) *Distributor* means any person who furthers the marketing of cigarettes or smokeless tobacco products, whether domestic or imported, at any point from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the cigarettes or smokeless tobacco products, or the package of the cigarettes or smokeless tobacco products.

(d) *Manufacturer* means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product. The term does not include any person who only distributes finished cigarettes or smokeless tobacco products.

(e) *Nicotine* means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or $C_{10}H_{14}N_2$, including any salt or complex of nicotine.

(f) *Package* means a pack, box, carton, or container of any kind in which cigarettes or smokeless tobacco products are offered for sale, sold, or otherwise distributed to consumers.

(g) *Point of sale* means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco products for personal consumption.

(h) *Retailer* means any person who sells or distributes cigarettes or smokeless tobacco products to individuals for personal consumption.

(i) *Smokeless tobacco* means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity.

Subpart B—Sale and Distribution to Persons Under 18 Years of Age

§ 897.10 General responsibilities of manufacturers, distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco products it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

§ 897.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall:

(a) Remove, from each point of sale, all self-service displays, advertising, labeling, and other manufacturer-supplied or manufacturer-owned items that do not comply with the requirements under this part;

(b) Through its representatives, when they visit any point of sale in their normal course of business, visually inspect and ensure that the products are labeled, advertised, and distributed in accordance with this part.

§ 897.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco products to any person (other than a distributor or retailer) comply with the following requirements:

(a) The retailer or an employee of the retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing or intending to purchase the product is younger than 18 years of age;

(b) The cigarette or smokeless tobacco product shall be provided to the person purchasing the product by the retailer or by an employee of the retailer, without the assistance of any electronic or mechanical device (such as a vending machine or remove-operated machine); and

(c) The retailer or an employee of the retailer shall not break or otherwise open any cigarette package or smokeless tobacco product to sell or distribute individual cigarettes or number of cigarettes or any quantity of cigarette tobacco or of a smokeless tobacco product that is smaller than the quantity in the unopened product.

§ 897.16 Conditions of manufacture, sale, and distribution.

(a) *Restriction on product names.* A manufacturer may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for tobacco products on which a trade or brand name of a nontobacco product was in use on January 1, 1995.

(b) *Minimum cigarette package size.* No manufacturer, distributor, or retailer shall sell or cause to be sold, distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other ''impersonal'' modes of sale.* Cigarettes and smokeless tobacco products may be sold only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include, but are not limited, vending machines, self-service displays, mail-order sales, and mail-order redemption of coupons.

(d) *Free samples.* Manufacturers, distributors, and retailers may not distribute or cause to be distributed any free samples of cigarettes or smokeless tobacco products.

Subpart C—Labels and Educational Programs

§ 897.24 Established names for cigarettes and smokeless tobacco products.

Each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed shall bear the following established name: ''Cigarettes'', ''Cigarette Tobacco'', ''Loose Leaf Chewing Tobacco'', ''Plug Chewing tobacco'', ''Twist Chewing Tobacco'', ''Moist Snuff'', or ''Dry Snuff'', whichever name is appropriate.

§ 897.29 Educational programs concerning cigarettes and smokeless tobacco products.

(a) Each manufacturer shall establish and maintain an effective national public educational program to discourage persons under 18 years of age from using cigarettes and smokeless tobacco products. The major portion of this program must appear on television.

(b) Each manufacturer shall allocate an amount for the educational program that is proportionate to its share of the total advertising and promotional expenditures for the most recent year reported by all manufacturers to the Federal Trade Commission pursuant to the Federal Cigarette Labeling and Advertising Act or the Comprehensive Smokeless Tobacco Health Education Act. The Total amount to be spent shall be $150,000,000 per year.

Subpart D—Labeling and Advertising

§ 897.30 Scope of permissible forms of labeling and advertising.

(a) This subpart does not apply to cigarette or smokeless tobacco product package labels. A manufacturer, distributor, or retailer may distribute or cause to be distributed:

(1) Advertising which bears the cigarette or smokeless tobacco product brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification only in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, an placards in accordance with paragraph (b) of this section; and in nonpoint of sale promotional material (including direct mail); and

(2) Labeling which bears the cigarette or smokeless tobacco product brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification only in point of sale promotional material; audio and/or video formats delivered at a point of sale; and on entries and teams in sponsored events.

(b) No outdoor advertising, including but not limited to billboards, posters, or placards, may be placed within 1,000 feet of any playground, elementary school or secondary school.

§ 897.32 Format and content requirements for labeling and advertising.

(a) Each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, labeling and advertising permitted under § 897.30 shall use only black text on a white background. This section shall not apply to advertising appearing in adult newspapers, magazines, periodicals, or other publications (whether periodic or limited distribution). For the purposes of this section, an adult newspaper, magazine, periodical, or publication, as measured by competent and reliable survey evidence, is any newspaper, magazine, periodical, or publication:

(1) Whose readers aged 18 years or older constitute 85 percent or more of the total readership, and

(2) That is read by fewer than 2 million persons under age 18.

(b) Each manufacturer, distributor, and retailer 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 of the Federal Food, Drug, and Cosmetic Act, the product's established name and a statement of its intended use as follows: ''Cigarettes—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''.

(c) Each manufacturer, distributor, and retailer of cigarettes shall include, in all advertising, but not labeling, permitted under § 897.30(a), a brief statement, such as the one specified below, printed in black text on a white background:

About one out of three kids who become smokers will die from their smoking.

(d) The statement required under paragraph (c) of this section shall be readable, clear, conspicuous, prominent, and contiguous to the Surgeon General's warning.

§ 897.34 Sale and distribution of non-tobacco items and services, contests and games of chance and sponsorship of events.

(a) No manufacturer, distributor, or retailer shall market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item or service (other than cigarettes or smokeless tobacco products), which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar or identifiable to those used for cigarettes or smokeless tobacco products.

(b) No manufacturer, distributor, or retailer shall offer or cause to be offered any gift or item, or the right to participate in any contest, lottery, or

game of chance to any person purchasing cigarettes or smokeless tobacco products in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer shall sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event, in the brand name, logo, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification similar or identical to those used for cigarettes or smokeless tobacco products. A manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic or other social or cultural event in the name of the corporation which manufactures the tobacco product, provided that both the registered corporate name and the corporation were in existence prior to January 1, 1995.

§ 897.36 False or misleading labeling and advertising.

Labeling or advertising of any cigarette or smokeless tobacco product is false or misleading if the labeling or advertising contains any express or implied false, deceptive, or misleading statement, omits important information, lacks fair balance, or lacks substantial evidence to support any claims made for the product.

Subpart E—Miscellaneous Requirements

§ 897.40 Records and reports.

(a) Each manufacturer shall, on an annual basis, submit:

(1) Copies of all labels, except that a manufacturer may submit a representative sample of such labels if the labels will be similar for multiple packages or products; and

(2) Copies of all labeling and a representative sampling of advertising.

(b) The manufacturer shall send this information to the Document and Records Section, 12420 Parklawn Dr., Rockville, MD 20852. The information should be plainly marked as ''Labels'', or ''Labeling and Advertising'', whichever is appropriate.

(c) Manufacturers, distributors, and retailers shall, upon the presentation by an FDA representative of official credentials, make all records and other information collected under this part and all records and other information related to the events and persons identified in such records available to the FDA representative for purposes of inspection, review, copying, or any other use related to the enforcement of the Federal Food, Drug, and Cosmetic Act and this part.

§ 897.42 Preemption of State and local requirements and requests for advisory opinions.

(a) *General.* In addition to the requirements imposed under this part, manufacturers, distributors, and retailers shall comply with any more stringent State or local requirements relating to the sale, distribution, labeling, advertising, or use of cigarettes and smokeless tobacco products, provided that those State or local requirements do not conflict with the requirements under this part. These more stringent State or local requirements are not preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)).

(b) *Requests for advisory opinions.* (1) Any State or political subdivision of a State may request an advisory opinion from the Food and Drug Administration with respect to the preemptive effect of this part on any particular State or local requirement. The request for an advisory opinion should comply with the requirements at § 10.85 of this chapter. The agency may, in its discretion and after consulting the State or political subdivision, treat a request for an advisory opinion as an application for exemption from preemption under § 808.20 of this chapter.

(2) The Commissioner, on his or her own initiative, may issue an advisory opinion relating to a State or local requirement if he or she finds that:

(i) Section 521(a) of the Federal Food, Drug, and Cosmetic Act does not preempt a State or local requirement for which an application for exemption from preemption has been submitted under § 808.20 of this chapter because the State or local requirement is equal to or substantially equivalent to a requirement under the Federal Food, Drug, and Cosmetic Act, is not a requirement within the meaning of section 521(a) of the Federal Food, Drug, and Cosmetic Act, or is more stringent than and does not conflict with the requirements under this part, or

(ii) Issuance of an advisory opinion is in the public interest.

§ 897.44 Additional regulatory measures.

Seven years after the publication date of any final rule based on the proposed rule published in the **Federal Register** on (date of publication of the final rule), if the percentage of people under the age of 18 years who smoke cigarettes has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and/or if the percentage of males under the age of 18 years who use smokeless tobacco products has not decreased by 50 percent since 1994 (as determined by an objective, scientifically valid, and generally accepted program), and the percentage of females under the age of 18 years who use smokeless tobacco products has increased since 1994 (as determined by an objective, scientifically valid, and generally accepted program), then the agency shall take additional measures to help achieve the reduction in the use of tobacco products by children and adolescents described above.

Dated: August 9, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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