

cancer, cardiovascular disease, or lung disease.<sup>15</sup> In addition, smokeless tobacco use has been linked to oral cancer and other adverse effects.<sup>16</sup>

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.<sup>17</sup> 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.<sup>18</sup> Between 1985 and 1994, smoking among college freshmen increased from 9 percent to 12.5 percent.<sup>19</sup>

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.<sup>20</sup> 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.<sup>21</sup>

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.<sup>22</sup> 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.<sup>23</sup>

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.<sup>24</sup> 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.<sup>25</sup>

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