

PART THREE: REGULATORY OBJECTIVES

Smoking and other tobacco use is the single leading cause of preventable death in the United States. Each year, over one million children and adolescents begin using tobacco products. Most eventually become addicted. Any program devised by the Agency should be comprehensive, effective, and designed to prevent young people from experimenting with and becoming addicted to nicotine.

Currently 3 million young people are regular smokers and another 1 million use smokeless tobacco.⁶¹⁴ Every day another 3,000 children and teenagers become regular smokers.⁶¹⁵ Although adult rates continue to decline, the prevalence of smoking by young people has not declined for the last decade.⁶¹⁶ In fact, between 1992 and 1993, the prevalence of smoking among high school seniors increased from 17.2% to 19%.⁶¹⁷ Additionally, smoking among college freshmen increased from 9% in 1985 to 12.5% in 1994.⁶¹⁸ However, by the time

⁶¹⁴ U.S. Department of Health and Human Services. Preventing Tobacco Use Among Young People: A Report of the Surgeon General. 1994. Page 58.

⁶¹⁵ Institute of Medicine. Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths. National Academy Press. 1994. Page 5.

⁶¹⁶ See:
CDC. Cigarette Smoking Among Adults - United States, 1993. *MMWR*. 43:925-930. Dec. 23, 1994.

U.S. Department of Health and Human Services. Reducing the Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General. 1989. Page 269.

Institute of Medicine. Growing Up Tobacco Free: Preventing Tobacco Addiction in Children and Youths, *supra* at pp. 7-8.

⁶¹⁷ The University of Michigan. Monitoring the Future Study. January 27, 1994. Table 1 - "Trends in Prevalence of Various Drugs for Three Populations: Eight, Tenth, and Twelfth Grades."

⁶¹⁸ Washington Post, January 9, 1995. Page A2, col. 3.

young people are smoking regularly, they already regret having started.⁶¹⁹ A 1992 Gallup Survey confirmed this, showing that 70% of regular adolescent smokers regretted having begun to smoke and wished they could quit. If an adolescent's cigarette or smokeless tobacco use continues into adulthood, he or she may ultimately become one of the over 400,000 Americans who die from tobacco-caused diseases each year.⁶²⁰

Most adult smokers became regular smokers as youngsters. Among those adults who ever smoked regularly, nearly 90% began to smoke, and more than 70% became regular smokers, by age 18.⁶²¹ It is clear, therefore, that if smoking does not begin in childhood or adolescence, it is unlikely that it will ever begin. Thus, addiction to nicotine-containing tobacco products is, first and foremost, a pediatric disease.

FDA regulatory action should be based on a youth-centered strategy that is intended to reduce the risk that future generations of Americans will become dependent on nicotine without prohibiting access to these products by adults. The Agency recognizes the need for cigarettes and smokeless tobacco products to remain available to adults, because millions of American adults use and are addicted to these products. The potential disruption to society resulting from the elimination of tobacco products would be great, and therefore FDA does not intend to remove them from the market.

⁶¹⁹ George A. Gallup International Institute. Teenage Attitudes and Behavior Concerning Tobacco - Report of the Findings. Princeton, New Jersey. 1992.

⁶²⁰ U.S. Department of Health and Human Services. Reducing The Health Consequences of Smoking: 25 Years of Progress, A Report of the Surgeon General. 1989. Page 5.

⁶²¹ U.S. Department of Health and Human Services, Preventing Tobacco Use Among Young People, A Report of the Surgeon General, *supra*, at pp. 63-65.

A comprehensive and effective regulatory approach should be designed to reduce the many avenues of easy access to tobacco products available to children and teenagers, and to make it harder for young people to buy these products. The Agency should also act to reduce the powerful and alluring imagery used in tobacco advertising and promotion that tends to encourage impressionable young people to initiate tobacco use, and should attempt to enhance the positive image of a smoke-free generation. Further, such actions should seek to educate people about the specific and relevant health risks associated with tobacco use and to disseminate information about quitting.⁶²²

⁶²² The issues discussed in the "Regulatory Objectives" section were also addressed by David A. Kessler, M.D., Commissioner of Food and Drugs, in a speech at the Columbia University School of Law on March 8, 1994. A copy of the speech appears in Appendix 9.

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David A. Kessler,

Commissioner of Food and Drugs.

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