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 smokingrelated 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 smokingattributable 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 prevalencebased 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 ²/₃ 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 Stateoperated 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

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