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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801, et al.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, 807, 820, and 897

[Docket No. 95N–0253]

RIN 0910–AA48

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents.

The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples and prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

These regulations will address the serious public health problems caused by cigarettes and smokeless tobacco products. They will reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and will significantly decrease the amount of positive imagery that makes these products so appealing to that age group.

The regulations are predicated on the agency's assertion of jurisdiction under the Federal Food, Drug, and Cosmetic Act over cigarettes and smokeless tobacco as delivery devices for nicotine, incorporated as part of the regulations for purposes of, and to facilitate, congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996.

DATES: *Effective date.* The regulation is effective August 28, 1997, except that § 897.14(a) and (b) are effective February 28, 1997 and § 897.34(c) is effective February 28, 1998.

Compliance dates. Manufacturers and distributors are required to comply with the requirements of 21 CFR parts 803 and 804 August 28, 1997; manufacturers are required to comply with the requirements of 21 CFR parts 807 and 820 February 28, 1998.

ADDRESSES: References listed in the footnotes of this document have been placed on public display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy Yeates, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0867.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Introduction

A. Purpose and Overview of the Rule

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing FDA's determination that it has jurisdiction over these products under the Federal Food, Drug, and Cosmetic Act (the act). As described in "Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination" (the 1996 Jurisdictional Determination), annexed hereto, FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of "drug" and "device." The nicotine in cigarettes and smokeless tobacco is a "drug," which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.

FDA has chosen to regulate cigarettes and smokeless tobacco under the act's device authorities. This rule allows the continued marketing of these products, while employing measures to prevent future generations of Americans from becoming addicted to them. As discussed in section I.B. of this document, most people who use cigarettes and smokeless tobacco begin their use before the age of 18 and, therefore, before they fully understand the addictive nature and serious health risks of these products. Even though the sale of tobacco products to minors is illegal in 50 States, the tobacco industry has adopted extensive marketing campaigns which appeal to children and adolescents. Therefore, the rule effects measures that would both complement the existing State restrictions on access and prevent

operations which injuriously affect the value of or destroy property—for example, restrictions upon the height or character of buildings, destruction of diseased cattle, trees, etc., to prevent contagion—but for which no remedy is afforded. Contracts in this respect do not differ from other kinds of property." (*Id.* at pp. 508 through 509). The Court reviewed earlier decisions and stated that:

> The conclusion to be drawn * * * is, that for consequential loss or injury resulting from lawful governmental action, the law affords no remedy. The character of the power exercised is not material. * * * If, under any power, a contract or other property is *taken* for public use, the Government is liable; but, if injured or destroyed by lawful action, without a taking, the Government is not liable.
> (*Id.* at p. 510)

The Court held that while the Government took the steel, it did not take the contract itself and that "[f]rustration and appropriation are essentially different things" (*Id.* at p. 513). (See *also Louisville & Nashville R.R. Co.* v. *Mottley*, 219 U.S. 467, 484 (1911); *NL Industries, Inc.* v. *United States*, 839 F.2d 1578, 1579 (Fed. Cir.), *cert. denied*, 488 U.S. 820 (1988) ("frustration of a business by loss of a customer was not a taking"); *Carruth*, 627 F.2d at 1081 ("[I]n cases where there has been no direct appropriation of property by governmental agencies, consequential damages resulting from the exercise of lawful regulations are not compensable takings within the purview of the Fifth Amendment").)

Thus, FDA disagrees with the comments suggesting that the rule will result in a taking of jobs or future revenues associated with sponsored events.

(9) Several comments said that the 1995 proposed rule's restrictions on the use of trade names constitute a taking of trade names or the goodwill associated with a tradename or asserted that one has a "right" to use a brand name in any manner.

As discussed in section XI. of this document, the agency disagrees that any provision in this rule effects a taking of trademarks and goodwill.

XIV. Environmental Impact

In the **Federal Register** of August 11, 1995 (60 FR 41314), the preamble to the proposed rule stated that FDA had determined under § 25.24(a)(8), (a)(11), and (e)(6) that the proposed action was of a type that does not individually or cumulatively have a significant impact on the human environment. No new information or comments have been received that would affect the agency's previous determination that this action has no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

XV. Analysis of Impacts

A. Introduction and Summary

The Food and Drug Administration (FDA) has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (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; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of such rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any year. Section 205 of the Unfunded Mandates Reform Act also requires 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 rule is consistent with the principles set forth in the Executive Order and in these two statutes.

FDA published its preliminary economic analysis in the preamble to its 1995 proposed regulation. In response, the agency received thousands of comments raising economic issues or concerns. Representatives of affected industry sectors emphasized burdens in excess of those estimated in the preliminary economic analysis. Other comments stressed the considerable economic value of the expected public health benefits. Although few comments provided quantifiable data on projected economic impacts, whether benefits or burdens, a report prepared by the Barents Group and presented as Volume 11 of the Tobacco Institute submission provided a comprehensive critique of the methodology, assumptions, and cost estimates presented in FDA's preliminary economic analysis and developed alternative estimates of regulatory costs. Other comments addressed selected economic issues. FDA carefully examined and evaluated the reasoning and data presented in these comments, accepted those that were persuasive, and presents this revised analysis of the final rule.

In its preliminary analysis, FDA based the benefits of the 1995 proposed rule on a finding that compliance could help to achieve the Department's "Healthy People 2000" goal of reducing underage tobacco use by one-half. Comments received in response to the proposal have reinforced the agency's conviction that this goal can be realized, although it will require the active support and participation of State and local governments and civic and community organizations, as well as manufacturers and retail dispensers of tobacco products. In the **Federal Register** of January 19, 1996 (61 FR 1492), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a regulation governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. SAMHSA predicted that its rule would cut the rate of underage tobacco consumption by between one-tenth and one-third. FDA can not separately quantify the incremental benefits of the respective agency programs, due to the substantial interdependencies and uncertainties regarding future compliance with these rules; but finds that its final rule and the SAMHSA regulation are fully complementary and, working together, will produce results that would more than equal the sum of their independent efforts.

Each year, an estimated 1 million adolescents under the age of 18 begin to smoke cigarettes. The Centers for Disease Control and Prevention (CDC) estimate that approximately one in three of these adolescents will die of smoking-related diseases, and FDA has concluded that this projection provides the best estimate of the excess fatality rate. FDA finds that even overly conservative projections indicate that achieving the "Healthy People 2000" goal of reducing underage tobacco use by one-half 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. The monetary value of these health benefits (at a 3 percent discount rate) is estimated to total $28 to $43 billion per year and includes $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 the total benefits to about $9.2 to $10.4 billion per year). If the agency's goal were exceeded, these benefits would be even larger. Moreover, if even a fraction of the goal were achieved, the benefits would substantially outweigh the costs of the rule. As shown in Table 1c, 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 $2.8 to $4.3 billion a year. In addition, although FDA has not quantified the benefits of reducing the number of serious illnesses attributable to the use of smokeless tobacco by youngsters under the age of 18, the agency is convinced that these benefits also will be substantial.

TABLE 1c.—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES (UNDISCOUNTED LIVES AND LIFE-YEARS; 3% DISCOUNT RATE FOR MONETARY VALUES)[1]

Fraction of Teenage Cohort Deterred	Fewer Teenagers who will Smoke as Adults[3] (No.)	Smoking Related Deaths Averted (No.)	Life-Years Saved (No.)	Medical Savings ($bils.)	Morbidity-Related Productivity Savings ($bils.)	Mortality-Related Willingness-to-Pay		Total Benefits	
						Life-Yrs. Saved ($bils.)	Deaths Averted ($bils.)	Low ($bils.)	High ($bils.)
1/2[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	18.7	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.8	15.9	11.2	17.3
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	2.8	4.3

[1] Totals may not add due to rounding.
[2] Estimate used in analysis.
[3] Assumes 50% of adolescents who are deterred from smoking continue to refrain as adults.

In its evaluation of the economic impact on industry, FDA also includes those costs that might be attributable to the SAMHSA program, as the rules of both agencies work collectively to reduce youth access to tobacco products. As a result, the overall estimated compliance costs of the rules range from $174 million to $187 million in one-time costs and from $149 million to $185 million in annual operating costs (see Table 2). Manufacturers of tobacco products will incur one-time costs ranging from $78 million to $91 million, primarily for removing prohibited point-of-sale promotional items and self-service displays, and for changing package labels. As the responsibility for removing the prohibited point-of-sale promotional and display items resides with the owner, manufacturers and retailers may ultimately share the costs of removal and replacement. FDA's cost estimates assume that manufacturers will pay for most removal and installation activities and retailers will pay for most replacement items. (If, in fact, retailers assume most removal responsibilities, the estimated manufacturer costs fall by about $47 million).

TABLE 2.—COSTS OF FDA AND SAMHSA REGULATIONS ($ mils.)[1]

Requirements By Sector	One-Time Costs	Annual Operating Costs
Tobacco Manufacturers	**78–91**	**2**
Point-of-Sale Advertising	30	
Self-Service Ban	40	
Label Changes	4–17	
Paperwork Requirements		1.2
Training	1.5	0.2
Readership Surveys	2	1
Retail Establishments	**96**	**78**
Training	34	20
I.D. Checks		43
Self-Service Ban	57	11
Point-of-Sale Advertising	5	
Vending Machines		3.5
Consumers		**41–50**
I.D. Checks		41–50
Government		**28–55**
States (SAMHSA)		25–50
FDA		3–5
TOTAL	**174–187**	**149–185**

[1] Assumes manufacturers remove prohibited retail display. If retailers bear full burden, manufacturer one-time costs fall by about $47 million and retailer one-time costs rise by about $17 million. Advertising restrictions are considered under distributional effects. Excludes costs of short-term resource dislocation and educational programs.

Retail establishments will incur an estimated $96 million in one-time costs. About $57 million of these costs are due to the self-service restriction, primarily for replacing display cases and other functional promotional items. (If retailers rather than manufacturers remove the prohibited point-of-sale advertising and display items, the estimated retailer costs rise by about $17 million). The retail sector will also incur about $78 million in annual costs. In addition to new labor costs attributable to the self-service restrictions, both the FDA and SAMHSA rules impose costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers, and for foregoing profits due to reduced vending machine sales. Consumers will bear costs of up to $50 million annually for incurring some delay in checkout lines. Finally, enforcement of these rules may cost the FDA from $3 million to $5 million per year and State governments from $25 million to $50 million per year for administering various SAMHSA enforcement programs.

FDA could not, however, quantify every regulatory cost. For example, the agency may require certain tobacco manufacturers to broadcast educational messages under the agency's notification process. Cost estimates for these activities will be developed in parallel with the program elements. In addition, a number of commercial sectors will experience costs for short-term dislocations of current business activities. Neither FDA nor any of the industry comments on the agency's proposal projected the magnitude of these costs, but they would be mitigated for those businesses that anticipate the adjustments in long-term business plans.

In addition to the costs described previously, the rule will create significant distributional and transitional effects. Some industry comments asserted that FDA had neglected the cost of lost sales revenues in its preliminary economic analysis and one industry study estimated these "Illustrative Costs" at from $1.3 billion to $3.3 billion per year. In fact, FDA had considered these sector-specific revenue reductions, but described the impacts as distributional effects, rather than as net societal costs. For example, any lost sales experienced by suppliers of advertising were considered distributional impacts, because dollars not spent on advertising will not be lost to the U.S. economy, but will be spent on other goods and services. As acknowledged by the authors of one of the economic impact analyses commissioned by the tobacco manufacturing industry:

* * * when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

Similarly, the anticipated slow but persistent decline in tobacco product sales revenues are not societal costs, because the dollars not spent on tobacco-related items will be spent on other goods or services.

Nevertheless, FDA is aware that many tobacco-related industry sectors will be adversely affected by this rule. Tobacco manufacturers and suppliers will face increasingly smaller sales, because reduced tobacco consumption by youth will lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues, however, will be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent. Also, if State and Federal excise tax rates on tobacco products remain at current levels, tax revenues would decrease slowly over time, falling by about $231 million and $196 million, respectively, by the 10th year following compliance with the regulation.

Tobacco manufacturers spent $6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent may be substantially altered to reflect the various "text only"

restrictions or other prohibitions. If tobacco companies choose to reduce advertising and promotional activities due to the FDA restrictions, the sectors affected would include advertising agencies and communications media, owners of retail and outdoor advertising space, and recipients of corporate brand-name sponsorships (especially auto racing). These businesses would need to attract new revenues to maintain current levels of profitability. Similarly, vending machine operators will need to find substitute products to replace up to 3 percent of their sales revenues.

In summary, FDA finds that compliance with this rule will bring significant health benefits to the U.S. population. The rule will also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors. With regard to small businesses, many near-term impacts will be small or transitory, but some business will be adversely affected. For a small retail convenience store not currently complying with this rule, the additional first year costs could average $400. For those convenience stores that already check customer identification, these costs average $137, largely to relocate tobacco product displays. Moreover, the rule will not produce significant economic problems at the national level, as the long-term displacement within tobacco-related sectors will be offset by increased output in other areas. Thus, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current rule is the least burdensome and most cost-effective alternative that would meet the objectives of this rule.

B. Statement of Need for 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. 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.[268]

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 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 agrees that various elements of market failure are relevant to the problem of teenage use and tobacco addiction, the agency also believes that this regulatory action would be justified even in the absence of a traditional market failure. As noted previously, 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. FDA, however, 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"[269] to note that "[t]he economic analysis of market failure deals with choice by adults." Although both Beales[270] and Viscusi find that young persons balance risks and rewards in making decisions on whether or not to smoke, Viscusi explains that:

[n]evertheless, there are some classes of choices that have major consequences, and for that reason society may wish to reserve the privilege of making these choices until a particular age is reached. These limits should, however, be set according to the age at which individuals are believed to be capable of making reasonable long-term decisions regarding their welfare, rather than some arbitrary date independent of the choice context. The emerging consensus of smoking restriction policies has focused age 18 as the minimum age for the purchase of cigarettes.[271]

FDA concludes, therefore, that even if some children do make rational choices, 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.[272]

In particular, FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. Section VI. of this document describes numerous studies on the shortcomings of the risk perceptions held by children. Health economist Victor R. Fuchs describes the typical sequence:

There is considerable evidence that the [time discount] rate falls as children mature. Infants and young children tend to live very much for the present; the prospect of something only a week in the future usually has little influence over their behavior. As children get older their time horizons lengthen, but once adult status is reached there seems to be little correlation between time discount and age.[273]

Thus, although most youngsters acknowledge the existence of tobacco-related health risks, the agency finds that 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 not adequately remedied by existing 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."[274] Although several empirical studies have

[268] 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, pp. 1–2, April 28, 1994.

[269] Littlechild, S. C., "Smoking and Market Failure," in "Smoking and Society: Toward a More Balanced Assessment," edited by R. D. Tollison, Lexington Books, p. 271, 1986.

[270] Beales III, J. Howard, "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

[271] Viscusi, W. K., "Smoking: Making the Risky Decision," Oxford University Press, New York, p. 149, 1992.

[272] Goodin, R. E., "No Smoking: The Ethical Issues," University of Chicago Press, pp. 30–32, 1989.

[273] Fuchs, V. R., "How We Live," Harvard University Press, Cambridge, MA, pp. 228–229, 1983.+

[274] Becker, G. S., and K. M. Murphy, "A Theory of Rational Addiction," Journal of Political Economy, vol. 96, No. 4, pp. 675–700, 1988.

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,[275] 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."[276]

FDA's justification of this regulation relies on the total costs associated with childhood addiction to tobacco, rather than on the external or spillover costs to nonusers. Nevertheless, a further market failure would exist if the use of tobacco imposed such 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 the issue of whether smokers pay their own way is the 1991 study by Manning, et al.,[277] 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 concurred with the study's conclusion,[278] although many uncertainties remain regarding the potential magnitude of the omitted cost elements.

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the regulation include the costs that would be avoided by reducing 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.[279]

In a recent statement, the former 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.[280] More recently, the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at $50 billion.[281] 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."[282] 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 regulation-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 relied on these incidence-based studies for its original analysis of the proposed rule to value the beneficial effects of the 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 will 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 will translate to reduced rates of lifetime tobacco consumption;
- A projection of the extent to which the reduced rates of lifetime tobacco consumption will decrease the number of premature deaths and lost life-years; and
- An exploration of various means of estimating the monetary value of the expected health improvements.

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[275] 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., T. W. Hu, P. G. Barnett, and W. G. Manning, "Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence," *Journal of Health Economics*, vol. 12, pp. 1–18, 1993.

[276] Chaloupka, F., "Rational Addictive Behavior and Cigarette Smoking," *Journal of Political Economy*, vol. 99, No. 4, p. 740, 1991.

[277] Manning, W. G., E. B. Keeler, J. P. Newhouse, E. M. Sloss, and J. Wasserman, "The Costs of Poor Health Habits, A RAND Study," Harvard University Press, Cambridge, MA, 1991.

[278] 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.

[279] See "Smoking and Health in the Americas: A 1992 Report of the Surgeon General in collaboration with the Pan American Health Organization," Department of Health and Human Services (DHHS), Public Health Service (PHS), CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), pp. 105–112, 1992, (hereinafter referred to as "1992 SGR") for a full summary of these methodologies and findings.

[280] 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, p. 2, April 28, 1994.

[281] "Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993," in *Morbidity and Mortality Weekly Reports (MMWR)*, CDC, DHHS, vol. 43, No. 26, pp. 469–472, July 8, 1994.

[282] 1992 SGR, p. 111.

The annual benefits of the 1995 proposed rule were 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. Upon review of the public comments, FDA found none that would persuade the agency to revise its projections. In general, the relevant comments expressed no objection to the basic methodology or model, but some disputed the accuracy of the specific data estimates. The following paragraphs describe the FDA assumptions that underlie these benefit estimates and present the agency's response to the applicable public comments.

3. Reduced Incidence of New Young Smokers

FDA's preliminary analysis assumed that 1 million youngsters become new smokers each year. One trade association comment questioned this figure, asserting that the relevant studies included individuals over the age of 18. However, the 1985 National Health Interview Survey reported 1.08 million 20-year old smokers, and the Combined National Health Interview Surveys for 1987–1988 found that 92 percent of 20-year old smokers had started smoking by age 18. Taking 92 percent of 1.08 million yields 993,600 new underage smokers per year. This figure is supported by parallel estimates of the SAMHSA. Based on data from the 1994 National Household Survey on Drug Abuse, SAMHSA estimated that 1.29 million persons under age 20 became daily smokers in 1993, and that 1.1 million of these persons were under the age of 18. As a result, FDA retains confidence in its original estimate of 1 million new smokers per year.

The regulation targets youngsters 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 at the local level. 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). [283]

Advertising and promotional restrictions will augment these efforts to limit the attractiveness of tobacco products to underage consumers. As discussed in detail in section VI. of this document, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, much of the relevant research indicates that advertising restrictions will 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." [284] Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the United Kingdom Department of Health determined that, "the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption." [285] A detailed evaluation of the effects of advertising on youth consumption of tobacco products is provided in section VI. of this document.

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 by 40 to 80 percent. [286]

In its analysis of the 1995 proposed rule, FDA argued that, while quantitative estimates of the effectiveness of its regulation cannot be made with certainty, 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. In the **Federal Register** of January 19, 1996 (61 FR 1492) SAMHSA published a regulation governing a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. SAMHSA had originally estimated that its program would reduce tobacco consumption by youth and children by from one-third to two-thirds, but subsequently determined that reductions of between one-tenth and one-third would be "more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion." [287] While strongly supporting the objectives of the SAMHSA program, FDA finds that achieving the "Healthy People 2000" goal will demand a full arsenal of controls to complement and fortify the new State inspectional programs, including restrictions on industry advertising and promotions and quite possibly educational messages to counter the influence of ongoing marketing activities.

Numerous public comments to the 1995 proposal addressed the issue of the effectiveness of the regulation. Many argued that tobacco advertising does not increase tobacco use, or that the enforcement of existing or forthcoming State laws, alone, could accomplish reasonable goals. In contrast, many others supported a comprehensive regulation, contending that only vigorous enforcement of new restrictions would bring significant results. As outlined earlier in the preamble in this document, FDA has determined, based on a full examination of the evidence, that the combined effect of the regulations (restricting advertising and promotion, prohibiting self-service sales, providing new labeling information, and imposing age verification obligations) and educational programs will significantly diminish the allure as well as the access to tobacco products by youth. The agency acknowledges the imposing size of the required effort, but is confident that its goals are reasonable and presents regulatory benefits based on the presumption that the "Healthy People 2000" goals will be met.

[283] Jason, L. A., P. Y. Ji, M. D. Anes, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *The Journal of the American Medical Association (JAMA)*, vol. 266, No. 22, p. 3159, December 11, 1991.

[284] DHHS, "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 (the 1989 SGR).

[285] Leaney, K., "Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence," Economics and Operational Research Division, Department of Health, London, p. 22, October 1992.

[286] 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, Stop Tobacco Access to Minors Program (STAMP), Petaluma, CA, p. 4, November 3, 1994.

[287] 61 FR 1502, January 19, 1996

FDA agrees, however, that these projections are uncertain and therefore also presents estimates of benefits at effectiveness levels that are considerably smaller. The agency conducted this exercise not because its estimates are excessively speculative or arbitrary, as suggested by one comment, but because sensitivity analyses are part of generally accepted "best practice" for the conduct of cost-benefit analysis and are recommended by OMB guidance. These results demonstrate that even if the rule were only modestly effective in reducing tobacco use, it yields justifiable benefits.

One comment urged the agency to demonstrate the effectiveness of tobacco marketing restrictions over and above those for access restrictions or public information campaigns. FDA is unable to forecast the independent results of each regulatory provision, due to the high degree of interdependence among the various requirements, but notes that SAMHSA concluded that its access restrictions, alone, would reduce underage tobacco consumption by one-tenth to one-third. If so, accomplishing the "Healthy People 2000" goal implies that the FDA rule would generate incremental tobacco use reductions of between 17 and 40 percent for youngsters under 18 years of age.

4. Reduced Number of Adult Smokers

The major beneficiaries of the rule are those individuals who would otherwise begin using tobacco early in life and who, accordingly, are unlikely to start using tobacco products as an adult. Evidence suggests that this percentage will be high, as over half of adult smokers had become daily cigarette smokers before the age of 18. Moreover, 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."[288] Although some comments disagreed with that conclusion, FDA believes that the Surgeon General's Report is correct. Nonetheless, to account for the possibility that some would-be smokers who are prevented from smoking until they are age 18 may eventually start smoking as adults, FDA uses the more conservative assumption that these rules will lead to a tobacco free adult life for only one-half of the estimated 500,000 youngsters who will be deterred from starting to smoke each year. Accordingly, FDA calculates the annual benefits from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult. Further, in response to comments that challenge this estimate, FDA presents sensitivity analysis showing results using a wide range of alternative rates.

5. Lives Saved

Based largely on data from Peto, et al., who found that about half of all adolescents who continue to smoke regularly throughout their lives will eventually die from a smoking-related disease,[289] CDC estimates that about one in three adolescent smokers will die prematurely.[290] Although the CDC projection provides the best estimate of this excess fatality rate, it does not provide a distribution of the smoking-related fatalities over time. Consequently, FDA derived this distribution by comparing age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate are 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 multiplied differences in the probabilities of death for smokers versus nonsmokers within each 10-year period by the number of smokers remaining at the start of each 10-year period. Assuming an equal number of males and females, the excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. FDA recognizes that this methodology probably understates the current risk of smoking, because it arbitrarily assumes that the smoking-related risks for females will continue to be smaller than for males, even though female smoking patterns are presently comparable to those of males. Nevertheless, FDA used this model to support its proposed regulation and maintains the calculation to demonstrate the robustness of the results. Moreover, because some comments suggested that these data may not account for all potentially confounding variables, such as alcohol consumption or other lifestyle differences, FDA further adjusted the mortality estimate to 24 percent to reflect findings by Manning et al., that such nontobacco versus tobacco lifestyle factors may account for 13 percent of excess medical care expenditures. Thus, the benefits projections presented below conservatively rely on the probabilities

[288] 1994 SGR, pp. 5 and 65.

[289] Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developing Countries, 1950–2000," Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

[290] Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from national Vital Statistics," Oxford University Press, Oxford, 1994.

shown in Table 3, corrected by the 13 percent lifestyle influence adjustment. In sum, they indicate that achieving the "Healthy People 2000" performance goal will prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.

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 is used to calculate the present value of the projections. (This rate was recommended by the Panel on Cost-Effectiveness in Health and Medicine, a nonfederal multidisciplinary group of experts in cost-effectiveness analysis, convened by the Office of the Assistant Secretary for Health in 1993.[291] Since the Office of Management and Budget (OMB) Circular A–94 recommends the use of 7 percent as a base case, FDA presents summary estimates below for discount rates of both 3 percent and 7 percent.) On the assumption that it would be roughly 20 years for each year's cohort of new adults to reach the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that the present value of these benefits equate to 15,863 lives per year.

6. Life-Years Saved

The number of life-years that will 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 nonsmokers. 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.[292] Deducting the 13-percent lifestyle adjustment indicates that, over the full lifetime of each cohort, the regulations will gain an estimated 905,000 life-years, which translates to almost 4 years per smoker and 15 years per life saved.[293] The present value of these additional life-years equates to 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 developed estimates of the value of the reduced medical costs and the increased worker productivity that will result from fewer tobacco-related illnesses. In addition, since productivity measures do not adequately address the avoidance of premature death, FDA 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,[294] 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).[295] As noted earlier, the incidence-based study by Manning, et al., implies that about 13 percent of the excess medical costs were attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index 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). Because FDA projects that achieving the "Healthy People 2000" goals will prevent 250,000 of these individuals from smoking as adults, the medical cost savings are 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 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 is due to discounting.[296] Accordingly, 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.,[297] 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. Although one comment mistakenly assumed that FDA had made no adjustment for lifestyle differentials between smokers and nonsmokers, in fact, these estimates were further

[291] Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, "Cost-effectiveness in Health and Medicine," Oxford University Press, p. 232, 1996.

[292] 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.

[293] The calculation procedure probably understates total life-years saved, because it misses smoking related-fatalities that occur within the same 10-year age interval. However, because more of these misses involve fatalities that, if avoided, would add few life-years, the resulting 15-year average life-years saved may be high. FDA's benefit estimates, however, remain understated because they are based on total life-years saved, not average life-years saved.

[294] Hodgson, T. A., "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, p. 97, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

[295] *Id.* (Using the average of the male and female totals).

[296] 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.

[297] 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.

reduced by 13 percent to reflect the Manning, et al., findings. Finally, because the long-term decline in smoking prevalence has exceeded the growth in population, FDA reduced the incidence-based costs 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 1 year's cohort of 1,000,000 new smokers, is about $3.5 billion. Thus, the estimated annual morbidity-related savings associated with preventing 250,000 new youths per year from smoking as adults is estimated at about $879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB guidance 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.[298] 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[299] 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.[300] 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 is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age and 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 methodologies, 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 converts to about $116,500 per life year. Since achieving the agency's goals were estimated to save 211,391 discounted life-years annually, this calculation yields annual benefits of $24.6 billion.

FDA notes that even these values understate the full value of the health impact, because they fail to quantify any reduction in either the adverse effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking. Moreover, these totals may not capture the heavy toll of psychic loss to surviving family members, or the corresponding economic losses among family members for the mental health care of grief-related depression and other conditions that often follow the premature death of middle aged adults.[301]

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.[302] A reduction in the number of smokers, and the corresponding number of cigarettes smoked, will result in a drop in the number of future fires. In the 1995 proposal, FDA estimated that if the number of fires falls by the same percentage as the expected reduction in cigarette sales, this implies present value savings 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.

One comment denied the existence of any association between fires and cigarette consumption. FDA acknowledges that the relationship may be nonlinear, but finds the asserted lack of a positive correlation implausible. This comment further stated that residential fires caused by smoking and deaths from residential fires caused by smoking decreased from 1983 to 1992 by 39 percent and 40 percent, respectively, or about 5.5 percent annually. Accounting for this trend would lower FDA's fire cost estimate to a present value savings of $145 million for the value of lives saved and $17 million for the value of averted property damage, totaling $162 million annually over a 40-year period. Even these estimated savings significantly underestimate the potential benefits, however, because they exclude both nonfatal injuries and the need for temporary housing.

12. Smokeless Tobacco

The Smokeless Tobacco Council, Inc., remarked that FDA had not attempted to measure the benefits that would result from the decreased use of smokeless tobacco products by underage youths. The introduction to the 1995 proposed regulation, however, explained that the use of smokeless tobacco causes severe health effects. While data are not available on age-specific differences in the probability of survival for smokeless tobacco users as compared to nonusers, the 1994 Surgeon General Report indicates that the "primary health consequences during adolescence include leukoplakia, gum recession, nicotine addiction, and increased risk of becoming a cigarette smoker. Leukoplakia and/or gum recession occur in 40 to 60 percent of smokeless tobacco users."[303] Oral leukoplakias have a 5-percent chance of becoming malignancies in 5 years.[304] Cancers of the nasal cavity, pharynx, larynx, esophagus, stomach, urinary tract and pancreas have also been linked to smokeless tobacco use.[305] Other effects include discoloration of teeth, periodontal disease and excessive tooth wear and decay.[306] One study of female snuff users showed that it increased one's risk of developing oral and

[298] Schelling, T. C., "Economics and Cigarettes," *Preventive Medicine*, vol. 15, pp. 549–560, 1986.

[299] 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.

[300] Viscusi, W. K., "Fatal Tradeoffs: Public and Private Responsibilities for Risk," Oxford University Press, p. 24, 1992.

[301] Harris, M., "The Loss That is Forever The Lifelong Impact of the Early Death of a Mother or Father," Penguin Books, 1995.

[302] 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.

[303] 1994 SGR, p.39.

[304] *Id.*

[305] Goolsby, M. J., "Smokeless Tobacco: The Health Consequences of Snuff and Chewing Tobacco", *Nurse Practitioner*, vol. 17, No. 1, p. 31, January 1992.

[306] *Id.*

pharyngeal cancer between 1.5 to 4.2 times. [307]

If the provisions pertaining to smokeless tobacco are as effective as those pertaining to cigarettes, the rule will prevent about 36,500 youths from becoming adult users of smokeless tobacco. This projection assumes that the number of underage users will decrease by 50 percent and one-half of those youths will remain nonusers after reaching 18 years of age. The estimate also assumes that the ratio of new underage users to total underage users parallels that of cigarette users (i.e., approximately one-third) and that about 440,000 youths under the age of 18 are current users of smokeless tobacco products. [308]

Leukoplakia and/or gum recession are estimated to occur in 40 to 60 percent of smokeless users. [309] If even 50 percent of these cases were caused by smokeless tobacco use, the previous assumptions imply that these regulations will prevent from 7,300 to 11,000 cases of leukoplakia and/or gum recessions per year. Although FDA can not estimate the number of oral or other cancers prevented, the realized number will be substantial.

13. Summary of Benefits

The discussion above demonstrates the formidable magnitude 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 smoking-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 $9.2 to $10.4 billion). These totals do not include the benefits expected from fewer fires (over $160 million annually), reduced passive smoking, or infant death and morbidity associated with mothers' smoking. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates still yield impressive results. Table 1c of this section summarizes 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. In addition, while FDA could not quantify the benefits that will result from the projected decline in the use of smokeless tobacco, they would be considerable.

D. Regulatory Costs

A recently issued guideline for conducting economic analysis of Federal regulations, prepared under the auspices of OMB, states that:

> [T]he preferred measure of cost is the "opportunity cost" of the resources used or the benefits foregone as a result of the regulatory action. Opportunity costs include, but are not limited to, private-sector compliance costs and government administrative costs. Opportunity costs also include losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time * * *. An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth. While transfers should not be included in the [Economic Analyses'] estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation. [310]

Accordingly, FDA finds that the final rule will impose new cost burdens on manufacturers, retailers, consumers, and Government regulators of tobacco products. In addition, certain industry sectors will experience lost sales and employment, but these revenue losses will be at least partly offset by gains to other sectors, as discussed in the "Distributional Effects" section of this document. [311] While a number of industry comments argued that the agency's preliminary analysis was deficient for not including these lost revenues in its cost-benefit assessment, FDA finds that the revenue losses suggested by these comments do not meet the previous definition of "opportunity cost;" because they fail to provide the changes in net costs that are necessary to estimate producer surplus, conventionally defined as sales minus variable costs. This rule will affect producer surplus in several industries and only net changes in these surplus' are social costs. Calculating such changes would require a multi-market model of economic changes over many years. Such general equilibrium models have not been used by Federal agencies for regulatory analyses, are not specifically recommended by the OMB guidance, and would be impractical to use, especially where major markets are dominated by few firms.

The most comprehensive critique of FDA's preliminary economic analysis was prepared by the Barents Group, economic consultants to the Tobacco Institute. While the Barents Group developed independent estimates of economic costs, in many instances its methodology was consistent with FDA's analysis of its 1995 proposal. Often, however, the Barents Group had access to more recent data, or to additional data provided by the affected industries. FDA's revised cost estimates rely extensively on these new data, but as described below, the agency's final cost estimates are far smaller than those presented by the Barents Group.

1. Number of Affected Retail Establishments

A critical variable underlying the agency's cost estimates is the number of retail outlets currently selling over-the-counter (OTC) tobacco products. A major confounding factor is that the U.S. Census publishes product line data only for establishments with payroll. For its original estimate of the number of retail establishments selling tobacco products, FDA relied on 1987 Census data to count the number of affected payroll establishments and very conservatively included every nonpayroll establishment in those categories that traditionally sell tobacco products (general merchandise stores, grocery stores, service stations, eating and drinking places, drug stores, and liquor stores). FDA estimated that the number of establishments selling tobacco products OTC included 275,000 payroll establishments and 215,000 nonpayroll establishments, for a total of 490,000 retail establishments. To account for all other business categories that might sell

[307] Winn, D. M., W. J. Blot, C. M. Shy, L. W. Pickle, A. Toledo, and J. F. Fraumeni, "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, Table 2. March 26, 1981.

[308] Estimates of youth smokeless usage vary. This projection relies on a conservative estimate of total youth (ages 12–17) usage calculated from data in the Statistical Abstract of the U.S. 1995, 115th edition, Tables 16 and 218.

[309] 1994 SGR, p.39.

[310] Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996. Prepared by intoragency group convened by OMB and co-chaired by a Member of the Council of Economic Advisers.

[311] This analysis evaluates the regulation following the Kaldor-Hicks criteria for societal welfare maximization.

OTC tobacco products, FDA estimated a total upper bound range of 600,000 establishments. FDA did not know how many locations currently served by cigarette vending machines would convert to OTC operations following implementation of the regulation, but estimated the number at 100,000, raising the upper bound total to 700,000 future establishments.

FDA still has no definitive estimate of the number of retail outlets selling tobacco products. For their economic analysis, the Barents Group used 1992 U.S. Census estimates for the number of affected retail establishments with payroll, but adopted an alternative methodology to estimate the number of affected establishments without payroll. The Barents Group subdivided retail businesses into 10 categories: General merchandise stores, supermarket/grocery stores, convenience stores without gas, convenience stores with gas, gasoline service stations, eating places, drinking places, drug and proprietary stores, specialty tobacco stores, and miscellaneous retail stores. Within each category, the Barents Group assumed that the percentage of nonpayroll establishments selling tobacco products would be the same as the percentage of payroll establishments selling tobacco products. As a result, they concluded that the number of retail payroll establishments selling tobacco products OTC is approximately 283,000, and the number of retail nonpayroll establishments selling tobacco products OTC is about 107,000, for a total of 390,000 retail outlets. The Barents Group's subsequent calculations are less clear and not documented in their appendix on methodology. Noting that FDA had estimated an upper bound of 600,000 establishments selling OTC tobacco products, they assumed the existence of an additional 100,000 to 200,000 nonretail establishments, such as operations within manufacturing or service businesses, that sell OTC tobacco products. Finally, the Barents Group accepted FDA's estimate that about 100,000 current vending machine locations would convert to OTC sales for tobacco products and proposed total lower and upper bound estimates of from 500,000 to 700,000 establishments.

For this final economic analysis, FDA adopts the apparent mid-point of the Barents Group's forecast of the number of establishments that will sell tobacco products, or about 500,000 current establishments and a total of 600,000 future establishments. FDA estimates by business category are displayed in Table 4 and follow closely the methodology presented by the Barents Group, except for slight adjustments to eliminate nonstore outlets. Because Census data on the number of establishments without payroll were not reported separately for convenience stores, convenience stores with gas, or specialty tobacco stores, these outlets are counted with the higher level outlet categories.

2. Removing Self-Service and Other Prohibited Retail Displays

The 1995 proposed regulation restricted all point of purchase advertising to "text only" and banned the use of all self-service displays by requiring vendors to physically provide the regulated tobacco product to purchasers. In its original analysis, FDA explained that the proposed ban on self-service displays would affect many retail stores selling tobacco products, although shoplifting concerns had already caused a large number of these stores to place tobacco products in areas not directly accessible to customers. Those retailers that discontinued self-service displays typically modified their stores by either: (1) Placing tobacco products behind or above store cashiers or in locked cases located within close reach of store cashiers; (2) placing tobacco products behind only one or two checkout lines, 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 also 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 dictates 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. [312]

[312] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

TABLE 4.—ESTIMATED NUMBER OF ESTABLISHMENTS CURRENTLY SELLING TOBACCO PRODUCTS OVER-THE-COUNTER

Kind of Business	Number of Retail Establishments with Payroll	Percentage of Retail Establishments with Payroll Selling Tobacco Products	Number of Retail Establishments with Payroll Selling Tobacco Products	Total Number of Retail Establishments without Payroll	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products[j]	Estimated Total of Establishments Selling Tobacco Products Over-the-Counter[k]
	(1)	(2)	(3)	(4)	(5)	(6)
Retail Establishments:						
General Merchandise	34,606	35.01%	12,117	28,010 [f]	9,807	21,924
Supermarket/Grocery	126,785[a]	56.19%	71,240	97,061[g]	54,538	125,778
Convenience Stores	30,748	95.62%	29,400	– [h]	–	29,400
Convenience Stores with Gas	57,033[b]	91.02%	51,913	– [h]	–	51,913
Service Stations	71,336[c]	53.21%	37,958	14,248	7,581	45,539
Eating Places	377,760[d]	3.17%	11,992	96,538	3,065	15,057
Drinking Places	55,848	19.24%	10,745	27,733	5,336	16,081
Drug Stores	48,142	60.33%	29,046	3,031	1,829	30,875
Tobacco Stores	1,477	100.00%	1,477	– [h]	–	1,477
Miscellaneous Retail Stores	273,256[e]	9.15%	24,995	490,633[i]	44,879	69,874
Other Establishments	–	–	–	–	–	100,000
Total	1,076,991		280,883	757,254	127,035	507,918

(a) Category contains food stores (SIC 54) with payroll, excluding convenience food stores (SIC 541 pt) and convenience food/gasoline stores (SIC 541 pt).
(b) Category contains convenience food/gasoline stores (SIC 541 pt) and gasoline/convenience food stores (SIC 554 pt).
(c) Category excludes gasoline/convenience food stores (SIC 554 pt).
(d) Category contains eating and drinking places (SIC 58), excluding drinking places (SIC 5813).
(e) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596) and tobacco stores and stands (SIC 5993).
(f) 1992 Nonemployer Statistics Series only provides data on variety and miscellaneous general merchandise establishments without payroll.
(g) 1992 Nonemployer Statistics Series only provides data on grocery stores, retail bakeries, and other food stores without payroll.
(h) 1992 Nonemployer Statistics Series does not provide data on establishments without payroll for these categories.
(i) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596).
(j) Column (2) times Column (4).
(k) Column (3) plus Column (5).
Source: Columns (1)–(4) from U.S. Census of Retail Trade Merchandise Line Sales and Nonemployer Statistics Series; Columns (5) and (6) projections according to Barents Group LLC Appendix I methodology.

Because prevailing business practice is for tobacco manufacturers to assist and even pay for most product display equipment,[313] FDA had assumed that manufacturers would share with retailers any expense of relocating displays and that the majority of the costs would be to relocate self-service displays for cartons. FDA estimated one-time costs of $22 million to be shared by manufacturers and retailers and additional annual operating costs of $14 million to be incurred by retailers (all in 1994 dollars). In stark contrast, the Barents Group projected one-time costs of from $558 to $780 million in 1996 dollars ($520 to $728 million in current dollars), with 62 percent attributed to the replacement of display items by retailers and the remaining 38 percent to manufacturers due to "time costs involved in removing banned display and promotional items, whether the work would be performed directly by a manufacturer's employee or subcontracted out to a display distributor." As explained below, FDA finds that many aspects of the Barents Group's estimates are seriously flawed. Nevertheless, the agency has adopted the basic framework of that analysis and its revised estimates reflect the Barents Group's methodology and data, unless specifically modified as discussed below.

a. *The Barents Group's methodology.* The Barents Group's cost projections were based on estimates of an average outlet cost for each of seven outlet categories. Each average outlet cost was multiplied by the total number of outlets of that category in the United States to produce national cost estimates. The actual outlet cost data were collected by A. T. Kearney, Inc., still another business consulting firm. The Barents Group explained that:

> [O]ur estimates are based on a compliance audit study conducted especially for this purpose by A. T. Kearney, Inc. A. T. Kearney performed an in-depth study of the actions and efforts that would be required of tobacco manufacturers' representatives, of point-of-sale display item distributors, and of tobacco retailers in order to bring stores into compliance with the proposed regulations. Detailed surveys were conducted of seven categories of retail outlets in five U.S. metropolitan areas, for a total of 88 retail outlets. Surveyors performed a detailed inventory of the many types of tobacco product displays and promotional materials which are currently found in stores. The surveyors noted which items would need to be modified or replaced.

A. T. Kearney reportedly completed a comprehensive on site compliance protocol checklist at 88 establishments randomly selected in 5 general regions of the United States. The individual display items were grouped into 41 discrete item categories and a lengthy discussion of the methodology and results are presented as a Technical Appendix to the Barents Group's comments.

b. *The Barents Groups's miscalculations.* To evaluate these results, FDA carefully reviewed the A. T. Kearney survey data and the Barents Group's extrapolation procedures and attempted to replicate the aggregate estimates. In doing so, numerous computational discrepancies were identified. For example, in calculating retailer time costs, the Barents Group intended to use an estimated retail employee wage of $9.51, but in fact used the estimated wage for a manufacturer's sales representative of $25.70. (See Appendix Table "Initial Compliance Effort Costs per Retail Store.") Also, the Barents Group's calculations relied on incorrectly transposed data for the average number of disposable displays per store and miscalculated compliance effort costs for five of the seven types of business. Further, A. T. Kearney reported that only one-third of the lighted signs and clocks would need to be replaced by retailers, but the Barents Group's calculations assumed that all would be replaced. Finally, A. T. Kearney reported that retailers would not replace most promotional posters, signs and displays, but the Barents Group's calculations assigned each $85 in replacement costs. Correcting these errors reduces the Barents Group's low and high cost estimates by $77 and $108 million, respectively.

Even more important, in aggregating the unit costs for "Compliance Activity No. 19—Remove and replace interior newsstands and shopping basket racks and baskets and shopping carts," A. T. Kearney committed a major error that dominates the aggregated cost totals. In discussing the costs for this item, A. T. Kearney focused on the need to replace shopping basket racks, which "* * * are free-standing units and contain about 20 shopping baskets, that also contain the name or logo of the cigarette manufacturer." Although it seems probable that the logos or brand names affixed to these items could be either removed or obscured, the survey data indicate that six supermarket/grocery stores, three convenience stores, two tobacco stores and one convenience store with gas would replace shopping basket racks. The detailed survey data for supermarket/grocery stores, however, reveal that one store supposedly possessed 71 racks, two stores 50 racks, and the remaining three stores 41, 32, and 10 racks, respectively. Even a casual review of these data suggests that individual hand-held shopping baskets rather than basket racks were counted. Indeed, an FDA contractor visited the five Washington, DC area outlets in which A. T. Kearney observed the largest number of racks and found scores of plastic hand-held baskets adorned with simple advertising stickers, but only a few basket racks.[314]

Although the advertising on these plastic baskets could easily be removed or covered, or new plastic baskets purchased quite inexpensively, the Barents Group's calculations inadvertently assumed that a distribution services contractor would be hired to remove each plastic hand-held shopping basket at a fee of $45 apiece and that a retailer would spend 30 minutes plus an additional $89 replacement fee for each plastic hand-held shopping basket in its possession. Thus, the estimated cost attributed to each hand-held basket was $138 and the cost for just the one outlet reporting 71 shopping baskets totaled $9,850. Extrapolating to each outlet category, the A. T. Kearney results implied that removing and replacing plastic hand-held baskets would cost, on average, over $1,300 for each supermarket/grocery store and $300 for each convenience store in the United States. Its projected costs for removing and replacing the hand-held shopping baskets in all supermarket/grocery stores in the United States ranged from $163 million to $229 million. For all outlet types, costs for these hand-held baskets were estimated at $194 to $271 million, or 43 percent of the national point-of-sale costs estimated by the Barents Group.

Based on site visits, FDA modified Kearney's field data for the correct number of shopping basket racks in the Washington, DC area establishments. Furthermore, FDA contractors determined that the hand-held shopping baskets could easily be modified by a marketing representative, who would take, at most, 5 minutes to affix new stickers on each basket or rack. For a rack of 20 baskets, this task was estimated to take a total of 105 minutes, plus about $42 for stickers. These adjustments reduce the Barents Group's estimated one-time costs by $180 to $252 million.

[313] *Id.*

[314] Buck, E., "Site Visit Report," April 24, 1996.

c. *The Barents Group's extrapolation procedure.* The Barents Group contributed still another bias by their method of extrapolating these survey results to the assumed range of 500,000 to 700,000 retail establishments. A. T. Kearney surveyed stores in only seven business categories: General Merchandise, Supermarket/Grocery, Tobacco Specialty, Convenience Store without Gas, Convenience Store with Gas, Service Station, and Drug Store. To represent all affected outlets, the Barents Group apportioned the full upper and lower bounds for their estimated number of establishments (500,000 and 700,000) among 10 business categories "based on the fractions they represent in the Census sample of with-payroll retail stores selling tobacco products." (Eating Places, Drinking Places, and Miscellaneous Retailers were added for this outlet allocation, but were assigned no costs because they are not "* * * the types of retail outlets where the vast majority (more than 90 percent) of tobacco product sales occur and where promotional items are most prevalent." That is, the Barents Group used a proportional adjustment to raise each establishment category count so that the lower and upper bound totals sum to 500,000 and 700,000, respectively. The estimated number of establishments in each category was then multiplied by the average cost for each business category using data from the A. T. Kearney site visits.

The implications of these inappropriate establishment number extrapolations are considerable. For example, A. T. Kearney surveyed a sample of 10 outlets from its first business category—General Merchandise Stores. These 10 outlets, which include three K-Mart and two Wal-Mart stores, averaged over 84,000 square feet of space, with the smallest store measuring 40,000 square feet. The U.S. Census reports only 12,117 such establishments with payroll. The Barents Group's proportional adjustment automatically expanded this outlet type count to between 21,299 and 29,818. (See Barents Group's Appendix Table.) Thus, to generate a national estimate of costs, the Barents Group applied the cost per establishment for its sample of very large general merchandise stores to roughly double the number reported in the U.S. Census for such establishments with payroll. This methodology inappropriately bases the per outlet cost for thousands of small nonpayroll and nonretail outlets on the per outlet cost reported for very large general merchandise stores.

The identical problem holds for the Barents Group's projection of the A. T. Kearney survey sample of 27 Supermarket/Grocery stores. Although this sample includes a few moderately sized establishments (1 less than 1,000 square feet and 4 less than 5,000 square feet), 21 of the establishments exceed 10,000 square feet and the average sized facility is almost 35,000 square feet. Nevertheless, the Barents Group's apportionment procedure inflates the number of establishments in this category from the U.S. Census estimate of 71,240 with payroll to 125,222 and 175,311, on the dubious assumption that thousands of small nonpayroll or other nonretail establishments are best represented by the A. T. Kearney sample of mostly large supermarkets/grocery stores.

FDA's fundamental concern is not with the Barents Group's estimate of 500,000 to 700,000 affected establishments (although the upper bound of this estimate should be 600,000, because there would be no display relocation costs for the additional 100,000 outlets assumed to be established at existing vending machine locations), but with the allocation of the small establishments among the largest business categories surveyed by A. T. Kearney. To offset this bias, FDA reallocated the number of establishments in the business categories used to extrapolate the outlet cost estimates. As shown, in Table 5, FDA takes the number of establishments in the first two business categories—General Merchandise and Supermarket/Grocery stores—directly from the U.S. Census number of establishments with payroll, because there would be very few nonpayroll or nonretail establishments equivalent to those surveyed. For outlet extrapolation purposes, FDA assigns its estimated number of nonpayroll establishments in these two business categories to the Convenience Store category, on the assumption that this category is most representative of the small establishments excluded from the Census product line data. Although the Barents Group omitted all costs for Eating Places, Drinking Places, and Miscellaneous Retail Stores, FDA groups these outlets under Other Establishments and assumes certain minimal costs, as explained below. This redistribution of the establishment category groupings reduces the Barents Group's low cost estimate by $65 million and its high cost estimate by $170 million.

TABLE 5.—ESTIMATED NUMBER OF ESTABLISHMENTS REMOVING SELF-SERVICE AND OTHER PROHIBITED RETAIL DISPLAYS

Kind of Business	Number of Retail Establishments with Payroll Selling Tobacco Products Over-the-Counter	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products Over-the-Counter	Estimated Total Number of Establishments Selling Tobacco Products Over-the-Counter
A. T. Kearney Categories:			
General Merchandise	12,117	– (A)	12,117
Supermarket/Grocery	71,240	– (B)	71,240
Convenience Stores	29,400	64,345 (C)	93,745
Convenience Stores with Gas	51,913	– (D)	51,913
Service Stations	37,958	7,581	45,539
Drug Stores	29,046	1,829	30,875
Tobacco Stores	1,477	– (E)	1,477
Other Establishments	–	–	201,012 (F)
Total	233,151	73,755	507,918

(A) Variety and miscellaneous general merchandise stores are tallied as convenience stores.
(B) Food stores are tallied as convenience stores.

(C) This category includes food, variety, and miscellaneous general merchandise stores. The 1992 Nonemployer Statistics Series does not provide information about convenience stores without payroll.
(D) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(E) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(F) Includes retail establishments excluded from the Kearney field audit and other establishments selling tobacco products over-the-counter.

d. *Further modifications.* The Barents Group faulted FDA for not including costs for the removal of banned display items or for the replacement of banned point-of-sale promotional materials. Their estimates assumed that manufacturers alone would bear these costs, since the proposed regulation required that manufacturers remove all prohibited advertising displays. The final regulation, however, places this responsibility on the owners of the displays, which may frequently be the retail establishments. FDA cannot forecast the ultimate distribution of display ownership, but in view of current business practices, assumes that the manufacturer representatives will at least participate in the removal process. Nevertheless, this change in regulatory responsibility is likely to shift a greater share of the cost burden to retailers.

On the other hand, the Barents Group assumed that retailers alone would replace those promotional items having a utilitarian function, including display cases, signs, shopping carts or baskets, newspaper racks, ash trays, and clocks. FDA believes that this assumption is unfounded, because many retailers will modify rather than replace these items and many manufacturers will share the replacement burden with retailers. For example, one report describing the results of a local self-service ban indicated that, "tobacco distributors and tobacco company sales representatives furnished behind-the-counter shelving and locking cases for tobacco products to retailers at no charge in order to assist retailers comply with self-service/ vendor-assisted regulations."[315] Again, however, the future allocation of these costs among manufacturers and retailers is unknown. For its initial estimates, except as explained below, FDA maintains the Barents Group's assumptions that removal costs are primarily borne by the manufacturer and replacement costs by the retailer. In fact, both cost categories will be shared and the implications of these assumptions are illustrated below through sensitivity analysis.

In February 1996, economic consultants to FDA attempted to replicate the A. T. Kearney field audit in Boston (the Eastern Research Group, Inc. (ERG),)[316] and in Washington, DC (an independent contractor). While most observations of the number of affected display cases were reasonably consistent with the A. T. Kearney findings, the observed number of exterior and interior promotional materials deviated significantly from the A. T. Kearney audit data. One explanation may be that the seasonal items available at the end of November had been removed by the following February. As a result, FDA has not adjusted its calculations to account for these discrepancies (except for the cost of basket racks in the Washington, DC stores), but used certain insights from these visits to revise the Barents Group's unit cost assumptions, as follows:

(i) The agency rejects the Barents Group's assumption that retailers rather than manufacturers will bear the costs of replacing promotional unattached counter displays. Because many of these items will be moved to visible locations behind counters, it is far more likely that manufacturers, not retailers, would pay for replacements. For its revised estimate, therefore, FDA assumes that manufacturers will pay replacement costs for unattached counter displays. Although total costs are unchanged, this assumption increases the costs for manufacturers by $17 million and decreases the costs for retailers by an equal amount.

(ii) A. T. Kearney and the Barents Group contradict themselves on the cost of removing disposable display cases. A. T. Kearney describes these units as temporary displays "frequently found in association with promotional offerings, sales, or seasonal themes," but assumes that retailers will replace them with permanent self-standing retail pack cases at $250 each. In contrast, the Barents Group calculations imply that a distribution services company will remove each display for a fee of $150 and retailers will replace each item for $50. FDA agrees with the Barents Group that retailers will not replace temporary units with permanent retail pack cases. Moreover, if a marketing representative can throw away free-standing ash trays filled with sand, as noted by A. T. Kearney, then a marketing representative can also dismantle and throw away disposable displays made of cardboard and plastic. FDA estimates, therefore, that instead of hiring a distribution services company, the manufacturer's representative will take no more than 15 minutes to remove each disposable unit, install a new unattached counter display and restock any excess inventory in a nonself-service area. This assumption decreases the estimated one-time costs by $7 million.

(iii) The A. T. Kearney cost-estimating methodology for the self-service ban implies that store modifications take place in a sequential pattern, with no allowances for economies of scale. For example, the outlet cost for hiring a distribution services contractor to relocate or replace display cases was calculated as a fixed multiple of the number of cases to be removed, even though many establishments must remove several display cases. This approach overstates costs by ignoring the significant scale economies achievable by performing all compliance activities at one time. Thus, FDA modified A. T. Kearney's distribution services costs for the removal, relocation and installation of small attached, retail pack, and carton self-service display cases by assuming that the first display unit in an outlet would be removed at a unit charge of $90, $150, or $185, respectively, but that each additional unit would be removed at one-half of these costs. For those stores with different sizes of display cases, the first unit was assumed to be the most expensive to remove (e.g., a carton display would be considered the first item when there is also a retail pack display or a small attached display). Adjusting for these scale economies reduces the estimated total costs by $15 million.

(iv) A. T. Kearney assumed that many promotional items, such as signs and clocks, would be removed by a distribution services company hired by the manufacturer. FDA's consultants, however, found that almost all of the promotional material observed could be easily removed or modified by retail personnel or marketing representatives.

[315] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

[316] "ERG's Review of Docket Materials Concerning FDA's Proposed Regulations Covering Tobacco Products: Final Site Visit Report," Eastern Research Group, April 22, 1996.

For example, rather than needing a contractor to remove the lighted sign in one of the sampled outlets, ERG found that the front panel was easily removable and could be quickly replaced by an acceptable panel. Although a few signs may require substantial time to dismantle, most of these items will take just a few minutes to remove. To account for this range, FDA assumes that a manufacturer's representative will take 15 minutes to remove and dispose of the various exterior signs, banners, clocks and news stand displays, as well as the interior lighted signs and clocks, lowering total costs by $27 million.

(v) A. T. Kearney assumed that many display cases located in nonself-service areas would be removed and replaced, because of improper advertising. They assumed that the manufacturer would pay for the removal of the old case and the installation of the new case, but that the retailer would purchase the new display case. Contrary to this finding, FDA consultants found no sites in the Boston or Washington, DC regions where it was necessary to replace nonself-service displays. Because in each instance, all visible advertising could be altered or obscured, retailers would almost always opt to cover impermissible advertising rather than to purchase new display cases costing up to $300. Accordingly, FDA estimated that it would take 15 minutes and $5 worth of stickers to cover each small attached display; 25 minutes and $10 worth of stickers to cover each retail pack display; and 35 minutes and $15 worth of stickers to cover each carton display. This modification decreases total costs by $20 million.

(vi) Even though the A. T. Kearney audit identified a number of self-service display cases that did not fit in the nonself-service area but could be retrofitted with locks, the Barents Group did not include cost estimates for these items. FDA estimates that it would take 30 minutes of retailer time and cost about $10 for materials to add a lock to these display cases, increasing the total one-time costs by $1.5 million.

(vii) In its analysis of the 1995 proposed regulation, FDA acknowledged that the required reconfiguration of tobacco displays may also impose added labor costs for some purchase transactions, especially for those stores that move inventory to areas located away from employee work stations. On the assumption 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, FDA had estimated costs of about $14 million per year. Although a few comments indicated that the self-service ban would increase labor costs, the Barents Group did not include such costs in its assessment. Nevertheless, FDA believes that some establishments, particularly those selling a substantial number of cigarette cartons that could not be stored within easy reach of a checkout station, could experience increased annual labor costs. Thus, FDA recalculated its estimate based on the updated retail employee compensation rate of $9.51 suggested by the Barents Group and the new site visit data from the A. T. Kearney study, which imply that only about 40 percent of cigarette cartons are purchased at establishments that sell cigarette cartons from self-service areas. These adjustments project additional annual labor costs of about $10.9 million per year.[317]

Except for those adjustments, FDA used the information found in the A. T. Kearney field audit to develop its revised estimate. For comparison, the original Barents Group estimates of the number of establishments and one-time point-of-sale costs (corrected for miscalculations as described above) are shown in Table 6 and FDA estimates of one-time costs in Table 7. Detailed summaries of the FDA one-time cost estimates are presented in Table 8 and Table 9 and indicate that costs related to self-service display cases comprise 73 percent of the total, followed by 18 percent for promotional materials and 9 percent for nonself-service display cases. As explained above, these estimates assume that manufacturers will bear the cost of removing all promotional items and retailers will bear the cost of replacing most functional items. Because the regulation places the removal responsibility on owners of the materials, FDA does not know how these obligations will be divided. However, if retail outlets, rather than manufacturers, must remove these items, the overall cost to manufacturers falls by about $47 million and the cost to retailers increases by about $17 million. (Retail compensation rates are about one-third of manufacturer rates, according to the Barents Group data). The following discussion describes specific compliance costs for each outlet category.

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[317] Derived from assumption that 10 percent of carton transactions are for multiple (2) cartons, and that cartons constitute 85 percent of tobacco sales at supermarket/grocery stores, general merchandise stores, drug stores, and tobacco stores, and 10 percent of tobacco sales at other outlets. Tobacco sales data from 1992 Census of Retail Trade, pp. 3–31. Kearney site visits found that 80 percent of general merchandise stores, 33 percent of supermarket/grocery stores, 25 percent of convenience stores, 17 percent of service stations, 30 percent of drug stores, 42 percent of tobacco stores had self-service carton display cases.

TABLE 6.—BARENTS GROUP LLC ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS [1]

Kind of Business	Estimated Number of Establishments		Average Cost per Facility ($)	Estimated Point-of-Sale Costs (Lower)			Estimated Point-of-Sale Costs (Upper)		
	Lower	Upper		Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)	Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	21,299	29,818	1,067	13,268,172	9,449,404	22,717,576	18,575,066	13,228,900	31,803,966
Supermarket/Grocery	125,222	175,311	2,356	182,028,407	112,960,223	294,988,630	254,840,061	158,144,493	412,984,554
Convenience Stores	51,678	72,349	925	24,408,368	23,382,610	47,790,978	34,171,621	32,735,564	66,907,185
Convenience Stores with Gas	91,250	127,750	515	21,656,668	25,294,382	46,951,050	30,319,336	35,412,134	65,731,470
Service Stations	66,721	93,409	217	4,894,902	9,616,053	14,510,955	6,852,833	13,462,416	20,315,250
Drug Stores	51,056	71,478	167	4,472,540	4,054,323	8,526,863	6,261,520	5,676,020	11,937,541
Tobacco Stores	2,596	3,635	2,940	4,486,055	3,147,456	7,633,511	6,281,514	4,407,166	10,688,680
Total	409,822	573,750		255,215,112	187,904,451	443,119,563	357,301,952	263,066,694	620,368,645

[1] Totals may not add due to rounding.

TABLE 7.—FDA ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS

Kind of Business	Estimated Number of Establishments[1]	Average Cost Per Facility ($)	Estimated Point-of-Sale Costs[2]		
			Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	12,117	919	7,874,058	3,263,894	11,137,952
Supermarket/Grocery	71,240	810	32,655,560	25,067,316	57,722,876
Convenience Stores	93,745	364	12,271,061	21,879,370	34,150,431
Convenience Stores with Gas	51,913	213	1,397,066	9,644,359	11,041,425
Service Stations	45,539	122	2,560,164	2,974,000	5,534,164
Drug Stores	30,875	160	2,978,007	1,966,563	4,944,570
Tobacco Stores	1,477	2,175	2,165,591	1,046,163	3,211,753
Other Establishments	210,012	19	522,765	3,384,741	3,907,506
Total	507,918		62,424,273	69,226,404	131,650,677

[1] Number of establishments from Table 5.
[2] Totals may not add due to rounding.

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Promotional Materials:																
No. 3 Ext. Attached Signs	•	•	1.19	0	•	•	•	•	1.07	1	•	•	•	•	•	•
No. 4 Ext. Movable Sign Board	•	•	0.95	0	6.43	2	2.86	1	3.75	3	•	•	8.57	0	•	•
No. 5 Ext. Decal/Stickers	•	•	0.85	0	6.03	2	2.82	1	0.85	1	•	•	4.02	0	•	•
No. 6 Ext. Lighted Signs/Clocks	•	•	0.61	0	4.09	1	9.08	4	1.36	1	•	•	16.34	1	•	•
No. 7 Ext. Signs, Posters & Displays	•	•	0.38	0	1.93	1	1.33	1	•	•	•	•	1.43	0	•	•
No. 8 Ext. Movable Window Signs	•	•	0.95	0	10.44	3	2.14	1	1.61	1	•	•	.54	0	•	•
No. 9 Ext. Open/Closed Signs	•	•	0.43	0	2.20	1	•	•	•	•	0.59	0	0.98	0	0.59	3
No. 10 Ext. Signs on Gas Pumps	•	•	•	•	•	•	0.24	0	0.14	0	•	•	•	•	•	•
No 11 Ext. News Stand Displays	•	•	7.42	1	•	•	•	•	•	•	•	•	•	•	•	•
No 12 Ext. Novelty Item Displays	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
No. 13 Ext. Banners	•	•	•	•	0.80	0	3.57	2	1.07	1	•	•	0.54	0	•	•
No. 14 Signs, Posters & Banners	0.34	0	1.14	0	1.71	0	1.71	1	1.71	1	0.17	0	2.14	0	0.17	1
No. 15 Lgted. Signs, Clocks/Mach. Dev.	19.61	2	10.29	1	18.39	5	16.34	8	8.17	7	3.27	2	28.60	1	3.27	17
No. 16 Decals/Stickers	0.26	0	0.79	0	2.36	1	0.67	0	0.71	1	1.29	1	0.93	0	1.29	7
No. 17 Shelf Marker w/Adv.	0.60	0	0.44	0	2.14	1	1.49	1	1.83	2	0.37	0	0.96	0	0.37	2
No. 18 Shopper Aids	0.04	0	0.42	0	0.19	0	0.31	0	0.02	0	0.04	0	0.21	0	0.04	0
No. 19 News Racks, Shop. Bask., Carts	•	•	83.75	10	43.49	12	9.66	5	•	•	•	•	14.50	1	•	•
No. 20 Fl. St. Ash Trays, Waste Basket	•	•	3.30	0	•	•	9.89	5	•	•	•	•	24.71	1	•	•
No. 21 Merch. w/ Ref. to Tobacco Prod.	•	•	•	•	0.48	0	0.71	0	1.18	1	•	•	1.93	0	•	•
Promotional Materials Subtotal:	20.85	2	112.92	14	100.67	28	62.82	30	23.47	19	5.73	4	106.39	5	5.73	29
Self-Service Display Cases:																
Small, Unattached																
No. 22 Space Available, Ads Removed	•	•	0.32	0	1.34	0	2.38	1	0.71	1	1.07	1	3.21	0	1.07	6
No. 23 Unit Must be Replaced	10.60	1	25.52	3	53.00	15	53.00	25	8.83	7	•	•	141.33	6	•	•
Small, Attached												•				
-- Removal and Installation/Relocation	13.50	1	65.00	8	•	•	10.00	5	•	•	9.00	6	•	•	9.00	46
No. 24 Unit Must be Replaced	10.00	1	55.56	7	•	•	•	•	•	•	•	•	•	•	•	•
No. 25 Space Available, Ads Removable	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Packs																
-- Removal and Installation	67.50	7	86.11	11	•	•	•	•	6.25	5	7.50	5	193.75	9		
No. 26 Space Available, No Ads	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
No. 27 Space Available, Ads Removable	0.79	0	0.29	0	•	•	0.88	0	•	•	•	•	0.66	0	•	•
No. 28 Unit Must Be Replaced	200.00	22	222.22	27	•	•	•	•	20.83	17	25.00	16	625.00	29	•	•
No. 29 Unit Modified w/Locking Doors	1.48	0	3.28	0	•	•	•	•	•	•	•	•	•	•	•	•

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Cartons																
-- Removal and Installation	166.50	18	65.09	8	46.25	13	•	•	15.42	13	37.00	23	262.08	12		
No. 30 Space Available, No Ads	•	•	0.26	0	•	•	•	•	•	•	•	•	•	•	•	•
	•	•	•	•	1.19	0	•	•	•	•	•	•	1.59	0	•	•
No. 32 Unit Must Be Replaced	390.00	42	155.56	19	112.50	31	•	•	25.00	21	60.00	37	775.00	36	•	•
No. 33 Unit Modified w/Locking Doors	35.41	4	3.83	0	•	•	•	•	3.69	3	8.85	6	11.07	1	•	•
No. 34 Disposable, Replaced	•	•	2.09	0	•	•	•	•	4.70	4	•	•	37.62	2	•	•
Self-Service Subtotal:	895.78	97	685.12	85	214.28	59	66.26	31	85.44	70	148.42	93	2,051.30	94	10.07	52
Non-Self-Service Display Cases:																
Small, Unattached																
No. 35 Advertising Removable	•	•	0.16	0	2.41	1	6.43	3	3.75	3	2.14	1	0.89	0	2.14	11
No. 36 Unit Must be Replaced	•	•	•	•	26.50	7	47.11	22	•	•	•	•	13.25	1	•	•
Small, Attached																
No. 37 Advertising Removable	•	•	1.27	0	3.75	1	4.52	2	2.86	2	1.50	1	2.14	0	1.50	8
No. 38 Unit Must be Replaced	•	•	•	•	8.57	2	•	•	0.95	1	•	•	•	•	•	•
Packs																
No. 39 Advertising Removable	•	•	0.40	0	1.07	0	0.48	0	0.36	0	1.71	1	0.18	0	•	•
No. 40 Unit Must be Replaced	•	•	2.30	0	•	•	•	•	•	•	•	•	•	•	•	•
Cartons																
No. 41 Advertising Removable	2.57	0	1.43	0	•	•	•	•	•	•	0.64	0	0.36	0	•	•
No. 42 Unit Must be Replaced	•	•	6.66	1	•	•	•	•	•	•	•	•	•	•	•	•
No. 43 Disposable, Replaced	•	•	•	•	7.05	2	25.08	12	4.70	4	•	•	•	•	•	•
Non-Self-Service Subtotal:	2.57	0	12.22	2	49.35	14	83.61	39	12.61	10	6.00	4	16.82	1	3.64	19
TOTAL:	919.20	100	810.26	100	364.29	100	212.69	100	121.53	100	160.15	100	2,174.51	100	19.44	100

[1] Totals may not add due to rounding.

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Promotional Materials:										
No. 3 Ext. Attached Signs	*	85	*	*	49	*	*	*	134	0.1
No. 4 Ext. Movable Sign Board	*	68	602	148	171	*	13	*	1,002	0.8
No. 5 Ext. Decal/Stickers	*	60	565	146	39	*	6	*	816	0.6
No. 6 Ext. Lighted Signs/Clocks	*	43	383	471	62	*	24	*	984	0.7
No. 7 Ext. Signs, Posters & Displays	*	27	181	69	*	*	2	*	279	0.2
No. 8 Ext. Movable Window Signs	*	68	979	111	73	*	1	*	1,232	0.9
No. 9 Ext. Open/Closed Signs	*	31	206	*	*	18	1	118	375	0.3
No. 10 Ext. Signs on Gas Pumps	*	*	*	12	7	*	*	*	19	0
No. 11 Ext. News Stand Displays	*	529	*	*	*	*	*	*	529	0.4
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	75	185	49	*	1	*	310	0.2
No. 14 Signs, Posters & Banners	4	81	161	89	78	5	3	34	456	0.3
No. 15 Lgted. Signs, Clocks/Mach. Dev.	238	733	1,724	848	372	101	42	657	4,715	3.6
No. 16 Decals/Stickers	3	57	221	35	33	40	1	258	647	0.5
No. 17 Shelf Marker w/Adv.	7	31	201	77	83	12	1	75	488	0.4
No. 18 Shopper Aids	1	30	18	16	1	1	0	9	75	0.1
No. 19 News Racks, Shop. Bask., Carts	*	5,967	4,077	502	*	*	21	*	10,566	8
No. 20 Fl. St. Ash Trays, Waste Basket	*	235	*	513	*	*	37	*	784	0.6
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	45	37	54	*	3	*	139	0.1
Promotional Materials Subtotal:	253	8,044	9,437	3,261	1,069	177	157	1,151	23,549	17.9
Self-Service Display Cases:										
Small, Unattached										
No. 22 Space Available, Ads Removed	*	23	125	124	33	33	5	215	557	0.4
No. 23 Unit Must be Replaced	128	1,818	4,968	2,751	402	*	209	*	10,277	7.8
Small, Attached										
-- Removal and Installation/Relocation	164	4,631	*	519	*	278	*	1,809	7,400	5.6
No. 24 Unit Must be Replaced	121	3,958	*	*	*	*	*	*	4,079	3.1
No. 25 Space Available, Ads Removable	*	*	*	*	*	*	*	*	*	*
Packs										
-- Removal and Installation	818	6,135	*	*	285	232	286	*	7,755	5.9
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	10	21	*	46	*	*	1	*	77	0.1
No. 28 Unit Must Be Replaced	2,423	15,831	*	*	949	772	923	*	20,898	15.9
No. 29 Unit Modified w/Locking Doors	18	234	*	*	*	*	*	*	251	0.2
Cartons										
-- Removal and Installation	2,017	4,637	4,336	*	702	1,142	387	*	13,222	10
No. 30 Space Available, No Ads	*	19	*	*	*	*	*	*	19	0
No. 31 Space Available, Ads Removable	*	*	111	*	*	*	2	*	114	0.1
No. 32 Unit Must Be Replaced	4,726	11,082	10,546	*	1,138	1,853	1,145	*	30,489	23.2
No. 33 Unit Modified w/Locking Doors	429	273	*	*	168	273	16	*	1,159	0.9
No. 34 Disposable, Replaced	*	149	*	*	214	*	56	*	419	0.3

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TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Self-Service Subtotal:	10,854	48,808	20,087	3,440	3,891	4,583	3,030	2,024	96,717	73.5
Non-Self-Service Display Cases:										
Small, Unattached										
No. 35 Advertising Removable	*	11	226	334	171	66	1	431	1,239	0.9
No. 36 Unit Must be Replaced	*	*	2,484	2,446	*	*	20	*	4,949	3.8
Small, Attached										
No. 37 Advertising Removable	*	90	351	235	130	46	3	301	1,157	0.9
No. 38 Unit Must be Replaced	*	*	803	*	43	*	*	*	847	0.6
Packs										
No. 39 Advertising Removable	*	28	100	25	16	53	0	*	223	0.2
No. 40 Unit Must be Replaced	*	164	*	*	*	*	*	*	164	0.1
Cartons										
No. 41 Advertising Removable	31	102	*	*	*	20	1	*	153	0.1
No. 42 Unit Must be Replaced	*	475	*	*	*	*	*	*	475	0.4
No. 43 Disposable, Replaced	*	*	661	1,302	214	*	*	*	2,177	1.7
Non-Self-Service Subtotal:	31	870	4,626	4,340	574	185	25	732	11,385	8.6
TOTAL:	11,138	57,723	34,150	11,041	5,534	4,945	3,212	3,908	131,651	100

[1] Totals may not add due to rounding.

e. *General merchandise stores.* None of the general merchandise stores in the A. T. Kearney sample had exterior promotional materials and only a few had interior promotional materials. Eighty percent of the stores had only self-service displays, with carton displays more numerous than pack displays at these locations. The average per facility one-time costs estimated by FDA were $919. Overall, 97 percent of the outlet costs related to the replacement of self-service display cases, although in some general merchandise stores, tobacco products were stocked on shelves rather than in special display cases, which suggests that the costs for this business category may be overstated.

f. *Supermarket/grocery.* Unlike general merchandise stores, supermarkets had significant promotional materials. While both packs and cartons were sold at most locations, over 75 percent of the stores already had nonself-service display areas. FDA estimates per facility costs at $810. Self-service display case removal and replacement amount to 85 percent of the total cost, whereas promotional materials account for 14 percent. Commenting on the feasibility of the proposed FDA self-service ban, the Food Marketing Institute argued that most retail food stores do not have adequate space at checkout lines for tobacco products and rejected the practicability of alternative procedures. They suggested that the only option available to many food retailers would be to remodel and set-up a controlled area for the sale of tobacco products, costing up to $50,000 per store. The A. T. Kearney audit, however, found that a majority of supermarket/grocery stores have already installed nonself-service areas for tobacco products and would not need to reconfigure their stores. While some establishments will incur costs above the average, the A. T. Kearney site visit data suggest that most stores could comply by either moving inventory to nonself-service areas or by purchasing new displays that are compatible with existing store configurations.

g. *Convenience stores.* Stores in this category exhibited numerous interior and exterior promotional items. All of the convenience stores surveyed had nonself-service display cases and 50 percent had carton displays. FDA estimates per facility costs of $364. Costs for removing and replacing self-service display cases made up 59 percent of the total, while costs for promotional materials and nonself-service display cases were 28 percent and 14 percent, respectively.

The National Association of Convenience Stores (NACS) faulted FDA on its assumption that the main cost of the self-service ban would be to relocate tobacco product inventory, contending that their members would incur thousands of dollars in reconfiguration costs. According to NACS:

[i]t is largely irrelevant that retailers already keep packs behind the counter. Many NACS members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales.

Based on an estimate from one member with a high volume of self-service cigarette sales, NACS suggested it could cost $4,320 and $10,120, respectively, to reconfigure a newer and older convenience store.

Based on other evidence, however, FDA does not believe that a large number of stores will be forced to undergo extensive modifications and finds that most convenience stores can adequately adapt space either behind or above checkout counters. As noted earlier, one regional survey reported that retail outlets readily complied with local self-service restrictions without architectural remodeling or substantial refitting of checkout counters or store aisles.[318] Space above counters is typically available for display cases either by suspending a case from the ceiling or by supporting a case on beams from the counter. In its survey, A. T. Kearney found at least some tobacco products sold from nonself-service space in every convenience store. Although it is possible that stores might incur added inventory handling costs if this space were smaller than optimal, FDA concludes that major reconfiguration would rarely be required and relies on the A. T. Kearney survey data, as adjusted, to project average costs for this sector.

h. *Convenience stores with gas.* Like convenience stores without gas, these establishments had numerous interior and exterior promotional materials. About 89 percent of the stores surveyed had nonself-service display cases. FDA estimates per facility costs of $213. Consistent with the findings of the Barents Group, the average outlet cost for this sector is about one-half that of convenience stores without gas.

In comments to the 1995 proposed rule, the Society of Independent Gasoline Marketers of America (SIGMA) did not present specific data on the cost to their members, but indicated that many members would be required to reconfigure their stores. They stated that:

[m]any SIGMA members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. At a minimum, these members would have to install new cabinets to accommodate tobacco products behind the counter. Many members would have to enlarge the counter area to make room for the new cabinets.

In contrast, the A. T. Kearney field audit found few convenience stores with gas that have self-service displays, other than unattached promotional counter displays. Costs to remove or replace promotional counter displays will be borne primarily by manufacturers, not retailers. In sum, the costs for self-service display cases amount to about 31 percent of the total, promotional material 30 percent, and nonself-service display cases 39 percent.

i. *Service stations.* These establishments had both interior and exterior promotional material. Seventy-five percent of the locations surveyed had only nonself-service display cases and one-fourth had carton displays. FDA estimates the per facility cost at $122.

j. *Drug stores.* Drug store outlets had few exterior and interior promotional materials. As in general merchandise stores, tobacco products were stocked on shelves in some locations. Ninety percent of the stores surveyed by A. T. Kearney already had nonself-service displays and approximately 70 percent had carton displays. FDA estimated $160 cost per facility for this category of business. About 93 percent of the total one-time costs are for replacement of self-service display cases.

k. *Tobacco stores.* These stores had substantial promotional materials and multiple display cases. FDA estimates per facility costs of $2,175. About 94 percent of the costs are for self-service display cases, with promotional materials and nonself-service display cases dividing the remaining 6 percent. While not reflected in the cost totals, these establishments may choose to operate as "adult only" restricted areas to avoid replacing self-service display cases.

l. *Other establishments.* This category includes eating/drinking establishments and miscellaneous retail stores, which

[318] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

were excluded from the A. T. Kearney audit, plus the estimated 100,000 nonretail establishments that sell tobacco products OTC, such as hotels, factories and sporting facilities. Due to the low volume of tobacco product sales at these establishments, FDA assumed that only a small quantity of packs and no cartons would be sold. Lacking detailed data, FDA assigned costs of $19 per outlet, based on the costs of removing promotional materials and relocating and replacing small attached display cases, as reported for drug stores.

3. Label Changes

The final regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA estimated the compliance costs for printing new labels in its earlier analysis of the proposed regulation and has received no comments that improve those original estimates.

Approximately 933 varieties of cigarettes are currently produced in the United States. [319] FDA does not have information on the number of smokeless tobacco varieties, but assumes that the total number of cigarette and smokeless tobacco varieties is roughly 1,000. Because most varieties of cigarettes are packaged in both single packs and cartons, the total number of labels is assumed to number about 2,000.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach relied on information compiled by The Research Triangle Institute (RTI) for its report to FDA on the cost of changing food labels. [320] 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 $5.6 million for all 2,000 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. [321] The Canadian Government estimated a cost of $30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are likewise sold in two sizes, but about 20 percent are also sold in flip top packages. [322] 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 in the United States; 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.

4. Educational Program

FDA may issue notification orders under section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360h(a)) to require manufacturers of cigarettes and smokeless tobacco products to fund consumer educational programs. While the precise details of these orders are still under development, these orders may involve the achievement of specific performance objectives by directing manufacturers to initiate informational programs designed to transmit messages that will reach the majority of young people. The 1995 proposed regulation directed manufacturers to spend at least $150 million annually on this program. While industry comments were critical, many other comments suggested that this figure was too low. One comment noted that $150 million is equivalent to about one week of pro-tobacco expenditures and another that the industry gained $221 million in profits from underage sales. Still another pointed out that the current dollar value of the informational advertising that was conducted under the Fairness Doctrine would amount to about $300 million per year. One study appears to indicate that 75 percent of adolescents aged 12 to 17 could have been reached in 1985 to 1986 with multiple messages at a cost of about $17 million a year. [323] FDA is still evaluating various types of informational programs, with respect to both effectiveness and practicality. Before a final decision is reached, the agency will determine the costs of selected alternatives.

5. Restricted Advertising and Promotional Activities

a. *Tobacco industry.* The determination of the societal costs attributable to the restrictions on tobacco product advertising and promotion is complex. While there is no doubt that individual manufacturers 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. In addition, if the primary motivation for tobacco advertising is to promote brand-switching, then, as long as all firms are equally restricted from advertising, the above mentioned loss in goodwill value will be substantially reduced.

In its comments, the tobacco industry claimed that tobacco advertising and promotion have virtually no effect on youth consumption. Although FDA does not accept this claim, the agency does not consider the expected voluntary reduction in the consumption of tobacco products to be a societal cost. Although industry sales will fall, they will reflect new consumer preferences and consumer dollars no longer used on tobacco products will be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales are not net costs and the potential magnitude of this revenue transfer is discussed below under the heading of Distributional Effects. Moreover, as shown in that discussion, any short-term frictional or relocation impacts will be significantly moderated by the gradual phase-in of the economic effects.

b. *Advertising industries.* In its original analysis, FDA argued that advertising and promotional restrictions will impose no long term net costs on society. The Barents Group's study found that the various suppliers of

[319] "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes," Federal Trade Commission, 1994.

[320] French, M. T., D. M. Neighbors, L. K. Carswell, K. B. Heller, and G. L. McDougal, "Compliance Costs of Food Labeling Regulations," Final Report, RTI Project Number 233U-3972-02 DFR, January 1991.

[321] 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.

[322] Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.

[323] Bauman, K. E., J. D. Brown, E. S. Bryan, L. A. Fisher, C. A. Padgett, and J. M. Sweeney, "Three Mass Media Campaigns to Prevent Adolescent Cigarette Smoking," *Preventive Medicine*, vol. 17, pp. 510-530, 1988.

industry advertising will incur substantial regulatory costs. It estimated that illustrative annual costs for this sector could reach $722 million to $2.17 billion, or up to one-half of its estimate of the total costs of the FDA proposal.

Upon review, FDA remains firmly convinced that its original position was correct. That is, from the standpoint of assessing societal costs and benefits, reduced revenues from tobacco advertising and promotional activities are not net costs and are appropriately considered a distributional impact. Indeed, FDA believes that a strong argument can be made that, even irrespective of health benefits, these advertising restrictions will decrease net societal costs by freeing productive resources for alternative uses. This does not imply that no individual business entities will be negatively impacted. Many of the companies that currently benefit from tobacco promotions (e.g., advertising agencies, publishers, sporting event promoters) will suffer lost revenues and those firms that specialize in those activities may lose a substantial part of their business. Nevertheless, from a societal perspective, these losses will be counterbalanced by an increase in demand for other consumption and investment goods, so that nontobacco-related entities will gain sales. Although overlooked in most industry comments, this result is acknowledged within the comments submitted for the Tobacco Institute by the Barents Group:

> A key assumption in the simulations is that, when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

That report also reveals the underlying distributional nature of the impacts by explaining that its modeling incorporates the assumption that:

> * * * in the long run economic losses in one sector of the economy will be redistributed to other sectors of the economy, i.e., winners and losers will generally balance out for the economy as a whole.

Further discussion of the impact of these revenue transfers is included below under the section on "Distributional Effects."

c. *Retail sector.* In addition to the previously estimated direct costs associated with the removal of prohibited point-of-purchase advertising, promotional restrictions will impact the retail sector because they will lead to a long-term decline in tobacco products sales and a potential fall in promotional allowances (slotting fees) from manufacturers. Once again, these impacts are not net societal costs, since reduced tobacco product sales will be counterbalanced by increased sales for other products or services; and smaller promotional allowances, if they occur, are gains to tobacco manufacturers that would be used for other purchases. Consequently, these impacts also are examined below under "Distributional Effects."

d. *Consumers.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. Firms engage in advertising to inform potential customers about their product (informative advertising) or to persuade customers that a product is desirable (persuasive advertising). According to the FTC's Bureau of Economics, 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.[324]

FDA has considered each of these issues. First, while agreeing that many forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that consumers will lose little utility from these particular advertising restrictions. The regulation does not prohibit factual, written advertising. Thus, the rule will not impede the dissemination of important information to most consumers. In its preliminary analysis, the agency concluded that, "[w]hile 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" (60 FR 41314 at 41368).

One industry comment strongly opposed this position, arguing that advertising is important for product improvement and that past restrictions on the advertising of "low tar" products retarded product innovation. The crux of the argument is that color and/or imagery are prerequisites for disseminating relevant quality information and that, in its absence, consumers could not be adequately informed about the merits of new products. FDA, however, is not persuaded that manufacturers will be unable to convey vital information. The agency finds that true product improvements in this industry are rare, but where they exist, manufacturers could rely on traditional ads in adult-oriented publications and on "text only" advertising elsewhere. Moreover, FDA and other public health agencies would likely coordinate with companies in disseminating truly important consumer safety information.

The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, are less certain, as various empirical studies have reached conflicting conclusions. One industry comment insisted that FDA's regulation will deprive consumers of the benefits of competition, stating that, "[u]ndoubtedly the clearest measure of consumer benefit is the effect of advertising on price." To support this view, the comment references several studies that demonstrate the ability of advertising to reduce product prices. The comment also contended that the "[e]limination of advertising will predictably consolidate the market as marginal brands are abandoned and fewer brands are introduced" and that, "[o]ver time this can also reduce the number of players, as companies with dominant brands drive out others."

FDA agrees that advertising can often lead to decreased product prices, but notes that the other industries referenced (e.g., eyeglasses and pharmaceuticals) are much more competitive than tobacco products. Moreover, economists have found that advertising can also serve as a barrier to entry in oligopolistic industries. One author, for example, determined that ready-to-eat breakfast foods companies used advertising programs to support brand proliferation strategies in order to dominate retail shelf space.[325] These programs helped to keep new firms out and prices high without necessarily

[324] 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.

[325] Sutton, J., "Sunk Costs and Market Structure," The MIT Press, Cambridge, Massachusetts, pp. 229–247, 1991.

embodying improved quality. Thus, in certain circumstances, oligopolistic firms can use extensive advertising to create barriers for suppressing innovation and competition. FDA cannot determine whether tobacco advertising restrictions would ultimately increase or decrease product prices.

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 will 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."[326]

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.[327] 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. This final rule allows 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 sharply in recent years and currently constitute less than 5 percent of the industry's total advertising and promotion budget).[328] Conversely, the extraordinary growth in industry advertising and promotion has occurred 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.

6. Training

a. *Retailers.* The final regulation does not explicitly require retail employees who sell tobacco products to be trained in checking customer I.D.'s. FDA understands, however, that some training is essential to effective performance. In its analysis of the proposed regulation, FDA estimated total annual costs of $10 million for employee training at retail outlets. This estimate assumed that an average of 12 employees per store at 467,000 retail stores (assuming 1/3 of 700,000 stores already conducted training) would receive 15 minutes of training at a compensation rate of $7.41/hour. The Barents Group commented that FDA's analysis did not account for many individual cost elements, resulting in a significant underestimate of total training costs. It estimated one-time training costs of $184 to $257 million and recurring annual training costs of $48 to $67 million.

Specifically, the Barents Group stated that FDA relied on outdated compensation data. FDA had obtained these data from a 1992 report prepared by Price Waterhouse for the Tobacco Institute, but agrees that more recent data are available and employs the suggested compensation rate of $9.51 for its revised estimate. The Barents Group also claimed that FDA failed to consider recurring training costs due to annual employee turnover and annual updating, focusing instead on one-time training costs only. This criticism is not valid. Table 2 of the original analysis (60 FR 41314 at 41360) clearly lists training costs for retail establishments as an annual operating cost and the text (60 FR 41314 at 41367) refers to a "per year" cost. Because employees would be trained when first hired, this estimate implied a 100 percent employee turnover rate.

To refine its analysis, however, FDA has disaggregated the cost elements. Although the Barents Group accepted FDA's preliminary estimate of 12 employees per retail store, FDA now believes that this figure is accurate only for retail stores with payroll. Stores without payroll constitute a significant percentage of the stores selling tobacco products and, on average, are much smaller. As explained above, FDA estimates that about 600,000 establishments will sell over-the-counter tobacco products, including the 100,000 that replace those vending machines that are removed. Table 10 presents the data that underlie FDA's revised estimates of the number of employees who will be trained. For existing retail establishments with payroll, FDA assumes that training will be needed for all employees in the affected outlets, except in General Merchandise and Supermarket/Grocery stores, where one-third of the employees will be trained. For establishments without payroll, nonretail establishments, and new establishments replacing vending machines, Census data on the number of employees is not available, but FDA assumes that an average of six employees will be trained. As shown in Table 10, these calculations indicate that training will be required for a total of 4.2 million workers.

The Barents Group further faulted FDA for underestimating the training time that would be required to educate retail sales clerks about recognizing proper forms of identification and handling related customer service problems. It assumed that 2 hours of training would be necessary. FDA, however, reviewed the time needed to present the training materials from several corporate entities and finds that they need not exceed one hour. For example, one large convenience store corporation uses a 45 minute training videotape that covers the sale of tobacco products, but also covers the sale of alcohol and possible inhalants, including means for recognizing inebriated or drugged individuals. Moreover, many establishments, especially small stores, will provide no formal training, but will provide instruction during the work day with minimal lost time. Thus, FDA believes that average costs are reasonably based on a 1-hour training program.

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[326] Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2nd edition, Rand McNally College Publishing Co., Chicago, IL, p. 380, 1980.

[327] 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.

[328] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, issued 1995.

TABLE 10.—NUMBER OF EMPLOYEES TO BE TRAINED

Kind of Business	Payroll Establishments				Nonpayroll Establishments		Total Employees Trained
	Establishments Selling Tobacco Products	Employees Per Store	Percent Trained	No. of Employees Trained	Establishments Selling Tobacco Products	No. of Employees Trained[1]	
General Merchandise	12,117	60.1	33%	242,593	9,807	58,842	301,435
Supermarket/Grocery	71,240	20.9	33%	497,253	54,538	327,228	824,481
Convenience Store/no gas	29,400	5.6	100%	164,718	—	—	164,718
Convience Store/gas	51,913	6.8	100%	353,868	—	—	353,868
Gas Station	37,958	6.0	100%	228,002	7,581	45,486	273,488
Eating Place	11,992	16.5	100%	198,212	3,065	18,390	216,602
Drinking Place	10,745	5.4	100%	58,498	5,336	32,016	90,514
Drug/Proprietary Store	29,046	12.2	100%	354,730	1,829	10,974	365,704
Specialty Tobacco	1,477	3.7	100%	5,530	—	—	5,530
Miscellaneous	24,995	5.2	100%	130,253	44,879	269,274	399,527
Retail Subtotal	**280,883**			**2,233,656**	**127,035**	**762,210**	**2,995,867**
Nonretail[2]							600,000
Converted Vending Machines[2]							600,000
Total							**4,195,867**

[1]Assumes 6 employees per establishment.
[2]Assumes 100,000 outlets with 6 employees to be trained.
Sources: Table 4 for description of establishment data; 1992 Census of Retail Trade, Subject Series: Establishment and Firm Size (Table 1) for employment data; FDA estimates for percent trained.

Adopting FDA's original estimate that about one-third of all affected establishments already provide employee training (also assumed by the Barents Group), implies one-time employee training costs of $26.6 million (4.2 million employees x 2/3 x $9.51). The Barents Group suggested, however, that even employees who currently receive training would need 5 extra minutes on the new regulations, which adds about $1.0 million to the cost estimate. Next, the Barents Group included costs for time spent by trainers, assuming that the training would be provided by an outside source. FDA believes that a more typical approach would have a store supervisor provide the training. Using $13.64 as the compensation rate for a retail manager, as suggested by the Barents Group, and adjusting for the assumed one-third current compliance rate in existing establishments, yields a one-time cost for trainer time of $6 million. Thus, FDA projects total one-time training costs of about $33.5 million.

In addition, FDA estimates that employee turnover, using the Barents Group suggested rate of 42 percent, will add annually recurring training costs of about $11.2 million. Also, new employees will receive I.D. check training as part of their initial orientation activities. Since stores may provide this to several new employees at once, using either written or video training materials, FDA estimates that retail managers, on average, would spend about 1 additional hour per year providing this training. This adds $6.0 million to the annual training costs. The Barents Group also recommended annual reinforcement training. An annual 10-minute reinforcement training period for employees of those establishments that do not already have a training program will cost about $2.9 million. In sum, these annual recurring training costs total about $20 million.

The Barents Group also assumed that retail managers would need extensive training to understand the new regulations. FDA estimated in its 1995 proposal that manufacturers' representatives would need about 8 hours of training on their new responsibilities and the Barents Group assumed that retail managers would need a similar duration of training. FDA rejects this estimate, however, as the final provisions affecting retailers are straight-forward and will be routinely communicated through traditional industry channels.

b. *Manufacturers representatives.* In its preliminary economic analysis, FDA estimated that 7,300 manufacturer representatives would be trained for 8 hours at a cost of $25.00 per hour. After noting FDA's "undocumented" cost estimate, the Barents Group proceeded to apply the identical number of training hours to their "documented" cost estimate of $25.70 per hour. They also suggested a 15 percent labor turnover premium, giving a total cost of $1.5 million. As the final rule eliminates the monitoring burden for these employees, this training cost should be correspondingly smaller. Nevertheless, these manufacturer employees will still need to determine the types of displays that remain permissible. FDA therefore accepts the $1.5 million cost estimate.

7. Access Restrictions

a. *Manufacturers.* Although voluntary decreases in the sale of consumer products do not impose long-term net societal costs, mandatory restraints on the access of consumers to desired products may imply economic costs. Economists typically measure producer-related 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 derived from Cummings, et al., indicate that youngsters under the age of 18 consume 316 million packs of cigarettes per year, leading to industry profits of $118 million.[329] On the assumption that the regulation would reduce teenage smoking by one-half, these profits would fall by about $59

[329] 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, p. 301, February 1994. (derived by subtracting sales to 18-years-olds from the reported 516 million packs consumed).

million. However, because most of this profit stems from illegal sales to youths, FDA has not counted this figure as a societal cost.

b. *Consumers.* 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. Because it reflects the difference between the price the consumer is willing to pay and the actual market price, it is used by economists to measure consumer welfare losses imposed by product bans. However, FDA's rule imposes no access restrictions on adults, who will be free to consume tobacco products if they so desire. Thus, FDA has not included any value for lost consumer surplus in its estimate of the societal costs of these access restrictions.

8. I.D. Checks

a. *Retailers.* For the 1995 proposed regulation, FDA estimated that retail establishments would bear annual compliance costs of $28 million for consumer identification checks. This figure was derived by multiplying the estimated retail employee compensation rate by the extra time that might be needed to complete purchase transactions. The estimate measured the cost to retailers for either increasing the number of working hours of existing staff or for hiring new staff to handle the added workload. The Barents Group commented on numerous aspects of this compliance cost estimation, accepting several key FDA assumptions, but rejecting others in deriving its estimate of $142 million per year.

In its preliminary analysis, FDA estimated the number of tobacco product transactions for the 18 to 26 year-old age group based on data that reflected the tobacco consumption of cigarette smokers 5 to 6 years after high school [330] and the annual per capita consumption of smokeless tobacco. [331] The Barents Group faulted FDA for limiting these transactions to 18 to 26 year-olds, asserting that the standard practice for alcohol sales is to request identification for anyone who appears to be 30 years old or younger. The Barents Group calculations actually estimated compliance costs on the assumption that customers up to age 34 would be asked for identification, because some older consumers would appear to be only 30 years old.

FDA has not accepted this Barents Group assumption for several reasons. First, the legal age of purchase for alcohol in all 50 States is 21 years, whereas the rule for cigarettes and smokeless tobacco sets 18 as the legal age of purchase. This 3-year difference implies that comparable cigarette and smokeless identification checks would be expected only up through age 27. Also, the current policy and practice of many retail stores is to request identification from tobacco consumers only up to age 26. Requiring proof of age for anyone who appears younger than 26 years of age was also recommended by a working group of 26 State Attorneys General. [332] Finally, the Barents Group's use of age 34 to provide a margin of safety for identifying those under the age of 30 is illogical, since the FDA rule requires retail stores to identify consumers who are under the age of 26, not 30.

The Barents Group accepted the FDA assumption that an I.D. check would take an average of 10 seconds, but referenced a study by A. T. Kearney that found that the actual time needed to verify a photo I.D. for a tobacco product sale averaged 8.3 seconds. Because FDA has no better data, the agency adopts 8.3 seconds as the average time needed to conduct an I.D. check. The Barents Group further commented that FDA used outdated employee compensation data in its calculations. FDA's revised totals use the Barents Group's employee compensation estimate of $9.51/hour (1994 dollars) as the time value for retail sales employees.

FDA originally assumed that only 75 percent of all retail transactions for the 18 to 26 year-old age group would be extended due to I.D. checks. The Barents Group argued that the correct percentage should be 100 percent, as the rule would apply to all sales to the relevant age group. FDA continues to believe that this assumption leads to an over-estimate of the probable costs. First, not every moment of a clerk's time is effectively utilized and a few seconds more per transaction will not always result in lost labor productivity. Second, many smokers patronize the same retail store almost daily and are well-known to clerks. I.D. checks for these customers will take little extra time. Finally, many customers will take less time to produce an I.D., once they realize that identification checks have become routine. Nevertheless, FDA adopts the Barents Group's 100-percent assumption to assure a full accounting of the relevant costs.

One comment claimed that FDA failed to include the cost of hiring additional sales clerks. As noted above, the FDA calculation does reflect the cost of the additional labor time that might be needed. The Barents Group also inexplicably asserts that FDA failed to consider I.D. checking costs as annual costs, instead listing them as a one-time cost. Table 2 of the original analysis (60 FR 41314 at 41360), clearly lists the $28 million identification check cost as an annual operating cost and the accompanying text (60 FR 41314 at 41367) refers to the figure as a "per year" cost. The Barents Group further faulted FDA for not taking into account the cost of checking I.D.'s for those youths under age 18, who will still attempt to buy cigarettes. While a small percentage of underage smokers may opt for this course of action, few would return to complying outlets. Thus, FDA believes that any plausible estimate of the associated costs would be less than $1 million annually.

FDA originally estimated the number of tobacco product transactions for the 18 to 26 year-old age group at 2.2 billion, but has updated its estimate to 2.5 billion. [333] Also, the 80-percent current noncompliance rate that had been assumed for the 1995 proposal may be too high, as the Surgeon General estimated that minors are unable to make an OTC purchase of tobacco products about one-third of the time. [334] Nevertheless, FDA retains this assumption to calculate a cost to

[330] 1994 SGR, p. 85.

[331] U.S. Department of Commerce, *Statistical Abstract of the United States 1993*, 113th edition, p. 137, 1993; DHHS, Office of Inspector General, *Spit Tobacco and Youth; Additional Analysis*, June 1993.

[332] "No Sale: Youth Tobacco and Responsible Retailing," Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.

[333] 1994 Population data for 18 to 26 year-olds from 1995 Statistical Abstract, Table 16. Cigarettes: Number of smokers for age group calculated from Table 217 (1993 data). Average packs/yr. and total packs/yr. for smokers aged 18 to 26 calculated from data in Table 20, 1994 SGR, p. 85. (Those smoking 1 to 5 cigarettes/day assumed to smoke 3, those smoking 20+ cigarettes/day assumed to smoke 25). The resulting number of packs smoked by 18 to 26 yr.-olds totals about 2.5 billion. If even 1 percent of these transactions were for cartons, this number falls to about 2.3 billion. Smokeless: Total units of smokeless products sold calculated from data in *Spit Tobacco and Youth: Additional Analysis*, Dept. of Health and Human Services, June 1993, Excise Tax calculations, Option 4; Units consumed by youths from the Institute of Medicine Report (the IOM Report) "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths", p. 8. 1994, Usage data and total units (cans or pouches) consumed for age group for those aged 18 to 26 from "Use of Smokeless Tobacco Among Adults-U.S., 1991" in "MMWR", CDC, DHHS, volume 42, No. 14, p. 264, 1993. The number of containers sold for 18 to 26 yr. old age group totals about 0.2 billion.

[334] IOM Report, p. 202.

retailers for I.D. checks of $43 million per year (2.5 billion transactions x 8.3 seconds/transaction x $9.51/hour ÷ 3600 seconds/hour x 80 percent noncompliance rate). This revised estimate exceeds FDA's original $28 million figure, but remains far below the $142 million estimate of the Barents Group.

b. *Consumers.* The Barents Group also criticized FDA for not quantifying the costs to consumers for the extra time needed to undergo I.D. verifications. They estimated this cost at $282 million a year. FDA agrees that consumers would incur time costs and, for its revised estimates, adopts the analytical framework suggested by the Barents Group, which counts only the time lost by young customers. (The Barents Group suggests that older consumers also would experience delays, but FDA's estimates already account for the cost of additional clerk time that would offset longer checkout lines. Younger customers, however, must wait while their age is verified, even when additional checkout clerks are available.) To estimate the time cost, FDA applies the same methodology that was used to estimate the time cost for retail employees. That is, 2.5 billion transactions taking an extra 8.3 seconds each for the 18 to 26 year-old age group, adjusted for a 20 percent current compliance rate. The Barents Group used an average hourly private sector compensation rate ($15.13/hour) as the basis of its consumer time cost estimate, but FDA finds this average rate too high for young consumers and estimates a range of $9 to $11 per hour.[335] As a result, FDA's estimate of the cost to consumers for lost time cost amounts to between $41 and $50 million per year.

9. Vending Machines

In its comments on the costs of FDA's proposed vending machine ban, the Barents Group reports that automatic vending machine operators will lose $403 million in annual revenues. They then subtract an estimated $281 million offset for future over-the-counter sales (calculated by assuming an equal number of future packs sold and an $.80 price premium for vending machine packs) to project a net $122 million of regulatory costs to the retail sector. Although not acknowledged, this methodology implicitly assumes that a redistribution of revenues (from vending machine owners to over-the-counter sellers) does not generate added societal costs. Elsewhere, the Barents Group includes distributional impacts in cost totals. Nevertheless, even this $122 million estimate is far too high.

The fundamental problem is that changes in revenue, as discussed above, do not measure economic costs. The relevant economic measure of regulatory costs to an industry is the change in producer surplus that a firm makes from selling a good or service. Because producer surplus' are difficult to measure, accounting profits are sometimes used as a proxy. By examining only lost revenues, the Barents Group ignores the difference in the operating costs of the alternative sales channel, despite its recognition that "[i]n general terms, the extra margin at vending machines reflects the costs to vending machine owners of operating these machines, in addition to a return on their labor effort and capital investments." In other words, the reason that cigarettes purchased from a vending machine are more expensive is that it costs more to sell a pack of cigarettes by vending machine. Consequently, if cigarette sales shift from more expensive-to-operate vending machines to OTC, the loss of industry profits is much smaller than the loss of industry revenues.

An approximate assessment of the net impact on retail profits requires a comparison of the pretax profit margins for vending machine operations as compared to OTC sales. The Barents Group cited survey results from the National Automatic Merchandising Association (NAMA) showing an average pretax profit margin of 3.8 percent in 1993 and 2.0 percent in 1992, for an average 2.9 percent for vending machine operations. Because cigarette vending machine sales have decreased in recent years, current profit margins might be even smaller. Coincidentally, the Barents Group reports that the estimated average industry profit margin for convenience stores is also 2.9 percent. If this rate applies to cigarette sales at convenience stores and if all lost vending machine cigarette sales were transferred to convenience stores, the net pretax cost to the industry would be $3.5 million, not $122 million ($403 million to $281 million) x 2.9 percent). Moreover, NAMA reports that over 50 percent of all vending machines are located in bars and taverns and many others in business establishments frequented only by adults. The final rule permits vending machines in those places where the owner can ensure that no young people under age 18 are present at any time. FDA does not know how many vending machines will be moved to restricted areas in compliance with this rule, but the number will further reduce this annual cost.

10. Readership Surveys

The Barents Group reported that 101 leading national magazines had advertisements for tobacco products in 1994. In addition, Barents obtained youth and adult readership data for 1994 from MediaMark Research, Inc. (MediaMark), for 41 of these 101 magazines. Applying the regulatory threshold of 2 million readers or 15 percent of total readership below the age of 18, Barents projected that advertisements in 32 of the 41 magazines (78 percent) would be restricted to "text only" by the proposed regulation. In comparison, FDA examined copyrighted youth and adult readership data from the Simmons Marketing Bureau, Inc. (Simmons), another major marketing research firm, and found that only 13 of the 27 magazines with tobacco ads (48 percent) had youth readership over the threshold. A comparison of youth readership levels from MediaMark and Simmons for magazines that had tobacco advertisements in 1992 is shown in Table 11.[336]

[335] Data from the 1995 *Statistical Abstract of the United States*, Table 677 lists weekly earnings for full time wage and salary workers for the group "16 to 24 year-olds" in 1994. Table 682 lists median hourly earnings for workers paid hourly rates for the same group in 1994. Assuming a 40 percent increase for benefits, the compensation rates for these two tables for 16 to 24 year-olds are $9.98/hour and $7.87/hour, respectively.

Using these figures will result in a low estimate for the 18 to 26 year-old group because 25 and 26 year-olds earn more than 16 and 17 year-olds. Conversely, using a benefits/wage ratio of 40 percent for 18 to 26 year-olds will overstate the costs because lower paid workers (hourly and part-time workers, college students) are more likely to have less generous benefits packages (little or none of the following: paid vacation, sick leave, employer-paid health insurance). FDA increased the estimated compensation rates to $9 to $11/hour to assure it does not underestimate the true compensation rate.

[336] Tobacco industry spending on magazine advertising was calculated using tobacco advertising share data from Barents and advertising revenues from *Advertising Age*. Advertising revenue was unavailable for five small publications that accounted for less than one percent of tobacco magazine advertising spending in 1994. To estimate tobacco advertising expenditures in these five publications, FDA assumed total advertising revenues for each publication equal to $14,388, which is the lowest total revenue reported in *Advertising Age* for 1994.

TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated[1,2]	10.0	5,201	18.0	4,614	17.1
People[1,2]	9.8	3,020	7.8	2,465	8.0
TV Guide[1,2]	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade[2]	3.7	n/a	n/a	6,059	6.9
Cosmopolitan[1]	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly[2]	2.9	n/a	n/a	674	15.3
Better Homes & Gardens[1]	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour[1,2]	2.0	2,216	17.1	1,540	17.4
Rolling Stone[1,2]	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver[1]	1.6	1,465	18.3	n/a	n/a
Life[1]	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life[1]	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track[1]	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle[1,2]	1.0	1,369	19.7	959	18.5
Vogue[1,2]	1.0	2,237	18.0	1,300	17.4
Hot Rod[1]	0.8	2,295	28.0	n/a	n/a
Ebony[1]	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly[1]	0.7	1,037	15.1	n/a	n/a
Motor Trend[1]	0.7	1,393	22.1	n/a	n/a
Premiere[1]	0.7	617	25.8	n/a	n/a
Sport[1,2]	0.7	2,274	33.8	1,132	24.0
Elle[1]	0.6	819	17.8	409	14.4
Essence[1]	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet[1]	0.4	1,724	16.7	1,169	12.2
Popular Science[1,2]	0.4	1,906	20.8	874	16.1
Self[1]	0.4	786	16.2	n/a	n/a
Harper's Bazaar[1]	0.3	718	18.2	n/a	n/a
The Sporting News[1,2]	0.3	1,394	27.8	666	15.7
Cable Guide[1]	0.2	3,358	22.6	n/a	n/a
Ski[1,2]	0.0	827	26.4	584	24.9

[1]MediaMark youth readership exceeds regulatory threshold.
[2]Simmons youth readership exceeds regulatory threshold.
Source: Barents Group LLC Tables IV–1 and A–2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, "The Ad Age 300," *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.

Because FDA does not know how tobacco manufacturers will adapt their marketing strategies to the new regulatory thresholds, it is difficult to predict the number of new readership surveys that may be initiated. It seems likely, however, that tobacco companies will both increase the frequency of advertising in "adult" magazines that already carry tobacco advertisements and find suitable "adult" magazines to replace many of the other magazines.

One plausible scenario is that approximately one-half, or 50, of the magazines with current tobacco ads would not qualify as "adult" publications, because they exceed the youth readership threshold; and that the tobacco industry would choose to advertise in 50 other "adult" publications that do not currently carry tobacco ads. To identify these 50 additional "adult" magazines, the industry might need to collect new youth readership data for up to 100 magazines. In addition, as noted above, of the original 100 magazines with current tobacco advertising, youth readership data is now available for at least 40. Thus, the tobacco industry may initially need to obtain new youth readership data for the remaining 60 magazines. In total, therefore, the tobacco industry might opt to obtain youth readership data for an additional 160 publications in the first year that the rule becomes effective. In subsequent years, this number might fall to about 100 surveys, as the industry would concentrate its survey efforts on publications very likely to qualify.

If a marketing research firm collects youth readership data, the cost may depend on the particular characteristics of the magazines being surveyed. The tobacco industry could choose, however, to hire a survey firm to develop and administer a questionnaire solely to gather readership data for magazines with tobacco advertising. While FDA is uncertain about which approach the industry would take, the agency estimates that such new surveys might cost approximately $2 million in one-time costs and $1 million in annual costs, based on an average cost of about $650 and $350 per sample household.

11. Records and Reports

Manufacturers will need to comply with device regulations governing submissions of representative labels and advertising, medical device reporting (MDR's), establishment registration and product listing, and current good manufacturing practices (CGMP's).

a. *Labels and advertising.* The rule requires that each manufacturer annually submit to FDA copies of representative samples of labels and advertising. While the agency expects about 1,000 product labels, FDA has no direct evidence on the number of advertisements that will be submitted. An approximate estimate, however, can be derived from the number of advertising samples submitted by the pharmaceutical industry. First, FDA calculated that of the $6.1 billion in advertising and promotional outlays reported to the FTC by the tobacco industry, only about $1.2 billion is spent on printed advertisements. (Derived by subtracting categories for "Coupons/Value Added," "Promotional Allowances," "Specialties Items," and "Free Samples" from the total $6.1 billion).

The pharmaceutical industry spends an estimated 22.5 percent of sales on marketing, of which about one-quarter may be allocated to advertising ethical pharmaceuticals.[337] The approximately $50 million in annual sales of pharmaceutical manufacturers, therefore, implies a $2.5 billion annual advertising budget. FDA estimates that it currently receives about 25,000 pieces of pharmaceutical advertising per year. As the pharmaceutical budget is roughly twice the size of the $1.2 billion tobacco industry figure derived above, the agency might receive half as many documents. Alternatively, reduced promotional activities may prompt an increase in the number of printed advertisements prepared by tobacco companies, although the Barents Group assumed this number would decline. Therefore, FDA projects that it will receive the same number of advertisements for tobacco products as it currently receives for pharmaceutical products, or about 25,000 per year, plus about 1,000 labels.

Estimates of the time burden of these paperwork submissions ranged from 20 minutes (The Barents Group) to 1 hour and estimates of the hourly cost ranged from $25.00 (Tobacco Institute) to $45.26 (the Barents Group). Using the high end of both ranges provides an upper bound cost estimate of $1.2 million. This figure is significantly lower than either the original FDA estimate, or the Barents Group estimate of $55 to $57 million, largely because the final rule imposes no specific paperwork requirements on retail establishments.

b. *MDR's.* The final rule will require MDR's for serious unexpected incidents. FDA assumes that 31 manufacturing companies[338] and 1,365 distributors[339] will bear total one-time costs of $21,000 and $231,000, respectively, for establishing and documenting procedures for MDR reporting. These costs include 32 hours of effort per manufacturing firm and 8 hours per distributor. Based on estimates previously developed for the Medical Device User Facility and Manufacturer Reporting Final Rule, these activities were distributed over wage rates averaging $21.17. Annual costs for MDR reporting requirements are more difficult to predict, because they depend on the number of adverse event reports that will be submitted. FDA projects, however, that followup investigation and reporting of a single event takes about 8 hours of labor and costs about $218. Thus, if 50 adverse event reports were filed annually, the annual cost would be about $11,000. In addition, if each manufacturing company submits a single baseline report and annual updates, these costs would be about $2,100 annually, based on unit costs of $54 and $14 per report, respectively. Annual certification is necessary, but is typically a formality in terms of data collection and reporting and is estimated to cost about $800 for all manufacturers and $35,000 for all distributors assuming 1 hour of professional and clerical time at $25.80 per hour.

c. *Registration and listing.* Registration and listing duties are estimated to take 41 manufacturing establishments 2 hours each to prepare at a unit cost of $42, totaling about $1,700 per year for the industry.

d. *CGMP's.* The Tobacco Institute asserted that cigarette manufacturers would need substantial time to comply with CGMP's as the industry "would need to adopt major new systems * * * [and] make major changes to their procedures just to accommodate the recordkeeping required." Conversely, the economics study prepared by the Barents Group for the Tobacco Institute showed no additional costs for this requirement. FDA agrees that these costs

[337] U.S. Congress, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," OTA-H-522 Washington, DC: U.S. Government Printing Office, pp. 303–304, February 1993.

[338] 1992 U.S. Census of Manufactures, Industry Series, Tobacco Products, Table 1a. A few U.S. agents designated to represent foreign manufacturers would also need to file forms, but these costs should be minimal.

[339] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States (unpublished data).

should be minimal for facilities with good quality assurance programs. Its CGMP's do not specify a specific format, but encompass a wide variety of broad requirements for documenting operating procedures. Contrary to the Tobacco Institute's claim that "even a well-run cigarette manufacturing facility would need to adopt major new systems," CGMP's are, in fact, based on the activities of well-run operations. Moreover, device CGMP's are currently under revision to bring them even closer to ISO 9001, the generally recognized international standard for quality assurance systems. Thus, while FDA has little experience with day-to-day tobacco manufacturing procedures, the agency does not anticipate the need for substantial quality system redesign. Wholesalers and distributors also submitted comments contending that the CGMP's would create added paperwork burdens, but the agency has exempted these sectors from the CGMP requirements.

12. Government Enforcement

FDA estimates of internal costs for administering and enforcing this regulation are extremely uncertain, as they will depend on the working relationships to be established with State tobacco control programs. As a best estimate, however, FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of $100,000 per FTE places the dollar cost at between $3 and $5 million per year. SAMHSA has estimated that State programs will need between $25 and $50 million annually to administer and enforce appropriate State operations.

13. Comparison of Benefits to Costs

FDA expects the net societal benefits of the rule to far exceed the regulatory costs. Based on the analysis presented above, the estimated one-time costs of the combined FDA and SAMHSA rules are $174 to $187 million and the estimated annual costs are $149 to $185 million. Taking the midpoint of the ranges and annualizing the one-time costs at 3 and 7 percent, respectively, yields total annualized costs of $172 million and $180 million. In contrast, the agency's best estimate of the monetized regulatory benefits that would follow a 50 percent reduction in underage tobacco use ranges from $28.1 to $43.2 billion at a 3 percent discount rate and from $9.2 to $10.4 billion at a 7 percent discount rate. Thus, as shown in Table 12, the *net* benefits (benefits minus costs) of a total effectiveness rate of 25 percent range from $27.9 to $43 billion at a 3 percent discount rate and from $9.0 to $10.2 billion at a 7 percent rate. Table 13 indicates that those figures imply a cost per life-year saved of from $800 to $4,700 and a cost per death avoided of from $11,000 to $52,000. As noted earlier, these benefits are exclusive of the substantial health improvements expected to result from the reduced consumption of smokeless tobacco.

The substantial differential between these estimated costs and benefits withstands rigorous sensitivity analysis (see Table 12). For example, SAMHSA estimated that its rule would reduce underage tobacco use by from one-third to one-tenth. The approximate midpoint of that estimate (20 percent) constitutes about 40 percent of the regulatory benefit of reducing underage tobacco use by one-half. If, for illustrative purposes, these results, as well as a proportional fraction of the relevant costs,[340] are attributed to SAMHSA, the *incremental* net benefits of the FDA rule still range from $16.8 to $25.8 billion at a 3 percent discount rate, and from $5.4 to $6.2 billion at a 7 percent discount rate.

Moreover, FDA assumed that reaching the "Healthy People 2000" goal would deter about one-quarter of the 1 million youth under age 18 who currently begin to smoke each year from ever smoking as an adult. Thus, this goal implies a 25 percent overall effectiveness rate. If, however, these rules prevent smoking as an adult for even 5 percent of the teenagers who would otherwise become adult smokers, they would produce estimated annual net benefits of from $5.4 billion to $8.5 billion at a 3 percent discount rate and from $1.7 billion to $1.9 billion at a 7 percent discount rate. Even if this latter scenario attributed 40 percent of the benefits and relevant costs to SAMHSA, the annual *net* benefits of the FDA rule would still range from $3.3 billion to $5.1 billion at a 3 percent discount rate and from $1.0 billion to $1.2 billion at a 7-percent discount rate. This last example implies a cost per life-year saved of $3,500 to $21,100 and a cost per death avoided of $47,000 to $234,246. These figures are well within the range of values for health interventions typically considered cost-effective.

TABLE 12.—NET BENEFITS

($ Billions)

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Low	High	Low	High	Low	High	Low	High	Low	High
3%	27.9	43.0	16.7	25.7	11.1	17.1	5.4	8.5	2.6	4.1
7%	9.0	10.2	5.3	6.1	3.5	4.0	1.7	1.9	0.74	0.86
Illustrative Incremental Net Benefits[1]										
3%	16.8	25.8	10.0	15.5	6.7	10.3	3.3	5.1	1.6	2.5
7%	5.4	6.2	3.2	3.7	2.1	2.4	1.0	1.2	0.45	0.53

[1] Attributes 40% of benefits and associated costs to SAMHSA

[340] Costs include 100 percent of SAMHSA's state enforcement costs, plus 40 percent of retail training costs, vending machine costs, and retail and consumer I.D. check costs.

TABLE 13.—COST EFFECTIVENESS

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)
3%	815	10,862	1,358	18,103	2,038	27,155	4,075	54,310	8,151	108,621
7%	4,722	52,423	7,870	87,372	11,804	131,059	23,609	262,117	47,218	524,235
Illustrative Incremental Cost-effectiveness[1]										
3%	706	9,413	1,177	15,689	1,766	23,533	3,532	47,067	7,064	94,134
7%	4,220	46,849	7,033	78,082	10,549	117,123	21,098	234,246	42,197	468,492

[1] Attributes 40% of benefits and associated costs to SAMHSA

E. Distributional Effects

These regulations will impose a variety of sector-specific distributional effects. Those sectors affiliated with tobacco and tobacco products will lose sales revenues and these losses will grow over time. Businesses engaged in the provision of tobacco product advertising may also face reduced revenues. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers and Distributors

For its calculation of regulatory benefits, FDA estimates that implementation of the regulations may reduce the cigarette consumption of underage smokers by one-half within 7 years. As discussed earlier in this section, based on data presented in Cummings, et al., FDA finds that teenage smokers under the age of 18 consumed about 316 million packs of cigarettes in 1994. A 50-percent cut in sales would drop the number of packs sold by 158 million. 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, decreasing the number of adult smokers by 250,000 per year. Because each adult smoker consumes about 500 packs per year, about 124 million fewer packs would be sold per year.

Thus, achieving the agency's goal would reduce cigarette consumption by 158 million packs in the first year (while only teenagers are affected), 158 million plus 124 million packs in the second year, 158 million plus 2 times 124 million packs in the third year, and so on. Since 1994 cigarette shipments totaled 36.3 billion packs,[341] cigarette consumption would fall by about 0.4 percent in the first year, 1.8 percent in the fifth year, and 3.5 percent in the tenth year following implementation. (In fact, these reductions may take even longer, because it may be several years before the 50-percent effectiveness level is achieved, and because young adults smoke fewer packs than older adults).

Hence, annual tobacco revenues will decline slowly over time. The U.S. Bureau of the Census estimates 1994 revenues for cigarette and smokeless tobacco manufacturers at about $25.9 billion.[342] Assuming comparable reductions in smokeless tobacco, these calculations imply that tobacco manufacturer revenues will fall by $128 million in the first year (0.5 percent), $501 million in the fifth year (1.9 percent), and $966 million in the tenth year (3.7 percent). While these reductions are significant, the gradual phasing of the impacts will significantly dissipate any associated economic disruption.

In a 1992 report prepared for the Tobacco Institute, Price Waterhouse estimated that the tobacco manufacturing, warehousing and wholesale trade sectors employed about 107,000 full-time workers.[343] Thus, a constant production-to-employment ratio projects that a 3.7-percent reduction in sales over a 10-year period would result in the displacement of about 4,000 jobs, or 400 jobs annually among manufacturers, warehousers, and wholesalers. Alternatively, a University of Virginia study concluded that "the Price Waterhouse study for the Tobacco Institute provides estimates of tobacco's impact that are high compared to other measures."[344] That study referenced a recent U.S. Department of Agriculture analysis by Gale that found that manufacturing and wholesale trade activities employ only 83,000 full-time equivalent workers.[345] If true, this finding reduces these job loss estimates to about 3,000 jobs, or 300 annually.

The smaller job loss estimate is generally confirmed by a recent study by Warner, et al., who applied a computer simulation model to forecast the regional impact of reductions in tobacco use.[346] The authors used "a state-of-the-art macroeconomic model to simulate what would happen if consumers reduced their tobacco expenditures, with the same level of spending redistributed to other goods and services * * *." One scenario assumed that tobacco control activities would reduce the expected rate of tobacco purchases by 2.06 percent per year, or roughly 5 times the estimated effect of the FDA rule. While this scenario does not present direct impacts to the tobacco industry alone, it forecasts job losses after 8 years of 6,401 for all U.S. wholesalers and 5,957 for Southeast Tobacco Region

[341] "Tobacco Situation and Outlook Report," U.S.D.A., Economic Research Service, p. 4, April 1995.

[342] "1994 Annual Survey of Manufactures: Value of Product Shipments," U.S. Department of Commerce, Bureau of the Census, Table 1, p. 210. ASM does not report data below the 5-digit SIC Code Level. FDA assumed chewing tobacco represented the same percentage of SIC Code 2131 (Chewing and Smoking Tobacco) in 1994 as it did in 1992 when it was classified at a 6-digit SIC code in the Census of Manufacturers.

[343] "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, p. ES-3, October 1992.

[344] Knapp, J. L., "Tobacco in Virginia," Weldon Cooper Center for Public Service, University of Virginia, p. 5, December 1995.

[345] Gale, F., "What Tobacco Farming Means to Local Economies," U.S. Department of Agriculture, Economic Research Service, Agriculture Economic Report Number 694, p. 5, September 1994.

[346] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, pp. 1241–1246, April 24, 1996.

manufacturers. Accounting for the multiple of 5, comparable job losses attributable to the FDA rule would total about 2,600 after 8 years, or about 325 annually.

The Barents Group did not address the long-term gradual decline in tobacco use projected by FDA. Nevertheless, it claimed that the agency underestimated the economic impact on industry by failing to account for the lost sales to adults that would result from the proposed ban on vending machines and self-service displays and the required checking of customer I.D.'s. The Barents Group argued that the added consumer inconvenience imposed by these provisions was tantamount to an increase in the effective price of tobacco products, which would rapidly decrease the consumption of tobacco by adults. Relying on "hypothetical scenarios" that assume demand declines of 5 and 10 percent, the Barents Group forecast that the tobacco manufacturing industry would lose from 1,800 to 3,700 jobs due to this increased consumer inconvenience.

FDA believes these Barents projections are substantially overstated. Impacts associated with cigarette consumption declines of 5 to 10 percent cannot possibly be attributed to the loss of vending machines, because vending machine purchases make up less than 1 percent of all cigarette purchases. Further, according to NAMA, there are only 141,000 cigarette vending machines currently in use (and that number is falling rapidly), and the cost analysis prepared by the Barents Group predicted that 100,000 of these machines would be replaced by new OTC establishments. Thus, the Barents Group's own analysis eliminates any added consumer inconvenience from three-quarters of the existing inventory of machines. Moreover, the near-term impact on adult tobacco consumption will be further moderated both because the final rule allows vending machines in "adult" facilities, and because the added inconvenience cost will be partially offset by the lower price of the OTC product. These factors together make it extremely unlikely that fewer vending machines will lead to a substantial near-term fall in tobacco industry sales revenues.

The likelihood that tobacco sales will decline significantly due to inconvenience imposed on adult customers by the self-service restriction is similarly remote. While some purchasers would need more time to complete a transaction, other purchasers would save time by no longer having to search and retrieve a desired product. In the absence of empirical evidence, the result is indeterminate; but FDA has seen no convincing evidence or arguments to demonstrate that any delays caused by the self-service restriction will significantly curtail adult tobacco use.

Finally, although FDA calculated above that increased delays due to I.D. checking could cost young adult consumers under the age of 26 up to $50 million per year, even this cost would not lead to significant consumption declines. As described, the increased checkout waiting time for young purchasers was estimated to average about 8.3 seconds, which translates to a cost of about 2.3 cents per transaction, or 1.35 percent of the cost of a pack of cigarettes. According to the Barents Group, representative estimates of demand elasticities for cigarettes range from -0.6 to -1.0. Young adults under the age of 26, however, purchase only about 10 percent of all tobacco products. Thus, the fall in total tobacco sales would be, at most, 0.1 percent, not the 5 to 10 percent assumed by the Barents Group. Moreover, even the 0.1 percent figure is an overestimate, because those consumers irritated by the delay will increase the volume of tobacco products purchased per transaction. As a result, the number of cartons sold will rise, but the decline in tobacco product sales revenues attributable to the inconvenience effects of I.D. checks will be negligible.

2. Tobacco Growers

As explained above, total cigarette and chewing tobacco consumption is expected to decrease by 0.5 percent in the first year, 1.9 percent by the fifth year, and 3.7 percent by the tenth year, following compliance with the regulation. Price Waterhouse estimated that, on a full-time equivalent basis, about 153,000 farmers grew tobacco in 1990. Based on these figures, constant production-to-employment ratios imply employment losses among tobacco growers of about 5,700 after 10 years, or about 570 annually. Alternatively, the Gale study for the U.S. Department of Agriculture (USDA)[347] estimated the number of full-time equivalent tobacco farmers to be only 65,400, which would reduce the job loss estimate to about 2,500 by the tenth year, or 250 annually.

This latter figure also closely fits the findings of Warner, et al., who, as described above, used a "state-of-the-art" macroeconomic simulation model to project the employment effects of declining tobacco consumption.[348] Assuming domestic tobacco consumption decreases of 2.06 percent per year, Warner, et al. predicted about 7,500 job losses within an 8-year period for "Southeast Tobacco Region" farmers. As this fall in tobacco use is roughly five times that projected by FDA, the analogous job loss estimate would be about 1,500 over the 8-year period, or about 190 per year.

According to the USDA study by Gale, "[f]or most farms, tobacco growing is a part-time, seasonal enterprise, and production per farm is usually small. About two-thirds of tobacco farmers work off-farm."[349] Citing 1987 Census of Agriculture data, Gale notes that only 65 percent of the farms growing tobacco in the United States reported earning more than half of their receipts from tobacco, and of those farms, approximately 80 percent had total farm sales under $20,000. He explains that the availability of alternative land uses will dictate the economic results:

> The key factor in adjustment to a smaller tobacco industry is the alternative uses available for land, labor, and capital used in tobacco production * * * For the most part, concern is focused on rural areas where tobacco is grown because this stage of production has the most specialized resources with fewer attractive alternative uses. In many areas, small farms that are unviable without tobacco profits would cease production and their land would be absorbed into larger neighboring farms or converted to other uses * * * In marginal farming areas * * * much of the land devoted to tobacco would be converted to residential, commercial, industrial, or forestry uses, in which case it would still generate income for the local economy * * * This land is already being converted to nonfarm uses in rapidly growing areas like southern Maryland and Raleigh-Durham, North Carolina.[350]

FDA notes that the economic consequences of these trends will be substantially mitigated by the very moderate pace of the projected changes.

3. Vending Machine Operators

The final regulation prohibits all vending machine sales of regulated tobacco products except for those machines located in a facility where

[347] Gale, F., "What Tobacco Farming Means to Local Economics," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 5, September 1994.

[348] Warner, K. E., G. A. Fulton, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, pp. 1241–1246, April 24, 1996.

[349] Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 1, September 1994.

[350] *Id.*, p. iii.

persons under the age of 18 are not present at any time. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. According to the NAMA:

[t]he 1986 cigarette location survey mirrored an industry with about 700,000 cigarette vending machines on location. In 1994, the vending industry was estimated to have between 141,000 and 400,000 cigarette machines. This represents a decline in the number of cigarette vending machines on location of between 43 percent and 80 percent.

The U.S. Department of Commerce [351] reports that 1992 sales of tobacco products by automatic merchandising machine operators were about $452 million, or 7.1 percent of that sector's total sales, but a NAMA fact sheet shows this rate continuing to fall, dropping from 8.5 percent in 1990 to 2.7 percent in 1994. One trade magazine explains that, "[c]igarette vending, once an industry mainstay, is now a niche business increasingly conducted by specialized enterprises." [352]

Referring to 1992 Census data, NAMA declared that over 3,000 vending machine operators supply cigarettes, not including the bars, restaurants, hotels, and bowling alleys that own their own machines. On average, these mostly small firms receive 10 percent of their revenues from cigarette sales, although some firms are even more dependent. While some vending machines can be converted to sell other products, one large cigarette machine manufacturer maintained that more than 85 percent of the existing machines can be converted only for new products with packaging similar in dimension and form to cigarette packages.

While vending operators will need to develop new markets to replace the already dwindling sales revenues from cigarette vending machines, the overall economic impact will be mitigated somewhat by FDA's decision to exempt "adult only" locations from the ban. According to a 1995 NAMA survey, 58 percent of cigarette vending machines are located in bars and cocktail lounges, 11 percent in factory/plant locations, and 3 percent in business offices. [353] Those locations that do not permit the entry of youngsters under the age of 18 will be exempted from the cigarette vending machine restriction.

4. Advertising Sector

In annual reports to FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of $6.0 billion and $119 million, respectively (see Table 14). About $2.6 billion (43 percent) of these outlays went 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 remaining $1.9 billion (31 percent) were related to consumer advertising activities that will be significantly modified by the "text only" restrictions.

TABLE 14.—TOBACCO ADVERTISING/PROMOTIONAL EXPENDITURES 1993 (Millions of Dollars)[1]

Promotion Type	Cigarettes	Smokeless	Total
Coupons/Value Added	2,559	32	2,591
Promotional Allowances	1,558	13	1,571
Point of Sale	401	13	414
Specialties Items	756	4	760
Outdoor	231	1	232
Magazines	235	7	242
Public Entertainment	84	23	107
Free Samples	40	16	56
Transit	39	0	39
Newspapers	36	1	37
Direct Mail	31	1	32
Endorsements	0	0	0
All Others	64	7	71
Total	**6,035**	**119**	**6,154**

[1] Totals may not add due to rounding.
Source: U.S. Federal Trade Commission

FDA cannot project the ultimate industry response to these advertising restrictions. On the one hand, the effectiveness of many advertisements will fall. On the other hand, many alternative marketing promotional activities will be prohibited or constrained even more stringently, raising the relative desirability of the remaining advertising options. Moreover, as described above, FDA may require new informational programs that would generate a substantial increase in advertising industry revenues. Nevertheless, if tobacco outlays fall, there will be short-term dislocations as industry resources are redirected to other uses. One firm that depends heavily on tobacco advertising warned of severe economic burdens, pointing to income and job losses for many of its employees and suppliers. Most advertising suppliers, however, are not overly specialized with respect to particular consumer products and would redirect resources to other advertising purchasers, albeit at some revenue loss. While FDA is aware that such demand shifts cause short-term disruption, the U.S. economy creates and discards thousands of products each day. For most advertising media, the ability to respond rapidly to

[351] U.S. Department of Commerce, "Merchandise Line Sales," *1992 Census of Retail Trade*, RC92-S-3RV, pp. 3-27, 3-31.

[352] *Vending Times*, Census of the Industry Issue, p. 36-D, 1995.

[353] National Automatic Merchandising Association, Cigarette Vending Machine Location Study, conducted August 31, 1995.

changing markets is a mainstay of economic survival.

a. *Print media.* The final regulation requires that advertising of cigarettes or smokeless tobacco be restricted to black text on a white background in those publications where youthful readers constitute more than 15 percent of total readership or number more than 2 million. FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but foresees a possible fall in the $242 million worth of magazine advertising and the $37 million worth of newspaper advertising that tobacco manufacturers reported to the FTC in 1993. These advertising revenues comprised about 1.1 percent and 0.1 percent of the 1992 value of shipments for periodicals and newspapers, respectively.[354] The Barents Group identified 32 leading magazines with tobacco advertising in 1994 that have youth readership levels exceeding the regulatory threshold and found that these publications received, on average, 7.3 percent of their total advertising revenues from tobacco in 1994. They also predicted, based on the sharp downward trend of these advertising outlays, a 21-percent drop in magazine advertising and a 45-percent drop in newspaper advertising for tobacco products by 1996, irrespective of the FDA regulation.

The impact of these restrictions on the various advertising media and agencies is difficult to determine. The Barents Group contended that FDA had argued in its original analysis that "regulations for print media will have little or no adverse impact." In fact, FDA made no such projection, although the agency did present several historical examples of advertising bans (e.g., the broadcast ban on tobacco products) where advertising revenues rebounded in spite of new legal restrictions. The Barents Group also faulted FDA for not comparing actual revenues after the broadcast ban to revenues "that *would have* been expected in the absence of the ban." FDA, however, does not believe that this "counter factual" logic for estimating costs precludes the agency from suggesting that income and employment would not necessarily fall in the wake of new advertising restrictions.

Several comments declared that advertising outlays would fall sharply and subscription prices rise. According to the Barents Group, imagery is a prerequisite for effective promotion and, in its absence, magazine and newspaper advertising revenues would fall by 25 to 75 percent. It also predicted that the reduced revenues would, in turn, force publication subscription prices to rise.

FDA agrees that there will be adverse impacts on certain publications, but notes that the tobacco industry is currently shifting its advertising budget away from print media and that only 6 of the 32 affected magazines identified by the Barents Group received over 10 percent of their revenues from tobacco products. Moreover, as noted earlier, while FDA cannot project the tobacco industry's marketing strategies, the agency suggests that restricted promotion alternatives could reestablish print advertising as a relatively attractive option for conveying product information to adult readers; thereby slowing or even reversing the recent slide in this type of tobacco advertising.

The Barents Group also asserted that the commercial printing industry, as well as other industry sectors, would be harmed by restrictions on coupons and "retail value added" promotions. These expenditures, which account for $2.6 billion, or 42 percent of the total tobacco advertising and promotional outlays reported to FTC in 1993, include outlays associated with cents-off coupons and multiple pack promotions, such as "buy one, get one free" or "buy two, get one free;" as well as other give-away promotions, such as "buy cigarettes and get a free promotional item." The former activity will be permitted but the latter prohibited under the final regulation. Although a comment submitted by the Tobacco Institute noted that, "[a]nalytically, such spending is more akin to a price cut than to advertising,"[355] the Barents Group, nonetheless, concluded that, "[a] considerable part of this spending would likely be eliminated by the proposed regulations." FDA, however, does not agree that the printing industry will be significantly affected by changes in "coupons and value added" outlays. Cents-off coupons and multiple pack promotions are the principal components of these promotions and will continue to be available under the final rule.

b. *Advertising agencies and other suppliers.* Advertising agency revenues are directly tied to the level of advertising expenditures by product manufacturers. If tobacco manufacturers reduce advertising outlays, these agencies will lose income. The Barents Group found that, in 1993, tobacco companies routed almost $1 billion through ad agencies (less than 1 percent of the reported $131.3 billion spent on U.S. media advertising in 1992).[356] Assuming agency fees of 10 percent (while overlooking the proposed $150 million educational campaign), it suggested that advertising declines of 25 to 75 percent would decrease agency annual revenues by $25 million to $77 million. Assuming a 50 percent drop ($140 million) in magazine and newspaper advertising, the Barents Group next applied a simulation model to predict that supplier firms among advertising agencies, government, business and professional services, and commercial printers businesses would lose revenues of from $12 to $23 million. While acknowledging that, "* * * there will be eventual offsetting revenue gains in other industries not shown * * *," these other sectors were not identified and the offsetting revenues not explicitly quantified. The Barents Group correctly noted that the adjustments will involve short-term costs to the affected sectors, but did not estimate the expected magnitude of these adjustment costs.

c. *Outdoor advertising industry and public transit authorities.* The final rule restricts tobacco billboards and public transit advertising to black text on a white background and bans all stationary outdoor tobacco ads within a 1,000-foot radius of any school or public playground. The Barents Group predicted that almost all urban areas would be covered by the ban and expected almost no new outdoor tobacco advertising "even in permitted areas due to the relative ineffectiveness of black-and-white text as an advertising medium." Further, explaining that the $232 million spent on outdoor advertising in 1993 accounts for about 14 percent of all outdoor advertising in the United States, the Barents Group found it unlikely that the industry could find new means of maintaining its current revenues.

In fact, the billboard industry and public transit districts will have to find replacements irrespective of this regulation. According to the Barents Group projections, spending on outdoor advertising by tobacco companies will fall by almost 40 percent between 1988 and 1996 (Appendix Table). One billboard trade source notes that, "almost 60 percent of the industry's 1979 revenues were derived from

[354] *Statistical Abstract of the United States*, p. 750, 1995.

[355] Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," vol. 44, p. 13, 1993.

[356] Endicott, R. C., "Top Advertisers Rebound, Spending to $36 Billion," *Advertising Age*, vol. 64, No. 41, p. 1, September 29, 1993.

tobacco and alcohol advertisers. Today that number is down to 13 percent, replaced by retail, business and consumer services, entertainment, and travel advertisers." [357] Similarly, FDA's preliminary economic analysis had recognized that Canada's billboard industry had rapidly adjusted to a recently imposed advertising ban and "quickly replaced $20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer." [358]

In 1993, tobacco industry spending on public transit ads ($39.1 million) contributed less than 1 percent to total public transit revenues, having declined by 35 percent from 1990 to 1993. Acknowledging that these expenditures would continue to fall, irrespective of this rule, the Barents Group argued that since relatively few transit authorities accept tobacco ads, the impact of the regulation would be significant for those few.

d. *Specialty item suppliers.* The prohibition of nontobacco specialty items bearing the name or logo of tobacco products will affect a substantial number of specialty manufacturers. In earlier comments to FTC, [359] the Specialty Advertising Association International noted that it "represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses." 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.

The Barents Group projected that manufacturer outlays for these promotional items, in the absence of the FDA rule, would triple between 1993 and 1996, rising from $760 million to $2.2 billion, assumed that the rule would cause revenue decreases of 25 to 75 percent, and modeled the impacts among other affected industry sectors (e.g., miscellaneous manufacturers producing matches and matchbooks, cigarette lighters, pens and pencils, sporting goods, etc.). The revenue and employment losses, therefore, were measured from a baseline that assumed a tripling of future industry revenues. While these growth projections may be optimistic, they demonstrate the rapid swings that typify the market for many of these industries. Indeed, the Barents Group's forecasts imply that even if the FDA rule were to reduce the 1996 level of tobacco industry advertising on specialty items by 50 percent, these outlays would still exceed the 1995 level.

In any case, FDA believes that the Barents Group's forecasted impacts may be overestimated, as they primarily reflect static outcomes, whereas firms supplying such products are constantly adjusting production in response to rapidly shifting patterns of demand. While these regulatory changes will impose short-term dislocation costs, these costs will be significantly mitigated in view of the extensive lead time provided. Again, the Barents Group noted that FDA had not quantified these transitory costs, but it also provided no estimate.

e. *Sponsorship recipients.* According to reports submitted to FTC, U.S. tobacco companies spent $107 million on public entertainment, primarily sporting events, in 1993. [360] In comparison, total spending on corporate sponsorships for sports, arts, and other entertainment by all North American companies is estimated to reach $5.4 billion in 1996. [361] FDA received numerous public comments asserting that the loss of sponsorship revenues for sporting events would increase ticket prices and, in turn, reduce spectator attendance. In particular, comments pointed to the potential loss of jobs, employee benefits, and business revenues associated with race track events.

The Barents Group contended that a substantial part of the payments made by tobacco manufacturers would be eliminated by a ban on tobacco brand sponsorships, because few sponsors would agree to continue sponsorships under corporate names. Acknowledging the lack of reliable information on economic impacts; it, nonetheless, referenced several studies showing that lost sponsorship dollars decrease revenues and temporary jobs for local economies. The Barents Group predicted that, as tobacco companies eliminate payments, other advertisers would replace the major sponsorships, but leave reduced or no funding for the less popular events. On this basis, it projected a 25 to 75 percent reduction in sponsorship dollars, calculated to result in revenue losses of $27 to $80 million.

Among the affected U.S. sporting events, the auto racing industry receives the greatest amount of tobacco sponsorship revenues. The Barents Group relied on various editions of the *IEG Intelligence Reports* (IEG) to list these sponsorships. In reviewing the IEG data and other sources, FDA found that about $29 million worth of 1995 tobacco sponsorship revenues were designated for the National Association for Stock Car Auto Racing (NASCAR); [362] which amounted to about 8.3 percent of estimated NASCAR sponsorship revenues [363] and about 1.4 percent of estimated NASCAR total revenues. [364] The IEG data listed Indy Car tobacco sponsorships totaling only about $13 million, although these data did not cover all events.

As the majority of the NASCAR tobacco sponsorship revenues were directed to the Winston Cup or other lead series, FDA agrees that a major effect of the ban will be to decrease the price of sponsorships, permitting smaller sponsors to "trade up" to the more prestigious sponsorships left vacant by tobacco companies. Although new company sponsors will be attracted by the lower overall sponsorship costs, this "ripple effect" will impose shortfalls for some smaller or lower profile events. This economic impact will be somewhat mitigated, however, by the rapid growth in nontobacco sponsorships. According to IEG estimates, over the past year, motorsport sponsorship spending rose by about 17 percent [365] and total North American corporate sponsorship spending by about 15 percent. [366]

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[357] Burns, K., "Driving Into the Future with New Technology," *Outdoor Advertising Magazine*, p. 5, January/February 1995.

[358] Wolfson, A., "Canada's Ad Ban Puts Cigarettes Out of Sight," *The Courier-Journal*, pp. A1, A4, August 1, 1994.

[359] 56 FR 11661 (March 20, 1991).

[360] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, p. 18, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986, p. 24, 1995.

[361] EPM Communications, Inc. "Entertainment Marketing Letter," February 1, 1996. Based on IEG Sponsorship Report.

[362] 1995 IEG Intelligence Report lists $26.7 million in tobacco sponsorships of NASCAR. Two tobacco-sponsored events did not list the sponsorship fees, which FDA estimates at about $1 million apiece.

[363] Koenig, B., "NASCAR takes Lead in Race for Sponsors: Stock-car Racing Gains Corporate Funds as CART and IRL Lag in Money and Ratings", *The Indianapolis Star*, March 8, 1996, *Business* p. F01.; MacCrae, M., "Ricky Craven Collectibles Boost Intensive Fan Interest in Driver", *Bangor Daily News*, May 2, 1996.

[364] Oliver, S., "A Fan-Friendly Sport," *Forbes*, p. 70, July 3, 1995; Horovitz, B., "Fine-Tuning an Image-New Sponsors Race to NASCAR," *USA Today*, Final Edition, p. 1B, April 5, 1996.

[365] MacCrae, M., "Ricky Craven Collectibles Boost Intensive Fan Interest in Driver," *Bangor Daily News*, May 2, 1996.

[366] *IEG's Complete Guide to Sponsorship*, p. 3, 1995.

5. Retail Sector

In addition to incurring the economic costs described earlier, certain segments of the retail industry will experience adverse distributional impacts to the extent that they receive smaller promotional allowances (slotting fees) from manufacturers. In 1993, industry promotional allowances totaled $1.6 billion dollars. According to FTC:

Promotional allowances are designed to encourage wholesalers and retailers to stock and promote a company's products, including such things as trade allowances and slotting allowances. Trade allowances provide deals to cigarette wholesalers, dealers and merchants in the form of free goods or price reductions in return for the purchase of specific quantities of goods. Slotting allowances include fees that the cigarette manufacturers pay retailers to encourage them to carry a new product or to allocate premium shelf space to a product. Trade contests and incentives, training programs, and trade shows may also be counted as promotional allowances.

One major convenience store association, estimating that its members currently receive about $5,000 per store, remarked that convenience stores would "bear a disproportionate burden should such allowances be eliminated as a result of the ban on self-service displays." Other retailers expressed similar concerns over the prohibition of self-service displays and promotional advertising, fearing it would lead to the elimination of these revenues.

The Barents Group argued that there were strong reasons to believe that promotional allowances would fall sharply as "tobacco products are withdrawn to inaccessible areas of the store, [and] the products taking their place will offer lower allowances." While acknowledging that, "[t]he possibility of promotional payments continuing may depend on whether the proposed regulations would allow the tobacco packages and cartons to be displayed from behind the check-out counter or from some other secured location in the stores," they nonetheless presented "illustrative" revenue reductions of from 25 to 50 percent and projected total revenue losses to the retail sector of $556 to $1,112 million. Using the higher percentage, their analysis implies that pretax profit margins would fall 12.4 percent for the average sized convenience store and even more for smaller stores. Moreover, they predicted that about 2 percent of currently profitable convenience stores would thereafter incur losses.

FDA suspects that many of these concerns are unwarranted as tobacco manufacturers will continue to place significant value on having their products situated in highly visible locations. Although desirable locations behind counters or in locked display cases will be more limited, there is little reason to believe that manufacturers would stop competing for the best display space available. One comment indicated that following a self-service ban in a local area of Northern California, some retailers:

* * * reported losses of tobacco industry-paid slotting fees * * * because of the removal of self-service promotional tobacco displays, racks and kiosks; * * * other retailers reported they did not loose [sic] tobacco industry-paid slotting fees if tobacco displays, racks or kiosks are relocated behind the counter or if they are replaced by locking cases * * * [There were] no reported losses of other tobacco industry-paid advertising fees, promotional allowances or other financial incentives paid to retailers for advertising, promoting and marketing tobacco products in their stores. [367]

Because of the regional aspects of this ban, it was a "worst case" situation for retail stores. If self-service displays were a prerequisite for promotional allowances, tobacco manufacturers would have quickly transferred them to other near-by localities, where self-service was permitted. The fact that this did not generally occur demonstrates that factors other than self-service displays can support manufacturer promotional payments to retailers.

Another comment noted that, "[i]n at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves." In discussing the effects of the Canadian advertising ban, a Canadian study [368] suggested 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." Moreover, because FDA has not banned all point-of-purchase tobacco advertising, "text only" advertising at retail stores will be extremely important to tobacco product marketers.

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." [369] That same Northern California study expressly noted the "[r]eplacement of self-service tobacco displays, racks and kiosks with * * * non-tobacco products such as candy, gum and soft drinks for which the retailer receives slotting fees from the manufacturers of these products." [370]

In sum, FDA cannot predict with certainty the direction of future payments by product manufacturers to retailers. The agency points out, however, that this rule would affect neither the trade allowances that are commonly paid to both wholesalers and retailers, nor the slotting allowances paid to retailers to encourage them to carry a new product or to assure the availability of a particular brand in a retail outlet. Further, while many current promotional activities will be prohibited, a substantial number will remain available. As the competitive pressures that drive promotional allowances are unlikely to abate, manufacturers will continue to compete vigorously through programs involving both "text only" promotions and select product placements.

6. Other Private Sectors

FDA is aware of several recent studies that address the contribution of tobacco to the U.S. economy; or alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related expenditures. The Tobacco Institute's Price Waterhouse report [371] purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. That

[367] 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, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[368] "When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products," Expert Panel Report, Prepared at the request of Health Canada, p. 140, March 1995.

[369] "P-O-P Scores with Marketers," *Advertising Age*, p. 2, September 26, 1994.

[370] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[371] "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, October 1992.

report concluded that the induced or multiplier effects support 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, a review of that report, by Arthur Andersen Economic Consulting, explained that such multipliers lead to "massive and unrealistic estimates."[372] That review further emphasized that "money now being spent on tobacco would not disappear if demand for tobacco were to fall," though the Price Waterhouse report implicitly made that assumption. The Arthur Andersen review concluded that these multipliers "provide no basis by themselves for predicting how many jobs would be lost by a reduction in tobacco spending." FDA strongly supports this latter view.

The American Economics Group (AEG), in a new study submitted by the Tobacco Institute, employed a national input-output model to project broad sectoral and regional estimates of "the induced impact of the FDA proposed regulations nationwide." Applying the low and high illustrative costs estimated by the Barents Group, AEG predicted job losses of between 32,000 and 92,500. In addition to the printing and publishing industries, significant employment cutbacks were found for food, apparel and textiles, paper, metals, motor vehicles, and other miscellaneous manufacturers.

FDA is skeptical of the results of this AEG study. First, the input-output methodology employs an inherently static approach for estimating economic impacts. Indeed, the Barents Group, in its second report for the Tobacco Institute, explained that input-output models will not capture changing economic conditions, because they fail to account for changing market prices. Thus, "the input-output approach fails to measure the effects of reallocating displaced workers and resources to other parts of the economy." Furthermore, the AEG study suffers from the same fundamental problem as the earlier Price Waterhouse analysis: It assumes that all reduced industry revenues are lost to the economy. This methodology is simply inappropriate. Finally, the AEG study is based upon the illustrative cost estimates of the Barents Group. As described in detail above, these cost estimates are unreasonably high. Although some tobacco advertising may decrease, a significant portion will be redirected towards the remaining permissible promotional activities.

In a second report, the Barents Group presented the results of using its own cost estimates in a general equilibrium model to simulate the impacts of the estimated reductions in advertising and promotional spending on revenue and employment for 56 sectors of the U.S. economy. This model predicted 21,000 to 44,000 U.S. job losses, largely among wholesale and retail businesses, but also within advertising, printing, apparel and miscellaneous manufacturing industries. FDA finds, however, that this study also is subject to several serious deficiencies. In particular, the Barents Group relies on its own illustrative cost estimates as model inputs. As noted above, FDA believes these estimates are far too high. Next, the study focuses solely on those industry sectors predicted to lose jobs, while ignoring those sectors expected to gain jobs. In fact, the study explicitly acknowledges that the underlying model assumes that:

> the aggregate level of employment is not changed in the long run as a result of implementing the new regulations. In other words, though particular jobs in particular industries are expected to disappear permanently, the number of man-hours worked per year in the economy as a whole is assumed not to change in the long run
> * * *

The Barents Group selectively shows changes in revenue and employment for the losers only.

Other analysts concluded that such models should not be used to assess longer term national economic impacts, because resources diverted from one use would be reallocated to the production of other goods and services. As one economist explained "[i]f the focus is longer term, involving a period of, say, more than 2 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."[373]

Some comments addressed regional issues, pointing to the importance of tobacco products to the economies of several states. Comments noted, for example, that about 177,000 North Carolinians were employed by tobacco and that Price Waterhouse estimated that the economic activity of these workers supported total State employment of 260,000. FDA is aware that tobacco growing states will experience some adverse economic effects. Nevertheless, as discussed above, the agency finds that the income and employment impacts associated with reduced tobacco consumption will be extremely gradual. Moreover, reduced tobacco consumption will minimally affect or even boost the economies of nontobacco states. For example, a recent economic simulation of the regional impacts of spending on tobacco products by Warner, et al., found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment); whereas the nontobacco regions of the United States would gain 56,300 jobs.[374] That study concluded that "[t]he primary concern about tobacco should be the enormity of its toll on health and not its impact on employment."

7. Excise Tax Revenues

The rule will decrease State and Federal tobacco tax revenues as fewer youths will become addicted to tobacco products. These excise tax losses will increase as more youths become nonsmoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled $6.2 billion for the year ending June 30, 1993.[375] As State excise taxes on other tobacco products (including smokeless tobacco) are reported at $226 million, FDA assumes that the value of all State excise taxes affected by this regulation is about $6.4 billion annually. Federal excise taxes on cigarettes totaled $5.5 billion for the year ending June 30, 1993. Federal excise taxes on smokeless tobacco are expected to be about $27 million, according to the Smokeless Tobacco Council. As described above, FDA estimates that compliance will reduce tobacco product sales by a gradually increasing rate over time; tobacco sales will fall by 0.5 percent in the 1st year, 1.9 percent in the 5th year, and 3.7 percent in the 10th year. Thus, the rule will decrease State excise taxes on affected tobacco products by from $30 million in the 1st year to $231 million in the 10th year and Federal tobacco

[372] "A Review of the Price Waterhouse Economic Impact Report and Tobacco Institute Estimates of 'Economic Losses from Increasing the Federal Excise Tax'," Arthur Andersen Economic Consulting, p. 93, October 6, 1993.

[373] Gray, H. P., and I. Walter, "The Economic Contribution of the Tobacco Industry," in *Smoking and Society: Toward a More Balanced Assessment*, edited by R. D. Tollison, Lexington Books, p. 248, 1986.

[374] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, April 24, 1996.

[375] The Tobacco Institute, "The Tax Burden on Tobacco," vol. 28, p. 4, 1993.

taxes by from $25 million in the 1st year to $196 million in the 10th year.

Since tobacco taxes represented less than 1 percent of total revenues on both the State and Federal level in 1992,[376] even the estimated tenth year impact measures only 0.03 percent of all State tax revenues and less than 0.02 percent of all Federal revenues. Nonetheless, if necessary, governments could raise tobacco product excise rates to offset these revenue losses. A full evaluation of the fiscal consequences, however, would involve a variety of public health ramifications. For example, State Medicaid programs will benefit from reduced tobacco-related medical care expenditures, but will need to finance additional nursing home expenditures associated with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a rule will have a significant economic impact on a substantial number of small entities. Analyses in this section, as well as in other sections of this preamble, constitute the agency's compliance with this requirement. According to the Regulatory Flexibility Act, the final regulatory flexibility analysis must contain "a succinct statement of the need for, and objectives of, the rule." Section XV.B. of this document explains that the need for action stems from the enormous toll on the public health that is directly attributable to the consumption of tobacco by children and adolescents under the age of 18. As described, the primary objective of the regulation is to achieve the "Healthy People 2000" goal of reducing by one-half the number of youngsters who use tobacco.

The final regulatory flexibility analysis must also provide "a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments." The analyses presented previously in this section addressed the first two of these elements.

With respect to the changes made in the proposed rule as a result of public comments, the agency has reconsidered several of its earlier decisions, at least partly due to their projected effect on small businesses. The preamble above describes these changes and presents the agency's rationale for each modification. For example, the proposed regulation banned all vending machine sales of tobacco products. In response to public comment, the final regulation exempts from the ban those vending machines in "adult only" locations. FDA does not know how many small businesses will be able to take advantage of this exemption, but it will maintain at least one line of sales for small vending machine operators without jeopardizing the protection of young people.

In addition, the proposed regulation prohibited direct mail-order sales of tobacco products. The public comments, however, indicated that many adults, especially those who are elderly or who have limited mobility, would be substantially inconvenienced and several small businesses would be adversely affected by this ban. Even more importantly, studies suggest that teenagers purchase cigarettes from vending machines or retail merchants rather than from nonretail channels. FDA took these considerations into account and the final regulation does not prohibit mail-order sales of cigarettes.

The final regulatory flexibility analysis must also include "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available." U.S. Census data for 1993 indicate that most cigarette manufacturers are large businesses, with only 4 employing fewer than 500 employees.[377] The small business size standard established by the U.S. Small Business Administration (SBA) for this industry is 1,000 employees.[378] The Federal Trade Commission (FTC) provided a list of 52 cigarette importers and small cigarette manufacturers filing plans with that agency, but could not distinguish manufacturers from importers.[379] The 1993 Census data show that 14 of the 20 firms manufacturing chewing and smoking tobacco employ fewer than 500 employees, the SBA size standard for this sector.[380] Also, most of the nation's 124,000 tobacco farms are small; almost 99 percent of the farms growing tobacco in 1992 had total farm sales under the SBA small business size standard of $500,000, and almost 91 percent had total farm sales under $50,000.[381] Further, 1993 Census data show that 1,332 of 1,365 tobacco wholesale trade firms (98 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA.[382] As noted above, the effect of the regulation on tobacco manufacturing, growing, and wholesale trade operations will be very gradual, taking over 10 years to reach a 4 percent reduction.

The regulation will affect numerous retail establishments, including food stores, small general merchandise stores, small tobacco stores and small gasoline stations. Table 15 displays the relative share of the tobacco market for the major types of tobacco-dispensing outlets with payroll in 1992. As shown, food stores and service stations received about 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 7 percent of the total sales of many of these establishments. Table 16 indicates that the great majority of all retail outlets in these sectors are small businesses.

[376] U.S. Department of Commerce, *Statistical Abstract of the United States 1994*, 114th edition, No. 464, p. 298, 1994.

[377] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 68.

[378] U.S. Small Business Administration, "Table of Size Standards," March 1, 1996.

[379] Federal Trade Commission, "Cigarette Importers and Small Manufacturers Plans Filed, May 26, 1993–October 14, 1994."

[380] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 69.

[381] 1992 Census of Agriculture, U.S., vol. 1, excerpts from pp. 109–110, 125–126.

[382] Special Census Tabulation prepared by U. S. Bureau of Census for U.S. Small Business Administration, Table 3—United States.

TABLE 15.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1992
(Establishments with Payroll Only)

Establishment Type	Tobacco Sales		% of Total Sales	
	($ Mils)	(%)	Establishments Handling Tobacco	All Establishments
All	30,559	100	4.5	2.9
Food Stores	16,132	52	4.5	4.4
Service Stations	7,136	23	7.1	5.3
Drug and Proprietary	2,235	7	3.7	2.9
General Merchandise	3,182	10	2.4	1.3
Liquor Stores	1,045	3	8.0	5.1
Eating and Drinking	219	1	3.0	0.1
Tobacco Stores & Stands	610	2	78.1	78.1

Source: 1992 Census of Retail Trade, Merchandise Line Sales

TABLE 16.—NUMBER OF SMALL RETAIL BUSINESSES

Establishment Type	Firms With Payroll		Establishments Without Payroll
	Total	Small[1]	
All	588,505	473,668	275,432
Food Stores	127,575	104,541[2]	97,061
Service Stations	62,585	53,288[3]	14,248
Drug and Proprietary	28,606	25,396	3,031
General Merchandise	10,264	8,176	28,010
Liquor Stores	26,565	22,859	8,811
Eating and Drinking	331,703	258,381	124,271
Tobacco Stores & Stands	1,207	1,027	n.a.

[1] Assumes Small Business Administration size standard of $20 million in annual sales for food stores, $6.5 million for service stations and $5 million for all others.
[2] Due to data limitations, includes firms with annual sales up to $25 million.
[3] Due to data limitations, includes firms with annual sales up to $10 million.
Source: 1992 Census of Retail Trade, Establishment and Firm Size, 1992 Census of Retail Trade, Summary.

To illustrate the effects of this proposal on a typical small retail store, FDA separately utilized Census data to estimate that the average-sized convenience store sells 177 packages of tobacco products daily, of which about 25 might be purchased by young adults aged 18 to 26.[383] Based on the cost assumptions described previously, the outlet's first year costs would total about $400, with the largest single cost, $199, 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 $137.

This estimate does not account for the possible reduction in promotional allowances, as FDA believes that competitive pressures will continue to lead manufacturers to rely on promotional allowances to compete for the best shelf space available for their products. Because FDA rejected the idea of prohibiting any visible display of tobacco products, retailers can retain slotting fees by choosing to display tobacco products either behind counters or in transparent locked display cases. Nevertheless, some small establishments might experience reduced promotional payments following a ban on self-service marketing.

Census data for 1992 indicate that almost 4,000 of 4,800 merchandising machine operator businesses (83 percent) reported annual receipts below the SBA size standard of $5 million.[384] One trade association noted that almost three quarters of all vending machine operators had annual sales of less than $1 million.[385] As explained earlier, prohibiting all cigarette vending machines would initially reduce the revenues of vending machine operators by an average of 2.8 percent. Because only about one-half of the merchandising machine establishments sell cigarettes, some businesses specializing in cigarette sales would experience greater revenue declines; although this effect will be moderated to the extent that cigarette vending machines are placed in areas restricted to adults, which would not be prohibited by the final rule.

The rule would also affect the distribution of specialty items showing a tobacco product logo or name. Industry comments do not provide precise data on the size distribution of these firms, but as noted above, the Specialty Advertising Association International indicates that 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below $2 million. While the marketplace in which these firms traditionally compete demands a quick response to shifting consumer trends, this rule would have at least short-term impact on some small firms.

FDA has received no data that would allow it to estimate the number of small firms that are currently involved with some aspect of tobacco advertising or the fraction of these firms that will be affected. In 1992, 861 of 904 year-round outdoor advertising firms (95 percent) reported sales revenues of less than the SBA size standard of $5 million.[386] The impact of this rule, however, is difficult to assess without knowing how the tobacco industry will alter its advertising strategies. Indeed, one of the largest outdoor advertising firms recently decided to reject all tobacco business, potentially increasing sales to the smaller firms.[387]

The regulation restricts tobacco advertising to "text only" in magazines with youth readership above the regulatory threshold. Of the identified 101 magazines with tobacco ads in 1994, 79 were published by large firms (over 500 employees). Less than 3 percent of the total revenue of the remaining 22 publications (which include, Inc., Rolling Stone and Penthouse) was derived from tobacco ads.[388] It is likely, moreover, that many of these magazines could avoid the "text only" restriction for tobacco advertising by demonstrating a low youth readership.

The regulation will also affect a substantial number of small race tracks, although FDA does not know how many small tracks currently receive significant revenues from tobacco sponsors. As discussed previously, some small operations will likely lose promotional revenues from tobacco companies, but the sport is growing rapidly and other product manufacturers should make up a substantial part of the shortfall.

The final regulatory flexibility analysis must include "a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record." A full description of the requirements and classes of affected small entities has been provided earlier in this section and a quantitative review of the paperwork burdens imposed by the rule is provided in section XVI. of this document. No special professional skills will be required to prepare the reports or records required by the regulation.

The final regulatory flexibility analysis must also include "a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

The earlier sections of this document provide a full explanation of the agency's basis for selecting each provision of the final rule. In each instance, FDA evaluated the implications of each reasonable regulatory alternative and selected only those requirements that were absolutely necessary to satisfy the agency's statutory goals. As described, FDA found that its objectives for reducing the use of tobacco by young people could not be achieved with a partial or one-dimensional approach, but required a comprehensive set of regulatory restrictions. Thus, the final set of selected provisions reflect a careful examination of the relevant facts presented to the rulemaking record, the agency's objective of curtailing the use of tobacco by youngsters without creating unnecessary economic burdens, and a full assessment of the agency's legal authorities. Because the rejected alternatives would either provide less protection of public health, or achieve

[383] Based on data form the 1994 SGR, p. 85, and the "Tobacco Situation and Outlook Report" April, 1995, p. 4, FDA estimates that smokers aged 18 to 26 account for about 10 percent of all cigarettes smoked. Alternatively, data from the Statistical Abstract, tables 16 and 218, show that smokers aged 18 to 26 comprise 18 percent of all smokers. FDA used the midpoint of the 10 to 18 percent range to avoid underestimating the cost to small retailers. In addition, data from the 1996 Census of Retail Trade, Subject Series-Merchandise Line Sales, pp. 3–9 on the number of convenience stores with payroll and their total tobacco sales, and the average price per pack, were used to estimate the average number of packs sold daily at convenience stores to smokers aged 18 to 26.

[384] 1992 Census of Retail Trade, "Establishment and Firm Size," Table 4 p. 1–99.

[385] "1993: Industry Posts Best Growth in Four Years," *Automatic Merchandiser*, p. A2, August 1994.

[386] 1992 Census of Service Industries, pp. 1-145 and 1-195.

[387] Collins, G., "Major Advertising Company to Bar Billboard Ads for Tobacco," *New York Times*, A15, May 3, 1996.

[388] *1996 Directory of Corporate Affiliations U.S. Private Companies*, New Providence, NJ; Reed Elsevier, Inc.; "Company Profiles" database, Information Access Co., Foster City, CA.

only minimal improvements at unwarranted cost, the agency found that the approach selected for the final rule best fit its statutory mandate.

As noted, earlier sections of the preamble fully describe the agency's rationale for selecting each provision of the final rule and for rejecting each alternative approach. Although many alternatives were considered, specific exemptions based solely on business size were not adopted, because FDA believes that children would too frequently exploit such opportunities. Unlike certain other regulations where restrictions on large firms alone might be acceptable, tobacco products are purchased easily from small, as well as large firms. An exemption for small retailers, for instance, would shift underage sales to those locations, lessening or eliminating the benefits of the remaining access restrictions. The following discussion summarizes the agency's consideration of several other regulatory alternatives.

G. Other Alternatives

One regulatory alternative would have banned all tobacco advertising; or alternatively, all tobacco advertising in selected media, such as all written publications, or all outdoor billboards. FDA rejected this approach in order to focus on those media and aspects of advertising that children are routinely exposed to and that have the greatest effect on youngsters. For example, the final rule permits black and white "text only" tobacco advertising in all written publications and color and imagery in magazines with fewer than 2 million youthful readers if youth constitute less than 15 percent of the publication's readership. Billboards are permitted to show black and white "text only" ads if located at least 1,000 feet from schools or public playgrounds. Thus, the rule leaves the informational aspects of advertising largely untouched.

Another suggested alternative was to combat underage tobacco use by relying on either voluntary compliance or on better enforcement of laws prohibiting sales to minors. As discussed earlier in this document, the tobacco industry's voluntary advertising code has failed to stop illegal sales to underage buyers. FDA agrees that these approaches can be partially effective, but finds that they inadequately counter the appeal of tobacco products for young people that is created by advertising and promotions. Thus, the agency concludes that there is no less burdensome alternative for achieving its goals that would exclude appropriately tailored restrictions on tobacco advertising.

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 were 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.

Another suggested alternative would have required package inserts containing educational information in cigarette and smokeless tobacco. FDA had incomplete data to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, tentatively projected one-time costs of about $490 million and annual operating costs of about $54 million. This alternative was not selected because the agency was not certain that the benefits of this provision would justify the 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 and can easily purchase tobacco products for younger classmates. This alternative would have added costs of about $34 million annually, mostly due to lost producer profits. The final regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

H. Unfunded Mandates Reform Act of 1995

On the basis of the preceding discussion, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives as discussed in section XV.G. of this document and determined that the current rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule.

XVI. Paperwork Reduction Act of 1995

The 1995 proposed rule would have collected information from manufacturers, distributors, and retailers of cigarettes and smokeless tobacco. Proposed § 897.24 would have required such persons to use established names for cigarettes and smokeless tobacco. Proposed § 897.29 would have required manufacturers to establish and maintain educational programs. Proposed § 897.32 would have required manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising. Proposed § 897.40 would have required manufacturers to submit labels, labeling, and advertising to FDA.

The preamble to the 1995 proposed rule, in discussing the Paperwork Reduction Act, also invited comments on four questions: (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 (60 FR 41314 at 41356).

A. Comments on the Paperwork Reduction Act Statement

A small number of comments, primarily from a trade association representing cigarette manufacturers and from distributors, addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA's figures were incorrect or that the rule would duplicate existing reporting requirements. Few comments provided any figures or evidence to justify using different estimates.

(1) One comment, submitted by a trade association representing major cigarette manufacturers, said FDA's Paperwork Reduction Act statement underestimated the paperwork burden due to the exclusion of burden on retailers. The comment asserted that FDA did not explain how it calculated the number of respondents and burden hours for these sections and that the absence of an explanation made it difficult to assess the agency's estimate.

federal register

Wednesday
August 28, 1996

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801, et al.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 804, 807, 820, and 897

[Docket No. 95N–0253]

RIN 0910–AA48

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing regulations governing access to and promotion of nicotine-containing cigarettes and smokeless tobacco to children and adolescents.

The regulations prohibit the sale of nicotine-containing cigarettes and smokeless tobacco to individuals under the age of 18; require manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; require retailers to verify a purchaser's age by photographic identification; prohibit all free samples and prohibit the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time; limit the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format; prohibit the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; prohibit sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permit such sponsorship in a corporate name; and require manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.

These regulations will address the serious public health problems caused by cigarettes and smokeless tobacco products. They will reduce children's and adolescents' easy access to cigarettes and smokeless tobacco and will significantly decrease the amount of positive imagery that makes these products so appealing to that age group.

The regulations are predicated on the agency's assertion of jurisdiction under the Federal Food, Drug, and Cosmetic Act over cigarettes and smokeless tobacco as delivery devices for nicotine, incorporated as part of the regulations for purposes of, and to facilitate, congressional review under the Small Business Regulatory Enforcement Fairness Act of 1996.

DATES: *Effective date.* The regulation is effective August 28, 1997, except that § 897.14(a) and (b) are effective February 28, 1997 and § 897.34(c) is effective February 28, 1998.

Compliance dates. Manufacturers and distributors are required to comply with the requirements of 21 CFR parts 803 and 804 August 28, 1997; manufacturers are required to comply with the requirements of 21 CFR parts 807 and 820 February 28, 1998.

ADDRESSES: References listed in the footnotes of this document have been placed on public display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy Yeates, Office of Policy (HF–26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0867.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Introduction

A. Purpose and Overview of the Rule

This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing FDA's determination that it has jurisdiction over these products under the Federal Food, Drug, and Cosmetic Act (the act). As described in "Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination" (the 1996 Jurisdictional Determination), annexed hereto, FDA has determined that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, within the meaning of the act's definitions of "drug" and "device." The nicotine in cigarettes and smokeless tobacco is a "drug," which produces significant pharmacological effects in consumers, including satisfaction of addiction, stimulation, sedation, and weight control. Cigarettes and smokeless tobacco are combination products consisting of the drug nicotine and device components intended to deliver nicotine to the body.

FDA has chosen to regulate cigarettes and smokeless tobacco under the act's device authorities. This rule allows the continued marketing of these products, while employing measures to prevent future generations of Americans from becoming addicted to them. As discussed in section I.B. of this document, most people who use cigarettes and smokeless tobacco begin their use before the age of 18 and, therefore, before they fully understand the addictive nature and serious health risks of these products. Even though the sale of tobacco products to minors is illegal in 50 States, the tobacco industry has adopted extensive marketing campaigns which appeal to children and adolescents. Therefore, the rule effects measures that would both complement the existing State restrictions on access and prevent

operations which injuriously affect the value of or destroy property—for example, restrictions upon the height or character of buildings, destruction of diseased cattle, trees, etc., to prevent contagion—but for which no remedy is afforded. Contracts in this respect do not differ from other kinds of property." (*Id.* at pp. 508 through 509). The Court reviewed earlier decisions and stated that:

> The conclusion to be drawn * * * is, that for consequential loss or injury resulting from lawful governmental action, the law affords no remedy. The character of the power exercised is not material. * * * If, under any power, a contract or other property is *taken* for public use, the Government is liable; but, if injured or destroyed by lawful action, without a taking, the Government is not liable.

(*Id.* at p. 510)

The Court held that while the Government took the steel, it did not take the contract itself and that "[f]rustration and appropriation are essentially different things" (*Id.* at p. 513). (See *also Louisville & Nashville R.R. Co.* v. *Mottley*, 219 U.S. 467, 484 (1911); *NL Industries, Inc.* v. *United States*, 839 F.2d 1578, 1579 (Fed. Cir.), *cert. denied*, 488 U.S. 820 (1988) ("frustration of a business by loss of a customer was not a taking"); *Carruth*, 627 F.2d at 1081 ("[I]n cases where there has been no direct appropriation of property by governmental agencies, consequential damages resulting from the exercise of lawful regulations are not compensable takings within the purview of the Fifth Amendment").)

Thus, FDA disagrees with the comments suggesting that the rule will result in a taking of jobs or future revenues associated with sponsored events.

(9) Several comments said that the 1995 proposed rule's restrictions on the use of trade names constitute a taking of trade names or the goodwill associated with a tradename or asserted that one has a "right" to use a brand name in any manner.

As discussed in section XI. of this document, the agency disagrees that any provision in this rule effects a taking of trademarks and goodwill.

XIV. Environmental Impact

In the **Federal Register** of August 11, 1995 (60 FR 41314), the preamble to the proposed rule stated that FDA had determined under § 25.24(a)(8), (a)(11), and (e)(6) that the proposed action was of a type that does not individually or cumulatively have a significant impact on the human environment. No new information or comments have been received that would affect the agency's previous determination that this action has no significant impact on the human environment, and that neither an environmental assessment nor an environmental impact statement is required.

XV. Analysis of Impacts

A. Introduction and Summary

The Food and Drug Administration (FDA) has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act of 1995 (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; and distributive impacts and equity). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of such rule on small entities. Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any year. Section 205 of the Unfunded Mandates Reform Act also requires 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 rule is consistent with the principles set forth in the Executive Order and in these two statutes.

FDA published its preliminary economic analysis in the preamble to its 1995 proposed regulation. In response, the agency received thousands of comments raising economic issues or concerns. Representatives of affected industry sectors emphasized burdens in excess of those estimated in the preliminary economic analysis. Other comments stressed the considerable economic value of the expected public health benefits. Although few comments provided quantifiable data on projected economic impacts, whether benefits or burdens, a report prepared by the Barents Group and presented as Volume 11 of the Tobacco Institute submission provided a comprehensive critique of the methodology, assumptions, and cost estimates presented in FDA's preliminary economic analysis and developed alternative estimates of regulatory costs. Other comments addressed selected economic issues. FDA carefully examined and evaluated the reasoning and data presented in these comments, accepted those that were persuasive, and presents this revised analysis of the final rule.

In its preliminary analysis, FDA based the benefits of the 1995 proposed rule on a finding that compliance could help to achieve the Department's "Healthy People 2000" goal of reducing underage tobacco use by one-half. Comments received in response to the proposal have reinforced the agency's conviction that this goal can be realized, although it will require the active support and participation of State and local governments and civic and community organizations, as well as manufacturers and retail dispensers of tobacco products. In the **Federal Register** of January 19, 1996 (61 FR 1492), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued a regulation governing a program of State-operated enforcement activities to restrict the sale or distribution of tobacco products to individuals under the age of 18. SAMHSA predicted that its rule would cut the rate of underage tobacco consumption by between one-tenth and one-third. FDA can not separately quantify the incremental benefits of the respective agency programs, due to the substantial interdependencies and uncertainties regarding future compliance with these rules; but finds that its final rule and the SAMHSA regulation are fully complementary and, working together, will produce results that would more than equal the sum of their independent efforts.

Each year, an estimated 1 million adolescents under the age of 18 begin to smoke cigarettes. The Centers for Disease Control and Prevention (CDC) estimate that approximately one in three of these adolescents will die of smoking-related diseases, and FDA has concluded that this projection provides the best estimate of the excess fatality rate. FDA finds that even overly conservative projections indicate that achieving the "Healthy People 2000" goal of reducing underage tobacco use by one-half 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. The monetary value of these health benefits (at a 3 percent discount rate) is estimated to total $28 to $43 billion per year and includes $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 the total benefits to about $9.2 to $10.4 billion per year). If the agency's goal were exceeded, these benefits would be even larger. Moreover, if even a fraction of the goal were achieved, the benefits would substantially outweigh the costs of the rule. As shown in Table 1c, 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 $2.8 to $4.3 billion a year. In addition, although FDA has not quantified the benefits of reducing the number of serious illnesses attributable to the use of smokeless tobacco by youngsters under the age of 18, the agency is convinced that these benefits also will be substantial.

TABLE 1c.—ANNUAL ILLNESS-RELATED BENEFITS OF ALTERNATIVE EFFECTIVENESS RATES (UNDISCOUNTED LIVES AND LIFE-YEARS; 3% DISCOUNT RATE FOR MONETARY VALUES)[1]

Fraction of Teenage Cohort Deterred	Fewer Teenagers who will Smoke as Adults[3] (No.)	Smoking Related Deaths Averted (No.)	Life-Years Saved (No.)	Medical Savings ($bils.)	Morbidity-Related Productivity Savings ($bils.)	Mortality-Related Willingness-to-Pay		Total Benefits	
						Life-Yrs. Saved ($bils.)	Deaths Averted ($bils.)	Low ($bils.)	High ($bils.)
1/2[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	18.7	28.8
1/5	100,000	24,100	362,100	1.1	0.4	9.8	15.9	11.2	17.3
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	2.8	4.3

[1] Totals may not add due to rounding.
[2] Estimate used in analysis.
[3] Assumes 50% of adolescents who are deterred from smoking continue to refrain as adults.

In its evaluation of the economic impact on industry, FDA also includes those costs that might be attributable to the SAMHSA program, as the rules of both agencies work collectively to reduce youth access to tobacco products. As a result, the overall estimated compliance costs of the rules range from $174 million to $187 million in one-time costs and from $149 million to $185 million in annual operating costs (see Table 2). Manufacturers of tobacco products will incur one-time costs ranging from $78 million to $91 million, primarily for removing prohibited point-of-sale promotional items and self-service displays, and for changing package labels. As the responsibility for removing the prohibited point-of-sale promotional and display items resides with the owner, manufacturers and retailers may ultimately share the costs of removal and replacement. FDA's cost estimates assume that manufacturers will pay for most removal and installation activities and retailers will pay for most replacement items. (If, in fact, retailers assume most removal responsibilities, the estimated manufacturer costs fall by about $47 million).

TABLE 2.—COSTS OF FDA AND SAMHSA REGULATIONS ($ mils.)[1]

Requirements By Sector	One-Time Costs	Annual Operating Costs
Tobacco Manufacturers	**78–91**	**2**
Point-of-Sale Advertising	30	
Self-Service Ban	40	
Label Changes	4–17	
Paperwork Requirements		1.2
Training	1.5	0.2
Readership Surveys	2	1
Retail Establishments	**96**	**78**
Training	34	20
I.D. Checks		43
Self-Service Ban	57	11
Point-of-Sale Advertising	5	
Vending Machines		3.5
Consumers		**41–50**
I.D. Checks		41–50
Government		**28–55**
States (SAMHSA)		25–50
FDA		3–5
TOTAL	**174–187**	**149–185**

[1] Assumes manufacturers remove prohibited retail display. If retailers bear full burden, manufacturer one-time costs fall by about $47 million and retailer one-time costs rise by about $17 million. Advertising restrictions are considered under distributional effects. Excludes costs of short-term resource dislocation and educational programs.

Retail establishments will incur an estimated $96 million in one-time costs. About $57 million of these costs are due to the self-service restriction, primarily for replacing display cases and other functional promotional items. (If retailers rather than manufacturers remove the prohibited point-of-sale advertising and display items, the estimated retailer costs rise by about $17 million). The retail sector will also incur about $78 million in annual costs. In addition to new labor costs attributable to the self-service restrictions, both the FDA and SAMHSA rules impose costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers, and for foregoing profits due to reduced vending machine sales. Consumers will bear costs of up to $50 million annually for incurring some delay in checkout lines. Finally, enforcement of these rules may cost the FDA from $3 million to $5 million per year and State governments from $25 million to $50 million per year for administering various SAMHSA enforcement programs.

FDA could not, however, quantify every regulatory cost. For example, the agency may require certain tobacco manufacturers to broadcast educational messages under the agency's notification process. Cost estimates for these activities will be developed in parallel with the program elements. In addition, a number of commercial sectors will experience costs for short-term dislocations of current business activities. Neither FDA nor any of the industry comments on the agency's proposal projected the magnitude of these costs, but they would be mitigated for those businesses that anticipate the adjustments in long-term business plans.

In addition to the costs described previously, the rule will create significant distributional and transitional effects. Some industry comments asserted that FDA had neglected the cost of lost sales revenues in its preliminary economic analysis and one industry study estimated these "Illustrative Costs" at from $1.3 billion to $3.3 billion per year. In fact, FDA had considered these sector-specific revenue reductions, but described the impacts as distributional effects, rather than as net societal costs. For example, any lost sales experienced by suppliers of advertising were considered distributional impacts, because dollars not spent on advertising will not be lost to the U.S. economy, but will be spent on other goods and services. As acknowledged by the authors of one of the economic impact analyses commissioned by the tobacco manufacturing industry:

> * * * when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

Similarly, the anticipated slow but persistent decline in tobacco product sales revenues are not societal costs, because the dollars not spent on tobacco-related items will be spent on other goods or services.

Nevertheless, FDA is aware that many tobacco-related industry sectors will be adversely affected by this rule. Tobacco manufacturers and suppliers will face increasingly smaller sales, because reduced tobacco consumption by youth will lead, over time, to reduced tobacco consumption by adults. The impact of this trend on industry revenues, however, will be extremely gradual, requiring over a decade to reach an annual decrease of even 4 percent. Also, if State and Federal excise tax rates on tobacco products remain at current levels, tax revenues would decrease slowly over time, falling by about $231 million and $196 million, respectively, by the 10th year following compliance with the regulation.

Tobacco manufacturers spent $6.2 billion on advertising, promotional, and marketing programs in 1993, and about 30 percent may be substantially altered to reflect the various "text only"

restrictions or other prohibitions. If tobacco companies choose to reduce advertising and promotional activities due to the FDA restrictions, the sectors affected would include advertising agencies and communications media, owners of retail and outdoor advertising space, and recipients of corporate brand-name sponsorships (especially auto racing). These businesses would need to attract new revenues to maintain current levels of profitability. Similarly, vending machine operators will need to find substitute products to replace up to 3 percent of their sales revenues.

In summary, FDA finds that compliance with this rule will bring significant health benefits to the U.S. population. The rule will also exact long-term revenue losses on the tobacco industry and short-term costs on various affiliated industry sectors. With regard to small businesses, many near-term impacts will be small or transitory, but some business will be adversely affected. For a small retail convenience store not currently complying with this rule, the additional first year costs could average $400. For those convenience stores that already check customer identification, these costs average $137, largely to relocate tobacco product displays. Moreover, the rule will not produce significant economic problems at the national level, as the long-term displacement within tobacco-related sectors will be offset by increased output in other areas. Thus, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the current rule is the least burdensome and most cost-effective alternative that would meet the objectives of this rule.

B. Statement of Need for 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. 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.[268]

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 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 agrees that various elements of market failure are relevant to the problem of teenage use and tobacco addiction, the agency also believes that this regulatory action would be justified even in the absence of a traditional market failure. As noted previously, 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. FDA, however, 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"[269] to note that "[t]he economic analysis of market failure deals with choice by adults." Although both Beales[270] and Viscusi find that young persons balance risks and rewards in making decisions on whether or not to smoke, Viscusi explains that:

[n]evertheless, there are some classes of choices that have major consequences, and for that reason society may wish to reserve the privilege of making these choices until a particular age is reached. These limits should, however, be set according to the age at which individuals are believed to be capable of making reasonable long-term decisions regarding their welfare, rather than some arbitrary date independent of the choice context. The emerging consensus of smoking restriction policies has focused age 18 as the minimum age for the purchase of cigarettes.[271]

FDA concludes, therefore, that even if some children do make rational choices, 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.[272]

In particular, FDA finds that the pervasiveness and imagery used in industry advertising and promotional programs often obscure adolescent perceptions of the significance of the associated health risks and the strength of the addictive power of tobacco products. Section VI. of this document describes numerous studies on the shortcomings of the risk perceptions held by children. Health economist Victor R. Fuchs describes the typical sequence:

There is considerable evidence that the [time discount] rate falls as children mature. Infants and young children tend to live very much for the present; the prospect of something only a week in the future usually has little influence over their behavior. As children get older their time horizons lengthen, but once adult status is reached there seems to be little correlation between time discount and age.[273]

Thus, although most youngsters acknowledge the existence of tobacco-related health risks, the agency finds that 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 not adequately remedied by existing 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."[274] Although several empirical studies have

[268] 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, pp. 1–2, April 28, 1994.

[269] Littlechild, S. C., "Smoking and Market Failure," in "Smoking and Society: Toward a More Balanced Assessment," edited by R. D. Tollison, Lexington Books, p. 271, 1986.

[270] Beales III, J. Howard, "Advertising and the Determinants of Teenage Smoking Behavior," p. 44, 1993.

[271] Viscusi, W. K., "Smoking: Making the Risky Decision," Oxford University Press, New York, p. 149, 1992.

[272] Goodin, R. E., "No Smoking: The Ethical Issues," University of Chicago Press, pp. 30–32, 1989.

[273] Fuchs, V. R., "How We Live," Harvard University Press, Cambridge, MA, pp. 228–229, 1983.+

[274] Becker, G. S., and K. M. Murphy, "A Theory of Rational Addiction," Journal of Political Economy, vol. 96, No. 4, pp. 675–700, 1988.

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,[275] 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."[276]

FDA's justification of this regulation relies on the total costs associated with childhood addiction to tobacco, rather than on the external or spillover costs to nonusers. Nevertheless, a further market failure would exist if the use of tobacco imposed such 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 the issue of whether smokers pay their own way is the 1991 study by Manning, et al.,[277] 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 concurred with the study's conclusion,[278] although many uncertainties remain regarding the potential magnitude of the omitted cost elements.

C. Regulatory Benefits

1. Prevalence-Based Studies

The benefits of the regulation include the costs that would be avoided by reducing 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.[279]

In a recent statement, the former 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.[280] More recently, the CDC estimated the 1993 smoking-attributable costs for medical care, alone, at $50 billion.[281] 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."[282] 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 regulation-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 relied on these incidence-based studies for its original analysis of the proposed rule to value the beneficial effects of the 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 will 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 will translate to reduced rates of lifetime tobacco consumption;
- A projection of the extent to which the reduced rates of lifetime tobacco consumption will decrease the number of premature deaths and lost life-years; and
- An exploration of various means of estimating the monetary value of the expected health improvements.

[275] 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., T. W. Hu, P. G. Barnett, and W. G. Manning, "Taxation, Regulation, and Addiction: A Demand Function for Cigarettes Based on Time-Series Evidence," *Journal of Health Economics*, vol. 12, pp. 1–18, 1993.

[276] Chaloupka, F., "Rational Addictive Behavior and Cigarette Smoking," *Journal of Political Economy*, vol. 99, No. 4, p. 740, 1991.

[277] Manning, W. G., E. B. Keeler, J. P. Newhouse, E. M. Sloss, and J. Wasserman, "The Costs of Poor Health Habits, A RAND Study," Harvard University Press, Cambridge, MA, 1991.

[278] 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.

[279] See "Smoking and Health in the Americas: A 1992 Report of the Surgeon General in collaboration with the Pan American Health Organization," Department of Health and Human Services (DHHS), Public Health Service (PHS), CDC, National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Office on Smoking and Health (OSH), pp. 105–112, 1992, (hereinafter referred to as "1992 SGR") for a full summary of these methodologies and findings.

[280] 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, p. 2, April 28, 1994.

[281] "Medical-Care Expenditures Attributable to Cigarette Smoking—United States, 1993," in *Morbidity and Mortality Weekly Reports (MMWR)*, CDC, DHHS, vol. 43, No. 26, pp. 469–472, July 8, 1994.

[282] 1992 SGR, p. 111.

The annual benefits of the 1995 proposed rule were 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. Upon review of the public comments, FDA found none that would persuade the agency to revise its projections. In general, the relevant comments expressed no objection to the basic methodology or model, but some disputed the accuracy of the specific data estimates. The following paragraphs describe the FDA assumptions that underlie these benefit estimates and present the agency's response to the applicable public comments.

3. Reduced Incidence of New Young Smokers

FDA's preliminary analysis assumed that 1 million youngsters become new smokers each year. One trade association comment questioned this figure, asserting that the relevant studies included individuals over the age of 18. However, the 1985 National Health Interview Survey reported 1.08 million 20-year old smokers, and the Combined National Health Interview Surveys for 1987–1988 found that 92 percent of 20-year old smokers had started smoking by age 18. Taking 92 percent of 1.08 million yields 993,600 new underage smokers per year. This figure is supported by parallel estimates of the SAMHSA. Based on data from the 1994 National Household Survey on Drug Abuse, SAMHSA estimated that 1.29 million persons under age 20 became daily smokers in 1993, and that 1.1 million of these persons were under the age of 18. As a result, FDA retains confidence in its original estimate of 1 million new smokers per year.

The regulation targets youngsters 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 at the local level. 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). [283]

Advertising and promotional restrictions will augment these efforts to limit the attractiveness of tobacco products to underage consumers. As discussed in detail in section VI. of this document, no one study has definitively quantified the precise impact of advertising or of advertising restrictions. Nevertheless, much of the relevant research indicates that advertising restrictions will 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." [284] Similarly, after a careful examination of available studies, Clive Smee, Chief Economic Adviser to the United Kingdom Department of Health determined that, "the balance of evidence thus supports the conclusion that advertising does have a positive effect on consumption." [285] A detailed evaluation of the effects of advertising on youth consumption of tobacco products is provided in section VI. of this document.

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 by 40 to 80 percent. [286]

In its analysis of the 1995 proposed rule, FDA argued that, while quantitative estimates of the effectiveness of its regulation cannot be made with certainty, 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. In the **Federal Register** of January 19, 1996 (61 FR 1492) SAMHSA published a regulation governing a program of State-operated enforcement activities that would restrict the sale or distribution of tobacco products to individuals under 18 years of age. SAMHSA had originally estimated that its program would reduce tobacco consumption by youth and children by from one-third to two-thirds, but subsequently determined that reductions of between one-tenth and one-third would be "more realistic given the uncertainties implicit in varying levels of State enforcement and the absence of meaningful controls on tobacco advertising and promotion." [287] While strongly supporting the objectives of the SAMHSA program, FDA finds that achieving the "Healthy People 2000" goal will demand a full arsenal of controls to complement and fortify the new State inspectional programs, including restrictions on industry advertising and promotions and quite possibly educational messages to counter the influence of ongoing marketing activities.

Numerous public comments to the 1995 proposal addressed the issue of the effectiveness of the regulation. Many argued that tobacco advertising does not increase tobacco use, or that the enforcement of existing or forthcoming State laws, alone, could accomplish reasonable goals. In contrast, many others supported a comprehensive regulation, contending that only vigorous enforcement of new restrictions would bring significant results. As outlined earlier in the preamble in this document, FDA has determined, based on a full examination of the evidence, that the combined effect of the regulations (restricting advertising and promotion, prohibiting self-service sales, providing new labeling information, and imposing age verification obligations) and educational programs will significantly diminish the allure as well as the access to tobacco products by youth. The agency acknowledges the imposing size of the required effort, but is confident that its goals are reasonable and presents regulatory benefits based on the presumption that the "Healthy People 2000" goals will be met.

[283] Jason, L. A., P. Y. Ji, M. D. Anes, and S. H. Birkhead, "Active Enforcement of Cigarette Control Laws in the Prevention of Cigarette Sales to Minors," *The Journal of the Amercian Medical Association (JAMA)*, vol. 266, No. 22, p. 3159, December 11, 1991.

[284] DHHS, "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 (the 1989 SGR).

[285] Leaney, K., "Effect of Tobacco Advertising on Tobacco Consumption: A Discussion Document Reviewing the Evidence," Economics and Operational Research Division, Department of Health, London, p. 22, October 1992.

[286] 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, Stop Tobacco Access to Minors Program (STAMP), Petaluma, CA, p. 4, November 3, 1994.

[287] 61 FR 1502, January 19, 1996.

FDA agrees, however, that these projections are uncertain and therefore also presents estimates of benefits at effectiveness levels that are considerably smaller. The agency conducted this exercise not because its estimates are excessively speculative or arbitrary, as suggested by one comment, but because sensitivity analyses are part of generally accepted "best practice" for the conduct of cost-benefit analysis and are recommended by OMB guidance. These results demonstrate that even if the rule were only modestly effective in reducing tobacco use, it yields justifiable benefits.

One comment urged the agency to demonstrate the effectiveness of tobacco marketing restrictions over and above those for access restrictions or public information campaigns. FDA is unable to forecast the independent results of each regulatory provision, due to the high degree of interdependence among the various requirements, but notes that SAMHSA concluded that its access restrictions, alone, would reduce underage tobacco consumption by one-tenth to one-third. If so, accomplishing the "Healthy People 2000" goal implies that the FDA rule would generate incremental tobacco use reductions of between 17 and 40 percent for youngsters under 18 years of age.

4. Reduced Number of Adult Smokers

The major beneficiaries of the rule are those individuals who would otherwise begin using tobacco early in life and who, accordingly, are unlikely to start using tobacco products as an adult. Evidence suggests that this percentage will be high, as over half of adult smokers had become daily cigarette smokers before the age of 18. Moreover, 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." [288] Although some comments disagreed with that conclusion, FDA believes that the Surgeon General's Report is correct. Nonetheless, to account for the possibility that some would-be smokers who are prevented from smoking until they are age 18 may eventually start smoking as adults, FDA uses the more conservative assumption that these rules will lead to a tobacco free adult life for only one-half of the estimated 500,000 youngsters who will be deterred from starting to smoke each year. Accordingly, FDA calculates the annual benefits from the lifetime health gains associated with preventing 250,000 adolescents from ever smoking as an adult. Further, in response to comments that challenge this estimate, FDA presents sensitivity analysis showing results using a wide range of alternative rates.

5. Lives Saved

Based largely on data from Peto, et al., who found that about half of all adolescents who continue to smoke regularly throughout their lives will eventually die from a smoking-related disease, [289] CDC estimates that about one in three adolescent smokers will die prematurely. [290] Although the CDC projection provides the best estimate of this excess fatality rate, it does not provide a distribution of the smoking-related fatalities over time. Consequently, FDA derived this distribution by comparing age-specific differences in the probability of survival for smokers and nonsmokers. The probability of survival data for the agency's estimate are 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 multiplied differences in the probabilities of death for smokers versus nonsmokers within each 10-year period by the number of smokers remaining at the start of each 10-year period. Assuming an equal number of males and females, the excess deaths among smokers in all age groups totaled almost 28 percent of the 250,000 cohort. FDA recognizes that this methodology probably understates the current risk of smoking, because it arbitrarily assumes that the smoking-related risks for females will continue to be smaller than for males, even though female smoking patterns are presently comparable to those of males. Nevertheless, FDA used this model to support its proposed regulation and maintains the calculation to demonstrate the robustness of the results. Moreover, because some comments suggested that these data may not account for all potentially confounding variables, such as alcohol consumption or other lifestyle differences, FDA further adjusted the mortality estimate to 24 percent to reflect findings by Manning et al., that such nontobacco versus tobacco lifestyle factors may account for 13 percent of excess medical care expenditures. Thus, the benefits projections presented below conservatively rely on the probabilities

[288] 1994 SGR, pp. 5 and 65.

[289] Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, Jr., "Mortality from Smoking in Developing Countries, 1950–2000," Oxford University Press, p. A10, 1994. Indirect estimates from national vital statistics.

[290] Memorandum from Michael P. Eriksen (CDC) to Catherine Lorraine (FDA) August 7, 1995 and CDC Fact Sheet; citing Pierce, J. P., M. C. Fiore, T. E. Novotny, E. J. Hatziandreu, and R. M. Davis, "Trends in Cigarette Smoking in the United States: Projections to the Year 2000," *JAMA*, vol. 261, pp. 61–65, 1989; Unpublished data from the 1986 National Mortality Followback Survey, CDC, OSH; Peto, R., A. D. Lopez, J. Boreham, M. Thun, and C. Heath, "Mortality from Smoking in Developed Countries, 1950–2000: Indirect Estimates from national Vital Statistics," Oxford University Press, Oxford, 1994.

shown in Table 3, corrected by the 13 percent lifestyle influence adjustment. In sum, they indicate that achieving the "Healthy People 2000" performance goal will prevent about 60,200 smoking-related fatalities among each year's cohort of potential new smokers.

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 is used to calculate the present value of the projections. (This rate was recommended by the Panel on Cost-Effectiveness in Health and Medicine, a nonfederal multidisciplinary group of experts in cost-effectiveness analysis, convened by the Office of the Assistant Secretary for Health in 1993.[291] Since the Office of Management and Budget (OMB) Circular A–94 recommends the use of 7 percent as a base case, FDA presents summary estimates below for discount rates of both 3 percent and 7 percent.) On the assumption that it would be roughly 20 years for each year's cohort of new adults to reach the midpoint of the 35 to 45 age bracket and 60 years to reach the 75 to 85 age bracket, these calculations indicate that the present value of these benefits equate to 15,863 lives per year.

6. Life-Years Saved

The number of life-years that will 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 nonsmokers. 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.[292] Deducting the 13-percent lifestyle adjustment indicates that, over the full lifetime of each cohort, the regulations will gain an estimated 905,000 life-years, which translates to almost 4 years per smoker and 15 years per life saved.[293] The present value of these additional life-years equates to 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 developed estimates of the value of the reduced medical costs and the increased worker productivity that will result from fewer tobacco-related illnesses. In addition, since productivity measures do not adequately address the avoidance of premature death, FDA 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,[294] 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).[295] As noted earlier, the incidence-based study by Manning, et al., implies that about 13 percent of the excess medical costs were attributable to factors other than smoking. Accounting for this reduction and adjusting by the consumer price index 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). Because FDA projects that achieving the "Healthy People 2000" goals will prevent 250,000 of these individuals from smoking as adults, the medical cost savings are 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 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 is due to discounting.[296] Accordingly, 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.,[297] 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. Although one comment mistakenly assumed that FDA had made no adjustment for lifestyle differentials between smokers and nonsmokers, in fact, these estimates were further

[291] Gold, M. R., J. E. Siegel, L. B. Russell, and M. C. Weinstein, "Cost-effectiveness in Health and Medicine," Oxford University Press, p. 232, 1996.

[292] 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.

[293] The calculation procedure probably understates total life-years saved, because it misses smoking related-fatalities that occur within the same 10-year age interval. However, because more of these misses involve fatalities that, if avoided, would add few life-years, the resulting 15-year average life-years saved may be high. FDA's benefit estimates, however, remain understated because they are based on total life-years saved, not average life-years saved.

[294] Hodgson, T. A., "Cigarette Smoking and Lifetime Medical Expenditures," *The Milbank Quarterly*, vol. 70, No. 1, p. 97, 1992. (Based on data from the American Cancer Society's Cancer Prevention Study II).

[295] *Id.* (Using the average of the male and female totals).

[296] 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.

[297] 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.

reduced by 13 percent to reflect the Manning, et al., findings. Finally, because the long-term decline in smoking prevalence has exceeded the growth in population, FDA reduced the incidence-based costs 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 1 year's cohort of 1,000,000 new smokers, is about $3.5 billion. Thus, the estimated annual morbidity-related savings associated with preventing 250,000 new youths per year from smoking as adults is estimated at about $879 million.

10. Benefits of Reduced Mortality Rates

From a societal welfare perspective, OMB guidance 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.[298] 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[299] 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.[300] 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 is intuitively appealing because it places a greater value on the avoidance of death at a younger than at an older age and 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 methodologies, 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 converts to about $116,500 per life year. Since achieving the agency's goals were estimated to save 211,391 discounted life-years annually, this calculation yields annual benefits of $24.6 billion.

FDA notes that even these values understate the full value of the health impact, because they fail to quantify any reduction in either the adverse effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking. Moreover, these totals may not capture the heavy toll of psychic loss to surviving family members, or the corresponding economic losses among family members for the mental health care of grief-related depression and other conditions that often follow the premature death of middle aged adults.[301]

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.[302] A reduction in the number of smokers, and the corresponding number of cigarettes smoked, will result in a drop in the number of future fires. In the 1995 proposal, FDA estimated that if the number of fires falls by the same percentage as the expected reduction in cigarette sales, this implies present value savings 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.

One comment denied the existence of any association between fires and cigarette consumption. FDA acknowledges that the relationship may be nonlinear, but finds the asserted lack of a positive correlation implausible. This comment further stated that residential fires caused by smoking and deaths from residential fires caused by smoking decreased from 1983 to 1992 by 39 percent and 40 percent, respectively, or about 5.5 percent annually. Accounting for this trend would lower FDA's fire cost estimate to a present value savings of $145 million for the value of lives saved and $17 million for the value of averted property damage, totaling $162 million annually over a 40-year period. Even these estimated savings significantly underestimate the potential benefits, however, because they exclude both nonfatal injuries and the need for temporary housing.

12. Smokeless Tobacco

The Smokeless Tobacco Council, Inc., remarked that FDA had not attempted to measure the benefits that would result from the decreased use of smokeless tobacco products by underage youths. The introduction to the 1995 proposed regulation, however, explained that the use of smokeless tobacco causes severe health effects. While data are not available on age-specific differences in the probability of survival for smokeless tobacco users as compared to nonusers, the 1994 Surgeon General Report indicates that the "primary health consequences during adolescence include leukoplakia, gum recession, nicotine addiction, and increased risk of becoming a cigarette smoker. Leukoplakia and/or gum recession occur in 40 to 60 percent of smokeless tobacco users."[303] Oral leukoplakias have a 5-percent chance of becoming malignancies in 5 years.[304] Cancers of the nasal cavity, pharynx, larynx, esophagus, stomach, urinary tract and pancreas have also been linked to smokeless tobacco use.[305] Other effects include discoloration of teeth, periodontal disease and excessive tooth wear and decay.[306] One study of female snuff users showed that it increased one's risk of developing oral and

[298] Schelling, T. C., "Economics and Cigarettes," *Preventive Medicine*, vol. 15, pp. 549–560, 1986.

[299] 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.

[300] Viscusi, W. K., "Fatal Tradeoffs: Public and Private Responsibilities for Risk," Oxford University Press, p. 24, 1992.

[301] Harris, M., "The Loss That is Forever The Lifelong Impact of the Early Death of a Mother or Father," Penguin Books, 1995.

[302] 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.

[303] 1994 SGR, p.39.

[304] *Id.*

[305] Goolsby, M. J., "Smokeless Tobacco: The Health Consequences of Snuff and Chewing Tobacco", *Nurse Practitioner*, vol. 17, No. 1, p. 31, January 1992.

[306] *Id.*

pharyngeal cancer between 1.5 to 4.2 times. [307]

If the provisions pertaining to smokeless tobacco are as effective as those pertaining to cigarettes, the rule will prevent about 36,500 youths from becoming adult users of smokeless tobacco. This projection assumes that the number of underage users will decrease by 50 percent and one-half of those youths will remain nonusers after reaching 18 years of age. The estimate also assumes that the ratio of new underage users to total underage users parallels that of cigarette users (i.e., approximately one-third) and that about 440,000 youths under the age of 18 are current users of smokeless tobacco products. [308]

Leukoplakia and/or gum recession are estimated to occur in 40 to 60 percent of smokeless users. [309] If even 50 percent of these cases were caused by smokeless tobacco use, the previous assumptions imply that these regulations will prevent from 7,300 to 11,000 cases of leukoplakia and/or gum recessions per year. Although FDA can not estimate the number of oral or other cancers prevented, the realized number will be substantial.

13. Summary of Benefits

The discussion above demonstrates the formidable magnitude 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 smoking-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 $9.2 to $10.4 billion). These totals do not include the benefits expected from fewer fires (over $160 million annually), reduced passive smoking, or infant death and morbidity associated with mothers' smoking. Moreover, while FDA believes these effectiveness projections are plausible, much lower rates still yield impressive results. Table 1c of this section summarizes 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. In addition, while FDA could not quantify the benefits that will result from the projected decline in the use of smokeless tobacco, they would be considerable.

D. Regulatory Costs

A recently issued guideline for conducting economic analysis of Federal regulations, prepared under the auspices of OMB, states that:

[T]he preferred measure of cost is the "opportunity cost" of the resources used or the benefits foregone as a result of the regulatory action. Opportunity costs include, but are not limited to, private-sector compliance costs and government administrative costs. Opportunity costs also include losses in consumers' or producers' surpluses, discomfort or inconvenience, and loss of time * * *. An important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth. While transfers should not be included in the [Economic Analyses'] estimates of the benefits and costs of a regulation, they may be important for describing the distributional effects of a regulation. [310]

Accordingly, FDA finds that the final rule will impose new cost burdens on manufacturers, retailers, consumers, and Government regulators of tobacco products. In addition, certain industry sectors will experience lost sales and employment, but these revenue losses will be at least partly offset by gains to other sectors, as discussed in the "Distributional Effects" section of this document. [311] While a number of industry comments argued that the agency's preliminary analysis was deficient for not including these lost revenues in its cost-benefit assessment, FDA finds that the revenue losses suggested by these comments do not meet the previous definition of "opportunity cost;" because they fail to provide the changes in net costs that are necessary to estimate producer surplus, conventionally defined as sales minus variable costs. This rule will affect producer surplus in several industries and only net changes in these surplus' are social costs. Calculating such changes would require a multi-market model of economic changes over many years. Such general equilibrium models have not been used by Federal agencies for regulatory analyses, are not specifically recommended by the OMB guidance, and would be impractical to use, especially where major markets are dominated by few firms.

The most comprehensive critique of FDA's preliminary economic analysis was prepared by the Barents Group, economic consultants to the Tobacco Institute. While the Barents Group developed independent estimates of economic costs, in many instances its methodology was consistent with FDA's analysis of its 1995 proposal. Often, however, the Barents Group had access to more recent data, or to additional data provided by the affected industries. FDA's revised cost estimates rely extensively on these new data, but as described below, the agency's final cost estimates are far smaller than those presented by the Barents Group.

1. Number of Affected Retail Establishments

A critical variable underlying the agency's cost estimates is the number of retail outlets currently selling over-the-counter (OTC) tobacco products. A major confounding factor is that the U.S. Census publishes product line data only for establishments with payroll. For its original estimate of the number of retail establishments selling tobacco products, FDA relied on 1987 Census data to count the number of affected payroll establishments and very conservatively included every nonpayroll establishment in those categories that traditionally sell tobacco products (general merchandise stores, grocery stores, service stations, eating and drinking places, drug stores, and liquor stores). FDA estimated that the number of establishments selling tobacco products OTC included 275,000 payroll establishments and 215,000 nonpayroll establishments, for a total of 490,000 retail establishments. To account for all other business categories that might sell

[307] Winn, D. M., W. J. Blot, C. M. Shy, L. W. Pickle, A. Toledo, and J. F. Fraumeni, "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, Table 2, March 26, 1981.

[308] Estimates of youth smokeless usage vary. This projection relies on a conservative estimate of total youth (ages 12–17) usage calculated from data in the Statistical Abstract of the U.S. 1995, 115th edition, Tables 16 and 218.

[309] 1994 SGR, p.39.

[310] Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996. Prepared by interagency group convened by OMB and co-chaired by a Member of the Council of Economic Advisers.

[311] This analysis evaluates the regulation following the Kaldor-Hicks criteria for societal welfare maximization.

OTC tobacco products, FDA estimated a total upper bound range of 600,000 establishments. FDA did not know how many locations currently served by cigarette vending machines would convert to OTC operations following implementation of the regulation, but estimated the number at 100,000, raising the upper bound total to 700,000 future establishments.

FDA still has no definitive estimate of the number of retail outlets selling tobacco products. For their economic analysis, the Barents Group used 1992 U.S. Census estimates for the number of affected retail establishments with payroll, but adopted an alternative methodology to estimate the number of affected establishments without payroll. The Barents Group subdivided retail businesses into 10 categories: General merchandise stores, supermarket/grocery stores, convenience stores without gas, convenience stores with gas, gasoline service stations, eating places, drinking places, drug and proprietary stores, specialty tobacco stores, and miscellaneous retail stores. Within each category, the Barents Group assumed that the percentage of nonpayroll establishments selling tobacco products would be the same as the percentage of payroll establishments selling tobacco products. As a result, they concluded that the number of retail payroll establishments selling tobacco products OTC is approximately 283,000, and the number of retail nonpayroll establishments selling tobacco products OTC is about 107,000, for a total of 390,000 retail outlets. The Barents Group's subsequent calculations are less clear and not documented in their appendix on methodology. Noting that FDA had estimated an upper bound of 600,000 establishments selling OTC tobacco products, they assumed the existence of an additional 100,000 to 200,000 nonretail establishments, such as operations within manufacturing or service businesses, that sell OTC tobacco products. Finally, the Barents Group accepted FDA's estimate that about 100,000 current vending machine locations would convert to OTC sales for tobacco products and proposed total lower and upper bound estimates of from 500,000 to 700,000 establishments.

For this final economic analysis, FDA adopts the apparent mid-point of the Barents Group's forecast of the number of establishments that will sell tobacco products, or about 500,000 current establishments and a total of 600,000 future establishments. FDA estimates by business category are displayed in Table 4 and follow closely the methodology presented by the Barents Group, except for slight adjustments to eliminate nonstore outlets. Because Census data on the number of establishments without payroll were not reported separately for convenience stores, convenience stores with gas, or specialty tobacco stores, these outlets are counted with the higher level outlet categories.

2. Removing Self-Service and Other Prohibited Retail Displays

The 1995 proposed regulation restricted all point of purchase advertising to "text only" and banned the use of all self-service displays by requiring vendors to physically provide the regulated tobacco product to purchasers. In its original analysis, FDA explained that the proposed ban on self-service displays would affect many retail stores selling tobacco products, although shoplifting concerns had already caused a large number of these stores to place tobacco products in areas not directly accessible to customers. Those retailers that discontinued self-service displays typically modified their stores by either: (1) Placing tobacco products behind or above store cashiers or in locked cases located within close reach of store cashiers, (2) placing tobacco products behind only one or two checkout lines, 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 also 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 dictates 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. [312]

[312] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

TABLE 4.—ESTIMATED NUMBER OF ESTABLISHMENTS CURRENTLY SELLING TOBACCO PRODUCTS OVER-THE-COUNTER

Kind of Business	Number of Retail Establishments with Payroll	Percentage of Retail Establishments with Payroll Selling Tobacco Products	Number of Retail Establishments with Payroll Selling Tobacco Products	Total Number of Retail Establishments without Payroll	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products[j]	Estimated Total of Establishments Selling Tobacco Products Over-the-Counter[k]
	(1)	(2)	(3)	(4)	(5)	(6)
Retail Establishments:						
General Merchandise	34,606	35.01%	12,117	28,010 [f]	9,807	21,924
Supermarket/Grocery	126,785[a]	56.19%	71,240	97,061[g]	54,538	125,778
Convenience Stores	30,748	95.62%	29,400	– [h]	–	29,400
Convenience Stores with Gas	57,033[b]	91.02%	51,913	– [h]	–	51,913
Service Stations	71,336[c]	53.21%	37,958	14,248	7,581	45,539
Eating Places	377,760[d]	3.17%	11,992	96,538	3,065	15,057
Drinking Places	55,848	19.24%	10,745	27,733	5,336	16,081
Drug Stores	48,142	60.33%	29,046	3,031	1,829	30,875
Tobacco Stores	1,477	100.00%	1,477	– [h]	–	1,477
Miscellaneous Retail Stores	273,256[e]	9.15%	24,995	490,633[i]	44,879	69,874
Other Establishments	–	–	–	–	–	100,000
Total	1,076,991		280,883	757,254	127,035	507,918

(a) Category contains food stores (SIC 54) with payroll, excluding convenience food stores (SIC 541 pt) and convenience food/gasoline stores (SIC 541 pt).
(b) Category contains convenience food/gasoline stores (SIC 541 pt) and gasoline/convenience food stores (SIC 554 pt).
(c) Category excludes gasoline/convenience food stores (SIC 554 pt).
(d) Category contains eating and drinking places (SIC 58), excluding drinking places (SIC 5813).
(e) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596) and tobacco stores and stands (SIC 5993).
(f) 1992 Nonemployer Statistics Series only provides data on variety and miscellaneous general merchandise establishments without payroll.
(g) 1992 Nonemployer Statistics Series only provides data on grocery stores, retail bakeries, and other food stores without payroll.
(h) 1992 Nonemployer Statistics Series does not provide data on establishments without payroll for these categories.
(i) Category contains miscellaneous retail stores (SIC 59 ex. 591), excluding nonstore retailers (SIC 596).
(j) Column (2) times Column (4).
(k) Column (3) plus Column (5).
Source: Columns (1)–(4) from U.S. Census of Retail Trade Merchandise Line Sales and Nonemployer Statistics Series; Columns (5) and (6) projections according to Barents Group LLC Appendix I methodology.

Because prevailing business practice is for tobacco manufacturers to assist and even pay for most product display equipment,[313] FDA had assumed that manufacturers would share with retailers any expense of relocating displays and that the majority of the costs would be to relocate self-service displays for cartons. FDA estimated one-time costs of $22 million to be shared by manufacturers and retailers and additional annual operating costs of $14 million to be incurred by retailers (all in 1994 dollars). In stark contrast, the Barents Group projected one-time costs of from $558 to $780 million in 1996 dollars ($520 to $728 million in current dollars), with 62 percent attributed to the replacement of display items by retailers and the remaining 38 percent to manufacturers due to "time costs involved in removing banned display and promotional items, whether the work would be performed directly by a manufacturer's employee or subcontracted out to a display distributor." As explained below, FDA finds that many aspects of the Barents Group's estimates are seriously flawed. Nevertheless, the agency has adopted the basic framework of that analysis and its revised estimates reflect the Barents Group's methodology and data, unless specifically modified as discussed below.

a. *The Barents Group's methodology.* The Barents Group's cost projections were based on estimates of an average outlet cost for each of seven outlet categories. Each average outlet cost was multiplied by the total number of outlets of that category in the United States to produce national cost estimates. The actual outlet cost data were collected by A. T. Kearney, Inc., still another business consulting firm. The Barents Group explained that:

> [O]ur estimates are based on a compliance audit study conducted especially for this purpose by A. T. Kearney, Inc. A. T. Kearney performed an in-depth study of the actions and efforts that would be required of tobacco manufacturers' representatives, of point-of-sale display item distributors, and of tobacco retailers in order to bring stores into compliance with the proposed regulations. Detailed surveys were conducted of seven categories of retail outlets in five U.S. metropolitan areas, for a total of 88 retail outlets. Surveyors performed a detailed inventory of the many types of tobacco product displays and promotional materials which are currently found in stores. The surveyors noted which items would need to be modified or replaced.

A. T. Kearney reportedly completed a comprehensive on site compliance protocol checklist at 88 establishments randomly selected in 5 general regions of the United States. The individual display items were grouped into 41 discrete item categories and a lengthy discussion of the methodology and results are presented as a Technical Appendix to the Barents Group's comments.

b. *The Barents Groups's miscalculations.* To evaluate these results, FDA carefully reviewed the A. T. Kearney survey data and the Barents Group's extrapolation procedures and attempted to replicate the aggregate estimates. In doing so, numerous computational discrepancies were identified. For example, in calculating retailer time costs, the Barents Group intended to use an estimated retail employee wage of $9.51, but in fact used the estimated wage for a manufacturer's sales representative of $25.70. (See Appendix Table "Initial Compliance Effort Costs per Retail Store.") Also, the Barents Group's calculations relied on incorrectly transposed data for the average number of disposable displays per store and miscalculated compliance effort costs for five of the seven types of business. Further, A. T. Kearney reported that only one-third of the lighted signs and clocks would need to be replaced by retailers, but the Barents Group's calculations assumed that all would be replaced. Finally, A. T. Kearney reported that retailers would not replace most promotional posters, signs and displays, but the Barents Group's calculations assigned each $85 in replacement costs. Correcting these errors reduces the Barents Group's low and high cost estimates by $77 and $108 million, respectively.

Even more important, in aggregating the unit costs for "Compliance Activity No. 19—Remove and replace interior newsstands and shopping basket racks and baskets and shopping carts," A. T. Kearney committed a major error that dominates the aggregated cost totals. In discussing the costs for this item, A. T. Kearney focused on the need to replace shopping basket racks, which "* * * are free-standing units and contain about 20 shopping baskets, that also contain the name or logo of the cigarette manufacturer." Although it seems probable that the logos or brand names affixed to these items could be either removed or obscured, the survey data indicate that six supermarket/grocery stores, three convenience stores, two tobacco stores and one convenience store with gas would replace shopping basket racks. The detailed survey data for supermarket/grocery stores, however, reveal that one store supposedly possessed 71 racks, two stores 50 racks, and the remaining three stores 41, 32, and 10 racks, respectively. Even a casual review of these data suggests that individual hand-held shopping baskets rather than basket racks were counted. Indeed, an FDA contractor visited the five Washington, DC area outlets in which A. T. Kearney observed the largest number of racks and found scores of plastic hand-held baskets adorned with simple advertising stickers, but only a few basket racks.[314]

Although the advertising on these plastic baskets could easily be removed or covered, or new plastic baskets purchased quite inexpensively, the Barents Group's calculations inadvertently assumed that a distribution services contractor would be hired to remove each plastic hand-held shopping basket at a fee of $45 apiece and that a retailer would spend 30 minutes plus an additional $89 replacement fee for each plastic hand-held shopping basket in its possession. Thus, the estimated cost attributed to each hand-held basket was $138 and the cost for just the one outlet reporting 71 shopping baskets totaled $9,850. Extrapolating to each outlet category, the A. T. Kearney results implied that removing and replacing plastic hand-held baskets would cost, on average, over $1,300 for each supermarket/grocery store and $300 for each convenience store in the United States. Its projected costs for removing and replacing the hand-held shopping baskets in all supermarket/grocery stores in the United States ranged from $163 million to $229 million. For all outlet types, costs for these hand-held baskets were estimated at $194 to $271 million, or 43 percent of the national point-of-sale costs estimated by the Barents Group.

Based on site visits, FDA modified Kearney's field data for the correct number of shopping basket racks in the Washington, DC area establishments. Furthermore, FDA contractors determined that the hand-held shopping baskets could easily be modified by a marketing representative, who would take, at most, 5 minutes to affix new stickers on each basket or rack. For a rack of 20 baskets, this task was estimated to take a total of 105 minutes, plus about $42 for stickers. These adjustments reduce the Barents Group's estimated one-time costs by $180 to $252 million.

[313] *Id.*

[314] Buck, E., "Site Visit Report," April 24, 1996.

c. *The Barents Group's extrapolation procedure.* The Barents Group contributed still another bias by their method of extrapolating these survey results to the assumed range of 500,000 to 700,000 retail establishments. A. T. Kearney surveyed stores in only seven business categories: General Merchandise, Supermarket/Grocery, Tobacco Specialty, Convenience Store without Gas, Convenience Store with Gas, Service Station, and Drug Store. To represent all affected outlets, the Barents Group apportioned the full upper and lower bounds for their estimated number of establishments (500,000 and 700,000) among 10 business categories "based on the fractions they represent in the Census sample of with-payroll retail stores selling tobacco products." (Eating Places, Drinking Places, and Miscellaneous Retailers were added for this outlet allocation, but were assigned no costs because they are not "* * * the types of retail outlets where the vast majority (more than 90 percent) of tobacco product sales occur and where promotional items are most prevalent." That is, the Barents Group used a proportional adjustment to raise each establishment category count so that the lower and upper bound totals sum to 500,000 and 700,000, respectively. The estimated number of establishments in each category was then multiplied by the average cost for each business category using data from the A. T. Kearney site visits.

The implications of these inappropriate establishment number extrapolations are considerable. For example, A. T. Kearney surveyed a sample of 10 outlets from its first business category—General Merchandise Stores. These 10 outlets, which include three K-Mart and two Wal-Mart stores, averaged over 84,000 square feet of space, with the smallest store measuring 40,000 square feet. The U.S. Census reports only 12,117 such establishments with payroll. The Barents Group's proportional adjustment automatically expanded this outlet type count to between 21,299 and 29,818. (See Barents Group's Appendix Table.) Thus, to generate a national estimate of costs, the Barents Group applied the cost per establishment for its sample of very large general merchandise stores to roughly double the number reported in the U.S. Census for such establishments with payroll. This methodology inappropriately bases the per outlet cost for thousands of small nonpayroll and nonretail outlets on the per outlet cost reported for very large general merchandise stores.

The identical problem holds for the Barents Group's projection of the A. T. Kearney survey sample of 27 Supermarket/Grocery stores. Although this sample includes a few moderately sized establishments (1 less than 1,000 square feet and 4 less than 5,000 square feet), 21 of the establishments exceed 10,000 square feet and the average sized facility is almost 35,000 square feet. Nevertheless, the Barents Group's apportionment procedure inflates the number of establishments in this category from the U.S. Census estimate of 71,240 with payroll to 125,222 and 175,311, on the dubious assumption that thousands of small nonpayroll or other nonretail establishments are best represented by the A. T. Kearney sample of mostly large supermarkets/grocery stores.

FDA's fundamental concern is not with the Barents Group's estimate of 500,000 to 700,000 affected establishments (although the upper bound of this estimate should be 600,000, because there would be no display relocation costs for the additional 100,000 outlets assumed to be established at existing vending machine locations), but with the allocation of the small establishments among the largest business categories surveyed by A. T. Kearney. To offset this bias, FDA reallocated the number of establishments in the business categories used to extrapolate the outlet cost estimates. As shown, in Table 5, FDA takes the number of establishments in the first two business categories—General Merchandise and Supermarket/Grocery stores—directly from the U.S. Census number of establishments with payroll, because there would be very few nonpayroll or nonretail establishments equivalent to those surveyed. For outlet extrapolation purposes, FDA assigns its estimated number of nonpayroll establishments in these two business categories to the Convenience Store category, on the assumption that this category is most representative of the small establishments excluded from the Census product line data. Although the Barents Group omitted all costs for Eating Places, Drinking Places, and Miscellaneous Retail Stores, FDA groups these outlets under Other Establishments and assumes certain minimal costs, as explained below. This redistribution of the establishment category groupings reduces the Barents Group's low cost estimate by $65 million and its high cost estimate by $170 million.

TABLE 5.—ESTIMATED NUMBER OF ESTABLISHMENTS REMOVING SELF-SERVICE AND OTHER PROHIBITED RETAIL DISPLAYS

Kind of Business	Number of Retail Establishments with Payroll Selling Tobacco Products Over-the-Counter	Estimated Number of Retail Establishments without Payroll Selling Tobacco Products Over-the-Counter	Estimated Total Number of Establishments Selling Tobacco Products Over-the-Counter
A. T. Kearney Categories:			
General Merchandise	12,117	– (A)	12,117
Supermarket/Grocery	71,240	– (B)	71,240
Convenience Stores	29,400	64,345 (C)	93,745
Convenience Stores with Gas	51,913	– (D)	51,913
Service Stations	37,958	7,581	45,539
Drug Stores	29,046	1,829	30,875
Tobacco Stores	1,477	– (E)	1,477
Other Establishments	–	–	201,012 (F)
Total	233,151	73,755	507,918

(A) Variety and miscellaneous general merchandise stores are tallied as convenience stores.
(B) Food stores are tallied as convenience stores.

(C) This category includes food, variety, and miscellaneous general merchandise stores. The 1992 Nonemployer Statistics Series does not provide information about convenience stores without payroll.
(D) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(E) The 1992 Nonemployer Statistics Series does not provide information about establishments without payroll for this category.
(F) Includes retail establishments excluded from the Kearney field audit and other establishments selling tobacco products over-the-counter.

d. *Further modifications.* The Barents Group faulted FDA for not including costs for the removal of banned display items or for the replacement of banned point-of-sale promotional materials. Their estimates assumed that manufacturers alone would bear these costs, since the proposed regulation required that manufacturers remove all prohibited advertising displays. The final regulation, however, places this responsibility on the owners of the displays, which may frequently be the retail establishments. FDA cannot forecast the ultimate distribution of display ownership, but in view of current business practices, assumes that the manufacturer representatives will at least participate in the removal process. Nevertheless, this change in regulatory responsibility is likely to shift a greater share of the cost burden to retailers.

On the other hand, the Barents Group assumed that retailers alone would replace those promotional items having a utilitarian function, including display cases, signs, shopping carts or baskets, newspaper racks, ash trays, and clocks. FDA believes that this assumption is unfounded, because many retailers will modify rather than replace these items and many manufacturers will share the replacement burden with retailers. For example, one report describing the results of a local self-service ban indicated that, "tobacco distributors and tobacco company sales representatives furnished behind-the-counter shelving and locking cases for tobacco products to retailers at no charge in order to assist retailers comply with self-service/vendor-assisted regulations."[315] Again, however, the future allocation of these costs among manufacturers and retailers is unknown. For its initial estimates, except as explained below, FDA maintains the Barents Group's assumptions that removal costs are primarily borne by the manufacturer and replacement costs by the retailer. In fact, both cost categories will be shared and the implications of these assumptions are illustrated below through sensitivity analysis.

In February 1996, economic consultants to FDA attempted to replicate the A. T. Kearney field audit in Boston (the Eastern Research Group, Inc. (ERG),)[316] and in Washington, DC (an independent contractor). While most observations of the number of affected display cases were reasonably consistent with the A. T. Kearney findings, the observed number of exterior and interior promotional materials deviated significantly from the A. T. Kearney audit data. One explanation may be that the seasonal items available at the end of November had been removed by the following February. As a result, FDA has not adjusted its calculations to account for these discrepancies (except for the cost of basket racks in the Washington, DC stores), but used certain insights from these visits to revise the Barents Group's unit cost assumptions, as follows:

(i) The agency rejects the Barents Group's assumption that retailers rather than manufacturers will bear the costs of replacing promotional unattached counter displays. Because many of these items will be moved to visible locations behind counters, it is far more likely that manufacturers, not retailers, would pay for replacements. For its revised estimate, therefore, FDA assumes that manufacturers will pay replacement costs for unattached counter displays. Although total costs are unchanged, this assumption increases the costs for manufacturers by $17 million and decreases the costs for retailers by an equal amount.

(ii) A. T. Kearney and the Barents Group contradict themselves on the cost of removing disposable display cases. A. T. Kearney describes these units as temporary displays "frequently found in association with promotional offerings, sales, or seasonal themes," but assumes that retailers will replace them with permanent self-standing retail pack cases at $250 each. In contrast, the Barents Group calculations imply that a distribution services company will remove each display for a fee of $150 and retailers will replace each item for $50. FDA agrees with the Barents Group that retailers will not replace temporary units with permanent retail pack cases. Moreover, if a marketing representative can throw away free-standing ash trays filled with sand, as noted by A. T. Kearney, then a marketing representative can also dismantle and throw away disposable displays made of cardboard and plastic. FDA estimates, therefore, that instead of hiring a distribution services company, the manufacturer's representative will take no more than 15 minutes to remove each disposable unit, install a new unattached counter display and restock any excess inventory in a nonself-service area. This assumption decreases the estimated one-time costs by $7 million.

(iii) The A. T. Kearney cost-estimating methodology for the self-service ban implies that store modifications take place in a sequential pattern, with no allowances for economies of scale. For example, the outlet cost for hiring a distribution services contractor to relocate or replace display cases was calculated as a fixed multiple of the number of cases to be removed, even though many establishments must remove several display cases. This approach overstates costs by ignoring the significant scale economies achievable by performing all compliance activities at one time. Thus, FDA modified A. T. Kearney's distribution services costs for the removal, relocation and installation of small attached, retail pack, and carton self-service display cases by assuming that the first display unit in an outlet would be removed at a unit charge of $90, $150, or $185, respectively, but that each additional unit would be removed at one-half of these costs. For those stores with different sizes of display cases, the first unit was assumed to be the most expensive to remove (e.g., a carton display would be considered the first item when there is also a retail pack display or a small attached display). Adjusting for these scale economies reduces the estimated total costs by $15 million.

(iv) A. T. Kearney assumed that many promotional items, such as signs and clocks, would be removed by a distribution services company hired by the manufacturer. FDA's consultants, however, found that almost all of the promotional material observed could be easily removed or modified by retail personnel or marketing representatives.

[315] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

[316] "ERG's Review of Docket Materials Concerning FDA's Proposed Regulations Covering Tobacco Products: Final Site Visit Report," Eastern Research Group, April 22, 1996.

For example, rather than needing a contractor to remove the lighted sign in one of the sampled outlets, ERG found that the front panel was easily removable and could be quickly replaced by an acceptable panel. Although a few signs may require substantial time to dismantle, most of these items will take just a few minutes to remove. To account for this range, FDA assumes that a manufacturer's representative will take 15 minutes to remove and dispose of the various exterior signs, banners, clocks and news stand displays, as well as the interior lighted signs and clocks, lowering total costs by $27 million.

(v) A. T. Kearney assumed that many display cases located in nonself-service areas would be removed and replaced, because of improper advertising. They assumed that the manufacturer would pay for the removal of the old case and the installation of the new case, but that the retailer would purchase the new display case. Contrary to this finding, FDA consultants found no sites in the Boston or Washington, DC regions where it was necessary to replace nonself-service displays. Because in each instance, all visible advertising could be altered or obscured, retailers would almost always opt to cover impermissible advertising rather than to purchase new display cases costing up to $300. Accordingly, FDA estimated that it would take 15 minutes and $5 worth of stickers to cover each small attached display; 25 minutes and $10 worth of stickers to cover each retail pack display; and 35 minutes and $15 worth of stickers to cover each carton display. This modification decreases total costs by $20 million.

(vi) Even though the A. T. Kearney audit identified a number of self-service display cases that did not fit in the nonself-service area but could be retrofitted with locks, the Barents Group did not include cost estimates for these items. FDA estimates that it would take 30 minutes of retailer time and cost about $10 for materials to add a lock to these display cases, increasing the total one-time costs by $1.5 million.

(vii) In its analysis of the 1995 proposed regulation, FDA acknowledged that the required reconfiguration of tobacco displays may also impose added labor costs for some purchase transactions, especially for those stores that move inventory to areas located away from employee work stations. On the assumption 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, FDA had estimated costs of about $14 million per year. Although a few comments indicated that the self-service ban would increase labor costs, the Barents Group did not include such costs in its assessment. Nevertheless, FDA believes that some establishments, particularly those selling a substantial number of cigarette cartons that could not be stored within easy reach of a checkout station, could experience increased annual labor costs. Thus, FDA recalculated its estimate based on the updated retail employee compensation rate of $9.51 suggested by the Barents Group and the new site visit data from the A. T. Kearney study, which imply that only about 40 percent of cigarette cartons are purchased at establishments that sell cigarette cartons from self-service areas. These adjustments project additional annual labor costs of about $10.9 million per year.[317]

Except for those adjustments, FDA used the information found in the A. T. Kearney field audit to develop its revised estimate. For comparison, the original Barents Group estimates of the number of establishments and one-time point-of-sale costs (corrected for miscalculations as described above) are shown in Table 6 and FDA estimates of one-time costs in Table 7. Detailed summaries of the FDA one-time cost estimates are presented in Table 8 and Table 9 and indicate that costs related to self-service display cases comprise 73 percent of the total, followed by 18 percent for promotional materials and 9 percent for nonself-service display cases. As explained above, these estimates assume that manufacturers will bear the cost of removing all promotional items and retailers will bear the cost of replacing most functional items. Because the regulation places the removal responsibility on owners of the materials, FDA does not know how these obligations will be divided. However, if retail outlets, rather than manufacturers, must remove these items, the overall cost to manufacturers falls by about $47 million and the cost to retailers increases by about $17 million. (Retail compensation rates are about one-third of manufacturer rates, according to the Barents Group data). The following discussion describes specific compliance costs for each outlet category.

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[317] Derived from assumption that 10 percent of carton transactions are for multiple (2) cartons, and that cartons constitute 85 percent of tobacco sales at supermarket/grocery stores, general merchandise stores, drug stores, and tobacco stores, and 10 percent of tobacco sales at other outlets. Tobacco sales data from 1992 Census of Retail Trade, pp. 3–31. Kearney site visits found that 80 percent of general merchandise stores, 33 percent of supermarket/grocery stores, 25 percent of convenience stores, 17 percent of service stations, 30 percent of drug stores, 42 percent of tobacco stores had self-service carton display cases.

TABLE 6.—BARENTS GROUP LLC ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS [1]

Kind of Business	Estimated Number of Establishments		Average Cost per Facility ($)	Estimated Point-of-Sale Costs (Lower)			Estimated Point-of-Sale Costs (Upper)		
	Lower	Upper		Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)	Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	21,299	29,818	1,067	13,268,172	9,449,404	22,717,576	18,575,066	13,228,900	31,803,966
Supermarket/Grocery	125,222	175,311	2,356	182,028,407	112,960,223	294,988,630	254,840,061	158,144,493	412,984,554
Convenience Stores	51,678	72,349	925	24,408,368	23,382,610	47,790,978	34,171,621	32,735,564	66,907,185
Convenience Stores with Gas	91,250	127,750	515	21,656,668	25,294,382	46,951,050	30,319,336	35,412,134	65,731,470
Service Stations	66,721	93,409	217	4,894,902	9,616,053	14,510,955	6,852,833	13,462,416	20,315,250
Drug Stores	51,056	71,478	167	4,472,540	4,054,323	8,526,863	6,261,520	5,676,020	11,937,541
Tobacco Stores	2,596	3,635	2,940	4,486,055	3,147,456	7,633,511	6,281,514	4,407,166	10,688,680
Total	409,822	573,750		255,215,112	187,904,451	443,119,563	357,301,952	263,066,694	620,368,645

[1] Totals may not add due to rounding.

TABLE 7.—FDA ESTIMATE OF ONE-TIME POINT-OF-SALE REGULATORY COSTS

Kind of Business	Estimated Number of Establishments[1]	Average Cost Per Facility ($)	Estimated Point-of-Sale Costs[2]		
			Retail Costs ($)	Manufacturer Costs ($)	Total Costs ($)
General Merchandise	12,117	919	7,874,058	3,263,894	11,137,952
Supermarket/Grocery	71,240	810	32,655,560	25,067,316	57,722,876
Convenience Stores	93,745	364	12,271,061	21,879,370	34,150,431
Convenience Stores with Gas	51,913	213	1,397,066	9,644,359	11,041,425
Service Stations	45,539	122	2,560,164	2,974,000	5,534,164
Drug Stores	30,875	160	2,978,007	1,966,563	4,944,570
Tobacco Stores	1,477	2,175	2,165,591	1,046,163	3,211,753
Other Establishments	210,012	19	522,765	3,384,741	3,907,506
Total	507,918		62,424,273	69,226,404	131,650,677

[1] Number of establishments from Table 5.
[2] Totals may not add due to rounding.

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Promotional Materials:																
No. 3 Ext. Attached Signs	•	•	1.19	0	•	•	•	•	1.07	1	•	•	•	•	•	•
No. 4 Ext. Movable Sign Board	•	•	0.95	0	6.43	2	2.86	1	3.75	3	•	•	8.57	0	•	•
No. 5 Ext. Decal/Stickers	•	•	0.85	0	6.03	2	2.82	1	0.85	1	•	•	4.02	0	•	•
No. 6 Ext. Lighted Signs/Clocks	•	•	0.61	0	4.09	1	9.08	4	1.36	1	•	•	16.34	1	•	•
No. 7 Ext. Signs, Posters & Displays	•	•	0.38	0	1.93	1	1.33	1	•	•	•	•	1.43	0	•	•
No. 8 Ext. Movable Window Signs	•	•	0.95	0	10.44	3	2.14	1	1.61	1	•	•	.54	0	•	•
No 9 Ext. Open/Closed Signs	•	•	0.43	0	2.20	1	•	•	•	•	0.59	0	0.98	0	0.59	3
No. 10 Ext. Signs on Gas Pumps	•	•	•	•	•	•	0.24	0	0.14	0	•	•	•	•	•	•
No. 11 Ext. News Stand Displays	•	•	7.42	1	•	•	•	•	•	•	•	•	•	•	•	•
No. 12 Ext. Novelty Item Displays	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
No. 13 Ext. Banners	•	•	•	•	0.80	0	3.57	2	1.07	1	•	•	0.54	0	•	•
No. 14 Signs, Posters & Banners	0.34	0	1.14	0	1.71	0	1.71	1	1.71	1	0.17	0	2.14	0	0.17	1
No. 15 Lgted. Signs, Clocks/Mach. Dev.	19.61	2	10.29	1	18.39	5	16.34	8	8.17	7	3.27	2	28.60	1	3.27	17
No. 16 Decals/Stickers	0.26	0	0.79	0	2.36	1	0.67	0	0.71	1	1.29	1	0.93	0	1.29	7
No. 17 Shelf Marker w/Adv.	0.60	0	0.44	0	2.14	1	1.49	1	1.83	2	0.37	0	0.96	0	0.37	2
No. 18 Shopper Aids	0.04	0	0.42	0	0.19	0	0.31	0	0.02	0	0.04	0	0.21	0	0.04	0
No. 19 News Racks, Shop. Bask., Carts	•	•	83.75	10	43.49	12	9.66	5	•	•	•	•	14.50	1	•	•
No. 20 Fl. St. Ash Trays, Waste Basket	•	•	3.30	0	•	•	9.89	5	•	•	•	•	24.71	1	•	•
No. 21 Merch. w/ Ref. to Tobacco Prod.	•	•	•	•	0.48	0	0.71	0	1.18	1	•	•	1.93	0	•	•
Promotional Materials Subtotal:	20.85	2	112.92	14	100.67	28	62.82	30	23.47	19	5.73	4	106.39	5	5.73	29
Self-Service Display Cases:																
Small, Unattached																
No. 22 Space Available, Ads Removed	•	•	0.32	0	1.34	0	2.38	1	0.71	1	1.07	1	3.21	0	1.07	6
No. 23 Unit Must be Replaced	10.60	1	25.52	3	53.00	15	53.00	25	8.83	7	•	•	141.33	6	•	•
Small, Attached																
-- Removal and Installation/Relocation	13.50	1	65.00	8	•	•	10.00	5	•	•	9.00	6	•	•	9.00	46
No. 24 Unit Must be Replaced	10.00	1	55.56	7	•	•	•	•	•	•	•	•	•	•	•	•
No. 25 Space Available, Ads Removable	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Packs																
-- Removal and Installation	67.50	7	86.11	11	•	•	•	•	6.25	5	7.50	5	193.75	9		
No. 26 Space Available, No Ads	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
No. 27 Space Available, Ads Removable	0.79	0	0.29	0	•	•	0.88	0	•	•	•	•	0.66	0	•	•
No 28 Unit Must Be Replaced	200.00	22	222.22	27	•	•	•	•	20.83	17	25.00	16	625.00	29	•	•
No. 29 Unit Modified w/Locking Doors	1.48	0	3.28	0	•	•	•	•	•	•	•	•	•	•	•	•

TABLE 8.--SUMMARY OF AVERAGE COMPLIANCE COSTS BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise		Supermarket/ Grocery		Convenience Stores		Convenience Stores with Gas		Service Stations		Drug Stores		Specialty Tobacco Stores		Other Establishments	
	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%	Avg. Outlet Cost ($)	%
Cartons																
-- Removal and Installation	166.50	18	65.09	8	46.25	13	•	•	15.42	13	37.00	23	262.08	12		
No. 30 Space Available, No Ads	•	•	0.26	0	•	•	•	•	•	•	•	•	•	•	•	•
	•	•	•	•	1.19	0	•	•	•	•	•	•	1.59	0	•	•
No. 32 Unit Must Be Replaced	390.00	42	155.56	19	112.50	31	•	•	25.00	21	60.00	37	775.00	36	•	•
No. 33 Unit Modified w/Locking Doors	35.41	4	3.83	0	•	•	•	•	3.69	3	8.85	6	11.07	1	•	•
No. 34 Disposable, Replaced	•	•	2.09	0	•	•	•	•	4.70	4	•	•	37.62	2	•	•
Self-Service Subtotal:	895.78	97	685.12	85	214.28	59	66.26	31	85.44	70	148.42	93	2,051.30	94	10.07	52
Non-Self-Service Display Cases:																
Small, Unattached																
No. 35 Advertising Removable	•	•	0.16	0	2.41	1	6.43	3	3.75	3	2.14	1	0.89	0	2.14	11
No. 36 Unit Must be Replaced	•	•	•	•	26.50	7	47.11	22	•	•	•	•	13.25	1	•	•
Small, Attached																
No. 37 Advertising Removable	•	•	1.27	0	3.75	1	4.52	2	2.86	2	1.50	1	2.14	0	1.50	8
No. 38 Unit Must be Replaced	•	•	•	•	8.57	2	•	•	0.95	1	•	•	•	•	•	•
Packs																
No. 39 Advertising Removable	•	•	0.40	0	1.07	0	0.48	0	0.36	0	1.71	1	0.18	0	•	•
No. 40 Unit Must be Replaced	•	•	2.30	0	•	•	•	•	•	•	•	•	•	•	•	•
Cartons																
No. 41 Advertising Removable	2.57	0	1.43	0	•	•	•	•	•	•	0.64	0	0.36	0	•	•
No. 42 Unit Must be Replaced	•	•	6.66	1	•	•	•	•	•	•	•	•	•	•	•	•
No. 43 Disposable, Replaced	•	•	•	•	7.05	2	25.08	12	4.70	4	•	•	•	•	•	•
Non-Self-Service Subtotal:	2.57	0	12.22	2	49.35	14	83.61	39	12.61	10	6.00	4	16.82	1	3.64	19
TOTAL:	919.20	100	810.26	100	364.29	100	212.69	100	121.53	100	160.15	100	2,174.51	100	19.44	100

[1] Totals may not add due to rounding.

TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS[1]

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Promotional Materials:										
No. 3 Ext. Attached Signs	*	85	*	*	49	*	*	*	134	0.1
No. 4 Ext. Movable Sign Board	*	68	602	148	171	*	13	*	1,002	0.8
No. 5 Ext. Decal/Stickers	*	60	565	146	39	*	6	*	816	0.6
No. 6 Ext. Lighted Signs/Clocks	*	43	383	471	62	*	24	*	984	0.7
No. 7 Ext. Signs, Posters & Displays	*	27	181	69	*	*	2	*	279	0.2
No. 8 Ext. Movable Window Signs	*	68	979	111	73	*	1	*	1,232	0.9
No. 9 Ext. Open/Closed Signs	*	31	206	*	*	18	1	118	375	0.3
No. 10 Ext. Signs on Gas Pumps	*	*	*	12	7	*	*	*	19	0
No. 11 Ext. News Stand Displays	*	529	*	*	*	*	*	*	529	0.4
No. 12 Ext. Novelty Item Displays	*	*	*	*	*	*	*	*	*	*
No. 13 Ext. Banners	*	*	75	185	49	*	1	*	310	0.2
No. 14 Signs, Posters & Banners	4	81	161	89	78	5	3	34	456	0.3
No. 15 Lgted. Signs, Clocks/Mach. Dev.	238	733	1,724	848	372	101	42	657	4,715	3.6
No. 16 Decals/Stickers	3	57	221	35	33	40	1	258	647	0.5
No. 17 Shelf Marker w/Adv.	7	31	201	77	83	12	1	75	488	0.4
No. 18 Shopper Aids	1	30	18	16	1	1	0	9	75	0.1
No. 19 News Racks, Shop. Bask., Carts	*	5,967	4,077	502	*	*	21	*	10,566	8
No. 20 Fl. St. Ash Trays, Waste Basket	*	235	*	513	*	*	37	*	784	0.6
No. 21 Merch. w/ Ref. to Tobacco Prod.	*	*	45	37	54	*	3	*	139	0.1
Promotional Materials Subtotal:	253	8,044	9,437	3,261	1,069	177	157	1,151	23,549	17.9
Self-Service Display Cases:										
Small, Unattached										
No. 22 Space Available, Ads Removed	*	23	125	124	33	33	5	215	557	0.4
No. 23 Unit Must be Replaced	128	1,818	4,968	2,751	402	*	209	*	10,277	7.8
Small, Attached										
-- Removal and Installation/Relocation	164	4,631	*	519	*	278	*	1,809	7,400	5.6
No. 24 Unit Must be Replaced	121	3,958	*	*	*	*	*	*	4,079	3.1
No. 25 Space Available, Ads Removable	*	*	*	*	*	*	*	*	*	*
Packs										
-- Removal and Installation	818	6,135	*	*	285	232	286	*	7,755	5.9
No. 26 Space Available, No Ads	*	*	*	*	*	*	*	*	*	*
No. 27 Space Available, Ads Removable	10	21	*	46	*	*	1	*	77	0.1
No. 28 Unit Must Be Replaced	2,423	15,831	*	*	949	772	923	*	20,898	15.9
No. 29 Unit Modified w/Locking Doors	18	234	*	*	*	*	*	*	251	0.2
Cartons										
-- Removal and Installation	2,017	4,637	4,336	*	702	1,142	387	*	13,222	10
No. 30 Space Available, No Ads	*	19	*	*	*	*	*	*	19	0
No. 31 Space Available, Ads Removable	*	*	111	*	*	*	2	*	114	0.1
No. 32 Unit Must Be Replaced	4,726	11,082	10,546	*	1,138	1,853	1,145	*	30,489	23.2
No. 33 Unit Modified w/Locking Doors	429	273	*	*	168	273	16	*	1,159	0.9
No. 34 Disposable, Replaced	*	149	*	*	214	*	56	*	419	0.3

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TABLE 9.--SUMMARY OF TOTAL COSTS FOR COMPLIANCE ACTIVITIES BY KIND OF BUSINESS--(CONTINUED)

Compliance Activities	General Merchandise ($000)	Supermarket/ Grocery ($000)	Convenience Stores ($000)	Convenience Stores with Gas ($000)	Service Stations ($000)	Drug Stores ($000)	Specialty Tobacco Stores ($000)	Others ($000)	ALL ESTABLISHMENTS ($000)	%
Self-Service Subtotal:	10,854	48,808	20,087	3,440	3,891	4,583	3,030	2,024	96,717	73.5
Non-Self-Service Display Cases:										
Small, Unattached										
No. 35 Advertising Removable	*	11	226	334	171	66	1	431	1,239	0.9
No. 36 Unit Must be Replaced	*	*	2,484	2,446	*	*	20	*	4,949	3.8
Small, Attached										
No. 37 Advertising Removable	*	90	351	235	130	46	3	301	1,157	0.9
No. 38 Unit Must be Replaced	*	*	803	*	43	*	*	*	847	0.6
Packs										
No. 39 Advertising Removable	*	28	100	25	16	53	0	*	223	0.2
No. 40 Unit Must be Replaced	*	164	*	*	*	*	*	*	164	0.1
Cartons										
No. 41 Advertising Removable	31	102	*	*	*	20	1	*	153	0.1
No. 42 Unit Must be Replaced	*	475	*	*	*	*	*	*	475	0.4
No. 43 Disposable, Replaced	*	*	661	1,302	214	*	*	*	2,177	1.7
Non-Self-Service Subtotal:	31	870	4,626	4,340	574	185	25	732	11,385	8.6
TOTAL:	11,138	57,723	34,150	11,041	5,534	4,945	3,212	3,908	131,651	100

[1] Totals may not add due to rounding.

e. *General merchandise stores.* None of the general merchandise stores in the A. T. Kearney sample had exterior promotional materials and only a few had interior promotional materials. Eighty percent of the stores had only self-service displays, with carton displays more numerous than pack displays at these locations. The average per facility one-time costs estimated by FDA were $919. Overall, 97 percent of the outlet costs related to the replacement of self-service display cases, although in some general merchandise stores, tobacco products were stocked on shelves rather than in special display cases, which suggests that the costs for this business category may be overstated.

f. *Supermarket/grocery.* Unlike general merchandise stores, supermarkets had significant promotional materials. While both packs and cartons were sold at most locations, over 75 percent of the stores already had nonself-service display areas. FDA estimates per facility costs at $810. Self-service display case removal and replacement amount to 85 percent of the total cost, whereas promotional materials account for 14 percent. Commenting on the feasibility of the proposed FDA self-service ban, the Food Marketing Institute argued that most retail food stores do not have adequate space at checkout lines for tobacco products and rejected the practicability of alternative procedures. They suggested that the only option available to many food retailers would be to remodel and set-up a controlled area for the sale of tobacco products, costing up to $50,000 per store. The A. T. Kearney audit, however, found that a majority of supermarket/grocery stores have already installed nonself-service areas for tobacco products and would not need to reconfigure their stores. While some establishments will incur costs above the average, the A. T. Kearney site visit data suggest that most stores could comply by either moving inventory to nonself-service areas or by purchasing new displays that are compatible with existing store configurations.

g. *Convenience stores.* Stores in this category exhibited numerous interior and exterior promotional items. All of the convenience stores surveyed had nonself-service display cases and 50 percent had carton displays. FDA estimates per facility costs of $364. Costs for removing and replacing self-service display cases made up 59 percent of the total, while costs for promotional materials and nonself-service display cases were 28 percent and 14 percent, respectively.

The National Association of Convenience Stores (NACS) faulted FDA on its assumption that the main cost of the self-service ban would be to relocate tobacco product inventory, contending that their members would incur thousands of dollars in reconfiguration costs. According to NACS:

[i]t is largely irrelevant that retailers already keep packs behind the counter. Many NACS members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. Based on an estimate from one member with a high volume of self-service cigarette sales, NACS suggested it could cost $4,320 and $10,120, respectively, to reconfigure a newer and older convenience store.

Based on other evidence, however, FDA does not believe that a large number of stores will be forced to undergo extensive modifications and finds that most convenience stores can adequately adapt space either behind or above checkout counters. As noted earlier, one regional survey reported that retail outlets readily complied with local self-service restrictions without architectural remodeling or substantial refitting of checkout counters or store aisles.[318] Space above counters is typically available for display cases either by suspending a case from the ceiling or by supporting a case on beams from the counter. In its survey, A. T. Kearney found at least some tobacco products sold from nonself-service space in every convenience store. Although it is possible that stores might incur added inventory handling costs if this space were smaller than optimal, FDA concludes that major reconfiguration would rarely be required and relies on the A. T. Kearney survey data, as adjusted, to project average costs for this sector.

h. *Convenience stores with gas.* Like convenience stores without gas, these establishments had numerous interior and exterior promotional materials. About 89 percent of the stores surveyed had nonself-service display cases. FDA estimates per facility costs of $213. Consistent with the findings of the Barents Group, the average outlet cost for this sector is about one-half that of convenience stores without gas.

In comments to the 1995 proposed rule, the Society of Independent Gasoline Marketers of America (SIGMA) did not present specific data on the cost to their members, but indicated that many members would be required to reconfigure their stores. They stated that:

[m]any SIGMA members keep large quantities of packs and cartons in self-service displays and would have to reconfigure their stores to comply with the ban on self-service sales. At a minimum, these members would have to install new cabinets to accommodate tobacco products behind the counter. Many members would have to enlarge the counter area to make room for the new cabinets.

In contrast, the A. T. Kearney field audit found few convenience stores with gas that have self-service displays, other than unattached promotional counter displays. Costs to remove or replace promotional counter displays will be borne primarily by manufacturers, not retailers. In sum, the costs for self-service display cases amount to about 31 percent of the total, promotional material 30 percent, and nonself-service display cases 39 percent.

i. *Service stations.* These establishments had both interior and exterior promotional material. Seventy-five percent of the locations surveyed had only nonself-service display cases and one-fourth had carton displays. FDA estimates the per facility cost at $122.

j. *Drug stores.* Drug store outlets had few exterior and interior promotional materials. As in general merchandise stores, tobacco products were stocked on shelves in some locations. Ninety percent of the stores surveyed by A. T. Kearney already had nonself-service displays and approximately 70 percent had carton displays. FDA estimated $160 cost per facility for this category of business. About 93 percent of the total one-time costs are for replacement of self-service display cases.

k. *Tobacco stores.* These stores had substantial promotional materials and multiple display cases. FDA estimates per facility costs of $2,175. About 94 percent of the costs are for self-service display cases, with promotional materials and nonself-service display cases dividing the remaining 6 percent. While not reflected in the cost totals, these establishments may choose to operate as "adult only" restricted areas to avoid replacing self-service display cases.

l. *Other establishments.* This category includes eating/drinking establishments and miscellaneous retail stores, which

[318] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, p. 5, November 3, 1994.

were excluded from the A. T. Kearney audit, plus the estimated 100,000 nonretail establishments that sell tobacco products OTC, such as hotels, factories and sporting facilities. Due to the low volume of tobacco product sales at these establishments, FDA assumed that only a small quantity of packs and no cartons would be sold. Lacking detailed data, FDA assigned costs of $19 per outlet, based on the costs of removing promotional materials and relocating and replacing small attached display cases, as reported for drug stores.

3. Label Changes

The final regulation requires that the tobacco product package contain the established name of the tobacco product in a specified size. FDA estimated the compliance costs for printing new labels in its earlier analysis of the proposed regulation and has received no comments that improve those original estimates.

Approximately 933 varieties of cigarettes are currently produced in the United States.[319] FDA does not have information on the number of smokeless tobacco varieties, but assumes that the total number of cigarette and smokeless tobacco varieties is roughly 1,000. Because most varieties of cigarettes are packaged in both single packs and cartons, the total number of labels is assumed to number about 2,000.

FDA used two approaches to estimate the cost to industry of changing these labels. The first approach relied on information compiled by The Research Triangle Institute (RTI) for its report to FDA on the cost of changing food labels.[320] 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 $5.6 million for all 2,000 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.[321] The Canadian Government estimated a cost of $30 million to change labels for about 300 cigarette varieties. Most Canadian cigarettes are likewise sold in two sizes, but about 20 percent are also sold in flip top packages.[322] 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 in the United States; 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.

4. Educational Program

FDA may issue notification orders under section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C.360h(a)) to require manufacturers of cigarettes and smokeless tobacco products to fund consumer educational programs. While the precise details of these orders are still under development, these orders may involve the achievement of specific performance objectives by directing manufacturers to initiate informational programs designed to transmit messages that will reach the majority of young people. The 1995 proposed regulation directed manufacturers to spend at least $150 million annually on this program. While industry comments were critical, many other comments suggested that this figure was too low. One comment noted that $150 million is equivalent to about one week of pro-tobacco expenditures and another that the industry gained $221 million in profits from underage sales. Still another pointed out that the current dollar value of the informational advertising that was conducted under the Fairness Doctrine would amount to about $300 million per year. One study appears to indicate that 75 percent of adolescents aged 12 to 17 could have been reached in 1985 to 1986 with multiple messages at a cost of about $17 million a year.[323] FDA is still evaluating various types of informational programs, with respect to both effectiveness and practicality. Before a final decision is reached, the agency will determine the costs of selected alternatives.

5. Restricted Advertising and Promotional Activities

a. *Tobacco industry.* The determination of the societal costs attributable to the restrictions on tobacco product advertising and promotion is complex. While there is no doubt that individual manufacturers 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. In addition, if the primary motivation for tobacco advertising is to promote brand-switching, then, as long as all firms are equally restricted from advertising, the above mentioned loss in goodwill value will be substantially reduced.

In its comments, the tobacco industry claimed that tobacco advertising and promotion have virtually no effect on youth consumption. Although FDA does not accept this claim, the agency does not consider the expected voluntary reduction in the consumption of tobacco products to be a societal cost. Although industry sales will fall, they will reflect new consumer preferences and consumer dollars no longer used on tobacco products will be redirected to other more highly valued areas. Thus, for the most part, the resulting reduction in industry sales are not net costs and the potential magnitude of this revenue transfer is discussed below under the heading of Distributional Effects. Moreover, as shown in that discussion, any short-term frictional or relocation impacts will be significantly moderated by the gradual phase-in of the economic effects.

b. *Advertising industries.* In its original analysis, FDA argued that advertising and promotional restrictions will impose no long term net costs on society. The Barents Group's study found that the various suppliers of

[319] "Tar, Nicotine, and Carbon Monoxide of the Smoke of 933 Varieties of Domestic Cigarettes," Federal Trade Commission, 1994.

[320] French, M. T., D. M. Neighbors, L. K. Carswell, K. B. Heller, and G. L. McDougal, "Compliance Costs of Food Labeling Regulations," Final Report, RTI Project Number 233U-3972-02 DFR, January 1991.

[321] 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.

[322] Kaiserman, M., Department of National Health and Welfare, Canadian Government, personal communication, February 1, 1995.

[323] Bauman, K. E., J. D. Brown, E. S. Bryan, L. A. Fisher, C. A. Padgett, and J. M. Sweeney, "Three Mass Media Campaigns to Prevent Adolescent Cigarette Smoking," *Preventive Medicine*, vol. 17, pp. 510-530, 1988.

industry advertising will incur substantial regulatory costs. It estimated that illustrative annual costs for this sector could reach $722 million to $2.17 billion, or up to one-half of its estimate of the total costs of the FDA proposal.

Upon review, FDA remains firmly convinced that its original position was correct. That is, from the standpoint of assessing societal costs and benefits, reduced revenues from tobacco advertising and promotional activities are not net costs and are appropriately considered a distributional impact. Indeed, FDA believes that a strong argument can be made that, even irrespective of health benefits, these advertising restrictions will decrease net societal costs by freeing productive resources for alternative uses. This does not imply that no individual business entities will be negatively impacted. Many of the companies that currently benefit from tobacco promotions (e.g., advertising agencies, publishers, sporting event promoters) will suffer lost revenues and those firms that specialize in those activities may lose a substantial part of their business. Nevertheless, from a societal perspective, these losses will be counterbalanced by an increase in demand for other consumption and investment goods, so that nontobacco-related entities will gain sales. Although overlooked in most industry comments, this result is acknowledged within the comments submitted for the Tobacco Institute by the Barents Group:

> A key assumption in the simulations is that, when tobacco product manufacturers decrease their advertising expenditures, the money not spent translates into increased profits for the industry. The increased profits ultimately end up in the hands of the companies' owners (shareholders) either as direct payouts or as investments on their behalf in other lines of business. In general, these profits are ultimately recycled into increased consumption and investment by the owners of the companies.

That report also reveals the underlying distributional nature of the impacts by explaining that its modeling incorporates the assumption that:

> * * * in the long run economic losses in one sector of the economy will be redistributed to other sectors of the economy, i.e., winners and losers will generally balance out for the economy as a whole.

Further discussion of the impact of these revenue transfers is included below under the section on "Distributional Effects."

c. *Retail sector.* In addition to the previously estimated direct costs associated with the removal of prohibited point-of-purchase advertising, promotional restrictions will impact the retail sector because they will lead to a long-term decline in tobacco products sales and a potential fall in promotional allowances (slotting fees) from manufacturers. Once again, these impacts are not net societal costs, since reduced tobacco product sales will be counterbalanced by increased sales for other products or services; and smaller promotional allowances, if they occur, are gains to tobacco manufacturers that would be used for other purchases. Consequently, these impacts also are examined below under "Distributional Effects."

d. *Consumers.* Advertising restrictions may impose costs on society if they disrupt the dissemination of relevant information to consumers. Firms engage in advertising to inform potential customers about their product (informative advertising) or to persuade customers that a product is desirable (persuasive advertising). According to the FTC's Bureau of Economics, 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.[324]

FDA has considered each of these issues. First, while agreeing that many forms of advertising offer substantial benefits to consumers, the agency nevertheless believes that consumers will lose little utility from these particular advertising restrictions. The regulation does not prohibit factual, written advertising. Thus, the rule will not impede the dissemination of important information to most consumers. In its preliminary analysis, the agency concluded that, "[w]hile 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" (60 FR 41314 at 41368).

One industry comment strongly opposed this position, arguing that advertising is important for product improvement and that past restrictions on the advertising of "low tar" products retarded product innovation. The crux of the argument is that color and/or imagery are prerequisites for disseminating relevant quality information and that, in its absence, consumers could not be adequately informed about the merits of new products. FDA, however, is not persuaded that manufacturers will be unable to convey vital information. The agency finds that true product improvements in this industry are rare, but where they exist, manufacturers could rely on traditional ads in adult-oriented publications and on "text only" advertising elsewhere. Moreover, FDA and other public health agencies would likely coordinate with companies in disseminating truly important consumer safety information.

The implications of FTC's second point, which addresses the effect of advertising restrictions on market power and prices, are less certain, as various empirical studies have reached conflicting conclusions. One industry comment insisted that FDA's regulation will deprive consumers of the benefits of competition, stating that, "[u]ndoubtedly the clearest measure of consumer benefit is the effect of advertising on price." To support this view, the comment references several studies that demonstrate the ability of advertising to reduce product prices. The comment also contended that the "[e]limination of advertising will predictably consolidate the market as marginal brands are abandoned and fewer brands are introduced" and that, "[o]ver time this can also reduce the number of players, as companies with dominant brands drive out others."

FDA agrees that advertising can often lead to decreased product prices, but notes that the other industries referenced (e.g., eyeglasses and pharmaceuticals) are much more competitive than tobacco products. Moreover, economists have found that advertising can also serve as a barrier to entry in oligopolistic industries. One author, for example, determined that ready-to-eat breakfast foods companies used advertising programs to support brand proliferation strategies in order to dominate retail shelf space.[325] These programs helped to keep new firms out and prices high without necessarily

[324] 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.

[325] Sutton, J., "Sunk Costs and Market Structure," The MIT Press, Cambridge, Massachusetts, pp. 229–247, 1991.

embodying improved quality. Thus, in certain circumstances, oligopolistic firms can use extensive advertising to create barriers for suppressing innovation and competition. FDA cannot determine whether tobacco advertising restrictions would ultimately increase or decrease product prices.

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 will 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." [326]

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. [327] 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. This final rule allows 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 sharply in recent years and currently constitute less than 5 percent of the industry's total advertising and promotion budget). [328] Conversely, the extraordinary growth in industry advertising and promotion has occurred 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.

6. Training

a. *Retailers.* The final regulation does not explicitly require retail employees who sell tobacco products to be trained in checking customer I.D.'s. FDA understands, however, that some training is essential to effective performance. In its analysis of the proposed regulation, FDA estimated total annual costs of $10 million for employee training at retail outlets. This estimate assumed that an average of 12 employees per store at 467,000 retail stores (assuming 1/3 of 700,000 stores already conducted training) would receive 15 minutes of training at a compensation rate of $7.41/hour. The Barents Group commented that FDA's analysis did not account for many individual cost elements, resulting in a significant underestimate of total training costs. It estimated one-time training costs of $184 to $257 million and recurring annual training costs of $48 to $67 million.

Specifically, the Barents Group stated that FDA relied on outdated compensation data. FDA had obtained these data from a 1992 report prepared by Price Waterhouse for the Tobacco Institute, but agrees that more recent data are available and employs the suggested compensation rate of $9.51 for its revised estimate. The Barents Group also claimed that FDA failed to consider recurring training costs due to annual employee turnover and annual updating, focusing instead on one-time training costs only. This criticism is not valid. Table 2 of the original analysis (60 FR 41314 at 41360) clearly lists training costs for retail establishments as an annual operating cost and the text (60 FR 41314 at 41367) refers to a "per year" cost. Because employees would be trained when first hired, this estimate implied a 100 percent employee turnover rate.

To refine its analysis, however, FDA has disaggregated the cost elements. Although the Barents Group accepted FDA's preliminary estimate of 12 employees per retail store, FDA now believes that this figure is accurate only for retail stores with payroll. Stores without payroll constitute a significant percentage of the stores selling tobacco products and, on average, are much smaller. As explained above, FDA estimates that about 600,000 establishments will sell over-the-counter tobacco products, including the 100,000 that replace those vending machines that are removed. Table 10 presents the data that underlie FDA's revised estimates of the number of employees who will be trained. For existing retail establishments with payroll, FDA assumes that training will be needed for all employees in the affected outlets, except in General Merchandise and Supermarket/Grocery stores, where one-third of the employees will be trained. For establishments without payroll, nonretail establishments, and new establishments replacing vending machines, Census data on the number of employees is not available, but FDA assumes that an average of six employees will be trained. As shown in Table 10, these calculations indicate that training will be required for a total of 4.2 million workers.

The Barents Group further faulted FDA for underestimating the training time that would be required to educate retail sales clerks about recognizing proper forms of identification and handling related customer service problems. It assumed that 2 hours of training would be necessary. FDA, however, reviewed the time needed to present the training materials from several corporate entities and finds that they need not exceed one hour. For example, one large convenience store corporation uses a 45 minute training videotape that covers the sale of tobacco products, but also covers the sale of alcohol and possible inhalants, including means for recognizing inebriated or drugged individuals. Moreover, many establishments, especially small stores, will provide no formal training, but will provide instruction during the work day with minimal lost time. Thus, FDA believes that average costs are reasonably based on a 1-hour training program.

[326] Scherer, F. M., *Industrial Market Structure and Economic Performance*, 2nd edition, Rand McNally College Publishing Co., Chicago, IL, p. 380, 1980.

[327] 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.

[328] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, issued 1995.

TABLE 10.—NUMBER OF EMPLOYEES TO BE TRAINED

Kind of Business	Payroll Establishments				Nonpayroll Establishments		Total Employees Trained
	Establishments Selling Tobacco Products	Employees Per Store	Percent Trained	No. of Employees Trained	Establishments Selling Tobacco Products	No. of Employees Trained[1]	
General Merchandise	12,117	60.1	33%	242,593	9,807	58,842	301,435
Supermarket/Grocery	71,240	20.9	33%	497,253	54,538	327,228	824,481
Convenience Store/no gas	29,400	5.6	100%	164,718	—	—	164,718
Convience Store/gas	51,913	6.8	100%	353,868	—	—	353,868
Gas Station	37,958	6.0	100%	228,002	7,581	45,486	273,488
Eating Place	11,992	16.5	100%	198,212	3,065	18,390	216,602
Drinking Place	10,745	5.4	100%	58,498	5,336	32,016	90,514
Drug/Proprietary Store	29,046	12.2	100%	354,730	1,829	10,974	365,704
Specialty Tobacco	1,477	3.7	100%	5,530	—	—	5,530
Miscellaneous	24,995	5.2	100%	130,253	44,879	269,274	399,527
Retail Subtotal	**280,883**			**2,233,656**	**127,035**	**762,210**	**2,995,867**
Nonretail[2]							600,000
Converted Vending Machines[2]							600,000
Total							**4,195,867**

[1]Assumes 6 employees per establishment.
[2]Assumes 100,000 outlets with 6 employees to be trained.
Sources: Table 4 for description of establishment data; 1992 Census of Retail Trade, Subject Series: Establishment and Firm Size (Table 1) for employment data; FDA estimates for percent trained.

Adopting FDA's original estimate that about one-third of all affected establishments already provide employee training (also assumed by the Barents Group), implies one-time employee training costs of $26.6 million (4.2 million employees x 2/3 x $9.51). The Barents Group suggested, however, that even employees who currently receive training would need 5 extra minutes on the new regulations, which adds about $1.0 million to the cost estimate. Next, the Barents Group included costs for time spent by trainers, assuming that the training would be provided by an outside source. FDA believes that a more typical approach would have a store supervisor provide the training. Using $13.64 as the compensation rate for a retail manager, as suggested by the Barents Group, and adjusting for the assumed one-third current compliance rate in existing establishments, yields a one-time cost for trainer time of $6 million. Thus, FDA projects total one-time training costs of about $33.5 million.

In addition, FDA estimates that employee turnover, using the Barents Group suggested rate of 42 percent, will add annually recurring training costs of about $11.2 million. Also, new employees will receive I.D. check training as part of their initial orientation activities. Since stores may provide this to several new employees at once, using either written or video training materials, FDA estimates that retail managers, on average, would spend about 1 additional hour per year providing this training. This adds $6.0 million to the annual training costs. The Barents Group also recommended annual reinforcement training. An annual 10-minute reinforcement training period for employees of those establishments that do not already have a training program will cost about $2.9 million. In sum, these annual recurring training costs total about $20 million.

The Barents Group also assumed that retail managers would need extensive training to understand the new regulations. FDA estimated in its 1995 proposal that manufacturers' representatives would need about 8 hours of training on their new responsibilities and the Barents Group assumed that retail managers would need a similar duration of training. FDA rejects this estimate, however, as the final provisions affecting retailers are straight-forward and will be routinely communicated through traditional industry channels.

b. *Manufacturers representatives.* In its preliminary economic analysis, FDA estimated that 7,300 manufacturer representatives would be trained for 8 hours at a cost of $25.00 per hour. After noting FDA's "undocumented" cost estimate, the Barents Group proceeded to apply the identical number of training hours to their "documented" cost estimate of $25.70 per hour. They also suggested a 15 percent labor turnover premium, giving a total cost of $1.5 million. As the final rule eliminates the monitoring burden for these employees, this training cost should be correspondingly smaller. Nevertheless, these manufacturer employees will still need to determine the types of displays that remain permissible. FDA therefore accepts the $1.5 million cost estimate.

7. Access Restrictions

a. *Manufacturers.* Although voluntary decreases in the sale of consumer products do not impose long-term net societal costs, mandatory restraints on the access of consumers to desired products may imply economic costs. Economists typically measure producer-related 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 derived from Cummings, et al., indicate that youngsters under the age of 18 consume 316 million packs of cigarettes per year, leading to industry profits of $118 million.[329] On the assumption that the regulation would reduce teenage smoking by one-half, these profits would fall by about $59

[329]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, p. 301, February 1994, (derived by subtracting sales to 18-years-olds from the reported 516 million packs consumed).

million. However, because most of this profit stems from illegal sales to youths, FDA has not counted this figure as a societal cost.

b. *Consumers.* 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. Because it reflects the difference between the price the consumer is willing to pay and the actual market price, it is used by economists to measure consumer welfare losses imposed by product bans. However, FDA's rule imposes no access restrictions on adults, who will be free to consume tobacco products if they so desire. Thus, FDA has not included any value for lost consumer surplus in its estimate of the societal costs of these access restrictions.

8. I.D. Checks

a. *Retailers.* For the 1995 proposed regulation, FDA estimated that retail establishments would bear annual compliance costs of $28 million for consumer identification checks. This figure was derived by multiplying the estimated retail employee compensation rate by the extra time that might be needed to complete purchase transactions. The estimate measured the cost to retailers for either increasing the number of working hours of existing staff or for hiring new staff to handle the added workload. The Barents Group commented on numerous aspects of this compliance cost estimation, accepting several key FDA assumptions, but rejecting others in deriving its estimate of $142 million per year.

In its preliminary analysis, FDA estimated the number of tobacco product transactions for the 18 to 26 year-old age group based on data that reflected the tobacco consumption of cigarette smokers 5 to 6 years after high school [330] and the annual per capita consumption of smokeless tobacco. [331] The Barents Group faulted FDA for limiting these transactions to 18 to 26 year-olds, asserting that the standard practice for alcohol sales is to request identification for anyone who appears to be 30 years old or younger. The Barents Group calculations actually estimated compliance costs on the assumption that customers up to age 34 would be asked for identification, because some older consumers would appear to be only 30 years old.

FDA has not accepted this Barents Group assumption for several reasons. First, the legal age of purchase for alcohol in all 50 States is 21 years, whereas the rule for cigarettes and smokeless tobacco sets 18 as the legal age of purchase. This 3-year difference implies that comparable cigarette and smokeless identification checks would be expected only up through age 27. Also, the current policy and practice of many retail stores is to request identification from tobacco consumers only up to age 26. Requiring proof of age for anyone who appears younger than 26 years of age was also recommended by a working group of 26 State Attorneys General. [332] Finally, the Barents Group's use of age 34 to provide a margin of safety for identifying those under the age of 30 is illogical, since the FDA rule requires retail stores to identify consumers who are under the age of 26, not 30.

The Barents Group accepted the FDA assumption that an I.D. check would take an average of 10 seconds, but referenced a study by A. T. Kearney that found that the actual time needed to verify a photo I.D. for a tobacco product sale averaged 8.3 seconds. Because FDA has no better data, the agency adopts 8.3 seconds as the average time needed to conduct an I.D. check. The Barents Group further commented that FDA used outdated employee compensation data in its calculations. FDA's revised totals use the Barents Group's employee compensation estimate of $9.51/hour (1994 dollars) as the time value for retail sales employees.

FDA originally assumed that only 75 percent of all retail transactions for the 18 to 26 year-old age group would be extended due to I.D. checks. The Barents Group argued that the correct percentage should be 100 percent, as the rule would apply to all sales to the relevant age group. FDA continues to believe that this assumption leads to an over-estimate of the probable costs. First, not every moment of a clerk's time is effectively utilized and a few seconds more per transaction will not always result in lost labor productivity. Second, many smokers patronize the same retail store almost daily and are well-known to clerks. I.D. checks for these customers will take little extra time. Finally, many customers will take less time to produce an I.D., once they realize that identification checks have become routine. Nevertheless, FDA adopts the Barents Group's 100-percent assumption to assure a full accounting of the relevant costs.

One comment claimed that FDA failed to include the cost of hiring additional sales clerks. As noted above, the FDA calculation does reflect the cost of the additional labor time that might be needed. The Barents Group also inexplicably asserts that FDA failed to consider I.D. checking costs as annual costs, instead listing them as a one-time cost. Table 2 of the original analysis (60 FR 41314 at 41360), clearly lists the $28 million identification check cost as an annual operating cost and the accompanying text (60 FR 41314 at 41367) refers to the figure as a "per year" cost. The Barents Group further faulted FDA for not taking into account the cost of checking I.D.'s for those youths under age 18, who will still attempt to buy cigarettes. While a small percentage of underage smokers may opt for this course of action, few would return to complying outlets. Thus, FDA believes that any plausible estimate of the associated costs would be less than $1 million annually.

FDA originally estimated the number of tobacco product transactions for the 18 to 26 year-old age group at 2.2 billion, but has updated its estimate to 2.5 billion. [333] Also, the 80-percent current noncompliance rate that had been assumed for the 1995 proposal may be too high, as the Surgeon General estimated that minors are unable to make an OTC purchase of tobacco products about one-third of the time. [334] Nevertheless, FDA retains this assumption to calculate a cost to

[330] 1994 SGR, p. 85.

[331] U.S. Department of Commerce, *Statistical Abstract of the United States 1993*, 113th edition, p. 137, 1993; DHHS, Office of Inspector General, *Spit Tobacco and Youth; Additional Analysis*, June 1993.

[332] "No Sale: Youth Tobacco and Responsible Retailing," Findings and Recommendations of Working Group of State Attorneys General, p. 28, December 1994.

[333] 1994 Population data for 18 to 26 year-olds from 1995 Statistical Abstract, Table 16. Cigarettes: Number of smokers for age group calculated from Table 217 (1993 data). Average packs/yr. and total packs/yr. for smokers aged 18 to 26 calculated from data in Table 20, 1994 SGR, p. 85. (Those smoking 1 to 5 cigarettes/day assumed to smoke 3, those smoking 20+ cigarettes/day assumed to smoke 25). The resulting number of packs smoked by 18 to 26 yr.-olds totals about 2.5 billion. If even 1 percent of these transactions were for cartons, this number falls to about 2.3 billion. Smokeless: Total units of smokeless products sold calculated from data in *Spit Tobacco and Youth: Additional Analysis*, Dept. of Health and Human Services, June 1993, Excise Tax calculations, Option 4; Units consumed by youths from the Institute of Medicine Report (the IOM Report) "Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths", p. 8. 1994, Usage data and total units (cans or pouches) consumed for age group for those aged 18 to 26 from "Use of Smokeless Tobacco Among Adults-U.S., 1991" in "MMWR", CDC, DHHS, volume 42, No. 14, p. 264, 1993. The number of containers sold for 18 to 26 yr. old age group totals about 0.2 billion.

[334] IOM Report, p. 202.

retailers for I.D. checks of $43 million per year (2.5 billion transactions x 8.3 seconds/transaction x $9.51/hour ÷ 3600 seconds/hour x 80 percent noncompliance rate). This revised estimate exceeds FDA's original $28 million figure, but remains far below the $142 million estimate of the Barents Group.

b. *Consumers.* The Barents Group also criticized FDA for not quantifying the costs to consumers for the extra time needed to undergo I.D. verifications. They estimated this cost at $282 million a year. FDA agrees that consumers would incur time costs and, for its revised estimates, adopts the analytical framework suggested by the Barents Group, which counts only the time lost by young customers. (The Barents Group suggests that older consumers also would experience delays, but FDA's estimates already account for the cost of additional clerk time that would offset longer checkout lines. Younger customers, however, must wait while their age is verified, even when additional checkout clerks are available.) To estimate the time cost, FDA applies the same methodology that was used to estimate the time cost for retail employees. That is, 2.5 billion transactions taking an extra 8.3 seconds each for the 18 to 26 year-old age group, adjusted for a 20 percent current compliance rate. The Barents Group used an average hourly private sector compensation rate ($15.13/hour) as the basis of its consumer time cost estimate, but FDA finds this average rate too high for young consumers and estimates a range of $9 to $11 per hour.[335] As a result, FDA's estimate of the cost to consumers for lost time cost amounts to between $41 and $50 million per year.

9. Vending Machines

In its comments on the costs of FDA's proposed vending machine ban, the Barents Group reports that automatic vending machine operators will lose $403 million in annual revenues. They then subtract an estimated $281 million offset for future over-the-counter sales (calculated by assuming an equal number of future packs sold and an $.80 price premium for vending machine packs) to project a net $122 million of regulatory costs to the retail sector. Although not acknowledged, this methodology implicitly assumes that a redistribution of revenues (from vending machine owners to over-the-counter sellers) does not generate added societal costs. Elsewhere, the Barents Group includes distributional impacts in cost totals. Nevertheless, even this $122 million estimate is far too high.

The fundamental problem is that changes in revenue, as discussed above, do not measure economic costs. The relevant economic measure of regulatory costs to an industry is the change in producer surplus that a firm makes from selling a good or service. Because producer surplus' are difficult to measure, accounting profits are sometimes used as a proxy. By examining only lost revenues, the Barents Group ignores the difference in the operating costs of the alternative sales channel, despite its recognition that "[i]n general terms, the extra margin at vending machines reflects the costs to vending machine owners of operating these machines, in addition to a return on their labor effort and capital investments." In other words, the reason that cigarettes purchased from a vending machine are more expensive is that it costs more to sell a pack of cigarettes by vending machine. Consequently, if cigarette sales shift from more expensive-to-operate vending machines to OTC, the loss of industry profits is much smaller than the loss of industry revenues.

An approximate assessment of the net impact on retail profits requires a comparison of the pretax profit margins for vending machine operations as compared to OTC sales. The Barents Group cited survey results from the National Automatic Merchandising Association (NAMA) showing an average pretax profit margin of 3.8 percent in 1993 and 2.0 percent in 1992, for an average 2.9 percent for vending machine operations. Because cigarette vending machine sales have decreased in recent years, current profit margins might be even smaller. Coincidentally, the Barents Group reports that the estimated average industry profit margin for convenience stores is also 2.9 percent. If this rate applies to cigarette sales at convenience stores and if all lost vending machine cigarette sales were transferred to convenience stores, the net pretax cost to the industry would be $3.5 million, not $122 million ($403 million to $281 million) x 2.9 percent). Moreover, NAMA reports that over 50 percent of all vending machines are located in bars and taverns and many others in business establishments frequented only by adults. The final rule permits vending machines in those places where the owner can ensure that no young people under age 18 are present at any time. FDA does not know how many vending machines will be moved to restricted areas in compliance with this rule, but the number will further reduce this annual cost.

10. Readership Surveys

The Barents Group reported that 101 leading national magazines had advertisements for tobacco products in 1994. In addition, Barents obtained youth and adult readership data for 1994 from MediaMark Research, Inc. (MediaMark), for 41 of these 101 magazines. Applying the regulatory threshold of 2 million readers or 15 percent of total readership below the age of 18, Barents projected that advertisements in 32 of the 41 magazines (78 percent) would be restricted to "text only" by the proposed regulation. In comparison, FDA examined copyrighted youth and adult readership data from the Simmons Marketing Bureau, Inc. (Simmons), another major marketing research firm, and found that only 13 of the 27 magazines with tobacco ads (48 percent) had youth readership over the threshold. A comparison of youth readership levels from MediaMark and Simmons for magazines that had tobacco advertisements in 1992 is shown in Table 11.[336]

[335] Data from the 1995 *Statistical Abstract of the United States*, Table 677 lists weekly earnings for full time wage and salary workers for the group "16 to 24 year-olds" in 1994. Table 682 lists median hourly earnings for workers paid hourly rates for the same group in 1994. Assuming a 40 percent increase for benefits, the compensation rates for these two tables for 16 to 24 year-olds are $9.98/hour and $7.87/hour, respectively.

Using these figures will result in a low estimate for the 18 to 26 year-old group because 25 and 26 year-olds earn more than 16 and 17 year-olds. Conversely, using a benefits/wage ratio of 40 percent for 18 to 26 year-olds will overstate the costs because lower paid workers (hourly and part-time workers, college students) are more likely to have less generous benefits packages (little or none of the following: paid vacation, sick leave, employer-paid health insurance). FDA increased the estimated compensation rates to $9 to $11/hour to assure it does not underestimate the true compensation rate.

[336] Tobacco industry spending on magazine advertising was calculated using tobacco advertising share data from Barents and advertising revenues from *Advertising Age*. Advertising revenue was unavailable for five small publications that accounted for less than one percent of tobacco magazine advertising spending in 1994. To estimate tobacco advertising expenditures in these five publications, FDA assumed total advertising revenues for each publication equal to $14,388, which is the lowest total revenue reported in *Advertising Age* for 1994.

TABLE 11.—AVAILABLE YOUTH READERSHIP DATA FOR PUBLICATIONS WITH TOBACCO ADVERTISEMENTS IN 1994

Publications with Youth and Adult Readership Data	Estimated Percentage of 1994 Tobacco Industry Spending on Magazine Advertisements	MediaMark Research Inc. (1994 readership data)		Simmons Market Research Bureau, Inc. (1994 readership data)	
		Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)	Number of Readers Under 18 (000)	Percent of Readers Under 18 (%)
Sports Illustrated[1,2]	10.0	5,201	18.0	4,614	17.1
People[1,2]	9.8	3,020	7.8	2,465	8.0
TV Guide[1,2]	6.5	6,739	13.2	7,102	15.6
Time	4.1	1,972	7.7	n/a	n/a
Parade[2]	3.7	n/a	n/a	6,059	6.9
Cosmopolitan[1]	3.1	2,279	12.8	1,410	11.4
Woman's Day	3.0	1,202	4.8	n/a	n/a
Entertainment Weekly[2]	2.9	n/a	n/a	674	15.3
Better Homes & Gardens[1]	2.4	2,042	5.5	785	3.4
Newsweek	2.4	1,911	8.0	n/a	n/a
Family Circle	2.1	1,210	4.2	646	3.5
Field & Stream	2.1	1,760	11.1	815	7.9
Glamour[1,2]	2.0	2,216	17.1	1,540	17.4
Rolling Stone[1,2]	2.0	1,869	18.5	1,506	20.1
Ladies' Home Journal	1.7	838	4.4	n/a	n/a
McCall's	1.7	1,274	6.7	506	3.7
Redbook	1.7	1,153	7.8	565	5.4
Car & Driver[1]	1.6	1,465	18.3	n/a	n/a
Life[1]	1.6	2,665	12.9	n/a	n/a
Popular Mechanics	1.5	1,617	14.5	744	10.3
Outdoor Life[1]	1.3	1,579	18.0	569	8.8
Us	1.2	814	13.8	n/a	n/a
New Woman	1.1	685	14.0	n/a	n/a
Road & Track[1]	1.1	1,234	20.6	n/a	n/a
Soap Opera Digest	1.1	1,299	14.4	853	12.6
Mademoiselle[1,2]	1.0	1,369	19.7	959	18.5
Vogue[1,2]	1.0	2,237	18.0	1,300	17.4
Hot Rod[1]	0.8	2,295	28.0	n/a	n/a
Ebony[1]	0.7	2,111	15.8	1,046	9.4
Gentlemen's Quarterly[1]	0.7	1,037	15.1	n/a	n/a
Motor Trend[1]	0.7	1,393	22.1	n/a	n/a
Premiere[1]	0.7	617	25.8	n/a	n/a
Sport[1,2]	0.7	2,274	33.8	1,132	24.0
Elle[1]	0.6	819	17.8	409	14.4
Essence[1]	0.6	1,251	16.9	537	9.4
Sports Afield	0.6	n/a	n/a	0	0.0
True Story	0.5	740	14.8	n/a	n/a
Jet[1]	0.4	1,724	16.7	1,169	12.2
Popular Science[1,2]	0.4	1,906	20.8	874	16.1
Self[1]	0.4	786	16.2	n/a	n/a
Harper's Bazaar[1]	0.3	718	18.2	n/a	n/a
The Sporting News[1,2]	0.3	1,394	27.8	666	15.7
Cable Guide[1]	0.2	3,358	22.6	n/a	n/a
Ski[1,2]	0.0	827	26.4	584	24.9

[1]MediaMark youth readership exceeds regulatory threshold.
[2]Simmons youth readership exceeds regulatory threshold.
Source: Barents Group LLC Tables IV–1 and A–2; Simmons Market Research Bureau, Inc.; R. Craig Endicott, "The Ad Age 300," *Advertising Age*, June 19, 1995.

The final regulation requires that specific youth and adult readership data be available for any magazine that displays a tobacco advertisement with color or imagery. Simmons currently conducts interviews with adults in approximately 20,000 households annually and subsequently returns to about 3,000 of these households to interview their youth members. In general, however, marketing research firms collect data on youth readership only for those magazines commonly read by this age group. Thus, although 78 percent and 48 percent of the magazines in the two youth readership samples described above exceeded the regulatory readership threshold, these sample results likely overestimate the percentage of magazines with current tobacco ads that exceed the threshold.

Simmons now collects adult readership data for about 230 magazines and youth readership for about 65 magazines. Because tobacco manufacturers currently advertise in about 100 magazines, the industry could often add magazines that are currently part of an ongoing adult readership survey to a youth survey, saving approximately 60 percent of the cost of collecting both adult and youth data.

Because FDA does not know how tobacco manufacturers will adapt their marketing strategies to the new regulatory thresholds, it is difficult to predict the number of new readership surveys that may be initiated. It seems likely, however, that tobacco companies will both increase the frequency of advertising in "adult" magazines that already carry tobacco advertisements and find suitable "adult" magazines to replace many of the other magazines.

One plausible scenario is that approximately one-half, or 50, of the magazines with current tobacco ads would not qualify as "adult" publications, because they exceed the youth readership threshold; and that the tobacco industry would choose to advertise in 50 other "adult" publications that do not currently carry tobacco ads. To identify these 50 additional "adult" magazines, the industry might need to collect new youth readership data for up to 100 magazines. In addition, as noted above, of the original 100 magazines with current tobacco advertising, youth readership data is now available for at least 40. Thus, the tobacco industry may initially need to obtain new youth readership data for the remaining 60 magazines. In total, therefore, the tobacco industry might opt to obtain youth readership data for an additional 160 publications in the first year that the rule becomes effective. In subsequent years, this number might fall to about 100 surveys, as the industry would concentrate its survey efforts on publications very likely to qualify.

If a marketing research firm collects youth readership data, the cost may depend on the particular characteristics of the magazines being surveyed. The tobacco industry could choose, however, to hire a survey firm to develop and administer a questionnaire solely to gather readership data for magazines with tobacco advertising. While FDA is uncertain about which approach the industry would take, the agency estimates that such new surveys might cost approximately $2 million in one-time costs and $1 million in annual costs, based on an average cost of about $650 and $350 per sample household.

11. Records and Reports

Manufacturers will need to comply with device regulations governing submissions of representative labels and advertising, medical device reporting (MDR's), establishment registration and product listing, and current good manufacturing practices (CGMP's).

a. *Labels and advertising.* The rule requires that each manufacturer annually submit to FDA copies of representative samples of labels and advertising. While the agency expects about 1,000 product labels, FDA has no direct evidence on the number of advertisements that will be submitted. An approximate estimate, however, can be derived from the number of advertising samples submitted by the pharmaceutical industry. First, FDA calculated that of the $6.1 billion in advertising and promotional outlays reported to the FTC by the tobacco industry, only about $1.2 billion is spent on printed advertisements. (Derived by subtracting categories for "Coupons/Value Added," "Promotional Allowances," "Specialties Items," and "Free Samples" from the total $6.1 billion).

The pharmaceutical industry spends an estimated 22.5 percent of sales on marketing, of which about one-quarter may be allocated to advertising ethical pharmaceuticals.[337] The approximately $50 million in annual sales of pharmaceutical manufacturers, therefore, implies a $2.5 billion annual advertising budget. FDA estimates that it currently receives about 25,000 pieces of pharmaceutical advertising per year. As the pharmaceutical budget is roughly twice the size of the $1.2 billion tobacco industry figure derived above, the agency might receive half as many documents. Alternatively, reduced promotional activities may prompt an increase in the number of printed advertisements prepared by tobacco companies, although the Barents Group assumed this number would decline. Therefore, FDA projects that it will receive the same number of advertisements for tobacco products as it currently receives for pharmaceutical products, or about 25,000 per year, plus about 1,000 labels.

Estimates of the time burden of these paperwork submissions ranged from 20 minutes (The Barents Group) to 1 hour and estimates of the hourly cost ranged from $25.00 (Tobacco Institute) to $45.26 (the Barents Group). Using the high end of both ranges provides an upper bound cost estimate of $1.2 million. This figure is significantly lower than either the original FDA estimate, or the Barents Group estimate of $55 to $57 million, largely because the final rule imposes no specific paperwork requirements on retail establishments.

b. *MDR's.* The final rule will require MDR's for serious unexpected incidents. FDA assumes that 31 manufacturing companies[338] and 1,365 distributors[339] will bear total one-time costs of $21,000 and $231,000, respectively, for establishing and documenting procedures for MDR reporting. These costs include 32 hours of effort per manufacturing firm and 8 hours per distributor. Based on estimates previously developed for the Medical Device User Facility and Manufacturer Reporting Final Rule, these activities were distributed over wage rates averaging $21.17. Annual costs for MDR reporting requirements are more difficult to predict, because they depend on the number of adverse event reports that will be submitted. FDA projects, however, that followup investigation and reporting of a single event takes about 8 hours of labor and costs about $218. Thus, if 50 adverse event reports were filed annually, the annual cost would be about $11,000. In addition, if each manufacturing company submits a single baseline report and annual updates, these costs would be about $2,100 annually, based on unit costs of $54 and $14 per report, respectively. Annual certification is necessary, but is typically a formality in terms of data collection and reporting and is estimated to cost about $800 for all manufacturers and $35,000 for all distributors assuming 1 hour of professional and clerical time at $25.80 per hour.

c. *Registration and listing.* Registration and listing duties are estimated to take 41 manufacturing establishments 2 hours each to prepare at a unit cost of $42, totaling about $1,700 per year for the industry.

d. *CGMP's.* The Tobacco Institute asserted that cigarette manufacturers would need substantial time to comply with CGMP's as the industry "would need to adopt major new systems * * * [and] make major changes to their procedures just to accommodate the recordkeeping required." Conversely, the economics study prepared by the Barents Group for the Tobacco Institute showed no additional costs for this requirement. FDA agrees that these costs

[337] U.S. Congress, Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks and Rewards," OTA-H-522 Washington, DC: U.S. Government Printing Office, pp. 303–304, February 1993.

[338] 1992 U.S. Census of Manufactures, Industry Series, Tobacco Products, Table 1a. A few U.S. agents designated to represent foreign manufacturers would also need to file forms, but these costs should be minimal.

[339] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States (unpublished data).

should be minimal for facilities with good quality assurance programs. Its CGMP's do not specify a specific format, but encompass a wide variety of broad requirements for documenting operating procedures. Contrary to the Tobacco Institute's claim that "even a well-run cigarette manufacturing facility would need to adopt major new systems," CGMP's are, in fact, based on the activities of well-run operations. Moreover, device CGMP's are currently under revision to bring them even closer to ISO 9001, the generally recognized international standard for quality assurance systems. Thus, while FDA has little experience with day-to-day tobacco manufacturing procedures, the agency does not anticipate the need for substantial quality system redesign. Wholesalers and distributors also submitted comments contending that the CGMP's would create added paperwork burdens, but the agency has exempted these sectors from the CGMP requirements.

12. Government Enforcement

FDA estimates of internal costs for administering and enforcing this regulation are extremely uncertain, as they will depend on the working relationships to be established with State tobacco control programs. As a best estimate, however, FDA projects that between 30 to 50 full-time employees (FTE's) will be needed to implement the rule. Fully loaded employee costs vary with the type of employee (e.g., field inspectors versus administrative), but an average of $100,000 per FTE places the dollar cost at between $3 and $5 million per year. SAMHSA has estimated that State programs will need between $25 and $50 million annually to administer and enforce appropriate State operations.

13. Comparison of Benefits to Costs

FDA expects the net societal benefits of the rule to far exceed the regulatory costs. Based on the analysis presented above, the estimated one-time costs of the combined FDA and SAMHSA rules are $174 to $187 million and the estimated annual costs are $149 to $185 million. Taking the midpoint of the ranges and annualizing the one-time costs at 3 and 7 percent, respectively, yields total annualized costs of $172 million and $180 million. In contrast, the agency's best estimate of the monetized regulatory benefits that would follow a 50 percent reduction in underage tobacco use ranges from $28.1 to $43.2 billion at a 3 percent discount rate and from $9.2 to $10.4 billion at a 7 percent discount rate. Thus, as shown in Table 12, the *net* benefits (benefits minus costs) of a total effectiveness rate of 25 percent range from $27.9 to $43 billion at a 3 percent discount rate and from $9.0 to $10.2 billion at a 7 percent rate. Table 13 indicates that those figures imply a cost per life-year saved of from $800 to $4,700 and a cost per death avoided of from $11,000 to $52,000. As noted earlier, these benefits are exclusive of the substantial health improvements expected to result from the reduced consumption of smokeless tobacco.

The substantial differential between these estimated costs and benefits withstands rigorous sensitivity analysis (see Table 12). For example, SAMHSA estimated that its rule would reduce underage tobacco use by from one-third to one-tenth. The approximate midpoint of that estimate (20 percent) constitutes about 40 percent of the regulatory benefit of reducing underage tobacco use by one-half. If, for illustrative purposes, these results, as well as a proportional fraction of the relevant costs,[340] are attributed to SAMHSA, the *incremental* net benefits of the FDA rule still range from $16.8 to $25.8 billion at a 3 percent discount rate, and from $5.4 to $6.2 billion at a 7 percent discount rate.

Moreover, FDA assumed that reaching the "Healthy People 2000" goal would deter about one-quarter of the 1 million youth under age 18 who currently begin to smoke each year from ever smoking as an adult. Thus, this goal implies a 25 percent overall effectiveness rate. If, however, these rules prevent smoking as an adult for even 5 percent of the teenagers who would otherwise become adult smokers, they would produce estimated annual net benefits of from $5.4 billion to $8.5 billion at a 3 percent discount rate and from $1.7 billion to $1.9 billion at a 7 percent discount rate. Even if this latter scenario attributed 40 percent of the benefits and relevant costs to SAMHSA, the annual *net* benefits of the FDA rule would still range from $3.3 billion to $5.1 billion at a 3 percent discount rate and from $1.0 billion to $1.2 billion at a 7-percent discount rate. This last example implies a cost per life-year saved of $3,500 to $21,100 and a cost per death avoided of $47,000 to $234,246. These figures are well within the range of values for health interventions typically considered cost-effective.

TABLE 12.—NET BENEFITS

($ Billions)

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Low	High	Low	High	Low	High	Low	High	Low	High
3%	27.9	43.0	16.7	25.7	11.1	17.1	5.4	8.5	2.6	4.1
7%	9.0	10.2	5.3	6.1	3.5	4.0	1.7	1.9	0.74	0.86
	Illustrative Incremental Net Benefits[1]									
3%	16.8	25.8	10.0	15.5	6.7	10.3	3.3	5.1	1.6	2.5
7%	5.4	6.2	3.2	3.7	2.1	2.4	1.0	1.2	0.45	0.53

[1] Attributes 40% of benefits and associated costs to SAMHSA

[340] Costs include 100 percent of SAMHSA's state enforcement costs, plus 40 percent of retail training costs, vending machine costs, and retail and consumer I.D. check costs.

TABLE 13.—COST EFFECTIVENESS

Discount Rate	Effectiveness Rates									
	25%		15%		10%		5%		2.5%	
	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)	Cost/Life-Year Saved ($)	Cost/Death Avoided ($)
3%	815	10,862	1,358	18,103	2,038	27,155	4,075	54,310	8,151	108,621
7%	4,722	52,423	7,870	87,372	11,804	131,059	23,609	262,117	47,218	524,235
Illustrative Incremental Cost-effectiveness[1]										
3%	706	9,413	1,177	15,689	1,766	23,533	3,532	47,067	7,064	94,134
7%	4,220	46,849	7,033	78,082	10,549	117,123	21,098	234,246	42,197	468,492

[1] Attributes 40% of benefits and associated costs to SAMHSA

E. Distributional Effects

These regulations will impose a variety of sector-specific distributional effects. Those sectors affiliated with tobacco and tobacco products will lose sales revenues and these losses will grow over time. Businesses engaged in the provision of tobacco product advertising may also face reduced revenues. Simultaneously, nontobacco-related industries will gain sales, because dollars not spent for tobacco products will be spent on other commodities.

1. Tobacco Manufacturers and Distributors

For its calculation of regulatory benefits, FDA estimates that implementation of the regulations may reduce the cigarette consumption of underage smokers by one-half within 7 years. As discussed earlier in this section, based on data presented in Cummings, et al., FDA finds that teenage smokers under the age of 18 consumed about 316 million packs of cigarettes in 1994. A 50-percent cut in sales would drop the number of packs sold by 158 million. 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, decreasing the number of adult smokers by 250,000 per year. Because each adult smoker consumes about 500 packs per year, about 124 million fewer packs would be sold per year.

Thus, achieving the agency's goal would reduce cigarette consumption by 158 million packs in the first year (while only teenagers are affected), 158 million plus 124 million packs in the second year, 158 million plus 2 times 124 million packs in the third year, and so on. Since 1994 cigarette shipments totaled 36.3 billion packs,[341] cigarette consumption would fall by about 0.4 percent in the first year, 1.8 percent in the fifth year, and 3.5 percent in the tenth year following implementation. (In fact, these reductions may take even longer, because it may be several years before the 50-percent effectiveness level is achieved, and because young adults smoke fewer packs than older adults).

Hence, annual tobacco revenues will decline slowly over time. The U.S. Bureau of the Census estimates 1994 revenues for cigarette and smokeless tobacco manufacturers at about $25.9 billion.[342] Assuming comparable reductions in smokeless tobacco, these calculations imply that tobacco manufacturer revenues will fall by $128 million in the first year (0.5 percent), $501 million in the fifth year (1.9 percent), and $966 million in the tenth year (3.7 percent). While these reductions are significant, the gradual phasing of the impacts will significantly dissipate any associated economic disruption.

In a 1992 report prepared for the Tobacco Institute, Price Waterhouse estimated that the tobacco manufacturing, warehousing and wholesale trade sectors employed about 107,000 full-time workers.[343] Thus, a constant production-to-employment ratio projects that a 3.7-percent reduction in sales over a 10-year period would result in the displacement of about 4,000 jobs, or 400 jobs annually among manufacturers, warehousers, and wholesalers. Alternatively, a University of Virginia study concluded that "the Price Waterhouse study for the Tobacco Institute provides estimates of tobacco's impact that are high compared to other measures."[344] That study referenced a recent U.S. Department of Agriculture analysis by Gale that found that manufacturing and wholesale trade activities employ only 83,000 full-time equivalent workers.[345] If true, this finding reduces these job loss estimates to about 3,000 jobs, or 300 annually.

The smaller job loss estimate is generally confirmed by a recent study by Warner, et al., who applied a computer simulation model to forecast the regional impact of reductions in tobacco use.[346] The authors used "a state-of-the-art macroeconomic model to simulate what would happen if consumers reduced their tobacco expenditures, with the same level of spending redistributed to other goods and services * * *." One scenario assumed that tobacco control activities would reduce the expected rate of tobacco purchases by 2.06 percent per year, or roughly 5 times the estimated effect of the FDA rule. While this scenario does not present direct impacts to the tobacco industry alone, it forecasts job losses after 8 years of 6,401 for all U.S. wholesalers and 5,957 for Southeast Tobacco Region

[341] "Tobacco Situation and Outlook Report," U.S.D.A., Economic Research Service, p. 4, April 1995.

[342] "1994 Annual Survey of Manufactures: Value of Product Shipments," U.S. Department of Commerce , Bureau of the Census, Table 1, p. 210. ASM does not report data below the 5-digit SIC Code Level. FDA assumed chewing tobacco represented the same percentage of SIC Code 2131 (Chewing and Smoking Tobacco) in 1994 as it did in 1992 when it was classified at a 6-digit SIC code in the Census of Manufacturers.

[343] "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, p. ES-3, October 1992.

[344] Knapp, J. L., "Tobacco in Virginia," Weldon Cooper Center for Public Service, University of Virginia, p. 5, December 1995.

[345] Gale, F., "What Tobacco Farming Means to Local Economies," U.S. Department of Agriculture, Economic Research Service, Agriculture Economic Report Number 694, p. 5, September 1994.

[346] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, pp. 1241–1246, April 24, 1996.

manufacturers. Accounting for the multiple of 5, comparable job losses attributable to the FDA rule would total about 2,600 after 8 years, or about 325 annually.

The Barents Group did not address the long-term gradual decline in tobacco use projected by FDA. Nevertheless, it claimed that the agency underestimated the economic impact on industry by failing to account for the lost sales to adults that would result from the proposed ban on vending machines and self-service displays and the required checking of customer I.D.'s. The Barents Group argued that the added consumer inconvenience imposed by these provisions was tantamount to an increase in the effective price of tobacco products, which would rapidly decrease the consumption of tobacco by adults. Relying on "hypothetical scenarios" that assume demand declines of 5 and 10 percent, the Barents Group forecast that the tobacco manufacturing industry would lose from 1,800 to 3,700 jobs due to this increased consumer inconvenience.

FDA believes these Barents projections are substantially overstated. Impacts associated with cigarette consumption declines of 5 to 10 percent cannot possibly be attributed to the loss of vending machines, because vending machine purchases make up less than 1 percent of all cigarette purchases. Further, according to NAMA, there are only 141,000 cigarette vending machines currently in use (and that number is falling rapidly), and the cost analysis prepared by the Barents Group predicted that 100,000 of these machines would be replaced by new OTC establishments. Thus, the Barents Group's own analysis eliminates any added consumer inconvenience from three-quarters of the existing inventory of machines. Moreover, the near-term impact on adult tobacco consumption will be further moderated both because the final rule allows vending machines in "adult" facilities, and because the added inconvenience cost will be partially offset by the lower price of the OTC product. These factors together make it extremely unlikely that fewer vending machines will lead to a substantial near-term fall in tobacco industry sales revenues.

The likelihood that tobacco sales will decline significantly due to inconvenience imposed on adult customers by the self-service restriction is similarly remote. While some purchasers would need more time to complete a transaction, other purchasers would save time by no longer having to search and retrieve a desired product. In the absence of empirical evidence, the result is indeterminate; but FDA has seen no convincing evidence or arguments to demonstrate that any delays caused by the self-service restriction will significantly curtail adult tobacco use.

Finally, although FDA calculated above that increased delays due to I.D. checking could cost young adult consumers under the age of 26 up to $50 million per year, even this cost would not lead to significant consumption declines. As described, the increased checkout waiting time for young purchasers was estimated to average about 8.3 seconds, which translates to a cost of about 2.3 cents per transaction, or 1.35 percent of the cost of a pack of cigarettes. According to the Barents Group, representative estimates of demand elasticities for cigarettes range from -0.6 to -1.0. Young adults under the age of 26, however, purchase only about 10 percent of all tobacco products. Thus, the fall in total tobacco sales would be, at most, 0.1 percent, not the 5 to 10 percent assumed by the Barents Group. Moreover, even the 0.1 percent figure is an overestimate, because those consumers irritated by the delay will increase the volume of tobacco products purchased per transaction. As a result, the number of cartons sold will rise, but the decline in tobacco product sales revenues attributable to the inconvenience effects of I.D. checks will be negligible.

2. Tobacco Growers

As explained above, total cigarette and chewing tobacco consumption is expected to decrease by 0.5 percent in the first year, 1.9 percent by the fifth year, and 3.7 percent by the tenth year, following compliance with the regulation. Price Waterhouse estimated that, on a full-time equivalent basis, about 153,000 farmers grew tobacco in 1990. Based on these figures, constant production-to-employment ratios imply employment losses among tobacco growers of about 5,700 after 10 years, or about 570 annually. Alternatively, the Gale study for the U.S. Department of Agriculture (USDA)[347] estimated the number of full-time equivalent tobacco farmers to be only 65,400, which would reduce the job loss estimate to about 2,500 by the tenth year, or 250 annually.

This latter figure also closely fits the findings of Warner, et al., who, as described above, used a "state-of-the-art" macroeconomic simulation model to project the employment effects of declining tobacco consumption.[348] Assuming domestic tobacco consumption decreases of 2.06 percent per year, Warner, et al. predicted about 7,500 job losses within an 8-year period for "Southeast Tobacco Region" farmers. As this fall in tobacco use is roughly five times that projected by FDA, the analogous job loss estimate would be about 1,500 over the 8-year period, or about 190 per year.

According to the USDA study by Gale, "[f]or most farms, tobacco growing is a part-time, seasonal enterprise, and production per farm is usually small. About two-thirds of tobacco farmers work off-farm."[349] Citing 1987 Census of Agriculture data, Gale notes that only 65 percent of the farms growing tobacco in the United States reported earning more than half of their receipts from tobacco, and of those farms, approximately 80 percent had total farm sales under $20,000. He explains that the availability of alternative land uses will dictate the economic results:

> The key factor in adjustment to a smaller tobacco industry is the alternative uses available for land, labor, and capital used in tobacco production * * * For the most part, concern is focused on rural areas where tobacco is grown because this stage of production has the most specialized resources with fewer attractive alternative uses. In many areas, small farms that are unviable without tobacco profits would cease production and their land would be absorbed into larger neighboring farms or converted to other uses * * * In marginal farming areas * * * much of the land devoted to tobacco would be converted to residential, commercial, industrial, or forestry uses, in which case it would still generate income for the local economy * * * This land is already being converted to nonfarm uses in rapidly growing areas like southern Maryland and Raleigh-Durham, North Carolina.[350]

FDA notes that the economic consequences of these trends will be substantially mitigated by the very moderate pace of the projected changes.

3. Vending Machine Operators

The final regulation prohibits all vending machine sales of regulated tobacco products except for those machines located in a facility where

[347] Gale, F., "What Tobacco Farming Means to Local Economics," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 5, September 1994.

[348] Warner, K. E., G. A. Fulton, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, pp. 1241–1246, April 24, 1996.

[349] Gale, F., "What Tobacco Farming Means to Local Economies," USDA, Economic Research Service, Agriculture Economic Report Number 64, p. 1, September 1994.

[350] *Id.*, p. iii.

persons under the age of 18 are not present at any time. In recent years, cigarette vending sales have dropped precipitously, due to numerous restrictive State and local ordinances. According to the NAMA:

[t]he 1986 cigarette location survey mirrored an industry with about 700,000 cigarette vending machines on location. In 1994, the vending industry was estimated to have between 141,000 and 400,000 cigarette machines. This represents a decline in the number of cigarette vending machines on location of between 43 percent and 80 percent.

The U.S. Department of Commerce [351] reports that 1992 sales of tobacco products by automatic merchandising machine operators were about $452 million, or 7.1 percent of that sector's total sales, but a NAMA fact sheet shows this rate continuing to fall, dropping from 8.5 percent in 1990 to 2.7 percent in 1994. One trade magazine explains that, "[c]igarette vending, once an industry mainstay, is now a niche business increasingly conducted by specialized enterprises." [352]

Referring to 1992 Census data, NAMA declared that over 3,000 vending machine operators supply cigarettes, not including the bars, restaurants, hotels, and bowling alleys that own their own machines. On average, these mostly small firms receive 10 percent of their revenues from cigarette sales, although some firms are even more dependent. While some vending machines can be converted to sell other products, one large cigarette machine manufacturer maintained that more than 85 percent of the existing machines can be converted only for new products with packaging similar in dimension and form to cigarette packages.

While vending operators will need to develop new markets to replace the already dwindling sales revenues from cigarette vending machines, the overall economic impact will be mitigated somewhat by FDA's decision to exempt "adult only" locations from the ban. According to a 1995 NAMA survey, 58 percent of cigarette vending machines are located in bars and cocktail lounges, 11 percent in factory/plant locations, and 3 percent in business offices. [353] Those locations that do not permit the entry of youngsters under the age of 18 will be exempted from the cigarette vending machine restriction.

4. Advertising Sector

In annual reports to FTC, manufacturers of cigarettes and smokeless tobacco reported 1993 advertising and promotional/marketing expenditures of $6.0 billion and $119 million, respectively (see Table 14). About $2.6 billion (43 percent) of these outlays went 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 remaining $1.9 billion (31 percent) were related to consumer advertising activities that will be significantly modified by the "text only" restrictions.

TABLE 14.—TOBACCO ADVERTISING/PROMOTIONAL EXPENDITURES 1993 (Millions of Dollars)[1]

Promotion Type	Cigarettes	Smokeless	Total
Coupons/Value Added	2,559	32	2,591
Promotional Allowances	1,558	13	1,571
Point of Sale	401	13	414
Specialties Items	756	4	760
Outdoor	231	1	232
Magazines	235	7	242
Public Entertainment	84	23	107
Free Samples	40	16	56
Transit	39	0	39
Newspapers	36	1	37
Direct Mail	31	1	32
Endorsements	0	0	0
All Others	64	7	71
Total	**6,035**	**119**	**6,154**

[1] Totals may not add due to rounding.
Source: U.S. Federal Trade Commission

FDA cannot project the ultimate industry response to these advertising restrictions. On the one hand, the effectiveness of many advertisements will fall. On the other hand, many alternative marketing promotional activities will be prohibited or constrained even more stringently, raising the relative desirability of the remaining advertising options. Moreover, as described above, FDA may require new informational programs that would generate a substantial increase in advertising industry revenues. Nevertheless, if tobacco outlays fall, there will be short-term dislocations as industry resources are redirected to other uses. One firm that depends heavily on tobacco advertising warned of severe economic burdens, pointing to income and job losses for many of its employees and suppliers. Most advertising suppliers, however, are not overly specialized with respect to particular consumer products and would redirect resources to other advertising purchasers, albeit at some revenue loss. While FDA is aware that such demand shifts cause short-term disruption, the U.S. economy creates and discards thousands of products each day. For most advertising media, the ability to respond rapidly to

[351] U.S. Department of Commerce, "Merchandise Line Sales," *1992 Census of Retail Trade*, RC92-S-3RV, pp. 3-27, 3-31.

[352] *Vending Times*, Census of the Industry Issue, p. 36-D, 1995.

[353] National Automatic Merchandising Association, Cigarette Vending Machine Location Study, conducted August 31, 1995.

changing markets is a mainstay of economic survival.

a. *Print media.* The final regulation requires that advertising of cigarettes or smokeless tobacco be restricted to black text on a white background in those publications where youthful readers constitute more than 15 percent of total readership or number more than 2 million. FDA cannot reasonably forecast the future marketing strategies of tobacco manufacturers, but foresees a possible fall in the $242 million worth of magazine advertising and the $37 million worth of newspaper advertising that tobacco manufacturers reported to the FTC in 1993. These advertising revenues comprised about 1.1 percent and 0.1 percent of the 1992 value of shipments for periodicals and newspapers, respectively.[354] The Barents Group identified 32 leading magazines with tobacco advertising in 1994 that have youth readership levels exceeding the regulatory threshold and found that these publications received, on average, 7.3 percent of their total advertising revenues from tobacco in 1994. They also predicted, based on the sharp downward trend of these advertising outlays, a 21-percent drop in magazine advertising and a 45-percent drop in newspaper advertising for tobacco products by 1996, irrespective of the FDA regulation.

The impact of these restrictions on the various advertising media and agencies is difficult to determine. The Barents Group contended that FDA had argued in its original analysis that "regulations for print media will have little or no adverse impact." In fact, FDA made no such projection, although the agency did present several historical examples of advertising bans (e.g., the broadcast ban on tobacco products) where advertising revenues rebounded in spite of new legal restrictions. The Barents Group also faulted FDA for not comparing actual revenues after the broadcast ban to revenues "that *would have* been expected in the absence of the ban." FDA, however, does not believe that this "counter factual" logic for estimating costs precludes the agency from suggesting that income and employment would not necessarily fall in the wake of new advertising restrictions.

Several comments declared that advertising outlays would fall sharply and subscription prices rise. According to the Barents Group, imagery is a prerequisite for effective promotion and, in its absence, magazine and newspaper advertising revenues would fall by 25 to 75 percent. It also predicted that the reduced revenues would, in turn, force publication subscription prices to rise.

FDA agrees that there will be adverse impacts on certain publications, but notes that the tobacco industry is currently shifting its advertising budget away from print media and that only 6 of the 32 affected magazines identified by the Barents Group received over 10 percent of their revenues from tobacco products. Moreover, as noted earlier, while FDA cannot project the tobacco industry's marketing strategies, the agency suggests that restricted promotion alternatives could reestablish print advertising as a relatively attractive option for conveying product information to adult readers; thereby slowing or even reversing the recent slide in this type of tobacco advertising.

The Barents Group also asserted that the commercial printing industry, as well as other industry sectors, would be harmed by restrictions on coupons and "retail value added" promotions. These expenditures, which account for $2.6 billion, or 42 percent of the total tobacco advertising and promotional outlays reported to FTC in 1993, include outlays associated with cents-off coupons and multiple pack promotions, such as "buy one, get one free" or "buy two, get one free;" as well as other give-away promotions, such as "buy cigarettes and get a free promotional item." The former activity will be permitted but the latter prohibited under the final regulation. Although a comment submitted by the Tobacco Institute noted that, "[a]nalytically, such spending is more akin to a price cut than to advertising,"[355] the Barents Group, nonetheless, concluded that, "[a] considerable part of this spending would likely be eliminated by the proposed regulations." FDA, however, does not agree that the printing industry will be significantly affected by changes in "coupons and value added" outlays. Cents-off coupons and multiple pack promotions are the principal components of these promotions and will continue to be available under the final rule.

b. *Advertising agencies and other suppliers.* Advertising agency revenues are directly tied to the level of advertising expenditures by product manufacturers. If tobacco manufacturers reduce advertising outlays, these agencies will lose income. The Barents Group found that, in 1993, tobacco companies routed almost $1 billion through ad agencies (less than 1 percent of the reported $131.3 billion spent on U.S. media advertising in 1992).[356] Assuming agency fees of 10 percent (while overlooking the proposed $150 million educational campaign), it suggested that advertising declines of 25 to 75 percent would decrease agency annual revenues by $25 million to $77 million. Assuming a 50 percent drop ($140 million) in magazine and newspaper advertising, the Barents Group next applied a simulation model to predict that supplier firms among advertising agencies, government, business and professional services, and commercial printers businesses would lose revenues of from $12 to $23 million. While acknowledging that, "* * * there will be eventual offsetting revenue gains in other industries not shown * * *," these other sectors were not identified and the offsetting revenues not explicitly quantified. The Barents Group correctly noted that the adjustments will involve short-term costs to the affected sectors, but did not estimate the expected magnitude of these adjustment costs.

c. *Outdoor advertising industry and public transit authorities.* The final rule restricts tobacco billboards and public transit advertising to black text on a white background and bans all stationary outdoor tobacco ads within a 1,000-foot radius of any school or public playground. The Barents Group predicted that almost all urban areas would be covered by the ban and expected almost no new outdoor tobacco advertising "even in permitted areas due to the relative ineffectiveness of black-and-white text as an advertising medium." Further, explaining that the $232 million spent on outdoor advertising in 1993 accounts for about 14 percent of all outdoor advertising in the United States, the Barents Group found it unlikely that the industry could find new means of maintaining its current revenues.

In fact, the billboard industry and public transit districts will have to find replacements irrespective of this regulation. According to the Barents Group projections, spending on outdoor advertising by tobacco companies will fall by almost 40 percent between 1988 and 1996 (Appendix Table). One billboard trade source notes that, "almost 60 percent of the industry's 1979 revenues were derived from

[354] *Statistical Abstract of the United States*, p. 750, 1995.

[355] Beales, J. H., "Advertising and the Determinants of Teenage Smoking Behavior," vol. 44, p. 13, 1993.

[356] Endicott, R. C., "Top Advertisers Rebound, Spending to $36 Billion," *Advertising Age*, vol. 64, No. 41, p. 1, September 29, 1993.

tobacco and alcohol advertisers. Today that number is down to 13 percent, replaced by retail, business and consumer services, entertainment, and travel advertisers."[357] Similarly, FDA's preliminary economic analysis had recognized that Canada's billboard industry had rapidly adjusted to a recently imposed advertising ban and "quickly replaced $20 million in lost cigarette revenues with ads for food, soap, toothpaste and beer."[358]

In 1993, tobacco industry spending on public transit ads ($39.1 million) contributed less than 1 percent to total public transit revenues, having declined by 35 percent from 1990 to 1993. Acknowledging that these expenditures would continue to fall, irrespective of this rule, the Barents Group argued that since relatively few transit authorities accept tobacco ads, the impact of the regulation would be significant for those few.

d. *Specialty item suppliers.* The prohibition of nontobacco specialty items bearing the name or logo of tobacco products will affect a substantial number of specialty manufacturers. In earlier comments to FTC,[359] the Specialty Advertising Association International noted that it "represents 4,400 firms that manufacture or sell utilitarian objects imprinted with advertising * * * predominantly small businesses." 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.

The Barents Group projected that manufacturer outlays for these promotional items, in the absence of the FDA rule, would triple between 1993 and 1996, rising from $760 million to $2.2 billion, assumed that the rule would cause revenue decreases of 25 to 75 percent, and modeled the impacts among other affected industry sectors (e.g., miscellaneous manufacturers producing matches and matchbooks, cigarette lighters, pens and pencils, sporting goods, etc.). The revenue and employment losses, therefore, were measured from a baseline that assumed a tripling of future industry revenues. While these growth projections may be optimistic, they demonstrate the rapid swings that typify the market for many of these industries. Indeed, the Barents Group's forecasts imply that even if the FDA rule were to reduce the 1996 level of tobacco industry advertising on specialty items by 50 percent, these outlays would still exceed the 1995 level.

In any case, FDA believes that the Barents Group's forecasted impacts may be overestimated, as they primarily reflect static outcomes, whereas firms supplying such products are constantly adjusting production in response to rapidly shifting patterns of demand. While these regulatory changes will impose short-term dislocation costs, these costs will be significantly mitigated in view of the extensive lead time provided. Again, the Barents Group noted that FDA had not quantified these transitory costs, but it also provided no estimate.

e. *Sponsorship recipients.* According to reports submitted to FTC, U.S. tobacco companies spent $107 million on public entertainment, primarily sporting events, in 1993.[360] In comparison, total spending on corporate sponsorships for sports, arts, and other entertainment by all North American companies is estimated to reach $5.4 billion in 1996.[361] FDA received numerous public comments asserting that the loss of sponsorship revenues for sporting events would increase ticket prices and, in turn, reduce spectator attendance. In particular, comments pointed to the potential loss of jobs, employee benefits, and business revenues associated with race track events.

The Barents Group contended that a substantial part of the payments made by tobacco manufacturers would be eliminated by a ban on tobacco brand sponsorships, because few sponsors would agree to continue sponsorships under corporate names. Acknowledging the lack of reliable information on economic impacts; it, nonetheless, referenced several studies showing that lost sponsorship dollars decrease revenues and temporary jobs for local economies. The Barents Group predicted that, as tobacco companies eliminate payments, other advertisers would replace the major sponsorships, but leave reduced or no funding for the less popular events. On this basis, it projected a 25 to 75 percent reduction in sponsorship dollars, calculated to result in revenue losses of $27 to $80 million.

Among the affected U.S. sporting events, the auto racing industry receives the greatest amount of tobacco sponsorship revenues. The Barents Group relied on various editions of the *IEG Intelligence Reports* (IEG) to list these sponsorships. In reviewing the IEG data and other sources, FDA found that about $29 million worth of 1995 tobacco sponsorship revenues were designated for the National Association for Stock Car Auto Racing (NASCAR);[362] which amounted to about 8.3 percent of estimated NASCAR sponsorship revenues[363] and about 1.4 percent of estimated NASCAR total revenues.[364] The IEG data listed Indy Car tobacco sponsorships totaling only about $13 million, although these data did not cover all events.

As the majority of the NASCAR tobacco sponsorship revenues were directed to the Winston Cup or other lead series, FDA agrees that a major effect of the ban will be to decrease the price of sponsorships, permitting smaller sponsors to "trade up" to the more prestigious sponsorships left vacant by tobacco companies. Although new company sponsors will be attracted by the lower overall sponsorship costs, this "ripple effect" will impose shortfalls for some smaller or lower profile events. This economic impact will be somewhat mitigated, however, by the rapid growth in nontobacco sponsorships. According to IEG estimates, over the past year, motorsport sponsorship spending rose by about 17 percent[365] and total North American corporate sponsorship spending by about 15 percent.[366]

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[357] Burns, K., "Driving Into the Future with New Technology," *Outdoor Advertising Magazine*, p. 5, January/February 1995.

[358] Wolfson, A., "Canada's Ad Ban Puts Cigarettes Out of Sight," *The Courier-Journal*, pp. A1, A4, August 1, 1994.

[359] 56 FR 11661 (March 20, 1991).

[360] Federal Trade Commission Report to Congress for 1993: Pursuant to the Federal Cigarette Labeling and Advertising Act, p. 18, 1995; Federal Trade Commission Report to Congress: Pursuant to the Comprehensive Smokeless Tobacco Health Education Act of 1986, p. 24, 1995.

[361] EPM Communications, Inc. "Entertainment Marketing Letter," February 1, 1996. Based on IEG Sponsorship Report.

[362] 1995 IEG Intelligence Report lists $26.7 million in tobacco sponsorships of NASCAR. Two tobacco-sponsored events did not list the sponsorship fees, which FDA estimates at about $1 million apiece.

[363] Koenig, B., "NASCAR takes Lead in Race for Sponsors: Stock-car Racing Gains Corporate Funds as CART and IRL Lag in Money and Ratings", *The Indianapolis Star*, March 8, 1996, *Business* p. F01.; MacCrae, M., "Ricky Craven Collectibles Boost Intensive Fan Interest in Driver", *Bangor Daily News*, May 2, 1996.

[364] Oliver, S., "A Fan-Friendly Sport," *Forbes*, p. 70, July 3, 1995; Horovitz, B., "Fine-Tuning an Image-New Sponsors Race to NASCAR," *USA Today*, Final Edition, p. 1B, April 5, 1996.

[365] MacCrae, M., "Ricky Craven Collectibles Boost Intensive Fan Interest in Driver," *Bangor Daily News*, May 2, 1996.

[366] *IEG's Complete Guide to Sponsorship*, p. 3, 1995.

5. Retail Sector

In addition to incurring the economic costs described earlier, certain segments of the retail industry will experience adverse distributional impacts to the extent that they receive smaller promotional allowances (slotting fees) from manufacturers. In 1993, industry promotional allowances totaled $1.6 billion dollars. According to FTC:

Promotional allowances are designed to encourage wholesalers and retailers to stock and promote a company's products, including such things as trade allowances and slotting allowances. Trade allowances provide deals to cigarette wholesalers, dealers and merchants in the form of free goods or price reductions in return for the purchase of specific quantities of goods. Slotting allowances include fees that the cigarette manufacturers pay retailers to encourage them to carry a new product or to allocate premium shelf space to a product. Trade contests and incentives, training programs, and trade shows may also be counted as promotional allowances.

One major convenience store association, estimating that its members currently receive about $5,000 per store, remarked that convenience stores would "bear a disproportionate burden should such allowances be eliminated as a result of the ban on self-service displays." Other retailers expressed similar concerns over the prohibition of self-service displays and promotional advertising, fearing it would lead to the elimination of these revenues.

The Barents Group argued that there were strong reasons to believe that promotional allowances would fall sharply as "tobacco products are withdrawn to inaccessible areas of the store, [and] the products taking their place will offer lower allowances." While acknowledging that, "[t]he possibility of promotional payments continuing may depend on whether the proposed regulations would allow the tobacco packages and cartons to be displayed from behind the check-out counter or from some other secured location in the stores," they nonetheless presented "illustrative" revenue reductions of from 25 to 50 percent and projected total revenue losses to the retail sector of $556 to $1,112 million. Using the higher percentage, their analysis implies that pretax profit margins would fall 12.4 percent for the average sized convenience store and even more for smaller stores. Moreover, they predicted that about 2 percent of currently profitable convenience stores would thereafter incur losses.

FDA suspects that many of these concerns are unwarranted as tobacco manufacturers will continue to place significant value on having their products situated in highly visible locations. Although desirable locations behind counters or in locked display cases will be more limited, there is little reason to believe that manufacturers would stop competing for the best display space available. One comment indicated that following a self-service ban in a local area of Northern California, some retailers:

* * * reported losses of tobacco industry-paid slotting fees * * * because of the removal of self-service promotional tobacco displays, racks and kiosks; * * * other retailers reported they did not loose [sic] tobacco industry-paid slotting fees if tobacco displays, racks or kiosks are relocated behind the counter or if they are replaced by locking cases * * * [There were] no reported losses of other tobacco industry-paid advertising fees, promotional allowances or other financial incentives paid to retailers for advertising, promoting and marketing tobacco products in their stores. [367]

Because of the regional aspects of this ban, it was a "worst case" situation for retail stores. If self-service displays were a prerequisite for promotional allowances, tobacco manufacturers would have quickly transferred them to other near-by localities, where self-service was permitted. The fact that this did not generally occur demonstrates that factors other than self-service displays can support manufacturer promotional payments to retailers.

Another comment noted that, "[i]n at least some areas, cigarette companies have continued payments to retailers for favored display space. For instance, Philip Morris has provided clear, plastic cases for the display of cigarette packs and cartons in some stores. These cases are placed on a checkout counter but only accessed from the clerk's side. This arrangement permits prominent display of cigarette packs to customers who are thereby offered cigarettes at close range while being unable to pick up packs or cartons themselves." In discussing the effects of the Canadian advertising ban, a Canadian study [368] suggested 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." Moreover, because FDA has not banned all point-of-purchase tobacco advertising, "text only" advertising at retail stores will be extremely important to tobacco product marketers.

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." [369] That same Northern California study expressly noted the "[r]eplacement of self-service tobacco displays, racks and kiosks with * * * non-tobacco products such as candy, gum and soft drinks for which the retailer receives slotting fees from the manufacturers of these products." [370]

In sum, FDA cannot predict with certainty the direction of future payments by product manufacturers to retailers. The agency points out, however, that this rule would affect neither the trade allowances that are commonly paid to both wholesalers and retailers, nor the slotting allowances paid to retailers to encourage them to carry a new product or to assure the availability of a particular brand in a retail outlet. Further, while many current promotional activities will be prohibited, a substantial number will remain available. As the competitive pressures that drive promotional allowances are unlikely to abate, manufacturers will continue to compete vigorously through programs involving both "text only" promotions and select product placements.

6. Other Private Sectors

FDA is aware of several recent studies that address the contribution of tobacco to the U.S. economy; or alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related expenditures. The Tobacco Institute's Price Waterhouse report [371] purports to measure the induced effect on the national economy of spending by the tobacco core and supplier sector employees and their families. That

[367] 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, Stop Tobacco Access for Minors Program (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[368] "When Packages Can't Speak: Possible impacts of plain and generic packaging of tobacco products," Expert Panel Report, Prepared at the request of Health Canada, p. 140, March 1995.

[369] "P-O-P Scores with Marketers," *Advertising Age*, p. 2, September 26, 1994.

[370] 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, Stop Tobacco Access for Minors Project (STAMP), Petaluma, CA, pp. 2–3, November 3, 1994.

[371] "The Economic Impact of the Tobacco Industry on the United States in 1990," Price Waterhouse, October 1992.

report concluded that the induced or multiplier effects support 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, a review of that report, by Arthur Andersen Economic Consulting, explained that such multipliers lead to "massive and unrealistic estimates." [372] That review further emphasized that "money now being spent on tobacco would not disappear if demand for tobacco were to fall," though the Price Waterhouse report implicitly made that assumption. The Arthur Andersen review concluded that these multipliers "provide no basis by themselves for predicting how many jobs would be lost by a reduction in tobacco spending." FDA strongly supports this latter view.

The American Economics Group (AEG), in a new study submitted by the Tobacco Institute, employed a national input-output model to project broad sectoral and regional estimates of "the induced impact of the FDA proposed regulations nationwide." Applying the low and high illustrative costs estimated by the Barents Group, AEG predicted job losses of between 32,000 and 92,500. In addition to the printing and publishing industries, significant employment cutbacks were found for food, apparel and textiles, paper, metals, motor vehicles, and other miscellaneous manufacturers.

FDA is skeptical of the results of this AEG study. First, the input-output methodology employs an inherently static approach for estimating economic impacts. Indeed, the Barents Group, in its second report for the Tobacco Institute, explained that input-output models will not capture changing economic conditions, because they fail to account for changing market prices. Thus, "the input-output approach fails to measure the effects of reallocating displaced workers and resources to other parts of the economy." Furthermore, the AEG study suffers from the same fundamental problem as the earlier Price Waterhouse analysis: It assumes that all reduced industry revenues are lost to the economy. This methodology is simply inappropriate. Finally, the AEG study is based upon the illustrative cost estimates of the Barents Group. As described in detail above, these cost estimates are unreasonably high. Although some tobacco advertising may decrease, a significant portion will be redirected towards the remaining permissible promotional activities.

In a second report, the Barents Group presented the results of using its own cost estimates in a general equilibrium model to simulate the impacts of the estimated reductions in advertising and promotional spending on revenue and employment for 56 sectors of the U.S. economy. This model predicted 21,000 to 44,000 U.S. job losses, largely among wholesale and retail businesses, but also within advertising, printing, apparel and miscellaneous manufacturing industries. FDA finds, however, that this study also is subject to several serious deficiencies. In particular, the Barents Group relies on its own illustrative cost estimates as model inputs. As noted above, FDA believes these estimates are far too high. Next, the study focuses solely on those industry sectors predicted to lose jobs, while ignoring those sectors expected to gain jobs. In fact, the study explicitly acknowledges that the underlying model assumes that:

> the aggregate level of employment is not changed in the long run as a result of implementing the new regulations. In other words, though particular jobs in particular industries are expected to disappear permanently, the number of man-hours worked per year in the economy as a whole is assumed not to change in the long run
> * * *

The Barents Group selectively shows changes in revenue and employment for the losers only.

Other analysts concluded that such models should not be used to assess longer term national economic impacts, because resources diverted from one use would be reallocated to the production of other goods and services. As one economist explained "[i]f the focus is longer term, involving a period of, say, more than 2 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." [373]

Some comments addressed regional issues, pointing to the importance of tobacco products to the economies of several states. Comments noted, for example, that about 177,000 North Carolinians were employed by tobacco and that Price Waterhouse estimated that the economic activity of these workers supported total State employment of 260,000. FDA is aware that tobacco growing states will experience some adverse economic effects. Nevertheless, as discussed above, the agency finds that the income and employment impacts associated with reduced tobacco consumption will be extremely gradual. Moreover, reduced tobacco consumption will minimally affect or even boost the economies of nontobacco states. For example, a recent economic simulation of the regional impacts of spending on tobacco products by Warner, et al., found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment); whereas the nontobacco regions of the United States would gain 56,300 jobs. [374] That study concluded that "[t]he primary concern about tobacco should be the enormity of its toll on health and not its impact on employment."

7. Excise Tax Revenues

The rule will decrease State and Federal tobacco tax revenues as fewer youths will become addicted to tobacco products. These excise tax losses will increase as more youths become nonsmoking adults. According to the Tobacco Institute, State cigarette excise taxes totaled $6.2 billion for the year ending June 30, 1993. [375] As State excise taxes on other tobacco products (including smokeless tobacco) are reported at $226 million, FDA assumes that the value of all State excise taxes affected by this regulation is about $6.4 billion annually. Federal excise taxes on cigarettes totaled $5.5 billion for the year ending June 30, 1993. Federal excise taxes on smokeless tobacco are expected to be about $27 million, according to the Smokeless Tobacco Council. As described above, FDA estimates that compliance will reduce tobacco product sales by a gradually increasing rate over time; tobacco sales will fall by 0.5 percent in the 1st year, 1.9 percent in the 5th year, and 3.7 percent in the 10th year. Thus, the rule will decrease State excise taxes on affected tobacco products by from $30 million in the 1st year to $231 million in the 10th year and Federal tobacco

[372] "A Review of the Price Waterhouse Economic Impact Report and Tobacco Institute Estimates of 'Economic Losses from Increasing the Federal Excise Tax'," Arthur Andersen Economic Consulting, p. 93, October 6, 1993.

[373] Gray, H. P., and I. Walter, "The Economic Contribution of the Tobacco Industry," in *Smoking and Society: Toward a More Balanced Assessment*, edited by R. D. Tollison, Lexington Books, p. 248, 1986.

[374] Warner, K. E., G. A. Fulton, P. Nicolas, and D. R. Grimes, "Employment Implications of Declining Tobacco Product Sales for the Regional Economies of the United States," *JAMA*, April 24, 1996.

[375] The Tobacco Institute, "The Tax Burden on Tobacco," vol. 28, p. 4, 1993.

taxes by from $25 million in the 1st year to $196 million in the 10th year.

Since tobacco taxes represented less than 1 percent of total revenues on both the State and Federal level in 1992,[376] even the estimated tenth year impact measures only 0.03 percent of all State tax revenues and less than 0.02 percent of all Federal revenues. Nonetheless, if necessary, governments could raise tobacco product excise rates to offset these revenue losses. A full evaluation of the fiscal consequences, however, would involve a variety of public health ramifications. For example, State Medicaid programs will benefit from reduced tobacco-related medical care expenditures, but will need to finance additional nursing home expenditures associated with increased life expectancy.

F. Small Business Impacts

The Regulatory Flexibility Act requires agencies to prepare a final regulatory flexibility analysis if a rule will have a significant economic impact on a substantial number of small entities. Analyses in this section, as well as in other sections of this preamble, constitute the agency's compliance with this requirement. According to the Regulatory Flexibility Act, the final regulatory flexibility analysis must contain "a succinct statement of the need for, and objectives of, the rule." Section XV.B. of this document explains that the need for action stems from the enormous toll on the public health that is directly attributable to the consumption of tobacco by children and adolescents under the age of 18. As described, the primary objective of the regulation is to achieve the "Healthy People 2000" goal of reducing by one-half the number of youngsters who use tobacco.

The final regulatory flexibility analysis must also provide "a summary of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments." The analyses presented previously in this section addressed the first two of these elements.

With respect to the changes made in the proposed rule as a result of public comments, the agency has reconsidered several of its earlier decisions, at least partly due to their projected effect on small businesses. The preamble above describes these changes and presents the agency's rationale for each modification. For example, the proposed regulation banned all vending machine sales of tobacco products. In response to public comment, the final regulation exempts from the ban those vending machines in "adult only" locations. FDA does not know how many small businesses will be able to take advantage of this exemption, but it will maintain at least one line of sales for small vending machine operators without jeopardizing the protection of young people.

In addition, the proposed regulation prohibited direct mail-order sales of tobacco products. The public comments, however, indicated that many adults, especially those who are elderly or who have limited mobility, would be substantially inconvenienced and several small businesses would be adversely affected by this ban. Even more importantly, studies suggest that teenagers purchase cigarettes from vending machines or retail merchants rather than from nonretail channels. FDA took these considerations into account and the final regulation does not prohibit mail-order sales of cigarettes.

The final regulatory flexibility analysis must also include "a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available." U.S. Census data for 1993 indicate that most cigarette manufacturers are large businesses, with only 4 employing fewer than 500 employees.[377] The small business size standard established by the U.S. Small Business Administration (SBA) for this industry is 1,000 employees.[378] The Federal Trade Commission (FTC) provided a list of 52 cigarette importers and small cigarette manufacturers filing plans with that agency, but could not distinguish manufacturers from importers.[379] The 1993 Census data show that 14 of the 20 firms manufacturing chewing and smoking tobacco employ fewer than 500 employees, the SBA size standard for this sector.[380] Also, most of the nation's 124,000 tobacco farms are small; almost 99 percent of the farms growing tobacco in 1992 had total farm sales under the SBA small business size standard of $500,000, and almost 91 percent had total farm sales under $50,000.[381] Further, 1993 Census data show that 1,332 of 1,365 tobacco wholesale trade firms (98 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA.[382] As noted above, the effect of the regulation on tobacco manufacturing, growing, and wholesale trade operations will be very gradual, taking over 10 years to reach a 4 percent reduction.

The regulation will affect numerous retail establishments, including food stores, small general merchandise stores, small tobacco stores and small gasoline stations. Table 15 displays the relative share of the tobacco market for the major types of tobacco-dispensing outlets with payroll in 1992. As shown, food stores and service stations received about 75 percent of all tobacco sales revenue and tobacco products comprised 5 to 7 percent of the total sales of many of these establishments. Table 16 indicates that the great majority of all retail outlets in these sectors are small businesses.

[376] U.S. Department of Commerce, *Statistical Abstract of the United States 1994*, 114th edition, No. 464, p. 298, 1994.

[377] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 68.

[378] U.S. Small Business Administration, "Table of Size Standards," March 1, 1996.

[379] Federal Trade Commission, "Cigarette Importers and Small Manufacturers Plans Filed, May 26, 1993–October 14, 1994."

[380] Special Census Tabulation prepared by U.S. Bureau of Census for U.S. Small Business Administration, Table 3—United States p. 69.

[381] 1992 Census of Agriculture, U.S., vol. 1, excerpts from pp. 109–110, 125–126.

[382] Special Census Tabulation prepared by U. S. Bureau of Census for U.S. Small Business Administration, Table 3—United States.

TABLE 15.—SALES OF TOBACCO PRODUCTS AS A PERCENTAGE OF TOTAL SALES—1992
(Establishments with Payroll Only)

Establishment Type	Tobacco Sales		% of Total Sales	
	($ Mils)	(%)	Establishments Handling Tobacco	All Establishments
All	30,559	100	4.5	2.9
Food Stores	16,132	52	4.5	4.4
Service Stations	7,136	23	7.1	5.3
Drug and Proprietary	2,235	7	3.7	2.9
General Merchandise	3,182	10	2.4	1.3
Liquor Stores	1,045	3	8.0	5.1
Eating and Drinking	219	1	3.0	0.1
Tobacco Stores & Stands	610	2	78.1	78.1

Source: 1992 Census of Retail Trade, Merchandise Line Sales

TABLE 16.—NUMBER OF SMALL RETAIL BUSINESSES

Establishment Type	Firms With Payroll		Establishments Without Payroll
	Total	Small[1]	
All	588,505	473,668	275,432
Food Stores	127,575	104,541[2]	97,061
Service Stations	62,585	53,288[3]	14,248
Drug and Proprietary	28,606	25,396	3,031
General Merchandise	10,264	8,176	28,010
Liquor Stores	26,565	22,859	8,811
Eating and Drinking	331,703	258,381	124,271
Tobacco Stores & Stands	1,207	1,027	n.a.

[1] Assumes Small Business Administration size standard of $20 million in annual sales for food stores, $6.5 million for service stations and $5 million for all others.
[2] Due to data limitations, includes firms with annual sales up to $25 million.
[3] Due to data limitations, includes firms with annual sales up to $10 million.
Source: 1992 Census of Retail Trade, Establishment and Firm Size, 1992 Census of Retail Trade, Summary.

To illustrate the effects of this proposal on a typical small retail store, FDA separately utilized Census data to estimate that the average-sized convenience store sells 177 packages of tobacco products daily, of which about 25 might be purchased by young adults aged 18 to 26.[383] Based on the cost assumptions described previously, the outlet's first year costs would total about $400, with the largest single cost, $199, 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 $137.

This estimate does not account for the possible reduction in promotional allowances, as FDA believes that competitive pressures will continue to lead manufacturers to rely on promotional allowances to compete for the best shelf space available for their products. Because FDA rejected the idea of prohibiting any visible display of tobacco products, retailers can retain slotting fees by choosing to display tobacco products either behind counters or in transparent locked display cases. Nevertheless, some small establishments might experience reduced promotional payments following a ban on self-service marketing.

Census data for 1992 indicate that almost 4,000 of 4,800 merchandising machine operator businesses (83 percent) reported annual receipts below the SBA size standard of $5 million.[384] One trade association noted that almost three quarters of all vending machine operators had annual sales of less than $1 million.[385] As explained earlier, prohibiting all cigarette vending machines would initially reduce the revenues of vending machine operators by an average of 2.8 percent. Because only about one-half of the merchandising machine establishments sell cigarettes, some businesses specializing in cigarette sales would experience greater revenue declines; although this effect will be moderated to the extent that cigarette vending machines are placed in areas restricted to adults, which would not be prohibited by the final rule.

The rule would also affect the distribution of specialty items showing a tobacco product logo or name. Industry comments do not provide precise data on the size distribution of these firms, but as noted above, the Specialty Advertising Association International indicates that 80 percent of the manufacturers and 95 percent of the distributors in this industry have annual sales below $2 million. While the marketplace in which these firms traditionally compete demands a quick response to shifting consumer trends, this rule would have at least short-term impact on some small firms.

FDA has received no data that would allow it to estimate the number of small firms that are currently involved with some aspect of tobacco advertising or the fraction of these firms that will be affected. In 1992, 861 of 904 year-round outdoor advertising firms (95 percent) reported sales revenues of less than the SBA size standard of $5 million.[386] The impact of this rule, however, is difficult to assess without knowing how the tobacco industry will alter its advertising strategies. Indeed, one of the largest outdoor advertising firms recently decided to reject all tobacco business, potentially increasing sales to the smaller firms.[387]

The regulation restricts tobacco advertising to "text only" in magazines with youth readership above the regulatory threshold. Of the identified 101 magazines with tobacco ads in 1994, 79 were published by large firms (over 500 employees). Less than 3 percent of the total revenue of the remaining 22 publications (which include, Inc., Rolling Stone and Penthouse) was derived from tobacco ads.[388] It is likely, moreover, that many of these magazines could avoid the "text only" restriction for tobacco advertising by demonstrating a low youth readership.

The regulation will also affect a substantial number of small race tracks, although FDA does not know how many small tracks currently receive significant revenues from tobacco sponsors. As discussed previously, some small operations will likely lose promotional revenues from tobacco companies, but the sport is growing rapidly and other product manufacturers should make up a substantial part of the shortfall.

The final regulatory flexibility analysis must include "a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record." A full description of the requirements and classes of affected small entities has been provided earlier in this section and a quantitative review of the paperwork burdens imposed by the rule is provided in section XVI. of this document. No special professional skills will be required to prepare the reports or records required by the regulation.

The final regulatory flexibility analysis must also include "a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected."

The earlier sections of this document provide a full explanation of the agency's basis for selecting each provision of the final rule. In each instance, FDA evaluated the implications of each reasonable regulatory alternative and selected only those requirements that were absolutely necessary to satisfy the agency's statutory goals. As described, FDA found that its objectives for reducing the use of tobacco by young people could not be achieved with a partial or one-dimensional approach, but required a comprehensive set of regulatory restrictions. Thus, the final set of selected provisions reflect a careful examination of the relevant facts presented to the rulemaking record, the agency's objective of curtailing the use of tobacco by youngsters without creating unnecessary economic burdens, and a full assessment of the agency's legal authorities. Because the rejected alternatives would either provide less protection of public health, or achieve

[383] Based on data form the 1994 SGR, p. 85, and the "Tobacco Situation and Outlook Report" April, 1995, p. 4, FDA estimates that smokers aged 18 to 26 account for about 10 percent of all cigarettes smoked. Alternatively, data from the Statistical Abstract, tables 16 and 218, show that smokers aged 18 to 26 comprise 18 percent of all smokers. FDA used the midpoint of the 10 to 18 percent range to avoid underestimating the cost to small retailers. In addition, data from the 1996 Census of Retail Trade, Subject Series-Merchandise Line Sales, pp. 3–9 on the number of convenience stores with payroll and their total tobacco sales, and the average price per pack, were used to estimate the average number of packs sold daily at convenience stores to smokers aged 18 to 26.

[384] 1992 Census of Retail Trade, "Establishment and Firm Size," Table 4 p. 1–99.

[385] "1993: Industry Posts Best Growth in Four Years," *Automatic Merchandiser*, p. A2, August 1994.

[386] 1992 Census of Service Industries, pp. 1-145 and 1-195.

[387] Collins, G., "Major Advertising Company to Bar Billboard Ads for Tobacco," *New York Times*, A15, May 3, 1996.

[388] *1996 Directory of Corporate Affiliations U.S. Private Companies*, New Providence, NJ; Reed Elsevier, Inc.; "Company Profiles" database, Information Access Co., Foster City, CA.

only minimal improvements at unwarranted cost, the agency found that the approach selected for the final rule best fit its statutory mandate.

As noted, earlier sections of the preamble fully describe the agency's rationale for selecting each provision of the final rule and for rejecting each alternative approach. Although many alternatives were considered, specific exemptions based solely on business size were not adopted, because FDA believes that children would too frequently exploit such opportunities. Unlike certain other regulations where restrictions on large firms alone might be acceptable, tobacco products are purchased easily from small, as well as large firms. An exemption for small retailers, for instance, would shift underage sales to those locations, lessening or eliminating the benefits of the remaining access restrictions. The following discussion summarizes the agency's consideration of several other regulatory alternatives.

G. Other Alternatives

One regulatory alternative would have banned all tobacco advertising; or alternatively, all tobacco advertising in selected media, such as all written publications, or all outdoor billboards. FDA rejected this approach in order to focus on those media and aspects of advertising that children are routinely exposed to and that have the greatest effect on youngsters. For example, the final rule permits black and white "text only" tobacco advertising in all written publications and color and imagery in magazines with fewer than 2 million youthful readers if youth constitute less than 15 percent of the publication's readership. Billboards are permitted to show black and white "text only" ads if located at least 1,000 feet from schools or public playgrounds. Thus, the rule leaves the informational aspects of advertising largely untouched.

Another suggested alternative was to combat underage tobacco use by relying on either voluntary compliance or on better enforcement of laws prohibiting sales to minors. As discussed earlier in this document, the tobacco industry's voluntary advertising code has failed to stop illegal sales to underage buyers. FDA agrees that these approaches can be partially effective, but finds that they inadequately counter the appeal of tobacco products for young people that is created by advertising and promotions. Thus, the agency concludes that there is no less burdensome alternative for achieving its goals that would exclude appropriately tailored restrictions on tobacco advertising.

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 were 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.

Another suggested alternative would have required package inserts containing educational information in cigarette and smokeless tobacco. FDA had incomplete data to estimate the additional cost of this requirement, but based on comments submitted by industry in response to a Canadian proposal, tentatively projected one-time costs of about $490 million and annual operating costs of about $54 million. This alternative was not selected because the agency was not certain that the benefits of this provision would justify the 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 and can easily purchase tobacco products for younger classmates. This alternative would have added costs of about $34 million annually, mostly due to lost producer profits. The final regulation restricts access to regulated tobacco products for persons under the age of 18, because most adult smokers have already become smokers by the age of 18, and because that age limit is already consistent with most State and local laws.

H. Unfunded Mandates Reform Act of 1995

On the basis of the preceding discussion, under the Unfunded Mandates Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives as discussed in section XV.G. of this document and determined that the current rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule.

XVI. Paperwork Reduction Act of 1995

The 1995 proposed rule would have collected information from manufacturers, distributors, and retailers of cigarettes and smokeless tobacco. Proposed § 897.24 would have required such persons to use established names for cigarettes and smokeless tobacco. Proposed § 897.29 would have required manufacturers to establish and maintain educational programs. Proposed § 897.32 would have required manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising. Proposed § 897.40 would have required manufacturers to submit labels, labeling, and advertising to FDA.

The preamble to the 1995 proposed rule, in discussing the Paperwork Reduction Act, also invited comments on four questions: (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 (60 FR 41314 at 41356).

A. Comments on the Paperwork Reduction Act Statement

A small number of comments, primarily from a trade association representing cigarette manufacturers and from distributors, addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA's figures were incorrect or that the rule would duplicate existing reporting requirements. Few comments provided any figures or evidence to justify using different estimates.

(1) One comment, submitted by a trade association representing major cigarette manufacturers, said FDA's Paperwork Reduction Act statement underestimated the paperwork burden due to the exclusion of burden on retailers. The comment asserted that FDA did not explain how it calculated the number of respondents and burden hours for these sections and that the absence of an explanation made it difficult to assess the agency's estimate.