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

D. Regulatory Costs

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

A critical variable underlying several of the cost estimates is the number of retail outlets that sell tobacco products. According to the Retail Trade Census, a total of 2.4 million retail trade establishments operated in 1987. Unfortunately, the Retail Trade Census

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

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

Neither the census nor the New Jersey data account for those outlets that may convert cigarette vending machine sales to over-the-counter sales once vending machines are banned as proposed in this regulation. Industry estimates of the number of cigarette vending machines in operation in 1993 vary from 182,000³² to 480,000³³. FDA does not know how many of these operations would convert to over-the-counter sales, but for this study, the agency has assumed that about 100,000 establishments would initiate new overthe-counter operations to replace lost vending machine sales. Thus, FDA estimates that a maximum of about

700,000 retail outlets would continue to sell tobacco products.

1. Costs to Manufacturers

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

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

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