

underestimated the health benefits from preventing nonfatal cases.

There are also medical costs for nonfatal cases of CHD. The American Heart Association estimates that the cost of a new CHD case is about \$22,700 and the total annual costs are \$51.1 billion (Ref. 75). If 1.1 million cases lead to \$22,700 per case, then all these cases cost about \$25 billion. The remaining 13.9 million cases average about \$1,900 per year  $((\$51.1 \text{ billion} - \$25 \text{ billion}) / 13.9 \text{ million})$ . FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

Under the first approach, the total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by a value per life year plus the medical costs of \$22,700 plus \$1,900 per year times the discounted life years. FDA estimates the morbidity cost per case to be about \$282,000  $((0.29 \times \$100,000 \times$

$8.4) + (\$1,900 \times 8.4) + \$22,700)$ , assuming a value of \$100,000 per quality-adjusted life year (VSLY).

In the first approach, FDA uses a range to estimate the value of an additional year of life to reflect the uncertainty in the literature. As a lower bound, FDA uses \$100,000 per (quality-adjusted) statistical life year. Cutler and Richardson (Ref. 77) use a similar estimate, and Garber and Phelps (Ref. 157) conclude that estimates of the value of a life year are about twice the level of income, though they present a broad range to reflect uncertainty associated with risk aversion and discount rates. Updating Garber and Phelps' estimates suggests that \$100,000 per life year is a reasonable estimate, given that median family income in 2002 was about \$51,000 (Ref. 158). Moreover, this estimate is close to the estimate used in FDA's economic analysis of the regulations

implementing the 1990 amendments. FDA received no public comments on that estimate. To reflect other underlying literature, and following suggestions from other Federal agencies, we begin with an estimate of the value of a statistical life (VSL) of \$6.5 million. This estimate is consistent with the survey by Viscusi and Aldy (Ref. 159) on the premium for risk observed in labor markets. Annuitying this value over 35 years at 3 percent and at 7 percent discount rates, as is consistent with OMB guidance, implies estimates of a value of an additional year of life of about \$300,000 and \$500,000. Therefore, table 11a shows estimated benefits for three estimates of VSLYs: \$100,000, \$300,000 and \$500,000, for both of the methods of estimating gains in life years. Total benefits differ from mortality-related benefits by including the value of reduced morbidity and health care costs.

TABLE 11A.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	Discount Rate	Number of Discounted Life Years Gained		Mortality Related Benefits Estimated In Year 3 After the Effective Date and Annually Thereafter (in millions)		Total Benefits (in millions)	
		Method 1	Method 2	Method 1	Method 2	Method 1	Method 2
\$100,000	7 percent	1,920	3,840	\$192	\$384	\$234	\$477
\$300,000	3 percent	2,640	5,280	\$792	\$1,584	\$968	\$1,973
\$500,000	7 percent	1,920	3,840	\$960	\$1,920	\$1,127	\$2,295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of \$5 million and \$6.5 million. These values represent reasonable central tendencies for a larger range of VSL estimates reported in the literature: \$1 million to \$10 million (Ref. 159). The two values FDA

uses here are also consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks (Refs. 159 and 160). FDA uses the lower value to reflect the fact that many of the estimates of willingness to pay to reduce mortality risk from papers not surveyed by Viscusi and Aldy are

relatively low. Table 11B shows the annual benefits estimated in this way for the two different VSLs using both a 3 and 7 percent discount rate. The totals in the final 2 columns of the table are discounted, so direct multiplication of the previous columns does not give the totals in the final columns.

TABLE 11B.—BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE AND DISCOUNT RATES

VSL and Discount Rate	Expected Deaths Averted		Average Medical Costs per Nonfatal Case	Expected Nonfatal Cases Averted		Total Benefits Estimated in Year 3 After the Effective Date and Annually Thereafter (in millions)	
	Method 1	Method 2		Method 1	Method 2	Method 1	Method 2
\$5,000,000 (3%)	240	480	\$43,000	360	720	\$1,112	\$2,225
\$6,500,000 (3%)			\$43,000			\$1,442	\$2,884
\$5,000,000 (7%)			\$39,000			\$991	\$1,982
\$6,500,000 (7%)			\$39,000			\$1,285	\$2,570

#### F. Overview of Benefits and Costs

To provide an overview of this analysis, we can compare the estimated total benefits and costs and summarize

the sources of information used in making these estimates.

#### 1. Summary of Benefits and Costs

Table 12 shows the timing of the discounted benefits and costs estimated for this rule, as well as the totals. The