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b. *Value of CHD morbidity and mortality prevented.* FDA estimates the benefits of this rule using two approaches that reflect different methods used in the economics literature. First, it calculates benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the number of nonfatal cases prevented multiplied by the costs of nonfatal cases, plus the savings in medical costs associated with reductions in nonfatal CHD. Its second calculation is like the first, except that it values reductions in mortality risk as the number of statistical deaths prevented multiplied by the willingness to pay to reduce the risk of death (rather than the extensions to longevity multiplied by the value of increases in life-years gained), and calculates the value of reducing the number of nonfatal cases as simply the savings in medical costs. This section presents these two approaches in turn, beginning with the costs of nonfatal cases and medical costs.

Under the first approach, FDA estimated the costs of nonfatal cases to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have 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 this case the average cost per nonfatal case was estimated at about \$281,000.

In the first approach FDA uses a range to estimates of 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 Aldy and Viscusi (Ref. 159) on the premium for risk observed in labor markets. Annuitizing 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.— ANNUAL BENEFITS FOR DIFFERENT VALUES OF STATISTICAL LIFE YEARS

Value of Statistical Life Years Gained	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	1,920	3,840	\$192	\$384	234	477
\$300,000 (VSL=\$6.5 million, discount rate=3%)			\$576	\$1152	968	1973
\$500,000 (VSL=\$6.5 million, discount rate=7%)			\$960	\$1920	1127	2295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of \$5 million and \$6.5 million. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to reduce mortality risks. (Ref. 159 and Ref. 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 Aldy and Viscusi 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.— ANNUAL 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%)						\$1,442	\$2,884
\$5,000,000 (7%)			\$991			\$1,982	
\$6,500,000 (7%)			\$1,285			\$2,570	
			\$39,000				

F. 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 benefits reported in Table 12 are based on a VSLY of \$300,000 and a discount rate of 3%.** The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted

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Under the first approach, FDA estimated the costs of nonfatal cases to be the sum of the medical costs, the cost of functional disability, and the cost of pain and suffering. The functional disability, and pain and suffering combine to reduce the quality of life for victims. In a recent study, Cutler and Richardson (Ref. 77) estimated from National Center for Health Statistics data that the quality adjusted life year for a CHD survivor was 0.71, which indicates that the annual loss to the victim is 0.29 quality adjusted years. This loss represents the combined effects of functional disability and pain and suffering. FDA assumed that the loss lasts for 13 years, or 8.4 discounted years (discounted at 7 percent), or 10.6 discounted years discounted at 3 percent. FDA did not estimate the extent to which nonfatal cases reduce life expectancy or increase other health costs. Because nonfatal cases probably do have these effects, FDA may have 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.

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\$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 Aldy and Viscusi (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.

In a May 30, 2003 Memorandum to the President's Management Council, OIRA Administrator John D. Graham recommended that agencies, when performing benefit cost-analysis, present results using both VSL and VSLY methods. Below we present estimates using both methods. The Memorandum also recommends that agencies present analyses with larger VSLY estimates for senior citizens. Since many of the beneficiaries of this final rule are senior citizens, larger VSLY values than the ones we have used will increase benefits further.

TABLE 11a.— ANNUAL 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	1920	3840	\$192	\$384	\$234	\$477
\$300,000	3 percent	2840	5280	\$576	\$1152	\$968	\$1873
\$500,000	7 percent	1920	3840	\$960	\$1920	\$1127	\$2295

In applying the second approach to calculating benefits, FDA assumes values of a statistical life of \$5 million and \$6.5 million. This range of VSL estimates is consistent with one reasonable interpretation of studies of willingness to pay to

reduce mortality risks. (Ref. 159 and Ref. 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 Aldy and Viscusi 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.— ANNUAL 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
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\$6,500,000 (7%)			\$1,285			\$2,570	

F. 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 benefits reported in Table 12 are based on a VSLY of \$300,000 and a discount rate of 3%.** The effectiveness of this final rule can also be seen in the relatively low cost per life year saved. For example, if we express the one time costs as annualized cost over 20 years (discounted

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the value of preventing both fatal and nonfatal cases of CHD. FDA assumed that the cases of CHD prevented by this rule will have the same proportions of fatal and nonfatal cases as currently exist in the population. The AHA estimates that 1.1 million heart attack cases of CHD occur annually, with 40 percent of them fatal (Ref. 134). The average years of life lost per fatal case is 13, or 8 years discounted to the present at 7 percent, ^{or 11 years discounted to the present at 3 percent.} FDA used these estimates as the baseline for the estimated benefits. The number of cases varies from year to year, so FDA treated the annual number of cases as a distribution with a mean equal to 1.1 million (and a standard deviation of 110,000). FDA applied the estimated decline in the probability of CHD to the baseline to get estimates of the number of cases and fatalities prevented by the final rule. FDA used these estimates in the analysis for the proposed rule, and comments on this are discussed in the previous section on changes in health states. FDA estimated the effects using Method 1, which considers changes only in LDL-C, and using Method 2, which considers changes in both LDL-C and HDL-C.

The benefits are expected to begin 3 years after the effective date. The 3-year lag occurs because a dietary change takes several years to begin to affect the CHD risk (Ref. 137). With Method 1, FDA estimated that 3 years after the effective date, the final rule would annually prevent 600 cases of CHD and 240 deaths. Preventing 240 deaths would annually save about 1,920 discounted life years (240 deaths x 8 years) ^{using a 7 percent discount rate, or 2,640 discounted life years (240 deaths x 11 years) using a 3 percent discount rate.} With Method 2, FDA estimated that 3 years after the effective date, the final rule would annually prevent 1,200 cases of CHD and 480 deaths, saving about 3,840 discounted life years (480 deaths x 8 years) ^{using a 7 percent discount rate, or 5,280 discounted life years (480 deaths x 11 years) using a 3 percent discount rate.} Because the association between *trans* fat consumption and CHD through changes in LDL-C is more conclusive, the benefits estimated using