

July 10, 2003

fat consumption and CHD through changes in LDL-C is more conclusive, the benefits estimated using Method 1 should be regarded as more certain than the benefits estimated using Method 2.

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b. Value of CHD morbidity and mortality prevented. In the proposed analysis, the per case valuations of morbidity and mortality prevented were estimated. There was no controversy over these estimates. The average cost per fatal case of CHD is about \$836,000. The average cost per nonfatal case is about \$281,000.

The annual benefits of the final rule equal the number of deaths prevented multiplied by the cost per death, plus the number of nonfatal cases prevented multiplied by the costs per nonfatal case. Because these benefits occur at different times and recur annually, they must be discounted to the time of publication of this final rule. Table 11 shows the timing of the undiscounted expenditures and the present value (discounted at 7 percent) of the costs at the time of publication of the final rule. Because benefits continue in perpetuity, the present value calculation has been made of an infinite stream of benefits discounted at 7 percent.

TABLE 11.—TIMING OF UNDISCOUNTED BENEFITS AND PRESENT VALUE OF BENEFITS (DISCOUNTED AT 7 PERCENT)

	Year 3 and Annually After the Effective Date	Present Value as of the Effective Date
Method 1	\$234 million	\$4.1 billion
Method 2	\$476 million	\$8.3 billion

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. Although the rule will generate high setup costs, the later benefits should dwarf those costs. 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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at 7 percent), the medium cost estimate in table 12 comes to about \$16 million per year. With Method 1, the cost per life year saved would be \$10,000 (\$16 million/4,000 life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.

TABLE 12.—SUMMARY OF COSTS AND BENEFITS BY YEAR AFTER PUBLICATION, DISCOUNTED TO EFFECTIVE DATE, IN MILLIONS OF DOLLARS

	Years After Publication	Effective Date						Infinite Stream	
		2	3	4	5	6	7		
Costs									
Low		\$106	none	none	none	none	none	...	\$106
Medium		\$163	none	none	none	none	none	...	\$163
High		\$255	none	none	none	none	none	...	\$255
Benefits									
Method 1	Annual Cumulative	none	none	none	\$234	\$219	\$205	...	\$4,100
					\$234	\$453	\$658		
Method 2	Annual Cumulative	none	none	none	\$476	\$446	\$416	...	\$8,345
					\$476	\$922	\$1,338		

G. Peer Review

FDA submitted this economic analysis to the Interagency Economic Peer Review (IEPR) for peer review. The IEPR is a voluntary review process composed of, but not limited to, Federal economists and analysts who review Regulatory Impact Analyses and Regulatory Flexibility Analyses prior to OMB clearance to improve the quality of economic analysis.

Two Federal economists reviewed this analysis. Their specific comments and FDA's responses are detailed in Ref. 155. FDA made the following changes to the analysis in response to the comments of the reviewers:

- Added several sections to repeat information contained in the analysis that accompanied the proposal to provide more background and context for the reader,
- Made some style changes for clarity,
- Added explanations for how some numbers were calculated,

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.

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. In the following tables 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.

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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
\$500,000 (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

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\$5,000,000

F. Overview of Benefits and Costs

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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 benefits reported in table 12 are based on a VSLY of \$300,000 and a discount rate of 3 percent. 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 at 3 percent), the medium cost estimate in table 12 comes to about \$12 million per year. With Method 1, the cost per life year saved would be about \$4,500 (\$12 million/2,600 life years). These ratios would be even lower if we included the quality-adjusted life years associated with nonfatal cases. The deaths prevented alone demonstrate the effectiveness of this final rule.