

June 30, 2003

CHANGES FOR PAGE 195. June 27, 2003 (5:53pm)

Randy Lutter

JUN 30 2003

10AM

b. *Value of CHD morbidity and mortality prevented.* 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.

FDA therefore 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 benefits as the extensions to longevity multiplied by the value of such increases in life-years gained, plus the prevented 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 (discounted at 7 percent), and 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.

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's 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 reduced health care costs..

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	2640	5280	\$792	\$1584	\$968	\$1973
\$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. 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 (Ref. 159 and Ref. 160). FDA uses the lower value (\$5 million) 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	

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 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

*RL's edits
after reviewing*

JUN 30 2003

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

	Years After Publication	Effective Date					Cumulative Total as of Year 20		
		2	3	4	5	6		7	
	Cumulative				\$968	\$1,908	\$2,821	...	\$13,130
Method 2	Annual	none	none	none	\$1,973	\$1,916	\$1,860	...	
	Cumulative				\$1,973	\$3,889	\$5,784	...	\$26,757

2. Summary of Information Sources

Table 12a summarizes the inputs, data sources and assumptions used in the Final Regulatory Impact Analysis for this final rule.

Table 12a. Summary of Inputs, Data Sources, and Assumptions

Name of input	Value or distribution used	Type of estimate	Source of data or assumption
Current trans fat intake	Total intake, 2.55% of energy; intake from hydrogenated fat, 2.03% of energy (table 1 of this document)	FDA's best estimate from available data. USDA trans fat food composition database, (Ref. 40); USDA food group data from CSFII	1994-96, (Ref. 115).
Adjustment of trans fat intake for current level of margarine reformulation	0.063% of energy, decrease in current amount of trans fat intake from margarine (table 2 of this document)	FDA's best estimate from available data.	15% decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation	0.0359% of energy decrease (table 2 of this document)	Low assumption based on uncertainty	Assume 10% decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice	0.0019% of energy decrease (table 2 of this document)	Low assumption based on uncertainty. Assume 0.1% decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.	
Overall change in trans fat intake due to labeling	0.0378% of energy decrease (tables 2 and 10 of this document)	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine.	Sum of two previous values.
Number of products to be tested	154,000 (table 3 of this document)	High estimate based on uncertainty. Includes many products that have already been tested.	Main data sources: RTI labeling cost model (Ref. 129) for number of products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing	\$261 to \$371 (table 4 of this document)	Data	RTI labeling cost model, Ref. 129.
Percent of SKU label changes that can be coordinated with scheduled labeling changes	84% of branded SKUs, 50% of private label SKUs	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of relabeling	Varies (table 5 of this document)	Data	RTI labeling cost model, Ref. 129.
Number of margarines reformulated	30 (table 6 of this document)	Low assumption based on uncertainty	Assume 10% of margarine products reformulate
Per product cost of reformulation	\$440,000 (table 6 of this document)	Data	Industry supplied information (64 FR 62745 at 62782, November 17, 1999).
Overall change in CHD risk per change in trans fat intake	0.147% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 1 (table 8 of this document)	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: $-0.1\% \times 1.5 \times 0.7 \times 1.4 = -0.147\%$, decrease in CHD risk.

Table 12a. Summary of Inputs, Data Sources and Assumptions—Continued

Name of input	Value or distribution used	Type of estimate	Source of data or assumption
Overall change in CHD risk per change in trans fat intake	0.287% decrease in CHD risk per 0.1% of energy decrease in trans fat intake. Method 2 (table 8 of this document) / intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: $-0.1\% \times -0.4 \times -2.5 \times 1.4 = -0.140\%$, decrease in CHD risk due to change in HDL-C.	Add to result from Method 1: $-0.147\% + (-0.140\%) = -0.287\%$, decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document)	Data <i>stat</i>	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (table 8 of this document)	Data	Published meta-analyses, Refs. 62 and 69.
Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat	Various coefficients shown in table 9 of this document.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C	0.7% increase per 1 mg/dL increase in LDL-C (table 8 of this document)	Data <i>stat</i>	Published meta-analyses, Refs. 59, 60 and 61.
Changes in CHD risk with changes in HDL-C	2.5% increase per 1 mg/dL decrease in HDL-C (table 8 of this document)	Data <i>stat</i>	Published meta-analyses, Refs. 59, 60 and 61.
Adjustment for regression dilution	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (table 8 of this document)	Data <i>stat</i>	Published data, Ref. 64.
Overall change in CHD risk due to labeling	-0.052%, Method 1; -0.106%, Method 2 (table 10 of this document)	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50% cis-monounsaturated and 50% saturated fat as the minimum, the change with 100% cis-monounsaturated fat as intermediate, and the change for a mixture of 50% cis-monounsaturated and 50% cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.
Time lag between effective date of labeling and first health benefits	3 years (table 10 of this document)	Data <i>stat</i>	3 years for serum lipid changes from dietary change. Ref. 137.
Heart attacks per year	Mean 1.1 million cases, std. dev. 110,000 cases	Data for mean. Assumption for std. dev.	Published data, Ref. 134.
Percent of heart attacks per year that are fatal	40%	Data <i>stat</i>	Published data, Ref. 134.
Life-years saved	13, or 8.4 years discounted to the present at 7% (table 10 of this document)	FDA's best estimate from available data.	Published data, Refs. 75, 76, 134.
Life-years saved	13, or 10.6 years discounted to the present at 3% (table 10 of this document)	FDA's best estimate from available data.	Published data, Refs. 75, 76, 134.
Medical Costs saved per non-fatal case	\$39,000 at 7% discount rate; \$43,000 at 3% discount rate (table 11 of this document)	FDA's best estimate from data and life expectancy calculations	Published data, Ref. 134.
Value of Statistical Life Year (VSLY)	\$100,000; \$300,000; \$500,000 (table 11 of this document)	Data and FDA's best estimate from available data.	\$100,000 from Refs. 77, 68; \$300,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 3%; \$500,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 7% (Ref. 159).
Value of Statistical Life (VSL)	\$5 million; \$6.5 million (table 11 of this document)	Data	General VSL literature (Ref. 159).

REVISIONS

DRAFT

2. Summary of Information Sources

JUN 30 2003

Table 12a summarizes the inputs, data sources and assumptions used in the Final Regulatory Impact Analysis for this final rule.

Table 12A. Summary of Inputs, Data Sources and Assumptions

Name of input	Value or distribution used	Type of estimate	Source of data or assumption
Current trans fat intake	Total intake, 2.55% percent of energy; intake from hydrogenated fat, 2.03 percent of energy (Table 1)	FDA's best estimate from available data.	USDA trans fat food composition database, (Ref. 40); USDA food group data from CSFII 1994-96, (Ref. 115).
Adjustment of trans fat intake for current level of margarine reformulation	0.063 percent of energy, decrease in current amount of trans fat intake from margarine (Table 2)	FDA's best estimate from available data.	15 percent decrease in current amount of trans fat intake from margarine based on industry comments on proposed rule.
Change in trans fat intake due to margarine reformulation	0.035 percent of energy decrease (Table 2)	Low assumption based on uncertainty.	Assume 10 percent decrease in remaining trans fat from margarine.
Change in trans fat intake due to consumer choice	0.0019 percent of energy decrease (Table 2)	Low assumption based on uncertainty.	Assume 0.1 percent decrease in remaining trans fat intake from hydrogenated fat after margarine reformulation.
Overall change in trans fat intake due to labeling	0.0378 percent of energy decrease (Table 2 and 10)	Low assumption based on uncertainty. Excludes possible reformulation of products other than margarine.	Sum of two previous values.
Number of products to be tested	154,000 (Table 3)	High estimate based on uncertainty. Includes many products that have already been tested.	Main data sources: RTI labeling cost model (Ref. 129) for number of products likely to be affected and our judgement about what categories of products are likely to be affected.
Per product cost of testing	\$261 to \$371 (Table 4)	Data.	RTI labeling cost model, Ref. 129.

of this document

RD

Percent of SKU label changes that can be coordinated with scheduled labeling changes	84 percent of branded SKUs, 50% percent of private label SKUs	FDA interpolation of information on 24 and 36 month compliance period proportions.	RTI labeling cost model, Ref. 129.
Per product category cost of relabeling	Varies (Table 5)	Data.	RTI labeling cost model, Ref. 129.
Number of margarines reformulated	30 (Table 6)	Low assumption based on uncertainty.	Assume 10% percent of margarine products reformulate
Per product cost of reformulation	\$440,000 (Table 6)	Data.	Industry supplied information (64 FR 62745 at 62782, November 17, 1999)
Overall change in CHD risk per change in trans fat intake	0.147 percent decrease in CHD risk per 0.1% percent of energy decrease in trans fat intake. Method 1 (Table 8)	Low estimate, assuming change in CHD risk is entirely through effect of trans fat on LDL-C.	Multiply change in trans fat intake by factors below: $-0.1\% \text{ percent} \times 1.5 \times 0.7 \times 1.4 = -0.147\% \text{ percent}$, decrease in CHD risk.
Overall change in CHD risk per change in trans fat intake	0.287 percent percent decrease in CHD risk per 0.1% percent of energy decrease in trans fat intake. Method 2 (Table 8)	Intermediate estimate, assuming change in CHD risk is through effect of trans fat on both LDL-C and HDL-C. Excludes other possible mechanisms linking trans fat to CHD risk.	Multiply change in trans fat intake by factors below: $-0.1\% \text{ percent} \times -0.4 \times -2.5 \times 1.4 = -0.140\% \text{ percent}$, decrease in CHD risk due to change in HDL-C. Add to result from Method 1: $-0.147\% \text{ percent} + (-0.140\% \text{ percent}) = -0.287\% \text{ percent}$, decrease in CHD risk, Method 2.
Change in LDL-C with change in trans fat intake	1.5 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (Table 8)	Data.	Published meta-analyses, Refs. 62 and 69.
Change in HDL-C with change in trans fat intake	-0.4 mg/dL per 1% of energy from trans fat substituted for cis-monounsaturated fat (Table 8)	Data	Published meta-analyses, Refs. 62 and 69.

of this document

Changes in LDL-C and HDL-C with substitutions of other macronutrients for trans fat	Various coefficients shown in Table 9.	FDA's best estimate from available data.	Published meta-analyses, Ref. 65, combined with meta-analyses in Refs. 62 and 69.
Changes in CHD risk with changes in LDL-C	0.7% increase per 1 mg/dL increase in LDL-C (Table 8)	Data	Published meta-analyses, Refs. 59, 60 and 61.
Changes in CHD risk with changes in HDL-C	2.5% increase per 1 mg/dL decrease in HDL-C (Table 8)	Data	Published meta-analyses, Refs. 59, 60 and 61.
Adjustment for regression dilution	Factor of 1.4 increase in relationship of change in CHD risk with changes in LDL-C and HDL-C (Table 8)	Data	Published data, Ref. 64.
Overall change in CHD risk due to labeling	-0.05% percent, Method 1; -0.106% percent, Method 2 (Table 10)	Factors above combined with probabilistic model to account for macronutrient substitutions.	BetaPERT distribution, using the change in CHD risk for a mixture of 50% percent cis-monounsaturated and 50% percent saturated fat as the minimum, the change with 100 percent cis-monounsaturated fat as intermediate, and the change for a mixture of 50% percent cis-monounsaturated and 50 percent cis-polyunsaturated fat as the maximum. The mean of a BetaPERT distribution = (minimum + (4 x intermediate) + maximum)/6.
Time lag between effective date of labeling and first health benefits	3 years (Table 10)	Data	3 years for serum lipid changes from dietary change. Ref. 137.
Heart attacks per year	Mean 1.1 million cases, std. dev. 110,000 cases	Data for mean. Assumption for std. dev.	Published data, Ref. 134.
Percent of heart attacks per year that are fatal	40 percent %	Data	Published data, Ref. 134.
Life-years saved	13, or 8.4 years discounted to the present at 7	FDA's best estimate from available data.	Published data, Refs. 75, 76, and 134.

of this document

	percent (Table 10)		
Life-years saved	13, or 10.6 years discounted to the present at 3 ⁷ percent (Table 10)	FDA's best estimate from available data.	Published data, Refs. 75, 76, 134.
Medical Costs saved per non-fatal case	\$39,000 at 7 ³ percent discount rate; \$43,000 at 3 ⁷ percent discount rate (Table 11)	FDA's best estimate from data and life expectancy calculations	Published data, Ref. 134.
Value of Statistical Life Year (VSLY)	\$100,000; \$300,000; \$500,000 (Table 11)	Data and FDA's best estimate from available data.	\$100,000 from Refs. 77, 68; \$300,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 3 percent; \$500,000 from \$6.5 million for value of statistical life discounting 35 remaining years at 7 percent (Ref. 159).
Value of Statistical Life (VSL)	\$5 million; \$6.5 million (Table 11)	Data	General VSL literature (Ref. 159).

of this document

REVISIONS

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	\$49,000	360	720
\$6,500,000 (3%)	\$49,000		\$1,442		\$2,884		
\$5,000,000 (7%)	\$39,000		\$991		\$1,982		
\$6,500,000 (7%)	\$39,000		\$1,285		\$2,570		

Overview

F. Summary of Benefits and Costs

1. Summary 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.

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 [start page 196] 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 \$6,000 (\$12 million/2,000 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.

Cumulative Total as of Year 20

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		\$139	none	none	none	none	none	...	\$139
Medium		\$185	none	none	none	none	none	...	\$185
High		\$275	none	none	none	none	none	...	\$275
Benefits									
Method 1	Annual	none	none	none	\$968	\$940	\$913	...	\$903
	Cumulative				\$968	\$1,908	\$2,821	...	\$13,130
Method 2	Annual	none	none	none	\$1,973	\$1,916	\$1,860	...	\$1,836
	Cumulative				\$1,973	\$3,889	\$5,784	...	\$26,757

delete