

Method 2 results in higher benefit estimates than Method 1.

The reduction in CHD risk is highly uncertain primarily because of the difficulties in estimating the amount of reformulation, consumer response, and the reduction in CHD risk due to a decrease in *trans* intake. Also, these changes will occur over time and can be affected by other, unanticipated events. FDA dealt with the uncertainty by estimating a range of possible reductions in CHD risk associated with the final rule. The low and high estimated benefits can be interpreted as a range of potential effects. When we lacked direct evidence on uncertain values, we dealt with the uncertainty by choosing values that generated lower-bound estimates of benefits. This practice and the evidence in the previous section both imply that the actual realized benefits may exceed the range given by the two methods.

a. *CHD morbidity and mortality prevented.* FDA calculated the benefits from the final rule as the reduction (from the baseline) in CHD multiplied by 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 Method 1 should be regarded as more certain than the benefits estimated using Method 2.

For nonfatal cases, FDA estimated the cost 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.

The medical costs for nonfatal CHD are also important. The American Heart Association estimates that the cost of a new event 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 billion - \$25 billion) / 13.9 million). FDA, therefore, estimated medical costs per case as \$22,700 in the first year and about \$1,900 per year thereafter.

The total cost per nonfatal case is the sum of lost quality-adjusted life years multiplied by \$100,000 per life year plus the medical costs of \$22,700 plus \$1,900 per year times the discounted life years. FDA estimated the morbidity cost per case to be about \$282,000 $((0.29 \times \$100,000 \times 8.4) + (\$1,900 \times 8.4) + \$22,700)$.

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