

TABLE 9.—HEALTH BENEFITS USING RECALL DATA—Continued

Dollar estimate of health benefit for preventing an illness associated with a class 1 recall	\$60,000
Dollar estimate of health benefit for preventing an illness associated with a class 2 recall	\$5,000
Dollar estimate of annual health benefits, recall base (million)	\$39

ii. *Health benefits from preventing a rare catastrophic event.* We estimated the marginal health benefits from reducing the probability of a catastrophic event as follows:

Marginal health benefits = Change in probability of rare catastrophic event caused by poor manufacturing practices brought about by the proposed regulation × the number of illnesses caused by the rare event × health cost saved per illness.

In 1989, there was a widespread outbreak of EMS resulting from consumption of contaminated L-Tryptophan. More than 1,500 cases (175 acute illnesses and 1,287 chronic illnesses) and 38 deaths were identified in 50 states (Refs. E21 and E22). The outbreak prompted a recall of all dietary supplements that contained more than 100 mg per daily dose, which later was expanded to almost all products containing L-Tryptophan. We used the public health cost of this event as an estimate of the cost of a future rare catastrophic event associated with dietary supplements.

EMS is characterized by severe myalgia and elevated eosinophils counts. Some of the most common symptoms are fatigue, weakness, fever, and arthralgia. Although a repeat of the EMS outbreak is not expected, it is an example of the rare, catastrophic events that should be prevented or mitigated by the proposed CGMP regulation. The testing provisions of the proposed regulation should reduce the probability that contaminated ingredients would be released to the public. The provisions for keeping complaint files and investigating complaints would allow more rapid identification of a major

health event; the defective products could be identified and withdrawn well before the event claimed as many victims as L-Tryptophan.

To estimate the benefits from preventing reduction in the probability of a rare catastrophic event occurring, we first estimated the period between now and the last rare catastrophic event, 1989, and we needed to make baseline assumptions about the likely time interval between events. The last catastrophic event occurred over 13 years ago, so we assumed that the lower bound would be 50 years. For lack of data, we then assumed a uniform probability distribution between these two bounds, which leads to a rough estimate of once in 30 years. We do not know how likely rare events are, nor do we actually know the likelihood of reducing these events by the proposed regulation. There can be no conclusive empirical support for the likelihood of a future event because the past may not predict the future in the absence of a stable frequency distribution that reflects a statistically significant number of similar events. All we know is that such an event occurred at least once in the recent past, and remains a possibility. We recognize that our lack of information about such events creates significant uncertainty about the social costs of these events and the health benefits from reducing their impact. Our estimate is meant to convey the potential or hypothetical enormity of such an event, not the certainty of such an event. We would like comments regarding our estimate of such an event.

The health cost of the EMS outbreak was large because of the number, severity, and duration of the cases. One followup study (Ref. E21) found 88

percent of EMS patients were still symptomatic 21 to 64 months after onset. The symptoms associated with EMS also frequently lead to activity limitations. Another study of victims (Ref. E22) found that 74 percent of symptomatic EMS sufferers were limited in their functions 12 months after the onset of illness.

To find the health cost of the outbreak, we estimated the cost of the following health outcomes: Death, acute illness only, chronic illness with no activity limitation, chronic illness with mild activity limitation, chronic illness with moderate limitation, and chronic illness with severe limitations. To determine the cost for each of these health outcomes, we multiplied the lost quality-adjusted life days over the duration of the illness by the value of a life day. For medical costs, we estimated the cost of hospitalization for the EMS patients who required hospitalization (32 percent of all victims), by assuming 3 days per hospital stay. We used \$1,284 as the cost per day of time spent in a hospital (Ref. E17). We assumed that chronic sufferers visited the doctor once a year at a cost of \$84 per visit. We estimated the total cost of the event to be about \$2 billion. Most of the cost of the outbreak comes from the deaths and severe chronic illnesses. Table 10 of this document shows the values used in the calculation. Note that the categories are not mutually exclusive. The average age of victims was about 50, so the value of statistical life was adjusted accordingly. If the event occurs about once in 30 years in the absence of the proposed rule, then the expected average annual cost would be about \$66 million.

TABLE 10.—HEALTH BENEFITS FROM PREVENTING RARE CATASTROPHIC EVENT

	Number	Costs per case
Hospitalization	480	\$3,741
Death	38	4,214,301
Acute Illness	175	8,760
Chronic illness not limited	380	1,091,849
Mild chronic illness, limited	190	1,349,002
Moderate chronic illness, limited	307	1,601,539
Severe chronic illness, limited	409	1,602,844
Visits to physicians	1,287	1,539