

The benefits attributable to this proposed rule from preventing a rare catastrophic event are highly uncertain. We do not know if such an event would, in the absence of the proposed regulation, ever occur again. The EMS outbreak may have been a unique event, although the recent severe public health effects associated with aristolochic acid in Europe show that such similar events remain possible (Ref. E23). We also do not know that if another catastrophic event occurred, the health effects would be as large as for L-Tryptophan. Some of the smaller clusters associated with dietary supplements could represent small events potentially prevented by the proposed CGMP regulations (Ref. E15).

We included reducing the likelihood of a catastrophic public health event as a benefit of the rule because the battery of checks and controls that would be required under the proposed regulation would reduce the likelihood of such an event occurring again. In particular, the requirement that establishments keep records of consumer complaints should lead to early identification and prevention of potential catastrophic events related to manufacturing practices.

Our estimate of the health benefits associated with this proposal is based on two models that estimate future illnesses and deaths prevented by this proposed rule: Illnesses caused by sporadically adulterated products and predicted by recall data; and rare catastrophic outbreaks of illnesses, as predicted by one previous event in the United States and corroborated by one in Europe. The frequency and magnitude of a rare catastrophic event is largely hypothetical. In contrast, sporadic illnesses are small but frequent events that happen routinely. Small sporadic events are characterized by significant underreporting primarily because of the difficulty linking an illness with the cause of an illness. Determining the cause of an illness in small sporadic events is made even more difficult because only the most serious illnesses are likely to be reported and because of the difficulty of linking the cause of an illness with poor manufacturing practices. Catastrophes are large but infrequent events that create hundreds of illnesses with reporting that is close to complete because the public health system typically devotes considerable care in identifying the origin and magnitude of the problem. Adding these two models should not lead to double counting the health benefits. Double counting would most likely occur if a recalled product caused both sporadic illnesses and a

catastrophic number of illnesses and the public health system accurately recorded the full number of both sporadic and catastrophic illnesses.

b. Fewer products recalled.

Implementation of the proposed regulation would reduce the number of adulterated products distributed to the public, which would reduce the number of products recalled. Manufacturing practices, such as testing of finished products and better recordkeeping, will increase the ability of establishments to identify problems before products are released for distribution. If adulterated products are caught before they are distributed, they will not be recalled.

To estimate the direct benefits from fewer recalled adulterated dietary supplements, we estimated the baseline number of annual recalls of dietary supplements due to contamination before the proposed regulation. From 1990 to 1999, FDA received reports on an average of 20 recalls per year (Ref. E12). The average figure reported here includes class 3 recalls. The number of units of dietary supplements for each recalled product varied, so we used a distribution per recalled product of 1,000 units to 34,000 units (Ref. E12). Product price also varied, with most prices falling between \$5 per unit and \$9 per unit; we used a most likely price of \$7.70 per unit. We also included an adjustment for the goodwill lost by the establishment as a result of the recall. Studies of changes in market valuations of firms after recalls indicate that the value of lost customer goodwill, based on the decline of the share price of publicly traded stocks from recalls is often as large as the cost of the recall itself (Ref. E24). We multiplied the direct cost of the recall by two in order to include the lost goodwill. The result is an estimated savings of about \$3 million per year.

We based the estimated benefits from fewer recalled products on our recall data. If there were private recalls due to contaminated supplements that were not included in our data, the benefits from reduced recalls may be understated.

c. Reduced hypothetical search costs as a measure of the benefit from increased assurance of quality.

Consumers incur a cost if they purchase products but do not get the quality of product they anticipated. Determining the cost they incur is difficult, because we cannot look at the price of poor quality products and conclude that consumers paid too much, even when they did not get the quality they anticipated. We cannot disentangle the price consumers are paying, from the price they should be paying, because we

assume consumers expect some unknown number of their products may not meet their expectations but purchase them anyway. In other words, we cannot rule out the possibility that the purchase price already incorporates the expectations of consumers that some products will be "lemons." Because we cannot look into the minds of consumers to determine their expectations or their willingness to pay for these products, we can only estimate the benefits from more uniform quality by estimating the changes in behavior that would occur if consumers were aware of the change in quality brought about by the proposed rule. In other words, we assume that if the quality attributes of dietary supplements were observable, then consumers would spend time searching for those attributes, as they do for other goods. We measured this benefit as a reduction in the hypothetical search costs for product quality, meaning the identity, quality, purity, strength, and composition claimed on the label.

The hypothetical measure of quality starts by assuming the existence of a baseline amount of search necessitated by the existence of poor manufacturing practices. Our hypothetical consumers must search for products made with good manufacturing practices, because they cannot take such practices for granted when purchasing dietary supplements. Although the search we use as a measure of the benefits from improved quality is hypothetical, the values we use in estimating our search model are based on data and inferences about real searches for other products.

To get the products they want, people search across the range of market alternatives. Several recent articles have noted the large variation in product quality for different goods and services (Refs. E25, E26, and E27). Searching takes time and resources that could be used for other purposes, so a regulation that reduces search provides measurable benefits to consumers. To reduce the effort devoted to searching, consumers of dietary supplements should therefore be willing to pay some amount. We lack, however, a measure of what they would be willing to pay, partly because some consumers may not know that dietary supplements may contain more or less (or something not even expected) of what they think they are buying. Indeed, if consumers of dietary supplements could determine the quality of these products by merely examining the product or the label, the market alone would be sufficient to ensure that firms responded to consumer preferences for product quality. Consumers would search for those brands that are more