

Defective products can cause isolated cases of illnesses, but also rare catastrophic events such as the outbreak of eosinophilia myalgia syndrome (EMS) that resulted from the consumption of contaminated L-Tryptophan. That outbreak caused 38 deaths and over 1,500 illnesses.

The provisions that require establishments to maintain consumer complaint files related to manufacturing practices will generate additional health benefits. The use of these files by manufacturers and the agency will help identify dietary supplements that were manufactured or contaminated in ways that could cause a significant or unreasonable risk of illness or injury. These records may reduce the likelihood of catastrophic events, because a cluster of illness complaints could be identified, and preventive action taken before the number of illnesses reached catastrophic levels.

Improved product quality will also reduce the number of products recalled. Certain manufacturing practices, such as more frequent finished product quality testing, help establishments to identify problems before the products are released for consumption. If defective products are caught before they are released, they will not be recalled.

Creating minimum requirements should also generate benefits for consumers by reducing the variation in product quality. Creating verifiable minimum manufacturing requirements reduces the private effort necessary to distinguish products manufactured, packaged, and held using good practices from those using poor practices. Reducing the effort needed to find products with the identity, purity, strength, quality, and composition, among other characteristics, creates a potentially substantial, though implicit, benefit for consumers.

The benefits from the proposed rule, then, are from:

- Reduced health costs caused by the reduced number of illness;
- Fewer product recalls, and;
- Greater assurance of consistent and better quality products.

a. *Reduced illnesses.* The proposed regulation would improve the safety of

dietary supplements, which would reduce the number of illnesses and the probability of deaths caused by manufacturing problems. The proposed rule would also improve product safety through the provisions requiring records and investigations of consumer complaints related to manufacturing practices. We assumed that the proposed rule would reduce both sporadic illnesses and catastrophic outbreaks. We estimated the reduction of sporadic or annual illnesses by using the agency's recall records as evidence of possible illnesses; class 1 and class 2 recalls of dietary supplements all involved adulterated products that could have caused illness if ingested. We estimated the reduction of illnesses from preventing catastrophic events by using the public health effects of the outbreak of EMS that resulted from consumption of contaminated L-Tryptophan.

i. *Reduced illnesses estimated from recall data.* For annual illnesses, we used this formula for estimating the benefits from fewer illnesses:

Marginal health benefits = baseline (or current) number of illnesses caused by poor manufacturing practices × expected reduction in the number of illnesses brought about by the proposed regulation × health cost saved per prevented illness.

We estimated the annual expected health benefits for the proposed rule by taking the values in table 8 of this document and weighing them by their incidence in the table. We computed the expected health benefits from preventing a single illness (of any type) associated with a class 1 recall as a weighted average of all potential illnesses (see table 8 of this document), with the potential illness divided by the total number of class recalls.

The following formulas show how we calculated the average health benefits of preventing a single illness associated with a class 1 recall.

$$\text{\$health}_{ij} = (\text{QALD} \times \text{days} \times \$ \text{ per QALD})_{ij} + \$ \text{ medical}_{ij}$$

$$\text{EB}_j = \sum_i (f_{ij} \times \text{\$health}_{ij})$$

$$\text{EB} [\text{c1}] = \sum_j (w_j \times \text{EB}_j)$$

$$w_j = r_j / (\sum_j r_j)$$

Where:

$\text{\$health}_{ij}$ = health costs of severity level i of illness j;

QALD = quality adjusted life day;

\$ per QALD = dollar value of a statistical day;

\$ medical = direct medical costs;

EB_j = expected health benefit from preventing a single case of illness j;

f_{ij} = frequency of severity i of illness j ($\sum f_{ij} = 1$);

m = number of levels severity for illness j;

EB [c1], EB [c2] = expected benefits from preventing an average illness associated with a class 1 recall or a class 2 recall;

w_j = weight of illness j;

r_j = number of product recalls for hazard j;

n = number of hazards or potential types of illness.

We then repeated the procedure for class 2 recalls and the associated illnesses in table 8 of this document. Table 9 of this document shows the average value of preventing a single illness associated with class 1 and class 2 recalls.

We estimated the annual marginal health benefits as the health benefits per illness for each class of recall multiplied by the estimated number of recalls.

Health Benefits = (EB[c1] × estimated annual number of class 1 illnesses prevented) + (EB[c2] × estimated annual number of class 2 illnesses prevented).

To estimate the number of illnesses prevented, we started with the average annual number of products recalled for the decade 1990 to 1999—six class 1 and seven class 2. As discussed above, we then assumed that these recalled products represented proxies for about 1 percent of all illnesses caused by these problems leading to the recalls. With that assumption, we get 600 illnesses from class 1 recalls and 700 illnesses from class 2 recalls (see table 9 of this document).⁶

Table 9 of this document shows the estimated value of the health benefits from the proposed rule using class 1 and 2 recall data.

TABLE 9.—HEALTH BENEFITS USING RECALL DATA

| | |
|---|-------|
| Total number of illnesses prevented, recall base | 1,300 |
| Total number of illnesses associated with class 1 recalls | 600 |
| Total number of illnesses associated with class 2 recalls | 700 |

⁶We used a probability distribution to represent the uncertainty associated with the number of illnesses. We modeled the number of illnesses prevented for each class as the average number of recalled products plus a negative binomial distribution representing unknown cases. The

negative binomial distribution estimates the number of failures (unknown cases) that will occur before some number of successes (known cases) for a given probability of success. In the negative binomial distribution, we assumed that the number of recalled products were reported cases and that

the probability of reporting equaled 1 percent (Ref. E16). The result is that the mean estimated number of illnesses is 100 times the reported number of recalls.