

dietary supplements. Mild cases are the most underreported. For instance, victims rarely notify public health authorities when they have minor gastrointestinal tract related illnesses. It is even more rare to report the likely source of a mild illness. It is also widely believed that severe illnesses and death are reported much more frequently than milder illnesses, even when the cause of illness or death is not included in the report. Although the number of deaths that are reported probably approach 100 percent, the cause of death from a contaminated dietary supplement product might not be reported. We believe that using a single composite factor—100—to represent the total number of all unreported cases, including mild, severe, and death, does not invalidate our assumption. The factor of 100 represents an estimate of the composite probability of the full range of probabilities for each severity level of an illness being reported. Increasing the factor multiplier from 100 to some number higher would increase the health benefits, while lowering the multiplier would decrease the health benefits. If we assume that all illnesses are reported—there are no unreported illnesses and no factor of 100, then the health benefits from fewer sporadic illnesses will be less than \$1 million.

5. Introducing CGMP's will reduce the probability of a recall to zero. We believe that the proposed CGMP's creates the most reliable means for discovering product adulteration. Indeed, we believe that it will, if strictly used, cause the discovery of all adulteration. Therefore, we assume that once an establishment fully adopts the requirements, there should be no more health risk from adulterated dietary supplements and consequently, no more class 1 and 2 recalls. This conclusion rests on the assumption that there will be 100 percent compliance with this regulation. We recognize that human error is inescapable. If recalls—or a health risk from adulteration—would still exist, then we overstated the true health benefits of the regulation.

The assumptions for the health benefits from lowering the likelihood of rare catastrophic event model are:

1. We assume that a rare catastrophic event would occur every 30 years. We recognize that the occurrence of a single event provides little evidence about what will happen in the future. If the event reported in this analysis was in fact a one-time occurrence, then our estimate of the benefits from the prevention of the catastrophic health event would overstate the true benefits, which in fact should be zero. There would have been no future event, and

there would be no benefit from adopting a rule to avoid it. If a rare event would have happened more frequently than our estimate of once every 30 years, then our estimate of the benefits would underestimate the true health benefits.

2. Number of illnesses per rare event. We based our estimate of the health impact from contaminated L-Tryptophan. If the number of illnesses from a future rare event differed—either more or less—then the health benefits would differ from our estimated benefits. If a future event would have had 10,000 cases, not 1,500 cases, then our estimate would understate the true health benefits of avoiding such a large catastrophe.

The assumptions for fewer products recalled are:

1. The reported class 1 and 2 recalls that have occurred over the last 10 years represent the number and type of recalls that would have occurred in the future but for the implementation of this regulation. If the number or types of recalls are not representative, then we over or under estimated the benefit of avoiding recalls. Avoiding one very large recall could result in significantly higher benefits. Conversely, merely avoiding fewer or smaller recalls would result in smaller benefits.

2. A product recall causes sellers to lose both goodwill and the value of the recalled product and lost goodwill equals the value of the recalled product. These two embedded assumptions have empirical support from Ref. E24. A product recall adversely affects the wealth of sellers—a recall leads to lost goodwill—by signaling to consumers that products are defective. From evaluating the declines in public share prices after product recalls in various industries, the authors in Ref. E24 determined that the loss in share price is twice the value of the loss of the actual value of the product recalled. They attribute the difference to lost firm goodwill.

3. Full compliance with the proposed CGMP's will reduce the probability of a recall to zero. As in our earlier assumption about the probability of recalls after the rule is adopted, consistency requires that if we believe that the rule will reliably cause the discovery of adulterated products before they are commercially available, there should be no more health risk from adulterated dietary supplements. Consequently, there should be no more recalls.

We developed the hypothetical search model to estimate the implicit value to consumers of better product quality although we lacked a model that could enable us to directly estimate consumer

preferences for dietary supplement quality. With the adoption of the proposed rule, the standardization of manufacturing practices will reduce product differentiation. In a perfect information market, the change in product differentiation would be reflected in the change in the price differences between low and high quality products. In the existing market, price differences alone are an inadequate signal because the differences in product quality are typically hidden from the view of both consumers and (though less so) manufacturers. In this hypothetical model, we assumed that if there were actually indicators of product quality in the market now, consumers would spend a certain amount of time attempting to find a reasonably high quality product. Time spent searching is an economic cost. In fact, in markets where quality is discernible prior to purchase, such search does take place and it is from those markets that our estimates were derived. In such a world of easily available product quality signals, this regulation, by standardizing product quality at the high end, would reduce that search time. Our assumption is that this is a reasonable indicator of consumers' value for high quality products. Further, we assume that in fact consumers of dietary supplements do wish to purchase high quality products, as the absence of quality could mean either an ineffective product or worse, illness or death. We used various assumptions at each step in our model, and the benefits change when the assumptions change. The assumptions that we used for the search model are:

1. Consumers will search until the expected benefits of the search equal the expected cost of additional search. The expected cost is the value of their time, which we estimated is the average wage rate for manufacturing workers—\$15.65/hour. If the true wage rate is different, the benefits of the rule will be different.

2. The three models—drug store, use of time and grocery store models—represent consumers of dietary supplements. If not, then we will not have estimated the true preferences of consumers. If consumers value dietary supplements more highly than either drugs, groceries or other uses of time, and they search more for better quality, then we understated the benefits of product standardization. If consumers value dietary supplements less highly than either drugs, they search more for better quality, then we overstated the benefits.

3. The quality controls will reduce consumer search time by approximately