

33 percent. If our estimate is not representative of the true average reduction, then our estimate will be wrong.

4. The type and number of consumers represent the true value. If children, the elderly or other consumers search for these products in significantly greater amounts than average workers or the estimated population, then we may have overstated the benefits, because their foregone wages would be less than that of average workers.

In an ideal analysis, the benefits and costs of each provision would be evaluated. We were not able to quantify the benefits for each of the provisions in our analysis although we do have fairly detailed estimates of the cost. We request comments on marginal costs and benefits of specific provisions in the rule. Comments can be directed either at how well a specific provision might work to make dietary supplements either safer or of higher quality, or be directed at the cost of the provision. An example of this type of provision follows for recordkeeping:

Benefits of Recordkeeping

Mandatory recordkeeping is intended to help the discovery of manufacturing

practices that create defective products. Recordkeeping ensures that preventative controls are carried out for each batch of dietary supplements produced.

Records serve as a checklist that quality control personnel can consult to monitor that necessary controls are implemented or corrective actions taken. Further, mandatory recordkeeping provides an incentive for manufacturers to comply more fully with the provisions of the rule where recordkeeping is required. Knowing that FDA inspectors will examine records and that falsifying them is a criminal offense provides strong incentives to keep thorough and accurate records that the required safety functions have been performed adequately and in a timely manner. Thus, the benefits of recordkeeping are to permit detection of defective products and increase compliance with the provisions for which recordkeeping is required. If, for example: (1) The total benefits of the requirements that have recordkeeping attached to them were \$50 million (not the real value); (2) only half of the requirements would be met without recordkeeping; and, (3) recordkeeping raised the compliance rate to 100

percent, then the benefits of recordkeeping would be \$25 million. We were not able to quantify the marginal benefits of this requirement with numbers like this. Comments are requested for how well records are likely to perform this function. We estimate that the additional cost to society for the proposed new recordkeeping requirement will be approximately 10 percent of the total annual cost of the proposed regulation, or a little less than \$9 million per year.

Further, we request comments on all of the provisions that would be of a similar nature to this example.

The costs of the rule depend on our assumptions about the amount and cost of testing. The amount of testing is highly uncertain; we have tried to model the number of tests based on number of ingredients and types of tests.

We first characterized the uncertainty as a probability distribution. We ran 1,000 computer simulations to estimate both benefits and costs. The simulations used distributions and assumptions from tables 8 through 13 of this document in place of single estimates.

TABLE 19.—DISTRIBUTION OF SIMULATION RESULTS FOR ANNUAL BENEFITS AND COSTS

[In millions]

| | 5th Percentile | Median | Mean | 95th Percentile |
|-----------------------|-------------------|--------|-------|--------------------|
| Annual benefits | \$89 | \$198 | \$218 | \$405 |
| Annual costs | 62 | 80 | 86 | 128 |

The computer simulation gives the distribution of estimated benefits and costs. If the underlying distributions capture the uncertainty of the estimates,

then the results in table 19 of this document give a clear picture of the uncertainty. Another way to show the uncertainty is to see how sensitive the

results are to plausible changes in individual variables. We start with benefits.

TABLE 20.—SENSITIVITY OF BENEFITS

[In millions]

| Description | Estimated annual benefits |
|---|---------------------------|
| The proposed rule | \$218 |
| If reporting rate of illness is 0.1 (baseline is 0.01) | 182 |
| If reporting rate of illness is 0.005 (baseline is 0.01) | 257 |
| If the value of a statistical life is \$3 million (baseline is \$5 million) | 175 |
| If the value of a statistical life is \$7 million (baseline is \$5 million) | 259 |
| If consumer search time per item is 1 minute (baseline is 3.75 minutes) | 137 |
| If consumer search time per item is 5 minutes (baseline is 3.75 minutes) | 250 |
| If consumer search time equals 40 percent of shopping time (baseline is 70 percent) | 166 |
| If consumer search time is equal to shopping time (baseline is 70 percent) | 254 |
| If consumer search for quality accounts for 30 percent of search time (baseline is 20 percent) | 278 |
| If consumer search time for quality accounts for 10 percent of search time (baseline is 20 percent) | 158 |
| If catastrophic events are not prevented (baseline is \$66 million annual benefit from prevention) | 152 |

We mainly looked at the cost effects of changing assumptions about testing and consumer complaints. As table 21 of this document shows, annual costs are quite sensitive to the assumptions about the average cost and number of tests.