

To estimate the time spent searching for supplements from the use-of-time study, we assumed that the share of all shopping time devoted to supplements would be proportional to the share of a consumer's budget spent on supplements. We recognize that it could well be higher if supplements require more search than the average commodity. According to an industry source and FDA projections, consumers spent about \$15.5 billion on dietary supplements in 1999 (see table 5 of this document). Consumers spent about \$6,250 billion on all personal consumption in 1999, which means that dietary supplements accounted for about 0.24 percent of those expenditures. Personal consumption expenditures included in this estimate are food, alcoholic beverages, housekeeping supplies (such as laundry and postage), household furnishings and equipment (such as furniture and appliances), apparel (includes footwear), personal care products and services, reading materials, tobacco products, and smoking supplies. Annual shopping time per person for dietary supplements would therefore be about 44.6 minutes per year ($= (\$15.5 \text{ billion} / \$6,250 \text{ billion}) \times 346 \text{ minutes per week} \times 52 \text{ weeks}$). We converted shopping time to search time by assuming that search time equaled 40 to 100 percent of shopping time. Total search time equaled search time per adult multiplied by 205 million adults. We assumed that all adults would perform search, although we recognize that not all adults consume dietary supplements and not all search is conducted by adults. Children might search for these products also. The opportunity cost for children, as measured by their wage rate is much less than for adults, so we assumed their search time could be ignored. We used the total adult population rather than just the adult consumers of dietary supplements, because the shopping time studies are for all adults.

We estimated search time in the grocery store model with assumptions similar to those in the use-of-time model. We assumed that the ratio of search time for supplements to search time for groceries would equal the ratio of expenditures on supplements to expenditures on groceries. Estimates from the 1998 Consumer Expenditure Survey (Ref. E39) (adjusted for changes in prices between 1998 and 1999) reveal that consumers spent approximately \$710 billion on grocery store purchases in 1999. Grocery store purchases included food, alcoholic beverages, housekeeping supplies, personal care

products, tobacco products, and smoking supplies. Annual shopping time per person for dietary supplements would therefore be about 52.5 minutes per year ($= (\$15.5 \text{ billion} / \$710 \text{ billion}) \times 46.2 \text{ minutes per week} \times 52 \text{ weeks}$). We again converted shopping time to search time by assuming that search time equaled 40 to 100 percent of shopping time. Like the estimate from the use of time model, this value was then multiplied by 205 million adults.

We used these three models based on different assumptions because we wanted to explore a range of studies to avoid systematic bias in our analysis. We recognize that the three estimated annual search times for dietary supplements do not represent the search for quality alone. Consumers search for a variety of features; only part of every search will be devoted to quality. We assumed that 10 to 30 percent of pure search time involves quality searches. Estimating the impact of CGMP regulations on consumers' search time is difficult, since no previous studies have analyzed the changes in search time following the adoption of CGMP regulations or from increases in product quality standardization. However, a consistent finding from the literature is that search time should decline following a decrease in the variation in product quality (Refs. E35 and E40). In the absence of previous empirical studies, we assumed that the proposed rule would reduce the hypothetical search time for quality "the search time of sophisticated consumers" by 1 to 50 percent, with 33 percent the most likely value. A survey of pharmacists reported their belief that 30 percent of their customers place manufacturing quality as a top priority in selecting one herbal over another (Ref. E41). We also used evidence from product tests that indicated that up to 33 percent of products were missing key ingredients or contained unwanted ingredients (Refs. E25, E26, and E27). If the proposed rule guarantees that products will contain what the label claims, then perhaps search time for quality will decline by that percentage.

To estimate the value of the possible reduction in searching for quality, we multiplied our estimated time saving by the average wage rate, which is an estimate of the value of time. The average hourly wage rate for U.S. workers was \$15.65.⁷ We ran computer simulations of all three models. The

⁷ Personnel Employment, Hours, and Earnings. Series ID: EES00510006 Seasonally Adjusted, Industry: Goods-producing Data Type: Average hourly earnings of production workers, Employment Cost Index, Bureau of Labor Statistics.

results for the three models are shown in table 11 of this document.

d. *Other benefits.* The proposed regulation could also reduce the total time and effort that all covered establishments expend to monitor ingredient suppliers and holders of their products. Because all ingredients and holders would be subject to the same uniform minimum requirements, variation in their practices would decline, so firm monitoring of upstream and downstream vendors could decline.

The provision that requires establishments to maintain complaints files would allow a manufacturer to more readily be able to identify a product that causes a significant or unreasonable risk of illness or injury. The manufacturer can then take necessary steps to prevent any additional adverse health impact. We have attempted to quantify this benefit for preventing catastrophic events, but not for reducing smaller risks. FDA adverse event reports, however, imply that many such small events occur, and the proposed rule could prevent some of them (Ref. E15).

In addition, if the same adverse events show up in complaints received by different firms selling products with the same or similar manufacturing problems, no one firm selling such products may recognize the need to investigate the complaints especially if the risk is relatively low. Because we would have access to complaint files, our review would be more likely than any individual firm's review to identify the need to investigate the complaint because of a reasonable possibility of a relationship between the manufacturing process of a dietary supplement and the adverse event.

e. *Total measured benefits.* The total measured benefits from the proposed rule are the sum of the value of health benefits, the value of the reduced number of product recalls, and the reduction in hypothetical search costs. Table 13 of this document shows the total benefits.

TABLE 12.—THREE MODELS TO ESTIMATED SEARCH COST SAVINGS

Baseline model	Cost savings (in millions)
Drug store model	\$108
Use of time model	101
Grocery store model	119
Average of three baseline models	109