

practices. They seldom have access to competitors' proprietary information, and they may fear that advertising based on differences in practices would discredit the entire industry.

- Without public disclosure of product quality and adverse health events, the link between manufacturing practice and health hazard is difficult to establish. The link is probabilistic, requires data pooling across products and establishments (in order to establish cross sectional variation), and can be interpreted in a variety of ways.

- Because many consumers already mistakenly believe that the Federal Government guarantees safety, businesses have weak incentives to adopt good manufacturing practices, which are costly. In one recent survey of the nation's consumers, 34 percent report that they believe that the government regulates dietary supplements to ensure safety and that products do what they claim to do. (For details of the survey, see Ref. E3.) If people believe that good manufacturing practices are already followed, manufacturers may believe they gain little from voluntarily adopting them.

Information about manufacturing practices for dietary supplements is imperfect and costly to produce, so well-informed people should be willing to pay for improvements in the quality of information. An important benefit of the proposed regulations will be to reduce variation in manufacturing practices and ensure minimum quality for dietary supplement products. Reducing the variation in product quality by creating industry-wide minimum requirements reduces the information consumers now attempt to get through costly and uncertain sources in order to make purchasing decisions.

2. Regulatory Options

FDA considered several regulatory options for dealing with current manufacturing, packaging, and holding practices that may not ensure product quality. The options considered include: (a) No new regulatory action, (b) fewer requirements for vitamins and minerals, (c) more restrictive regulations than the proposed CGMP regulations, (d) HACCP without the other elements of CGMP regulations, (e) final product testing only, (f) regulations for high-risk products or hazards only, and (g) the proposed rule.

a. *No new regulatory action.* Under this option, consumers would probably rely on the following as protection against defective products:

- Possible enforcement action by FDA under, for example, section 402(a)(3) and (a)(4) of the act, regarding

adulterated foods that consist of filthy, putrid, or decomposed substances or foods that have been prepared, packed, or held under insanitary conditions so that they may become contaminated or may be rendered injurious to health;

- Publicity from private consumer groups or health agencies on the risks from products not manufactured using CGMP regulations, manufacturers assurances, and the voluntary adoption of some or all provisions of the proposed regulations;

- Current or enhanced State and local enforcement activity to bring about a reduction of potential harm from contaminated or poor quality dietary supplements; or

- Litigation or the threat of litigation by consumers who allege harm from consumption of the dietary supplement.

We believe that there are compelling reasons not to rely on these alternatives alone.

If public and private health agencies, consumer groups, competitors, trade organizations or other third parties publicized the risks from products not manufactured using private good manufacturing practices, then consumers would decide for themselves on the risks of contaminated or poor quality products. The weakness of this alternative is that third-party organizations cannot easily discover many of the problems caused by poor manufacturing practices because manufacturers are reluctant to voluntarily share information to third parties about their manufacturing practices.

Actions by manufacturers, such as by voluntarily introducing good manufacturing practices, occur when the expected private economic benefits of the actions exceed the private costs. Voluntary adoption of good manufacturing practices will occur when it is profitable to do so. Many establishments appear to be adopting some publicly available good manufacturing practice models in order to meet the demand for safer and more uniform products. NNFA is implementing a good manufacturing practice certification program. The USP sets standards for strength, purity, disintegration, and dissolution for individual and combination vitamins and minerals. Also, Consumerlab.com is introducing a certification label, CL, to show when ingredients meet their minimum requirements. However, 36 percent of recently surveyed dietary supplement establishments do not follow any good manufacturing practice models for their products (Ref. E2). The breakdown of survey results shows that 48 percent of very small firms, 27

percent of small firms and 11 percent of large firms do not follow a good manufacturing practice model. The survey results also show that 32 percent of vitamins and mineral establishments, 39 percent of amino acid/protein/animal extract establishments, 41 percent of herbal and botanical establishments, and 59 percent of establishments not already classified, do not follow a good manufacturing practice model.

Without industry-wide uniform requirements, some establishments may follow different practices but convey the message that they follow good manufacturing practices. In short, people who want to discriminate between establishments that use good practices and those that do not would not have sufficient information to do so. Another reason for our skepticism about universal voluntary adoption of good manufacturing practices is that good practices appear to be taken for granted by many consumers. Indeed, some consumers already believe that the Federal Government regulates the manufacturing practices of the industry, so firms lack an incentive to provide additional assurance (Ref. E3).

Current or enhanced State and local regulations could bring about a reduction of potential harm from contaminated supplements. This alternative has the advantage that State and local governments can exercise more discretion when responding to local manufacturing conditions or consumer health practices than the Federal Government. Because most of the industry engages in interstate commerce, however, Federal regulations are appropriate. Also, Federal regulations would apply uniformly across the country, whereas State and local regulations might impose different standards on establishments that supply supplements across State and local boundaries.

Litigation or the threat of litigation may help to bring about the goals of the proposed rule. The potential of costly litigation from the harm caused by deficient manufacturing practices creates an incentive for manufacturers to reduce the risks from defective products. However, we do not believe that litigation or the threat of litigation has created the incentives for all manufacturers to implement the manufacturing practices that we believe are necessary to avoid adulterated or misbranded products. As discussed earlier, not all surveyed dietary supplement manufacturers reported that they followed good manufacturing practices. Furthermore, in some cases it is difficult and costly to demonstrate to the courts that the harm to plaintiffs was