Institute of Medicine (IoM) Report on Dietary Supplements Paints an Incomplete Picture of the Regulatory Framework

On January 12, 2005, the National Academy of Science's Institute of Medicine (IoM) issued a report entitled "Complementary and Alternative Medicine (CAM) in the United States." The report's conclusions about dietary supplements received extensive coverage in the news media the next day. For example, the New York Times stated that the Dietary Supplement Health and Education Act of 1994 (DSHEA) "lets supplement manufacturers not be responsible for safety and efficacy tests." USA Today reported that "consumers can't count on getting the product promised on the label, the IoM panel warns."

When viewed in the proper context, however, many of the IoM's observations reflect efforts either already underway or do not accurately characterize the current regulatory framework for dietary supplements. Notably absent is any reference to FDA's new initiative, announced in November 2004, for implementing DSHEA, with efforts focused on: (1) monitoring and evaluating product and ingredient safety; (2) assuring product quality; and (3) monitoring and evaluating product labeling. (Presumably the omission is due only to the relatively short time between FDA's announcement and the completion of the report). The following discussion provides some perspective on the IoM report's conclusions about dietary supplement safety/efficacy and product quality.

• Safety and Efficacy

The IoM report states that "manufacturers of dietary supplements are not required to test their products for safety or efficacy." (IoM Report, page 279). However, product manufacturers are, in fact, subject to a number of provisions of the Federal Food, Drug, and Cosmetic Act (FDC Act) that deal with product safety. For example, a food (including a dietary supplement) is "adulterated" (and therefore unlawful) if it "bears or contains any poisonous or deleterious substance which may render it injurious to health" under recommended conditions of use. FDC Act §§ 402(a)(1), (f)(1)(D). The product does not have to be shown to be "actually" injurious. Similarly, a food/dietary supplement is adulterated if it is "otherwise unfit for food." FDC Act § 402(a)(3). Under a provision added by DSHEA, a dietary supplement is adulterated if it "presents a significant or unreasonable risk of illness or injury under" its intended conditions of use. FDC Act § 402(f)(1)(A).

Manufacturers have a general responsibility to assure that their products are in compliance with the FDC Act. The safety-related adulteration provisions impose an obligation on a product manufacturer to take appropriate steps to ensure that its products are not adulterated. Given the clear health-related concerns of the adulteration provisions, it is apparent that manufacturers do have an obligation to assess the safety of their products. FDA has the authority to take action when the obligation has not been satisfied (as it did in 2004 with respect to products containing ephedrine alkaloids and androstenedione).

With respect to product effectiveness, a similar obligation also is already in place. For example, a food (again including a dietary supplement) is "misbranded" (and again unlawful) if its labeling is "false or misleading in any particular." FDC Act § 403(a)(1). Separately, a dietary supplement manufacturer making, for example, a bodily structure or function claim about the product is required to have "substantiation that such claim is truthful and not
misleading.” FDC Act § 403(r)(6)(B).

As with safety, these provisions impose an obligation on a dietary supplement producer to have adequate support for the claims made for its products or face regulatory consequences. Indeed, FDA has recently increased its enforcement activities against unsubstantiated claims for dietary supplements. For example, several manufacturers of weight loss products received Warning Letters in late 2004, asserting that the supplements were misbranded because their products’ claims lacked adequate substantiation. Apart from FDA, the Federal Trade Commission (FTC) has been very active in monitoring advertising for dietary supplements and taking enforcement action against unsubstantiated claims.

• Product Quality

The IoM report asserts that “[a]t present, there is a lack of quality control for dietary supplements which is troubling because an adulterated product could compromise that product’s safety.” (IoM, page 270). Acknowledging FDA’s proposed regulations on current good manufacturing practices (cGMPs) for dietary supplements, the report nevertheless states that “until these [cGMPs] are implemented, manufacturers are accountable to consumers only on the basis that they have made a good faith effort to ensure that their products contain pure substances and are not contaminated, weakened, or mislabeled.” (IoM, page 265).

However, even in the absence of finalized cGMP regulations specific to dietary supplements, manufacturers are still subject to the cGMPs that apply to manufacturers of conventional food. 21 C.F.R. Part 110. These requirements are far from insubstantial and they have been found to be appropriate to assure the quality of food products for many years. In addition, appropriate manufacturing controls are necessary to assure compliance with the various adulteration and misbranding provisions. The dietary supplement industry has been a leading proponent of supplement-specific cGMP regulations for years and has pushed for FDA to finalize the regulations. In many cases, responsible manufacturers have already instituted programs to help ensure consistent product quality.

The IoM highlights certain reports of product quality issues with some supplements. However, it is simply unreasonable to expect there will be no quality issues in a nearly $20 billion a year industry with tens of thousands of marketed products. A cursory look at FDA’s Weekly “Enforcement Report” reveals quality issues involving many individual food products, yet the US food supply is overwhelming held in high regard.

• Conclusion

In short, the IoM report in many places incompletely (and perhaps unfairly) characterizes the current state of dietary supplement regulation in the US. Numerous requirements with respect to safety, efficacy, and product quality are already in place.

[The report can be viewed online for free at www.nap.edu/catalog/11182.html but must be purchased from the National Academy Press to obtain it as a hard copy.]

For further information about the IoM report’s recommendations, or FDA’s regulation of dietary supplements generally, please contact Frederick A. Stearns at 202-434-4288 or via e-mail at stearns@khlaw.com.