A Surprising Quirk Of Dietary Supplement Regulation

Law360, New York (November 20, 2013, 7:21 PM ET) -- If you are asked to defend a manufacturer or distributor of a nutritional supplement that allegedly caused a personal injury because it was contaminated, you need to know that the U.S. Food and Drug Administration will have treated those supplements more like a food than like a drug. The relative lack of regulation of nutritional supplements by the FDA may impact the nature and amount of evidence that will be available in your case.

On Nov. 9, the FDA announced a voluntary recall of approximately 90 tons of ready-to-eat salads and wraps manufactured by a firm in Richmond, Calif., that were distributed in eight western states, according to an article in The Los Angeles Times. That same day, USPlabs LLC of Dallas recalled certain OxyElite Pro dietary supplement products as a result of an FDA investigation concerning a potential link to liver illnesses and a reasonable probability that the products are adulterated.

If a consumer becomes ill from eating these salads, one would not expect the FDA to have required testing of this food before it was placed on the market. If another consumer ingests a bottle of tablets of "dietary supplements" purchased at a "vitamin" shop, only to learn that the tablets were contaminated with arsenic, one might assume that the FDA would have required prior testing before these tablet supplements were placed on the market just as it would any other new drug.

What may be surprising is that the FDA does not regulate the presence of potentially harmful contaminants in nutritional supplements in a significantly different manner than in these salads and wraps once they are on the market. This is because the FDA generally regulates nutritional supplements as "foods," rather than as drugs; therefore, dietary and herbal supplements are not regulated in the same manner as conventional drugs.

First, unlike drugs, supplement manufacturers usually are not required to obtain FDA approval before selling their products. Second, supplements that turn out to contain dangerous contaminants, such as heavy metals, also are regulated in the same way as foods: The remedy for selling contaminated or dangerous supplements is a recall or seizure of the contaminated supplements.

Although there is no general preapproval process for supplements, manufacturers are nevertheless responsible under federal law for: (1) ensuring supplements are safe before they are marketed, (2) preventing the distribution of adulterated supplements, and (3) following certain manufacturing practices. The FDA can show that a product is unsafe after it is marketed and can then take regulatory or other action to restrict or remove the product from the market, just as it can with food products.

The FDA does not set general limits on the presence of certain contaminants in foods or supplements, so there are no specific standards for a manufacturer to measure against in determining if their supplement is safe. But there are other sources of nonregulatory guidance that one might use as evidence of negligence or strict liability in a contaminated supplement case.

Supplements are Regulated as "Food" Under the Food, Drug & Cosmetic Act

Dietary supplements are regulated under 21 U.S.C. § 342(f)'s general food regulations. According to 21 U.S.C. § 342(a), as a type of "food," a dietary supplement is generally "adulterated" within the meaning of § 342 if it "bears or contains any poisonous or deleterious substance which may render it injurious to health[.]" This includes potentially harmful contaminants, such as lead, mercury, arsenic and cadmium.

Additionally, § 342(f) states that a supplement is "adulterated" if, among other things, it contains a dietary ingredient that "presents a significant or unreasonable risk of injury" when used as directed or as commonly used or contains a dietary ingredient that is adulterated as defined by the regular definition of adulterated food. "Dietary ingredient" is defined as a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance for use by man to supplement the diet by increasing the total dietary intake (e.g., enzymes or tissues from organs or glands), or a concentrate, metabolite, constituent or extract of any of the above. Again, under 21 U.S.C. § 321(ff)(1), this would appear to exclude potentially harmful contaminants from inclusion in the definition of "dietary ingredient."

While there is no private right of action created by an alleged violation of the FDA's adulterated food laws, a tort plaintiff could nevertheless try to fit the distribution of an allegedly adulterated food into a negligence or strict liability theory.

The FDA Does Not Generally Regulate the Levels of Contaminants in Supplements

As set forth above, laws implemented by the FDA generally require supplement manufacturers to not distribute supplements that contain ingredients that “may render [the supplement] injurious to health. The FDA does not specifically regulate the levels of these substances in foods. However, the Centers for Disease Control and Prevention’sAgency for Toxic Substances and Disease Registry ("ATSDR") has listed minimal risk levels ("MRLs") for exposures to various substances, at or below which there is “minimal” risk to health. The MRLs for some example metals:

Arsenic: 0.005 mg/kg/day, acute (less than or equal to 14 days) oral exposure

0.0003 mg/kg/day, chronic (greater than or equal to one year) oral exposure

Cadmium: 0.0005 mg/kg/day, intermediate (15-364 days) oral exposure

0.0001 mg/kg/day, chronic oral exposure

Lead: None

Mercury: 0.0002 mg/m3, chronic inhaled exposure

The MRLs are not standards or limits or regulations. They are simply the ATSDR’s assessment of what constitutes a “safe” level of exposure to certain substances. They are primarily used in EPA actions involving environmental contamination. Is a manufacturer to extrapolate from these MRLs to determine what might constitute an adulteration? Clearly, if dietary supplements were treated as drugs, the approval and regulatory scheme would be much different.

Conclusion

Supplements are regulated as food under FDA regulatory schemes. The general requirement is that supplements not contain any harmful substances. Levels of potentially harmful contaminants are not individually limited in supplements. However, other sources of guidance and regulation of other products could be used as evidence of negligence or strict liability in a product liability case involving allegedly contaminated supplements.

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