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Dietary Supplements—Regulatory Issues and Implications for Public Health

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In October 1994, President Clinton signed into law the Dietary Supplement Health and Education Act (DSHEA), and 17 years later, health experts, policy makers, and industry lobbyists continue to spar over the legislation. Classifying dietary supplements as a subcategory of food, DSHEA allowed supplement manufacturers to market products without submitting proof of safety or efficacy to the US Food and Drug Administration (FDA).[1] Currently, for a tainted or otherwise hazardous product to be removed from the supplement marketplace, an agency such as the FDA or the Drug Enforcement Administration must offer evidence that the product is unsafe, contains a controlled substance, or is absent ingredients listed on the product label after the product has appeared in retail outlets.[2] For US health professionals, the fact that more than 150 million US residents use dietary supplements should be a point of concern as many users will almost certainly forgo conventional medical treatment in favor of using products that may offer no medicinal value and taking health advice from medically untrained sales representatives.[3]

Counterintuitively, DSHEA became law 5 years after the L-tryptophan amino acid disaster of 1989, in which 38 individuals died and 1500 sustained adverse reactions.[1] When the FDA appeared heavy-handed in its response to the supplement catastrophe, industry lobbyists began applying pressure to lawmakers, especially those with a vested political interest in the economic success of supplement companies. US Senator Orrin Hatch, representing Utah, a major producer of dietary supplements, responded to industry appeals by coauthoring DSHEA and shepherding it through Congress. In doing so, Hatch sought to help manufacturers enjoy the freedom they had profited from during the 1980s after the Proxmire Amendment of 1976 barred the FDA from using potency levels to classify dietary supplements as drugs.[4] To date, no public official has defended the interests of the supplement industry to a similar extent.

In 2009, a US Government Accountability Office (GAO) report found that "consumers are not well-informed about the safety and efficacy of dietary supplements and have difficulty interpreting the labels on these products."[2] In fact, one of the most significant problems with DSHEA is that it allows structure and function claims to appear on product labels; as long as products do not claim to treat, prevent, or cure specific diseases, they can enter and remain in the marketplace.[1] The concern is that consumers may not differentiate between technical descriptions and marketing language and may attempt to use dietary supplements in place of medicines that have been tested in rigorous trials. To that end, a 2010 GAO investigation found that sellers of dietary supplements may actually encourage consumers to substitute supplements for physician-prescribed medications.[3]

In preparing its 2010 report, the GAO investigated 22 retailers of herbal dietary supplements, hiring an accredited laboratory to examine 40 single-ingredient supplements for the presence of lead, arsenic, mercury, cadmium, and assorted pesticides.[3] Although none of the supplements qualified as having an acute toxicity hazard, trace amounts of at least 1 contaminant were found in 37 of 40 products.[3] According to the GAO, more troubling than the contaminants was the dubious and potentially hazardous advice offered to investigators who had posed as elderly customers. The GAO gathered written materials from online retailers, observing claims of treating, preventing, and curing conditions such as diabetes, cancer, and cardiovascular disease. Among the more egregious marketing efforts were claims that garlic could be taken in place of high blood pressure medication and that ginkgo biloba could be used to treat Alzheimer disease, depression, and impotence.[3] Studies conducted by the National Center for Complementary and Alternative Medicine have shown that ginkgo biloba, in particular, does not reduce the risk of cancer nor does it prove effective in reducing high blood pressure among older adults.[5] Careful review of National Center for Complementary and Alternative Medicine studies reveals a similar lack of efficacy for garlic, chromium picolinate, and St John's wort.[5]

On occasion, policy makers have attempted to address at least some of the problems associated with dietary supplements. For example, citing the 2009 GAO report,[6] Senators John McCain and Byron Dorgan introduced the Dietary Supplement Safety Act (S 3002) in February 2010.[7] Although this act did not propose significant changes in efficacy assessment, it would have required supplement manu-

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facturers to register with the FDA and disclose all product ingredients. The legislation also would have given the FDA mandatory recall authority, the lack of which had resulted in the agency taking 10 years to remove ephedra from the marketplace.[6] But S 3002 never became law. With the support of industry lobbies, Hatch and Senator Tom Harkin persuaded McCain and Dorgan to drop S 3002, introducing in its place the Dietary Supplement Full Implementation and Enforcement Act (S 3414).[8] Announced on May 25, 2010, S 3414, which also did not become law, proposed allocating additional monies to the FDA such that the agency could enforce DSHEA more effectively. Hatch has long argued that funding is the key to enforcement success, perhaps because the argument cannot be falsified; that is, whenever problems with DSHEA arise, proponents can simply request additional funding for enforcement efforts. However, such bills have amounted to little more than the perpetual tabling of legislative reform, leaving the FDA in the untenable position of having no premarket screening authority while simultaneously facing critics who blame the agency for not enforcing DSHEA.

Few industries enjoy the level of protection DSHEA provides supplement manufacturers. Legislators, with the support of industry lobbies, continue to find ways to relax regulations. For example, on April 5, 2011, US Representatives Jason Chaffetz and Jared Polis introduced the Free Speech About Science Act (HR 1364),[9] which would allow supplement manufacturers to cite research showing health benefits without the FDA classifying corresponding supplements as unapproved drugs. Given that products touted as scientifically formulated already may be marketed by companies that gather and analyze data on a proprietary basis and then cite DSHEA as a means of keeping results private and shielded from robust peer review, the intent of this legislation might be questioned. The basic tenets of science are frequently ignored by companies that use the term to lend credence to their industry, and it is safe to assume that supplement manufacturers will not make an announcement each time a study finds no relationship between a dietary supplement and a health condition. For cases in which the null hypothesis is actually rejected, HR 1364 would allow industry leaders to promote their findings—a practice with which they appear comfortable.

Since October 1994, when DSHEA became law, industry statements about life in a free society and the rights of consumers have frequently overridden practical arguments about the safety and efficacy of dietary supplements, resulting in a conversation that has privileged demagoguery over informed debate. The conversation needs a more sophisticated tone and the FDA took a positive step in 2007, issuing a rule on good manufacturing practices.[10] Ideally, good manufacturing practices will help reduce availability of products containing contaminants such as pesticide residue or oxidation by-products; however, as the GAO investigations revealed, there is still room for improvement. Physicians should support future efforts to improve or reform DSHEA because individuals with serious medical conditions may be relying on products with no medicinal value. Like dietary supplements, the regulations should be efficacious and formulated for legitimate ends.

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