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The FDA has it dead wrong

By Michelle Minton, fellow, Competitive Enterprise Institute - 01/31/12 01:50 PM ET

When policy makers responsible for writing a bill send a letter telling an enforcement agency that it is out of line, one would hope the agency would sit up and listen. This week, Senators Tom Harkin (D-Iowa) and Orrin Hatch (R-Utah) wrote to the Food and Drug Administration (FDA) claiming that the agency's recently released guidelines on dietary supplements undermines the statutory framework for regulating such supplements, as outlined in a bill crafted by the two Senators. If the outcry in the supplement industry and consumer advocates hasn't got the attention of FDA Commissioner Margaret Hamburg, perhaps the Senators' letter will.

In 2011, Congress passed the Food Safety Modernization Act (FSMA), which among other things, required the FDA to provide clarification on when supplement manufacturers must file New Dietary Ingredient notifications (NDI) and what information they must provide to the agency. The NDI filing system was meant to be a streamlined way for makers of new supplements to notify the FDA of the proper dosage and uses for the product, as well as why it is reasonably expected to be safe. As noted in the Senators' letter, the guidance required by the FSMA was meant to clarify the NDI filing process and work in conjunction with legislation already on the books - namely, the Dietary Supplement Health and Education Act of 1994 (DSHEA), which Hatch and Harkin wrote and which created the regulatory framework for the dietary supplements market.

DSHEA was created to, among other things, differentiate dietary supplements - minerals, herbs, and other natural substances - from drugs - chemical compounds meant to alter the structure of function of the human body. DSHEA was considered necessary for the U.S. to maintain vibrant supplement market. Supplements, unlike drugs, are generally non-patentable, so do not need to go through the same costly and time consuming process of pre-approval as drugs.

However, the NDI draft guidelines released by the FDA this summer would create a de facto pre-approval process on virtually all supplements on
the market, thus giving the agency carte blanche to pull any supplement off the shelf without the need to prove that it is unsafe. Naturally, Harkin and Hatch are not happy, nor are the many thousands of vitamin and supplement users and the employees of companies that manufacture them.

Despite what many critics have claimed, the market for supplements is not unregulated. Prior to the FDA's draft guidance, a "new" dietary ingredient was one that had not been marketed or widely used prior to 1994. Manufacturers had to provide evidence of why they believed the ingredient to be safe and wait 75 days before putting the product on the market. The FDA has full authority to pull supplements off the market if it finds they are unsafe. And manufacturers must comply with other laws regarding safety, such as the Nutrition Labeling and Education Act, the
Fair Packaging and Labeling Act, and Good Manufacturing Practices guidelines.

The FDA's proposed changes would force nearly all supplements currently on the market to apply for retroactive approval - even those that were around before 1994. The new draft guidance requires any supplement containing new ingredients, or ingredients that have been chemically altered or manufactured in a new way, to file for approval. Because the FDA defines these terms broadly, it is likely that almost all supplements on the market would meet this requirement and be forced to file an NDI. As a result, many supplements would disappear from shelves for good and those that return will likely cost consumers much more.

The documentation required by the guidance is so extensive that it seems impossible for many or most of the supplement makers to obtain the required evidence of safety. Even if companies could document 25 years of safe use, toxicology studies on animals and humans, two-year carcinogenesis studies, and the like, it's very unlikely that FDA, with its ever increasing backlog, would ever get around to approving any of the NDIs. By the agency's own admission, there are more than 55,000 NDIs that should be filed but haven't been.

So, what would happen to all of those supplements? Well, if the FDA does not officially approve the NDI, the manufacturer may market the product.
However, doing so gives the FDA an open door to pull those supplements off the shelves, not because they pose any threat to public safety, but simply because the agency considers them to be "adulterated."

If the FDA's proposed NDI guidance is adopted, supplement manufacturers will be left with a choice: either submit their products to similarly rigorous pre-approval trials as drugs, or give the FDA the power to ban product without justification and with full impunity. Senators Hatch and Harkin are right when they insist that the FDA's guidelines undermine the very heart of the supplement regulation they authored and Congress
passed.

If the FDA continues on this rogue effort to unilaterally expand its authority, the Senate Health, Education, Labor, and Pensions Committee, which Senator Harkin chairs, should be ready to ask the agency some tough questions.

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