Senators Step Up

Tom Harkin and Orrin Hatch demand the FDA rework NDI Draft Guidance.

Senators Orrin Hatch and Tom Harkin—instrumental architects and defenders of DSHEA—have re-emerged as champions of the natural health movement. In December, Hatch and Harkin wrote a letter to the Food and Drug Administration (FDA), pointing out that the New Dietary Ingredient (NDI) Draft Guidance undermines the Dietary Supplement Health and Education Act (DSHEA) that has preserved our health freedom since 1994.

Hatch (R-Utah) and Harkin (D-Iowa) closed their letter by urging the FDA to immediately withdraw the NDI draft guidance as it stands and begin writing a new draft that is consistent with DSHEA. With this letter, the massive public outcry against the FDA's NDI Draft Guidance has been greatly amplified. Now we have the backing of two elected officials with legendary roles in the protection of health freedom.

A Flawed First Draft

Hatch and Harkin should be commended for addressing major flaws in the NDI Draft Guidance. Their letter specifically points out the following problems with NDI.

First, the current Draft Guidance proposes a bureaucratic notification process that would require dietary supplement manufacturers to submit NDI paperwork for every supplement that contains a new dietary ingredient. Hatch and Harkin correctly recognize that this needless redundancy would drain manufacturers' resources to the point of bankruptcy.

Second, Hatch and Harkin point out that this NDI direction is not consistent with DSHEA, which set forth that only the intent to use a *new* dietary ingredient would require notification. Hatch and Harkin assert in their letter that the FDA's NDI draft guidance

does nothing to improve safety benefits for consumers, but instead would "undermine the access to safe, affordable dietary supplement products that DSHEA was designed to ensure."

FDA Self-Contradiction

Hatch and Harkin also correctly call the FDA on their double standard—namely their narrow definition of "dietary ingredient" and their broad view of what makes a dietary ingredient new. The narrow definition: Under proposed NDI draft guidelines, many ingredients used before 1994 that were "grandfathered" in place by DSHEA could be pulled from store shelves. These natural ingredients with decades of proven safety and efficacy would be subjected to NDI paperwork that might prevent them from ever returning to the market. Under the proposed guidelines, the list of accessible "dietary ingredients" would shrink. The public's choice of supplements would narrow right along with them.

The broad view: According to the FDA's new NDI Draft Guidelines, bioidentical ingredients, nutritional innovations and recently discovered natural ingredients would all be classified as NDIs. These health-enhancing nutritional compounds—for example, new probiotic strains, astaxanthin, ubiquinol and other nutritional advancements—would get tangled in bureaucratic paperwork and might never even reach store shelves.

Hatch and Harkin, in addressing these flaws, seem to be acutely aware of how the NDI draft guidance could potentially remove safe, natural supplements from store shelves while severely restricting the cutting-edge innovation that is a hallmark of the entire natural health industry.

We must rise up along with Hatch and Harkin and demand the FDA withdraw its New Dietary Ingredient Draft Guidance! Send a fax today to Senators Tom Harkin at 202-224-9369 and Orrin Hatch at 202-224-6331. Let them know that their fight against the FDA's NDI Draft Guidelines will make them heroes in the health freedom movement and that as long as they keep fighting for our right to take supplements, we will support them with our votes. The supplement industry is joining forces for a major call to arms against NDI as currently proposed, so stay tuned. Visit www.NHA2012.com for up-to-the-minute news! ❖

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