NPA Letter Spells Out Perceived Failings of Proposed Dietary Supplement Listing Act

Daniel Fabricant, NPA president and CEO, lays out 'grave concerns' with mandatory product listing bill in message to Sens. Durbin and Braun.

By Mike Montemarano, Associate Editor, Nutraceutical World. April 29;2022

Following introduction of the Dietary Supplement Listing Act, which seeks to establish a mandatory product listing (MPL) for dietary supplements sold in the U.S., Natural Products Association (NPA) president and CEO Daniel Fabricant, PhD, submitted a letter to the bill's sponsors, Senators Dick Durbin (D-IL) and Mike Braun (R-IN).

Fabricant expressed the association's opposition and "grave concerns" regarding the impact that MPL would have on the marketplace.

NPA directly opposes MPL, considering it "pre-market approval" that presents an undue burden on dietary supplement companies, as Fabricant said when FDA requested modernization to the Dietary Supplement Health and Education Act (DSHEA) in its FY2023 budget request.

NPA: MPL Will Not Benefit Reputable Companies

In NPA's letter to Durbin and Braun, Fabricant, who served as director of the Division of Dietary Supplement Programs (now an Office at NIH) from 2011 to 2014, outlined a series of potential negative impacts that MPL would have on the dietary supplements industry.

"I can tell you during my time as the chief regulator for dietary supplements when we had some of the most impactful enforcement actions in the program's history, we had more than adequate tools to find a specific problem with a product or ingredient. To reiterate, we had no problem 'seeing' into industry and addressing issues when they arose."

The industry already provides plenty of information to FDA about products and ingredients, Fabricant continued. "Unfortunately, FDA fails to use this information currently. Are there any plans to understand the transparency behind this?"

While introducing the bill on the Senate floor on Apr. 26, Durbin called attention tianeptine, an unapproved drug in the U.S. that had been found in adulterated products marketed as dietary supplements in 2018. FDA sent Warning Letters to two companies in November that year, but according to a Consumer Reports article, the agency knew of these products for 9 months before taking action.

Fabricant and NPA argued that the Durbin-Braun bill would not solve problems like tianeptine, which was marketed and sold by criminals who would not have voluntarily filed information with FDA.

"This legislation would not address that issue or the failures of the FDA. Furthermore, the sellers of tianeptine are criminal drug traffickers," Fabricant said. "Criminals do not report their illegal activity to the government. Finally, the makers and sellers of tianeptine will not add their products to a mandatory product listing so the FDA can 'see' where they are and what they're up to. Even if they sent their labels to FDA, the FDA would still be required to take enforcement action. However, recently, there has been a historical pattern of inactivity and misaligned priorities by the FDA."

Objections

Overall, Fabricant said the Dietary Supplement Listing Act would reduce government accountability in several ways:

MPL would offer FDA an administrative tool to remove anything it believed isn't a dietary ingredient from the marketplace, even in instances "where they have applied the law inappropriately or incorrectly." Fabricant offered CBD/cannabinoids, N-acetyl-L-cysteine, and several probiotics as potential examples.

The legislation would delay market access for new and safe supplements, and increase supplement prices while divesting resources from facility inspections, which have not returned to pre-COVID levels.

This divestment would "harm consumer safety by leading to fewer FDA inspections and enforcement actions," Fabricant wrote. "The agency has clearly demonstrated that it is unable or unwilling to do the vital work that Congress has already authorized it to carry out."

Additionally, the bill would "impose a hefty new tax" on supplement companies, saddling other stakeholders with a "new and unnecessary regulatory burden," Fabricant said. "This would pour gas on the inflationary fire for products that Americans use every day, especially hitting low-income consumers and those on fixed incomes the hardest."

Essentially, the legislation would reward criminals that ignore MPL requirements, offering them a "significant market edge" over reputable, law-abiding companies. Bad actors could also create "cheap imitation products with illegal substances," he argued, while legitimate brands await FDA approval.

Fabricant also said the bill would "impose an unfair burden on dietary supplements" compared to foods and beverages fortified with many of the same nutrients found in supplement form.

Lastly, "Prior legislation dealing with FDA authority on supplements and other related industries has always provided for pre-emption of the states. This bill with a proposed public-facing list will be used most frequently by plaintiff's attorneys looking to bring meaningless nuisance lawsuits against the industry. The industry needs one regulator, not 51," Fabricant argued.

Prioritize Inspections

Citing Office of the Inspector General data which demonstrated that food facility inspections conducted by the FDA have been on the decline, Fabricant suggested that FDA focus on ramping up inspections, as it is mandated to do by the Food Safety Modernization Act (FSMA).

"In 2017, the Office of the Inspector General published a report about the agency's progress toward food facility inspection goals. The annual number of food facilities inspected dropped from 29% in 2004 to 19% in 2015. The report highlighted that despite increasing spending for domestic food facility inspections, the number of reviews proportionately decreased. This was five years before the global pandemic, but inspections continue to drop further," Fabricant said. "The same Office of Inspector General report also analyzed FDA's follow-up inspectional findings. The report highlighted that the agency 'often took no action in response to significant inspection violations.'"

FDA Already has Enough Tools

Fabricant's letter characterized FDA's existing enforcement authority as sufficient enough to remove harmful or illegal products from the marketplace in a timely manner.

New Dietary Ingredient (NDI) Notifications, which companies are required to submit to FDA 75 days before entering commerce, covers all ingredients that are not currently approved for use in dietary supplements. "What is proposed is legislation that would require companies marketing products with 'old dietary ingredients' such as vitamins and minerals but with a new flavor to get FDA approval via a listing before entering the market," Fabricant said. "This is an excessive administrative burden" that exceeds current scientific safety evaluations.

Additionally, the Food, Drug, and Cosmetic Act already requires companies to submit details about structure/function claims prior to adding them to product labels, no later than 30 days after marketing said dietary supplement. Fabricant described this as a redundancy, given that FDA maintains a database of structure/function claims. "FDA never stated why these submissions can't be used as an enforcement tool," Fabricant noted.

Companies are also required to file any and all serious adverse event reports (SAERs) associated with dietary supplement products.

“The FDA already has access to information regarding who is making dietary supplements, where they are making them, what products are made at which facilities, when new ingredients are introduced into commerce, and whether any products are associated with serious adverse events,” Fabricant’s letter said. In addition, the Office of Dietary Supplement Programs at the NIH already maintains a Dietary Supplement Label Database, he noted, calling for more support to the ODSP and a budget that increases enforcement actions spelled out in DSHEA.

“As proposed, there are only two primary winners/benefactors of this so-called transparency of mandatory product listing. First, are disreputable individuals looking to create counterfeit products based on the ingredients and formulations in the database submitted by legitimate companies, hoping they can turn a quick profit with imitation products likely comprised of illicit ingredients. The second is the plaintiff bar, which would eagerly pull in as many companies as possible into class-action lawsuits based on alleged injuries caused by foods or supplements.”

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