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Supplement Lobbies Support Incentives But First Want More Enforcement

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The heads of two major dietary supplement lobbies support establishing incentives for the dietary supplement industry, including the possibility of exclusivity, but they are adamant such incentives should not mirror exclusivity as it exists in the prescription drug space. They add, however, that FDA should first pursue stricture enforcement of new dietary ingredient (NDI) notification requirements from dietary supplement companies to help ensure product safety.

Former FDA Commissioner Scott Gottlieb raised the idea of exclusivity for dietary supplements in February, when he announced an initiative to reform FDA's supplement regulation. He noted some stakeholders have suggested the 1994 Dietary Supplement Health and Education Act (DSHEA) be amended to establish avenues for dietary supplement exclusivity, and he said FDA will look at what the right incentives might be for establishing exclusivity.

Daniel Fabricant, president and CEO of the industry group Natural Products Association (NPA), said he would be happy to talk about exclusivity in the supplement space, but first he wants FDA to crack down on supplement makers who come to market with a new ingredient without submitting an NDI, which he argued could harm customers and spoil the reputation of companies that do file NDIs.

Meanwhile, Steve Mister, president and CEO of the Council for Responsible Nutrition (CRN), said he wants to avoid replicating exclusivity that exists in the prescription drug space for the supplement space because prescription drug exclusivity has a reputation for encouraging anti-competitive practices and high prices.

"Exclusivity is not necessarily a popular term among consumers," Mister told *Inside Health Policy*. "It's certainly not what we're talking about when we talk about innovation in dietary supplements."

Mister called for FDA to better enforce its requirement for supplement companies to submit NDI notifications when bringing a new ingredient to market. That way, he argued, if one supplement company conducts safety research, submits an NDI notification and brings an NDI to market, another company can't bring the same ingredient to market without submitting its own NDI notification.

The difference between such a system and exclusivity, Mister explained, is that in the supplement space other companies would not be prohibited from submitting an NDI for an ingredient for which another company had already submitted an NDI. But the second company would have to conduct its own safety research and submit its own NDI to get to market.

"What's missing [in the current system] is FDA enforcement," Mister said.

Mister believes that when Gottlieb discussed the possibility of exclusivity, he was using the term in a loose sense, rather than referring exactly to what occurs in the prescription drug space.

"Exclusivity gets used a lot in the pharmaceutical world, but it's probably not the most precise word for what we're talking about," he said. The CEO added that he has also not heard CRN member companies calling for exclusivity as it's known in the drug space.

"The fact that that's not what our members are telling us is helping us get to a point of saying maybe FDA is misspeaking about what they really mean," Mister said.

Other sources argued the supplement industry does not need exclusivity.

Joanne Hawana, counsel at Mintz Levin, has represented supplement companies in the past, said exclusivity isn't necessary to encourage innovation in the supplement industry. Supplement companies face virtually none of the premarket safety or efficacy testing that drug companies do when building a new drug application, she said, so there is less of an upfront cost to creating new products.

"Certainly there are more small and mid-sized companies in the supplement space, because as of today it's easier to get to market with a product like that than almost anything else," said Hawana, whose practice now focuses mostly on drugs, food, cosmetics, electronic nicotine delivery systems and medical devices.

Furthermore, Hawana said if exclusivity were to happen in the supplement space, companies would raise prices for their products during their exclusivity period. That would have the effect of limiting consumer access to those products, the lawyer said.

"It would sort of undercut the whole access point," Hawana said. If FDA were to require some kind of clinical trials to justify an exclusivity period, that could raise the cost even further, she added.

Fabricant, who previously served as director of FDA's Division of Dietary Supplement Programs, argued that the current system disincentivizes safety research, since companies that conduct research and submit NDI notifications gain no market advantage over other companies that don't. People are often willing to pay a premium "for the peace of mind" that a new ingredient has gone through FDA's review process, he said.

Mister added that he does not believe consumer advocates would have a problem with an increase in dietary supplement prices, as they would want research and innovation to be rewarded.

"No one says a company should not be able to reap the rewards of their hard work," he said. "But consumer advocates say the amount of rewards in pharma is out of whack."

Peter Lurie, president of the Center for Science in the Public Interest, and a former associate commissioner for public health strategy and analysis at FDA, argued that innovation in the supplement industry falls within the marketing realm and not within the scientific realm.

"In the absence of properly controlled research designed to establish safety and/or efficacy, exclusivity should not even be on the table," he told *IHP*.

Even though he supports granting incentives to supplement companies that conduct research, Fabricant argued FDA needs to first focus on getting NDI notifications.

"I think the scenario I'm more worried about is the scenario where someone has an NDI and then someone else comes to market without an NDI," he said. "We have to start with the NDI notification requirement. We're happy to talk about exclusivity and such, but statutorily we're not there yet."

In some ways, FDA is already taking steps to require NDI notifications. On Tuesday (April 16), the agency launched of a list of unlawful dietary supplement ingredients and sent warning letters to 11 companies for using ingredients that either do not meet the statutory definition of a dietary ingredient or for which the company had not sent in an NDI notification. FDA will also host a public meeting to discuss supplements with stakeholders on May 16.

In his February statement, Gottlieb said NDI notifications would help FDA keep tabs on the safety of supplements before they hit the market.

Some supplement companies have been sending NDI notifications to FDA. The agency keeps a spreadsheet of the 1,078 notifications it has received since 1995. Lurie said the spreadsheet has a far higher number of NDIs than he anticipated.

"I would guess there would be almost none, because why bother," Lurie said, considering the lack of enforcement when a company does not submit an NDI notification. Still, he said it would be a good step forward if FDA could finalize a guidance on the subject.

The advocate blamed DSHEA for having "handcuffed" FDA oversight, which he said is part of the reason for the supplement industry's tremendous growth. However, now that the supplement industry has grown to its current size and wealth, Lurie argued established actors with more responsible manufacturing practices are welcoming Gottlieb's proposals as a means to eliminate fly-by-night actors from the competition.

“What’s most striking is the lack of bellicose comments from really anybody [from industry],” Lurie said. “But the guys selling supplements out of their garage won’t be happy.”

Within the discussion of supplement regulation is the question of whether FDA has the resources to carry out the expanded authorities Gottlieb called for and the increased enforcement that industry and CSPI desire. Mister and Lurie worry that FDA’s current resources under DSHEA may not be sufficient.

“They say they want to spur more innovation in the industry, but we’re concerned whether they’ll take that enforcement role more seriously,” Mister said.

The CRN CEO explained that enforcing NDI notification requirements may require FDA to protect the intellectual property of supplement companies that have submitted NDIs, as well as perform the agency’s typical duty of protecting the public health.

“FDA would have to go after safety and protect innovation,” Mister said. “I think the two are linked. If someone has not done the research, how can they possibly know that it’s expected to be safe? We have to convince FDA that it’s all interrelated.”

Fabricant was less concerned about the question of resources.

“They have pens and paper,” he said. “Having been there, so much of what FDA does is driven by willpower … if there’s a will there’s a way.” -- *David Roza* (droza@iwpnews.com)

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