Latest FDA moves could stop further research on supplements

…and turn supplements into drugs. What is this agency thinking? ***Action Alert!***

What the FDA does about supplements is usually complicated—we think intentionally so, in order to confuse Congress and critics. Bear with us as we try to disentangle the threads.

We need to get this story out now because the FDA has just opened a public comment period. It is vital to flood the agency and especially Congress with messages.

The FDA has a history of preventing scientific information about food and supplements from being disseminated. Now, if the agency gets its way, the FDA will be able to keep scientific research from being performed in the first place. In fact, our confidential sources tell us that studies on nutrients and dietary supplements are already coming to an abrupt halt. And it's all because of the FDA's guidance on INDs, or Investigational New Drug applications.

By law, if any nutrient studies actually do get published, the FDA in most instances won't allow the nutrient in question to

be purchased in supplement form. Even more shockingly, if a drug company wants to turn the supplement into a drug, they will have market exclusivity because the supplement forms would be banned. That's right: the public will no longer be able to obtain the nutrients and supplements that were studied, because the FDA says they may become drugs. The FDA is essentially making sure their drugs have no competition from supplements.

The FDA's guidance requires companies to start a burdensome and expensive drug approval process if a nutrient is to be studied for its potential disease prevention or treatment—even if the supplement won't make any related health claims or be marketed as a drug.

Companies are required to submit an Investigational New Drug (IND) application if their research*could* support new health claims or the expansion of existing health claims. Historically, INDs haven't been required for nutrients or food products simply because research does not speak to the intended *use* of the food product.

More to the point, nutrient studies are important because they include adverse event reporting (and so can help assess safety), and they give us better understanding about the effects of the nutrient on the body, as well as any potential uses for the nutrient in the future. The public relies on such research (increasingly available on the Internet) to make informed health decisions.

There is absolutely no reason for this guidance to include food and nutrients since they are already regulated. DSHEA (the Dietary Supplement Health and Education Act) and the Orphan Drug Actalready establish that dietary supplements and medical foods are *not* considered drugs. Having to submit new drug applications makes the companies publicly claim they're marketing drugs—even if they're not.

Even worse, medical foods have always been able to make disease claims—that's their sole reason for being, after all—but this guidance means that all medical foods would now require an IND—even if a New Dietary Ingredient (new supplement) notification has already been filed. (Medical foods can still stay on the market after the research is published if they had filed an NDI, but they still have to apply for an IND and pay the $2.3 million.)

There is so little research done on nutrients because of the Catch-22 of drug economics, but now with this new rule, there will be even less incentive for research. There is an exception to a supplement being classified as a drug once study data is published: if a New Dietary Ingredient (new supplement) notification has previously been sent to the FDA. But because the FDA is twenty years behind schedule on the NDI guidance, very few notifications have been filed, making this exception a very rare one.

There is also an exception if the supplement was sold before 1994. But there is no agreed upon list of these, and in the past the FDA has interpreted this provision of the law as narrowly as possible. It is not at all clear which supplements will eventually be found to qualify, and this might take years of litigation.

Here's the final kicker: this guidance is changing the industry even though the FDA hasn't taken it through the Administrative Procedure Act's formal rulemaking process. The nutrient industry has no choice but to act as if this guidance is binding law—it is especially difficult to challenge, since it is not actually law:

- According to our sources, institutional review boards (IRBs) are currently rejecting clinical studies about supplements, mainly because the boards aren't clear about the FDA's authority or the ramifications of this guidance.

- Insiders also tell us that industry giants like Nestle, PepsiCo, and Danone/Dannon are taking their research money overseas to avoid the extra cost and time to get the required IND—it takes years!—avoiding the process altogether.

Connie M. Weaver, PhD, is distinguished professor and department head for the nutrition science program at Purdue University. In an interview with ANH-USA, Dr. Weaver told us that many are worried that the effects of this guidance "would decrease the competitive edge of US research."

Joshua Miller, PhD, professor of Nutritional Sciences at Rutgers University, told us, "As an academic department chair, I would be hesitant to advise junior faculty to take up precious time applying and waiting for IND approval [for a nutrient study] as they work toward tenure. For academic research, it's a major burden. This [guidance] may shut down new research on dietary supplements in academia. It also reduces U.S. jobs—industry will take the research overseas where they won't need an IND."

The cost of an IND application is currently $2.3 million. Supplement and medical foods companies can't usually file for an IND without Pharma money—and a way to recoup their investment on a nutrient, which is not usually patentable.

Research proposals are dropped because the whole process becomes "too daunting," which in turn limits innovation. A large pharmaceutical company told us that a proposed study to investigate a popular medical food for secondary uses was rejected by an IRB for not having an IND. Another source told us that their grant was approved by the IRB, but they were told that the proposal needed to be cleared with the FDA regarding the IND requirement.

And all of this is by design: it is the FDA making the rules, and the FDA ultimately benefiting: they get $2.3 million and

full regulatory authority over the product being researched, which is now classified as a drug.

Let us say that again: as soon as the research is conducted and published, these nutrients and supplements would essentially become classified as drugs. This alone will stop most research dead in its tracks, and any research that does occur is likely to eliminate access to the very nutrient being studied. Filing the IND application sets up a process that virtually guarantees that any nutrients that are studied become drugs and can no longer be marketed as supplements once that research is published.

This is nothing more than "an administrative power grab." With this guidance, the FDA is vying for more administrative control over medical foods, dietary supplements, and conventional foods—even those whose manufacturers don't intend to market for their ability to treat diseases. US food science research is suppressed once again.

Action Alert! The FDA has opened a request for comments regarding the burden of filing an IND, the first step toward drug approval. Tell them that food nutrition research has no part in the drug approval regime. And tell them to make clear through their website or letters to IRBs that the guidance has *not* been finalized and therefore legally cannot be enforced, to help the boards know they are acting according to current regulations. ***Send your message today!***

This article originally appeared on the Alliance for National Health website.