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The Omega-3 Revolution

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Healthy Innovation Must be Nourished

By Steve Mister

Innovation is a hot topic these days. FDA (U.S. Food and Drug Administration) appears focused on protecting pharmaceutical innovation in the face of dietary supplements, but I've been thinking about how to protect supplement innovation in the face of encroaching pharmaceuticals. Continuous product innovation has long been the lifeblood of the dietary supplement marketplace—consumers constantly demand new products based on the latest science, newest delivery forms and latest ingredients, and this industry has delivered.

A steady stream of innovative products requires creative R&D suites, investments in clinical research, keen understanding of consumer "wants," and company leadership that's willing to take chances. It also takes a regulatory climate that incentivizes and rewards innovation and protects those advancements. That kind of regulatory climate starts with a firm commitment by FDA to enforce existing laws and use seizures, recalls, detentions at the port, and other available tools to police products that infringe on intellectual property.

Critics proposing changes to the regulatory climate can either enhance or threaten our future for innovation—here are three ways to safeguard it:

1. Keep Proprietary Blends to Protect Secret Formulas

A number of voices are calling to disallow proprietary blends, one of the few protections enshrined in the Dietary Supplement Health and Education Act of 1994 (DSHEA). Just like Coca-Cola and KFC have secret recipes, supplement companies use proprietary blends to protect their intellectual property. Whether a secret formula is based on folk medicine, traditional herbal preparations, or the result of highly scientific research and years of clinical investigation, proprietary blends' creators have a special interest in protecting their trade secrets.

DSHEA expressly created a unique labeling requirement for proprietary blends: While the law generally requires labels provide the precise quantity of each ingredient, it allows the label of a proprietary blend simply to provide the total quantity of the blend per serving—not the amounts of each ingredient. So, while the identity of each ingredient is disclosed, their individual amounts are not.

Companies of all sizes use the labeling of proprietary blends to protect their intellectual property. Disclosing exact formulas would allow competitors, store brands, and counterfeiters to duplicate and undercut the original products with lower-quality knockoffs. While reverse-engineering is possible, it's expensive and time-consuming, so the ability to keep one's formula a secret still has merit. Proprietary blend labeling preserves brand quality and ensures supplement users get the same blend that they know and trust—every time.

That's why it's concerning that some industry critics say it's time to get rid of this protection, that proprietary blends are dangerous or a "loophole" in the law. Both allegations are incorrect. FDA can obtain the exact ingredient mixture in proprietary blends when it conducts routine inspections of facilities under GMP (good manufacturing practice) regulations, so these recipes cannot hide risky ingredients that would be unsafe for human consumption.

Unlike in food labeling, consumers won't see an ingredient stand-in such as "natural and artificial flavors" on supplement labels. Because the label must identify the ingredients and FDA has access to the quantities, consumers can be assured their products are safe.

Ultimately, proprietary blends provide a level of intellectual property protection for supplements that creates incentives for innovation.

2. Establish Master Files to Protect New Ingredients

New dietary ingredient notifications (NDIs) should also protect innovation. FDA made clear in its 2011 and 2016 draft NDI guidances that it expects every company bringing its version of a new dietary ingredient to market to file its own notification—how else can the agency confirm that the manufacturing process is producing the same ingredient with the same safety profile as the original?

Establishing a master file for the data supporting an NDI presents another opportunity for innovation protection—but only if FDA actually enforces its position. Copycat ingredient formulators must be held to the requirement that they provide their own safety data demonstrating their ingredient is "reasonably expected to be safe," not just piggyback onto the innovator company. CRN has advocated for FDA to recognize master files for NDI submissions, allowing new ingredient formulators to provide their safety data and proprietary manufacturing processes to the agency on a protected basis. Unfortunately, FDA has refused to enforce NDI requirements, which means there is no consequence for copycat ingredient suppliers who don't bother to file notifications at all.

What's most concerning about this situation is FDA's excuse that it doesn't have resources to police intellectual property issues because its focus is on public health. Yet, the reasons for insisting each ingredient and finished product manufacturer submit its own NDI is supposedly based on protecting the public from the safety risks of unknown or unstudied ingredients. Master files enhance public health and offer dietary supplement formulators an added incentive to innovate, along with protection from copycats—but only if FDA takes its job as seriously for supplements as it does for pharmaceuticals.

3. Stop Protecting Drugs at the Expense of Supplements

It's also time to revisit DHSEA's so-called "drug preclusion provision" that gives drug developers a monopoly over an article if they bring it to market first or even conduct substantial clinical investigations on it prior to the ingredient's arrival in the supplement market. Industry has watched FDA invoke this preclusion against CBD, N-acetyl cysteine (NAC), and pyridoxamine to deny consumers access to these supplements to preserve incentives for pharmaceutical research.

The intent of the provision is abused when drug makers pursuing new potential therapeutic uses can invoke decades-old research on a different indication to remove a supplement from the market. At the very least, the drug preclusion provision should apply only to the same dosage form, a similar dosage amount, and somewhat-related indications as used in the original clinical research. Additionally, it's time FDA clarifies that the bar to supplement products is not retroactive and only applies to drugs brought to market after the passage of DSHEA. Pharmaceutical researchers in the 1960s certainly had no expectation of having a monopoly on their ingredients when the legal protection did not exist.

FDA has been quick to invoke this provision to protect drug innovation, but in this age of self-care, when consumers want options to stay healthy and avoid preventable illnesses, supplement research deserves a level playing field with pharmaceuticals.

It's Time for Congress and FDA to Step Up

While supplement firms invest in new research, take risks with product launches, and explore new applications for traditional ingredients, the legal framework must be revised to promote innovation. Regulators must protect the use of proprietary blends, implement master files to protect proprietary safety data, and balance our interests with those of our pharmaceutical brethren. Innovation, like good health, flourishes when properly nourished.

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