Injecting Safety into Supplements — Modernizing the Dietary Supplement Law

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More than 25 years have passed since one of us helped draft the law that defined the U.S. regulatory landscape for vitamins, minerals, botanicals, live microorganisms, and many other health products. The law, known as the Dietary Supplement Health and Education Act of 1994 (DSHEA), created a new category of products termed “dietary supplements.”

Today, this law does not adequately protect the public. Since it was written, the supplement industry has been reshaped by Internet sales and an increasingly complex global supply of new substances. What was a $4 billion market in 1994 with a few thousand products has grown into a more than $40 billion market with tens of thousands of dietary supplements.

We have become particularly concerned about the risks associated with newly discovered, sophisticated, and potentially potent biologic and botanical ingredients that are routinely introduced as new ingredients in supplements. The great majority of these ingredients are never reviewed by the Food and Drug Administration (FDA), even though review is mandated by the New Dietary Ingredients provision in DSHEA.

We believe the time has come to reform this law. For the first time, members of Congress, many manufacturers of dietary supplements, and the scientific community recognize that the law requires changes to enhance public safety.

We recommend reforming DSHEA such that all new ingredients, rather than only a small subset, are reviewed by the FDA and effective systems are implemented to track the safety of all supplements. This approach would provide an enhanced safety net for consumers while limiting the ability of unscrupulous companies to profit from the introduction of dangerous products that have bypassed FDA scrutiny.

The New Dietary Ingredients provision was designed to address the safety of newly introduced ingredients in supplements. For every new ingredient introduced into the market after 1994, manufacturers were expected to provide the FDA with a 75-day advance notice containing safety data establishing that the ingredient “will reasonably be expected to be safe.” Instead, a number of loopholes, vague language in the law, and lack of industry compliance have led to the majority of new ingredients being introduced without any safety evaluation by the FDA.

The FDA has also failed to enforce this provision — a failure that has led to even less industry compliance with the law and has contributed to the creation of the current supplement market. An estimated 75,000 new supplement products have been introduced since 1994, while the FDA has received adequate safety data for fewer than 250 new ingredients. The agency has no system for determining how many new ingredients are contained in the tens of thousands of new products on the market.

The safety risks associated with the current system are illustrated by the case of 1,3-dimethylamylamine (DMAA), a pharmaceutical...
stimulant, which was introduced into hundreds of workout and weight-loss products without being vetted by the FDA. By 2011, experts at the Department of Defense (DOD) had grown concerned that DMAA might increase troops’ risk of hemorrhagic stroke and sudden death. The DOD took the unusual step of prohibiting the sale of the stimulant on military bases and, under pressure, the FDA banned DMAA nationwide.

Many supplement manufacturers responded by reformulating their products with alternative stimulants. One replaced DMAA with a new combination of aegeline, higenamine, and caffeine, including synthetic versions of botanical constituents not traditionally consumed together. The firm did not notify the FDA of this change, nor did it provide safety data to the agency. Within a year of being introduced, the product, OxyELITE Pro, had been linked to an outbreak of severe hepatitis affecting 69 people; 32 of them were hospitalized, 3 required liver transplants, and 2 died.

This product and similar ones were introduced by companies that often claimed their products were exempt from safety notification under DSHEA. The law provides an exemption for ingredients that have been “present in the food supply as an article used for food in a form in which the food has not been chemically altered,” and manufacturers have used this provision to justify not submitting safety data to the FDA. The law was written with the expectation that this exemption would be used infrequently, but its language is not sufficiently clear. The exemption was not meant to apply to new chemicals, combinations, or synthetic compounds. Nonetheless, the FDA has appeared to condone the use of this loophole to permit countless substances to be introduced in the absence of submitted safety data.

The loophole has grown into the exemption that swallowed the law: industry developed, and the FDA accepted, an approach whereby manufacturers convene sympathetic food-safety experts to affirm that a new, nontraditional ingredient is “generally recognized as safe.” The firm then incorporates the new ingredient into an energy bar or drink. After the ingredient has been in the “food supply” for a few months, the manufacturer claims that it can market the new ingredient, at any dose, in dietary supplements.

Fortunately, momentum is building from many stakeholders to reform the law by closing this loophole and ensuring that all new ingredients are reviewed for safety by the FDA before products are sold. The solution we propose addresses the inherent tension between maximizing consumer access and protecting consumer safety and attempts to balance these interests. We believe that thoughtful reform is practical, can be passed by Congress, and should include three basic principles.

First, manufacturers should be required to submit all product labels to the FDA so that the agency is aware of, and can track, what products are on the market. Mandatory submission of product labels would enhance transparency and advance the FDA’s ability to use its authority under DSHEA to regulate products. The agency could be required to provide each product with a unique bar code or quick response (QR) code and could use these codes to track adverse effects, manufacturing problems, and adulteration. With this system in place, the FDA could determine whether a labeled ingredient is new and lacking adequate evidence of safety before a product appears on the market. The agency could flag products containing such ingredients in the label database so that retailers would be able to easily confirm that a product was properly listed with the FDA before making it available in retail stores or online.

Second, we believe that manufacturers should be required to submit basic safety data for all new ingredients to the FDA. The definition of “new” or “novel” ingredient should be changed so that exemptions apply only to extracted ingredients formulated in the same quantity and form as they are consumed in botanicals or food — for example, bioflavonoids extracted from citrus fruit. For all other new ingredients, regardless of their origin, firms would be required to submit evidence of safety to the FDA before selling their products.

Finally, for mandatory listing and safety screening of new ingredients to have meaningful effects on consumer safety, the FDA would need to aggressively enforce the law. New legislation will need to clearly delineate the FDA’s responsibilities and ensure that the agency receives adequate budgetary resources for necessary reorganization and increased enforcement.

With stronger safeguards incorporated into a thoughtful reform of DSHEA, we believe it is possible to create a modern reg-
ulatory framework for supplements that would achieve Congress’s original intent of providing consumers with access to a wide variety of safe vitamins, minerals, botanicals, and other dietary supplements.

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