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Invited Commentary | Complementary and Alternative Medicine

Ensuring the Safety and Value of Supplements

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Elsewhere in *JAMA Network Open*, Cohen et al[1] report on the contents of 57 purportedly performance-enhancing sports supplements. Remarkably, 23 (40%) contained no detectable amount of the declared ingredient. Given that the US Food and Drug Administration (FDA) does not preapprove these products or their claims, this might actually be good news: at least the risk of ingredient-caused adverse effects is removed. But 6 products included 1 FDA-prohibited pharmacologically active ingredient, 1 product contained 4, and many contained levels of active ingredients well above labeled quantities. Beyond the risk to the wallet, this study suggests that these products may pose a potential hazard to human health.

In fact, this report is only the most recent of a series of similar articles by some of the same authors looking at an array of other categories of dietary supplements. All document the extraordinarily poor quality of dietary supplements purchased online, from cognitive enhancers to melatonin to cannabidiol.[2,3]

This predicament can be traced to passage of the Dietary Supplement Health and Education Act (DSHEA) in 1994, which resulted in the underregulation of the dietary supplement market and underfunding of FDA's Office of Dietary Supplement Programs (ODSP). At the most fundamental level, the FDA cannot be expected to effectively police a marketplace of supplements when it does not even know what products are in that marketplace. While supplement manufacturing facilities must register with FDA, they are under no obligation to provide a list of their products, or what they contain, to the agency. A market that included approximately 4000 unique products at DSHEA's inception has exploded to include an estimated 95 000 products today.[4] And not only does the FDA not know what products are currently on the market, but companies can introduce new dietary supplement ingredients without even notifying the agency and can simply self-certify the ingredients as safe.

The FDA also cannot order a mandatory recall of apparently adulterated products like the 7 described by Cohen et al.[1] The adulteration of these products with pharmaceuticals converts them into unapproved drugs, and FDA's drug center has no mandatory recall authority. Moreover, devoid of the power to issue civil monetary penalties, the agency is reduced to issuing a series of warning letters. In a study of 776 supplements tainted with pharmaceuticals, only 360 (46%) led to voluntary recalls.[5]

And the agency is woefully underfunded. In fiscal year 2022, ODSP's budget was a paltry $12.7 million, which is completely inadequate to police an industry that had $56 billion in sales in 2020.[6] As a consequence, inspections are infrequent. However, citations during those inspections are not,[7] highlighting the need for greater oversight.

Finally, there is the matter of the claimed benefits of these products. By statute, supplement companies can make what are called structure/function claims (eg, builds strong bones) but are precluded from making disease claims (eg, prevents osteoporosis), which are the exclusive preserve of drugs, biologics, and devices.[8] But our own work at the Center for Science in the Public Interest has found a plethora of products variously claiming to treat opioid addiction, overweight, smoking, and infertility.[9] And while companies are required to be able to substantiate these claims, the FDA does not typically request this documentation, and PubMed searches and requests to companies for these data typically do not yield evidence supporting their claims.

As the work by Cohen et al[1] demonstrates, supplements often do not contain what is advertised or, more concerning, contain ingredients that may not be safe for consumers. This work underscores

the need for Congress to take action and increase oversight over supplements marketed and distributed in the United States. This may be the time; as the supplement market has become more lucrative, cracks in the previously unified supplement industry edifice have appeared, with some members of this community supporting at least a product-listing requirement. Moreover, some of the industry's stalwart defenders are no longer in Congress. It is not too late to reform an industry that has consistently underperformed.

ARTICLE INFORMATION

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