COVID-19 is more proof of why dietary supplements need regulation

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Pills, powders, gummies, tinctures, teas. Dietary supplements come in countless forms and are big business in the United States, racking up more than $55 billion in sales annually.

Which is curious when you consider that not one of the more than 75,000 vitamins, minerals, botanicals and other products sold as dietary supplements since 1994 has been approved by the Food and Drug Administration (FDA) for safety and efficacy. In fact, despite the trust consumers apparently have in them, supplements send tens of thousands of people to emergency departments annually.

And while this story is an old one to patient safety advocates, it now has a new chapter: With the onset of the COVID-19 pandemic, sales of dietary supplements to boost or support immunity almost doubled.

A study published in *JAMA Network Open* analyzed 30 dietary supplements purchased from Amazon.com that made claims related to immune health. Its results showed that fewer than half of the products had accurate labels, and only one-third were deemed likely safe by a scorecard developed by the Consortium for Health and Military Performance (CHAMP) at Uniformed Services University in Bethesda, Maryland.

**The public has a right to know**

According to the *Nutrition Business Journal*, sales of dietary supplements aimed at immunity totaled $3.4 billion in 2019. By the end of 2020, sales had jumped to $6 billion.

In addition, online sales of all supplements grew from $5 billion 2019 to $8.4 billion just one year later. About 77% of those were made on Amazon.


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“The growth in e-commerce, sales and manufacturing of dietary supplements, coupled with the limited resources for regulating dietary supplements, has created a challenge in keeping up with the market,” wrote the study’s authors, who include Patricia A. Deuster, PhD, MPH, of CHAMP in the Department of Military and Emergency Medicine, F. Edward Hébert School of Medicine at Uniformed Services University.

“Adulteration, misbranding and misleading claims are regularly reported,” they added.

Since December 2020, Amazon has required its sellers to provide outlined quality control documentation and a certificate of analysis for the dietary supplements they sell, ostensibly to help ensure these products are safe and unadulterated.

The study’s researchers tested the veracity of this requirement by purchasing 30 dietary supplement products that appeared with four-star or better reviews on Amazon in May 2021. One sample of each was then sent to the National Center for Natural Products Research at University of Mississippi for product analysis through liquid chromatography–mass spectrometry.

Read more about why dietary supplements are underregulated, unknown and maybe unsafe.

The upshot: More regulation needed

More than half of the products the researchers tested—17 of 30—were found to have inaccurate labels. Thirteen of those were misbranded, meaning they had ingredients listed that weren’t present—some were missing just one ingredient, while others were missing as many as six. And nine products had components that were detected but not claimed on the label.

Each product was then evaluated according to the Operation Supplement Safety (OPSS) scorecard, a tool developed by the Department of Defense who has taken an interest in dietary supplements because of their frequent use by members of the U.S. military. Only 10 of the 13 products with accurate labels received an OPSS score indicating they were likely OK or less risky.

“Claims made on the labels of most dietary supplement products seem to stretch what would be considered as allowable claims,” the authors wrote. “Some other claims sounded scientific but did not have any peer-reviewed publication cited. Therefore, it is unknown how or whether these claims were substantiated.”

The study’s findings provide fresh evidence of the need for FDA to have appropriate enforcement tools and policies related to dietary supplements.
Bipartisan legislation was introduced in the U.S. Senate earlier this year to improve safety and ensure transparency in the dietary supplement industry. The move was commended by the AMA, which has policy calling for increased regulation of dietary supplements.

Learn more with this AMA Ed Hub™ course, “Dietary Supplements: What Physicians Should Know.”