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### Authors

Katta, Rajani  
She, Jenny  
Perez-Sanchez, Ariadna

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# What your patients need to know about skin supplements

Rajani Katta<sup>1</sup> MD, Jenny She<sup>2</sup> BS, Ariadna Perez-Sanchez<sup>3</sup> MD

Affiliations: <sup>1</sup>Department of Dermatology, McGovern Medical School, University of Texas Houston, Houston, Texas, USA, <sup>2</sup>Baylor College of Medicine, Houston, Texas, USA, <sup>3</sup>Department of Medicine, Division of Hospital Medicine, University of Texas Health Sciences Center San Antonio, San Antonio, Texas, USA

Corresponding Author: Rajani Katta MD, Katta Dermatology, 6750 West Loop South, Suite 695, Bellaire, TX 77401, Tel: 281-501-3150, Email: [info@kattamd.com](mailto:info@kattamd.com)

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To the Editor:

As skin supplements continue to grow in popularity, physicians must educate their patients on several concerns. These include a lack of regulatory oversight, multiple quality and safety concerns, and a lack of monitoring for long-term side effects. They are not FDA approved and are regulated as foods, not medications, which means that premarket testing is not required. Lacking such testing, physicians must often tell patients that they simply do not have data on efficacy or safety. Quality concerns have been well-documented and range from contamination with heavy metals to toxic doses of ingredients. A lack of required monitoring for long-term side effects is troubling, as multiple concerns have been raised with vitamins and minerals consumed at supraphysiological doses.

It wasn't the first time I had been asked this question "I'd rather take something natural. Can you recommend a supplement?" In dermatology practice, we often encounter patients seeking "natural" solutions instead of prescription medications. For patients who are so inclined, they certainly have a lot of products to choose from. In fact, the number of dietary supplements available in the United States is estimated to be as high as 80,000 [1]. Before our patients reach for that supplement, they need to know several important points, including the lack of regulatory oversight as well as multiple documented quality and safety concerns.

To begin, we need to inform our patients that there is no such thing as FDA approval for dietary

supplements. These products are regulated as foods, not drugs, which means that a manufacturer can bring a product to the market without showing any proof of efficacy or even safety. Unlike prescription medications, which must undergo a rigorous FDA approval process and testing, there is essentially no approval process for dietary supplements [1]. This lack of regulation is likely one of the contributing factors to the remarkable growth of the supplement industry, with the market expanding from an estimated \$4 billion industry 25 years ago to a more than \$40 billion industry today [1].

Unfortunately, without any required pre-market clinical trials or testing, physicians often lack the data needed to provide an informed opinion. Patients may find it frustrating when a physician cannot confirm the efficacy or safety of a particular supplement, but with the current regulatory process, it should not be surprising.

Experts note that even with this remarkable growth in the supplement industry, safety and oversight practices have not kept pace. In fact, quality control remains a significant concern. Researchers and independent testing organizations have reported multiple quality control issues with supplements, including contamination with heavy metals, inaccurate reporting of ingredient levels, toxic doses of ingredients, inadequate disintegration of pills, and more [2]. Although supplement manufacturers are expected to adhere to good manufacturing practices, it is hard to know how many do so, and

how well they do so. Unfortunately, the FDA is only able to inspect a small fraction of manufacturing facilities. An FDA spokesperson revealed that in 2023, the FDA only conducted 461 domestic inspections and 40 foreign inspections. Shockingly, 60% of these foreign firms and 47% of these domestic firms received citations of noncompliance [3]. It therefore often becomes “buyer beware” when purchasing supplements.

Another major area of concern is that physicians and consumers alike frequently lack important information about the long-term effects of supplements. The short-term adverse effects of skin, hair, and nail supplements have been well-documented and include allergic reactions, sedation, interference with laboratory testing, and others [2]. The long-term adverse effects have been less well-documented, but even so, several alarming findings have been described. Notably, even vitamins and minerals, when consumed at doses above the recommended daily allowance, can result in adverse effects over the long-term. It is known that low doses of iron, for example, can result in iron toxicity if consumed over long periods of time. Many other vitamins and minerals consumed at supraphysiologic doses have similarly been linked to adverse effects with long-term use.

Unfortunately, in many cases, there has been no effort made to monitor for long-term side effects. With the increasing use of new ingredients and/or high doses of micronutrients in supplements, this is of concern. Although some supplements have been studied in clinical trials, even one year of study may not be enough to uncover long-term adverse effects.

In one instructive study, researchers instituted a randomized controlled trial (RCT) to evaluate the effects of high-dose antioxidants in the prevention of skin cancer [4]. This was a promising area of research, as multiple population, animal, and laboratory studies had demonstrated the benefits of dietary antioxidants in skin cancer prevention. Study subjects were given a daily antioxidant supplement containing vitamins C and E, minerals zinc and selenium, and beta-carotene. Unfortunately, it was found that the incidence of skin cancer in women

was actually higher in those consuming the antioxidant supplement (with a median follow-up of 7.5 years).

Researchers now believe that high-dose antioxidants can actually become pro-oxidants. As I explain to my patients, when it comes to micronutrients, the guiding principle is not “more is better.” A better analogy is that of salting your food: sometimes too much can be worse than not enough.

The long-term consumption of selenium supplements provides another example of adverse effects that may take years to become apparent. In one RCT, researchers found that five years of daily selenium consumption at a dose of 300µg per day increased all-cause mortality as assessed 10 years later [5]. Another RCT found that a selenium dose of 200µg per day, a dose found in some hair loss supplements, significantly increased the risk of developing type 2 diabetes within an average of 7.7 years [6].

As we field more questions from our patients about the benefits or risks of skin, hair, and nail supplements, we must advise them of the many unknowns regarding these products. At the very least, patients should seek out products that have undergone independent third-party testing to evaluate the purity of a product and the accuracy of its Supplement Facts label. The NIH Office of Dietary Supplements recommends seeking out “seals of approval” from organizations such as USP (US Pharmacopeia), NSF (National Sanitation Foundation), or Consumer Lab [7]. However, these seals do not indicate efficacy or safety of a product and patients should still maintain caution. Sometimes the hardest thing for physicians to say to our patients is “I don’t know,” but with the ever-expanding numbers of dietary supplements available to consumers, this statement may be one we need to increasingly make.

### Potential conflicts of interest

Rajani Katta MD: Advisor, Vichy Laboratories, and Consultant, National Eczema Association. The remaining authors declare no conflicts of interest.

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