Episode: *Author Interview: "What Should Dietary Supplement Oversight Look Like in the U.S.?*"

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[bright theme music]

TIM HOFF: Welcome to another episode of the Author Interview series from the *American Medical Association Journal of Ethics*. I'm your host, Tim Hoff. This series provides an alternative format for accessing the interesting and important work being done by Journal contributors each month. Joining me on this episode is Elizabeth Richardson, who directs the Health Care Products Project at the Pew Charitable Trusts in Washington, D.C. She's here to discuss her article coauthored with Farzana Akkas and Dr Amy Cadwallader, *What Should Dietary Supplement Oversight Look Like In The U.S.?*, in the May 2022 issue of the Journal, *Underregulated Supplements*. Liz, thank you so much for being on the podcast with me today. [music fades out]

LIZ RICHARDSON: It's my pleasure. Thanks for having me.

HOFF: So, to begin with, what's the main ethics point that you and your coauthors are making in this article?

RICHARDSON: Yeah. The key message we really wanted to highlight in our article is that the Food and Drug Administration, which is responsible for ensuring the safety of dietary supplements on the market, doesn't really have the ability to effectively oversee these products, at least not under the current regulatory framework. For example, manufacturers are not currently required to provide the agency with basic information about the products they market. That includes product names. It includes the full list of ingredients. It includes what claims they are making about those products. This poses, I think, several risk to public health. Most concerningly, I think, are the studies that have found hundreds of dietary supplements on the market containing undeclared or banned pharmaceutical ingredients.

But there have also been countless examples of manufacturers making false and misleading claims about their products, claims which they have never had to substantiate to FDA, which is, I think, is a key thing that distinguishes supplements from other products the agency regulates, like medical devices or pharmaceuticals. When supplements are mislabeled, when they include undeclared, risky ingredients, or they carry claims that are false or misleading, then the consumer really doesn't have a complete picture of the products they're taking. They can't fully weigh potential benefits against potential risks. And as a result, they really can't make an informed choice about their health and their well-being, and they may be putting themselves in harm's way without realizing it. And concepts like informed consent are obviously fundamental to ethics. And so, that's really the key point we wanted to make with our piece, though of course, there are other really interesting bioethical issues surrounding dietary supplements.

HOFF: So, what do you see as the most important thing for health professions students and trainees to take from your article?

RICHARDSON: The most important thing from our perspective is that legislative and regulatory reform is really needed in order to help address the gaps in oversight and to better protect consumers and patients. We lay out several specific reforms that've been proposed and which are currently under consideration in Congress. Some of them are quite simple. For example, supplement manufacturers should be required to list all of their products with the FDA and tell the agency all of the ingredients in those products, as well as the claims they are making about them. To me, as a consumer of dietary supplements, it was shocking to me when I realized that the agency did not have that information on file in some kind of central database.

HOFF: Mmhmm.

RICHARDSON: They are not, manufacturers are just not required to tell the agency everything they make.

The agency should also have clear authority to mandate the recall of supplements that have been tainted with active pharmaceutical ingredient. Right now, there's legal ambiguity around that. We cover several other interventions that really could be helpful in improving the existing regulatory framework. But even if all these reforms were implemented, health care providers have a really important ongoing role to play when it comes to informing their patients about the risks associated with some supplements.

There is sometimes a perception among consumers that supplements are safe because they are, quote-unquote "natural" or "more natural."

HOFF: Mmhmm.

RICHARDSON: And I think it's important for medical providers and clinicians to help to correct that perception where necessary. That could include asking patients what supplements they are taking and discussing any potential drug/supplement interactions. It includes informing them about variable quality of supplements and the presence of disreputable or adulterated products on the market.

Finally, I think clinicians should really consider supplements as a potential source of unexplained adverse events, and they should report suspected adverse events to FDA. There's a portal where clinicians can report adverse events related to supplements. It's an important part of the agency's regulatory framework. It's an important source of information they have to understand safety risks. So, it's important, I think, for clinicians to participate in that.

HOFF: And finally, if you could add a point to your article that you didn't have the time or space to fully explore, what would that be?

RICHARDSON: Mm. I think really only that the pandemic has really exposed, and in many cases deepened, a lot of the cracks in our systems for medical product oversight.

HOFF: Mmhmm.

RICHARDSON: The FDA has always struggled to adequately regulate dietary supplements owing largely to the limitations of their authority over these products and their

chronic underfunding. I believe the agency's budget for supplement oversight is in the realm of $11 million a year.

HOFF: Jeez.

RICHARDSON: Which [chuckles] they are supposed to use to oversee a multibillion-dollar market containing an estimated 80,000 products.

HOFF: Mmhmm, mm.

RICHARDSON: But over the last two years, they've also had to suspend a lot of their inspection activities because of the pandemic, which further limits their ability to root out problems. The reforms that we outline in our piece would be a big step forward in helping the agency to get a better handle on that market and allowing them to better target their limited resources and more effectively protect public health.

HOFF: Mmhmm.

RICHARDSON: So, final message really is that Congress should move quickly to pass legislation that would accomplish these reforms. [theme music returns]

HOFF: Well, Liz, thank you so much for your expertise and your time today. I appreciate your contribution to the podcast and to the Journal.

RICHARDSON: Oh no, thank you. I never like to miss an opportunity to [chuckling] push for my priorities!

HOFF: [laughs] Absolutely. Thank you for being here.

RICHARDSON: All right. Bye-bye.

HOFF: To read the full article, as well as the rest of the May 2022 issue for free, visit our site, JournalofEthics.org. We'll be back soon with more *Ethics Talk* from the *American Medical Association Journal of Ethics.*