

Episode: *Author Interview: "Is My Patient Taking an Unsafe Dietary Supplement?"*

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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 Dr Ilisa Bernstein, Senior Vice President of Pharmacy Practice and Government Affairs at the American Pharmacists Association. She's here to discuss her article coauthored with Karin Bolte, *Is My Patient Taking an Unsafe Dietary Supplement?* in the May 2022 issue of the Journal, [Underregulated Supplements](#). Dr Bernstein, thank you so much for being on the podcast today. [music fades out]

DR ILISA BERNSTEIN: Great. Thanks. Thanks for giving me the opportunity to bring the words to life.

HOFF: So, to begin with, what's the main ethics point in your article?

BERNSTEIN: Well, the article provides a basic overview of dietary supplement regulatory and legal requirements, which sounds pretty dry, but it's exciting. And it's really important information that clinicians should know because they should know about dietary supplements: what's required, what to look out for, and there are rogue products out there. So, the article covers information including the safety, manufacturing, labeling information that is required on packaging, adverse event reporting that's also required. And then, as I said, it describes some of that rogue activity because there are tainted dietary supplements out there that have really severe harm, cause harm to patients.

And the dietary supplement industry has exploded over the decades since the real last substantive law was passed, which was in 1994. And I was at FDA back then.

HOFF: Oh, really?

BERNSTEIN: Yes. And I worked on passage and implementation of that law. And although the market was smaller back then, it was still the Wild, Wild West, and that law helped out a lot.

HOFF: Can you clarify what law you're referring to?

BERNSTEIN: Yeah, it was the Dietary Supplement and Health Education Act.

HOFF: Mmhmm.

BERNSTEIN: And it just created some requirements and some oversight of the dietary supplement industry. And even though the marketplace is very overwhelming, what it does is—and kind of one of the main pieces of that legislation is—it required certain information

to go on labeling. And that's what patients and clinicians can use to look at to see what's in the product that they're going to be using.

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

BERNSTEIN: We have three takeaways in the article, and the first is that dietary supplements can have side effects.

HOFF: Mmhmm.

BERNSTEIN: They interact with foods, medicines, other supplements, and can be unsafe. And so, it's important for clinicians and others to specifically ask whether a patient is taking a dietary supplement, what the dose is. It should be listed on their chart, their medication chart, because it has just similar, could have some similar effects.

HOFF: Mmhmm.

BERNSTEIN: The second is that although people don't realize that FDA does not approve these products beforehand, similar to drugs, there are some legitimate labs that test these products, such as the USP, the U.S. Pharmacopeia, and consumer labs and others. So, looking for specific legitimate labs is helpful because they test them to know what's in them and making sure that the label is describing what's in them.

HOFF: Mm.

BERNSTEIN: And then the third takeaway is that there are a lot of wild claims out there about dietary supplements and that clinicians should counsel patients about those claims. And if they're too good to be true, they probably are, and that is a red flag.

HOFF: Sure. And finally, if you could add a point to your article, what would that be?

BERNSTEIN: Well, it's essential to know what you're taking and what your patient is taking. And there is some new legislation being considered that would require manufacturers to report their labeling information to FDA. There are no current requirements for manufacturers to list their products with FDA.

HOFF: Mmhmm.

BERNSTEIN: And so, although there are requirements of what has to go on the label, they don't have to tell FDA or provide FDA with those labels. So, what this legislation would do was provide FDA with information about what's in the products. And then that would create a database that pharmacists, health care providers, consumers, even FDA, and others can use to identify what's in them and whether they're legally on the market.

HOFF: Mmhmm.

BERNSTEIN: But that's not there yet. And so, until that happens, when you're looking for information about dietary supplements, be cautious about what's on the Internet, and go to tried and true legitimate sources. Contact the manufacturer or—and I have to add because I'm a pharmacist—or ask your pharmacist. [theme music returns]

HOFF: Sure. Well, Dr Bernstein, thank you so much for being on the podcast today and for you and your coauthor's contribution to the Journal this month.

BERNSTEIN: Thank you for having me.

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