

Episode: *Ethics Talk: Should You Trust Influencers' Posts About Dietary Supplements?*

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TIM HOFF: Welcome to *Ethics Talk*, the *American Medical Association Journal of Ethics* podcast on ethics in health and health care. I'm your host, Tim Hoff.

On every dietary supplement bottle you pick up in the grocery store or you walk by in the pharmacy, you'll see the same disclaimer: "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." But that same bottle on the front might claim to, "Promote cardiovascular health" or "Support energy and immune function." While the FDA might not technically consider these kinds of statements to be claims to treat or cure consumer ailments, that distinction is easy to lose in the sea of advertising language around dietary supplements. And where there's confusion around health claims, there's a risk of harm.

Most consumers might know that the FDA regulates food and drugs, but what they likely don't know is that dietary supplements are considered neither food nor drugs. This leaves them in a regulatory gap that allows advertisers to advance misleading or false claims before other regulatory processes are able to stop them.

Dr Amy Cadwallader, the Director of Regulatory and Public Policy Development for the U.S. Pharmacopeia and the former Director of Science & Drug Policy at the American Medical Association, as well as Assistant Secretary to the AMA Council on Science & Public Health, joins us to discuss the process of bringing dietary supplements to the market and how non-governmental organizations ensure customer safety by filling the regulatory gaps left by agencies in the U.S. Dr Cadwallader, thank you so much for being on the show with me today. [music fades out]

DR AMY CADWALLADER: Oh, it's my pleasure to be here. Thanks for having me.

HOFF: So, later on in the podcast, we're going to be talking to some other guests about how dietary supplement advertisements are regulated. But listeners might be surprised to hear what happens, or more specifically what doesn't happen, before a product even gets to the point that it's being advertised to the public. So, can you tell us a little bit about what kinds of regulation exists for dietary supplements before they enter the market?

CADWALLADER: Sure, I'd be happy to. But first, let's level set on the definition of a dietary supplement.

HOFF: Mm, mmhmm.

CADWALLADER: It's a product that is ingested and intended to supplement the diet. And the U.S. Food and Drug Administration, or the FDA, is the federal agency with the primary responsibility for the regulation of dietary supplements

HOFF: Mmhmm.

CADWALLADER: Under the Dietary Supplement Health and Education Act of 1994, often referred to as DSHEA, manufacturers and marketers of dietary supplements are responsible for ensuring that the products they sell are safe and lawful. Unlike FDA's role in regulating prescription drugs, dietary supplements are not subject to pre-approval requirements for safety and efficacy. Additionally, the FDA does not approve dietary supplement labeling before dietary supplements are sold to the public. In fact, companies can often introduce dietary supplements to the market without even notifying the FDA.

FDA's role in regulating dietary supplements primarily begins after the products enter the marketplace. They inspect manufacturing facilities for compliance with FDA regulations, including those related to product quality and labeling, including claims, and they monitor adverse event reports to identify products that might be potentially unsafe. If a product is found to be unsafe or not otherwise in compliance with the law, the FDA can work with the manufacturers to bring the product into compliance or possibly remove it from the market.

HOFF: Mm. So, when you talk about regulating the manufacture of these dietary supplements, if that doesn't happen before they're brought to market, at what point does the FDA begin auditing manufacturing facilities, for example? Is it just in response to adverse event claims, or how does that even come onto their radar?

CADWALLADER: That's exactly right. So, it happens when they learn about something from the marketplace. Some adverse event report or some contamination is reported. They will hear about those things and then look to remediate a problem if there is one.

HOFF: Mmhmm. Yeah. Thank you for clarifying. Consumers are often faced with what seems certainly like endless labels and warnings, especially on dietary supplements. And these labels can be confusing, and they can be apparently, to sort of an untrained consumer, contradictory. So, what are some basic labeling requirements that people should know about when they pick up a bottle of, let's say, multivitamins at the grocery store and look at, it says, "to support heart health," but then also, "these claims not evaluated by the FDA." How do they parse that information?

CADWALLADER: That's a really, really good question and a really good point to discuss. So, companies that manufacture or market dietary supplements are responsible for ensuring that their labels are truthful and not misleading. The FDA requires that certain information appear on supplement labels, including a statement clearly written on the front of the product identifying it as a dietary supplement or something similar, vitamin supplement, for example. Dietary supplements are required to have a supplement facts label on the back that lists serving size, how many servings are in the container, every dietary ingredient that's in the product, the amount of certain ingredients per serving, the information about dietary ingredients that are contained within proprietary blends (but not specific amounts or any additional details about what is in this proprietary blend), and other fillers such as binders, preservatives, sweeteners, flavorings.

Federal law does permit manufacturers and marketers to make certain claims, including claims that describe how the product affects either the structure or the function of the human body if they can substantiate that the claims are truthful and not misleading. Examples of this type of claim include, "Calcium builds stronger bones," and, "This is for mild memory loss associated with aging."

HOFF: Mmhmm.

CADWALLADER: If a manufacturer chooses to make these structure/function statements, they must notify the FDA and include a disclaimer on the product label that reads, “This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.” Claims to treat, diagnose, prevent, mitigate, or cure diseases are specifically for drugs and require FDA approval to be used on FDA-approved drug products. So, these kinds of claims are prohibited on dietary supplements, and if a consumer sees them, it should be a red flag.

HOFF: Sure. So, you say that they need to notify the FDA for these structure/function claims? So, when does that process happen? Is that something that needs to happen before it comes to market, or is it, when does that happen?

CADWALLADER: Before they put the label out, typically. They’re given a period of time before they put the product on the market for the FDA to review that claim.

HOFF: Okay. And then you also said that on the back it needs to list things that are dietary ingredients. Is that to say that they have things that they aren’t required to list, or are things that aren’t dietary ingredients, things like fillers and whatnot that you covered later?

CADWALLADER: Right. So, they’re the ingredients that are essentially the “active”—I’m using air quotes here—the “active” components of the dietary supplement. So, for example, if you’re purchasing an amino acid blend, then it will list those amino acids because they’re the dietary ingredient that is intended from the product. And you’re correct in your statement that other things are like excipients and fillers and sweeteners and flavorings, etc.

HOFF: Okay. Yeah. Gotcha. Thank you for clarifying that. So, how do organizations like USP help to fill these regulatory gaps that we see emerging in the dietary supplement industry and promote consumer safety?

The United States Pharmacopeia, or USP, isn’t a regulatory agency. We support consumer safety in the dietary supplement industry by developing science-based quality standards for medicines, foods, and dietary supplements. These standards include tests for the identity, strength, quality, and purity of the dietary ingredients in the products. We follow an open and transparent public process to consider and evaluate input from many stakeholders, including manufacturers, regulators, suppliers, and any other interested party who wants to provide information.

DSHEA named the *United States Pharmacopeia’s National Formulary* as official compendia for dietary supplements. The current version of this document includes almost 500 monographs that articulate quality standards for dietary supplement ingredients and finished dietary supplement products. And this covers most of the commonly found products that are in commerce currently. Although conformance to these standards isn’t mandatory, adherence can help ensure that dietary supplements are produced according to robust scientific expectations for quality and can help reduce that potential for a public health risk.

USP also has a dietary supplement verification program that’s open to manufacturers of dietary supplement finished products from around the world. Through a rigorous testing and auditing process, USP evaluates voluntarily submitted products against science-based

quality standards and FDA current good manufacturing practices. Dietary supplement products that meet the program's strict testing and evaluation criteria are awarded a USP-verified mark that they can put on their label.

In addition to our scientific standard setting, USP regularly convenes key stakeholders to discuss issues related to dietary supplement quality. For example, USP established a dietary supplement sector as part of its 500-member governing convention to engage stakeholders to improve widespread trust in the quality of dietary supplements and to advocate public health and patient safety.

And finally, USP is the convener of a very diverse multi-stakeholder group called the Dietary Supplement Quality Collaborative or the DSQC. This group of 27 organizations is committed to the advancement of policies and initiatives designed to improve and maintain the quality and safety of dietary supplement products. The DSQC supports policies and resources to advance innovation; help ensure safe, quality supplements; remove illegal products, including those that are tainted with chemicals, from the marketplace; and to promote consumer education.

HOFF: So, you had talked about the USP evaluating these voluntarily submitted supplements. What is essentially the incentive structure for companies to do that? Is it just the USP label that they get on their product or what? Tell me a little bit about why an organization might do that.

CADWALLADER: Well, currently that is the case. The incentive is that USP-verified mark that is really prominently placed on a label. And it's a signal for consumers that the company cares enough about quality and scientific rigor to have this verification to test for the presence, or lack of, contaminants and other, you know, bacterial contamination or chemical contamination so that the company really cares enough about quality to go that extra mile and get that verification.

HOFF: To wrap up, clinicians are often asked to recommend or comment on patients' dietary supplement use, but given the lack of regulation that we've been talking about, they might feel unprepared or not knowledgeable enough to do so. So, what should health professions students and trainees know about counseling patients about dietary supplements before they're in the position where they have to?

CADWALLADER: That's a really good and a really important question. It's very important to ask patients what they are taking during a review of their medical history. Some tips for discussions with patients include specifically asking about what dietary supplements or vitamins they're taking, including how much, how often, and why they're taking them. It's important to remind them to contact a health care professional before taking any supplement, and especially if they're experiencing any adverse reactions. And consider counseling patients about the potential benefits and risks of taking dietary supplements, including a discussion about the possible interactions with other medications and the varying quality of the products on the market. So, if they do choose to continue or begin use, they're better equipped to identify quality products and recognize some of the red flags.

Another important reminder for health care professionals is about adverse events. If a clinician suspects that a dietary supplement might've caused or contributed to an adverse event in their patient, such as a bad reaction, a side effect, an unexpected symptom, or an illness, they should tell the patient to immediately stop using the product. And then they

should notify the FDA by submitting a report through the safety reporting portal. And remember, as we talked about earlier, it's these queries or these reports from physicians that really help the FDA to determine those products that need some attention or should be addressed with a review. [mellow music returns]

HOFF: Well, Dr Cadwallader, thank you so much for your time and your expertise today. I really appreciate you coming on the podcast.

CADWALLADER: It was my pleasure to be here. Thanks for having me.

HOFF: The digital presence and audience of conspiracy-driven far-right commentators on one hand and New Age health gurus on the other might not seem to have much overlap at first. Both, however, take advantage of the lax regulatory environment around dietary supplements. They advertise products extensively on their podcasts and on their websites, and they rebrand already existing products for sale to their particular audiences.

In one particularly illuminating case, a health guru sells a dietary supplement containing Maca under the name Sex Dust and advertises it as a, "Lusty edible formula alchemized to ignite and excite sexy energy in both men and women." A far-right commentator also sells a Maca supplement as Super Male Vitality, which promises to, "Create superior vitality in males when working up to 12 hours a day or more in the fight for freedom."

While marketing and branding a product's effects is nothing new, the scope of Internet sales platforms and the lack of regulatory frameworks to address misleading or false claims about dietary supplements leaves consumers to wade through confusing claims themselves. Growth of social media influencers' roles in advertising dietary supplements has placed new and outsized pressure on FDA and FTC policies that were never designed to address them in the first place.

Joining us now to discuss the wave of social media influencers advertising dietary supplements and the potential route for regulating this new frontier is Scott Schweickart, Senior Research Associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago, Illinois, where he's also the Legal Editor for the *AMA Journal of Ethics*. And Josh Klein, a JD candidate at DePaul University College of Law in Chicago, Illinois, where he is Symposium Editor for *the DePaul Journal of Social Justice*, Public Relations Chair for OUTlaws, a Health Law Fellow at the Jaharis Health Law Institute, and the former DePaul Scholar Intern for the Council on Ethical and Judicial Affairs. Josh and Scott, thank you so much for being on the podcast with me today. [music fades out]

SCOTT SCHWEICKART: Absolutely. Thank you for having us.

JOSH KLEIN: Yeah, happy to be here. Thank you.

HOFF: To begin with, can you briefly explain why dietary supplements are considered food by the FDA as opposed to something like medication and how our dietary supplements are treated differently than medication by the FDA?

SCHWEICKART: So, essentially, why they're called food is that there is an act called the Dietary Supplement Health and Education Act that defines dietary supplements, and they define them specifically as things intended to supplement the diet that bears or contains one or more of the following dietary ingredients. And then the statute lists vitamin, mineral, herbs, amino acids are some examples here. So, specifically in the law, it's carved out to

not be a drug, and they deem it a food. And so, that does have profound consequences in terms of regulation because the FDA regulation of drugs is a lot more involved and profound. You have to have a new drug application. It has got to go through clinical trials, testing the clinical safety, testing efficacy. But when it's deemed a food, does none of that. No testing for safety, no testing if it works. It's just deemed a food.

Why that was made? It's controversial. There are some people that believe that some dietary supplements should be regulated like a drug, especially since sometimes they've been kind of promoted and advertised as having medicinal benefits.

HOFF: Mmhmm.

SCHWEICKART: So, there might be a broader policy reason why they view it as food, but it is controversial, and some people do argue that that there should be a change.

HOFF: Mmhmm. So, obviously, the FDA doesn't consider dietary supplements medication, and so, doesn't regulate them the same way. But why aren't current regulatory mechanisms sufficient for ensuring that dietary supplement advertising promotes safety in the first place? Obviously, we have regulations around the advertisements of food and of medications. So, where's the gap?

SCHWEICKART: Right. So, the gap, it's in two places. So, in terms of regulating these dietary supplements, you have the FDA, which, right, which does regulate it, but it deems it a food. And they will look for safety, but it's more, it takes a lot more before they're going to step in. So, for example, the first time they really ever stepped in with regulating a dietary supplement for safety was in 2004. There was a supplement called Ephedra that was promoted for weight loss, and it did cause some harm. And then finally, the FDA did come in and act against it. So, they still can act against it, but the burden's a lot higher than for drugs. So, that's part of it. So, they're there, but it just takes a lot more.

The other component of how they could be regulated is the FTC, which is the Federal Trade Commission. They can regulate advertising. And so, that's another way where these things can be regulated is in dietary supplement advertising. And so, the FTC, what they're looking at is whether or not an advertisement is truthful and non-misleading and whether or not there's any adequate substantiation to support these claims. So, the FTC's looking at that. But the problem there is again, especially in this kind of modern era of influencers, the FTC's not, they're not robust in terms of enforcing that. And maybe there's just too much out there that they can't get to it.

So, it's like we have, so these two agencies are there and they can do some things, and they do. But what we're just seeing in practice is that it's not enough, and there's a lot of stuff that's being out there that the FDA and FTC just can't get to by virtue of it's just overwhelmed, or they just don't want to. It's complicated. But that's what we're seeing is that it's...the reality is a lot of stuff falls through the cracks.

HOFF: Yeah.

SCHWEICKART: And the current system just can't regulate it properly.

HOFF: Can one of you talk a little bit more about the interplay between the FTC and the FDA? So, for example, if a social media user sees a post and they're not sure if it constitutes commercial advertising or they know that it's an advertisement and they

specifically know it's a false one, that seems like it'd be in the realm of the FTC to regulate. But then if that dietary supplement then goes on to cause harm, it seems like that would be the realm of the FDA. Does that seem like how it shakes out?

SCHWEICKART: Yeah. Yeah, I think that's right. The FDA's still looking at the safety, broadly speaking, of the supplement, whereas the FTC is looking at the advertising side of it. So, it is. It's two ways of regulating it. One specifically the supplement itself, and then one is more regulating the advertisers, how it's being advertised and is it false or misleading. So, that would be correct.

HOFF: And can you clarify a little bit further about the difference between, so it seems like there are two kinds of issues with advertising. So, one might be that the advertisement itself is just making false claims. It's claiming that this supplement does something that it can't. The other issue would be advertisements that might not look like advertisements in the first place, and so consumers might not be prepared to critically evaluate the claims being made in the way that they would if they knew what they were seeing was an ad. So, can you talk a little bit about how the FTC regulates this sort of more subtle issue of not being sure that things are commercial advertising, and making sure that advertising happening on social media platforms is flagged as such?

KLEIN: As Scott said, the FTC's tasked with, among other things, protecting consumers by stopping false or misleading advertising. In pursuit of that task, the FTC has authority under Section 5 of the FTC Act to issue two different types of rules. The first type of rule is an interpretative rule or a general statement of policy. These types of rules function more as guidelines. They don't carry the weight of formal law. And then—

HOFF: Can you clarify what that means? Just that there's no enforcement structure in place? Or what does that mean?

KLEIN: It means that if a influencer violates an interpretative rule, there aren't civil penalties associated with it, and the FTC isn't able to pursue any sort of consumer redress.

HOFF: Okay.

KLEIN: And then the second type of rule is one that defines with specificity the acts or practices that are unfair or deceptive. And these are actual formal rules of law. So, it grants the FTC the discretion to pursue civil penalties and consumer redress against violators. And the FTC has acted pursuant to its Section 5 authority and issued rules that apply to social media influencers when they advertise products. And these are the endorsement guides that the FTC has issued. They're interpretive guides, and they require that influencers, as well as any endorser, disclose any personal connection or financial connection that they have with the seller of a product. And these disclosures must be clearly and conspicuously placed. So, in the context of social media advertising, that would mean putting #Ad at the top of the hashtags as opposed to burying it amongst hundreds or in a post with multiple pages. It means disclosing it in the first page and not burying it at the end of all of the posts.

Now, as I pointed out, these guidelines are interpretive rules. They don't carry civil penalties, and if an influencer doesn't disclose any information, the FTC is forced to launch an investigation to determine whether the practices are unfair or deceptive under the language of the FTC Act. And that process is, it can be very time consuming and

expensive. And the FTC has limited resources. It just can't police the thousands of nano and micro influencers who are promoting products on social media. So, that has led to the FTC only seldomly seeking to impose liability on endorsers in general and very rarely when it comes to influencers specifically. And that has led to influencers repeatedly violating the endorsement guides and facing no liability.

So, although the FTC has the authority and is tasked with protecting consumers against this sort of advertising and has issued rules to do so, the reality is, is that many influencers disregard the rules, don't know about them, or don't comply with them. And consumers are left on their own to determine whether the post that they're seeing is an organic recommendation of a product or whether the influencer's being paid to say what they're saying.

HOFF: Hmm. So, you, I think, highlight this issue of there just being too many people on social media making sponsored posts to effectively police all of them. But what's the issue with going after the big fish, so to speak? Is the FTC perhaps just afraid of like an unequal application of the law? Does that open them up to some kind of legal jeopardy? Or what's stopping them from engaging at least the most prevalent of these kinds of advertisers?

KLEIN: So, part of it is the difficulty in establishing that failing to disclose is false or misleading, simply because the FTC has to rely on the language of the FTC Act. Whereas had they issued a rule that carried the formal weight of law, simply not disclosing an ad could make it much easier for the FTC to bring liability. Because they could point to that violation, and it's per se a violation of the law. The FTC wouldn't have to go through the whole process of an investigation. So, it's the choice of issuing interpretative rules as opposed to formal rules that causes such an issue.

And there have been a few instances where the FTC has responded to some of the big fish, like you said. There was an instance where Lord & Taylor had a few thousand influencers post photos of a dress, and none of them disclosed that it was an ad.

HOFF: Mm.

KLEIN: And the FTC sent warnings and sent letters telling influencers to comply, but it didn't come with liability, and it didn't come with civil penalties. So, there really isn't much of an incentive to comply with the endorsement guidelines.

HOFF: That's very interesting. Thank you. In your article this month, you note one possible route of redress of negligent misrepresentation, which might be a way to at least hold social media influencers themselves, if not the companies that they're advertising for, accountable for these false or misleading claims. So, can you explain a little bit about what negligent misrepresentation is and how it promotes safety for dietary supplements?

KLEIN: Yes. So, the consumers themselves can't enforce the FTC Act. So, if the FTC decides not to seek liability, the consumer doesn't really have much of an option. But many states have the common law claim of negligent misrepresentation. And this allows consumers to seek various types of injunctive relief, damages, attorneys' fees, punitive damages against endorsers who mislead or deceive their buyers. This requires that the consumer establish that the influencer supplied false information, the influencer failed to exercise reasonable care or competence in obtaining or communicating the information, that the influencer intends for the information to influence the buyer, and that the consumer was actually harmed as a result of that. So, they are fairly high bars to meet.

But the hope is that if a handful of high-profile cases against influencers are successful, it would have a cascading effect amongst influencers as a whole. And this would be that once influencers start seeing others facing liability for promoting products and making claims that aren't substantiated or justified, that they're going to be more careful in what products they choose to promote themselves. And in response to that, the hope would be that the marketing companies or manufacturers change their business practice so they can keep getting influencers to promote their product, because it is a very effective way to promote products.

HOFF: Do you know if any of these negligent misrepresentation claims have gone through? Is this something that's actually being pursued in the courts?

KLEIN: There haven't been any that I know of against influencers specifically.

HOFF: Mmhmm.

KLEIN: However, the FTC has brought actions against other endorsers that, although they're not negligent misrepresentation actions, the elements of the claim are very similar. So, they've imposed liability on endorsers who fail to substantiate the claims that they were making.

HOFF: Hmm.

KLEIN: So, even though they weren't the ones who got the information, they were held liable because they didn't verify that information. They didn't look to make sure that the manufacturer actually had data to support these claims, to make sure that the scientific research was there to support the claims. So, it puts that onus on the influencer to make sure that the—or it has the potential to put the onus on the influencer to make sure that—they are really looking into what the marketing company or the manufacturer is telling them.

HOFF: Hmm.

SCHWEICKART: And I might just add too that I think discussing the concept of using negligent misrepresentation as a common law claim, you're right. I don't know of any case that's done this yet going after influencers. We're kind of just suggesting it as a possibility. If the federal agencies can't regulate it appropriately, this might be another avenue. But there's definitely challenges with that too. I mean, it might take a class action kind of tort to go after this. But also, there's still challenges with it too, because there's a lot of bit players, bit player influencers, that it's going to be hard to get a claim, a serious claim against. So, there's challenges with this, too. So, I would say a holistic approach of using the common law, but then still realizing that the federal agencies probably need to modernize and revamp their regulatory structures to be able to go after influencers is still important. [mellow music returns]

HOFF: Josh and Scott, thank you so much for your time and your expertise both in the Journal and on the podcast today.

SCHWEICKART: Thank you.

KLEIN: Thank you for having us.

HOFF: That's it for this month. Thanks to Dr Cadwallader, Scott Schweickart, and Josh Klein for joining us. To read the full issue on underregulated supplements for free, you can head to our site, JournalofEthics.org. For all of our latest news and updates, follow us on [Twitter](#) and [Facebook @JournalofEthics](#). And be sure to tune in next time when we'll be discussing clinical care in conflict zones. Talk to you then.