

Episode: *Author Interview: “How Should Regulators and Manufacturers Prevent Avoidable Deaths of Children From Contaminated Cough Syrup?”*

Guest: Amy B. Cadwallader, PhD

Host: Tim Hoff

Transcript: Cheryl Green

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[bright theme music]

[00:00:03] 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 way to access the interesting and important work being done by Journal contributors each month. Joining me on this episode is Dr Amy Cadwallader, the director of regulatory and public policy development at US Pharmacopeia. She’s here to discuss her article, coauthored with Kavitha Nallathambi, “*How Should Regulators and Manufacturers Prevent Avoidable Deaths of Children From Contaminated Cough Syrup?*,” in the April 2024 issue of the Journal, [Global Medical Supply Chain Security](#). Dr Cadwallader, thank you so much for being on the podcast. [music fades]

DR AMY CADWALLADER: Thanks, Tim. I’m really glad to be here.

[00:00:48] HOFF: So, to begin with, what is the main ethics point that you and your co-author are making in this article?

CADWALLADER: That would be that all patients all over the world have a human right to safe and effective medicines that they can trust. There’s an ethical imperative to ensure that everybody can access quality medicines and that all of the ingredients used to make them are quality.

[00:01:10] HOFF: And so, what do you see as the most important thing for health professions students and trainees specifically to take from this article?

CADWALLADER: The issue of quality medicines and their ingredients is a universal global problem, not one that’s specific to low- or middle-income countries. Just last week, in the beginning of January 2024, the FDA sent out warning letters to manufacturers of over-the-counter products in the United States for failing to test their products for diethylene glycol, ethylene glycol, and other contaminants. So, awareness of this really critical issue to ensure that all patients are treated appropriately is really necessary for patient safety.

[00:01:54] HOFF: And finally, if you could add a point to this article that you didn’t have the time or the space to fully explore, what would that be?

CADWALLADER: I think it would be that supply chains, pharmaceutical supply chains, are very complex. And that complexity has made excipients in the raw materials that are used to make the medicines we all take vulnerable to contamination and adulteration. There’s really a clear need for greater regulatory focus on strong quality controls for testing and the analysis of these raw materials and active pharmaceutical ingredients and other ingredients that are in medicines. Not all countries around the world have the same quality assurance requirements and resources that we do in the United States. In particularly those low- and middle-income countries, this can

result to a risk to patients and patient safety. Pharmaceutical manufacturers and suppliers really need to live up to their responsibility when it comes to producing safe, quality products. Public quality standards that are applicable really apply across the entire supply chain, and they're available to support those who are developing medicines. [theme music returns] And using them and utilizing them appropriately can bring an end to preventable deaths due to the contaminations that we're talking about in this article.

[00:03:14] HOFF: Dr Cadwallader, thank you so much for your time on the podcast today, and thanks to you and your co-author for your contribution to the Journal this month.

CADWALLADER: Thanks, Tim. Thanks for having us.

HOFF: To read the full article, as well as the rest of this month's 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*.