Episode: *Author Interview: "What Should Prescribers and Policy Makers Know About US Drug Importation?"*

Guest: Nisha Quasba, MPH
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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 Nisha Quasba, a senior manager of health policy and government relations at Faegre Drinker in Washington, DC. She's here to discuss her article, coauthored with Elliot Vice, "*What Should Prescribers and Policy Makers Know About US Drug Importation?*," in the April 2024 issue of the Journal, *Global Medical Supply Chain Security*. Nisha, thank you so much for being on the podcast. [music fades]

NISHA QUASBA: Thank you, Tim, for having me. Really excited to be here.

[00:00:47] HOFF: So, to begin with, what is the main ethics point that you and your co-author are making in your article?

QUASBA: Sure. So, to step back just a moment as to just the background on the paper. So, as we know, the United States faces affordability challenges due to the escalating cost of prescription drugs, and it exceeds per capita spending compared to other high-income countries. That stat is probably the most well-known one. In response to those soaring prices, policymakers and the government had explored drug importation policy as a lever, not surprisingly, and it's been a policy lever for not just 2024, but actually one that has stood for over two decades, since the passage of the Medicare Prescription Drug Improvement and Modernization Act in 2003. So, right? We're about 20 years since that date. And then in 2020, there was an implementation of Section 804 Importation Program, which was aimed to significantly reduce costs for American consumers by allowing states to do wholesale drug importation. And the way to do so was for the state to do its due diligence and provide a proposal to the federal government, specifically FDA. And what the article essentially emphasizes is this perceived affordability and accessibility of imported medications from other countries but being carefully weighed up against the potential risks to patient safety, lighter regulatory oversight, and the possibility, to some extent, of even inequitable distribution of these medications.

[00:02:35] And so, I would bucket our ethical concerns that we lay out in our article into a number of categories. One, patient safety. So, patients will be exposed to imported drugs that really raise concerns of authenticity, purity, potency, and not really that great, what I would say is bucket number two, regulatory oversight. Definitely lighter regulatory oversight. When you have drugs that are coming from other countries, FDA has less of a lens into the drug quality and safety of those medications. Third, which I think folks don't really fully appreciate, is even the distribution of these imported drugs may actually exacerbate existing health disparities in the health care system, specifically thinking through how will these medications be distributed within a state and where certain populations or regions may have a greater access to drugs than

others even if you're importing drugs into a given state. I think another piece to it, which is bucket four, is we will be impacting the imported country's own drug supply chain. And one country that we emphasize quite a bit in the paper is Canada's drugs will be in shortage as a result. Just the basic size of the population of the United States, Canada, I think, is one third of the US population, but would be expected to be supplying quite a larger amount. And so, that would inherently have a very negative impact on the drugs within Canada with increased demand from the United States.

[00:04:25] Kind of coupled with patient safety is just the risk of counterfeit drugs. I think when you have lack of oversight from FDA, you're just running the risk of substantial counterfeits coming into the supply chain that otherwise, if gone through the regulatory process, we wouldn't see that as much. And lastly, just misleading consumers. I think there is a misconception that there will be some significant cost savings, and our paper goes into quite a bit of depth as far as that argument of affordability. Is that just a perceived affordability? And our conclusion is, yes, because many of the proposals that have been enacted ultimately have shown to actually maybe not give the end user, aka the patient, as much savings or money in their pocket as they may believe they would.

[00:05:24] HOFF: And so, what do you see as the most important thing for health professions students and trainees specifically to take from your article?

QUASBA: Yeah, I think that's a great question. So, for health professionals, students, and trainees, I think critically evaluating the implications of drug importation policies on patient safety is probably definitely within their wheelhouse. Effectively educating patients to not be swayed into what I consider the new bright, shiny object without taking into consideration all the ethical concerns I just noted.

So, earlier this month—and kind of using this in a practical sense—earlier this month, Florida had submitted its own state importation proposal to FDA a number of years ago, and earlier this month, FDA actually approved their importation program, meaning certain drugs can be imported through wholesale importation, not personal importation. And what I think would be helpful for health care providers to know, and students and trainees, is recognizing there's a distinction that does not mean a green light for someone to be able to go over and get their own medications. But actually, drugs could be imported to the state for wholesale importation, which is significantly different than personal importation.

I think there also needs to be a recognition, and this would be helpful for clinicians to be aware of is, it would only be effective in Florida. And also, even with the FDA approving Florida's state importation program earlier this month, there's a number of processes Florida still has to go through until it would actually go into real effect, meaning Canadian imported drugs would actually be at the counters of Florida pharmacies. And so, there's that waiting period. But I think folks read the headlines and kind of jump to an end conclusion, and I feel like that's where health care providers could help bridge that misunderstanding to an extent.

[00:07:38] 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?

QUASBA: It is absolutely no secret that the United States has a problem with high drug prices. That is undeniably the truth. I think what's more important, and what we hope to kind of glean into that in our paper but wish we had gone into a little bit deeper, is there needs to be an importance on exploring more comprehensive, systematic reform within the health care system

to address the root cause of these hikes in drug pricing. I think, in our opinion, drug importation is more so a Band-Aid. And what I mentioned earlier, the bright, shiny object, but does it effectively keep patients safe, one? Two, does it also give us cost savings? Three, is it going to be accessible to all those who need it? I think the answer to all those three questions is no. And so, even if the policy may sound great, in practice, we anticipate it to be far different. And there's a lot of research that proves that point.

And the patient safety angle is one that FDA has historically had and has been the reason why they haven't approved the programs beforehand. And so, this has been a significant shift with its announcement this month that they're approving the Florida State Importation Program. All to say, I think that will cause a domino effect for all the other states that have also submitted a state importation proposal to FDA. And so, we're going to see other states be in the same boat as Florida, and to see how they will be able to prove to FDA that there are no safety risks in their program has yet to be seen. [theme music returns]

[00:09:43] HOFF: Nisha, thank you so much for your time on the podcast today and for you and your co-author's contribution to the Journal this month.

QUASBA: Thank you. Thank you, Tim.

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*.