



Probiotic Safety—Reasonable Certainty of No Harm—Reply

Citation

Cohen PA. Probiotic Safety—Reasonable Certainty of No Harm—Reply. *JAMA Intern Med.* 2019;179(2):276–277. doi:10.1001/jamainternmed.2018.7492

Permanent link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:42642016>

Terms of Use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Open Access Policy Articles, as set forth at <http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#OAP>

Share Your Story

The Harvard community has made this article openly available.
Please share how this access benefits you. [Submit a story](#).

[Accessibility](#)

Title: Reply to 'probiotic safety'

Author: Pieter A. Cohen

Word count: 414

Conflicts of Interest: No additional conflicts since publication of Viewpoint.

I appreciate Cabana and colleagues' interest in my recent Viewpoint *Probiotic safety- no guarantees*.⁽¹⁾ However, they incorrectly characterize the safety standard for probiotics sold in the United States. Probiotics may be sold in a variety of products including as a constituent of food, a food additive or a dietary supplement. Each of these categories has different safety standards. Probiotics sold as dietary supplements, for example, are not required to have a *reasonable certainty of no harm*, as Cabana and colleagues' suggest.⁽²⁾ Rather, the standard for supplements requires only that a supplement ingredient cannot present "a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling".⁽³⁾

Since the term "probiotic" implies health benefits,⁽⁴⁾ probiotics should not only be safe, they should also offer health benefits. Unfortunately, there is no requirement that live microorganisms marketed as probiotics in the US have proven health benefits. These live bacteria and yeast should be accurately labeled as "live microorganisms" rather than "probiotics".

With respect to the ability of these strains to infect humans, there is no controversy. Live bacteria sold as commercial probiotics are capable of infecting immunocompromised hosts,(5) therefore probiotics have “inherent infective qualities”. This is well-established.(6)

I agree with Cabana and colleagues that there is extensive international experience in designing robust safety assessments of live microorganisms for human consumption. However, as Cabana and colleagues acknowledge, these state-of-the-art practices are not required for the microorganisms sold as probiotics in the US. They suggest that consumers should contact individual companies to obtain the results of safety testing. Even if it were provided, consumers are not in the best position to interpret safety assessments of live microorganisms. Instead, consumers would be better served by the US Food Drug Administration (FDA) requiring rigorous safety testing for all probiotics. If the agency cannot do so under the current law, the FDA should petition Congress for increased authority such that the agency can ensure that these live microorganisms are safe for consumption.

Finally, the authors advise clinicians to “make sure that a particular product they recommend is manufactured under standards that are safe for the intended patient”. In the current environment, this is an impractical

suggestion. The labels of probiotic supplements are not required to provide the specific strain, the quantity of live microorganisms or any safety information. Under the current regulatory framework, neither consumers nor clinicians can reliably obtain essential information regarding the efficacy or safety of live microorganisms marketed as probiotics in the US.

References

1. Cohen PA. Probiotic safety – no guarantees. [published online Sept 17, 2018] *JAMA Intern Med* 2018. doi:10.1001/jamainternmed.2018.5403
2. Cohen PA. Assessing supplement safety – the FDA’s controversial proposal. *N Eng J Med* 2012;366(5):389-391.
3. Dietary Supplement Health and Education Act of 1994. Pub L No. 103-417, 1994. 103rd Congress, 2nd sess., S784.
4. Food and Agriculture Organization of the United Nations/World Health Organization. Health and nutritional properties of probiotics in food including powder milk with live lactic acid bacteria. Córdoba, Argentina. Oct, 2001.
5. Kunz AN, Noel JM, Fairchok MP. Two cases of *Lactobacillus* bacteremia during probiotic treatment of short gut syndrome. *J Pedi Gastro Nutr* 2004;38:457-8.

6. Hempel S, Newberry S, Ruelaz A, et al. Safety of probiotics used to reduce risk and prevent or treat disease. *Evid Rep Technol Assess* (Full Rep). 2011; 200(200):1-645.