Probiotic Safety—Reasonable Certainty of No Harm—Reply

Title: Reply to 'probiotic safety'

Author: Pieter A. Cohen

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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

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