



Hello,

April 12, 2020

I am Ross Pelton and I “brand” myself as ***The Natural Pharmacist***. I am writing to express my outrage and disappointment at an article titled *The Probiotic Conundrum*¹ that was published in *JAMA* Viewpoint on March 3, 2020. The authors of this article make absurd generalizations and slanderous statements about probiotics and the whole field of microbiome science.

The fact that *JAMA* would publish such a biased article that does not contain scientific references for the outlandish claims the authors make brings *JAMA*’s integrity into question. *JAMA* purports to be a peer-reviewed medical journal. However, I doubt that *The Probiotic Conundrum* was peer-reviewed because reviewers would catch the glaring omission of references or citations to support the claims the authors have made.

The article’s authors Stephen Freedman², David Schnadower³ and Phillip Tarr⁴ have positions at respected medical and scientific institutions. However, they make the following unscientific and unsubstantiated claims about probiotics;

- a. they state that there is a “paucity of high-quality data supporting the value of probiotics”
- b. that reports of the efficacy of probiotics are “potentially biased”
- c. they also claim that there is “increasing concern about the safety of probiotics.”

It puzzles me that these three authors collectively state that there is “a paucity of high-quality data” in the probiotic industry when one of the authors, Phillip Tarr, MD, MPH is associated with Washington University School of Medicine in St Louis, Missouri. Is it possible that Dr. Tarr is unaware of the fact that Dr. Jeffrey Gordon, who is one of the world’s leading probiotic/microbiome scientists heads up one of the finest microbiome and genomic research centers in the world, namely The Edison

Family Center for Genome Sciences & Systems Biology?⁵ Dr. Gordon and his lab, which employs nearly thirty top-level scientists and staff, are located at Dr. Tarr's institution, the Washington University School of Medicine, in St. Louis, Missouri.

I'd like to remind the authors that the U.S. government committed \$140 million to fund the **Human Microbiome Project** (2007-2012). Then, in May 2016, the US White House Office of Science and Technology Policy announced **The National Microbiome Initiative** with \$121 million from US federal agencies and \$400 million from university and industry sources.

Other international microbiome research projects that have been initiated include the Canadian Microbiome Initiative (CMI)⁶, Canadian Microbiome Initiative 2 (CMI2)⁷, MetaHIT (METAGENOMICS of the Human Intestinal Tract) which was funded in 2008 involving countries from the European Union and China⁸, and the Human MetaGenome Consortium in Japan⁹.

A search in the Web of Science database revealed that there have been more than 50,000 research articles on the gut microbiome published in the past two decades and over 10,000 articles since Jan. 1, 2019.

Paralleling this explosion of scientific research into probiotics and the human microbiome, many probiotic and microbiome products and companies have been launched. Also, scientists involved in cutting edge microbiome research are frequently involved with start-up companies and new products. Yes, this can lead to conflicts of interest. Yes, there have been instances scientists and/or companies have mis-represented microbiome studies or made inappropriate health claims for various probiotic or microbiome-related products. But this is certainly not the "state of the industry" and broad generalizations suggesting a paucity of high-quality data and questioning the safety and efficacy of the whole industry are totally unjustified.

Let's take a look at the safety of commercial probiotic products. In 2015, there was just one single report of an infant death that was linked to a contaminated probiotic.¹⁰ To my knowledge, this is the ONLY death that has ever been associated with a probiotic product.

According to results from a Johns Hopkins Medicine study, over 250,000 people in the United States die every year because of medical mistakes.¹¹

These statistics from 2013 make doctors and the practice of medicine the third leading cause of death in the United States, behind heart disease (611,000 deaths) and cancer (584,000 deaths).

Research on probiotics and the human microbiome are leading to a whole new understanding of what it means to be human. Humans get one copy of each gene from their mother and father. However, we are not just the product of our human DNA. We now realize that over 99% of the DNA in our body is the DNA of our bacteria.¹² We are not just “us”, we are “us” plus “them”. We are a Human Superorganism functioning symbiotically with the approximately 100 trillion bacteria in our microbiome.

A Revolution in Microbiome Science

For decades, we’ve known that probiotic bacteria play important roles in the regulation of human health but until recently, probiotic mechanisms of action have remained a mystery. That is beginning to change with the growing understanding of the many functions of postbiotic metabolites.

Probiotic bacteria are amazingly complex little chemical manufacturing plants. There is an increasing understanding that the primary function of probiotic bacteria is to digest and ferment dietary fibers, which results in the production of a wide range compounds known as “postbiotic metabolites.” Scientists are learning that postbiotic metabolites are critical health-regulating compounds that influence every organ in the body, including the brain and the immune system.

I wrote an article titled **Postbiotic Metabolites: The New Frontier in Microbiome Science** that was published in the June 2019 issue the *Townsend Letter*¹³. This article explains how probiotic bacteria create postbiotic metabolites and how in turn, various classes of postbiotic metabolites control and regulate a vast amount of human health.

JAMA is one of the most widely read and respected medical journals in the world. However, when *JAMA* publishes an article like *The Probiotic Conundrum*, it makes me question the integrity of the editors and the journal. I don’t know if the authors of *The Probiotic Conundrum* had biases or conflicts of interest, or if they were just unaware/ignorant of the vast body of research on probiotics and microbiome science.

In closing, I just want to say, *JAMA*, shame on you for publishing such a

biased, unscientific article that questions the efficacy and safety of the whole microbiome/probiotic industry and all the dedicated scientists around the world who are doing ground breaking research in the fields of probiotics, postbiotic metabolites and microbiome science.

Thanks you,

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¹ Freedman SB, Schnadower D, Tarr PI. The probiotic conundrum: Regulatory confusion, conflicting studies, and safety concerns. *JAMA*. 2020;323(9): 823-824.

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⁵ Jeffrey Gordon, Ph.D. Research Lab. <https://gordonlab.wustl.edu/>.

⁶ Canadian Microbiome Initiative *Workshop Report*. https://cihr-irsc.gc.ca/e/documents/iii_microbiome_works_rep_e.pdf.

⁷ Canadian Microbiome Initiative 2 (CMI2). <https://cihr-irsc.gc.ca/e/39939.html>.

⁸ MetaHIT: The European Union Project on Metagenomics of the Human Intestinal Tract. https://www.researchgate.net/publication/225216838_MetaHIT_The_European_Union_Project_on_Metagenomics_of_the_Human_Intestinal_Tract.

⁹ HMGJ (Japan) https://link.springer.com/referenceworkentry/10.1007%2F978-1-4614-6418-1_560-2.

¹⁰ Vallabhaneni S, et al. Fatal Gastrointestinal Mucormycosis in a Premature Infant Associated with a Contaminated Dietary Supplement — Connecticut, 2014. *MMWR Morb Mortal Weekly Rep*. 2015 Feb 20;64(6):155-156.

¹¹ Makary MA and Daniel M. Medical error-the third leading cause of death in the US. *BMJ*. 2016;353;i2139.

¹² Zhu B, et al. Human gut microbiome: The second genome of the human body.

¹³ Pelton R. Postbiotic Metabolites: The New Frontier in Microbiome Science. *Townsend Letter*. June 2019;431:64-69.