# Researchers call for regulation of direct-to-consumer microbiome tests

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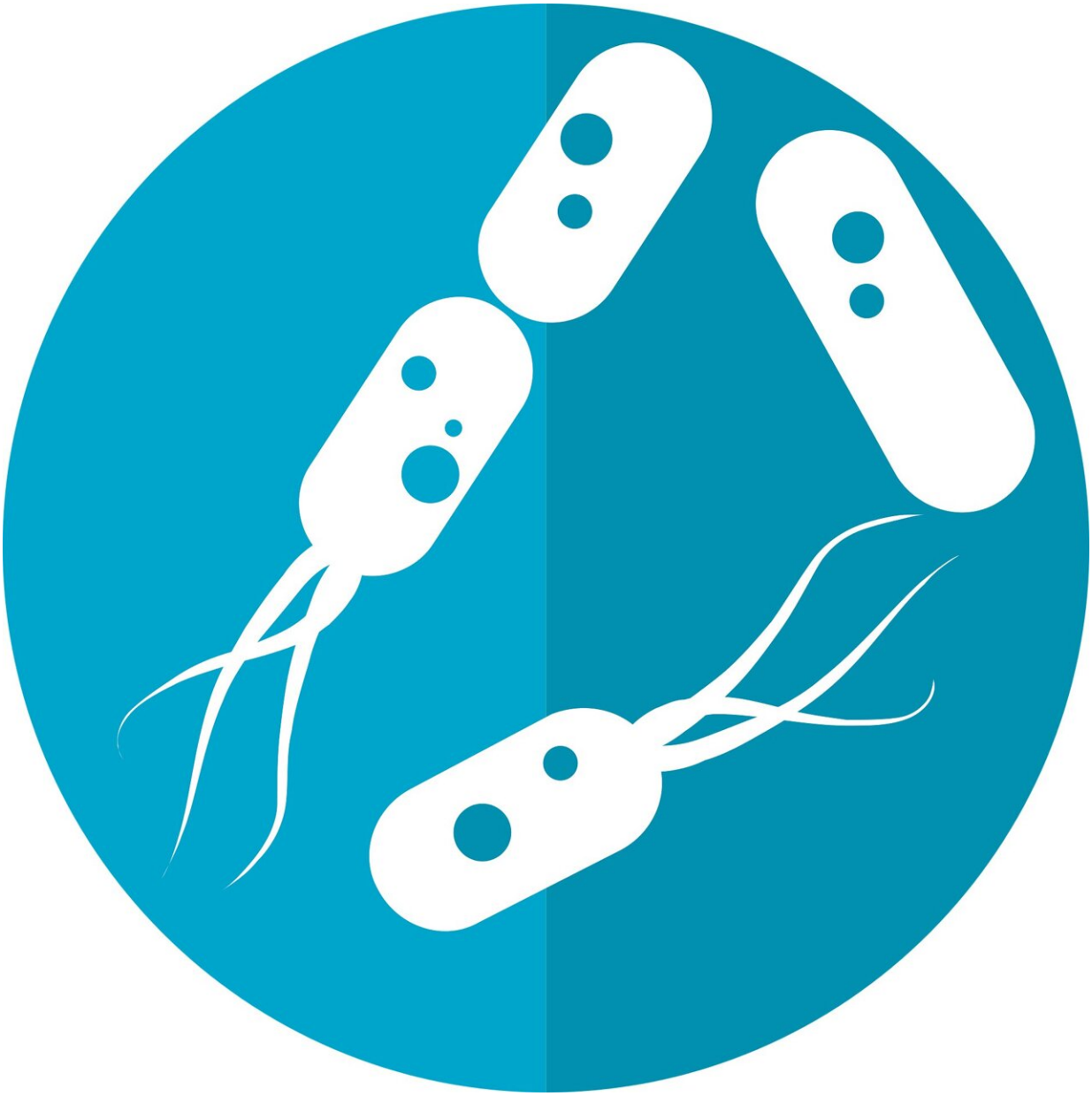

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Scientific research has linked a person's microbiome to everything from gut and mental health to immunity and predisposition to cancer. This research comes at a time when there is a burgeoning interest in wellness and alternative medicine, which has fueled consumers' curiosity about the composition of their own microbiomes.

This curiosity has led to a growing demand for direct-to-consumer (DTC) microbiome testing services. While the companies marketing these services claim to tell customers whether their microbiomes (gut, vaginal, skin…) are "healthy," researchers from the University of Maryland, Baltimore Schools of Law, Medicine, and Pharmacy question the tests' accuracy.

In a unique multidisciplinary collaboration, the researchers call for greater regulation of these products in a Perspectives article published in *Science.* Diane Hoffmann, JD, MS, Director of the Law and Health Care Program and the Jacob A. France Professor of Health Care Law at the University of Maryland Francis King Carey School of Law, led the collaboration.

The perspective is the result of a study that consisted of consultations with experts in food and drug law, microbiome sciences, gastroenterology, gynecology, government regulations, and bioethics as well as focus groups with clinicians and consumers using the products.

DTC microbiome testing services identify which microorganisms are present along with their relative abundance in a fecal or vaginal sample that the consumer collects. In some cases, the test may describe the metabolic functions of the microbes observed.

"There is a perception among consumers that these products will give them a real medical diagnosis and a way to treat an 'unbalanced' microbiome," said Jacques Ravel, Ph.D., co-author and Acting Director of the Institute for Genome Sciences and Professor of Microbiology and Immunology at the University of Maryland School of Medicine (UMSOM).

"There is no scientifically agreed-upon definition of a 'healthy' microbiome; the microbiome is dynamic and changes frequently; there is no clinical proof that these products work; and no standardization in the processes involved."

For consumers—who often suffer from diseases such as inflammatory bowel disease (IBD) or bacterial vaginosis (BV)—that means shelling out a lot of money for a test without a guarantee of useful or actionable medical information—and then often further investing in what companies tell them will help improve their microbiome, such as nutritional supplements including probiotics and prebiotics, or special diets. None of these interventions have been clinically validated or had their claims evaluated by the U.S. Food and Drug Administration (FDA).

"In addition to the cost, these tests could do real harm by convincing a person to delay medical care and substitute supplements for prescription medications," added Dr. Ravel, who studies the vaginal microbiome.

"We're calling for federal regulators with oversight of these testing companies to set standards for the analytical validity of their tests and require them to report on their performance," said Hoffmann. "Additionally, the FDA needs to determine if DTC microbiome tests are general wellness tests or if they make diagnostic claims that could harm consumers. If it is determined that these are diagnostic tests, then FDA regulation will be required."

In addition to the FDA, the authors write that government bodies like the National Institute of Standards and Technology (NIST) should set standards for the tests, including laboratory methods so that test results are accurate, can be trusted, and are comparable across labs; the Centers for Medicare and Medicaid Services (CMS) under the Clinical Laboratory Improvements Amendments (CLIA) should regulate the analytical validity of the tests, including the testing methods and algorithms used to formulate a report and should require the testing companies to adopt agreed upon standards and report their performance.

"We need further research and clinical evaluation before any of these companies can claim a relationship between a test result and a person's health, or if dietary changes and supplements can improve the microbiome and someone's health," said Hoffman.

"There are more than 60,000 pharmacies in the United States, and these are the source for at least some of the DTC microbiome tests," said Frank Palumbo, Ph.D., JD, Professor Emeritus of Practice, Sciences, and Health Outcomes Research at the University of Maryland School of Pharmacy.

"Pharmacists should be made aware of the issues these unregulated laboratory tests present, since they are in a position to counsel customers who buy these products."

All the authors agree that claims these testing companies make are premature and that additional clinical research and peer-validation is necessary before consumers can have confidence in the results.

**More information:** Diane E. Hoffmann, The DTC microbiome testing industry needs more regulation, *Science* (2024). DOI:

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