Researchers call for new rules to regulate probiotics

October 17 2013

The U.S. Food and Drug Administration (FDA) should consider the unique features of probiotics—bacteria that help maintain the natural balance of organisms in the intestines—in regulating their use and marketing, says Diane Hoffmann, JD, director of the Law and Health Care Program at the University of Maryland Francis King Carey School of Law and lead author of the a newly released *Science* article, "Probiotics: Finding the Right Regulatory Balance."

"The U.S. Food and Drug Administration (FDA) has no definition of probiotics and regulates them based on whether they fall into one of the existing regulated product categories," says Hoffmann, who along with faculty members from the University of Maryland School of Medicine's Institute for Genomics Sciences, the University of Maryland School of Pharmacy and the University of Maryland Carey School of Law, investigated how probiotics are being regulated.

The coauthors brought together a working group of scientists conducting microbiome and probiotics research, legal academics, food and drug law attorneys, government representatives, bioethicists and consumer advocates to examine the current regulatory structure to determine if it adequately accounts for the risks of probiotics as well as the accuracy of claims of effectiveness. They also considered whether the regulatory structure is flexible enough to allow for (or at least not discourage) research on new probiotic products that may have therapeutic benefits.

The project was supported by a three-year grant from the National

Institutes of Health as part of the Ethical, Legal and Social Issues (ELSI) component to the Human Microbiome Project. Claire Fraser, PhD, and Jacques Ravel, PhD, leading experts in the field of human microbiome science, participated in the study from the School of Medicine.

"One of the outcomes of the Human Microbiome Project is a tremendous interest in targeting these microbial communities with probiotics to both improve health and mitigate disease", says Fraser, a professor of medicine whose research focuses on the role of the gut microbiome in a number of chronic diseases and its interaction with the immune system. But, according to Ravel, a professor of microbiology and immunology, "There is confusion about the regulatory process, in particular knowing within which product category different types of probiotics fall, and the current regulatory framework discourages the development of probiotic food in preventing disease, improving health, or possibly treating disease."

In their article, the coauthors recommend that that FDA consider changing the way it characterizes probiotics and modifying two regulatory pathways. "This will help reduce the number of unsubstantiated probiotic claims and help consumers make more informed decisions as well as encourage more research on probiotics," says Hoffmann.

Probiotics, which contain live organisms that degrade over time, have been consumed for centuries in the form of yogurts and fermented milks. Supermarket shelves are lined with a variety of probiotics foods and probiotic supplements are being aggressively marketed in retail stores and over the Internet. Although no probiotic has of yet been approved for therapeutic purposes by the FDA, some are undergoing clinical trials and may soon be marketed as biologics or other drugs—a development that prompted Hoffmann and her colleagues to examine the potential regulation of probiotics.

Current FDA regulatory requirements are not customized for probiotics. While probiotics that make drug claims should normally be subjected to the same requirements as other drugs, under "limited circumstances," Hoffmann and her colleagues recommend an "abbreviated" process for some types of probiotic products. These products include: probiotic foods, dietary supplements and dietary ingredients for which there is adequate evidence of safety in the target population; approved food additives and substances generally recognized as safe (GRAS). An "abbreviated" process would allow probiotics to be excused from Phase l trials, the first step in clinical testing.

A second recommendation of the working group, said Frank Palumbo, PhD, JD, professor and executive director of the University of Maryland School of Pharmacy Center on Drugs and Public Policy, is that the FDA develop a monograph for probiotic foods and dietary supplements similar to that used in Canada or employed by the FDA for over-the-counter drugs. Because all claims in monographs must be substantiated by evidence-based science, requiring a monograph to accompany probiotics should significantly reduce the number of false scientific claims. Additionally, notes Palumbo, compliance with monograph requirements will lead to expedited review for the application for marketing probiotic products.

More information: "Probiotics: Finding the Right Regulatory Balance," by D.E. Hoffmann; K. Rothenberg et al. *Science*, 2013.

Provided by University of Maryland