Introductory Remarks - June 14th Probiotics Meeting

Good Morning. I'm Diane Hoffmann and I am the Associate Dean for Academic Programs and Director of the Law & Health Care Program here at the University of Maryland School of Law. I am delighted to welcome all of you here today for the first meeting convened as part of our NIH grant to study the regulation of probiotics, specifically to look at the current regulatory framework for probiotics in the US and to determine if it is appropriate and adequate and, if not, to recommend an alternative or some alternative frameworks. I was fortunate to meet several of you in New York City over the weekend at the New York Academy of Sciences probiotics meetings. For those of you who I'm meeting for the first time today - on behalf of all the members of the grant team, I'd like to welcome you to University of Maryland Baltimore - we are looking forward to working together over the next two years on this project.

As I mentioned, I am part of a team that was funded by NIH to work on this project. I'd like to take a few moments to introduce the team members to you. Two members of the team are from the Institute for Genome Sciences at the University of Maryland School of Medicine. Dr. Claire Fraser-Liggett is the Director of the Institute and a Professor of Medicine. She is also one the world's most prominent microbiome researchers and was previously the President and Director of The Institute for Genomic Research. She is known for her work in sequencing and analysis of human, animal, plant and microbial genomes to better understand the role that genes play in development, evolution, physiology and disease.

Dr. Jacques Ravel is an Associate Professor in Microbiology and Immunology at the Institute and the School of Medicine. Dr. Ravel's research focuses on microbial genomics. He is a former Adjunct Associate Investigator at the J. Craig Venter Institute in the area of microbial genomics and the PI for a human microbiome research protocol currently underway entitled, "Genomic tools for studying the ecology of the human vaginal microbiome." Both Dr. Fraser-Liggett and Dr. Ravel are currently working on NIH-funded human microbiome research studies.

Dr. Frank Palumbo is the Executive Director of the University of Maryland School of Pharmacy Center on Drugs and Public Policy and an adjunct professor at the law school. Dr. Palumbo is a licensed pharmacist and a member of the Maryland Bar and has practiced both pharmacy and food

and drug law.

Professor Jack Schwartz and I are faculty members within the law school's Law & Health Care Program. Professor Schwartz came to the law school two years ago after a long career at the Maryland Office of the Attorney General. During Professor Schwartz's tenure at the AG's office, he was involved in all levels of the health regulatory process in Maryland. I should also mention that he was with the FTC prior to joining the AG's office here in Maryland. While at the FTC he served in a variety of positions including Assistant to the Chairman and Deputy Assistant General Counsel.

As I mentioned, I direct the L&HC Program and have worked on a number of projects that involved studying the ethical, legal and social consequences of biotechnology and genetic research. My interest in the area began in 1988 when I started at the law school and also had an appointment at the Program on Public Issues in Biotechnology. In an article I published in 1989, I described the alternative regulatory structures that existed at the time to regulate newly emerging biotechnology products. In September 2003, I received a grant from the Department of Energy to hold a workshop on Future Public Policy and Ethical Issues facing the Agricultural and Microbial Genomics Sectors of the Biotechnology Industry. The workshop, which was similar to this meeting, brought together experts from various fields, including bioethics, to develop a short list of the most significant public policy and ethical issues that were likely to emerge as a result of advances in certain sectors of the biotechnology industry. I have also written about the ethical and legal implications of genetics research and genetic testing which may be relevant to ELSI issues relating to the Human Microbiome Project.

I also want to introduce Virginia Rowthorn, Managing Director of the Law & Health Care Program, who is a member of the project team and coordinating activities under the grant.

In addition to introducing our project team I wanted to give you a bit of information about our grant award and this project. This meeting is one of three meetings that we will be holding with all of you. It is being funded by a grant from NIH's Human Microbiome Project. As Dr. Claire Fraser-Liggett will describe in greater detail later this morning, the Human Microbiome Project is a $150 million, five-year NIH initiative. One might describe it as an extension of the Human

Genome Project in its effort to characterize and better understand all the microbes that humans have on and in their body including their genetic composition and how they interact, how they differ from person to person, and how they relate to human health and disease. As was done as part of the Human Genome Project, a portion of the Human Microbiome Project funds has been set aside to study the Ethical, Legal, and Social Implications (often referred to as the ELSI issues) of the project's scientific goals.

Our probiotics project to look at the legal and regulatory issues surrounding probiotics is one of five projects that have been funded and initiated as part of the ELSI component of the HMP. In addition to our project, one of these projects will involve interviews with the individuals who donated the samples to be studied to develop a reference microbiome resource, as well as with individuals who were asked to donate samples but declined, in order to explore general perceptions and attitudes in the public about this new area of research; another ELSI project will analyze how risk and benefit are conceptualized in human microbiome research; a fourth will investigate patient perceptions of bioengineered probiotics and clinical metagenomics; and the fifth will investigate the implications of research on the ancient and contemporary human microbiome for the social and ancestral identities of indigenous people.

Our proposal to look at the federal regulation of probiotics was actually a topic suggested by ELSI staff at NIH who in preliminary meetings about the ethical, legal and social implications of the Human Microbiome Project, identified this as an issue that deserved scrutiny and analysis. After some preliminary investigation we agreed that this was an issue ripe for study. Both research on probiotics and the marketing of probiotics products is rapidly increasing and new claims are being made about the role and value of probiotics in promoting human health and there is a good deal of uncertainty about how these products should be regulated. Our goal with this collaborative project is to create a healthy debate among you about how probiotics should be regulated. We have brought you each to this working group because you represent a variety of perspectives on the issue. In the room we have experts in various regulatory frameworks, bioethicists who work in the area of genetics or have been funded to study ethical issues as part of other ELSI projects, consumer protection, experts in food and drug law, in microbiology and the scientific issues related to the human microbiome, and in the development and marketing of new probiotic products. What we hope to do is to get your different perspectives on the legal and regulatory

issues surrounding probiotics, and try to come to a consensus on how they should be regulated or at least some recommendations for alternative regulatory frameworks or modifications to the current regulatory scheme.

As we described in our letters of invitation to you - today at our first meeting we will focus on some background about the human microbiome and the science of probiotics. The day is composed of a number of presentations as well as small group discussions. Given that we have such a mixed group with varying levels of background and expertise in probiotics we thought it would be a good idea to make sure that everyone is starting out with at least some basic information about these topics through a series of short presentations. Part of the goal of these presentations is to bring everyone up to speed on the evolution of the field of probiotics and where things stand today.

In the afternoon, we will begin moving in the direction of regulation and take a preliminary look at the different product categories that FDA regulates -- drugs and biologics, cosmetics, foods, medical foods, dietary supplements, medical devices -- and ask you to think about the question: Are these regulatory boxes an appropriate fit for probiotics or is there something different about probiotics that might lead us to want to create a different box or regulatory pathway for them. We also hope to stimulate your thinking about this question by a short presentation about the regulation of genetically modified food.

In our small group discussions, those of you who are stakeholders in this area will undoubtedly have more to say about your concerns about the regulation of probiotics and issues you believe need to be addressed. As experts and stakeholders in the field, we are looking to you to engage in issue spotting and to help us decide how best to proceed with the project. Others of you who are new to the area and don't have a strong stake in the outcome, except perhaps as possible consumers of probiotic products, bring a different kind of expertise to this project. For those of you in this latter group, we hope that you will ask questions of those who are identifying issues and concerns so that you understand the issues but we also hope that if appropriate you will challenge the experts and stakeholders about the bases for their statements and conclusions. We hope all of you are willing to roll up your sleeves and both share your perspectives with other members of your group and at the same time be willing to learn from the perspectives of others.

While those of you who don't have a strong background in probiotics may not have as much of a role to play today, we expect that you will have much more to say at our next two meetings. At the second meeting, we will evaluate in some depth the current regulatory framework for probiotics and whether it is adequate and/or appropriate as well as examine some of the challenges posed by the framework for researchers and industry attempting to manufacture and market probiotic products. We will also look at regulatory frameworks for probiotics used in several other countries and compare the pros and cons of those frameworks to our framework in the US and begin to discuss whether we should consider an alternative framework for probiotics here. At the third meeting, we will evaluate one or more alternative regulatory models and develop recommendations for the most appropriate framework to regulate probiotics.

So, in summing up, our goals for today are:

1) to identify the issues going forward that we should be sure to include and examine over the next two years of the project - to give us direction
2) to catalog concerns about the fit of probiotics into the current regulatory framework and develop a list of reasons why probiotics are unique or not unique in terms of their regulatory status

Now, I would like to turn the podium over to you and ask each of you to provide a brief (a couple of sentences) introduction that sets forth your interest and expertise in the area of probiotics or an area that is relevant to this study.