U.S. Food and Drug Administration
Part 15 Hearing - November 4, 2019
Use of Fecal Microbiota for Transplantation to Treat Clostridium difficile

8:00 – 9:00 am  Registration

9:00 – 9:10 am  FDA Opening Remarks

9:10 – 9:20 am  Introductory/Logistics Remarks
Theresa Finn, PhD, Associate Director for Regulatory Policy
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

Industry

9:20 – 9:30 am  Carolyn Edelstein, OpenBiome
Clinical Evidence of Effectiveness, Safety Evaluation, Impact of FDA’s Current Enforcement Policy on FMT Product Development

9:30 – 9:40 am  Kevin Horgan, MD, Seres Therapeutics, Inc., Future and Path Forward

9:40 – 9:50 am  Lee Jones, Rebiotix/Ferring,
Impact of FDA’s Current Enforcement Policy on FMT Product Development

9:50 – 10:00 am  Paul Kim, Foley Hoag LLP; Microbiome Therapeutics Innovation Group
Safety Evaluation, Impact of FDA’s Current Enforcement Policy on FMT Product Development, Future and Path Forward

10:00 – 10:10 am  Mark Smith, PhD, Finch Therapeutics Group
Impact of FDA’s Current Enforcement Policy on FMT Product Development, Future and Path Forward

Academia

10:10 – 10:20 am  Herbert DuPont, MD, UT Health, Houston/Kelsey Research Foundation
Clinical Evidence of Effectiveness, Safety Evaluation, Impact of FDA’s Current Enforcement Policy on FMT Product Development

10:20 – 10:30 am  Diane Hoffman, University of Maryland Carey School of Law
Safety Evaluation, Future and Path Forward

10:30 – 10:40 am  Amanda Kabage, University of Minnesota, Future and Path Forward

10:40 – 11:00 am  Break
Clinicians

11:00 – 11:10 am  Stacey Kahn, MD, Boston Children’s Hospital
Clinical Evidence of Effectiveness, Safety Evaluation

11:10 – 11:20 am  Colleen Kelly, MD, American Gastroenterological Association
Clinical Evidence of Effectiveness, Safety Evaluation, Future and Path Forward

11:20 – 11:30 am  Sahil Khanna, Mayo Clinic, Clinical Evidence of Effectiveness, Future and Path Forward

11:30 – 11:40 am  Colleen Kraft, MD, Emory University Hospital, Future and Path Forward

Patients

11:40 – 11:50 am  Christian Lillis, Peggy Lillis Foundation, Future and Path Forward

11:50 – Noon  Catherine Williams (Duff)), Future and Path Forward

Noon – 12:30 pm  Closing Remarks