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 – 10:50 am	Norman Javitt, MD, NYU Langone, *Clinical Evidence of Effectiveness*
10:50 – 11:10 am	**Break**

Clinicians

11:10 – 11:20 am	Stacey Kahn, MD, Boston Children's Hospital *Clinical Evidence of Effectiveness, Safety Evaluation*
11:20 – 11:30 am	Colleen Kelly, MD, American Gastroenterological Association *Clinical Evidence of Effectiveness, Safety Evaluation, Future and Path Forward*
11:30 – 11:40 am	Sahil Khanna, Mayo Clinic, *Clinical Evidence of Effectiveness, Future and Path Forward*
11:40 – 11:50 am	Colleen Kraft, MD, Emory University Hospital, *Future and Path Forward*

Patients

11:50 – Noon	Christian Lillis, Peggy Lillis Foundation, *Future and Path Forward*
Noon – 12:10 pm	Catherine Williams (Duff)), *Future and Path Forward*

12:10 – 12:30 pm **Closing Remarks**

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