

May 22, 2020

The Honorable Roy Blunt  
Chairman  
Labor, Health and Human Services, Education  
Appropriations Subcommittee  
Washington, DC 20510

The Honorable Patty Murray  
Ranking Member  
Labor, Health and Human Services, Education  
Appropriations Subcommittee  
Washington, DC 20510

**RE: Support for FMT Registry report language in FY2021 Labor/HHS Appropriations**

Dear Chairman Blunt and Ranking Member Murray:

We write to express our strong support for the inclusion of report language in the fiscal year (FY) 2021 Labor, Health and Human Services (HHS), Education, and Related Agencies appropriations bill urging the National Institutes of Health (NIH) to continue to support research efforts to better understand the short- and long-term impact of fecal microbiota transplantation (FMT) as it relates to recurrent *Clostridioides difficile* infection (CDI) and other clinical indications.

CDI has been described as a “major health threat” by the Centers for Disease Control and Prevention (CDC) and, in 2017, led to an estimated 223,900 cases in hospitalized patients and 12,800 deaths in the United States. Appropriate response to CDI is especially important given the growing threat of antimicrobial resistance, which costs the U.S. health care system an estimated \$21 billion to \$34 billion annually. FMT is the delivery of stool from a healthy donor to a recipient with the goal of mitigating disease by modifying the structure or function of the gut microbiome, and it has proven to be a highly effective therapeutic modality for recurrent CDI.

The American Gastroenterological Association Institute, in partnership with the Crohn’s and Colitis Foundation of America, Infectious Diseases Society of America, and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition created the FMT National Registry to collect clinical and patient-reported outcomes for adult and pediatric patients. The FMT National Registry provides a national, centralized vehicle for individual clinicians and their patients to contribute to the research and development of this important therapy. The FMT National Registry received funding from the National Institute of Allergy and Infectious Diseases (NIAID) for five years beginning in August 2016. As of January 2020, the FMT National Registry has enrolled 393 patients across 29 clinical sites in 17 states (including Washington, D.C.).

In reviewing the status of FMT, the Food and Drug Administration (FDA) has stated that it is a “drug” requiring an investigational new drug (IND) application. To help retain patient access to FMT for CDI, the FDA has decided to exercise “enforcement discretion” regarding INDs for the use of FMT in patients with CDI that is not responsive to standard therapies. In light of that FDA policy, additional research is warranted to better elucidate the short- and long-term effects of FMT for CDI, its effectiveness, and practice patterns. We urge appropriators to include the following report language in the FY2021 Labor, HHS, Education, and Related Agencies appropriations bill:

**REQUESTED REPORT LANGUAGE**

*“FMT National Registry. -- The Committee recognizes that the FDA has allowed for enforcement discretion to promote continued patient access to fecal microbiota transplantation*

*(FMT) for recurrent C. difficile infections. To help inform clinicians and patients regarding the safety and effectiveness of FMT in these patients, Congress encourages NIH to continue to support the FMT National Registry and related research efforts to better understand the short- and long-term safety profile and efficacy of FMT.”*

Thank you for your consideration of this request.

Sincerely,

American Gastroenterological Association  
American College of Gastroenterology  
American Neurogastroenterology and Motility Society  
American Society for Gastrointestinal Endoscopy  
Association of Gastrointestinal Motility Disorders  
Celiac Disease Foundation  
Crohn's & Colitis Foundation  
Digestive Disease National Coalition  
Global Liver Institute  
Infectious Diseases Society of America  
Massachusetts Gastroenterology Association  
The National Chronic Pancreatitis Support Network  
No Stomach For Cancer  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
North Carolina Society of Gastroenterology  
The Oley Foundation  
Peggy Lillis Foundation  
Society of Gastroenterology Nurses and Associates  
United Ostomy Associations of America