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.”

BACKGROUND

The American Gastroenterological Association (AGA) seeks report language that urges the National Institutes of Health 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). CDI has been described as a “major health threat” by the CDC and, in 2017, led to an estimated 223,900 cases in hospitalized patients and 12,800 deaths in the U.S.

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. This approach has proven to be a highly effective therapeutic modality for recurrent CDI. However, there are legitimate safety concerns about the use of FMT that extend beyond pathogen transmission, given known associations between the gut microbiota and other human disorders (e.g., obesity, diabetes, cancer).

The AGA 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 proposed the creation of the FMT National Registry to collect clinical and patient-reported outcomes for pediatric and adult patients. The FMT National Registry received funding from the National Institute of Allergy and Infectious Diseases for five years beginning in August 2016.

In reviewing the status of FMT, the 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.

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. As of January 2020, the FMT National Registry has enrolled 393 patients across 29 clinical sites in 17 states (including Washington, D.C.).

REQUESTING ORGANIZATION

American Gastroenterological Association (AGA)
4930 Del Ray Avenue
Bethesda, MD 20814

CONTACT

For questions or additional information, contact Kathleen Teixeira, Vice President of Government Affairs, at kteixeira@gastro.org or 240.482.3222.