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Ms. Leslie Kux
Assistant Commission for Policy
Office of Communication, Outreach and Development (HFM-40)
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
1401 Rockville Pike, Suite 200N
Rockville, MD 20852-1448

Re: Docket No. FDA-2013-D-0811: Guidance for Industry: Enforcement of Policy Regarding Investigational New Drug Requirements for use of Fecal Microbiota for Transplantion to Treat Clostridium difficile Infection Not Responsive to Standard Therapies

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Food and Drug Administration (FDA) for the opportunity to provide input into its draft Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies. APIC is a nonprofit, multi-disciplinary organization representing over 15,000 infection preventionists, whose mission is to create a safer world through prevention of infection. Our comments primarily reflect the views of our members, whose responsibilities include prevention of healthcare-associated infections.

APIC advocates for patient and product safety, while also recognizing the urgent need for therapies to treat patients suffering from *Clostridium difficile* infection (CDI). We support the use of fecal microbiota transplantation (FMT) to treat recurrent CDI as it has been shown in numerous peer-reviewed studies to be an effective treatment for CDI[1]. FMT has rapidly become a viable, safe, and effective treatment for recurrent CDI, especially due to the growing prevalence of CDI in the U.S. in the last 10 or more years.

APIC believes that classifying FMT as an investigational new drug (IND) is not appropriate, because doing so may limit access to this proven effective treatment. However, APIC supports FDA's oversight to ensure patient safety and urges the agency to expedite the process of reclassifying FMT so it can be regulated as a standard of care for CDI not responsive to other therapies.

In addition, the FDA proposes enforcement discretion only if the recipient or treating licensed healthcare professional knows the donor of the FMT and the treating licensed healthcare professional qualifies both the donor and stool. APIC is concerned that this language disqualifies the use of banked stool from standard donors and community donors for generating FMT product when this may be the only option available to patients and could potentially limit access to definitive care. As a comparison, research on directed vs. community blood donors has demonstrated that blood from directed donors is neither safer nor measurably less safe than blood from community volunteer donors when subjected to the same set of infectious disease tests used to screen volunteer blood[2]. There is no evidence to suggest that this would not be the same with FMT product.

APIC encourages the FDA to collaborate with the medical and scientific community to establish guidelines for donor screening to prevent the transmission of infectious diseases during FMT and hopes that further review will show that it is not appropriate for study under the agency's IND regulations. APIC encourages the FDA to consider adapting the regulatory guidance for FMT to fit that of a donated product such as blood and tissue. Blood and tissue donations require oversight of a physician, specific screening protocols for both patient and donor, and handling requirements, all of which would be applicable to FMT.

APIC recommendations:

- APIC supports use of FMT to treat recurrent *Clostridium difficile* infection.
- APIC believes that classification of FMT as an IND is inappropriate and recommends that FDA regulate FMT as it does other blood and tissue products from human donors.
- APIC urges FDA to expedite the process of reclassifying the FMT as standard practice.
- APIC encourages FDA to continue to collaborate with the medical and scientific community to establish guidelines for donor screening to prevent the transmission of infectious diseases during FMT.

APIC appreciates the opportunity to comment on FDA's draft guidance on FMT and we look forward to continuing to work with the agency as it carries out its mission to protect patients and promote the public health.

Sincerely,

Jennie L. Mayfield, BSN, MPH, CIC
2014 APIC President

[1] Rohlke F, Stollman N. Fecal microbiota transplantation in relapsing *Clostridium difficile* infection. Therap Adv Gastroenterol 2012;5(6):403-420.
[2] Williams, AE, Kleinman, S, Gilcher, RO, et al. Transfusion. 1992; 32:45S.