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March 27, 2014

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 Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies

Dear Ms. Kux:

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to comment on the recent FDA Guidance for Industry regarding the "Enforcement policy for use of fecal microbiota for transplantation (FMT) to treat *Clostridium difficile* infection not responsive to standard therapies." SHEA is a professional society representing more than 2,000 physicians and other healthcare professionals whose primary mission is to prevent and control healthcare-associated infections.

SHEA is supportive of FDA's decision to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies. However, the Society has concerns about inclusion of the restriction that "the FMT product is obtained from a donor known to either the patient or the treating licensed health care provider." While this requirement is well intentioned, it may result in both an increased risk of infection among FMT recipients or failure of the therapy. In addition, the requirement will limit the availability of this potentially life-saving, beneficial therapy for many patients.

Of specific concern is the implicit endorsement of the practice of donor-directed transplant (i.e. that the FMT product is obtained from a donor known to either the patient or to the healthcare provider treating the patient). While this approach to donor stool procurement may seem intuitive as there is an absence of evidence defining optimal source and characteristics for effective and safe donor stool, analogous experience from blood transfusion and banking suggests that this presumption may be incorrect and may potentially increase the risk of infection and complication among FMT recipients. Specifically, a study published by the American Red Cross in 2013 found that rates of donor-directed blood specimens had higher rates of HIV, Hepatitis C, Hepatitis B, and HTLV, compared to volunteer donations (Dorsey et al., *Transfusion*, 2013; 53:1250-1256). This uncertainty alone should serve as sufficient motivation to remove the endorsement for only donor-directed FMT.

Practitioners in our specialty are further concerned that the endorsement of only “known” stool donors could unnecessarily deny ready access to potentially life-saving therapy for appropriate patients due to the associated requirement for local donor screening. Currently, local donor stool procurement and processing is not readily available to the majority of physicians due to cost and laboratory restraints. This has the high potential for developing additional restriction of access to FMT for appropriate patients— again unacceptable from both a clinical and policy perspective.

As the relative advantages of the two approaches for donor identification are studied through research and careful monitoring of current practices, SHEA believes the FDA would best serve the American public by not restricting the source of donor stool at this time. We further recommend the FDA create a voluntary registry of patients, which would at minimum include donor stool source and processing, any complications and the clinical outcome of the FMT, to support the development of future best practice.

The leadership and membership of SHEA re-confirm our willingness to serve with the FDA in supporting safe and effective therapies for the American public. Thank you for this opportunity to provide comment on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel Diekema". The signature is fluid and cursive, written on a white background.

Daniel Diekema, MD, FSHEA, FIDSA
President