



July 15, 2013

Wellington Sun, MD
Director, Division of Vaccines and Related Product Applications
Office of Vaccines Research and Review
CBER
RM 2302
1451 Rockville Pike
Rockville, MD 20852


Re: Current Consensus Guidance on Donor Screening and Stool Testing for FMT

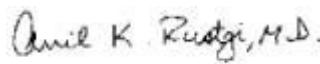
Dear Dr. Sun:


On behalf of the undersigned medical specialty societies, we thank you for the opportunity to provide guidance on appropriate screening and stool testing of potential stool donors for Fecal Microbiota Transplantation (FMT). Our consensus guidance on donor screening and stool testing is attached as an addendum to this letter.


Our organizations are interested in collaborating with the FDA on establishing a protocol for FMT that balances appropriate oversight of this effective, yet not fully understood, therapy with reasonable access for patients with recurrent *Clostridium difficile* infection (CDI), for whom few alternatives are available. We thank the FDA for the opportunity to provide our clinical input and we look forward to further collaboration aimed at allowing appropriate access to FMT therapy. Please contact Andres Rodriguez with any questions at 703-299-5146 or arodriguez@idsociety.org.

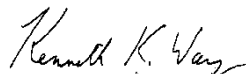
Sincerely,


David Relman, MD, FIDSA
President – IDSA


Anil K. Rustgi, MD, AGAF
President – AGA


Athos Bousvaros, MD
President - NASPGHAN


Ronald J. Vender, MD, FACG
President – ACG


Kenneth K. Wang, MD, FASGE
President - ASGE

Donor Selection and Screening:

- Preferred donor is an intimate, long-time partner of adult patient or, in the case of a pediatric patient, an adult first-degree relative, close family friend, or well-screened universal donor.
 - For the purposes of informed consent, donors should be over the age of 18. However, children could also potentially serve as donors as long as both parental consent and child assent (i.e., agreement to serve as a donor) are obtained.
- Donor questionnaire should be similar to current protocols for screening blood donors, (see AABB Donor History Questionnaire Documents available at <http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/ucm164185.htm>)
- Donor exclusion criteria should include:
 - A history of antibiotic treatment during the preceding 3 months of donation
 - A history of intrinsic gastrointestinal illnesses, including inflammatory bowel disease, irritable bowel syndrome, gastrointestinal malignancies or major gastrointestinal surgical procedures
 - A history of autoimmune or atopic illnesses or ongoing immune modulating therapy
 - A history of chronic pain syndromes (fibromyalgia, chronic fatigue) or neurologic, neurodevelopmental disorders
 - Metabolic syndrome, obesity (BMI of >30), or moderate-to-severe undernutrition (malnutrition)
 - A history of malignant illnesses or ongoing oncologic therapy

Serum Testing (to be performed within 4 weeks of donation):

- HAV-IgM
- HBsAg
- anti-HCV-Ab
- HIV-EIA
- RPR

Stool Testing (to be performed within 4 weeks of donation):

- *C. difficile* toxin B (preferably by PCR)
- Culture for enteric pathogens
- O+P, if travel history suggests