March 29, 2013

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Fecal Microbiota Transplantation

Dear Commissioner Hamburg:

The American Gastroenterological Association (AGA), American College of Gastroenterology (ACG), American Society for Gastrointestinal Endoscopy (ASGE), and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), would like to address a concern that was recently brought to our attention by members who perform fecal microbiota transplantation (FMT) for patients with *Clostridium difficile* infection (CDI or C. diff). Our societies have a responsibility to ensure our members are informed and that patients receive proper and outstanding care. It is in this regard that we would like to explore this issue further with the FDA.

Request for FDA Guidance

It has come to our attention that there may be potential issues surrounding FMT and CDI in as much as some clinicians have asked us to explore the FDA position on FMT. It is our understanding that a number of academic investigators have submitted IRB protocols for clinical studies and that their institutions have requested an investigational new drug (IND) number or approval of a research trial protocol by the FDA. The investigators have contacted the FDA which has indicated in correspondence via e-mail and IND application

communications that the FDA feels that FMT is a novel therapy and requires an IND for all clinical applications.

We have been unable to locate formal FDA public guidance or statements regarding the use of FMT by practitioners, outside of the private discussions the agency has had with those involved in clinical trials.

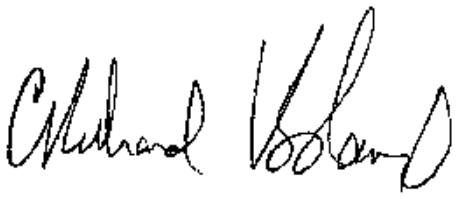
In order to ensure our patients are receiving proper and outstanding care, and our members are practicing medicine according to FDA guidance, we would request that the FDA provide guidance on this issue. Specifically, we would like to seek clarification from the FDA on the following questions:

- Is an IND required for C. diff only for clinical research study purposes or for all treatment of C. diff. when using FMT?
- Is an IND required for all uses of FMT for all disease state applications other than C. diff.?
- What steps will the FDA take to make known its position on FMT for CDI?
- What guidance can the FDA offer to our societies as to the most effective way to inform our members on this matter?

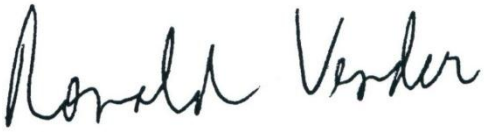
Conclusion

We would like to thank the FDA for continued leadership in ensuring that Americans have access to safe and appropriate care and services. On behalf of our patients and members, we look forward to working with the agency to ensure the correct information is disseminated to our members correctly and accurately. If we may provide any additional information, please contact Elizabeth Wolf, AGA Director of Regulatory Affairs at 240.482.3223 or ewolf@gastro.org; Brad Conway, ACG Vice President of Public Policy at 301.263.9000 or bconway@gi.org; Sam Reynolds, ASGE Assistant Director, Business and Practice Development at 630.570.6543 or sreynolds@asge.org; or Camille Bonta, consultant to NASPGHAN at 202.320.3658 or cbonta@summithealthconsulting.com.

Sincerely,



C. Richard Boland, MD, AGAF
Chair
American Gastroenterological Association



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