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March 28, 2014

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

Re: FDA-2013-D-0811-0003 – 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; Availability

Dear Commissioner Hamburg:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance published on Feb. 26, 2013 in the *Federal Register* regarding its enforcement policy for Investigational New Drug (IND) requirements for the use of Fecal Microbiota Transplantation (FMT) to treat *Clostridium difficile (C. difficile).*

With more than 1,500 members, NASPGHAN is the leading society in the field of pediatric digestive diseases. NASPGHAN's mission is to improve quality of care and health outcomes for infants, children and adolescents with disorders of the gastrointestinal tract, the liver and nutritional conditions by promoting advances in clinical care, research and education.

We appreciate FDA's concurrence with NASPGHAN and other provider organizations that requiring an IND for FMT may not be appropriate. Therefore, we strongly support the Agency's continued willingness to exercise enforcement discretion regarding the IND requirements for the use of FMT to treat *C. difficile* infection not responding to standard therapies.

We support the FDA's draft guidance on enforcement policy regarding IND requirements on the use of FMT to treat *C. difficile*. We believe FMT should be under the regulatory auspices of the FDA, but that it is a complicated area of regulation. In conditions like *C. difficile*, where FMT has shown benefit, it is important that FMT be accessible so long as physicians adhere to appropriate guidance that is not unnecessarily burdensome. Such guidance should include requirements for patient consent, donor screening, and stool testing. For other health care conditions, where the benefits of FMT are less clear, additional appropriate regulatory oversight may be necessary. We also encourage further discussion among clinicians, researchers, and regulatory officials to determine whether fecal material should be regulated like tissue (similar to blood and organ donation), or like a "drug."

NASPGHAN encourages the FDA to finalize its Feb. 26, 2014 draft guidance, and we look forward to working with the FDA as it further considers this matter and its enforcement policy. Should you require additional information on this topic, please feel free to contact Camille Bonta, NASPGHAN's Washington representative, at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

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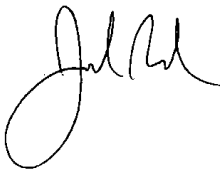

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