
NASPGHAN
PO Box 6
Flourtown PA 19031
215-233-0808
Fax 215-233-3918
Email:
naspghan@naspghan.org



PRESIDENT

Athos Bousvaros, MD, MPH

Children's Hospital, IBD Center
GI Hunnewell Ground
300 Longwood Ave
Boston, MA 02115
617-355-2962

athos.bousvaros@childrens.harvard.edu

PRESIDENT-ELECT

Carlo Di Lorenzo, MD

Nationwide Children's Hospital
The Ohio State University
700 Children's Drive
Columbus, OH 43205
614-722-3450

carlo.dilorenzo@nationwidechildrens.org

PAST PRESIDENT

Kathleen B. Schwarz, MD

Johns Hopkins University
School of Medicine
600 N Wolfe Street, Brady 320
Baltimore, MD 21287
410-955-8769
kschwarz@jhmi.edu

SECRETARY – TREASURER

James E. Heubi, MD

Cincinnati Children's Hospital Medical
Center
Division of GI & Nutrition
3333 Burnet Avenue
Cincinnati, OH 45229-3026
513-636-8046
james.heubi@cchmc.org

EXECUTIVE COUNCIL

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Aurora, CO

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Boston, MA

Alfredo Larrosa-Haro
Jalisco, Mexico

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Philadelphia, PA

Norberto Rodriguez-Baez, MD
Dallas, TX

Vicky L. Ng, MD
Toronto, ON

EXECUTIVE DIRECTOR

Margaret K. Stallings
mstallings@naspghan.org

**NASPGHAN Annual Meeting &
Postgraduate Course**
October 22-25, 2014
Atlanta, GA

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and Nutrition (NASPGHAN) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) draft guidance published on Feb. 26, 2013 in the *Federal Register* regarding its enforcement policy for Investigational New Drug (IND) requirements for the use of Fecal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,



Athos Bousvaros, MD
President, NASPGHAN
Children's Hospital, IBD Center
Boston, MA



Joel R. Rosh, MD
Director, Pediatric Gastroenterology
Goryeb Children's Hospital/Atlantic Health
Professor of Pediatrics
Icahn School of Medicine at Mount Sinai



George Russell, MD, MS
Co-Chair, Fecal Microbiota Transplant Special Interest Group, NASPGHAN
Director, Quality and Process Improvement, Mass General Hospital for Children



Stacy Kahn, MD
Co-Chair, Fecal Microbiota Transplant Special Interest Group, NASPGHAN
Assistant Professor of Pediatrics, Section of Pediatric Gastroenterology
Director, Transitional IBD Clinic
The University of Chicago Medicine