May 2014 NASPGHAN Washington Report

FDA Issues Draft Guidance for FMT

On February 26, the Food and Drug Administration (FDA) released draft guidance on enforcement policy regarding investigational new drug (IND) requirements for use of fecal microbiota (FMT) for transplantation to treat *C. difficile*. If finalized, this guidance would supersede FDA's July 18, 2013 guidance which informed members of the medical and scientific communities that the agency would exercise enforcement discretion regarding IND requirements, so long as the physician obtained adequate informed patient consent. Under the draft guidance, FDA would continue to exercise enforcement discretion provided that the following conditions are met: 1) the provider obtains adequate informed consent; 2) the FMT product is obtained from a donor known to either the patient or the licensed health care provider treating the patient; and 3) the stool donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his/her patient. NASPGHAN submitted a comment letter in support of the draft guidance. Last year, NASPGHAN joined with its specialty counterparts, including the American Gastroenterological Association (AGA), in submitting to FDA consensus guidance on donor screening and stool testing for FMT. NASPGHAN has also joined other organizations in calling upon the National Institutes of Health (NIH) to support development of a national FMT patient registry, to which the NIH responded that it lacks the resources to support the ongoing operation and maintenance of such a registry.

NASPGHAN Tells FDA that IND Guidance Could Hamper Nutrition Research

On March 4, NASPGHAN representatives participated in a meeting with officials from the FDA's Center for Food Safety & Applied Nutrition. The purpose of the meeting was to discuss concerns with guidance issued by the FDA in September 2013 for when an Investigational New Drug (IND) application is needed for food and nutritional research studies. Following issuance of the guidance, NASPGHAN joined a letter initiated by the American Society for Nutrition expressing concerns with the guidance. In response, the FDA reopened for public comment the cosmetic and food (including dietary supplement) sections of the guidance. NASPGHAN submitted comments on April 7. FDA officials made clear in the March meeting that the new guidance does not reflect an expansion of current policy or new policy and is not a response to safety concerns. Rather, FDA staff explained the September guidance attempts to provide clarity, through the use of examples, of when an IND is required for human research on foods, nutrients and dietary supplements. Consequently, NASPGHAN is concerned that FDA has expanded the types of research for which INDs will be required, which could stifle individual academic investigator-initiated pediatric nutritional studies and drive food, nutritional and dietary supplement research outside the United States.

CMS Finalizes Deep Cuts for Upper Endoscopy Services

In the Medicare Physician Fee Schedule Final Rule issued last November, the Centers for Medicare and Medicaid (CMS) finalized cuts to payments for upper endoscopy services averaging 11 percent, with cuts for some endoscopy services much more severe. In January,

NASPGHAN sent a letter to CMS supporting concerns raised by the AGA, the American Society for Gastrointestinal Endoscopy, and the American College of Gastroenterology about how CMS made its final determinations for the endoscopy codes. The adult GI societies point to flaws in CMS' rate setting methodologies, which assumes 10 minutes of physician time equals 1.00 work relative value units (RVUs) and does not take into consideration the range of intensities across all gastrointestinal endoscopic procedures and services. In its letter, NASPGHAN described the downstream implications CMS' payment reductions could have on private payer reimbursement for pediatric endoscopy services. In January, NASPGHAN called on its members to share their concerns with CMS. At least 112 pediatric gastroenterologists responded to the call to action. A response by CMS to comments received is not expected until issuance of the 2015 Physician Fee Schedule Final Rule, which will be released in November.

Pediatric Societies Prepared to Push for Loan Repayment Program Funding

Despite the disappointing exclusion in the President's FY 2015 budget of funding for the Pediatric Subspecialty Loan Repayment Program, NASPGHAN and other pediatric subspecialty organizations are lobbying appropriators to include $5 million for the program. A $5 million allocation was included in Senate FY 2014 Labor, Health and Human Services, and Education spending bill, but funding was dropped in final negotiations. The program was established under the Affordable Care Act (ACA). While the ACA authorized funding for the program over five years (FY2010-FY2014), the program has yet to receive an appropriation. On March 28, NASPGHAN issued a call-to-action, asking NASPGHAN members to contact their senators in support of the program.

Sunshine Act 101 Podcast Available

A three-part series entitled "What is the Sunshine Act?" is now available on the NASPGHAN website. This series discusses in practical terms what the Sunshine Act is, what's reportable and reporting accuracy. This law, the "Physician's Payments Sunshine Act", now known as "Open Payments", was passed as part of the ACA and was intended to increase public awareness of financial relationships between drug and device manufacturers and health care providers. The law requires that such relationships be made public by Sept. 30, 2014.

NASPGHAN Washington Day – Monday, June 2, 2014

The 3rd annual Washington Day will be held on June 2, 2014. This event, supported by NASPGHAN's Public Affairs and Advocacy Committee, provides NASPGHAN members a first-hand lobbying experience on Capitol Hill. NASPGHAN members can make a difference. For example, previous Washington Day efforts led to the action by the Consumer Product Safety Commission on high-powered magnet safety for children. NASPGHAN members interested in attending the Washington Day, in particular those who are close proximity to Washington, D.C., should contact NASPGHAN's Washington Representative at cbonta@summithealthconsulting.com.