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**NASPGHAN Annual Meeting &
Postgraduate Course**
October 8-11, 2015
Washington, DC

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton, Ranking Member Pallone and Congresswoman DeGette:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) is pleased to support the 21st Century Cures Act (H.R. 6). We commend you for recognizing the importance of maintaining the United States as a leader in medical research and innovation and for the open and transparent process you employed during the development of this landmark legislation. We believe your bill could be a game changer for pediatric research, particularly for pediatric rare diseases.

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 and the liver and with malnutrition by promoting advances in clinical care, research and education.

NASPGHAN is deeply grateful for the provisions that would reauthorize the National Institutes of Health (NIH) for three years at increased funding levels and would provide \$9.3 billion over the next five years (FY 2016-2020) for an innovation fund for the NIH and the Food and Drug Administration (FDA) to tackle the major challenges in biomedical research and have the potential to lead to breakthroughs, with \$1.75 billion directed to the NIH and \$110 million to the FDA per year. This infusion of mandatory funding will help revitalize and rebuild our nation's biomedical research capacity, which has eroded because of NIH losing nearly one-fourth of its budget after inflation in the past decade. We encourage you, however, to restore before House passage the innovation fund for the NIH to \$10 billion, as approved by the committee in May.

NASPGHAN specifically applauds the bill's inclusion of the following provisions:

Title 1 –

Sec. 1021 – Requires the NIH to complete a strategic plan, and, within the plan, requires NIH to “ensure that rare and pediatric diseases and conditions remain a priority.”

Sec. 1041 – Supports and improves the NIH pediatric loan repayment program.

Sec. 1081 – Requires the NIH to implement the National Pediatric Research Network Act.

Sec. 1082 – Establishes the “sense of Congress” that the NIH and FDA should support the development of a global pediatric clinical trials network.

Sec. 1083 – Requires the NIH to report every two years on the number of children, disaggregated by the pediatric age group, race, and gender, included in NIH-funded trials. The section also requires an NIH workshop and the publication of NIH guidance on inclusion criteria for children.

Sec. 1101 – Requires the standardization of health data submissions in ClinicalTrials.gov to improve the site for public use and to ensure that entries in the registry and data bank are easily compared.

Sec. 1124 – Promotes and advances medical research by revising and clarifying the HIPAA rules on the use and disclosure of protected health information for research purposes.

Title 2 –

Sec. 2151 – Establishes a new incentive for existing drugs that seek a new indication for a rare disease by extending marketing exclusivity by six months (additive of any exclusivity awarded under the Best Pharmaceuticals for Children Act).

Sec. 2152 – Reauthorizes the rare pediatric disease priority review voucher program through Dec. 31, 2018, and requires a Government Accountability Office report to evaluate the effectiveness of the program for incentivizing drug development for rare pediatric diseases.

Sec. 2261 – Requires NIH to finalize guidance on single institutional review board for multi-site studies.

Title 3 –

Sec. 3041 – Exempts from the Physician Payment Sunshine Act reporting certain transfers of value related to medical education, including journals, reprints, and other continuing medical education-related payments.

We hope for swift passage of H.R. 6 in the House and look forward to working with you as the bill continues its journey to final passage. Should you have any questions or require further information from NASPGHAN, please contact Camille Bonta at (202) 320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

A handwritten signature in cursive script, appearing to read "Carlo Di Lorenzo".

Carlo Di Lorenzo, MD
President
NASPGHAN