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April 29, 2021

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**NASPGHAN Annual Meeting**  
**November 4-6-2021**  
**Nashville, TN**

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The Honorable Lisa Murkowski  
522 Hart Senate Office Building  
U.S. Senate  
Washington, D.C. 20510

The Honorable Bill Cassidy  
520 Hart Senate Office Building  
U.S. Senate  
Washington, D.C. 20510

The Honorable Margaret Hassan  
324 Hart Senate Office Building  
U.S. Senate  
Washington, D.C. 20510

The Honorable Jacky Rosen  
713 Hart Senate Office Building  
U.S. Senate  
Washington, D.C. 20510

Dear Senators Murkowski, Hassan, Cassidy and Rosen:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) is pleased to offer its endorsement of the *Safe Step Act* (S. 464) to amend the Employee Retirement Income Security Act of 1974 to require a group health plan (or health insurance coverage offered in connection with such a plan) to provide an exceptions process for any medication step therapy protocol.

NASPGHAN is comprised of more than 2,500 pediatric gastroenterologists in 46 states, the District of Columbia, Puerto Rico, Mexico and eight provinces in Canada. The mission of NASPGHAN is to advance understanding of normal development, physiology and pathophysiology of diseases of the gastrointestinal tract (i.e., digestive disease), liver and pancreas in children, improve the quality of care for these children with digestive disease by fostering the dissemination of this knowledge through scientific meetings, professional and public education, and policy development, and serve as an effective voice for members and the profession.

Increasingly, payors are requiring step therapy, prior authorization, and non-medical drug switching for biologic therapies used in children with inflammatory bowel disease, often overriding prescribing recommendations of the treating physician. Most concerning is payors requiring pediatric patients who are stable on a biologic to switch to a different biologic, or typically what is called a biosimilar; requiring a limited choice of initial biologic; or designating the sequence of biologic therapies.

These decisions by payors are typically made without regard to medical necessity or clinical indications and without input from the primary pediatric gastroenterologist caring for the child.

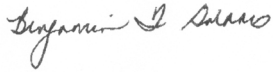
Biologics are vital therapeutic tools in the treatment of inflammatory bowel disease, but their use is coupled with ongoing collection of clinical efficacy and safety data, and their interchangeability is not well understood, with limited clinical data, especially in pediatric patients who face a lifetime of disease and treatment. NASPGHAN has had limited success in convincing payors to provide exceptions to non-medical switching of biologics in pediatric populations and is why passage of the *Safe Step Act* is critically needed.

We are specifically grateful your legislation would create an exception to medication step-therapy when a patient is stable on a medication previously approved. This exception will allow pediatric patients who are stable on a specific biologic therapy to remain on that biologic if that is the recommendation of the treating physician.

Pediatric gastroenterologists are spending entirely too much time fighting with insurance companies to ensure their patients get recommended care. NASPGHAN stands ready to work with you achieve enactment of the *Safe Step Act* this year.

Should you have questions or require additional information, please contact Camille Bonta, NASPGHAN policy advisor, at (202) 320-3658 or [cbonta@summithealthconsulting.com](mailto:cbonta@summithealthconsulting.com).

Sincerely,



Benjamin D. Gold, MD, FAAP, FACG  
President  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

cc: The Honorable Cindy Hyde-Smith  
The Honorable Kirsten Gillibrand  
The Honorable Kyrsten Sinema  
The Honorable Shelley Moore Capito  
The Honorable Mazie Hirono  
The Honorable Thom Tillis  
The Honorable Jeanne Shaheen  
The Honorable Kevin Cramer  
The Honorable Jeff Merkley  
The Honorable Richard Blumenthal