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**NASPGHAN Statement Regarding the Position Paper on
"The Use of Cisapride in Children"
February 9, 2005**

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) strives to improve the care of infants, children and adolescents with digestive disorders by promoting advances in clinical care, research and education.

Every grant NASPGHAN receives is under the sole authority of NASPGHAN and is used to fund educational initiatives for medical professionals and the public on a wide range of gastrointestinal disorders. To ensure there are no misunderstandings with potential donors, NASPGHAN functions according to a published set of 'Principles of Corporate Support and Partnership,' which clearly states that under no circumstances will NASPGHAN endorse any product, brand or company, permit any supporter to have input into the development or content of educational materials, or determine review criteria or selection of grant recipients.

NASPGHAN is responsible for all decisions regarding the identification and prioritization of educational needs, the determination of educational objectives and presentation of content, the selection of all persons and organizations that are in a position to control content, and the evaluation of educational activities. The principles that guide our relationships with corporate supporters applied to NASPGHAN's receipt of an unrestricted educational grant from Janssen Pharmaceutica in 1998 and 1999. The funds from these grants were used to support the ongoing general operations of the Society that included a wide variety of educational programs regarding children's digestive disorders.

On June 26, 1998, Janssen Pharmaceutica issued an announcement to physicians and patients that the labeling for cisapride was being changed to reflect increased warnings regarding the association between use of the drugs and adverse cardiac events. Additionally, the list of drugs that potentially could increase the risk of a cisapride-related adverse effect was expanded. The announcement had a major effect on practitioners because of the frequency with which cisapride is used throughout the world. Although well intended, the letter caused confusion as to whether cisapride should be used and if so, what precautions should be taken before or after administering the medication.

In response to this evolving scientific discussion, the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) convened a committee in August of 1998 to address these and other issues engendered by the new warnings regarding the use of cisapride. The purview of the Committee was to develop a Position Paper on the appropriate use of cisapride in infants and children. Members of the Committee included six pediatric gastroenterologists, two pediatric cardiologists, a pediatric pharmacologist, and a pediatric pharmacoepidemiologist. The Committee worked independently.

The Cisapride Committee had multiple conference calls. In addition, it performed several literature reviews on the efficacy and safety of cisapride in children. It also reviewed a 150-page report on the efficacy of cisapride; a 150-page report on safety issues, serious arrhythmias, and sudden deaths; and a report of 126 cases of overdoses (prepared by Janssen Pharmaceutica). In addition, the Cisapride Committee held a 2-day meeting in Chicago. Based on a detailed review of the available data, the Cisapride Committee developed a Position Paper regarding the use of cisapride in children.

The Nominal Group Technique was used to ascertain whether consensus was achieved among the Committee members. Consensus was reached on all points. The report was reviewed and approved by the Executive Council of NASPGN on January 25, 1999 and was published in the *Journal of Pediatric Gastroenterology and Nutrition* (Volume 28(5) May 1999 pp 529-533).

The published Position Paper entitled “The Use of Cisapride in Children” was based on published scientific data and developed according to a rigorous process of examining the evidence. Neither Janssen nor any other corporate supporter had any role in the development of the Position Paper or subsequent educational outreach programs.

NASPGHAN takes very seriously its role in educating healthcare professionals and the public about issues relevant to children’s digestive health issues and in advancing the science and practice of pediatric gastroenterology, hepatology and nutrition. NASPGHAN will continue to ensure that relationships with corporate supporters conform to established principles.

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The mission of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition is to be a world leader in advancing the science and clinical practice of pediatric gastroenterology, hepatology and nutrition in health and disease