Statement Submitted for Oral Presentation by:

Maria Oliva-Hemker, M.D.
Chief of Pediatric Gastroenterology and Nutrition
Stermer Family Professor of Pediatric Inflammatory Bowel Disease
Johns Hopkins Children's Center

On behalf of:
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

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Public Hearing on Notice of Proposed Rulemaking
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Safety Standards for High-Powered Magnet Sets

I am Dr. Maria Oliva-Hemker, Chief of Pediatric Gastroenterology and Nutrition and Stermer Family Professor of Pediatric Inflammatory Bowel Disease Johns Hopkins Children's Center in Baltimore, Maryland. Thank you for the opportunity to present testimony regarding the Commission's proposed standard to reduce the risk of injury associated with magnet ingestions by children. Specifically, I offer comments on behalf of North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) to demonstrate the correlation between the emergence of high-powered magnet sets in the commercial market and the rise in incidence of high-powered magnet ingestions.

Information from the medical literature tells us that about 80 percent of foreign body ingestions occur in children. As experts in foreign body ingestion, pediatric gastroenterologists expect most gastrointestinal foreign bodies pass spontaneously without symptoms. Only 10 to 20 percent require endoscopic removal and less than 1 percent require surgery. Surprisingly, even sharp objects such as pins and needles usually pass without incident.

High-powered magnets, however, are different than other ingested foreign bodies. These types of magnets are being increasingly ingested and can seriously injure the gastrointestinal tract. Unfortunately because the ingestion of high-powered magnets may initially cause no symptoms, there can be a marked delay in diagnosis and treatment and, at times, the ingestion is not discovered until the child presents with signs and symptoms of intestinal obstruction or perforation.

NASPGHAN became aware of an apparent rise in high-powered magnet ingestions in the spring of 2012 when it was noticed that more and more pediatric gastroenterologists were discussing these types of cases on a gastroenterology message forum.

NASPGHAN leaders determined that a survey study was needed to document any changes in the frequency of cases and complications associated with high-powered magnet ingestion. The study was performed from July 26, 2012 until October 10, 2012 and was divided into two parts. The first part of the survey was to determine the changes in frequency of physicians encountering magnet ingestions over the past 10 years. The second part of the survey was directed at providing clinical case information on patients who had ingested neodymium

magnet balls. This clinical case survey concentrated on the period from 2008 to the fall of 2012. Researchers chose 2008 as the start of clinical case review because this was the first year in which high-powered, or neodymium, magnet ball sets were marketed and sold in the United States.

The first part of the survey was completed by 355 physicians who reported a total of 481 magnet cases over a 10-year period. Physician respondents included 201 physicians from 44 states. All regions of the country, including Alaska and Hawaii, had at least one physician who had been involved in a magnet ingestion. The case incidence per year increased during each time period of the study, with 320 of the 481 cases occurring during the past three years (Slide 1).

All cases reported in the second part of the survey, which provided more detailed information about the patients, came from physicians practicing in the United States. Of these 123 clinical cases, 102 occurred in 2011 and 2012. A sharp increase was noted from 2010 to 2011 and this rate of increase extended into 2012 (Slide 2).

The data obtained from this survey is very important in providing us with patient-related information and outcomes. However, these are individual case reports and to get a sense as to whether there was a true trend in ingestions additional data was required.

Using the National Electronic Injury Surveillance System (NEISS) database Dr. Mazen Abbas and colleagues conducted a study of foreign body ingestions in children and obtained epidemiologic data on magnet ingestions from 2002-2011. This report is the first published study to report national estimates of emergency department visits for magnet foreign body ingestions in children and was recently published in the *Journal of Pediatric Gastroenterology and Nutrition*.

Since the NEISS database did not include an officially designated category for “magnets,” in this study each case narrative was manually reviewed for the term “magnet” and to further determine whether there was documentation that the magnets were round (e.g. spherical, ball or pebble shaped) and/or small sized, and how many magnets were involved. Additional data collected included date of emergency department visit, age, gender, type of product(s) ingested, and emergency department disposition. All children less than 18 years of age during the study period were included in this study.

During the 10-year study period, there were an estimated 16,386 magnet ingestion-related emergency department visits among children. These estimates were derived from 678 reported emergency department visits for magnet ingestions. As I mentioned earlier, because there was no "magnet" category in the database, most of these ingestions were reported under the categories of kitchen gadgets or toys which had to be manually reviewed to extract those emergency department visits that described small and/or round magnets. .

Of the more than 16,000 magnet ingestions, there was enough information to estimate that 7,159 emergency department visits were for ingestions of magnets described as small and/or round. Interestingly, patients ingesting small and/or round magnets when compared to those ingesting another type of magnet were more likely to be older than five years of --this goes against the general trend for foreign body ingestion in children where we typically find it is the younger children who are at highest risk for ingestions.

Further analysis of the cases with reported small and/or round magnet ingestion revealed that children older than 5 years of age were more likely to ingest multiple magnets compared to a single magnet. Those ingesting multiple small and/or round magnets had a statistically higher chance of being admitted, observed or transferred to another hospital compared with those who had ingested only a single magnet.

All age groups (0-4 years, 5-13 years and 14-17 years) had statistically significant trend increases of magnet ingestions over the 10-year study period. The age group 14-17 years had almost no documented magnet ingestion-related emergency department visits until 2009 after which a statistically significant rise is noted from a rate of 0.10 per 100,000 to 1.15 per 100,000 (Slide 3).

The age group 5-13 years had the largest increase in those suspected to have ingested multiple small and/or round magnets, a rate from 0.02 per 100,000 in 2007 to 1.22 per 100,000 in 2011, a 61-fold increase (Slide 4).

To summarize, the 10-year review of the NEISS database that was independently conducted by Dr. Abbas and colleagues provides important information on the trend of magnet ingestions in children in the United States. It was shown that during this 10-year period there were more than 16,000 emergency department magnet related visits and that such visits increased more than 8 fold. Importantly, it shows that magnet ingestions began to increase in 2009, following a drop in cases from 2007 to 2009. We speculate that the drop in cases from 2007 to 2009 is attributed to the Commission's recalls of numerous toy products that contained high-powered magnets and adherence to new toy safety standards. The increase in magnet ingestions correlates with 2009 being the first year of significant sales of high-powered magnet sets. For

example, based on data available from one company alone—1.5 million units of Buckyballs were sold between 2009 and 2011.

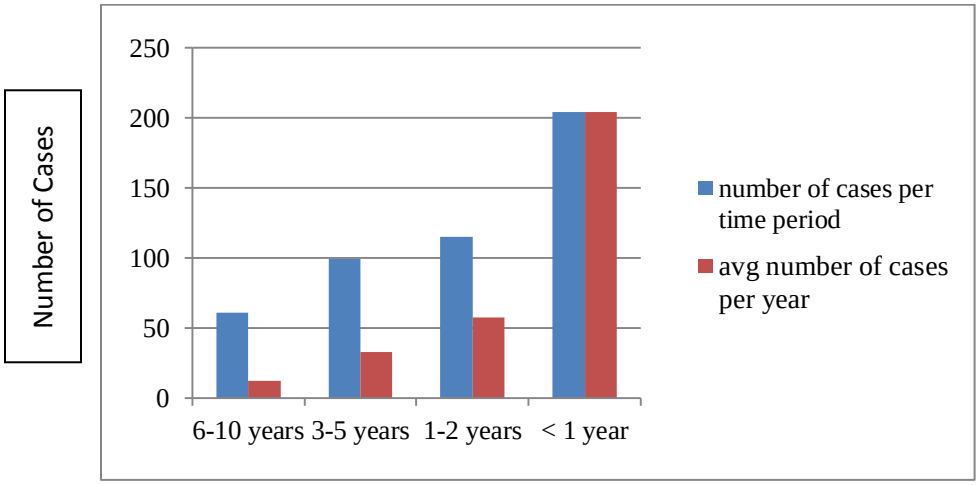
Critics of the Commission's proposed high-powered magnet safety standard have suggested that the Commission's estimate of ingestions of magnets from magnet sets is overstated. We disagree. In fact, it is highly possible that some number of the estimated 16,380 magnet ingested-related emergency department visits not classified as high-powered magnets could be attributable to high-powered magnet sets. However, many of the NEISS reports did not include sufficient detail to place them in that category, therefore our numbers most likely underestimate the prevalence of these ingestions.

On behalf of NASPGHAN, I urge the Commission to finalize this year its proposed safety standard for high-powered magnet sets. The sales of high-powered magnet sets by multiple manufacturers indicate that there are billions of high-powered magnet balls now in our environment. Consequently, the risk of ingestion of magnets by children will remain high for a period of time despite efforts by NASPGHAN, as well as other physician and consumer groups to educate the public about their dangers.

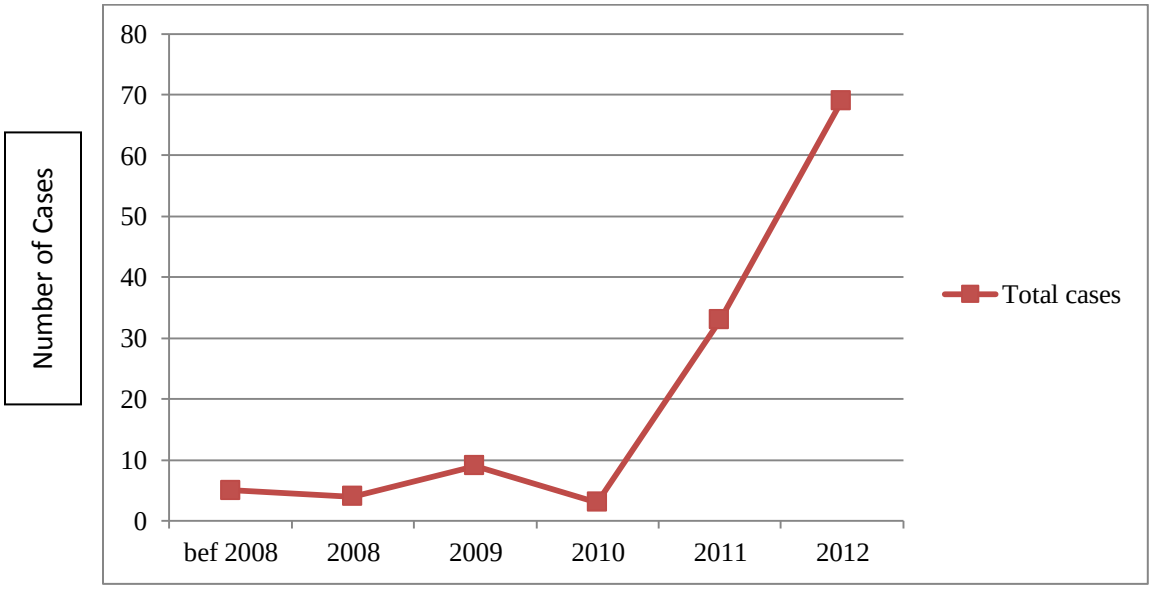
Thank you.

Slides to be presented during Dr. Oliva-Hemker's statement:

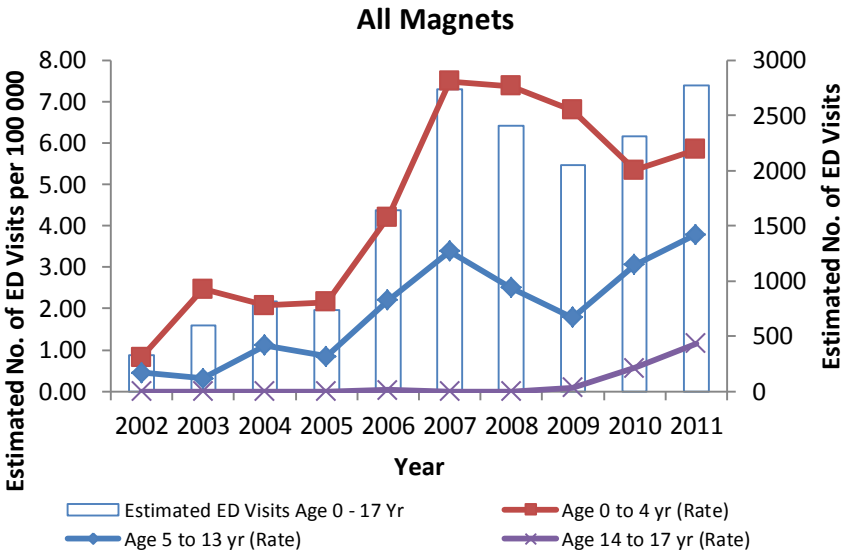
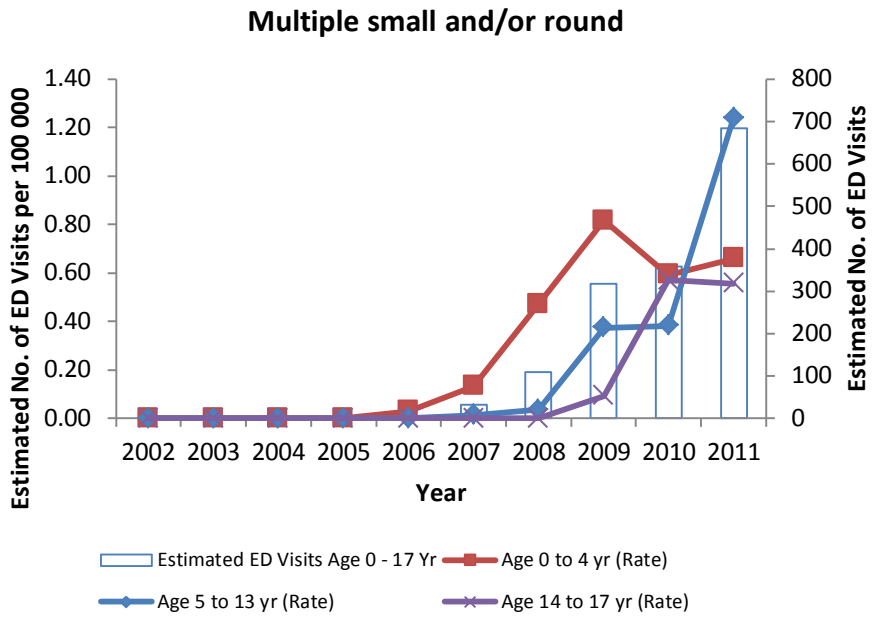
Slide 1. Number of cases versus time period in years.



Slide 2. Cases of neodymium magnet ingestions and year of occurrence.



Slide 3. Estimated number of pediatric magnet-related emergency department visits per 100,000 in the U.S. from 2002-2011 according to age group.



Slide 4. Estimated number of pediatric multiple small and/or round magnet related emergency department visits per 100,000 in the U.S. from 2002-2011 according to age group.