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November 18, 2012

Ms. Inez Tenenbaum
Chairman
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814-4408

Re: CPSC-2012-0050 – Safety Standard for Magnet Sets

Dear Chairman Tenenbaum:

On behalf of the more than 1,700 members of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), I appreciate the opportunity to comment in strong support of the Consumer Product Safety Commission's (CPSC) proposed safety standard for magnet sets.

As the largest body of experts on pediatric digestive and nutritional health, NASPGHAN applauds the CPSC for its proposal which would effectively prohibit certain high-powered, or neodymium, magnet sets. As detailed in the following comments, pediatric gastroenterologists are seeing a rise in the number of ingestions of these magnets by toddlers and teenagers, often with severe medical consequences. We thank the CPSC for taking swift action in July 2012 to remove these magnet sets from store shelves and online retail sites. Unfortunately, two of the 13 magnet set importers have refused to cease sales, although one of the two manufacturers recently announced it would discontinue two of its high-powered magnet sets that contain small sphere and cube magnets. Magnet ingestions continue to occur with alarming frequency. We hope that at the close of the public comment period the CPSC will act swiftly to finalize its proposed safety standard, which we believe will be most effective at preventing magnet ingestions from occurring in the future.

A History of High-Powered Magnet Injuries

In 2005, a child in Washington State died after he swallowed high-powered magnets from a Magnetix set[1] – magnets that are similar in size, strength and shape to the magnets used in current magnet set products intended for adults and which are the subject of this proposed rule.

The CPSC worked with toy manufacturers to set new standards in 2007 for toys that contained high-powered magnets so they could not detach or fall out of toys and be accidentally ingested. As detailed below, cases of high-powered magnet ingestions appeared to decline until new high-powered magnet set products entered the market in 2008. These high-powered magnet sets were initially marketed to children age 13 and older but are now labeled for consumers 14 years of age and older and most products include warnings to keep the product away from children. NASPGHAN is pleased to present, as part of this comment letter, details from a recent survey of pediatric gastroenterologists led by R.A. Noel, M.D., as well as a recently completed analysis of the National Electronic Surveillance System (NEISS) database. Both the NASPGHAN survey and the NEISS analysis show a rise in magnet ingestion cases despite warning labels.

Most of these high-powered magnets are made from an alloy of neodymium, iron and boron and are used in products such as computer hard drives, electric cars and power tools. We contend that manufacturing an industrial strength element into products that can be mistaken as toys or candy is a dangerous, and potentially deadly, combination for children and teenagers who come into contact with them.

Preventing Magnet Ingestions and Injury through Public Education

Between 2009 and June 2011, 1.5 million units of Buckyballs® were sold.[2] Along with the sales of high-powered magnet sets by other manufacturers, there are billions of high-powered magnet balls in the environment. Consequently, the risk of ingestion of magnets by children will remain high for a period of time even if CPSC finalizes its proposed safety standard for magnet sets. Therefore, it is critically important that education and awareness efforts aimed at the general public, and to health care professionals specifically, continue. NASPGHAN offers a number resources on its Website (www.NASPGHAN.org), including a handout for parents about the dangers associated with high-powered magnets. This year, a NASPGHAN task force led by Sunny Z. Hussain, M.D., developed a comprehensive algorithm for the management of ingested rare-earth magnets in children.[3] That algorithm was published in the *Journal of Pediatric Gastroenterology and Nutrition* and is posted on the NASPGHAN Website. One of the reasons why ingestion of high-powered magnets can result in serious injury is because ingestion often remains undetected until a patient becomes symptomatic – symptoms that often mirror those of influenza. Anecdotally, we know that misinformation among health care professionals persists about proper management of magnet ingestions.

NASPGHAN offers comments on the following aspects of the proposed rule:

- Injuries Resulting from High-Powered Magnet Ingestions
- Interventions to Remove High-Powered Magnets Following Ingestion
- Incidence of High-Powered Magnet Ingestions

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[1] New York Times. July 15, 2007. Toy Magnets Attract Sales, and Suits. Retrieved from http://www.nytimes.com/2007/07/15/business/yourmoney/15magnet.html?pagewanted=print

[2] Justia.com Dockets & Filings. June 2011. Retrieved from http://docs.justia.com/cases/federal/district-courts/illinois/ilndce/1:2011cv03872/256544/1/0.pdf.

[3] Hussain SZ, Bousvaros A, Gilger MA et al Management of ingested magnets in children. J Pediatr Gastroenterol Nutr 2012, 55:239-242.

- Proposed Definition of High-Powered Magnet Sets
- Medical Costs Associated with High-Powered Magnet Ingestions
- High-Powered Magnet Regulatory Alternatives

Injuries Resulting from High-Powered Magnet Ingestions

More than 100,000 cases of foreign body ingestion occur annually in the United States and about 80 percent of these occur in children.[4,5,6,7] In the United States, coins are the most common foreign bodies ingested by children. Fortunately, most gastrointestinal foreign bodies pass spontaneously without symptoms. Only 10 to 20 percent require endoscopic removal and less than 1 percent require surgery.[8,9] Even sharp objects such as pins and needles usually pass without incident, as the bowel wall typically relaxes if a sharp object impinges the bowel, commonly allowing complete intestinal passage.

High powered magnet ingestions are different than other ingested foreign bodies. Because immediate ingestion of magnets causes no symptoms, there can be marked delay in diagnosis and treatment. Also complicating early diagnosis is the often inability of a toddler or a child with a developmental or psychiatric disorder to verbalize that an ingestion has occurred. Initial symptoms such as abdominal pain from bowel trapped between magnets may take 8-24 hours to occur.[10] Later symptoms, such as fever or vomiting, are non-specific and resemble more common ailments such as acute infection (acute gastroenteritis). Bowel perforation with leaking of intestinal contents (peritonitis and /or sepsis) is a late complication which can take days or even weeks to manifest.

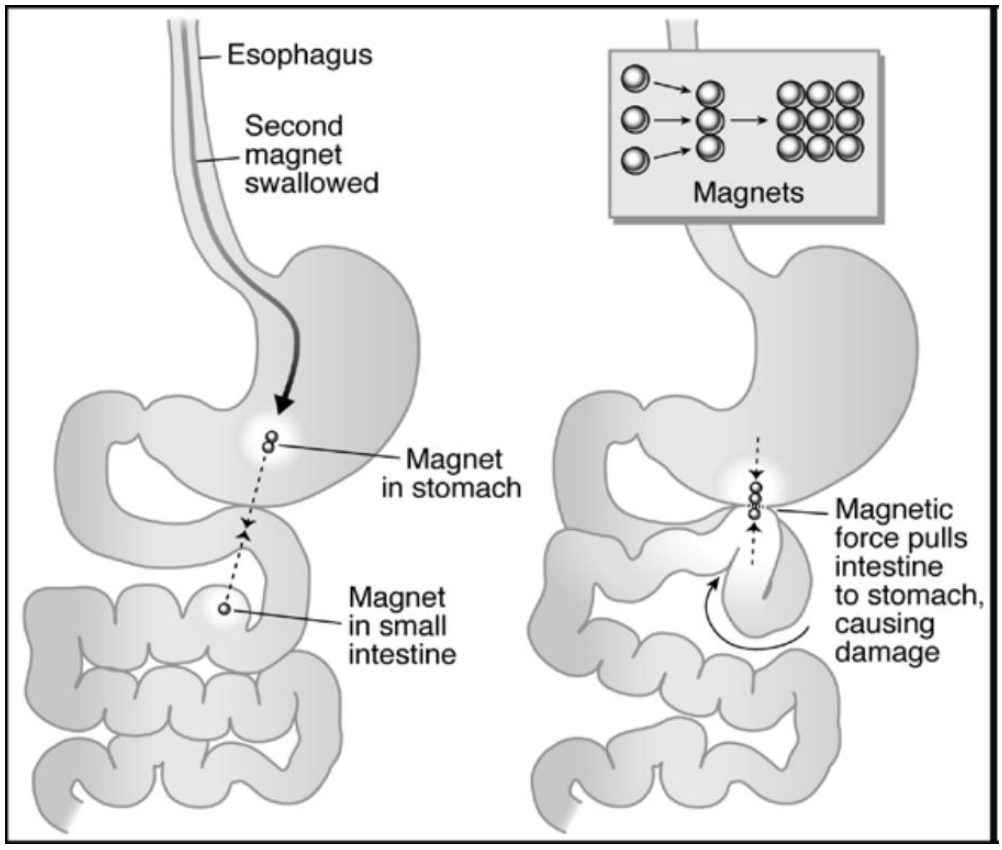
Ingestion of high-powered magnets is serious and life threatening. The proposed rule provides an accurate and detailed overview of the types of injuries that can result from magnet ingestion. In addition to the significant injury that high-powered magnet ingestion can inflict on the intestine and bowel wall, there is ingestion-associated risk of injury as a result of serial radiographs to monitor and manage magnet ingestion, as well as the risk associated with the administration of sedation for endoscopic and surgical intervention.

Bowel Wall Injury

After swallowing two or more magnets or one magnet and a metallic foreign body, there is high risk of a fold of intestine becoming trapped between the magnets or the magnet and the metallic foreign body (Fig. 1).

[4] Wyllie, R. Foreign bodies in the gastrointestinal tract. Curr Opin Pediatr 2006; 18:563.
[5] Webb, WA. Management of foreign bodies of the upper gastrointestinal tract: update. Gastrointest Endosc 1995; 41:39-44.
[6] Waltzman ML, Baskin M, Wypij D, Mooney D, Jones D, Fleisher G. A randomized clinical trial of the management of esophageal coins in children. Pediatrics 2005; 116:614-617.
[7] Little, DC, Shah, SR, St Peter, SD, et al. Esophageal foreign bodies in the pediatric population: our first 500 cases. J Pediatr Surg 2006; 41:914-918.
[8] Hussain SZ, Bousvaros A, Gilger MA et al Management of ingested magnets in children. J Pediatr Gastroenterol Nutr 2012, 55:239-242.
[9] Uyemura, MC. Foreign body ingestion in children. Am Fam Physician 2005; 72:287-289.
[10] Hussain SZ, Bousvaros A, Gilger MA et al Management of ingested magnets in children. J Pediatr Gastroenterol Nutr 2012, 55:239-242.

Figure 1: Diagram demonstrating passage of high powered magnets in the intestine with magnetic force attraction and entrapped bowel wall.



The attractive force (flux) allows the magnets to "find" each other across loops of bowel. The pressure exerted on the "trapped" intestinal bowel wall results in tissue injury and eventual tissue death (necrosis), causing ulceration and bowel perforation. Deep pressure ulceration can occur within eight hours following ingestion.[11] If left untreated, this can lead to bowel wall perforation, leakage of intestinal contents and subsequent infection.[12] Fistulization (e.g., gastro-enteric, entero-enteric, etc.) caused by high-powered magnet ingestion has also been reported.[13,14]

Bowel perforations represent a serious and immediate risk to the patient. The leaking of intestinal contents into the abdominal cavity rapidly results in infection and peritonitis (inflammation of the tissue that covers the intestine and internal organs). Left untreated, this can lead to life-threatening infection, or sepsis. In rare cases, ingested magnets may attract across several loops of intestine causing the bowels to twist, or volvulize. The twisted loop of bowel obstructs the flow of intestinal contents and blood flow, leading to lack of oxygen to the bowel wall and resultant ischemia. This is a surgical emergency requiring immediate operation. Delay in

[11] Hussain SZ, Bousvaros A, Gilger MA et al Management of ingested magnets in children. J Pediatr Gastroenterol Nutr 2012, 55:239-242.
[12] Hernandez AE, Gutierrez SRC, Barrios JE, et al. Intestinal perforation caused by magnetic toys. J Pediatri Surg 2007; 42:E13-16.
[13] Honzumi M, Shigemori C, Ito H et al, An intestinal fistula in a 3-year old children caused by ingestion of magnets:report of a case. Surg Today 1995;25:552-553.
[14] Ohno Y, Yoneda A, Enjoji A, et al. Gastroduodenal fistula caused by ingested magnets.Gastrointest Endosc 2005; 61:109-110.

treatment can lead to the need for resecting necrotic (dead) bowel. If too much bowel is removed, "short bowel" syndrome may be the result, requiring life-long intravenous nutrition (total parenteral nutrition).

Interventions to Remove High-Powered Magnets Following Ingestion

Following any foreign body ingestion in a child, teenager or young adult, the most appropriate course of action is for the patient and their family to seek emergency medical attention to determine the type of foreign body ingested, and the location of the foreign body, most often determined by X-ray. In the vast majority of cases, consultation with an appropriate sub-specialist provider is required to determine what additional steps need to be taken. In "typical" non-magnet, non-battery, non-sharp ingestions, an X-ray study determines if the foreign body can be safely followed for passage through the gastrointestinal tract without the need for endoscopic removal or surgery.

Ingestion of a single magnet is typically managed by a protocol for a comparably shaped and sized non-magnet foreign body. The exception to this is that contact with any other magnet outside of the body must be rigorously avoided as the magnet in the body can be attracted to a magnet outside of the body resulting in significant complications.

Ingestion of two or more magnets is associated with a substantially higher risk of complications as described throughout this comment letter due to their ability to attract across different segments of the gastrointestinal tract. At a minimum, serial radiography is required following ingestion of multiple magnets. However, because of the risk of fistula development due to attraction of the magnets across segments of the gastrointestinal tract as described above, endoscopy and or colonoscopy are frequently performed (based on presumed magnet location) to more accurately determine the precise location of the magnets, to assess the extent of injury, and to remove some or, if possible, all of the magnets.

Endoscopic removal of foreign bodies requires, at minimum, intravenous sedation, and frequently requires the administration of general anesthesia with its own associated risks, which include both morbidity and mortality. In addition, if the magnets have attracted across a segment of bowel and a fistula has developed, surgery may be required in conjunction with the endoscopic procedure or in addition to the endoscopic procedure with risk of additional patient morbidity and mortality.

In some cases of ingestion of multiple magnets, the magnets appear to be located in the small bowel outside of the reach of an upper endoscope or colonoscope, or, alternatively, they are located in the large bowel. In cases where endoscopy is not able to be performed, serial radiography to monitor passage of magnets is typically performed, frequently in conjunction with surgical consultation. In some of these cases, small bowel and colonic lavage utilizing a balanced electrolyte solution may be employed to assist with passage of magnets that are thought to be "mobile." This lavage procedure is uncomfortable for young patients and is analogous to undergoing a bowel preparation for colonoscopy. Lavage may require inpatient admission, insertion of a nasogastric tube for administration of the unpalatable solution and is not guaranteed to move magnets through the gastrointestinal tract, as they may already be or become lodged.

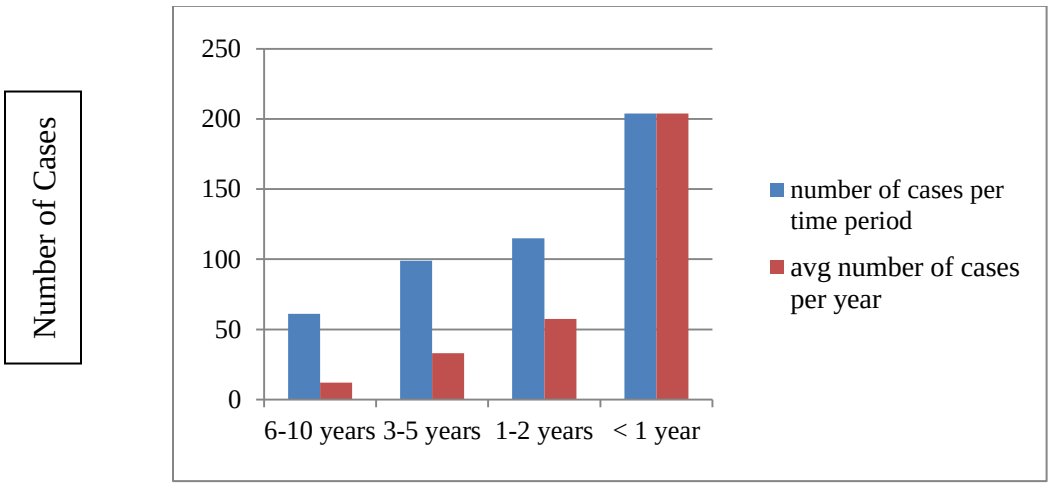
Incidence of High-Powered Magnet Ingestions

Survey of Pediatric Gastroenterologists

Neodymium, or rare earth, magnet ingestions have been a concern for pediatric gastroenterologists based on the apparent increase in cases that were posted in the spring of 2012 on the NASPGHAN Pediatric GI Bulletin Board. NASPGHAN leaders determined a survey study was needed to document any changes in the frequency of cases and complications associated with high-powered magnet ingestion. This study was approved by the Louisiana State University Health Science Center Institutional Review Board (IRB) and was performed from July 26, 2012 until October 10, 2012. The survey was divided in to 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. This part of the survey also provided information on the experience, location and type of physician practice. The second part of the survey was directed at providing clinical case information on patients who had ingested neodymium magnet balls. This part provided information on patient demographics, risk factors for ingestion, type of medical intervention provided, as well as the outcome of the patient following medical intervention. This clinical case survey concentrated on the period from 2008 (the first year in which neodymium magnet ball sets were marketed and sold in the United States) to the fall of 2012.

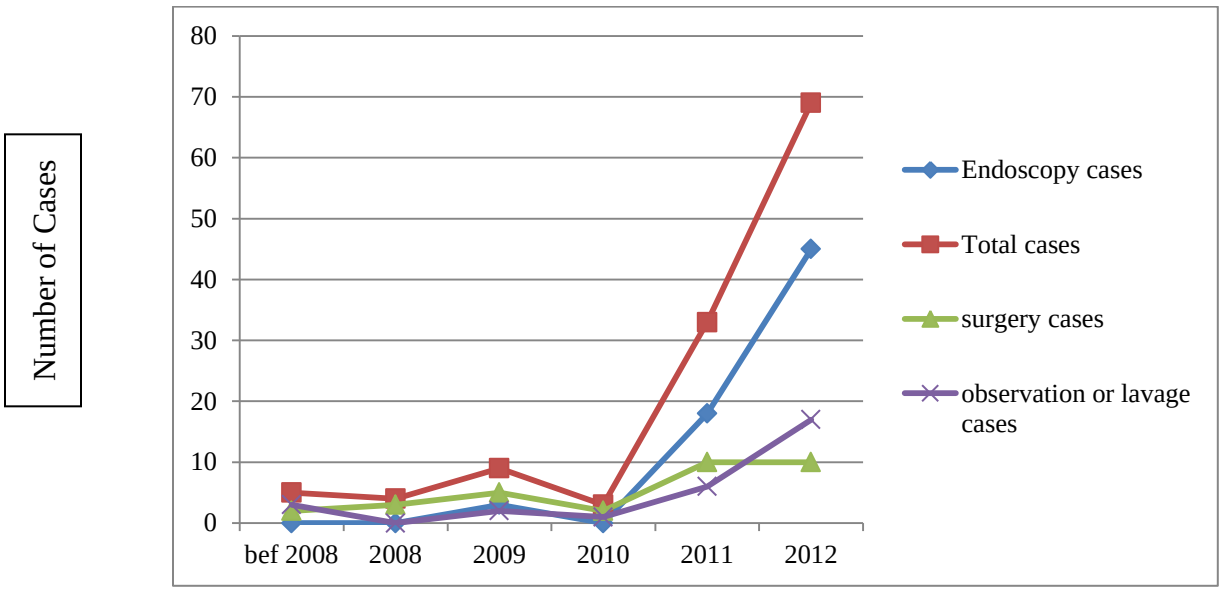
The first part of the survey was completed by 355 physicians who reported a total of 481 magnet cases over a 10-year period. Physician respondents included 201 physicians from 44 states, as well as physicians from Canada, Kenya, Guatemala and Mexico. All regions of the country, including Alaska and Hawaii, 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 (Fig. 2).

Figure 2: Number of cases versus time period in years.



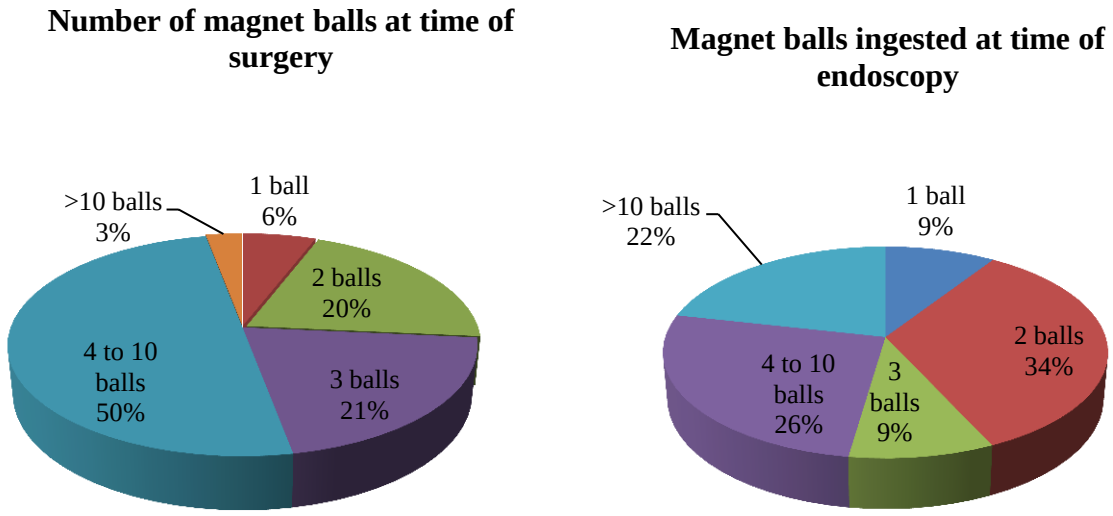
All cases reported in the second part of the survey came from physicians practicing in the United States. There were 123 clinical cases documented in the survey, with 102 occurring in 2011 and 2012. A sharp increase was noted from 2010 to 2011 and this rate of increase extended into 2012. Interventions for magnet ingestions showed similar increases during these time periods (Fig. 3). Of the 123 patients, 121 had radiographs done with 85 having serial X-rays performed.

Figure 3: Cases and types of intervention for neodymium magnet ingestions and the year of occurrence.



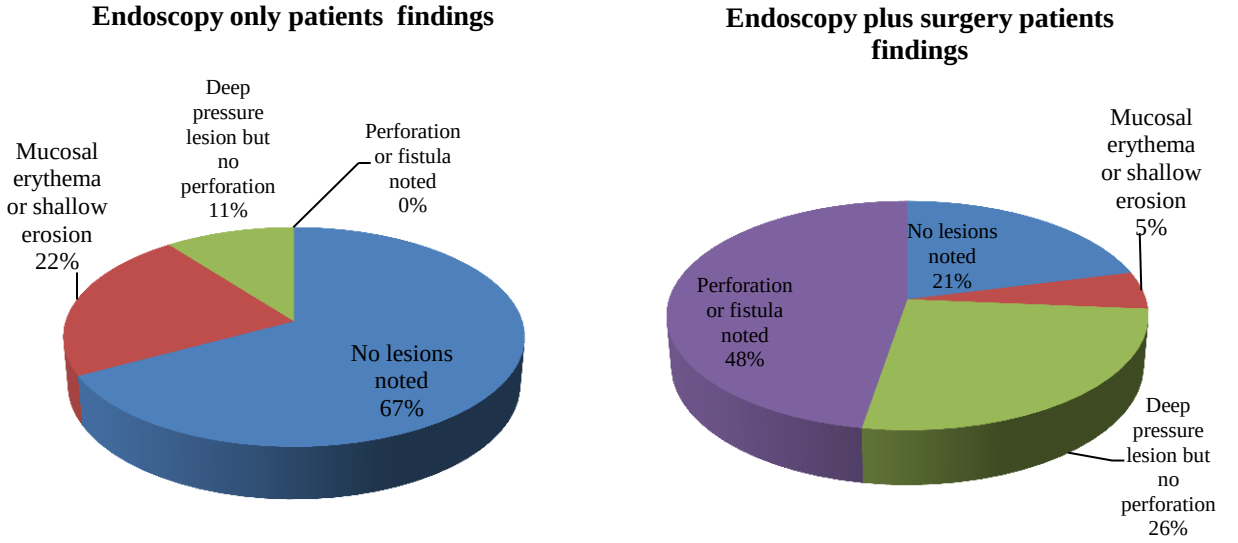
Ninety-eight (79.6%) of 123 patients underwent endoscopy, surgery or both types of intervention for either removal of magnets or repair of damage cause by the magnet ingestions. Twenty-five (25.5%) of the 98 patients with endoscopic procedures also had some type of surgical intervention. The types of surgery included laparotomy (78%), laparoscopy (19%) and thoracotomy (3%). The number of balls ingested did not correlate with the severity of interventions with only 3 percent of the patients requiring surgery for ingestion of more than 10 balls, compared to 20 percent of patients needing endoscopic intervention for ingestion of more than 10 magnet balls (Fig. 4).

Figure 4: Comparison of number of magnet balls ingested in surgical versus endoscopic cases.



There was significant morbidity associated with the magnet ingestions. The survey showed that patients who had endoscopic procedures alone had fewer complications because the magnet ingestion was at a stage where it could be effectively managed endoscopically (i.e. magnets removed). Figure 5 shows the medical findings in patients who underwent endoscopy and those who underwent endoscopy and surgery.

Figure 5: Comparison of endoscopic finding in those patients undergoing endoscopy only versus those that underwent both endoscopy and surgery for magnet ball ingestions.

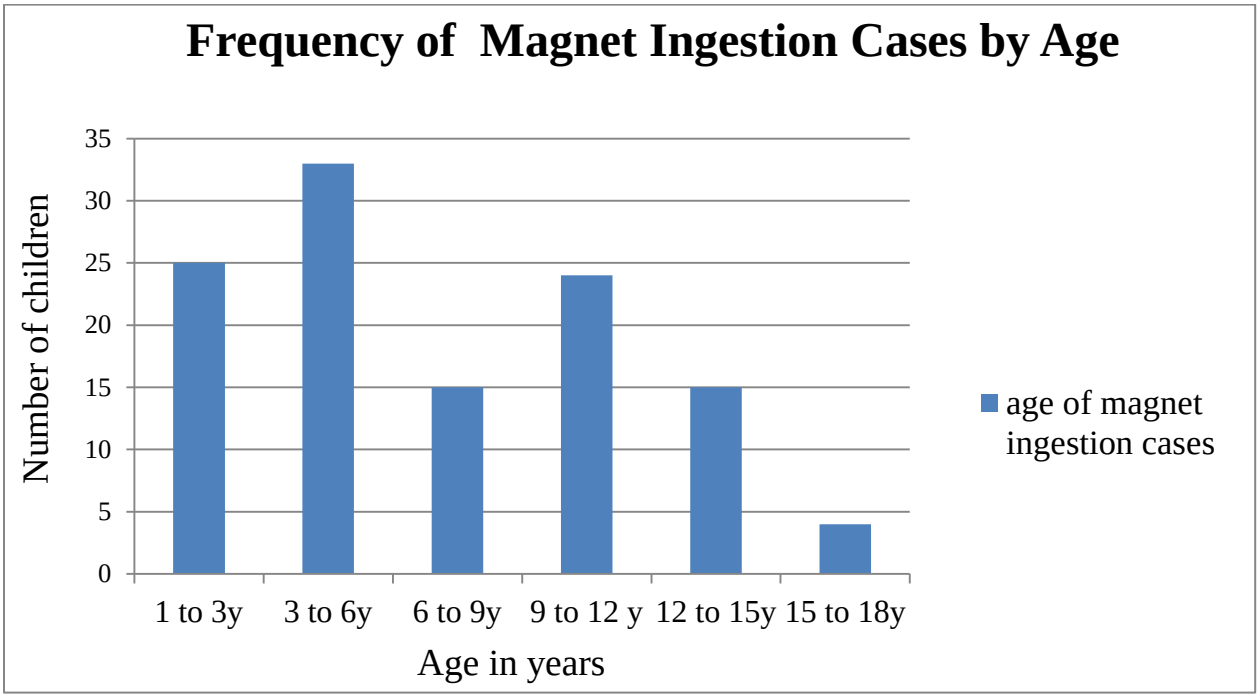


There were no perforations noted in the group of patients who underwent endoscopy alone compared to 48 percent of patients who underwent endoscopy plus surgery. Deep pressure lesions were also higher in the endoscopy plus surgery group at a 26 percent occurrence rate compared to 11 percent in the endoscopy alone intervention group. This difference is most likely due to patients in the endoscopy plus surgery group having a longer duration between the time of ingestion and the time of medical intervention.

The types of surgical intervention ranged from magnet removal alone to bowel resection. Magnet removal alone occurred in 31 percent undergoing surgery, while 43 percent required magnet removal plus an additional surgical procedure, such as multiple or single fistula repair (60%) and bowel resection (15%). Other surgical interventions included an appendectomy and gastrostomy. The overall surgical outcomes were good with 90 percent having no significant short-term complications. Nine percent required additional medical therapy.

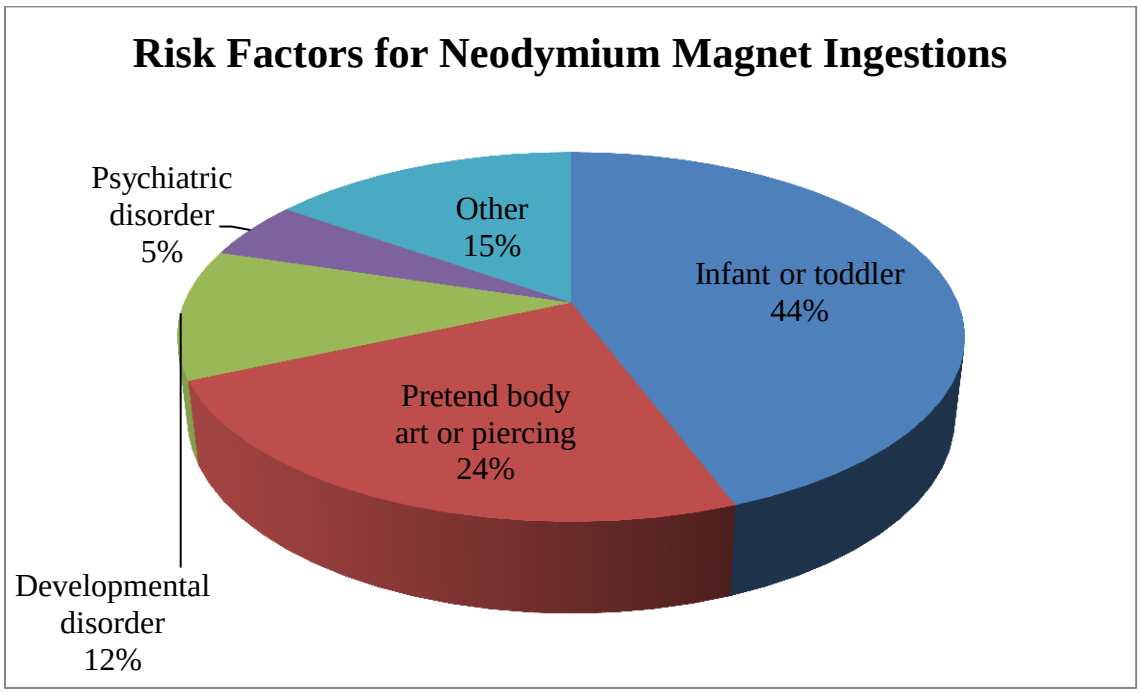
The survey also assessed the risk factors associated with magnet ball ingestions. Similar to other types of foreign body ingestions, children between the ages of 13 months and six years appear to be at the highest risk for ingestion, with slightly greater than 50 percent of ingestions. However, there is a significant population of older children and adolescents that ingest the magnet balls (Fig. 6).

Figure 6: The number of children in each age group that were reported in the NASPGHAN survey.



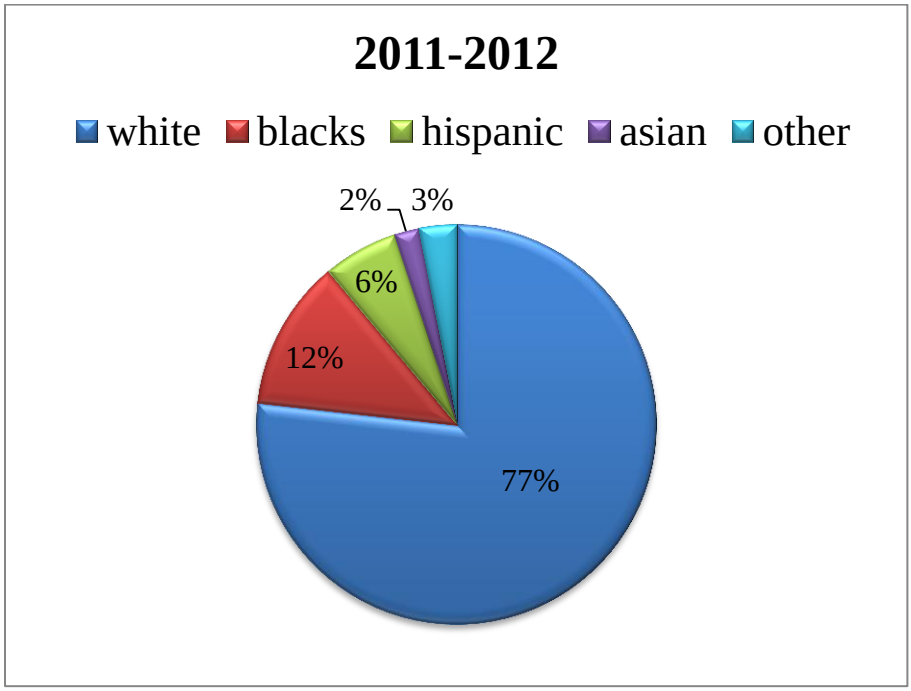
The main cause of the increase of magnet ingestions among older children appears to be secondary to the use of these magnets as pretend body art or piercings (Fig. 7).

Figure 7: Risk factors for rare earth magnet ball ingestions.



Prior to 2010, Caucasians accounted for most magnet ingestions. However, over the past two years, blacks, Hispanics and Asians have increased as a percentage of cases although Caucasians are still the ethnic group most affected (Fig. 8).

Figure 8: Ethnic makeup of children with magnet ingestions during the 2011 to 2012 time period.



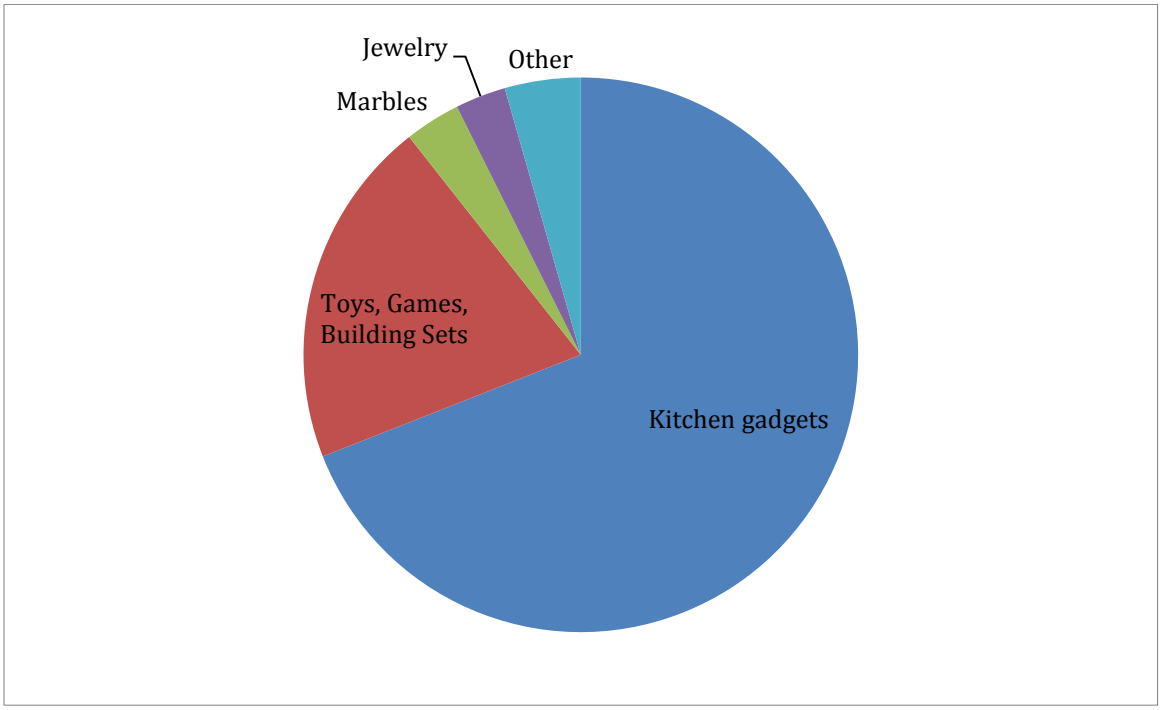
Our data indicate that the rate of magnet ball ingestions and associated medical intervention in children has significantly increased in the past three years, despite the use of warning labels. However, our survey likely underestimates these trends because pediatric gastroenterologists were the only group surveyed. For example, no pediatric surgeons, family practice or emergency room physicians were included in our survey, but these groups of physicians are also responsible for the care of children with magnet ingestions.

Analysis of NEISS Database

Using the NEISS database, Mazen Abbas, D.O., M.P.H., and Cade Nylund, M.D., at Uniformed Services University for the Health Sciences in Bethesda, MD, conducted a study of foreign body ingestions in children, including additional epidemiologic data on magnet ingestions. Their study was approved by that institution's IRB. To complete their study, they manually reviewed each case narrative of all listed foreign body ingestions for the term "magnet" and further determined 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.

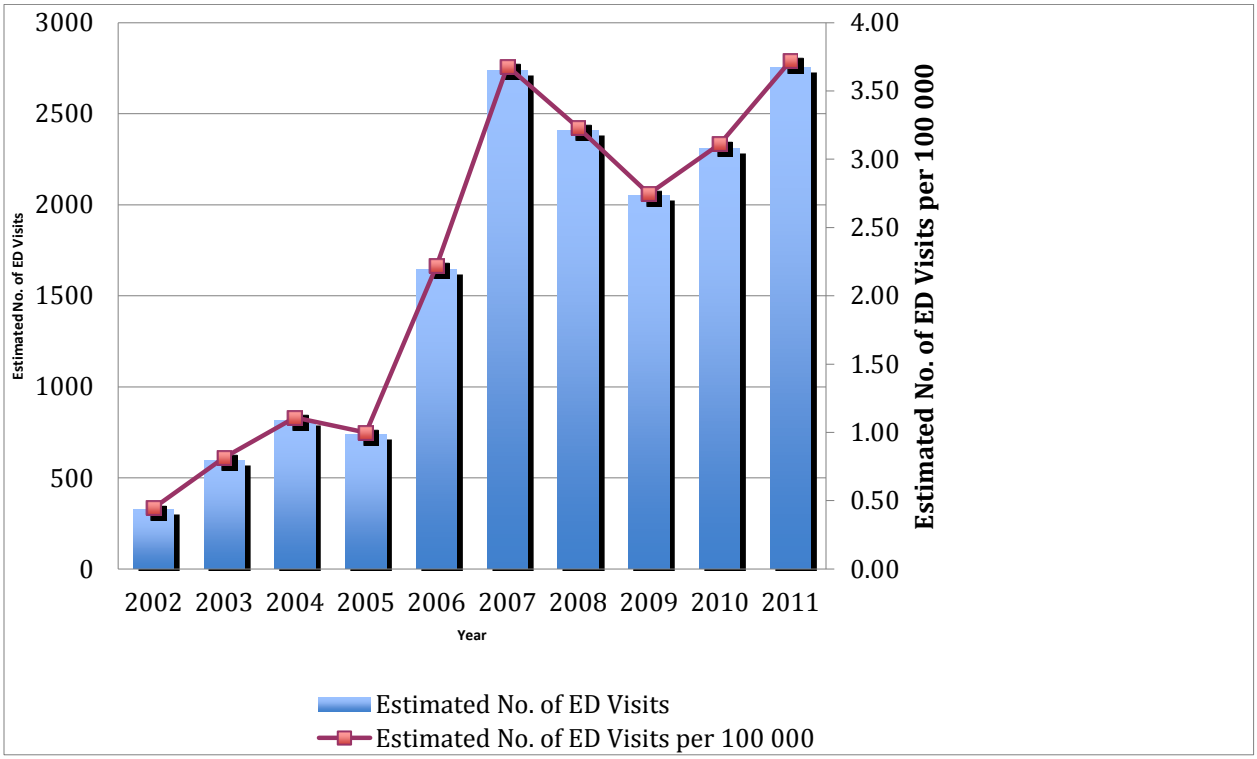
There were an estimated 16,386 (95% CI: 12,175-20,958) possible magnet ingestion-related emergency department visits among children <18 years during the 10-year study time period. These estimates were derived from 678 reported emergency department visits for magnet ingestions. Most of these ingestions were reported as kitchen gadgets or toys (Fig. 9).

Figure 9: Product coding for pediatric magnet ingestion-related emergency department visits in the United States, 2002 to 2011.



In 2002, the estimated number of emergency department visits for magnet ingestions was 327 (95%: 68-585) compared to 2770 (95%: 1784-3756) in 2011, representing an average annual increase of 75 percent. The rate of emergency department visits for magnet ingestions had a statistically significant rise from 0.45 per 100,000 (95% CI: 0.09 – 0.80) to 3.75 per 100,000 (95%: 2.39 – 5.06) during the same 10-year period, an 8.5 fold increase ($p<0.01$). There was a decrease noted from 2007 to 2009 in the estimated cases and rate. This trend reversed in the last three years with a 34 percent increase in the number of estimated cases (Fig. 10).

Figure 10: Estimated annual number and rate of pediatric magnet-related emergency department visits in the United States from 2002 to 2011.



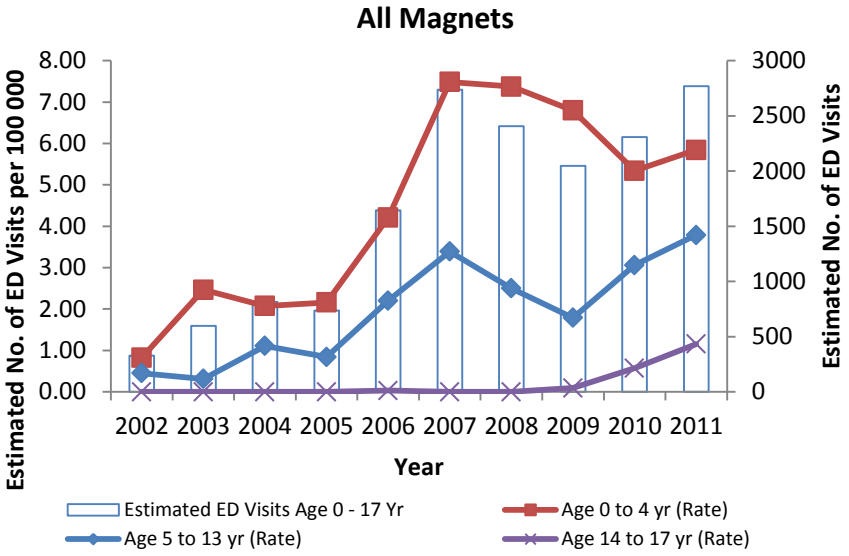
An overwhelming majority of the visits resulted in the patient being released from the emergency department after being examined and/or treated (96%).

Magnet ingestion-related emergency department visits that were described as small and/or round magnets accounted for an estimated 7,159 emergency department visits based on 275 reported cases. On the other hand, 278 visits (6343 estimated visits) did not describe the magnet ingested and another 125 were not described as a small and/or round (2883 estimated visits). 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 age (53%, mean age 5.6 years ± 0.23 vs. 29%, 3.7 years ± 0.29; $p < 0.001$).

Further analysis of small and/or round magnets into those who were suspected of ingesting multiple magnets when compared to those ingesting a single magnet, patients who ingested multiple were more likely to be older than five years of age (65%, mean age 7.1 years ± 0.56 vs. 50%, 5.0 years ± 0.23; $p < 0.001$). Furthermore, patients who ingested multiple magnets had a higher chance of being admitted, observed or transferred to another hospital compared to those that only ingested a single magnet (12.2% vs. 0.7%, $p < 0.001$).

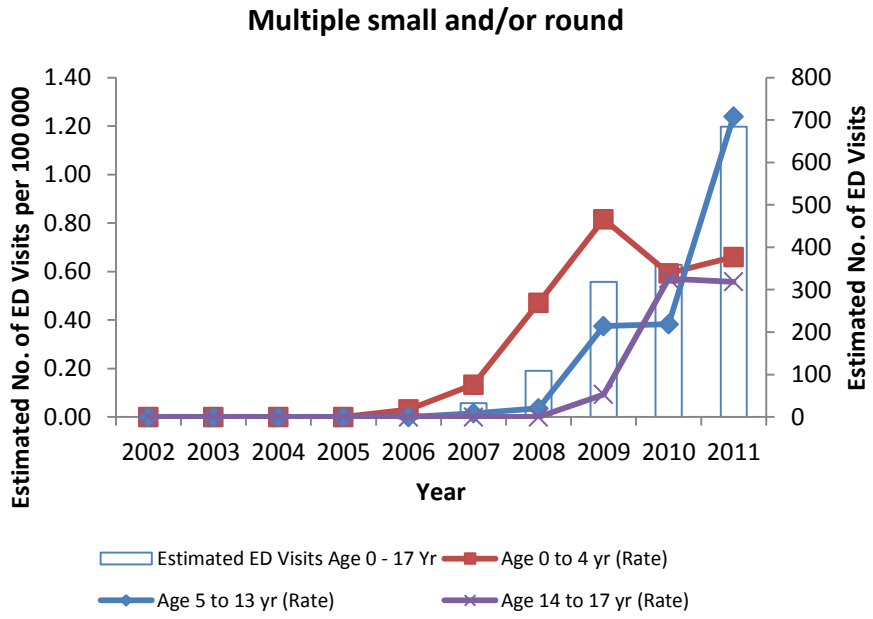
All age groups (0-4 years, 5-13 years and 14-17 years) had statistically significant trend increases of magnet ingestions over the 10-year study period ($p<0.001$). The age group 14-17 years had almost no documented magnet ingestion-related emergency department visits until 2009 after which a statistically significant rise is noted from a rate of 0.10 per 100,000 (95% CI: 0.00 – 0.29) to 1.15 per 100,000 (95 CI: 0.14 – 2.16) ($p=0.006$) (Fig. 11).

Figure 11: Estimated number of pediatric magnet-related emergency department visits per 100,000 in the United States from 2002 to 2011 according to age group.



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 (Fig.12).

Figure 12: Estimated number of pediatric multiple small and/or round magnet-related emergency department visits per 100,000 in the United States from 2002 to 2011 according to age group.



The CPSC three-year review of the NEISS database, as detailed in the proposed rule, provides important information on the estimated number of ingestions of magnets from magnet sets during the period when high-

powered magnet sets were marketed in the United States. However, the 10-year review of the NEISS database conducted by Dr. Abbas and Dr. Nylund provides important information on the trend of magnet ingestions, which 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 CPSC 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 magnet sets. As stated above, between 2009 and June 2011, 1.5 million units of Buckyballs® were sold.[15]

It is possible that some number of the estimated 16,380 magnet ingested-related injuries not classified as high-powered magnets could be attributable to high-powered magnet sets; however, a number of the NEISS reports did not include sufficient detail to place them in that category.

Proposed Definition of High-Powered Magnet Sets

NASPGHAN supports the CPSC's definition of magnet sets as any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief. We agree with CPSC's proposal that if a magnet set contains a magnet that fits within the CPSC's small parts cylinder, magnets from that set would be required to have a flux index of 50 or less.

NASPGHAN is concerned that manufacturers could work around the proposed restrictions by selling high-powered magnets individually. NASPGHAN also recognizes that these small high-powered magnets are used for purposes other than general entertainment, such as hanging artwork. We are particularly concerned that teenagers, who use high-powered magnets to mimic tongue, lip, cheek, and nose piercings, would still be able to easily purchase magnets individually. We recommend, at a minimum, that individual magnets that are sold to be used in conjunction with a magnet set should be required to meet the proposed safety standard. We suggest that CPSC also explore the feasibility of applying the proposed safety standard to all individual magnets or to consider other restrictions on the sale of individual magnets.

Medical Costs Associated with High-Powered Magnet Ingestions

High-powered magnets sold in the United States are produced cheaply in China and impose tremendous cost burden on our health care system when ingested. Aside from our primary goal of preventing injury to children, another benefit of the proposed rule is reducing the significant medical and societal costs that result from magnet ingestion. First and foremost, no child should have to endure the pain and suffering that many pediatric gastroenterologists have witnessed as a result of high-powered magnet ingestion. As a society, our number-one priority should be to protect children from unnecessary harm.

In the much publicized case of Braylon Jordon – the Mississippi toddler who swallowed eight high-powered magnets which resulted in significant bowel resection – medical costs have already reached an estimated $2.5-3 million, and the costs continue. Most recently, it cost Braylon's family roughly $3,000 to travel to Pennsylvania for bowel transplant consult. Prior to Braylon's injury, his mother was employed earning

[15] Justia.com Dockets & Filings. June 2011. Retrieved from http://docs.justia.com/cases/federal/district-courts/illinois/ilndce/1:2011cv03872/256544/1/0.pdf.

approximately $1,000 per month. She now must stay home to care for Braylon and has lost that much-needed income.

High-Powered Magnet Regulatory Alternatives

We ask the CPSC to regulate the safety of high-powered magnet sets under Sections 7 and 9 of the Consumer Product Safety Act (CPSA) rather than a ban under Section 8 of the CPSA or under similar provisions of the Federal Hazardous Substances Act. Promulgating a rule under Sections 7 and 9 provides an effective framework for manufacturers who may want to enter this product market in the future. While a ban under Section 8 may have the same immediate effect as a standard promulgated under Sections 7 and 9, the future impact of a standard would be profound in clearly identifying a standard that such product must meet in order to be legally sold in the United States.

We appreciate that the CPSC needed to discuss, as part of the proposed rule, alternatives to reduce the risk of injuries related to ingestion of magnets. We agree, however, with CPSC's conclusion that none of the alternatives considered would adequately reduce the risk of injury to children, including: voluntary recalls, a voluntary standard, warnings, packaging restrictions, or restrictions on sales of magnet sets.

We want to underscore our position that warning labels and child resistant packaging do not adequately reduce the injuries associated with high-powered magnet sets.

In 2008, high-powered magnet sets were introduced in the consumer market and generally marketed as adult desk toys. The product was initially labeled for use by children 13 years of age and older. Since 2010, high-powered magnet sets have been labeled for consumers 14 years of age and older, and most include warnings to keep the product away from children. Based on the survey of pediatric gastroenterologists detailed above, magnet ingestions and resulting injuries are increasing despite warnings and labels.

We do not believe that any level of labeling can adequately convey why high-powered magnets are hazardous to children. As a result, parents and other caregivers may not be vigilant in keeping these magnets out of reach of children. These magnet sets are designed as a toy for general entertainment, and while generally marketed to adults, children are also fascinated with high-powered magnets and may not regard them as a prohibited item like they would matches, knives, and other dangerous household products.

Some magnet sets include several warning labels on the packaging. The problem, however, is that magnet sets are not guaranteed to remain in their original packaging with the warning labels. Even if the magnet sets remain in their individual packaging, we agree with the CPSC that warnings would not be understood by most young children. We conclude, based upon our study findings, that warning labels are also ineffective at preventing ingestions in children with cognitive disorders. Furthermore, we are deeply troubled by the number of older children and teenagers who are ingesting magnets as a result of using them to mimic body art and piercings. Parents and other caregivers may purchase these magnet sets for older children because they do not anticipate the magnets being used for the unintended purpose of fake nose, lip, tongue, and cheek piercings, and, therefore, disregard the warnings. We also do not believe that older children and teenagers can fully appreciate the dangers associated with accidently swallowing these magnets.

In addition to labels not being able to effectively describe the consequences of magnet ingestion, these warnings are not displayed in a range of languages. While our study findings show that ingestions have been greatest in

Caucasian children, ingestions are increasing among blacks, Hispanics, Asians and other race/ethnicities. However, as stated above, even if warning labels were displayed on packaging in languages, other than just English, we still reject warnings as an effective way to prevent magnet ingestions.

Adherence to warnings is also made difficult due to the number of magnets that typically comprise high-powered magnet nets. The most popular magnet set currently on the market includes 216 BB-sized high-powered magnets. Because the magnets are so small, they can easily get lost in furniture or carpeting. Adherence to the warning labels assumes that adults will count each magnet after the magnet set is used if children live or visit the place or location in which the magnet set was used. In the case of Braylon Jordan, the parents didn't realize that a few of the magnets had gone missing after playing with the magnet set. Unfortunately, Braylon found those magnets and swallowed them.

Because magnet sets do not have a useful purpose other than play, we do not believe that it is worthwhile to experiment with safety-enhancing alternatives at the expense of the health and safety of our children. In addition to the alternatives discussed in the proposed rule, we understand that some manufacturers are considering "upgrades" to their magnet products that are designed to prevent magnet ingestions. Specifically, companies are considering coating high-powered magnets with a bitter substance to prevent mouthing by toddlers and to deter children and teenagers from using the magnets as fake piercings. NASPGHAN is a professional society composed of pediatric gastroenterologists, not consumer protection specialists. Therefore, we do not have the expertise to test product safety. We would prefer to leave those judgments concerning product safety to consumer protection professionals and organizations, such as the CPSC. At this time, we can only state with certainty that the high-powered magnets sets sold over the last few years are unsafe for children. Unless product modifications can be proven to be safe for children, we strongly oppose as an alternative to the proposed safety standard the promulgation of an alternative set of requirements that could reduce the risk of injury from magnet sets.

Our concerns about the use of bitter coatings on high-powered magnets include, but are not limited to:

- There is no guarantee that children, especially babies and toddlers, will not swallow the magnets as a reaction to their averse taste versus spitting them out.
- The magnets look like candy, regardless of a bitter coating.
- It is unclear whether the bitter coating would hold its strength over time.
- It is unclear whether there are any agents that could remove the bitter coating.

Conclusion

NASPGHAN is committed to fighting for a ban of high-powered magnet sets on behalf of Braylon Jordon and the hundreds of children who have been injured needlessly by these magnet toys. Recently when asked about their situation, Braylon Jordon's mother said that it would break her heart if what happened to Braylon happened to another child. We commend the Jordans for telling Braylon's story and helping NASPGHAN educate the public about this dangerous product.

NASPGHAN commends the CPSC for its actions and strongly supports the proposed safety standard for high-powered magnet sets. We believe that the CPSC response is appropriate based upon our data analysis and the experiences of NASPGHAN members in treating magnet ingestions. We underscore that magnet ingestions are unlike other foreign body ingestions, such as coins, "kitchen" magnets, and even sharp objects, because when

two neodymium magnets or one neodymium magnet and other metal foreign body are ingested intestinal injury can occur within hours.

The popularity of high-powered magnet sets and the lack of understanding about the dangers that they pose to children has undoubtedly contributed to the increased number of ingestions and resulting medical injury. We firmly believe that no warning will adequately reduce injuries associated with these high-powered magnet products.

NASPGHAN thanks the CPSC for consideration of its comments. Should have any questions or require additional information, please contact Camille Bonta, NASPGHAN's Washington representative, at (202) 320-3658 or cbonta@summithealthconsulting.com.

Sincerely,

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