



**Statement from the
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
on the ASTM ballot
Standard Specification for
Marketing and Labeling Adult Magnet Sets Containing Loose, Powerful Magnets**

January 13, 2020

Pediatric specialists, including members of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), are accustomed to children, adolescents and teens swallowing things they shouldn't for a variety of reasons. Roughly 98 percent of foreign body ingestions in children are unintentional and most are the result of developmentally appropriate behavior (infants and toddlers "mouthing" objects, teens taking risks due to peer pressure, etc.). While many foreign objects pass through the gastrointestinal tract and out in the stool without medical complications or medical intervention, ingestion of rare-earth, high-powered magnets are strikingly different. When two or more magnets are ingested, medical management, including repeated X-ray radiation exposure, is almost always necessary. In such cases, endoscopic or surgical removal of magnets is often required, as well.

Pediatric gastroenterologists, surgeons, and emergency medicine physicians across the country are witnessing a resurgence in high-powered magnet ingestion cases since magnet sets came back on the market in the United States following the decision of the U.S. Court of Appeals for the Tenth Circuit in November 2016. The U.S. Consumer Product Safety Commission (CPSC) standard for high-powered magnet sets was responsive, responsible and appropriate. As data show, the number of high-powered magnet ingestion cases dropped dramatically during the period the CPSC standard was in effect. It is irrefutable that the most effective strategy to dramatically reduce the number of accidental high-powered magnet ingestions is to restrict their availability through a strong safety standard.

NASPGHAN, as represented on the ASTM F15.77 Magnets Subcommittee by Bryan Rudolph, MD, MPH and Camille Bonta, MHS, holds the position that the proposed new standard for magnet sets containing small, loose, powerful magnets with a flux index ≥ 50 kG² mm² will not adequately protect children from their potential harms.

I. Scope

The proposed new standard covers marketing, packaging, labeling, and warning requirements for magnet sets containing small, powerful magnets. It does not, however, address the product, namely, the size and strength of the individual magnets that comprise the sets. Because NASPGHAN does not believe marketing, packaging, labeling and warning requirements will sufficiently reduce injuries, our position is that the standard's scope is insufficient.

Many others within the Subcommittee seem to agree. “Relying only on warning information will not effectively reduce the hazard with the ingestion of small, powerful magnets,” wrote Stephen Harsanyi, an Engineering Psychologist at the CPSC, in his letter to the F15.77 Subcommittee on October 18, 2019. The letter subsequently provides a rationale, among which are the following:

“Consumers are unlikely to consult and heed warning information for this product, which, in appearance, is simple, familiar, and non-threatening. Incident data and consumer reviews of magnet sets demonstrate that consumers commonly recognize magnet sets as suitable for children; this hinders the perceived credibility of warning information arguing to the contrary.”

“Consumers are particularly unlikely to anticipate and appreciate the vulnerability of children and teens who do not have a history of mouthing inedible objects. Therefore, consumers are unlikely to keep the magnets away from these populations, regardless of warning information.”

“Older children and teens are unlikely to comply with warnings. Sedney and Smith (2012) discussed that even though older children presumably comprehend the danger better than younger children due to their more advanced cognitive ability, they are likely to give in to peer pressure, test limits, bend rules, and underestimate the risk or consequences.”

“Incidents are continuing that involve products with warning labels, 14+ age labels, instructions, marketing, and packaging that address the ingestion hazard. Staff concludes that magnet sets present a significant hazard to children and teens, primarily due to the hidden nature of the hazard and the difficult-to-control chain of events that lead to injury and death.”

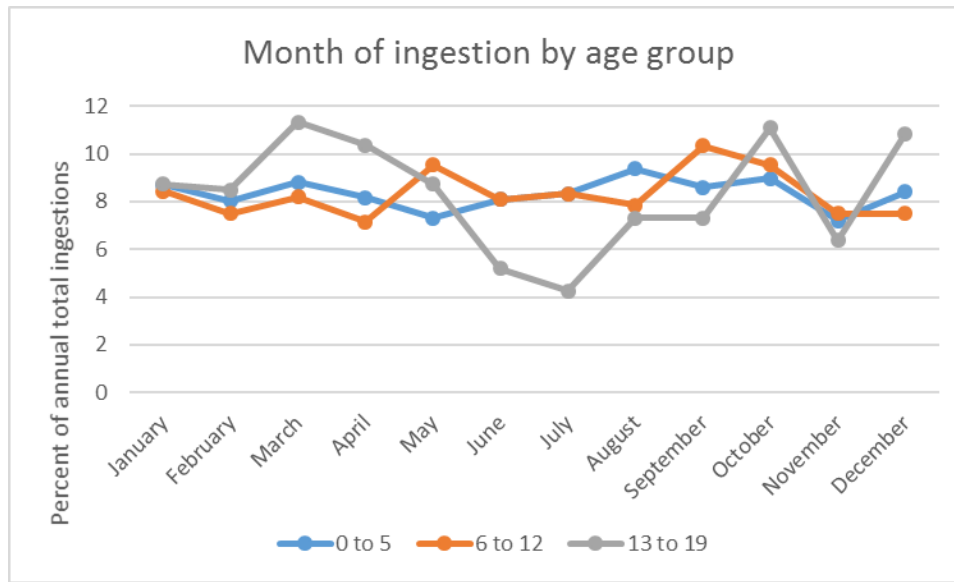
Though we do not have the expertise of human factors experts or engineering psychologists like others on this Subcommittee, these common sense conclusions are consistent with the anecdotal experience of many NASPGHAN members. For these reasons, NASPGHAN strongly agrees that warnings and labeling requirements will be insufficient to prevent needless injuries to children.

NASPGHAN has and continues to support a standard that is consistent, *at a minimum*, with the CPSC’s 2014 published safety standard, which requires that if a magnet set contains a magnet that fits within the CPSC’s small parts cylinder, each magnet in the magnet set must have a flux index of 50 kG² mm² or less. CPSC set a flux index of 50 kG² mm² or less based on the flux index requirement that appears in ASTM F963, *Consumer Safety Specification for Toy Safety*, which defines a “hazardous magnet” and a “hazardous magnet component” as one that has a flux index greater than 50 kG² mm² and that is a small object. According to the CPSC final rule (79 FR 59961), ASTM set the flux index value at 50 kG² mm² by measuring the weakest magnets in children’s toys that were suspected of causing injuries and then adding a safety factor.

Recently, it has become evident that that the problem of high-powered magnet ingestion is not limited to those magnets with a flux of 50 kG² mm² or greater, and that the scope of any safety standard should encompass magnets with a flux lower than 50 kG² mm², as well. At least two magnet ingestion cases occurring over the past month reportedly involved Speks, which have a flux lower than 50 kG² mm² and are routinely found in toy stores. It is therefore clear that the risks of these products may be higher than originally assumed. Furthermore, the ingestion of multiple lower powered magnets will, at a minimum, still require medical management and, because magnet strength may not be easily ascertained during imaging (e.g. x-ray), endoscopic or surgical removal may be needed anyway.

II. Product Marketing and Labeling

While powerful magnet sets are intended for adults (i.e., those persons 14 years of age and older), children, including teens, are exposed to high-powered magnet sets in homes, schools and other settings. And, despite warnings or labeling to the contrary, magnet sets are purchased for or shared with children under the age of 14 because of their innocuous-looking nature. Soon-to-be-published data, for example, suggests that magnet ingestions are more likely to occur in teens during the school year, for example. This difference is highly statistically significant.



Furthermore, the unique hazard resulting from the ingestion of small, high-powered magnets is unlikely to be obvious to the general public – even with improved product marketing and labeling. Therefore, it is NASPGHAN’s position that voluntary standards for the marketing, packaging, labeling, and warnings for magnet sets are inadequate when compared to the risk of injury and the severity of injuries that result from the ingestion of high-powered magnets.

The suggestion that a standard for marketing, packaging, labeling and warnings will force “bad actors” into compliance and prevent these products from landing in the hands of children fails to acknowledge that children are being harmed now, with increasing frequency, by high-powered magnet products that members of industry regard as **well labeled and already in compliance** with most of these new proposed standards.

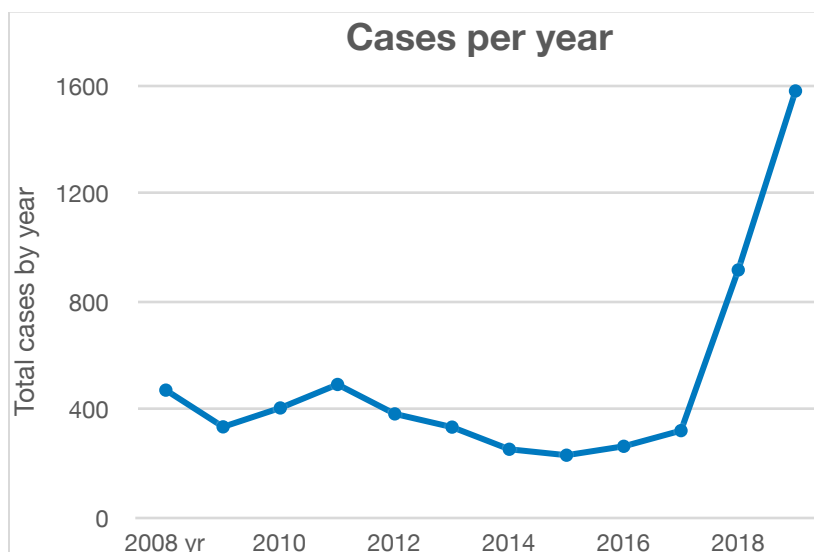
If the testimony of physicians who have witnessed the catastrophic internal damage caused by ingestion of high-powered magnets is not sufficiently compelling, then we implore members of this Subcommittee to consider a growing body of data that shows that the **only** significant reduction in ingestions from high-powered magnets occurred while the CPSC safety standard was in effect.

III. Compelling Evidence

Research shows the CPSC safety standard was working to protect children. The number of suspected magnet ingestions decreased from an estimated 3,167 cases in 2012 (before the CPSC rule) to 1,907 cases in 2015 (after the CPSC rule); this represents a 13.3 percent annual decrease in

the incidence rate over the study period.¹ Similarly, researchers studied the impact of Canada’s recall of high-powered magnets by comparing data on magnet ingestions during the two years before their recall (2011 and 2012) to the two years after their recall (2014 and 2015).² In the two early years, there were 22 multiple magnet ingestions, six operations to repair bowel, and nine endoscopic procedures. In the two years after the recall, there were five ingestions, one operation and four endoscopic procedures. “Government regulations are one of the strongest instruments in the policy toolbox to effect change,” researchers wrote. “... Our study shows that in this particular case, the policy intervention appears to have quickly mitigated the threat of multiple magnet ingestions.”

Data collected through the National Poison Data System offers a clear picture of the positive effect that the CSPC’s strong safety standard had in reducing the number of ingestion cases.



In 2017-2018, after high-powered magnets came back on the market, there was a dramatic increase in cases, with 1,580 estimated cases in 2019 (1,316 have been reported at the time of data collection).

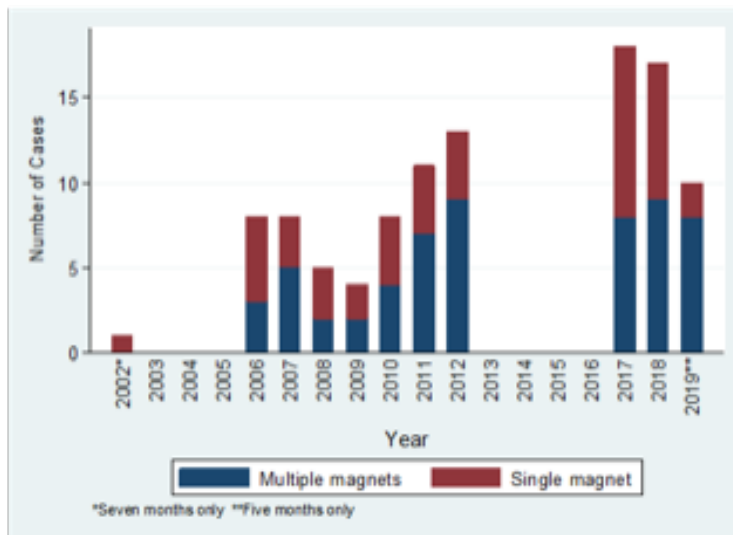
With regard to this data, we highlight a few key points:

- These are not estimates (other than 2019, as explained above) but represent actual cases of ingestion.
- There were 5,738 cases of magnet ingestions called into Poison Control Centers between 2008 to present; this includes all magnets, whether high-powered or other.
- Many cases get called to Poison Control Centers, but not all. Consequently, the number of cases is likely to be a significant under-estimate for national trends.

¹ Reeves PT, Nylund CM, et al. Trends of Magnet Ingestion in Children, an Ironic Attraction, *JPGN*: May 2018 - Volume 66 - Issue 5 - p e116–e121 doi: 10.1097/MPG.0000000000001830. https://journals.lww.com/jpgn/fulltext/2018/05000/Trends_of_Magnet_Ingestion_in_Children,_an_Ironic.9.aspx

² Rosenfield D, Strickland M, et al. After the Recall: Reexamining Multiple Magnet Ingestion at a Large Pediatric Hospital, *J Pediatr.*: 2017 Vol. 186, Pages 78–81. [https://www.jpeds.com/article/S0022-3476\(17\)30187-7/fulltext](https://www.jpeds.com/article/S0022-3476(17)30187-7/fulltext)

We were only able to get data from one institution in time for this ballot but, similarly, data from that hospital, Seattle Children's, mirrors the national trends after the CPSC safety standard was removed from the code of federal regulations.



IV. Conclusion

NASPGHAN's sole interest is the health and well-being of children. Members of the Subcommittee have not been presented with compelling evidence that the proposed standards for the marketing, packaging, labeling, and warnings of high-powered magnet sets will achieve *any* reduction in injuries, let alone the same dramatic reductions achieved by the former CPSC safety standard. Therefore, we urge the Subcommittee to protect children by enacting a standard with protections we know and has been shown to work: the requirement that individual magnets within a set contain a flux of 50 kG2 mm² or less or a size greater than 1.25 inches in diameter.