

March 28, 2022

The Honorable Alexander Hoehn-Saric, Chair
The Honorable Dana Baiocco, Commissioner
The Honorable Peter Feldman, Commissioner
The Honorable Richard Trumka, Commissioner
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, Maryland 20814

Re: “Safety Standard for Magnets Notice of Proposed Rulemaking” Docket No. CPSC–2021-0037

Dear Chair Hoehn-Saric and Commissioners Baiocco, Feldman, and Trumka:

The American Academy of Pediatrics (AAP) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) appreciate the opportunity to comment on the proposed safety standard for magnets as published on January 10, 2022 in the *Federal Register*.

The AAP is a non-profit professional organization of 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults. NASPGHAN represents more than 2,500 pediatric gastroenterologists in the United States, Canada, and Mexico, and is the only organization singularly dedicated to advocating for children with gastrointestinal disease. For more than a decade, NASPGHAN, AAP, and our physician members have advocated for a strong federal safety standard for tiny magnets that have the strength to cause serious medical injury and even death when two or more are accidentally ingested.

There is overwhelming scientific evidence and a growing body of peer-reviewed literature describing the significant hazard associated with magnets that have an attractive force, or flux index, of $50 \text{ kG}^2 \text{ mm}^2$ or greater. Our organizations welcome this opportunity to express strong support for the Consumer Product Safety Commission’s (CPSC) proposed magnet safety standard. AAP and NASPGHAN supported CPSC’s prior action to remove these dangerous products from the marketplace, and we were disappointed to see its rescission following a legal challenge. We urge the Commission to act swiftly to finalize the safety standard as proposed to protect children.

Health Risks and Medical Management of Magnet Ingestions

Most foreign body ingestions occurring in children are unintentional, and the large majority are the result of developmentally appropriate behavior. While many foreign objects pass through the gastrointestinal tract and exit the body in the stool without medical complications or interventions, the ingestion of high-powered magnets is strikingly different.

When two or more magnets are ingested, their attractive force allows the magnets to “find” each other across, or between different segments of the digestive tract, placing children at a remarkably high risk of catastrophic abdominal injury and death.

The medical consequences can include gastrointestinal perforations, abdominal abscesses, or fistulas in the bowel. Sometimes, the magnetic force of two more magnets causes the intestine to twist on itself, cutting off its blood supply and leading to bowel death.

The ingestion of multiple magnets almost always requires invasive intervention such as endoscopy and/or surgery. All require some form of emergency services, such as an emergency department visit and often multiple x-rays. In some lucky patients who swallow only a single magnet without another foreign body, the magnet eventually passes without further intervention. In all cases where there is more than one magnet, pediatric gastroenterologists and surgeons must be engaged to track the movement of magnets through the digestive tract. If the magnets fail to progress, patients require endoscopy and/or surgery to retrieve the magnets, to prevent complications, or to treat resultant injuries.

If the magnets cannot be removed endoscopically, a surgeon will first try to remove the magnets laparoscopically which requires small incisions and increases the lifetime risk of future adhesive bowel obstruction.¹ If the magnets cannot be removed laparoscopically, then open surgery is required. The challenge with managing multiple magnets that have already moved into the intestinal tract is that a physician cannot tell from an x-ray whether intestinal mucosa is trapped between two magnets, thus complicating medical management. Physicians must assume the worst-case scenario, given the devastating consequences, and intervene aggressively.

In a 2015 survey study of pediatric surgeons, of the 99 children they had treated who had ingested multiple magnets, 73 required abdominal surgery. More concerning, 17 percent of the children they had treated were found to have at least one perforation or fistula, and 34 percent of the children had multiple perforations found along their gastrointestinal tract.² The injuries that occur from magnets are serious and may have life-long consequences. Patients may need an ostomy, a surgically-placed feeding tube, or nutrition provided intravenously via a catheter tunneled from the skin to central blood vessels due to bowel resection or the cessation of function of the magnet-injured bowel.

Recent magnet ingestion outcomes data, including a retrospective cohort study recently published in the journal *Pediatrics*, examined the outcomes of 596 children who had a confirmed high-powered magnet exposure.³ This was conducted at 25 children's hospitals across the United States. The study found that most children, or 55.7 percent, required hospitalization, with four patients requiring admission to an ICU. During diagnosis and management, 81.4 percent of children received more than one x-ray, contributing to accumulating radiation exposure. A total of 276 children, or 46.3 percent, required endoscopy and/or surgery for magnet removal or treatment of complications. Nearly 10 percent of patients experienced life-threatening injuries including perforation, fistula formation, bowel obstruction, bleeding, infection, twisting of the intestine and/or bowel herniation. This study offers compelling evidence for why the proposed magnet safety standard should be finalized without delay.

¹ Barmparas G, Branco BC, Schnüriger B, Lam L, Inaba K, Demetriades D. The incidence and risk factors of post-laparotomy adhesive small bowel obstruction. *J Gastrointest Surg*. 2010 Oct;14(10):1619-28. doi: 10.1007/s11605-010-1189-8. Epub 2010 Mar 30. PMID: 20352368.

² Waters et al. Surgical management and morbidity of pediatric magnet ingestions. *J Surg Res* 2015 Nov;199(1):137-40.

³ Middelberg LK, Leonard JC, Shi J, et al. High-Powered Magnet Exposures in Children: A Multi-Center Cohort Study. *Pediatrics*. 2022;149(3):e2021054543

A Mandatory Safety Standard is Necessary to Protect Children

A federal safety standard for hazardous magnets is the most effective and powerful tool to prevent pediatric magnet ingestions. The refusal of one high-powered magnet company to comply with the CPSC effort in 2012, and its successful lawsuit against the magnet safety standard regulations, resulted in a major setback for public health efforts and led to the return of these magnets on the market. This led to a reversal of a prior downward trend when the safety standard was in place, and consequently, we saw a dramatic increase in pediatric ingestions of these dangerous objects.

Data, as presented in the proposed rule and obtained from the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System, show that the CPSC safety standard was working to protect children. There were far fewer magnet ingestions during the period of 2014 to 2016 when the initial magnet rule was announced and in effect, compared with both earlier and more recent periods. These data are supported by injury trends in the National Poison Data System,⁴ the database for American Association of Poison Control Centers, as well as independent analyses of the NEISS database.

Magnet ingestions were higher during the period of 2002 to 2011 prior to the CPSC mandatory magnet safety standard.⁵ A 2017 study showed 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.⁶

Similarly, researchers studied the impact of Canada's recall of high-powered magnets by comparing data on magnet ingestions during the two years before the country's recall (2011 and 2012) to the two years after their recall (2014 and 2015).⁷ In the two early years, there were 22 multiple magnet ingestions, six surgeries to repair bowel, and nine endoscopic procedures. In the two years after the recall, there were five ingestions, one surgery, 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 CPSC's strong safety standard had in reducing the number of ingestion cases.⁸

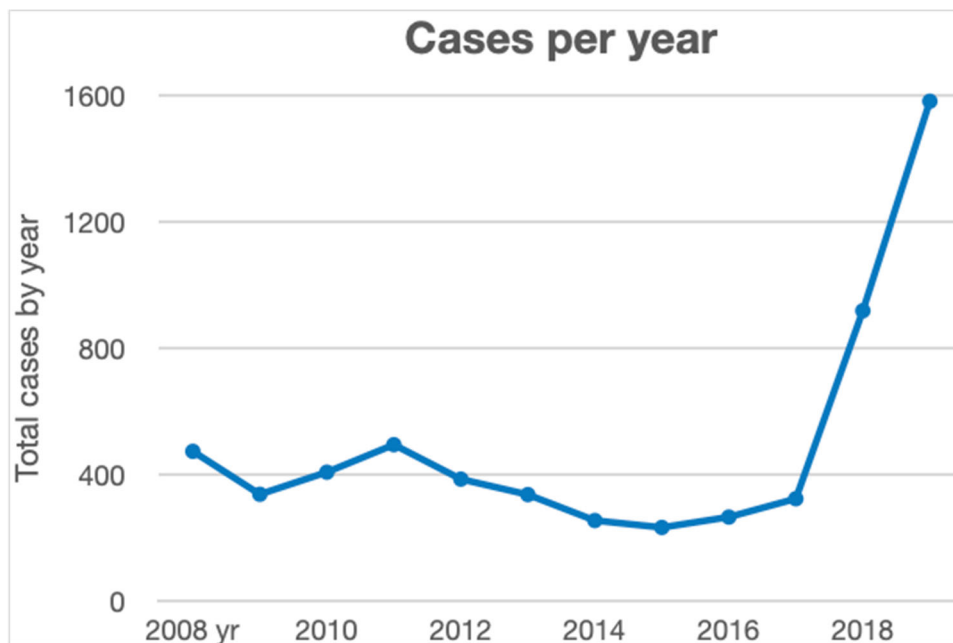
⁴ Middelberg LK, Funk AR, Hays HL, McKenzie LB, Rudolph B, Spiller HA. Magnet Injuries in Children: An Analysis of the National Poison Data System from 2008 to 2019. *The Journal of pediatrics*. 2021;232:251-256.e252.

⁵ Abbas et al. Magnet ingestions in children presenting to US emergency departments from 2002-2011. *J Pediatr Gastroenterol Nutr* 2013 Jul;57(1):18-22.

⁶ 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

⁷ 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)

⁸ Middelberg LK, Funk AR, Hays HL, McKenzie LB, Rudolph B, Spiller HA, Magnet Injuries in Children: An Analysis of the National Poison Data System From 2008-2019, *The Journal of Pediatrics* (2021), doi: <https://doi.org/10.1016/j.jpeds.2021.01.052>.



In 2017-2018, after high-powered magnets returned to the market, there was a dramatic increase in cases, with 1,580 estimated cases in 2019 (1,316 were reported at the time of data collection). We highlight a few key points from this data:

- These figures are not estimates (other than 2019, as explained above) but represent actual confirmed cases of ingestion.
- There were 5,738 cases of magnet ingestions reported to Poison Control Centers from 2008 to present; this includes all magnets, whether high-powered or other.
- When comparing 2018 to 2019 and 2012 with 2017, there was a 444 percent increase in overall magnet injuries and a 355 percent increase in hospital-treated injuries.
- Cases from 2018 and 2019 increased across all age groups and accounted for 39 percent of magnet cases since 2008.
- Although many cases are reported to local Poison Control Centers, the total number of cases is likely underestimated on a national level.

Product Labeling and Marketing

While powerful magnet sets are intended for persons 14 years of age and older, children, including teens, are exposed to high-powered magnet sets in homes, schools, and other settings. Despite warnings and clear labeling, magnet sets are purchased for or shared with children under the age of 14 because of their innocuous-looking nature. As the NEISS and poison control center data show, the vast majority of ingestions occur in children under the age of 14. These data highlight the ease with which children access high-powered magnets.

The unique hazard resulting from the ingestion of small, high-powered magnets is unlikely to be obvious to the public – even with improved product marketing and labeling. Young children are inherently curious, built to explore their environments, and due to developmentally appropriate exploratory behaviors, ingestion will remain a risk even with improvements in packaging and

labeling. Children may also be influenced by the attractiveness of some magnet set products, especially their colors, which can give them a candy-like appearance. CPSC staff's analysis shows that most incident reports involved products with clear labels and warnings to keep the product away from children. Despite these warnings, high-powered magnets are often in places where young children live and play, where they can find them and ingest them, without the knowledge of their parents. As a result, children can present with vomiting, abdominal pain, and severe illness, without parents always knowing the cause initially. This can lead to delays in diagnosis and increased morbidity from high-powered magnet ingestions in children.

It is therefore our position that voluntary standards for the marketing, packaging, labeling, and warnings for magnet sets do not adequately protect children from 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. These approaches are insufficient to address the severity of the risks these products pose. As detailed above, the growing body of data that shows the only significant reduction in ingestions from high-powered magnets occurred while the CPSC safety standard was in effect.

For nearly two years, NASPGHAN and AAP representatives participated in the discussions of the ASTM F15.77 Magnets Subcommittee. Our organizations are on record opposing the final ASTM Standard Specification for Marketing and Labeling Adult Magnet Sets Containing Loose, Powerful Magnets on the basis that:

- the standard does not address the product, namely, the size and strength of the individual magnets that comprise the sets; and
- the standard covers marketing, packaging, labeling, and warning requirements for magnet sets which have not been proven effective in reducing the hazard associated with high-powered magnets. Incidents of magnet ingestions continue to include products with warning labels, 14 and older age labels, instructions, marketing, and packaging that address the ingestion hazard.

A mandatory standard is necessary to effectively reduce the risk of injuries and death associated with magnet ingestions. Public education campaigns are important, and pediatricians can inform families about the risks of hazardous products, but that can only do so much. The most effective prevention measures are regulatory actions that can keep fundamentally dangerous products out of the marketplace.

Proposed Safety Standard

NASPGHAN and AAP strongly support the CPSC's proposed scope for this safety standard. The agency has correctly included a wide variety of consumer products in its definition of subject magnet products for this standard, including children's jewelry. The proposed rule would establish a two-part performance requirement, starting with a determination of whether a magnet is small enough to be swallowed. If the magnet is small enough to fit within the small parts cylinder, it must meet the strength requirement of a flux index less than $50 \text{ kG}^2 \text{ mm}^2$. We support this consensus flux index limit to protect children from the most dangerous products that they could ingest. We also support

ongoing prospective investigation and research into the risks of ingestion of magnets with a flux index below $50 \text{ kG}^2 \text{ mm}^2$.

CPSC set a flux index of $50 \text{ kG}^2 \text{ mm}^2$ 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 $50 \text{ kG}^2 \text{ mm}^2$ and that is a small object. According to the CPSC final rule (79 FR 59961), ASTM set the flux index value at $50 \text{ kG}^2 \text{ mm}^2$ by measuring the weakest magnets in children's toys that were suspected of causing injuries and then adding a safety factor.

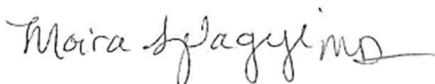
More recently, it has become evident the problem of high-powered magnet ingestion is not limited to those magnets with a flux of $50 \text{ kG}^2 \text{ mm}^2$ or greater. Products with a flux of less than $50 \text{ kG}^2 \text{ mm}^2$ are routinely found in toy stores. As noted above, it is important for the Commission to recognize the medical management of a magnet ingestion will not change through limiting the flux of these products because a physician cannot determine the flux of a magnet through visualization of an x-ray. As such, endoscopy and/or surgery may be required even for magnets that are ultimately determined to be a lower flux.

More information is needed about the characteristics of lower flux magnets. For example, what is the effect of ingestion of numerous lower flux magnets? Therefore, prospective investigation and research into the risks of ingestion of magnets with a flux index below 50 is needed. What is well understood, however, is that children are undergoing otherwise unnecessary medical procedures, all of which carry inherent risk, due to ingestion of all small magnets. These medical interventions could be avoided if the availability of small magnets is limited, thereby preventing ingestions of these dangerous products by children.

Conclusion

The AAP and NASPGHAN urge the CPSC to expeditiously finalize a comprehensive safety standard to protect children from the harms of magnet ingestions with an effective date as soon as is feasible. We are grateful that CPSC is pursuing strong action to address this hazard, and we thank you for the opportunity to provide input on this critical issue for child health and safety. We look forward to continuing to work with the Commission in protecting the health of all children. If you have any questions, please contact Lucas Allen with the AAP Washington, D.C. office at 202-347-8600 or lallen@aap.org or Camille Bonta with NASPGHAN at cbonta@summithealthconsulting.com or 202-320-3658.

Sincerely,



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