



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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BETHESDA, MARYLAND 20814

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DATE: June 3, 2020

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: John G. Mullan, General Counsel
Mary T. Boyle, Executive Director

FROM: Duane Boniface, Assistant Executive Director
Office of Hazard Identification and Reduction

SUBJECT: Informational Briefing Package Regarding Magnet Sets

Staff submits the following informational briefing package addressing a petition (Petition CP 17-1) filed by Zen Magnets, LLC (Petitioner), regarding high-powered magnet sets. The petition requested that the Commission initiate rulemaking to establish a safety standard for magnet sets to address the risk of injury when these magnets are “ingested, aspirated, or otherwise inserted into the body.” As CPSC’s petition procedures direct, staff prepared a draft briefing package, recommending to the Commission whether to grant, deny, or defer action on the petition. That draft briefing package was in final review when the Petitioner withdrew the petition on April 22, 2020.

Although the Petitioner withdrew Petition CP 17-1, staff nevertheless submits the prepared briefing package that remains formatted as a response to the petition. The Commission may consider the briefing package as an informational package and consider staff’s recommendation to continue its work on the hazards associated with magnet ingestion, and further consider pursuing rulemaking to address the hazard.

As the attached briefing package explains, available incident data suggest that there has been a statistically significant increase in magnet ingestion incidents and injuries since the Commission’s magnet sets regulation was vacated in November 2016. Based on incident data, analysis of the hazard scenarios, market information, and the serious health implications associated with ingestion of high-powered magnets, staff concludes that there is a significant risk to children and teens from ingesting high-powered magnets. Therefore, staff recommends that the Commission initiate rulemaking in this area.

With the Petition withdrawn, no vote from the Commission is called for at this time. Nevertheless, staff will seek Commission approval to continue working on the magnet ingestion hazard. In the FY 2021 Operating Plan, staff will propose pursuing data analysis and technical review (DA/TR), in anticipation of preparing a notice of proposed rulemaking (NPR) for FY

2022. Specifically, proposed FY 2021 activities will include additional research on magnet strength measurements and hazards, further efforts to obtain information about the magnets involved in incidents, and developing other information to inform a rulemaking.

As the informational briefing package demonstrates, staff disagrees that the Petitioner's proposed requirements, which focus on warning labels, instructions, packaging, and age recommendations, would effectively address the hazard. Consequently, staff proposes developing appropriate requirements during the course of rulemaking. In addition, in its FY 2021 work and subsequent rulemaking, staff would identify the appropriate scope of a standard and assess options regarding what magnet products and hazards should be covered.



United States
Consumer Product Safety Commission

Staff Briefing Package

In Response to Petition CP 17-1, Requesting
Rulemaking Regarding Magnet Sets

June 3, 2020

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Executive Summary

On August 17, 2017, the U.S. Consumer Product Safety Commission (CPSC) received a petition from Zen Magnets, LLC (Zen, or Petitioner), requesting CPSC initiate rulemaking to establish a mandatory standard under sections 7 and 9 of the Consumer Product Safety Act (CPSA: 15 U.S.C. §§ 2051-2089) to address the hazard associated with small high-powered magnets in magnet sets when “ingested, aspirated, or otherwise inserted into the human body.” The Petitioner requested several requirements that varied, depending on the age of the intended user, including size and strength limits, packaging, labels, instructions, and age recommendations. The Commission published a request for comments on the petition in the *Federal Register* on October 6, 2017 (82 FR 46740).¹

Magnet sets consist of small, high-powered magnets that typically come in sets of several hundred spheres with diameters of 2.5 to 5 millimeters; however, the shape, size, and number of magnets in the set can vary. CPSC staff identified several firms and individuals currently selling magnet sets marketed to various age groups. When ingested, high-powered magnets can attract through the gastrointestinal walls, trapping tissues, and causing serious injuries or death. Between January 1, 2009 and December 31, 2018, there were an estimated 4,500 incidents treated in U.S. hospital emergency departments. The incidents involved ingestion of magnet sets or magnets with characteristics that suggest the magnets were from magnet sets. In addition, from January 1, 2009 to December 31, 2019, CPSC received 176 reports of ingestions of magnet sets or magnets, whose description was identical to, or consistent with, magnet sets. These reported incidents resulted in 115 hospitalizations and two deaths in the U.S. The ingestions involved children from age 13 months to 16 years old, who reportedly obtained the magnets from a variety of sources, including accessing magnet sets belonging to family members, sharing among friends, at school, and unknown sources.

To date, CPSC has undertaken several enforcement actions to address this hazard, resulting in magnet set recalls by a number of firms. CPSC also enforces a mandatory standard for children’s toys that contain magnets. That standard is set forth in ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*, which is mandatory under 16 CFR part 1250. In addition, CPSC issued a mandatory standard, *Safety Standard for Magnet Sets*, 16 CFR part 1240, which was vacated in 2016. In 2019, CPSC staff began participating in the ASTM F15.77 subcommittee, which is developing a draft standard that focuses on marketing and labeling requirements for magnet sets intended for users 14 years and older.

In considering the hazards associated with ingesting high-powered magnets from magnet sets, staff assessed the requirements the Petitioner proposed to address this hazard. Incident data, current market information, and other relevant factors indicate that high-powered magnet sets continue to present a hazard to children and teens. Therefore, staff recommends that the Commission grant the petition and direct staff to begin a rulemaking project to address the hazard associated with high-powered magnet sets. Granting the petition does not require the Commission to issue a rule in the specific form requested by the petition.

¹ Consumer Product Safety Commission, Proposed Rule, Petition Requesting Rulemaking on Magnet Sets
FR Document:2017-21534Citation:82 FR 46740 Pages 46740-46741
<https://www.federalregister.gov/agencies/consumer-product-safety-commission>



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Briefing Memorandum

TO: The Commission
Alberta E. Mills, Secretary

THROUGH: John G. Mullan, General Counsel
Mary T. Boyle, Executive Director

FROM: Duane Boniface, Assistant Executive Director
Office of Hazard Identification and Reduction
Susan Bathalon, Project Manager
Risk Management Group
Office of Hazard Identification and Reduction

SUBJECT: Petition CP 17-1, Requesting Rulemaking Regarding Magnet Sets

I. Introduction

On August 17, 2017, Zen filed a petition with the CPSC requesting that the Commission initiate rulemaking to establish mandatory standards for high-powered magnet sets. The petition states that high-powered magnet sets present an internal injury risk to children if the high powered magnets are “ingested, aspirated, or otherwise inserted into the ... body.” The petition requested rulemaking under CPSA sections 7 and 9 (15 U.S.C. 2056 and 2058). The Commission published a *Federal Register* notice on October 6, 2017, which requested public comments on the petition (82 FR 46740).

CPSC staff’s briefing package to the Commission addresses information in the petition, reviews public comments received in response to the *Federal Register* notice, and discusses possible options and staff’s recommendation to grant the petition.

II. Background

A. The Petition

The petition requests alternative approaches to address magnet sets, based on whether the product is designed, marketed, manufactured, or intended to be used by children under 14 years of age or consumers age 14 years or older (which the Petitioner refers to as “general purpose” magnet sets).² The Petition proposes to subject magnet sets intended for children under age 14 to

² The Office of the General Counsel (OGC) did not docket several additional requirements the Petitioner requested because OGC concluded that they are not within the Commission’s authority. The Petitioner requested that the

a two-part standard to address the known internal injury hazards from ingesting strong, small magnets in magnet sets. Under this two-part requirement, magnet sets would need to satisfy one of the following:

- Each of the magnets must be too large to fit within the small parts cylinder (described in 16 CFR § 1501.4), or
- Each magnet must have a flux index (a calculated value of magnetic flux density and size) of 50 kG²mm² or less.³

The Petition proposes that “general purpose” magnet sets that are intended to be used by a consumer 14 years old or older should be required to have certain labeling, instructions, and packaging to prevent children from accessing the product. These recommended requirements include packaging that assists users in determining whether all of the magnets are returned to the package after use, child-resistant packaging that is difficult for children to open, on-product warnings, including age recommendations, and instructions about how to use the magnet set, and information on how to return it to the packaging after use.

B. The Product

Magnet sets generally consist of numerous identical small, powerful magnets. These magnets are made of magnetized alloys of neodymium, iron, and boron (commonly called NIB magnets), or other rare earth metals, and they are thinly coated to create a shiny appearance and prevent corrosion. Typically, magnet sets are sold in groups of 216 individual, identical magnets, most commonly sphere-shaped with 5 millimeter (mm) diameter, as shown in Figure 1. Magnet sets vary in magnet size from 2.5 mm possibly up to 15-25 mm. The magnets may be a set of cylinders, cubes, or spheres. Sets also are available with varied numbers of magnets, from a few replacement magnets to more than 1,000; and in magnet flux index strength, from less than to much greater than 50 kG²mm². Some magnet sets are marketed for use by children, and others are marketed for use by adults for a variety of purposes, including puzzles, desk toys, sculpturing uses, stress reducers, or for visualizing micro-structures or for similar purposes.

Commission require buyers to acknowledge reading warnings and consent to the risk of injury before purchasing magnet sets. The Petitioner also requested that the Commission adopt a requirement that only adults “of the age of majority” may purchase magnet sets that do not meet size and strength limits. Under the CPSA, the Commission may issue performance requirements and requirements for warnings and instructions, or may ban a product when no feasible standard would adequately protect the public from the unreasonable risk of injury associated with the product. OGC concluded that these proposed requirements did not fall within these authorities, so OGC did not docket these requests.

³ In several instances within the petition, the Petitioner describes the requested magnetic flux index value as less than (<) 50 kG²mm² and equal to or less than (≤) 50 kG²mm². For this briefing package, staff assumes that the petitioner’s request for the product intended for users younger than 14 years old to have a flux index less than 50 kG²mm² because that aligns with ASTM F963, *Standard Consumer Safety Specification for Toy Safety*.



Figure 1: Typical Magnet Set

The Petitioner does not define “magnet sets.” However, the Petitioner describes common characteristics and uses of the product, as well as features Zen’s magnet set products. The Petition describes magnet sets as small, rare earth magnets that have a variety of artistic, educational, and therapeutic uses, including making sculptures; as educational tools for math, science, and engineering; and for physical sciences research. The Petition states that magnet sets vary in shape, size, and flux index. Zen states that its magnet sets consist of shiny, metallic, spherical magnets that are about 5 mm in diameter and have a flux index of between 400 and 500 kG²mm.²

For this briefing package, staff generally considered magnet sets to consist of numerous identical, small, powerful magnets. Magnet sets vary in the number of magnets, and the size, shape, and strength of magnets. If the Commission grants the Petition, staff will develop an appropriate definition of “magnet sets.”⁴

⁴ The Commission’s previous rule on adult magnet sets (which was vacated, see *CPSC Activities Regarding Magnet Sets*, below) and the draft ASTM standard for adult magnet sets (see *Human Factors Discussion of Incident Data and Behavioral Considerations*, below) include definitions that could be useful in developing a rule. In the vacated rule, the Commission defined “magnet sets” as “any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.” Factors for determining the intended use of the product included the manufacturer’s stated intent, marketing, packaging, displays, and uses commonly recognized by consumers. 79 Fed. Reg. 59962 (Oct. 3, 2014). The draft ASTM standard defines “magnet sets” as an “aggregation of separable magnetic objects that are marketed or commonly used as a manipulative or construction item for puzzle working, sculpture building, mental stimulation, education, or stress relief.”

C. CPSC Activities Regarding Magnet Sets

Rulemaking

The memorandum from the Office of Compliance and Field Operations (Tab G) discusses rulemaking activities. The Commission published a final rule for magnet sets (16 CFR part 1240) on October 3, 2014, which took effect on April 1, 2015 (79 FR 59962). The final rule addressed the hazards associated with magnet set ingestions. This rule applied to magnet sets that were marketed or used for entertainment or stress relief, as well as individual magnets sold for use as part of magnet sets. The rule aimed to mitigate internal injuries from ingesting magnets by requiring that if a magnet from a magnet set fit inside the small parts cylinder, then each magnet in the set must have a flux index of 50 kG²mm² or less. On November 22, 2016, the U.S. Court of Appeals for the Tenth Circuit vacated and remanded the rule.⁵

Compliance Actions

The memorandum from the Office of Compliance and Field Operations (Tab G) also discusses several of CPSC's enforcement actions and recalls, to date, that address the hazards associated with magnet sets. Specifically, the compliance actions include recalls as well as enforcement of the mandatory magnet sets standard in 16 CFR part 1240 during the time it was in effect, and enforcement of the magnet requirements in ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*.

Information and Education Campaigns

The memorandum from the Division of Human Factors memorandum (Tab D) discusses magnet safety public campaign efforts. Since 2007, CPSC has drawn attention to the magnet set ingestion hazard through safety alerts and public safety bulletins. These educational campaigns, as well as those by other organizations, have attempted to raise consumer awareness about the ingestion hazard associated with magnet sets. Despite these educational campaigns, incident reports indicate that some caregivers are unaware of or misunderstand the nature and likelihood of the serious ingestion hazard.

D. Factors Relevant to the Commission's Decision on a Petition

The Commission's petition regulations set forth the factors that the Commission must consider when deciding whether to grant or deny a petition (16 CFR § 1051.9). These factors are whether: (1) the product presents an unreasonable risk of injury; (2) a rule is reasonably necessary to eliminate or reduce the risk of injury; and (3) not proceeding with a rulemaking would unreasonably expose consumers to the risk of injury the petition describes.

Staff considered these factors in reviewing and assessing the petition, and in developing the recommendation in this briefing package.

The regulation also states that, in considering these factors, the Commission is to evaluate the relative priority of the risk of injury associated with the product and the agency's resources available for rulemaking to address the hazard presented by ingestion of magnets in magnet sets.

⁵ Zen Magnets, LLC v. Consumer Product Safety Commission, 841 F.3d 1141 (10th Cir. 2016).

III. Discussion

A. Epidemiology Review of Injuries from Magnet Ingestions (Tab B)

CPSC's Division of Hazard Analysis staff evaluated emergency department-treated injury cases in the National Electronic Injury Surveillance System (NEISS) and incidents reported in the Consumer Product Safety Risk Management System (CPSRMS) involving magnet ingestions. For many incidents in these databases, particularly in NEISS, there was not sufficient detail about the product to determine whether the magnet came from a magnet set. Depending on the final scope of any proposed rulemaking, this uncertainty could be resolved in a number of ways, for example, defining the scope to include high powered magnet products that can be ingested. For this petition briefing package, staff identified any case that mentioned magnets and then excluded: (1) cases that did not involve ingestion, and (2) cases that reportedly involved unrelated products, such as a children's tile-building set with embedded magnets, or jewelry product. After removing unrelated product and non-ingestion incidents, staff sorted the remaining NEISS and CPSRMS data into categories based on the available narratives. Staff notes that criteria used to group incidents differ somewhat for the NEISS and CPSRMS data because the CPSRMS data often provided more narrative about the incident, more details about the product and victim, and in multiple cases, we obtained additional information from an In-Depth Investigation conducted by CPSC field staff.

NEISS incidents

Staff estimates that between January 1, 2009 and December 31, 2018, there were an estimated 18,600 magnet related ingestion cases treated in U.S. hospital emergency departments. Of those, a minimum of 4,500 involved magnet sets that fell into either the "yes" category (meaning cases that definitively identified a magnet set) or the "possible" category (meaning incidents with descriptions that indicated that the magnets met at least some criteria consistent with magnet sets). Of the estimated 4,500 "yes" and "possible" cases, an estimated 1,700 involved children younger than 5 years old; an estimated 1,400 involved children between 5 and 9 years old; and the remainder involved children 10 years of age or older.

It should be noted that the 4,500 magnet set total reflects a narrow definition and likely undercounts the magnet set ingestion cases as some portion of the additional estimated 14,000 magnet ingestion cases during this period likely also involved magnet sets. The NEISS narratives, however, did not generally provide enough details to conclusively include those incidents in the "yes" or "possible" categories as defined above, and staff, accordingly, excluded those incidents from those categories. Even using this strict categorization, however, it can observe that, overall, there are statistically significant changes in overall magnet ingestions during the 10 years from 2009 through 2018, which do not appear to reflect random variation.

Staff cannot estimate the number of "yes" and "possible" emergency-department treated magnet set ingestions for individual years because the data are insufficient to report annual statistical estimates. However, by dividing 2009 to 2018 NEISS data into five separate, 2-year periods, some statistical information is available when consolidating the "yes" and "possible" incidents involving ingestions of magnets from magnet sets. Analysis of the combined magnet ingestion

injuries indicates there were significantly fewer ingestions in 2015, compared with the earlier year 2012, or the more recent year 2018. In addition, the two most recent years, 2017 and 2018, each shows significant increases, compared with the year 2016. These trends suggest two noteworthy points. First, they suggest that a mandatory standard may reduce magnet ingestions, given there were significantly fewer ingestion incidents during the time when CPSC's mandatory standard for magnet sets was in effect from April 2015 to November 2016, compared to some other years. Second, the trends indicate that magnet ingestions have significantly increased in recent years, suggesting a resurgence of the hazard, and supporting the need for a mandatory standard.

CPSRMS Incidents

CPSRMS offers more descriptive information than NEISS and thus may include more detailed information about the product, victim, and incident scenario. Rather than statistical estimates, this additional information can provide useful anecdotal information and greater details about magnet ingestion incidents. From this data set, staff identified 176 reports of ingestions occurring during the period January 1, 2009 through December 31, 2019. The more detailed information derived from these incidents allowed staff to categorize the incidents using a different sorting system than they used for the NEISS data and characterizing the incidents as “yes,” “highly similar,” or “potentially” involving magnet sets.

The majority, or approximately 56 percent of these CPSRMS reports are categorized as “yes,” meaning the product is identified as a magnet set with a high degree of certainty because these reports specifically identified the brand or packaging of the magnet set. CPSRMS reports that provided pictures or details that appear similar or identical to high-powered magnet sets in performance, quantity, size, color, and shape, but did not specifically include a brand name or identifying packaging, are categorized as “highly similar” to a magnet set product. These reports constituted approximately 31 percent of the 176 reports. A relatively smaller percentage of the reports, approximately 14 percent, involved products that “potentially” were magnet sets. These reports provided product descriptions consistent with characteristics of magnet sets, but contained less specific detail compared to products included in the “yes” or “highly similar” previous CPSRMS categories.

Most of the CPSRMS reports identify how many magnets were ingested, which ranged from 1 to 93 magnets. For cases in which the age of the victim was reported, 57 were younger than 5 years old; 59 were between 5 and 9 years old; and 49 were 10 years and older. Across all age groups, children typically were playing with the magnets in their mouths just prior to ingestion. For ages 10 years and older, the magnets were being used to emulate piercings at the time of the incident. For incidents where the source of the magnet (*i.e.*, how the victim obtained the magnet) was known, in most cases, children obtained the magnets at school, from a friend or classmate, or from a relative. The 176 reported incidents involved 2 deaths and 115 hospitalizations in the U.S.

B. Health Sciences Review of Injury Outcomes of Magnet Ingestions (Tab C)

The Directorate for Health Sciences memorandum (Tab C) summarizes injury mechanisms related to magnet ingestions, in addition to describing the severity of injuries from ingestion of

two or more high-powered magnets. The memorandum discusses four deaths caused by ingestion of spherical magnets (two U.S. deaths and two overseas deaths) and two recently reported serious nonfatal incidents involving ingestion of very small spheres (2.5 mm diameter) from magnet set products.

Staff believes that the majority of magnet ingestion injuries involve unique and harmful compression injuries from strong magnets. When ingested, strong magnets, whether close or at some distance from one another, are mutually attracted through intestinal walls, with the interaction occurring rapidly and forcibly. The magnets remain coupled, regardless of passage of fluids or semi-solid gut contents, and muscular contractions that are functions of the small and large intestines. The sustained pressure exerted on the tissues trapped between the magnets causes these areas to die. Perforations can result, which present a serious risk of leakage of gut contents into the abdominal cavity. Within hours, an escalation can occur from the area of local infection, to infections of the abdominal cavity and its organs, and life-threatening systemic infection. Interacting magnets can also cause segments of the intestines to become twisted, resulting in intestinal blockage that deprives the twisted gut segment of blood. This is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped gut segment from dying, and thereafter, rupturing and contaminating the abdominal cavity. Delayed recognition and relief of these injuries can be fatal. All four of the children's deaths reportedly involved ingestion of multiple spherical magnets. Staff has limited information about one of the overseas deaths. However, three of the deaths (two U.S. fatalities and one overseas fatality) are known to have been caused by ingestion of spherical magnets that trapped and twisted their intestines, resulting in fatal bowel obstruction.

Staff regularly reviews ingestion incidents regarding magnet set products, with particular attention to the size, shape, and strength of the individual magnets. Typically, but not exclusively, magnet sets involved in ingestion injuries reported to CPSC and documented in medical literature are manufactured from NIB composite, which, on a size-for-size basis, is considered the most powerful common magnet material. Recent incident reports indicate that even the smaller sized magnets of 2.5 mm or 3 mm spheres or cubes have the magnetic strength to trap tissue and cause serious injuries. Staff is aware that some of these smaller products are advertised as having low flux index levels of less than 50 kG² mm.²

HS staff describes six separate health outcome categories related to ingestion of NIB magnets from magnet set products, and medical intervention procedures to remove the magnets and repair any injured tissues. In addition to removal by colonoscopy and endoscopy procedures, numerous cases required intestinal surgery involving laparoscopic or more invasive laparotomy techniques. The health outcome categories consider the number of magnets ingested and the length of time that the trapped tissue is compressed between the magnets before being removed. Life-threatening internal injuries with serious lasting complications and death can occur after the ingestion of powerful magnets, particularly if there is a delay in receiving appropriate medical intervention, and especially if the caregiver or treating physician is unaware that magnets have been ingested, or does not recognize that magnet ingestion can present a potentially lethal hazard.

The medical community, particularly the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), has sought to call attention to medical magnet ingestion cases to heighten awareness, explain proper treatment, and highlight

the danger for children.⁶ This authoritative medical professional society recommends urgent management of magnet ingestions through endoscopic removal within 24 hours or less if the objects are in an accessible location.⁷

C. Human Factors Discussion of Incident Data and Behavioral Considerations (Tab D)

The Division of Human Factors memorandum (Tab D) analyzes the CPSRMS incident data; examines product marketing and consumer reviews; discusses the potential effectiveness of the labeling, instruction, packaging, and age recommendation requirements that were recommended in the petition; addresses public comments on the petition; and discusses the draft ASTM standard for adult magnet sets. The information in the Human Factors memorandum supports the need for a mandatory standard for general purpose magnet sets and provides analysis of several proposals. To summarize the Human Factor's analysis, the incident data indicate that children of nearly all ages ingest magnet sets, including young children, who access the magnets without parental knowledge, and older children, who are capable of understanding the hazard. In addition, some products currently on the market include warnings and age recommendations, but children still access these magnets and ingest them. This suggests that a mandatory standard with performance requirements for these magnets is necessary, and that age recommendations, warnings, and packaging are insufficient to address the hazard. The following discussion provides additional information on these points.

Incident data. The Human Factors memorandum identifies several distinct use patterns evident in the CPSRMS data for different age groupings. Of the 176 CPSRMS-reported incidents, the age of the child who ingested the magnet was identified in 165 incidents. The incident data include victims who are age 13 months to 16 years old. The majority of the incidents with victims of a known age involved victims ages 8 years or older (~52%), whom caregivers would expect to understand warnings and not ingest inedible objects, such as magnets from magnet sets. Magnet ingestions by victims in this age grouping typically occurred unintentionally while the victim experimented with the magnets by mimicking piercings or playing, including orally exploring the magnetic properties.

The most commonly cited age is 2 years (~15% of victims with known ages). Two-year-olds are mobile in exploring their environment, unlikely to be under constant supervision (especially in a home setting), and frequently place non-food items in their mouths. For many of the incidents involving children 7 years old and younger, the use patterns cannot be determined because, frequently, the young child handling the magnet set was not observed by caregivers, was unable or unwilling to explain why they ingested the magnets, or both. Where use patterns were reported, children typically were mouthing the magnets or playing with the magnets when they

⁶ Transcript of U.S. Consumer Product Safety Commission Public Hearing on Safety Standard for Magnet Sets Notice of Proposed Rulemaking, Tuesday, October 22, 2013, Presentation by Dr. Mari Oliva-Hemker, page 75. <https://www.regulations.gov/document?D=CPSC-2012-0050-2597>

⁷ Intragastric Fistula After Multiple Sphere Magnet Ingestion, Sana Merchant, Gustavo Stringel, and Richard A. Rosencrantz, *Clinical Gastroenterology and Hepatology* 2017;15:e105–e106
Kramer R.E., Lerner, D.G., et al., Management of ingested foreign bodies in children: a clinical report of the NASPGHAN endoscopy committee. *JPGN* (2015) 60:562-574)

unintentionally or intentionally ate the magnets. This is consistent with expected behaviors and development of younger children.

Many of the incident reports describe how the victims obtained access to the magnets. The incident data show that children under 8 years primarily gained access to magnets of family members at home. The reports contain a number of explanations for the incidents, including: the child accessed magnets that were liberated from magnet sets and lost or left out in the household; the caregiver allowed the child access to the product, unaware of the hazard, and presuming ingestion would not occur, or both. Many of these cases demonstrate children receiving magnets without the caregiver knowing. Caregivers are especially unlikely to be able to manage access to magnets from magnet sets by victims ages 8 years and older, who typically obtain magnets from friends and classmates.

Marketing and Consumer Reviews. Human Factors staff also examined the advertising and marketing materials of online magnet set retailers from 2018 and 2019, to determine the associated labeling, packaging, warnings, and age groups to which these products are marketed. For many of the magnet sets, staff collected and examined exemplar product, including magnet sets samples from international and domestic online marketplaces. Staff found that the domestic and international labeling and safety information concerning the ingestion hazard and intended user population varied tremendously for seemingly identical products. International online marketplaces were less likely to have relevant warnings, and were more likely to advertise the product directly to children ages 8 years and older. The majority of the domestic online sellers provided magnet ingestion warnings similar to the warning proposed by the Petitioner, as well as age labels for 14 years and older, warnings to keep the product away from children, or both. Regardless of such warnings, staff found that it was common for consumer reviews to mention use of the product by children.

Draft ASTM Standard. The ASTM F15.77 subcommittee has been developing a draft voluntary standard, titled: *Specification for Marketing and Labeling Adult Magnet Sets Containing Small Loose, Powerful Magnets with a Flux Index $50 \text{ kG}^2\text{mm}^2$ WK68963*. The draft standard would apply to magnet sets with a flux index greater than or equal to $50 \text{ kG}^2\text{mm}^2$ and includes requirements that are similar to those requested by the Petitioner for “general purpose” magnet sets intended for ages 14 years and older. CPSC staff has participated in developing the draft standard since March 2019. Currently, the draft standard does not include performance requirements for size (to prevent ingestion), or strength (to mitigate the entrapment of intestinal tissue). Rather, it focuses on persuading consumers to avoid the hazard. Staff submitted information and two letters⁸ to the subcommittee regarding the inadequacy of the draft requirements. Staff continues to encourage the subcommittee to consider performance requirements that directly mitigate the ingestion hazard. Additionally, in subcommittee meetings, staff requested that the subcommittee investigate the suitability of the magnet testing methodology and flux index limit.

⁸ Tab D, Appendix A and B: Human Factors Assessment of the Petitioner’s Proposal and Response to Public Comments. Division of Human Factors, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission.

D. Economic Market and Injury Cost Considerations of Magnet Sets (Tab E)

In Tab E, staff from the Directorate for Economic Analysis discusses current market information on high-powered magnet set products, including the types of products on the market (material, size, and strength), domestic and import retail firms, available methods for consumers to purchase the product, and injury costs.

Products on the Market. Magnet sets currently offered for sale are comprised of spheres or cubes in a range of dimensions and numbers of individual magnets. Magnet sets staff identified mainly consist of 216 magnetic spheres, with diameters of 5 mm. Retail prices average under \$20 per set. A late 2018 market review had similar findings. Magnet sets comprised of spheres or cubes with smaller dimensions (2.5 mm to 3 mm) are also marketed, typically at lower prices. At least some of these smaller magnets claim to comply with ASTM, EN71 and CPSIA requirements or are advertised as having flux indices of less than 50 kG²mm².

Staff also reviewed products currently on the market to assess their compliance with the Petitioner's suggested packaging requirements and age restrictions for magnet sets intended for individuals 14 years of age and older. Staff found that for online sales, when stated or displayed, current packaging generally does not appear to offer much resistance to being opened by young children. Packaging commonly consists of metal cans or plastic cubes, with easily removable tops. Staff in CPSC's Engineering Sciences Division of Human Factors and Office of Compliance jointly conducted a comprehensive review of magnet set labeling, warnings, and packaging. That review found that suggested age limits are commonly stated on online product offerings, but many products have no suggested age limits.

Estimated Sales and Market. The number of magnet set products sold to U.S. consumers from 2009 through mid-2012 is estimated at 2.7 million sets, or an average of about 800,000 annually. Sales diminished from mid-2012 to April 2015 (when the mandatory standard took effect), which coincides with the Compliance activities of negotiated stop-sale agreements and recalls. Although staff believes the current rate of consumer purchasing of magnet sets is lower than during the 2009 to mid-2012 period, current sales are unknown.

At this time, it appears that nearly all of the current marketers (firms or individuals) sell their magnet sets through Internet sites, rather than through "brick-and-mortar" retailers. Some of the importers operate their own Internet retail sites, but the majority of sellers, in terms of distinct firms or individuals, appear to sell on the sites of Internet retailers and marketplaces, namely Amazon and eBay. Staff's recent review found 16 current Amazon sellers and 18 sellers on eBay. Most of the Amazon sellers appear to be in China; 4 of these Amazon sellers (25%) have orders fulfilled by Amazon. Of the 18 eBay sellers, 13 (87%) are located in the United States. In addition to Internet retailers in the United States, U.S. consumers can purchase a variety of magnet sets from online retailers in China. Magnet sets purchased from foreign Internet retailers may be shipped to U.S. consumers directly from China or from warehouse facilities located domestically.

Societal Costs of Injuries. The Directorate for Economic Analysis memorandum also discusses preliminary estimates of injuries and societal costs associated with magnet set ingestions. Staff used the CPSC's Injury Cost Model (ICM), which is fully integrated with NEISS, to estimate the societal costs of magnet ingestion injuries initially treated in U.S. hospital emergency

departments. The ICM also enabled the staff to estimate the number and societal costs of magnet ingestion injuries treated outside of hospital emergency departments.

In 2017 to 2018, there were 61 NEISS-reported hospital emergency room ingestion cases categorized as either involving (8 reported cases) or possibly involving (53 reported cases) the subject magnet sets. The annual 2017 to 2018 estimates of the injuries and the societal costs associated with injuries involving, or possibly involving magnet set ingestions totaled 962 medically treated injuries and \$78.2 million in societal costs. These estimated annual injuries, and the societal costs associated with the injuries, include injuries medically treated in various settings, including physician's offices, clinics, and other non-hospital settings, as well those initially treated in hospital emergency departments. Estimated medically treated injuries and their societal costs for the years 2017 to 2018 averaged approximately 72 percent greater than for the years 2015 to 2016 when the magnet set mandatory rule was in effect.

E. Existing Standards on Magnet Sets (Tab F)

The Petition requests distinct requirements for magnet sets, depending on whether the intended user is under 14 years old, or age 14 and older. Staff identified three standards that address magnet sets intended for users under 14 years old. Currently, there is a draft ASTM standard for magnet sets intended for users age 14 years and older, which is not a published voluntary standard (see Human Factors discussion, above, regarding the draft ASTM standard).

For products designed, marketed, or manufactured for children under 14 years of age, the Petitioner recommends a standard requiring that when a magnet in a magnet set fits completely within the small parts cylinder (as determined by 16 CFR §1501.4), the magnet must have a flux index of 50 kG²mm² or less.

In 2009, ASTM F963 became the mandatory CPSC Toy Safety Standard (Toy Standard) under section 106 of the Consumer Product Safety Improvement Act (CPSIA). ASTM F963 applies to toys intended for use by children under 14 years old. The current version of the toy standard is ASTM F963-17⁹, which the Commission incorporated by reference (with modifications unrelated to magnet sets) into 16 CFR part 1250 on November 28, 2017 (82 FR 57119).

ASTM F963-17 requires that toys, as-received, must not contain a loose hazardous magnet or magnetic component and shall not liberate a hazardous magnet or magnetic component after specified use and abuse testing. ASTM F963-17 defines a "hazardous magnet" and a "hazardous magnetic component" (*i.e.*, a toy piece that contains an embedded hazardous magnet) as one that is a small object (as determined by the small parts cylinder described in the standard) and has a flux index greater than or equal to 50 kG²mm².² Staff notes that this mandatory standard is the same as the requirements requested by the Petitioner. As such, this portion of the Petitioner's requested rulemaking is, in fact, already required under the Commission's regulation in 16 CFR part 1250. However, the standard has an exception specifically for magnetic/electrical experimental sets intended for children 8 years of age and over that contain loose as-received

⁹ ASTM F963-17 applies to toys intended for use by children under 14 years of age (sections 1.3 and 3.1.91). It also states that different age limits for various requirements are provided in the standard (section 1.3) and states that the requirements for magnets are "intended to address ingestion hazards associated with toys intended for children up to 14 years of age" (section 4.38).

hazardous magnets or loose as-received hazardous magnetic components, provided they comply with requirements for safety labeling described in the standard.¹⁰

ASTM F963-17 considers toys with magnets with flux indexes less than 50 kG²mm² to be below the hazardous threshold for ingestion injuries. Toys with magnets containing a flux index less than 50 kG²mm² are not subject to safety requirements in ASTM F963-17.

Staff identified two additional standards that apply to magnet sets intended for children under 14 years old. EN 71-1:2014, *Safety of Toys*, a European standard, and ISO 8124-1:2018, *Safety of Toys*, which is an international standard, apply to toys, meaning any product or material designed or clearly intended for use in play by children under 14 years of age. The requirements for toys containing magnets in these standards are essentially the same as those found in ASTM F963.

F. Compliance Actions on Magnet Sets (Tab G)

CPSC has pursued several types of compliance actions regarding magnet sets. CPSC has worked with firms and pursued legal action to recall magnet sets under section 15 of the CPSA (15 U.S.C. 2064). While CPSC's mandatory safety standard for magnet sets was in effect between April 1, 2015 and November 22, 2016, CPSC issued notices of noncompliance to firms distributing magnet sets that did not comply with the standard. CPSC issues notices of violation to firms distributing magnet sets that are marketed for children under 14 years old that do not comply with ASTM F963 (and 16 CFR part 1250).

IV. Public Comments Regarding the Petition

On October 6, 2017, the Commission published a *Federal Register* notice describing the petition and requesting public comments (82 FR 46740). CPSC received 21¹¹ comments. One commenter requested that only labeling of the product be required; other commenters expressed support for the requirements in the vacated CPSC rule for magnet sets; and some also suggested that staff research whether the flux index limit in the vacated rule is adequate to prevent all small sized magnets in a magnet set from causing GI tract injuries. Other commenters suggested that the Commission adopt a complete ban of magnet sets. The commenters requesting the more significant regulations suggested that removing the product from the market place or imposing requirements through regulation is more comprehensive and effective than stopping sales and similar actions, arguing that the standard would remove all hazardous magnet sets from the

¹⁰ "Magnetic/electrical experimental sets" are defined as "toy[s] containing one or more magnets intended for carrying out educational experiments involving both magnetism and electricity." The standard states: "The packaging and instructions of magnetic/experimental sets shall carry safety labeling. The labeling shall consist of the safety alert symbol followed by the signal word "WARNING" and contain, at a minimum, the following text or equivalent text which clearly conveys the same hazard alerting message: *'This product contains (a) small magnet(s). Swallowed magnets can stick together across intestines causing serious infections and death. Seek immediate medical attention if magnet(s) are swallowed or inhaled.'*"

¹¹ Several comments were outside the scope of the petition because they did not address magnet sets. Some of these comments referenced rare-earth magnets or neodymium magnets, but discussed them in applications other than magnets sets (e.g., wind turbines, electric cars, and general economic, health, environmental, and humanitarian issues). These comments are not addressed in this briefing package.

market place. Nearly all the comments concurred with Petitioner in the serious nature of the injuries and proposed regulations to address the magnet set ingestion risk; some comments provided alternative recommendations to mitigate the ingestion hazard. Staff presents several significant comments below.

Comments Concerning Size and Strength Requirements for Magnet Sets

CPSC received comments regarding the strength of magnet sets and the flux index method recommended in the petition. To briefly summarize, the Directorate for Health Sciences memorandum (Tab C) addresses comments concerning the relationship between flux index and injury. Commenters suggest examining what strength limits are appropriate to adequately reduce the risk of injury from magnet set ingestions, and staff concurs that the hazardous value of ingested magnet should be studied. Staff believes that rare earth magnets with a flux index below $50 \text{ kG}^2\text{mm}^2$ may have the potential to cause injury, depending on their size, shape, and material grade. In the last 2 years, CPSC has reviewed at least two reports of children ingesting 2.5 mm NIB spheres from a magnet set advertised as having a flux index value less than $50 \text{ kG}^2\text{mm}^2$; both victims required medical intervention to remove the magnets.

CPSC also received comments about whether size and strength restrictions should apply to all magnet sets or only to those intended for users under 14 years old. The Division of Human Factors memorandum (Tab D) addresses these comments. To summarize, magnet sets present a hazard to children and teens, regardless of the intended user age. Incident data indicate that children often obtain ingested magnets intended for adults and without an adult's knowledge, and older teens also ingest magnets.

Comments Concerning Packaging and Safety Information in Instructions and Labels, and Age Restrictions for Magnet Sets

CPSC received comments regarding the use of packaging and instructions and labels to address the hazard associated with magnet sets. The Division of Human Factors memorandum (Tab D) addresses these comments. Staff does not believe repackaging, labeling and instructional information is a dependable method of protection for children, for numerous reasons.

Consumers may forego reading labels and instruction information for the product due to familiarity with magnets and the simplicity of using them. Even if consumers do notice and read the safety information, many factors, such as past incident-free experience with the product or similar products, can discredit the safety information. When magnets are acquired individually, such as those found outdoors or received from friends, children are unlikely to see any precautionary information. Even if children do have access to such information, staff believes it is likely to be ineffective, especially in young children who lack the cognitive ability to appraise the nature of the hazard.

CPSC received comments concerning packaging that aids users in verifying that all magnets in a magnet set are returned to a storage container after use and childproof packaging. Staff believes that packaging requirements would only be effective if the product is correctly repackaged in its entirety after every use, which is unlikely for numerous reasons, including the need to

disassemble intricate sculptures, the difficulty of keeping track of individual magnets in the set, and the difficulty in reforming the magnets to fit entirely in the packaging. Child-resistant packaging would not offer protection for children 5 years and older, and it could increase the cost of compliance if it adds to the time and effort to use and repackage the product.

CPSC also received comments regarding age recommendations for magnet sets. To summarize, staff believes that age labels can help some consumers; however, labeling is not thought to be sufficient to address the hazard, for the reasons discussed above. Many of the magnets involved in incidents were labeled for older ages than the children involved in the incidents.

Comment Regarding the Use of Product Liability Actions

CPSC received a comment stating that, as an alternative to rulemaking, CPSC could rely on private product liability actions to address hazardous magnets on the free market. The commenter states that CPSC could facilitate this alternative by extending statute of limitations periods and removing caps on damages.

Under the CPSA, the Commission has authority to adopt consumer product safety standards in the form of performance standards, warnings, and instructions or to declare a product to be a banned hazardous substance. The Commission does not have authority over statutes of limitations, damage caps, or other private product liability actions.

Comments Requesting Compliance Enforcement of Magnets Requirements in the Toy Standard

CPSC received a comment suggesting that the Commission use compliance enforcement. Although the Commission has used enforcement actions, such as administrative actions, recalls, and stop-sale orders, magnet set ingestions continue to occur. The Office of Compliance and Field Operations memorandum (Tab G) addresses enforcement of the existing mandatory toy standard in more detail. Although these actions can help address the hazard posed by magnet set ingestions, these actions can only focus on specific products after they enter the market. Therefore, these actions do not prevent consumer exposure to the hazard, and furthermore, they address the hazard presented by a particular firm's product, not all magnet sets. The toy standard enforcement activities cannot address the hazard presented by magnet sets that are marketed to users 14 years old and older. However, incident data indicate that many ingestions involve children accessing products that are intended for users over 14.

Comments Regarding Effectiveness of Recalls and Regulations

One commenter¹² cited a *Journal of Pediatrics* article published in 2017, which discusses the reduction in the number of magnet ingestion incidents at a large pediatric hospital in Toronto,

¹² Comment 22, Authored and signed by The American Academy of Pediatrics (AAP), North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), Consumer Federation of America (CFA), Consumers Union (CU), Kids In Danger (KID), Public Citizen (PC), and the U.S. Public Interest Research Group (PIRG), dated November 27, 2017.

Canada in the 2-year period following the Health Canada mandatory recall of magnet sets.¹³ Canada's mandatory recall of magnet sets included the recall and prohibition of sales of magnet set products. Researchers studied the impact of Canada's recall, by comparing magnet ingestion diagnosis records for patients under 18 years old for a 2-year period before (2011-2012) and after (2014-2015) the recall. According to the comment, ingestion incidents of single and multiple magnets were significantly reduced following the mandatory recall. The commenter urges the CPSC to promptly establish a safety standard to protect children from established internal injury hazards associated with small rare earth magnet sets. CPSC staff agrees that regulations regarding magnet sets could be effective to reduce the hazard that magnet set ingestions pose to consumers.

V. Staff's Assessment of the Petition and Commission Options

Staff considered the Petitioner's proposed requirements to address the hazard associated with magnet set ingestions and assessed the potential impact of the requested requirements on injuries. To summarize, current market information demonstrates that magnet sets, of various sizes, strengths, and intended user ages, are available on the market. Incident data show that children and teens continue to ingest magnets and sustain injuries from magnet sets currently on the market. Incident data indicate that these ingestions occur even when the product is intended for users 14 years and older, and when products include age recommendations and warnings about the ingestion hazard. As the Health Sciences memorandum discusses, there are serious health implications when high-powered magnets are ingested, and severe injuries and deaths can result from these incidents. Accordingly, staff's assessment supports granting the petition for the reasons explained below.

A. Grant the Petition

Based on the factors discussed in II.D. *Factors Relevant to the Commission's Decision on a Petition*, the Commission may grant the petition if it believes that a mandatory standard may address an unreasonable risk of injury presented by magnet sets. See 16 CFR § 1051.9. Granting the petition does not require the Commission to issue a rule in the specific form requested in the petition. The Commission could begin rulemaking under sections 7 and 9 of the CPSA if the Commission determines that a rule is reasonably necessary to reduce an unreasonable risk of injury associated with magnet set ingestions.

Staff agrees with the Petitioner that magnet sets pose a hazard to consumers when ingested, and therefore, staff recommends that the Commission grant the petition. Staff's assessment supports granting the petition for the following reasons.

For one, although there is an existing ASTM standard for magnet sets and mandatory requirements as part of the toy standard, these standards only apply to magnet sets intended for users under 14 years old. They do not apply to magnet sets intended for users age 14 and older,

¹³ Rosenfield, D., Strickland, M., Hepburn C. M. (2017). After the Recall: Reexamining Multiple Magnet Ingestions at a Large Pediatric Hospital. *Journal of Pediatrics*, 186:78-81.

even though incident data indicate that children ingest these magnets. As such, staff believes that a standard addressing magnet sets intended for users age 14 and older is necessary.

In addition, although the development of a voluntary standard for magnet sets intended for users age 14 and older is underway, staff does not believe the draft standard would be effective at reducing the risk of injury from magnet set ingestions. The ASTM F15.77 subcommittee has been working on drafting requirements for a voluntary standard to address magnet sets that are intended for users 14 years of age and older since 2019. However, the draft, which includes requirements similar to those requested by the Petitioner, did not receive consensus for publication as an ASTM standard. Many of the F15.77 Subcommittee participants voted negative on the ballot. These numerous negatives, including staff's negative vote, explain that the draft standard does not include performance requirements, such as specifying magnet size or strength, which would inherently mitigate the internal tissue hazard or mitigate the ingestion hazard. Instead, the draft standard, through the use of warning labels, age recommendations, instructions, and packaging, relies on consumers to alter their behavior to avoid the hazard. For the reasons explained in this briefing package (regarding the Petitioner's requested requirements), staff does not believe that these types of requirements would effectively address the hazard of children ingesting magnets from magnet sets. Therefore, staff believes the ASTM F15.77 draft standard would do little to reduce injuries and fatalities.

Staff also considered the specific requirements in the petition, but has concerns about their likely effectiveness in reducing the hazard. The Division of Human Factors memorandum (Tab D) examines the potential impact of the requested requirements regarding warnings, age recommendations, instructions, and packaging, and explains the limitations of these requirements for reducing magnet set ingestions. Warnings, age recommendations, and instructions do not prevent the hazard. Rather, they rely on convincing users to alter their behavior, which may not be effective if users do not read the information, discard the information, or discredit it because of previous incident-free experiences with the product. Staff identified reports of incidents involving products with age labels and warnings similar to those recommended in the petition. Similarly, for packaging requirements to be effective, users must correctly repack the product in its entirety after every use, which is unlikely to happen because of the time, effort, and inconvenience of disassembling the magnet set, tracking the many small pieces, low perceived risk, and possible desire to retain the design created. What is more, child-resistant packaging would not offer protection for children 5 years and older; and again, consumers may not use this packaging because of the time and effort required to store the product. Magnets from magnet sets are often acquired by children without the packaging and instructions. Children share magnet sets and children find loose magnets in their environment. In such cases, any warning information displayed on packaging or instructions, as well as packaging features, become immaterial.

In addition, as the Directorate for Engineering Sciences memorandum (Tab F) explains, 16 CFR part 1250 already requires that magnet sets intended for users under 14 years old have a flux index less than $50 \text{ kG}^2\text{mm}^2$, if the magnets are small enough to fit within the small parts cylinder. Therefore, this portion of the Petitioner's request is already included in a mandatory standard.

For these reasons, staff believes that a mandatory standard is necessary to address an unreasonable risk of injury presented by magnet sets, and recommends that the Commission

grant the petition. At this stage, staff does not believe that additional information is necessary to determine whether rulemaking is appropriate. However, staff notes that, if the Commission grants the petition, additional information may be needed to support findings that would be required for the Commission to adopt a final rule (and that would need to be discussed in a proposed rule). In particular, the Directorate for Economic Analysis may need further information about firms offering high-powered magnet sets, and the number of magnet sets being sold to U.S. consumers. In addition, more complete or detailed datasets would assist in formulating an appropriate baseline for a regulatory analysis. Depending on the scope of the proposed rule, more information about whether ingestion cases actually involved magnet sets that would be regulated under a proposed rule, and information about the flux index of magnet sets involved in injury cases also would be useful. However, this information is not necessary at this stage; staff may collect this information in preparation for rulemaking, or as part of the rulemaking process. Granting a petition only requires that the Commission begin proceedings to issue a rule, and the Commission may make its final decision about a rule “on the basis of all available relevant information developed in the course of the rulemaking proceeding” (16 CFR § 1051.10(b)). Therefore, staff recommends granting the petition and collecting any additional information needed in the course of rulemaking.

B. Deny the Petition

Based on the factors in 16 CFR § 1051.9, the Commission may deny the petition if the Commission believes that magnet set ingestions do not pose an unreasonable risk of injury to consumers or a mandatory rule would not address the hazard. If the Commission denies the petition, it may continue to consider the issues raised in the petition and may take other actions to address the hazard associated with magnet set ingestions.

Staff believes that magnet set ingestions pose a hazard to consumers, in particular children and teens, based on current incident data and market information. Therefore, staff does not recommend that the Commission deny the petition.

C. Defer Action on the Petition

If the Commission concludes that more information is required before it can decide whether to grant or deny the petition, the Commission may defer a decision and direct staff to collect additional information and reconsider the petition after that is completed. If the Commission defers action on the petition, it may initiate rulemaking in the future, in response to this petition, or for other reasons.

As explained, although additional information may be needed to support the findings required for a final rule, staff does not recommend deferring action on the petition because current market information and incident data indicate that magnet set ingestions pose a hazard to consumers, warranting rulemaking, and additional information can be collected in the course of the rulemaking process. Furthermore, staff does not recommend waiting for the draft ASTM F15.77 standard to be published because it is not likely to be effective in addressing the hazards presented by magnet sets.

VI. Staff's Recommendation and Conclusion

Based on the information contained in this briefing package, CPSC staff recommends that the Commission grant the petition and direct staff to initiate rulemaking, including collecting any additional information needed to support rulemaking. Incident data and information about magnet sets currently on the market indicate that magnet set ingestions pose a hazard to consumers, including children and teens, and can result in serious injuries or deaths. Staff believes that a mandatory standard is necessary to adequately reduce this risk of injury.

TAB A: Petition

**BEFORE THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION**

**PETITION REQUESTING THE U.S. CONSUMER PRODUCT SAFETY
COMMISSION TO INITIATE A RULEMAKING TO ESTABLISH
SAFETY STANDARDS FOR HIGH-POWERED MAGNET SETS**

**PETITION
OF ZEN MAGNETS, LLC**

**BEFORE THE
U.S. CONSUMER PRODUCT SAFETY COMMISSION**

**PETITION REQUESTING THE U.S. CONSUMER PRODUCT SAFETY
COMMISSION TO INITIATE A RULEMAKING TO ESTABLISH
SAFETY STANDARDS FOR HIGH-POWERED MAGNET SETS**

**PETITION
OF ZEN MAGNETS, LLC**

INTRODUCTION

Pursuant to Sections 7 and 9 of the Consumer Product Safety Act, 15 U.S.C. §§ 2056 and 2058, the U.S. Consumer Product Safety Commission ("Commission") regulations, 16 C.F.R. § 1051 and Section 553(e) of the Administrative Procedure Act, 5 U.S.C. § 553(e), Zen Magnets, LLC ("Zen"), files this petition requesting the Commission to initiate rulemaking to (1) establish standards for magnet sets that are intended or marketed to be used with or as magnet sets, and (2) to establish requirements that said magnets be sold in packaging that has on it and inside of it clear and adequate warnings and instructions, as well as (3) requirements respecting the form of warnings and instructions accompanying said magnets. In support of its request, Zen submits the following information:

PROCEDURAL HISTORY

On October 3, 2014, the Commission published its final rule, Safety Standard for Magnet Sets. 79 Fed. Reg. 59,962. Petitioner Zen Magnets, LLC then challenged the rule in the Tenth Circuit Court of Appeals. *See Zen Magnets, LLC v. Consumer Product Safety Commission*, 841 F.3d 1141 (10th Cir. 2016). On November 22, 2016, the Tenth Circuit vacated and remanded the final rule to the Commission. *Id.* at 1155. The Commission voted 5-0 to remove the rule from its regulations on March 1, 2017. This Petition follows.

INTEREST OF THE PETITIONER

Zen Magnets, LLC (“Zen” or “Petitioner”) manufactures and distributes Zen Magnets™ and other small rare earth magnets (“SREMs”) designed to make sculptures and other works of art, as well as to provide educational tools to students, teachers, and researchers of the physical sciences. These are the subject products of this Petition. After the Commission promulgated its Safety Standards for Magnet Sets, 16 C.F.R. Part 1240, in October 2014, Zen was the sole remaining U.S. firm manufacturing and distributing non-industrial magnets with a flux index of over 50 kG²mm² that would fit in the Commission’s small parts cylinder (described in 16 C.F.R. § 1501.4). *See* 79 Fed. Reg. 59,962 (Oct. 3, 2014). While other firms have now entered the U.S. market, Zen endeavors to be an industry leader, ensuring that the subject products are sold to appropriately-aged consumers for safe use. It is for

this reason that Zen now seeks a uniform market safety standard. Magnets are to be respected, but need not be feared.

THE PRODUCTS

The subject magnets, such as Zen Magnets sold by Petitioner, are consumer products, as defined by the Consumer Product Safety Act ("CPSA"), 15 U.S.C. § 2052(a)(5). While the shape, size, and flux of the subject magnets may vary, Zen Magnets in particular are shiny, metallic, spherical magnets that are approximately 5 millimeters in diameter and have a flux index of between 400 and 550 kG²mm². The magnets are often available for purchase by consumers in sets containing a certain number of magnets.

When sold with proper labeling, warnings, and packaging, the subject products are general use products and are not designed, marketed, manufactured, or intended to be used by children under the age of 14.

Due to their inimitable physical characteristics, the subject magnets have a variety of artistic, educational, and therapeutic benefits. In addition to being used as a unique artistic medium,¹ the subject magnets are used in and outside of classrooms to teach principles of mathematics, physics, chemistry, biology, and engineering²

¹ See e.g. The Zen Gallery, *available at* <http://zenmagnets.com/gallery>.

² Edwards, Boyd F., 2016 Expert Report: Educational Value of Neodymium Magnet Spheres in the matter of Zen Magnets, LLC, CPSC Docket No. 12-2, Item 124, Exhibit 4, *available at*

(Edwards EJP 2017).³ Zen Magnets, for instance, are specifically designed to be uniformly magnetized spheres with highly consistent diameters. As such, the force between the magnets is identical to the force between point dipoles (Edwards et al. 2017; Edwards 2017⁴) (demonstrating that point dipole/sphere equivalence for magnetic interactions may be useful in teaching and research and hold pedagogical value, and explaining that the subject magnets provided motivation for the research). The magnets are also of exceptional educational value because they provide students and teachers with an engaging, “hands-on exposure to principles of magnetism” (Edwards EJP 2017), allowing people to learn and experience the energy of interaction between the magnets. While there are other, inferior tools for demonstrating principles of magnetism and lattice structures, the alternatives not only lack the versatility of the subject magnets (Edwards 2017), they also lack the magnets’ intrigue: the subject magnets ultimately inspire people to learn.

<http://cpsc.gov/en/Recalls/Recall-Lawsuits/Adjudicative-Proceedings/>.

³ Edwards, Boyd F., John M. Edwards, Dynamical Interactions Between Two Uniformly Magnetized Spheres. *European Journal of Physics*. Eur. J. Phys. 38 (2017) (hereafter “Edwards EJP 2017”).

⁴ Edwards, Boyd F., John M. Edwards, Periodic Nonlinear Sliding Modes for Two Uniformly Magnetized Spheres. *Chaos: An Interdisciplinary Journal of Nonlinear Science*. 27, 053107 (2017) (hereafter “Edwards 2017”).

THE RISK AND NATURE OF INJURY, REASON FOR INJURY

The subject magnets pose no inherent risk of injury. However, if they are misused in such a way that they are ingested, aspirated, or otherwise inserted into the human body, they can pose a risk of injury. Most notably, if more than one magnet is ingested, it can result in damage to gastrointestinal tissue. Historical injury data show that the risk of injury increases when appropriate warnings are not present.⁵ It is important to note, however, that the intended use of the magnets poses no risk of injury whatsoever. It is with this in mind that Zen asks the Commission to undertake a rulemaking to help ensure that the magnets are used as intended – by adults – in such ways that they pose no risk of harm to consumers.

⁵ Based on information and belief, from 2014 through November 2016, Zen was the only domestic firm selling the subject magnets in the U.S., and during that time, Zen included warnings and age recommendations on its products, its website, and in places of sale. Over the last five years, injuries associated with the subject magnets have decreased from fifty-two, to thirteen, to four, to one, to one, respectively. *See* Commissioner Mohorovic, Commission Meeting: Decisional Matter: Magnet Set Safety Standard – Removal from the Code of Federal Regulations (March 1, 2017). Additionally, magnets sold prior to 2009 did not have to comply with the requirements of F963, which requires that magnets designed, marketed, or manufactured in certain ways must comply with performance standards and warning requirements similar to those outlined in the original magnet safety standard promulgated by the Commission. *Id.* Subsequent to this and the CPSC's regulatory actions, data show that established injuries associated with the subject magnets have decreased markedly, as Commissioner Mohorovic discussed. *Id.*

COST-BENEFIT ANALYSIS

As a private firm, Zen is not in possession of industry-wide information regarding the sale and importation of the subject magnets. However, there are numerous costs associated with injuries caused by the misuse of the subject magnets. These costs include societal costs, medical costs, and other intangible costs. There are therefore obvious benefits to creating industry rules to mitigate such costs.

CURRENT STANDARDS

There are currently no consumer safety standards in the form of statutes, regulations, or voluntary standards that govern the sale or use of the subject magnets for general use purposes.

RATIONALE FOR THE REQUESTED ACTIONS

Petitioner Zen acknowledges that there is an ingestion risk posed by the subject magnets when they are misused in ways that could lead to ingestion, aspiration, or bodily insertion. Zen does not believe that a rule as broadly tailored to the one removed from the Code of Federal Regulations on March 1, 2017 is necessary to mitigate that risk. Zen does believe, however, that without proper warnings and age recommendations, the products can pose an unreasonable risk of injury.

The current regulatory schemes administered by the Commission do not address the misuse of the subject magnets. Therefore, Zen respectfully requests that the Commission take the following actions to address the ingestion risk.

SUBSTANCE OF THE PROPOSED RULE

I. Safety Standard

Zen proposes a physical safety standard where each magnet in a magnet set, and any individual magnet, that fits completely within the cylinder described in 16 C.F.R. § 1501.4 must have a flux index of 50 kG²mm² or less *if* it is designed, marketed, or manufactured for children under the age of 14. The rationale behind this standard is that magnets with a flux index of less than 50 lack the magnetic strength to attach across internal tissue and cause internal injury, and will comply with current ASTM standards for magnets in toys for children.

For general purpose magnets, *i.e.*, magnets such as those sold by Zen, Zen proposes the following additional regulations:

II. Warnings

Zen Proposes that the Commission promulgate regulations regarding the warnings associated with the subject magnets. These warnings should comply with the hallmark features of proper product warnings, including size, font, and graphical features such as triangles and exclamation marks. The warning (or warnings) should also make clear the ingestion hazard. When sold through online retailers, Zen

proposes that purchasers also be required to acknowledge (1) that they have read the warnings associated with the product and (2) that they assent to the risk should they misuse the products.

A proper warning shall contain, at minimum, the following or equivalent text:



Magnet Poisoning Hazard: These magnets are not toys for children. Swallowed magnets can stick together across intestines causing serious injury or death. Keep away from kids who do not understand the dangers of magnets.

SEAL REMOVAL IMPLIES ASSUMPTION OF RISK

III. Instructions

While the magnets naturally attract to one another, and therefore do not easily get “lost to the environment,”⁶ the magnets may be intentionally, manually separated from one another. To help ensure that intentionally separated magnets do not create an ingestion hazard, Zen sells its products with instructions that allow users to quickly and visually confirm that all magnets are returned to their container after

⁶ “One surprising property of small neodymium magnet spheres is how they generally find a way to attract each other. Placed in a repulsive configuration that might seem to lead to separation of two or more magnets, the magnets tend to twist and move until they attract and are drawn together. In years of informal experience with Zen Magnets (one brand of 5 mm diameter neodymium magnet spheres), we do not recall observing an initial configuration whose magnetic repulsion led eventually to separation of two or more magnets.” (Edwards EJP 2017) (internal citations omitted).

use, without the need for users to count individual magnets.⁷ Therefore, in addition to warnings, the subject magnets should also contain adequate instructions that explain to consumers how to avoid using the magnets in ways that can lead to ingestion, aspiration, or bodily insertion, and how to ensure that magnets are not unreturned to the packaging.

IV. Age Requirements or Recommendations

As discussed above, if the magnets are sold as children's toys, as defined by the CPSA and CPSIA, Zen recommends limiting the physical strength of the magnets to a flux index of less than 50 kG²mm². However, for the magnets to be of use in artistic, hobby, science, and craft applications, their flux index must be considerably higher. It is for this reason that Zen proposes the Commission adopt age requirements to the extent that the Commission has the jurisdiction to do so. Zen's proposed age requirement is 14 years or older (*i.e.*, the subject magnets cannot be sold to children under the age of 14). To the extent possible, Zen also proposes that the Commission restrict sales to children by requiring the purchase of the subject magnets be made by an adult of the age of majority.

Should the Commission deem that it lacks the authority to impose age requirements, Zen proposes, in the alternative, that the Commission impose an age

⁷ Other methods for counting magnets have been enunciated by people who routinely use the magnets, such as Dr. Boyd Edwards, the author of several publications that use and were inspired by Petitioner's magnets.

recommendation for the subject magnets of 14 years and older, to be visibly displayed on the magnet packaging, and in the warnings and instructions.

V. Packaging Requirements

Zen proposes additional packaging requirements to increase the likelihood that consumers view the warnings, and that children cannot access the magnets within a reasonable amount of time. Specifically, Zen proposes that the warnings affixed to the outside of the packaging containing the subject magnets also seal the container in such a way that the user must actively acknowledge the warning, by cutting through or otherwise removing the warning label in order to open the packaging. In addition to packaging warnings that must be actively acknowledged, there must also be conspicuous warnings affixed to the packaging that the user does not have to remove or cut.

Zen further proposes that the packaging be required to be “child resistant,” or “special packaging,” either with packaging that is lockable, or similar to the “special packaging” defined by the Poison Prevention Packaging Act,⁸ so that children would not be able to gain access to the magnets while they are still in the packaging. The packaging can also assist in the visual counting procedure discussed above. For

⁸ The Commission has the authority to regulate such packaging and does so via its PPPA regulations, found at 16 C.F.R. Parts 1700-1702.

instance, geometric shapes could also be built into the packaging itself to help users determine whether all magnets have been returned to the packaging after use.

**A SAFETY STANDARD IS ADEQUATE; AN ALL-AGES MARKET
REMOVAL OF THE MAGNETS IS NOT REQUIRED**

While historical NEISS data have shown that the subject magnets have the potential to cause serious injury, recent NEISS data show that consumers are able to understand the magnet ingestion hazard, and to mitigate the misuse of high-powered magnet sets.

The rule that would be created by this Petition would assist the Commission in creating consistent market standards for SREMs, and would help to promote safety by standardizing many of the voluntary policies that have already been proven by Zen to be effective.

REQUESTS TO INITIATE RULEMAKING AND FOR A HEARING

Petitioner Zen Magnets, LLC respectfully requests that the Commission initiate a rulemaking regarding the subject magnets identified above. Petitioner further requests a hearing before the Commission to consider the issues raised in this Petition.

Respectfully submitted this 16th day of August, 2017.

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REFERENCES

Edwards, Boyd F., D.M. Riffe, Jeong-Young Ji, William A. Booth, Interactions Between Uniformly Magnetized Spheres. *American Association of Physics Teachers*. Am. J. Phys. 85 (2), February (2017).

Edwards, Boyd F., 2016 Expert Report: Educational Value of Neodymium Magnet Spheres in the matter of Zen Magnets, LLC, CPSC Docket No. 12-2, Item 124, Exhibit 4, *available at* <http://cpsc.gov/en/Recalls/Recall-Lawsuits/Adjudicative-Proceedings/>.

Edwards, Boyd F., John M. Edwards, Dynamical Interactions Between Two Uniformly Magnetized Spheres. *European Journal of Physics*. Eur. J. Phys. 38 (2017).

Edwards, Boyd F., John M. Edwards, Periodic Nonlinear Sliding Modes for Two Uniformly Magnetized Spheres. *Chaos: An Interdisciplinary Journal of Nonlinear Science*. 27, 053107 (2017).

TAB B: Statistical Analysis



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: June 3, 2020

TO : Susan Bathalon
Magnet Sets Petition Project Manager
Office of Hazard Identification and Reduction

THROUGH : Risana Chowdhury
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : John Topping
Mathematical Statistician
Division of Hazard Analysis

SUBJECT : NEISS estimates and analysis of reported incidents related to ingestion of magnets of various shapes and sizes from, or possibly from, magnet sets¹⁴

Introduction

In response to Zen Magnet's petition for a rulemaking regarding magnet sets of various shapes and sizes, this memorandum (memo) provides analysis of incidents related to ingestion of magnets. This memo provides estimates for emergency department-treated, magnet-related ingestions from January 1, 2009, to December 31, 2018, obtained through the National Electronic Injury Surveillance System (NEISS). This memo also characterizes attributes of various magnet ingestions, as described in incidents collected in the Consumer Product Safety Risk Management System (CPSRMS) database, with incident dates from January 1, 2009, through December 31, 2019. The data were extracted on February 4, 2020.

Magnet sets generally consist of numerous identical, small, powerful magnets. Magnet sets vary in the number of magnets, and the size, shape, and strength of magnets. For this memorandum, staff describes the criteria it used to determine whether an incident involved a "magnet set." These criteria are based on this general definition and features that are common in products that meet this definition. The products discussed in this memo are similar to the class of products discussed in prior rulemaking efforts on magnet sets. Although the timeframe and analysis have been extended, this memo uses some of the language and methodology previously described in the 2012 memo, "*NEISS estimates and analysis of reported incidents related to ingestion of small, strong magnets that are part of a set of magnets of various sizes*" (Garland, 2012).

¹⁴ In this memorandum, unless otherwise specified, "magnet set" refers to magnet set products manufactured, marketed, intended, or some combination of these factors, consistent with the magnet set product identified by the Petitioner. For the purpose of this memorandum, staff's use of "magnet set" excludes irrelevant magnet set products, such as children's tile building sets with encased magnets, and sets of magnets in jewelry products."

Although more details are provided in the body of this memo, some findings are:

NEISS Estimates 2009-2018:

- An estimated 4,500 emergency department-treated ingestions involve magnets from or *possibly* from magnet sets (*possibly* from magnet sets means that the incident descriptions indicated that the magnets met at least some criteria consistent with magnet sets).
- Some proportion of an additional 14,000 estimated ingestions of magnets of unknown or other type may also involve magnet sets; but the narratives available in NEISS did not generally provide enough details to suggest or contraindicate characteristics of magnet sets.
- Combining the various cases discussed above, there have been an estimated 18,600^[15] emergency department-treated, magnet-related ingestions from 2009 to 2018 that may be relevant.
- Of these estimated 18,600 emergency department-treated, magnet-related ingestions, an estimated 8,300 victims (44.9%) are under 5 years old. For the estimated 4,500 ingestions of magnets from, or possibly from, magnet sets, an estimated 1,700 victims (37.1%) are under 5 years old.

CPSRMS Reported Incidents 2009-2019:

- Staff received 176 reports of magnet ingestion involving or possibly involving magnets from magnet sets. Of these 176 reports, 98 reports definitively identified relevant magnet sets, explicitly referring to the type of product or to a brand or manufacturer.
- Of the 176 reported incidents, 2 (1.1%) resulted in death¹⁶, and 115 (65.3%) resulted in hospitalization.
- Of the 176 victims, 57 (32.4%) are under 5 years of age, 59 (33.5%) are between 5 and 9 years of age, and 49 (27.8%) are 10 years of age or older. Age is unknown for the remaining 11 victims.
- Eleven of the 176 incidents (6.3%) involved victims 14 years or older, above the cutoff age recommended in the petition for general-use magnet sets.
- Of the 176 victims, 74 received the magnets from an unknown source (42%); 46 found or received magnets owned by a relative (26.1%); and 32 obtained magnets at school or from a friend or classmate (18.2%).
- Twenty-two (44.9%) of the 49 victims age 10+ were reported to be using the magnets to emulate piercings at the time of the incident. Similar behavior was observed among only 11 younger victims (all between the ages of 6 and 9 years old).
- Across all age groups, at the time of ingestion, there were some children reportedly simply playing with the magnets in their mouths, not intending to imitate jewelry, such as mouthing magnets, or sticking the magnets to their braces (24.6% or 14/57 of the less than 5 age group, 37.3% or 22/59 of the 5-9 age group, and 26.5% or 13/49 of the 10+ age group).

¹⁵ All NEISS injury estimates are presented after rounding to the nearest 100 injuries. Implied totals or percentages may therefore differ slightly from computations based upon exact point estimates.

¹⁶ Deaths outside the United States are not included here, but are discussed by other memoranda within this briefing package.

NEISS Estimates

Staff considered magnet-related ingestion cases in the NEISS database with treatment dates from January 1, 2009, to December 31, 2018, before removing cases determined irrelevant or too uncertain (using the criteria below). To gather all possible data related to the magnets of interest, staff implemented a keyword search and considered any case that mentioned “magnet” in the narrative field. This was completed across all products. Unless otherwise noted, all estimates span the 2009—2018 timeframe. From this master set, cases were *excluded* from the analysis, if any of the following applied:

- Any case known to have involved an out-of-scope child’s toy, such as a magnet from a “princess set” or from a “fish toy”;
- Any case determined to involve a different type of magnet than from magnet sets, such as reports of “kitchen magnets”;
- Any case where the magnet reported was most likely not the type of magnet of interest; for example, “swallowed a plastic-covered magnet . . .”;
- Any case that could not be determined to be magnet related, for example, “5YOF, acc swallowed dog toy vs magnet . . .”; and
- Any case with no ingestion, or with uncertainty as to whether any ingestion actually occurred;
- Any case with ambiguity about whether what was ingested included at least one *magnet*.

Consequently, cases describing “possible ingestion” or “may have ingested” are excluded, unless a final diagnosis confirming ingestion was explicit. Staff also excluded a few cases involving a magnet and a diagnosed ingestion, when staff was unable to discern whether the magnet was the object ingested. Collectively, the above criteria may exclude some ingestions of in-scope magnet sets, but the criteria also exclude cases that staff could conclude are beyond the focus of this petition package. For purposes of evaluating the specific hazard and product addressed in the petition, staff used the criteria described in this memorandum because of the varied, and often limited, level of information available in NEISS narratives. Including only cases that met the “Yes” criteria (described below) would likely have underrepresented the number of magnet set ingestions and would not allow staff to report nationwide estimates. Including cases that met the “Possible” criteria (described below) allowed staff to provide information about additional ingestion incidents that indicated characteristics consistent with magnet sets, but that provided insufficient information to include in the “Yes” category. However, because of the limited information available, the “Possible” category may include or exclude incidents that involved products other than magnet sets. If the Commission pursues rulemaking, it may be possible for staff to use a different data analysis approach, depending on the product scope and hazard the rule addresses and the level of information available about relevant incidents.

From the remaining dataset, staff placed each case in a category to answer the question: “Is the ingested magnet(s) from an in-scope magnet set?” The resulting magnet categories are described as follows¹⁷:

- *Yes* – includes cases definitively identifying a magnet set consisting of multiple small high-powered (rare earth) magnets. Only one case describes an executive desk toy magnet set in explicit terms, without indicating brand or manufacturer. The remaining cases could only be determined to fit this category with the benefit of brand- and/or manufacturer-specific information (which is usually not collected in the vast majority of NEISS data, but happened to be indicated for these particular cases).
- *Possible* – includes cases that mention the following terms that describe characteristics of magnet sets (without identifying any brand or manufacturer): “high-powered,” “magnetic ball,” “magnetic marble,” “BB size magnet,” or “magnet beads” (where no jewelry is mentioned). This excludes faux tongue rings, jewelry beads, and other jewelry, because these are classified in their own category. Not all magnets within this category are necessarily ball shaped; however, indications of a product being spherical (or “ball”) shaped were considered, among other factors, in categorizing these cases; thus, the data may be skewed toward being more inclusive of magnets of spherical shape. Although these cases describe magnet(s), by identifying characteristics that are typical of magnets from high-powered magnet sets that are the focus of this briefing package, observing such similarities does not rule out other possible sources of magnets.
- *Other*– includes cases that mention a magnetic rock or cases that describe the magnet as part of jewelry, such as a faux tongue ring. These cases have been set aside because the products are presumed to be beyond the scope of this petition, although not necessarily irrelevant to the issues it raises (*e.g.*, children *imitating* jewelry was observed among “Yes” cases).
- *Magnet, type unknown* – includes cases in which the narrative did not provide adequate context or characterization of the ingested magnets (*e.g.*, size, shape, strength) to classify the magnet into one of the other categories, or to exclude the incident from the data set, based on the criteria for exclusion explained above. Although some proportion of these cases may have involved magnet sets, the size of that proportion is unknown. However, because some proportion of these cases may have involved magnet sets, this category is included throughout this section.

¹⁷ These magnet category descriptions are *not* algorithms, but they are simply intended to help the reader understand each category.

The *yes* and *possible* magnet categories, and the *other* and *magnet, type unknown* categories were combined for the analysis.

Table 1 provides the number of cases for each original category and how they were combined. **Table 2** provides the overall estimates of emergency department-treated ingestions for the combined categories.

Table 1: Count of Magnet Ingestion Cases Treated in NEISS Hospital Emergency Departments by Magnet Category, 2009—2018

| Original Magnet Category | N (Original) | Combined Magnet Category | N (Combined) |
|--------------------------|--------------|----------------------------|--------------|
| Yes | 36 | Yes/Possible | 215 |
| Possible | 179 | | |
| Other | 38 | Magnet, type unknown/Other | 618 |
| Magnet, type unknown | 580 | | |
| Total | 833 | Total | 833 |

Table 2: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2009—2018

| Magnet Category | Estimate ¹⁸ | CV |
|----------------------------|------------------------|-------------|
| Yes/Possible | 4,500 | 0.17 |
| Magnet, type unknown/Other | 14,000 | 0.16 |
| Total | 18,600 | 0.15 |

Table 3 provides the total estimates for emergency department-treated, magnet-related ingestions from 2009 to 2018. This collapses both categories reported in Table 2, so that annual estimates can be reported. Some of the year-to-year changes may be attributable to random variation in the sample; however, some differences are statistically significant. Analysis of the combined magnet ingestion injuries suggests significantly greater emergency department-treated magnet ingestions in 2011, than for any of the years 2009, 2014, 2015, or 2016 (p-values = 0.0225, 0.0166, 0.0078, and 0.0196, respectively). Such analysis also suggests significantly fewer such ingestions in 2015, compared with the earlier year 2012, or the more recent year 2018 (p-values = 0.0323 and 0.0246, respectively). Finally, the two most recent years 2017 and 2018, each show significant increases, compared with the year 2016 (p-values = 0.025 and 0.0252, respectively).

¹⁸ Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 10 years from 2009 to 2018) are *not* annual averages.

Table 3: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Year, Combined Magnet Category Total

| Year | Estimate | CV |
|--------------|---------------|-------------|
| 2009 | 1,400 | 0.24 |
| 2010 | 1,800 | 0.17 |
| 2011 | 2,500 | 0.19 |
| 2012 | 2,600 | 0.28 |
| 2013 | 1,700 | 0.23 |
| 2014 | ** | ** |
| 2015 | 1,200 | 0.26 |
| 2016 | 1,300 | 0.25 |
| 2017 | 2,600 | 0.26 |
| 2018 | 2,200 | 0.19 |
| Total | 18,600 | 0.15 |

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variance (CV) cannot exceed 0.33, there must be at least 20 sample cases, and there must be at least 1,200 estimated injuries.

Although data are insufficient to report *annual* estimates for the categories “Yes/Possible” and “Magnet, type unknown/Other,” staff can report some of these estimates (in Table 4) by category when consolidating *bi-annually*, each 2-year period representing one-fifth of the 10-year period from 2009 to 2018. For the combined total injury estimates for each 2-year period, statistical testing finds that the combined injuries during the 2-year period from 2015 to 2016 to be significantly less when compared to the 2-year periods from 2011 to 2012 and from 2017 to 2018 (p-values=0.0085 and 0.0035, respectively). The ingestion injuries during the 2017 to 2018 period are also found to be significantly greater than the injuries in the earlier period 2013 to 2014 (p-value=0.0103).

Table 4: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Biannual Timeframe

| Magnet Category | 2009-2010 | 2011-2012 | 2013-2014 | 2015-2016 | 2017-2018 |
|----------------------------|--------------|--------------|--------------|--------------|--------------|
| Yes/Possible | * | 1,300 | * | * | 1,200 |
| Magnet, type unknown/Other | 2,300 | 3,800 | 2,200 | 2,100 | 3,600 |
| Total | 3,200 | 5,100 | 3,100 | 2,400 | 4,800 |

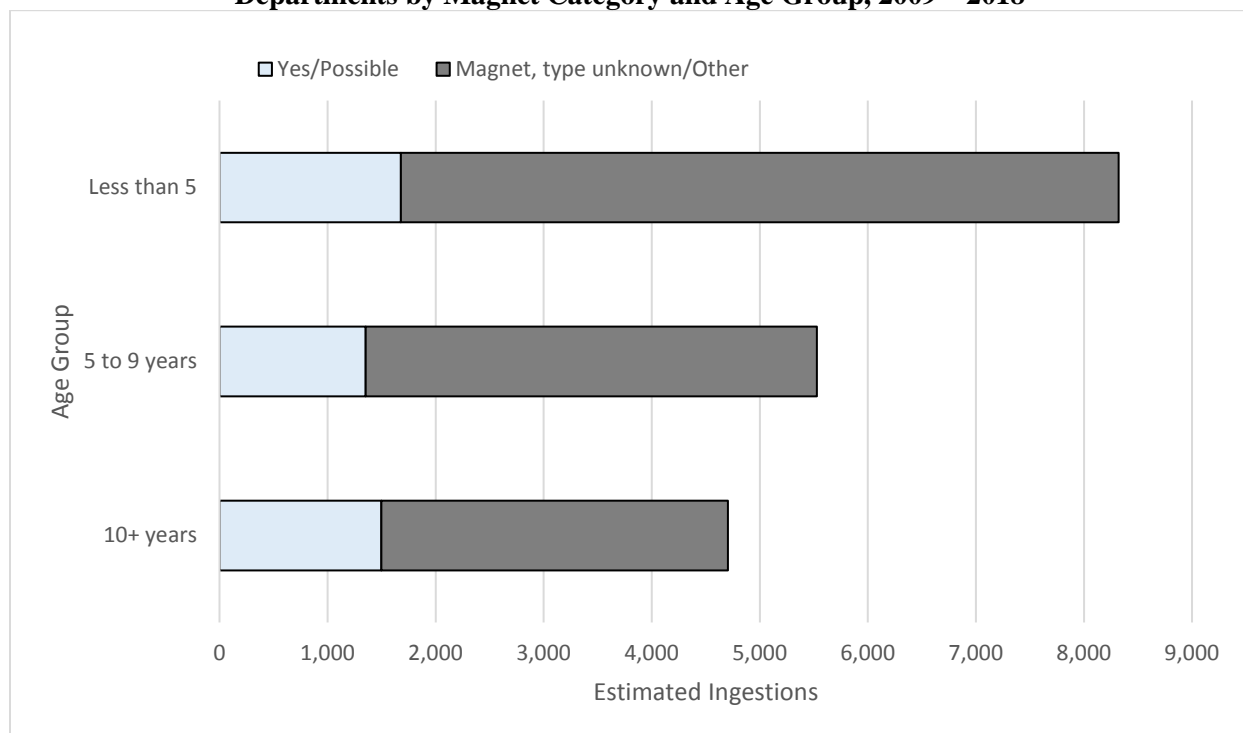
**This estimate does not meet reporting criteria. This table presents *biannual* estimates, *not* annual averages.

The following tables and figures collapse the years 2009—2018, so each estimate that follows corresponds to that 10-year timeframe.¹⁹ To explore the estimates further, **Table 5** and **Figure 1** present the overall breakdown by age group. The age groups are as follows: less than 5 years of age, 5 to 9 years of age, and 10 years of age, or more. The proportion of estimated injuries is more heavily weighted towards young children in the Magnet type unknown/Other category than in the Yes/Possible category.

Table 5: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Age Group, 2009—2018

| | Magnet Category | | | | | |
|--------------|-----------------|-------------|---------------------------|-------------|---------------|-------------|
| | Yes/Possible | | Magnet type unknown/Other | | Total | |
| | Estimate | CV | Estimate | CV | Estimate | CV |
| Age Group | | | | | | |
| Less than 5 | 1,700 | 0.19 | 6,600 | 0.19 | 8,300 | 0.17 |
| 5 to 9 years | 1,400 | 0.25 | 4,200 | 0.17 | 5,500 | 0.17 |
| 10+ years | 1,500 | 0.27 | 3,200 | 0.18 | 4,700 | 0.18 |
| Total | 4,500 | 0.17 | 14,000 | 0.16 | 18,600 | 0.15 |

Figure 1: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Age Group, 2009—2018



¹⁹ Collapsing all 10 years together allows some estimates to be reported that may not be fully reportable over shorter periods (e.g., annual, bi-annual, or otherwise). This is the case, for example, for some of the estimates by age group presented in Table 5 and Figure 1.

The estimated number of magnet-related, emergency department-treated ingestions for each sex, by magnet category, is provided in **Table 6**. Although estimates are higher for males than females for each magnet category, these do not reflect statistically significant differences in proportions for males and females across magnet categories. For the “Yes/Possible” magnet category across all years from 2009—2018, an estimated 55.2 percent of the victims were male. In the “Unknown/Other” category, an estimated 58.0 percent of the victims were male.

Table 6: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Sex, 2009—2018

| | Magnet Category | | | | | |
|--------------|-----------------|-------------|----------------------------|-------------|---------------|-------------|
| | Yes/Possible | | Magnet, type unknown/Other | | Total | |
| | Estimate | CV | Estimate | CV | Estimate | CV |
| Sex | | | | | | |
| Female | 2,000 | 0.21 | 5,900 | 0.17 | 7,900 | 0.15 |
| Male | 2,500 | 0.20 | 8,100 | 0.17 | 10,600 | 0.16 |
| Total | 4,500 | 0.17 | 14,000 | 0.16 | 18,600 | 0.15 |

The estimated number of emergency department-treated, magnet-related ingestions by disposition and category is provided in **Table 7**. Note that most are treated and released from the hospital, for both the overall estimate (15,400; 82.8%) and the individual estimates for “Yes/Possible” (3,400; 74.9%) and “Magnet, type unknown/Other” (12,000; 85.7%).

Table 7: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Disposition, 2009—2018

| | Magnet Category | | | | | |
|---------------------------|-----------------|-------------|----------------------------|-------------|---------------|-------------|
| | Yes/Possible | | Magnet, type unknown/Other | | Total | |
| | Estimate | CV | Estimate | CV | Estimate | CV |
| Disposition | | | | | | |
| Treated and Released | 3,400 | 0.16 | 12,000 | 0.16 | 15,400 | 0.15 |
| Hospitalized/ Transferred | * | * | 2,000 | 0.22 | 2,900 | 0.21 |
| Other ** | * | * | * | * | * | * |
| Total | 4,500 | 0.17 | 14,000 | 0.16 | 18,600 | 0.15 |

*This estimate does not meet reporting criteria.

**Dispositions observed among the “other” category in the sample cases include “Held for observation (includes admitted for observation)” and “Left without being seen/Left against medical advice.”

CPSRMS Reported Incidents Analysis Results

Reported incidents in the CPSRMS database often have more information about the products involved, such as the manufacturer and model, than reports in NEISS, which focuses on information most pertinent to treatment of the injury. Additionally, CPSRMS reports often have more information about the victim and the incident scenario. As such, this section of the memorandum characterizes the incident scenarios in more detail than in the NEISS section. Note that this section is limited to anecdotal summaries and observations, unlike NEISS, which supports statistically valid national estimates. The CPSRMS data collected is not a complete set of all incidents or a statistically representative sample, but can be considered a minimum case count.

Staff considered all reported incidents involving a magnet from January 1, 2009 through December 31, 2019, as part of the initial set of incidents. Then staff excluded from this set, magnets in out-of-scope toys and magnets determined to be a different product than magnet sets. Staff also excluded from this set, any hazard patterns other than magnet ingestions. Other reported hazard patterns, which staff excluded, included an allergic reaction, ear injuries, a hand injury, and small magnets entering the urethra from autoerotic activity. All of the tables in this section correspond to incidents with an ingestion hazard pattern.²⁰

Reporting is ongoing for magnet-related ingestion incidents occurring from January 1, 2009 through December 31, 2019. CPSC staff may receive additional reports and information about magnet-related ingestion incidents that occurred during this period.

A CPSRMS incident report can contain more information than a NEISS case. It may include very specific information or photographs of the original product, packaging, or warnings establishing that the ingested magnet or magnets came from a magnet set. However, highly detailed information (*e.g.*, photographs, descriptions) about only the extracted magnets do not necessarily identify the original product, other than to inform us of similarities. As an example, CPSC has the actual sample of a ring of colored magnets ingested by a child. In every way, staff is able to observe (*e.g.*, size, shape, color, magnetic attraction) that the magnets collected from that incident resemble magnets from magnet sets; however, because staff does not know the original source(s) of those magnets, staff can only conclude that the magnets are entirely *similar* to magnets from various magnet sets.

²⁰ One report suggests that 15 victims ingested magnets. The health care professional who submitted the report indicated that all such incidents come from desk toy magnet sets with magnets of varying diameters, typically around 1/4 inch (about 6 mm). However, the information provided was not sufficient to differentiate individual victims. It is possible some of the 15 victims are already accounted for among the rest of the CPSRMS incidents (based on reports from other sources). As such, this report of “15 victims” is disregarded in all incident counts presented elsewhere in this memo. In contrast, several other medical professionals reported age or some other characteristic of several victims (between 2 and 4 per report), allowing multiple incidents to be counted from those reports towards the total incident counts.

The magnet categories discussed in this section seek to address a similar objective as those defined in the NEISS section, asking and answering the same research question of whether the magnet involved was from an in-scope magnet set. However, to help determine the child's interaction with the magnet set product and grouping of in-scope incidents, the Division of Hazard Analysis collaborated with staff in the Division of Human Factors and identified the following narrowly constructed categories:

- *Yes* – This category corresponds to reported incidents specifically identifying magnets from a magnet set.²¹ Brand was indicated for most of these incidents. In a few incidents, product packaging demonstrated the products to be magnet sets, without indicating the specific brand. Incidents with conflicting product information, casting uncertainty about whether the products involved were really magnet sets, were excluded from this (*yes*) category. For example, staff excluded cases in which a medical professional stated a relevant brand name, but other information from the victim or investigator indicated the brand was not known.
- *Highly Similar* – Some incident reports provide pictures and/or various details that appear similar or identical to an in-scope high-powered magnet set in performance, quantity, size, color, and shape. However, these reports did not identify the product with certainty as a magnet set. In addition, incidents in this category did not include any information that would suggest the product was not a magnet set, and satisfied at least one of the following two criteria:
 - at least two of the four following criteria that are present in magnet sets: similar sizes (*e.g.*, 2 mm to 5 mm), shapes (*e.g.*, sphere, cube), quantities (*e.g.*, 100-200 pieces), or uses (*e.g.*, building set, fidget toy); or
 - the report references magnets with terminology directly indicative of in-scope magnet sets, such as “BBs.”²²
- *Potential* – This category includes incident reports that provide product descriptions that are consistent with characteristics of magnet sets, but with less specific detail to indicate they involved magnet sets than those in the *highly similar* category. For example, incident reports that stated “ingested small round magnets from unknown source,” or “swallowed 20 rare earth magnets” are included within this category.

In total, 176 ingestions reported in CPSRMS incidents were determined to be in scope and classified into these three categories (*i.e.*, 98 *Yes*, 54 *Highly Similar*, and 24 *Potential*). **Table 8** breaks down the number of reported magnet-related ingestions in each category. The majority of reported incidents, are in the *Yes* category (55.7%), as compared to *Highly Similar* (30.7%), and *Potential* (13.6%).

²¹ This *Yes* category does *not* include products described only as a “magnet set,” because the same term could describe an unrelated toy, household, or other magnet product.

²² Magnets from magnet sets are commonly very similar in shape and size to metal BBs used with BB guns, and are often described as such.

**Table 8: Magnet Category for Reported Magnet-Ingestions,
January 2009—December 2019***

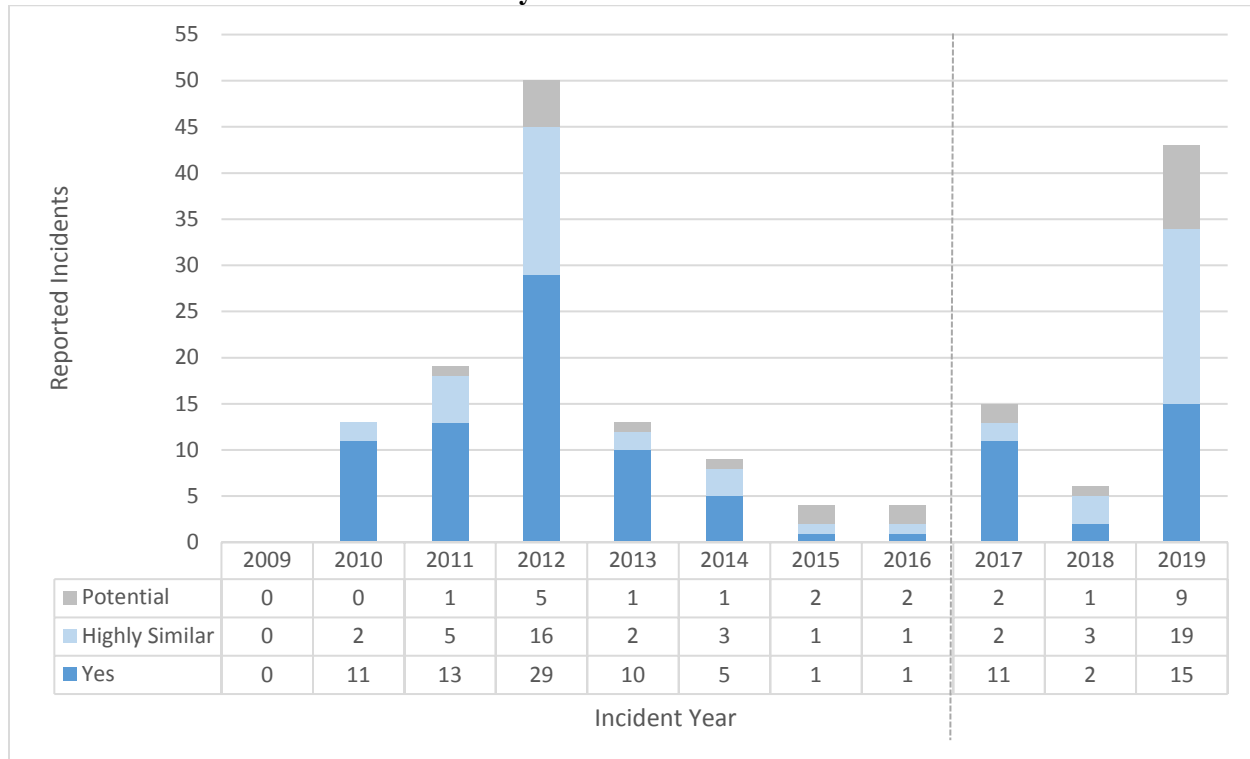
| Magnet Category | Incidents | Proportion |
|------------------------|------------------|-------------------|
| Yes | 98 | 55.7% |
| Highly Similar | 54 | 30.7% |
| Potential | 24 | 13.6% |
| Total | 176 | 100% |

* CPSRMS reporting for the years 2017-2019 is ongoing.

Figure 2 shows the year of incident by magnet category. In part because reporting to the CPSRMS databases may be influenced by media reports, this anecdotal reporting cannot be used to draw conclusions about trends in the number of cases occurring, but represents the number of reports that CPSC has received.²³ Reporting is not complete for the years 2017-2019, so counts for reported incidents in those years may increase as CPSC continues to collect data. In addition, some incidents may never be reported, and it is unknown how the frequency of unreported incidents may vary from year to year. There is no requirement that all consumers report every incident that occurs with a consumer product, thus there may be additional incidents that occurred that were not reported to CPSC.

²³ For trend information, see the *NEISS Estimates* section of this memorandum.

Figure 2: Histogram by Incident Year and Magnet Category for Reported Magnet-Ingestions, January 2009—December 2019*



*CPSRMS reporting for the years 2017-2019 is ongoing, and counts for those years may increase as reporting continues. None of the ingestions reported occurred in the first year (2009).

Table 9 shows the incident distribution for various quantities of ingested magnets (*i.e.*, how many were swallowed in each incident) by magnet category. For the 176 reported incidents in the *Yes*, *Highly Similar*, and *Potential* categories, most involved more than one ingested magnet (168 incidents; 95.5%). This includes 22 incidents for which more than one magnet was ingested, but an exact quantity was not specified. There were also reports in which a precise range was specified (*i.e.*, “5 to 7” and “6 or 7”), that could not be translated to a single number. Regardless of the uncertainty introduced by incidents with unspecified quantities or a range of quantities, it is evident among reported incidents that the most frequent quantity of ingested magnets (*i.e.*, the mode) is two, with at least 46 incidents of exactly two ingested magnets (26.1%). However, the majority of reported incidents involved ingestion of more than two magnets: at least 57 incidents (32.4%) involved ingestion of between three and nine magnets, and at least 43 incidents (24.4%) involved ingestion of 10 or more magnets.

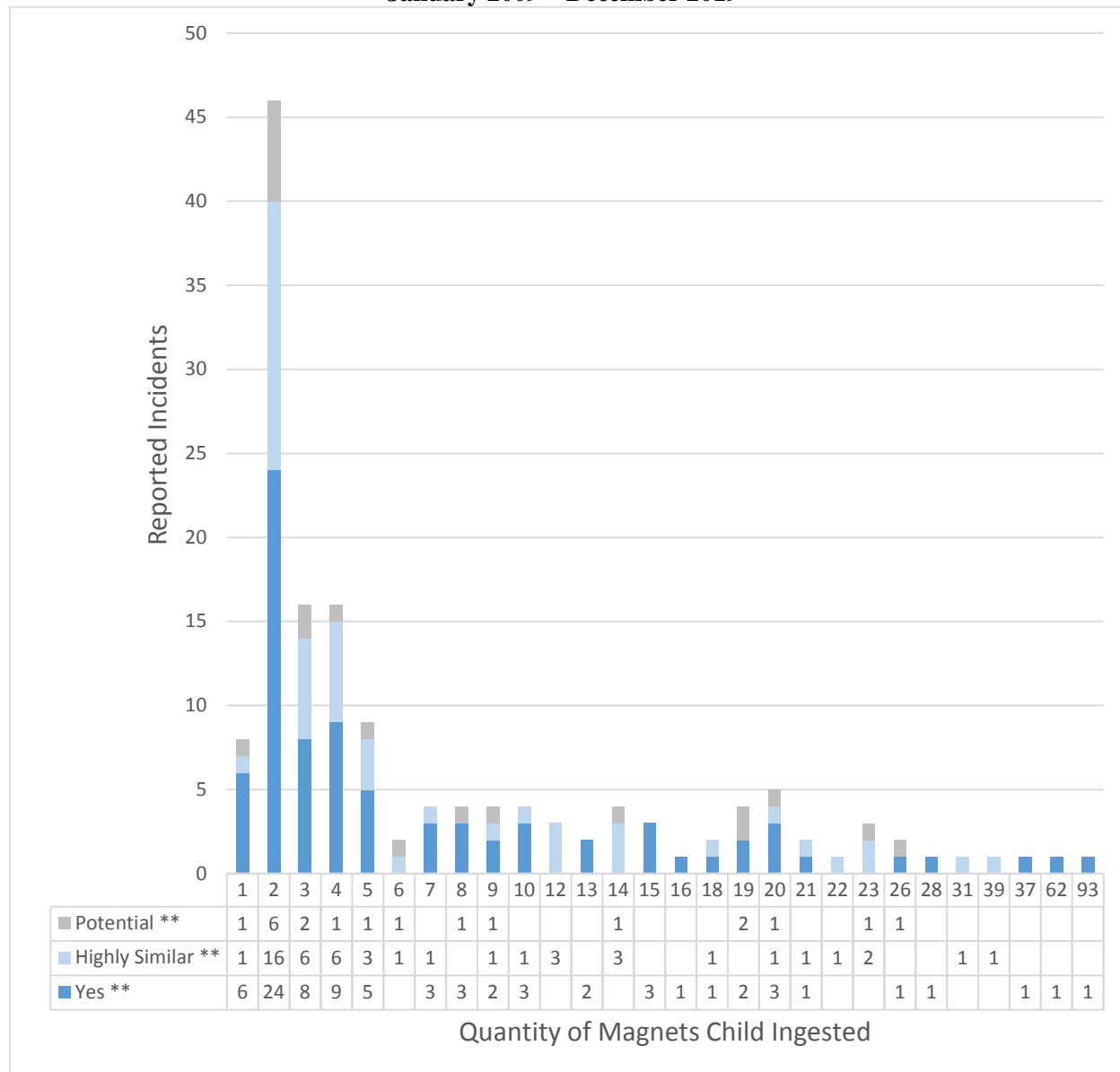
Table 9: Quantity Ingested by Magnet Category for Reported Magnet-Ingestions, January 2009—December 2019*

| Magnet Category | Quantity Ingested | | | | | |
|------------------------|--------------------------|-----------|---------------------------------|-------------|--------------------|--------------|
| | 1 magnet | 2 magnets | Unknown, but at least 2 magnets | 3-9 magnets | 10 or more magnets | Total |
| Yes | 6 | 24 | 15 | 32 | 21 | 98 |
| Highly Similar | 1 | 16 | 4 | 18 | 15 | 54 |
| Potential | 1 | 6 | 3 | 7 | 7 | 24 |
| Total | 8 | 46 | 22 | 57 | 43 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

Figure 3 presents a histogram of specified ingested magnet quantities, excluding 25 incidents for which an exact count was not specified. Among the 151 incidents reflected in the histogram below, the observed quantities range from a minimum of only one ingested magnet (8 such incidents) to a maximum of 93 magnets ingested (in 1 incident). The most common quantity (*i.e.*, the mode) was exactly two magnets ingested, with 46 such incidents. However, the average (*i.e.*, mean) was 8.4 ingested magnets, and the middle value (*i.e.*, median) was four ingested magnets.

Figure 3: Histogram by Quantity Ingested and Magnet Category for Reported Magnet-Ingestions, January 2009—December 2019*



*CPSRMS reporting for the years 2017-2019 is ongoing.

**Excludes incidents that do not specify the exact quantity of ingested magnets (25 excluded incidents in total).

Three of these exclusions indicated a range (*i.e.*, “5 to 7,” “6 to 7,” and “10 or more”). The other 22 exclusions implied that multiple magnets (*e.g.*, two or more) were ingested without specific numbers.

The horizontal axis of this graph is not scaled proportionally to the presumed number of magnets ingested,

Table 10 provides the number of reported incidents by disposition and magnet category. Of the 176 reported ingestions, 115 (65.3%) resulted in hospitalization and 2 (1.1%) resulted in death.

**Table 10: Disposition by Magnet Category for Reported Magnet-Ingestions,
January 2009—December 2019***

| Magnet Category | Disposition | | | |
|-----------------|-------------|-----------------|-----------|------------|
| | Death | Hospitalization | Other | Total |
| Yes | 0 | 63 | 35 | 98 |
| Highly Similar | 2 | 36 | 16 | 54 |
| Potential | 0 | 16 | 8 | 24 |
| Total | 2 | 115 | 59 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

“Other” includes all remaining incidents reported *without indicating* hospitalization or death.

Table 11 provides the summary of the number of individuals ingesting magnets by victim age group and magnet category. The youngest age groups have similar numbers of victims. Of all 176 reported victims, 57 (32.4%) are in the less than 5 age group and 59 (33.5%) are in the 5 to 9 years age group.

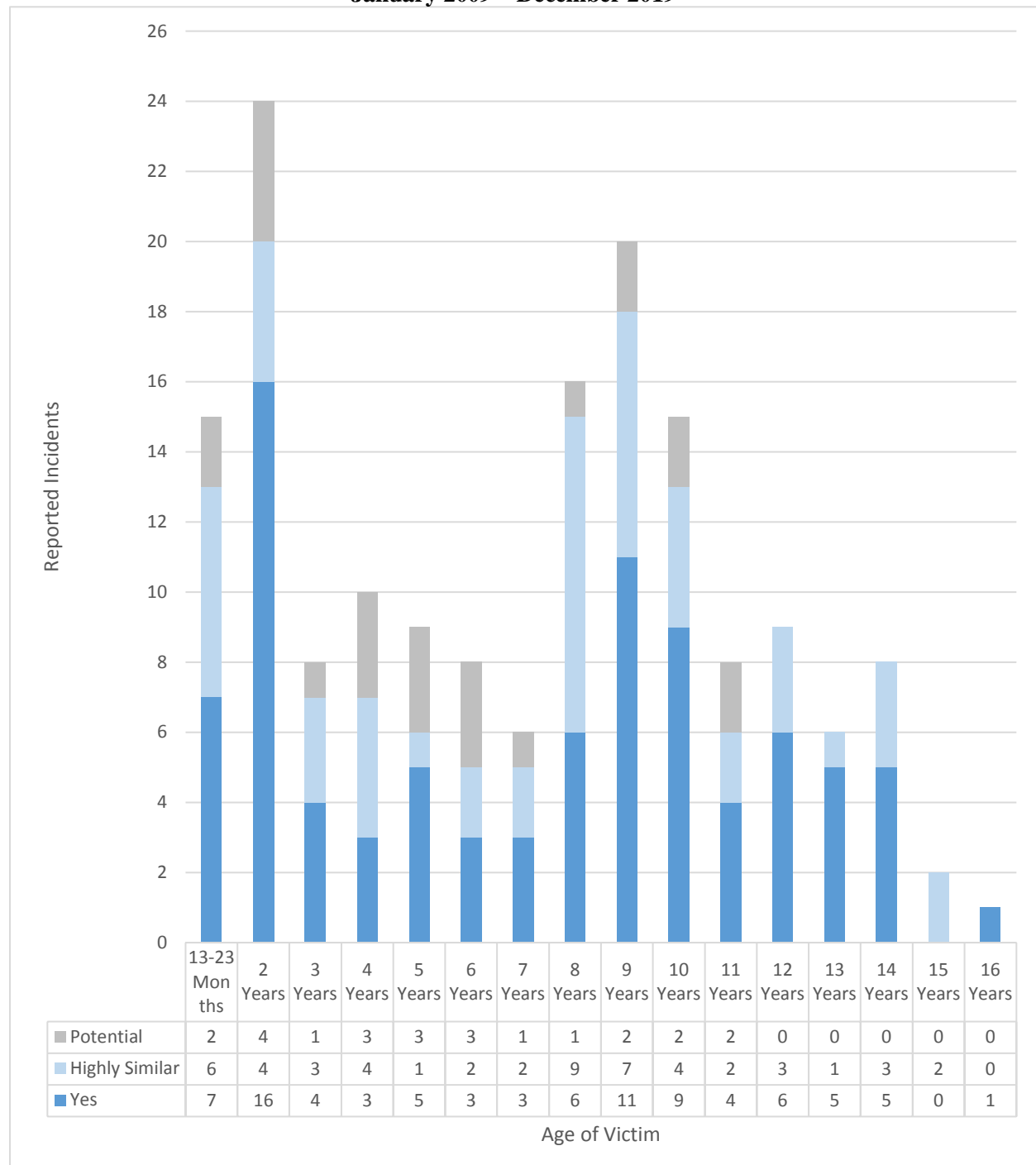
**Table 11: Victim Age Group by Magnet Category for Reported Magnet-Related Ingestions,
January 2009—December 2019***

| Magnet Category | Age Group | | | | |
|-----------------|-----------|-------------------|--------------|-----------|------------|
| | Unknown | Less than 5 years | 5 to 9 years | 10+ years | Total |
| Yes | 10 | 30 | 28 | 30 | 98 |
| Highly Similar | 1 | 17 | 21 | 15 | 54 |
| Potential | 0 | 10 | 10 | 4 | 24 |
| Total | 11 | 57 | 59 | 49 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

Figure 4 provides a histogram by age of individuals ingesting magnets, adding by magnet category. The observed distribution is bimodal (*e.g.*, two frequently indicated ages), with one mode at 2 years of age and the other mode at 9 years of age.

Figure 4: Histogram by Victim Age* and Magnet Category for Reported Magnet-Ingestions, January 2009—December 2019**



*Figure omits 11 incidents of unknown victim age (10 *Yes* and 1 *Highly Similar*), but does count one child as age 15 years despite uncertainty as to whether that child may have instead been age 16 years.

**CPSRMS reporting for the years 2017-2019 is ongoing.

All remaining tables (until the Appendix) compare victim age group against various categories (use pattern, source of magnet, and victim sex, respectively). Comparable tables broken down by magnet category (instead of by age group as below), can be found in the Appendix.

Table 12 provides the reported use pattern at the time of the incident by victim age group. For the 176 reported incidents, 94 victims are reported (53.4%) to have had the magnets in their mouths for a specific reason; while 82 had an unknown or other²⁴ use pattern. Uncertainties appear to be most pronounced for young children; 37 out of 57 (65%) of incidents reported to involve children younger than 5 years are classified as unknown/other use. The oldest age group had many incidents where children reported specifically having the magnets in their mouths to emulate piercings (22/49 or 44.9% of reported ingestions involving children ages 10+). Although some children within the 5 to 9 year age group also exhibited this jewelry imitating-behavior (11/59 or 18.6%), the more frequently observed behavior for 5 to 9 year olds was simply playing with magnets in the mouth (not emulating jewelry) (22/59 or 37.3%). This same mouth play was also reported in the younger and older age groups in about a quarter of reported incidents. One behavior reported, only among the two younger age groups, were children intentionally ingesting or eating the magnets (6/57 or 10.5% of children less than 5 and 5/59 or 8.5% of children 5 to 9).

**Table 12: Use by Victim Age Group for Reported Magnet-Ingestions,
January 2009—December 2019***

| Age Group | Use | | | | |
|--------------|----------------------------|---------------------------------------|----------------------------|----------------|------------|
| | Imitating jewelry in mouth | Playing with in mouth, not as jewelry | Intentionally Ate/Ingested | Unknown/ Other | Total |
| Unknown | 0 | 1 | 0 | 10 | 11 |
| Less than 5 | 0 | 14 | 6 | 37 | 57 |
| 5 to 9 | 11 | 22 | 5 | 21 | 59 |
| 10+ | 22 | 13 | 0 | 14 | 49 |
| Total | 33 | 50 | 11 | 82 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

²⁴ Miscellaneous “other” uses observed: transporting magnet in mouth, because hands were full; hiding magnet in mouth from brother; classmate threw magnet into victim’s mouth; falling off wall board into mouth.

Table 13 summarizes the reported source of the magnet(s), that is, who owned the magnet(s) or how the victim obtained the magnet(s) by the age group of the victim. For children ages 5 and up, only a total of 14 reports (12 for ages 5-9 and 2 for ages 10+) indicated the magnets were owned by a relative, while most reports involving children less than 5 (31/57 or 54.4%) indicated the magnets were owned by a relative. For the 5 to 9 age group, in 26 of 59 reported incidents (44.1%) the ingested magnets were either purchased as a gift for the child (by parent or older sibling), purchased by the victim, or obtained at school and/or from a friend. For the 10+ age group, most that came from a known source were from school, a friend, or a classmate.

**Table 13: Source by Victim Age Group for Reported Magnet-Ingestions,
January 2009—December 2019***

| Magnet Category | Source | | | | | | | Total |
|-----------------|-----------|---------------------|------------------------------|---------------------|----------------------------|----------|-------------------------------|------------|
| | Unknown | Owned by relative** | Purchased as gift for victim | Purchased by victim | School/Friend or Classmate | Neighbor | Found on street or playground | |
| Unknown | 10 | 1 | 0 | 0 | 0 | 0 | 0 | 11 |
| Less than 5 | 23 | 31 | 1 | 0 | 1 | 1 | 0 | 57 |
| 5 to 9 | 18 | 12 | 11 | 2 | 13 | 0 | 3 | 59 |
| 10+ | 23 | 2 | 3 | 2 | 18 | 0 | 1 | 49 |
| Total | 74 | 46 | 15 | 4 | 32 | 1 | 4 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

** This includes several incidents where the victim found the magnets located on the refrigerator (albeit presumably *not* refrigerator-type magnets) and at least one incident in which an adult permitted the child to play with the magnet set.

Finally, **Table 14** gives the incident breakdown by sex and age group. Overall, both males and females appear similarly represented.

**Table 14: Victim Sex by Age Group for Reported Magnet-Ingestions,
January 2009— December 2019***

| Age Group | Sex | | | |
|--------------|----------|-----------|-----------|------------|
| | Unknown | Female | Male | Total |
| Unknown | 5 | 1 | 5 | 11 |
| Less than 5 | 1 | 31 | 25 | 57 |
| 5 to 9 | 0 | 23 | 36 | 59 |
| 10+ | 2 | 30 | 17 | 49 |
| Total | 8 | 85 | 83 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

This table collapses magnet categories together.

Discussion

Based on NEISS data between 2009 and 2018,²⁵ an estimated 18,600 magnet-related ingestions were treated in hospital emergency departments. Of these, an estimated 4,500 involve or *possibly* involve a relevant magnet set. For the remaining 14,000 estimated magnet ingestions, a majority are described only as magnets, without further indication of product type. It is possible that if more information were available, a portion of this estimate could be moved to the “Yes/Possible” magnet category, potentially increasing the estimate substantially. Regardless, we can observe that, overall, there are statistically significant changes in overall magnet ingestions during the 10 years from 2009 through 2018, which do not appear to reflect random variation. The lowest injury estimates are observed during the 2 years from 2015 through 2016. The magnet ingestions during this 2-year period 2015 through 2016, are found significantly less, in comparison to both the subsequent period, 2017 to 2018, and the earlier period, 2011 through 2012. Magnet ingestions during the most recent 2-year period from 2017 through 2018 are found significantly greater than magnet ingestions during each of earlier 2-year periods 2013 through 2014 and 2015 through 2016.

From CPSRMS, a majority of reported ingestions were classified in the “Yes” magnet category. Specifically, of 176 CPSRMS ingestion incidents that staff determined to have a reasonable prospect of involving magnet sets, 98 were determined *Yes*, meaning the product information was specific enough to confirm that the magnets came from magnet sets (generally on the basis of determining the particular brand of magnet set). An additional 54 *Highly Similar* incidents described sizes, shapes, quantities, uses, or terminology consistent with magnet sets, but did not specifically identify a brand. Another 24 incidents were categorized *Potential* on the basis of less available information, but were still consistent with magnet sets. Counts for 2019 and other recent years (2017-2018) may increase as ongoing reporting continues. Among reported ingestions, a similar number of victims appear in both the less than 5 years and 5-to-9-year age groups. The magnets accessed by young children (younger than 5) were typically owned by a relative. In contrast, the 5-to-9-age group of victims commonly had reported access to the magnets through school and/or a friend, or through an adult, intentionally or unintentionally. Three of these victims reportedly found magnets out in the open, on the street or on a playground. For the majority of victims in the age 10+ group, ingestions involved intentionally placing the magnets in their mouth to imitate jewelry or to otherwise play with the magnets in their mouth.

²⁵ NEISS data for 2019 will become available in spring 2020.

Appendix

**Table A1: Use by Magnet Category for Reported Magnet-Ingestions,
January 2009—December 2019***

| Magnet Category | Use | | | | |
|-----------------|----------------------------|---------------------------------------|----------------------------|----------------|------------|
| | Imitating jewelry in mouth | Playing with in mouth, not as jewelry | Intentionally Ate/Ingested | Unknown/ Other | Total |
| Yes | 14 | 31 | 4 | 49 | 98 |
| Highly Similar | 15 | 15 | 6 | 18 | 54 |
| Possible | 4 | 4 | 1 | 15 | 24 |
| Total | 33 | 50 | 11 | 82 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

**Table A2: Source by Magnet Category for Reported Magnet-Ingestions,
January 2009—December 2019***

| Magnet Category | Source | | | | | | | Total |
|-----------------|-----------|---------------------|------------------------------|---------------------|-----------------------------|----------|-------------------------------|------------|
| | Unknown | Owned by relative** | Purchased as gift for victim | Purchased by victim | School/ Friend or Classmate | Neighbor | Found on street or playground | |
| Yes | 37 | 32 | 11 | 4 | 14 | 0 | 0 | 98 |
| Highly Similar | 23 | 6 | 4 | 0 | 16 | 1 | 4 | 54 |
| Potential | 14 | 8 | 0 | 0 | 2 | 0 | 0 | 24 |
| Total | 74 | 46 | 15 | 4 | 32 | 1 | 4 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

** This includes several incidents where the victim found the magnets located on the refrigerator (albeit presumably *not* refrigerator type magnets) and at least one incident in which an adult permitted the child to play with the magnet set.

**Table A3: Victim Sex by Magnet Category for Reported Magnet-Ingestions,
January 2009—December 2019***

| Magnet Category | Sex | | | |
|-----------------|----------|-----------|-----------|------------|
| | Unknown | Female | Male | Total |
| Yes | 7 | 46 | 45 | 98 |
| Highly Similar | 1 | 27 | 26 | 54 |
| Potential | 0 | 12 | 12 | 24 |
| Total | 8 | 85 | 83 | 176 |

*CPSRMS reporting for the years 2017-2019 is ongoing.

References

Garland, S. (2012). Memorandum, Subject: *NEISS estimates and analysis of reported incidents related to ingestion of small, strong magnets that are part of a set of magnets of various sizes*. Bethesda, MD: Division of Hazard Analysis, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

Garland, S. (2014). Memorandum, Subject: *Update to NEISS estimates and reported incidents related to ingestion of magnets from high-powered magnet sets*. Bethesda, MD: Division of Hazard Analysis, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

TAB C: Health Sciences Assessment



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: June 3, 2020

TO: Susan M. Bathalon, Project Manager
Magnet Sets Petition Project Manager
Office of Hazard Identification and Reduction (EXHR)

THROUGH: Jacqueline N. Ferrante, Ph.D., Acting Associate Executive Director
Directorate for Health Sciences (HS)
Division Director
Division for Pharmacology and Physiology Assessment (HSPP)
Directorate for Health Sciences (HS)

FROM: Sandra E. Inkster, Ph.D., Pharmacologist
Division for Pharmacology and Physiology Assessment (HSPP)

SUBJECT: Petition Requesting Rulemaking on Magnet Sets: Health Sciences Considerations and Response to Public Comments.

Introduction

This memorandum addresses health-related aspects of the petition submitted to the U.S. Consumer Product Safety Commission (CPSC, Commission) by Zen Magnets, LLC (Zen, or Petitioner) on August 17, 2017, requesting rulemaking on magnet sets (82 FR 46740, Oct. 6, 2017; docket number CPSC-2017-0037). The memo includes information on the mechanisms of magnet-specific injuries, and it provides updates on information found in previous Health Sciences (HS) staff memoranda regarding the understanding of injury scenarios, treatment, and outcomes related to ingestion of small, powerful magnets in magnet sets marketed to consumers. Lastly, the memo responds to health-related public comments received on the petition.

Background

On September 4, 2012, to address the growing risk of life-threatening internal injury in children resulting from ingestion of magnets found in various magnet set products, CPSC issued a notice of proposed rulemaking (NPR) for magnet set products containing small, powerful hazardous magnets (77 FR 53781). On October 3, 2014, the Commission published the magnet sets final rule (16 CFR Part 1240), which required any individual magnet from a magnet set that could fit within CPSC's small parts test cylinder,²⁶ to have a flux index value of 50 kG²mm² or lower.²⁷

²⁶ See 16 CFR part 1501: the small parts test cylinder has a circular opening measuring 1.25 inches (31.7 mm) diameter and varies in depth from 1 to 2.25 inches (25.5 to 57.1 mm).

This rule became effective on April 1, 2015 (79 FR 59962); however, Zen Magnets, LLC, challenged the rule, which was subsequently vacated by the U.S. Court of Appeals for the Tenth Circuit, on November 22, 2016 (*Zen Magnets, LLC v. Consumer Prod. Safety Comm'n*, 841 F.3d 1141 (10th Cir. 2016)). On March 1, 2017, the Commission voted to remove the rule from the Code of Federal Regulations, effective on March 7, 2017 (82 FR 12716).

Product Description

Magnet sets generally consist of numerous identical, small, powerful magnets. Magnet sets vary in the number of magnets, and the size, shape, and strength of magnets. Sales of magnet set products containing small, powerful magnets resumed shortly after the court vacated the magnet set rule. Many new suppliers who entered the market sell their products exclusively through the Internet (Smith, ECON, Tab E). Most magnet sets sold today contain multiple (27 to >1000) small, identical magnets made from a composite neodymium-iron-boron (NIB) rare earth magnet material. On a size-for-size basis, NIB composites are recognized as the strongest magnet material currently available.²⁸ Different grades of NIB magnet materials are available, where a higher grade number reflects a relatively stronger NIB composite.²⁹ Magnet sets can vary in magnet number, shape, size, and flux level. The most common magnet sets consist of 125, 216, or 1,000 individual 5 millimeter (mm) diameter spheres arranged as a cube; sphere diameters can range from 3 to 6 mm. Other variants include NIB cubes with dimensions ranging from 3 to 5 mm, also typically arranged as cubes of 125, 216, or 1,000 magnets. All individual, spherical, or cube NIB magnets with diameter or side dimensions equal to, or greater than 3 mm that HS staff has examined, to date, had flux index values exceeding 50 kG²mm², as measured by CPSC LSM staff. The Petitioner reports that its 5 mm NIB spherical magnets have flux index values ranging from 400 to 550 kG²mm².

A newer magnet set variant, consisting of 512 or 1,000 individual 2.5 mm diameter NIB spheres (arranged as cubes of 8 x 8 x 8 or 10 x 10 x 10 spheres), is also now being sold in retail stores and via the Internet. These tiny magnets are advertised as having flux index values less than 50

²⁷ Under the Commission's vacated final rule, flux index values were determined by the method described in ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, which defined a "hazardous magnet or magnet component" as a small part (*i.e.*, fitting within CPSC's small parts test cylinder) and having a flux index greater than 50 kG²mm². To mitigate the magnet ingestion hazard, from 2006 to 2007, the ASTM's magnet toy workgroup developed the novel concept of a magnet flux index. Since magnet requirements were introduced into ASTM F963, the flux index has been calculated by "multiplying the area of the pole surface (mm²) of the magnet by the square of the maximum surface flux density (kG²)."²⁸ In addition to the final rule on magnet sets, the Commission's toy standard, in 16 CFR part 1250, incorporates by reference ASTM F963, which includes requirements for magnets in children's toys. Under the toy standard, loose hazardous magnets or magnetic components are banned from toys intended for children up to 14 years of age, unless they are in a science or craft-type kit intended for children over 8 years of age. **NOTE:** there is now a discrepancy between the vacated 2014 magnet set final rule, which prohibited magnets that had a flux index value *exceeding* 50 kG²mm², and the current version of the toy standard, ASTM F963-17. The ASTM F963 definition of a "hazardous magnet" changed from the F963-11 version, which specified a flux index value *exceeding* 50 kG²mm², to the subsequent F963-16 version, which specifies a flux index value *equal to or greater than* 50 kG²mm² (as is found in the current F963-17 version).

²⁸ See <https://www.birmingham.ac.uk/Documents/college-eps/metallurgy/research/Magnetic-Materials-Background/Magnetic-Materials-Background-1-History.pdf> and Moosa, I.O. (2014) History and development of permanent magnets https://www.academia.edu/9175459/History_and_Development_of_Permanent_Magnets

²⁹ See websites of U.S. based industrial magnet suppliers *e.g.*, <https://www.kjmagnetics.com/FAQ.asp> and https://www.apexmagnets.com/faq/what_does_n_rating.

kG²mm², and staff has found advertisements reporting flux index values less than 30 kG²mm² for magnet sets containing individual magnet spheres with diameters ranging from 2.5 to 5 mm.^{30,31}

The Petition

The Petition requests the Commission to initiate rulemaking “to establish standards for magnet sets that are intended or marketed to be used with or as magnet sets.” The Petitioner acknowledges that misuse of strong magnets in magnet sets can pose a safety risk, if “they are ingested, aspirated or otherwise inserted into the human body,” and in particular, notes the risk of gastrointestinal (GI) injury if more than one magnet is ingested. The Petitioner also acknowledges that there are medical, societal, and other intangible costs related to magnet injuries.

The Petitioner provides specific recommendations for a magnet safety regulation that would differentiate between magnet sets intended for children under 14 years of age versus those intended for older children and adults. For magnet sets intended for children under 14 years, the Petitioner requests that, consistent with ASTM F963, and thus, 16 CFR part 1250, each magnet in a magnet set that fits completely within the small parts cylinder have a flux index of 50 kG²mm² or less. Part of the Petitioner’s rationale for this limit is based on an assumption that “magnets with a flux index of less than 50 lack the magnetic strength to attach across internal tissue and cause internal injury.” For magnet sets that are not intended for children under 14 years, the Petitioner requests requirements for magnet set packaging, warnings, and instructions.

Mechanisms of Magnet Ingestion Injuries

In medical terminology, the majority of magnet ingestion injuries are pressure necrosis injuries. The unique mechanism of injury involving harmful tissue compression by strong magnets (primarily, but not exclusively, NIB magnets) is now established (Alfonzo, Baum, 2016; Reeves, Nylund, *et al.*, 2018). When ingested, the reach of the magnetic fields allows strong magnets to be mutually attracted to each other through intestinal walls, and interaction occurs rapidly and forcibly. HS staff has observed that magnetic attraction between a pair of 5 mm spherical magnets can occur at distances over 40 mm; interaction distances can be greater as the number of magnets increases.

The attraction force operating between just one pair of magnets (or a magnet and another ferromagnetic object) is strong enough to withstand any normal muscular contractions of the GI tissues (peristaltic or mixing motions), as well as the intermittent turbulent flow of the considerable volumes of GI fluid in the small intestine, or the passage of semi-solid contents in the large intestine. HS staff is unaware of any incidents where the magnets became uncoupled on their own; unless removed by medical intervention, the magnets will remain coupled, exerting strong bilateral compression forces on the trapped GI tissues, sufficient to block the blood and nutrient supply. The compression forces also squeeze out fluids from the trapped tissues, rapidly reducing the gut wall thickness to micron values, and essentially mummifying the tissue *in situ*.

³⁰ Product information for some says they “meet all safety standards,” with ASTM and EN 71 children’s toy standards and CPSC’s CPSIA cited specifically.

³¹ Personal communication from CPSC Human Factors colleague, Stephen Harsanyi.

The extreme supra-physiological pressure exerted on the trapped tissues ultimately is directly responsible for progressive tissue injury, which starts with local inflammation and ulceration, progressing to tissue death, then perforation or fistula formation. Perforations present a serious risk of leakage of gut contents into the abdominal cavity. Within hours, this can escalate from an area of local infection, to infection of the abdominal cavity and its organs (secondary peritonitis), then life-threatening systemic infection (sepsis). Fistula formation appears to represent a slower rate of tissue damage, which allows cells at the margin of the pressure necrosis area to remain viable and then undergo remodeling to form an abnormal open channel between two previously unconnected gut areas. The abnormal fistula connections can allow GI contents to by-pass some GI segments so that passage through the intestines is shorter and faster, which can negatively impact digestion of food, nutrient uptake, and processing of waste materials. Fistulas can cause serious, debilitating symptoms, but generally are not as acutely urgent as perforations.

The worst-case, acute magnet ingestion-related injury involving spherical NIB magnets is now recognized to be a fatal volvulus injury; *i.e.*, where the intestine becomes twisted, obstructing the passage of gut contents and depriving the twisted gut segment of blood. This can occur rapidly when as few as two ingested 5 mm spherical NIB magnets in different locations attract through the intestinal walls. The mesentery tissues are specialized connective tissues that contain the nerves and blood and lymph vessels of the intestines and maintain the position of the intestines in the abdominal cavity. The mesentery tissues loosely connect the intestines to the posterior abdominal wall, which allows a considerable range of unrestricted intestinal movement during digestion. The relatively short mesentery connections of the duodenum and the ileo-cecal region of the small intestine are exceptions that anchor these two areas in more fixed positions, restricting their movement and predisposing them to being sites of volvulus injury. A volvulus injury (and any intestinal blockage) is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped gut segment from dying, then rupturing to result in contamination of the abdominal cavity. Delayed recognition and relief of volvulus injury can prove fatal. It is also noted that ingested magnets have trapped and perforated mesenteric tissues, presenting the possibility that larger blood vessels in the gut mesentery could be damaged, which could cause an intra-abdominal hemorrhage.

Some relevant information on the timing of tissue injury during compression by NIB magnets is known from unintentional injury to external body locations (*e.g.*, ears, nasal septum, lips, tongue frenulum, and genitals) (see Inkster, 2008, 2012). Greater understanding of the pressure levels and duration needed to cause injury to different tissues has come from intentional, therapeutic use of magnets in early research studies and clinical trials. In these studies, the level and duration of pressure applied to tissues was slowed and controlled (by varying size, shape, and material of novel magnetic devices) to facilitate desirable cellular death and tissue remodeling, as opposed to causing devastating cell and tissue injuries. The body of medical literature on therapeutic use of magnets has grown significantly since staff last reviewed the information for the magnet set ANPR.³²

³² Therapeutic, controlled magnet tissue compression has been used to reconnect GI segments (resected colon, or stomach and small intestine) and to reconnect cardiac blood vessels (resected during coronary bypass surgery) without using any sutures (*i.e.*, in medical terms, to achieve suture-less magnetic compression anastomoses). Therapeutic controlled magnet tissue compression has also been used to remove built up tissues causing harmful bile

Magnet Ingestion Injuries

Previous HS staff memoranda provided detailed descriptions of selected magnet set incidents and HS staff's evolving understanding of intestinal injuries resulting from ingestion of small, extremely powerful magnets (Inkster, 2008, 2012, and 2014³³). Below, HS staff summarizes part of its most detailed 2012 description and updates it, based on new information from reports of injuries specifically related to ingestion of spherical NIB magnets of the sizes found in currently marketed magnet sets.

Typically, but not exclusively, magnets involved in ingestion injuries reported to CPSC, or documented in the medical literature, are NIB-type magnets. This is true because the underlying mechanisms involved in NIB-type magnet injuries are the same, regardless of whether the magnets came from magnet sets considered to be subject products of this petition (*i.e.*, sets of numerous individual, identical, small powerful magnets) or from different types of toy products intended for children under 14 years of age (*e.g.*, construction sets, playsets, action figures). Although children's toys are not the focus of this briefing package (as they are covered by the Commission's toy standard, *i.e.*, the magnet requirements in ASTM F963), this section includes some discussion of injuries involving magnets in children's toys because staff's first understanding of magnet ingestion injury mechanisms came from incident data involving children's toys, which, in 2006, prompted staff to review the available medical literature on magnet injuries.

Typically, the small NIB magnets used in early children's magnet toys, recalled before ASTM F963 magnet requirements were developed, were cylinders or thin discs, rather than the spheres or cube-shaped magnets found in most magnet sets that are the subject of the petition. However, ingestion of just one cylinder-shaped magnet from a children's construction toy was found capable of causing magnet GI injuries when interacting with another construction toy component that was not a magnet, but could be attracted by a magnet (*i.e.*, a ferromagnetic stainless steel ball). The contact point between a magnet cylinder and a stainless steel ball from a child's construction set has the same area as the contact point between two spherical magnets from a magnet set, regardless of any sphere size. Additionally, the contact area between the opposing poles of two 5 mm diameter NIB magnet discs is reasonably similar to the contact area between two 5 mm NIB magnet cubes. As such, the types of injuries that can result from ingestion of NIB magnets from either product type are recognized to be similar, if not identical.

The potential for a fatal outcome due to ingestion of strong magnets was first recognized after the November 2005 death of a 20-month-old boy who ingested 9 cylindrical NIB magnets (6 mm diameter x 4 mm height discs) from an older sibling's construction toy. He died 40 hours after first vomiting and less than 1 hour after he was brought to a hospital emergency department.

duct blockage in patients who had pancreatic cancer or who had received a liver transplant (see Lambe, Riordain *et al.*, 2014; Hu and Ye, 2019).

³³ See Inkster 2008 (Tab B in magnet team 2008 status update package for senior management);

Inkster 2012 (Tab C in Magnet Sets 2012 NPR staff briefing package at https://www.cpsc.gov/s3fs-public/pdfs/foia_magnetstd.pdf;

Inkster 2014 (Tab E in Magnet Set 2014 Final Rule staff briefing package at https://www.cpsc.gov/s3fs-public/pdfs/blk_media_SafetyStandardforMagnetSets-FinalRule.pdf.

Autopsy revealed that the magnets, in different segments of his GI tract, attracted to each other through his intestinal walls. This caused the small intestine to twist on itself (volvulus injury), resulting in a GI blockage and loss of blood supply that led to necrosis and sepsis. The magnets also perforated the intestinal wall, but the primary cause of death was attributed to the magnet-induced volvulus injury (IDI 051213CCC3192). Due to this death, and the rapid increase in reports of children sustaining serious GI injuries requiring medical intervention resulting from ingestion of NIB magnets from various children's toy products, several toy products were recalled,³⁴ and ASTM established a magnet toy workgroup in summer 2006, which ultimately led to the addition of magnet requirements in ASTM F963.

Details of Fatalities Resulting from Ingestion of 5 mm Diameter Spherical Magnets

At the time of HS staff's 2012 NPR memorandum, staff was unaware of any deaths or volvulus injuries involving spherical magnets from magnet sets. When the magnet sets final rule was published in 2014, staff was aware of two children's deaths resulting from ingestion of multiple 5 mm NIB magnet spheres, one in Australia, and one in the United States (Inkster, 2014). Since then, staff has learned of another two deaths (one in the United States, and one in Poland) that also involved ingestion of 5 mm NIB spheres. Key details of these deaths³⁵ are summarized in Table. 1, and specific case details are provided below.

| Table 1. Summary Details of Children's Deaths Due to Ingestion of 5 mm Diameter NIB Magnet Spheres | | | | | | | |
|--|-----------------------------|-----------|-----------------|----------------------|--|--|--|
| Year Death | When Staff Learned of Death | Where | Victim Age, Sex | No. Magnets Ingested | Source Magnet Product | Cause of Death | Report Source |
| 2011 | 2012 | Australia | 18mM | 12 | Not clearly specified, but magnet set implied by Australian Government | No specific details | CPSC: Magnet Set ANPR Public Comment #2012-0050-1057 |
| 2013 | 2014 | USA | 19mF | 7 | Unknown | small intestine ischemia | CPSC: IPII X1410862A; IDI 140115CAA2304 |
| 2014 | 2018 | Poland | 8yM | 2 | Not clearly specified, but magnet set implied by report authors | small intestine ischemia due to twisting (volvulus injury) | Medical Literature: Olczak M, Skrzypek E (2015) Legal Medicine 17: 184-18; A case of child death caused by intestinal volvulus due to magnetic toy ingestion |
| 2018 | 2018 | USA | 2yM | 14 | Unknown | small intestine ischemia due to twisting (volvulus injury) | CPSC: IPII X18C0046A; IDI 181206CCC2102 |

³⁴ Serious gastrointestinal injuries are known to have occurred following ingestion of cylindrical or thin disc NIB magnets used in various recalled children's toys: *e.g.*, construction sets (03/31/06, recall #06-127 and 04/19/07, recall #07-164), playsets (11/21/06, recall #07-039), and toy figures (03/17/08, recall #08-223).

³⁵ HS staff included case details for the two children's deaths overseas to provide reported information on injury specifics, and on magnet type and number; typically, deaths that occur in foreign countries are not reported to CPSC's databases, and therefore, are not included in EPHA staff's data analyses in Tab B.

The 2011 death of a child in Australia, due to ingestion of small, spherical magnets, was first reported to CPSC in a public comment on the 2012 magnet sets NPR. CPSC staff's research found only limited details regarding the circumstances of this death, which apparently occurred in Queensland in late 2011, and involved 12 magnets ingested by an 18-month-old child. Although the specific source product involved was not identified, HS staff notes that this fatality was cited in the announcements of bans prohibiting sale of magnet set products, issued by the Australian and New Zealand governments. The announcements and media reports included text and photos describing products appearing similar, if not identical, to magnet set products that are the subject of this petition (see <https://www.productsafety.gov.au/news/wa-dangerous-magnets-banned-after-child-death-and-injuries>; <https://www.watoday.com.au/national/western-australia/injured-children-sparks-magnet-ban-20120823-24o84.html> and <https://www.beehive.govt.nz/release/ban-sale-high-powered-magnet-sets> also found as IPII X2010303A).

The 2013 U.S. based-death of a 19-month-old girl due to ischemia of the small bowel, caused by ingestion of 7 “very magnetic” 5 mm diameter, colored spheres was first reported to CPSC by a coroner's office, in early 2014 (X1410862A). The evening before she died, the girl was seen for symptoms of vomiting and diarrhea, then treated and released from the same hospital emergency department where she was pronounced dead the following morning, after her mother had found her lying unresponsive on her mattress. The ingested magnets were not discovered until autopsy, which noted they were found in a linear formation within her small intestine. Follow-up investigation reported that the mother was aware that one of her sons had obtained about 20 or 30 of the 5 mm magnet spheres from a 10- or 11-year-old neighbor. The mother advised that she had no idea that her daughter had ingested any of the magnets and, she noted that her daughter had been discharged from the first ER visit pending test results for a suspected strep throat infection. The recovered magnets have identical physical characteristics to spheres found in magnet set products, but their specific source product was not identified (IDI 140115CAA2304),

The 2014 death of an 8-year-old boy in Poland is of special note because it involves ingestion of just two 5 mm diameter NIB spheres that caused a volvulus injury. The boy had a 1-day history of bloody vomiting, then lost consciousness during examination in an emergency department (ED), and could not be resuscitated. At autopsy, two 5 mm NIB spheres were found in the distal small intestine and the entry to the large intestine, just below the ileocecal valve. A loop of twisted small intestine and bowel mesentery, with hemorrhagic necrosis of the intestine and bloody fluid contamination of the abdominal cavity was found. Although the specific source product for the two magnets was not clearly established, in drawing attention to the magnet ingestion hazard, the authors' final sentence states: *“Although producers claim that the magnetic toys are marketed only to adults (with labels warning on their danger to children), the problem still occurs (see Fig. 3).”* Their Fig. 3 is a photo of a “magnetic toy” showing more than a hundred 5 mm spheres identical to those retrieved from the victim (Olczak, Skrzypek, 2015).

The most recent 2018 U.S.-based death of a 2-year-old boy, due to ischemia of the small intestine caused by ingested “magnetic beads,” was first reported to CPSC by a medical examiner, within days of the fatality. The report stated: *“At autopsy, it was found that the decedent had ischemia of essentially all the small intestine due to torsion of distal ileum through a small intestinal loop created by the magnetic metallic beads”* (IPII X18C0046A). Follow-up investigation reported that the boy had stomach pains and was vomiting for 48 hours before he died. He was treated and released from an emergency room for these symptoms the evening

before he died, then had a very restless night. The next morning, when his mother returned home after dropping her older children at school, she found him non-responsive and ice cold. First responders to the scene pronounced the boy dead after rigor mortis (stiffening) was noted in his extremities. The full autopsy report attributed cause of death to “*Complications of small intestinal ischemia and obstruction due to small intestinal torsion due to ingestion of magnetic beads.*” Fourteen multicolored 5 mm diameter magnetic spheres recovered from his small intestine were seen, in post mortem x-ray images, to form a ring-shaped entity in his upper abdominal cavity. According to case records, the mother had no idea that her son had access to any magnets and had no idea where or how he got them. The recovered magnets have identical physical characteristics to spheres found in magnet set products, but their specific source product was not identified (IDI 181206CCC2102).

In addition to these four deaths, multiple additional magnet ingestion injuries have been reported involving spherical magnets, many of which required surgical intervention (see Topping, EPHA, Tab B; Harsanyi ESHF, Tab D).

Magnet Set Ingestion Scenarios, Injuries, Treatments, and Outcomes

Based on the cumulative information on deaths and injuries involving 5 mm magnet spheres, HS staff has updated its prior five categories of magnet set ingestion scenarios, injuries, treatments, and outcomes, and has added a sixth category for known fatal outcome, as follows:

1. Ingestion of a single magnet that passes through the GI tract uneventfully, but that can be monitored during passage, using one or more serial x-ray images.
2. Ingestion of two or more joined magnets that pass through the GI tract uneventfully, but that can be monitored using one or more serial x-ray images by health care professionals who are aware of the GI-MSI potential.
3. Ingestion of two or more magnets that are identified by x-ray imaging and that are removed from the stomach or small intestine via endoscopy shortly after ingestion and prior to causing any serious internal injuries.
4. Ingestion of two or more magnets that presents when the patient has had nonspecific GI symptoms for some time, indicating serious internal injury has started; health care professionals, who have a good understanding of the magnet ingestion hazard, immediately recognize this as an urgent situation requiring surgical intervention to remove magnets and repair any damage.
 - Least invasive surgical intervention involves laparoscopic access to the intestines to facilitate removal of some, or all, of the magnets, by endoscopy or colonoscopy.
 - In higher-severity cases, magnets are removed via enterectomy (a small incision made in the bowel wall).
 - In the most serious cases, more invasive open laparotomy might be needed to remove the magnets.
5. In more severe cases, patients who ingested two or more magnets, present after first becoming symptomatic, when serious internal injury has started, but where the urgency of the situation is not recognized immediately by caregivers and/or health care professionals. They may be totally unaware of magnet ingestion or may believe incorrectly that the objects (which may or may not be understood to be magnets) will be

voided naturally. This delays necessary surgical intervention, allowing significant worsening of life-threatening internal injuries and increased risk of serious complications (volvulus injuries are not as frequent as perforation injuries, but are more urgent). Serious complications can also result when medical professionals fail to appreciate that multiple bowel walls might be involved during a single event of magnet interaction; after finding and repairing two perforation sites, other perforations sites can be overlooked, which results in continued leakage of bowel contents into the abdominal cavity and much worsening risk of local infection, then systemic infection (septicemia).

- Higher-severity injuries tend to require more invasive surgical intervention (open laparotomy).
 - Some injuries may necessitate an appendectomy, and/or repair of damaged intestinal/stomach walls that might require removal (resection) of damaged segments of bowel tissue. The risk of short- and long-term complications is significantly greater with a laparotomy, compared to a laparoscopy.
6. In the worst-case scenarios, ingestion of small NIB magnet spheres results in a child's death, either at home, or shortly after being brought to a hospital. The few known magnet ingestion-related fatalities suggest volvulus injuries present a particularly serious acute risk of death, especially when intervention is delayed because magnet ingestion is not considered and/or nonspecific GI symptoms are not recognized as an urgent, rapidly escalating situation by caregivers and/or healthcare professionals.

Victims who survive serious magnet ingestion injuries may have post-operative complications of abdominal surgeries, including bleeding, infection, and ileus (temporary paralysis of gut motility). Adhesions (where bands of intraabdominal scar tissue form that can interfere with gut movement and can cause obstruction) are an adverse post-operative effect that may occur as a short-term or long-term (years) complication; frequently, this results in bowel obstructions requiring additional surgeries, and thus, creates a negative cycle. Female victims can have future fertility concerns related to such abdominal scar tissues and adhesions affecting reproductive organs. In cases where long segments of injured bowel have to be removed, digestive function of victims can be impaired permanently, resulting in malabsorption, diarrhea, cramping, and need for total parenteral nutritional feeding (and consequent frequent bouts of sepsis), and even death. This is a particular concern when the segment of bowel removed includes the important ileocecal valve, located at the junction of the small and large intestine, which controls flow of bowel contents, and hence, greatly impacts digestive function. In one of the most serious non-fatal cases, a 23-month-old boy who ingested eight spherical magnets, required multiple surgeries and lost most of his small intestine, leaving him in need of a bowel transplant (see IDI 120419CBB3615).

Public Comments on the Zen Petition

CPSC received several public comments supporting the need for a magnet set regulation based on a flux index limit of $50 \text{ kG}^2 \text{ mm}^2$ that is commonly used to identify hazardous magnets (by the Petitioner and ASTM F963-17). Some of these comments also drew attention to the reliability of the $50 \text{ kG}^2 \text{ mm}^2$ flux index cut-off value in preventing injury:

- Comment # 2017-0037-0007 (from a consumer) asserts that magnets that have a flux index less than $50 \text{ kG}^2 \text{ mm}^2$ are “*not strong enough to tear through human tissue.*”

- Comments #2017-0037-0016 and 0017 (from a student studying regulation) notes that *“it is necessary to confirm that the claim that the reduced strength of magnets [less than 50 kG²mm²] ensures that the magnets will not attach across internal tissues and cause damage upon ingestion.”*
- Comment #2017-0037-0021 (joint submission from five consumer advocacy groups and two professional medical societies) specifically urges the CPSC *“to continue to study the issue of whether its previous safety standard is adequate to protect against the potential hazards of magnets with a lower magnetic flux as it indicated it would do in the 2014 final rule.”* The commenters draw particular attention to a magnet set product promoted as having a flux index of less than 30 kG²mm², which they claim *“could conceivably connect across the bowel wall of a child and cause intestinal perforation or other significant injuries.”*

HS Staff Response:

If the Commission grants the petition and proceeds with rulemaking, staff supports the commenters’ suggestion to examine what strength limits are appropriate to adequately reduce the risk of injury from magnet set ingestions. As the briefing memorandum for the 2014 final rule acknowledged, *“Health Sciences staff believes that rare earth magnets with a flux index below 50 kG²mm² may have the potential to cause injury, depending on their size, shape, and material grade”* (Midgett, 2014). It is of serious concern that in the last 2 years, CPSC has received at least two reports of children ingesting 2.5 mm NIB spheres from a magnet set advertised as having a flux index value less than 50 kG²mm²; both victims required medical intervention to remove the magnets. Those incidents are described below.

HS staff’s review of the first of these incidents found misleading information in the IDI narrative for the 2018 case involving a 10-year-old girl, who had a small bowel transplant, as an infant, (IDI 181212CBB3124). It reports that after the victim complained of abdominal pain, her mother *“was advised to bring the victim to the emergency room. X-rays were taken of the victim’s abdomen, which revealed 26 spherical objects lodged in the intestine. The victim was immediately taken into surgery, where an endoscopy was done to remove 25 of the 26 objects.”* In fact, the available medical records report that the girl was admitted to a hospital via the ER due to complaints of abdominal pain. Despite early x-rays, magnet ingestion was not immediately recognized. She was transferred for treatment after it was eventually recognized that she had ingested 26 x 2.5 mm NIB spheres, which, in later x-ray reports, were described as *“a radiopaque foreign body likely representing swallowed jewelry such as a small bracelet.”* According to details in the IPII report (I18C0106A), the magnets were located in groups of 4 to 5 spheres in different segments of her GI tract. The separate groups of magnets had attracted to each other through separate areas of her intestinal wall, and, as the compression injury process developed, they became embedded in her intestinal walls. She required two endoscopic procedures to remove the magnets, and at least one of these procedures was done 4 days after she had first been admitted. HS staff does not have access to the surgical reports, but according to her mother, the child did not sustain a perforation injury. HS staff believes that without medical intervention, either fistula or potentially life-threatening perforation injury would likely have resulted. Note: available medical records indicate that a radiopaque spherical entity was seen in

follow up x-rays taken 12 days and 20 days after the girl had first been admitted, then discharged, after removal of 25 magnet spheres. It is not clear whether this is a residual magnet that was not retrieved during the two endoscopic procedures, or a new magnet that the girl might have ingested after being discharged.

Regarding the second case, which occurred in 2019, and involved the unintentional ingestion of 2 x 2.5 mm NIB spheres by a 5-year-old boy, it is unclear from the available records if any magnet compression injury of GI tissues occurred. However, the boy was transferred and admitted to a children's hospital, where over the course of 6 days, several unsuccessful attempts to remove the magnets were made, before their eventual removal by an appendectomy (IPII I19A0168A; IDI 191015CCC1039).

HS Staff's Conclusion

HS staff believes that based on the current injury reports found in CPSC databases and in the medical literature, a standard is necessary to address the hazards associated with children's magnet ingestion injuries.

References

- Alfonzo, M.J., Baum, C.R., (2016) *Magnetic Foreign Body Ingestions*. Pediatric Emergency Care 32:698-702.
- Harsanyi S. (2020) Current Petition Human Factors Memorandum, Tab D: *Human Factors Assessment of the Petitioner's Proposal and Response to Public Comments*. Division of Human Factors, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission.
- Hu, B., and Ye, L.S. (2019) *Endoscopic applications of magnets for the treatment of gastrointestinal diseases*. World J Gastrointest Endosc. 11:548-560.
- Inkster, S.E. (2008). HS Memorandum from magnet team status update package for upper management, Tab B: Review and analysis of the medical literature on magnet-specific injuries (MSIs); description of the gastrointestinal tract structure and function in relation to an analysis of the likely intestinal injury mechanisms involved in MSIs; comments on existing standards defining hazardous magnets, and suggested future considerations. Bethesda, MD: Directorate for Health Sciences, U.S. Consumer Product Safety Commission.
- Inkster, S.E. (2012). ANPR Memorandum, Tab C: *Assessment of injuries, complications, and acute and long-term health effects related to ingestion of magnets from magnet sets*. Bethesda, MD: Directorate for Health Sciences, U.S. Consumer Product Safety Commission. https://www.cpsc.gov/s3fs-public/pdfs/foia_magnetstd.pdf
- Inkster, S.E. (2014). Magnet Sets Final Rule Memorandum, Tab E: *Response to Public Comments Received on the NPR on Magnet Sets Concerning Medical and Health Sciences-Related Issues*. Bethesda, MD: Directorate for Health Sciences, U.S. Consumer Product Safety Commission. https://www.cpsc.gov/s3fs-public/pdfs/blk_media_SafetyStandardforMagnetSets-FinalRule.pdf
- Lambe, T, Riordain, MG, Cahill, RA, Cantillon-Murphy, P (2014) Magnetic compression in gastrointestinal and bilioenteric anastomosis: how much force? Surg. Innov. (2014) 21:65-73.
- Midgett J.M, (2014) Briefing Memorandum, Final Rule for Magnet Sets. Bethesda, MD: Office of hazard Identification and Reduction, U.S. Consumer Product Safety Commission.

https://www.cpsc.gov/s3fs-public/pdfs/blk_media_SafetyStandardforMagnetSets-FinalRule.pdf

- Mordecai, B. (2020) Current Petition Memorandum, Tab F: *LSM Existing standards and analysis of magnetic strength of magnet sets*, Bethesda, MD, Directorate for Laboratory Sciences, Division of Mechanical Engineering, U.S. Consumer Product Safety Commission.
- Olczak M, Skrzypek E (2015) A case of child death caused by intestinal volvulus due to magnetic toy ingestion. *Legal Medicine* 17: 184-18.
- Reeves, P.T, Nylund, C.M., Krishnamurthy J., Noel, R.A., Abbas, M.I. (2018) Trends in magnet ingestions in children, an ironic attraction. *J.P.G.N.* 66:e116-e121.
- Smith, C.L. (2020) Current Petition Economics Memorandum, Tab E: *Petition requesting rulemaking on magnet sets: economic considerations*. Bethesda, MD: Directorate for Economic Analysis, U.S. Consumer Product Safety Commission.
- Topping, J. (2020). Current Petition Human Factors Memorandum, Tab B: *NEISS estimates and analysis of reported incidents related to ingestion of magnets of various shapes and sizes from or possibly from magnet sets*. Bethesda, MD: Directorate for Epidemiology, Division of Hazard Analysis, U.S. Consumer Product Safety Commission.

TAB D: Human Factors Assessment



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

Memorandum

Date: June 3, 2020

TO: Susan Bathalon
Magnet Sets Petition Project Manager
Office of Hazard Identification and Reduction

FROM: Stephen Harsanyi, Engineering Psychologist
Division of Human Factors, Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Division Director
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of the Petitioner's Proposal and Response to Public Comments

I. Introduction

On August 17, 2017, Zen Magnets, LLC (Petitioner), petitioned the U.S. Consumer Product Safety Commission (CPSC) to initiate rulemaking to mandate safety standards for magnet sets. For this briefing package, staff considered magnet sets to generally consist of numerous identical, small, powerful magnets. Magnet sets vary in the number of magnets, and the size, shape, and strength of the magnets. The Petitioner does not define "magnet sets," but describes the subject products as sets of small, rare-earth magnets of various shapes, sizes, and flux indices, which are intended for artistic, educational, and therapeutic benefits. CPSC staff has found such sets commonly to be sold with hundreds of individual magnets, typically marketed as building sets, puzzles, and fidget toys.

The Petitioner requests two distinct safety standards for magnet sets: (1) for magnet sets "designed, marketed, or manufactured for children under the age of 14," each magnet that fits entirely within the "small parts cylinder" described in 16 CFR § 1501.4 shall have a flux index of $50 \text{ kG}^2\text{mm}^2$ or lower, and (2) for "general purpose" magnet sets, *i.e.*, for individuals 14 years of age and older, establish requirements for labeling, instructions, and packaging. Specifically, the Petitioner recommends the following for "general purpose" magnet sets: conspicuous warnings and age labels, safety instructions for returning the entire set to its package after use, "child-resistant" (CR) packaging, and some form of visual confirmation that all of the magnets in the set have been returned to their original container.

The Petitioner acknowledges that serious internal injuries can occur from the ingestion of two or more high-powered magnets, such as those found in magnet sets. As discussed in detail in the Directorate for Health Sciences (HS) memorandum in Tab C (Inkster, 2020), if a high-powered magnet and a ferromagnetic object or two or more high-powered magnets are ingested, they can attract each other through the walls of the gastrointestinal tract, causing serious injury and even death. HS staff describes the worst-case scenario as ingested magnets causing the intestine to

twist on itself, resulting in acute, life-threatening intestinal blockage (*i.e.*, a volvulus injury), which has been known to have caused children's deaths. Further complicating the issue, treatments for magnet ingestion-related injuries often are delayed because the symptoms frequently are misdiagnosed and not severe until serious injury has occurred.

In this memorandum, staff of the CPSC's Engineering Sciences Division of Human Factors (ESHF) provides: (1) findings from magnet ingestion incident data, (2) an examination of product marketing and consumer reviews, (3) an analysis of the Petitioner's human factors-related requests, (4) responses to human factors-related public comments regarding the petition, and (5) a summary of voluntary standard efforts for "adult" magnet sets.

II. Findings from Magnet Ingestion Incident Data

According to the Division of Hazard Analysis (EPHA) memorandum in Tab B (Topping, 2020), an estimated 4,500 magnet-related ingestions from, or possibly from, magnet sets³⁶ were treated in hospital emergency departments from January 1, 2009 through December 31, 2018, based on the reports obtained through the National Electronic Injury Surveillance System (NEISS). The estimated 4,500 cases involved magnets that either were from or possibly from magnet sets (possibly from means that the incident descriptions indicated that the magnets met at least some criteria consistent with magnet sets but it could not be definitively established that they were from magnet sets). A portion of an additional 14,000 estimated emergency-room treated ingestions of magnets during this period may also involve magnet sets.

For this memorandum, ESHF staff examined incident data from CPSC's Consumer Product Safety Risk Management System (CPSRMS).³⁷ The CPSRMS data typically provided more information than the NEISS data; so ESHF and EPHA staff separated the relevant or possibly relevant magnet ingestions into three groupings based on the level of product identification in the incident reports: (1) "Yes," (2) "Highly Similar," and (3) "Potential." The groupings are described in detail in the EPHA memorandum. At the time of staff's examination, there were CPSRMS reports for 176 magnet ingestions that occurred from January 2010 through December 2019, which involved products categorized in these three groupings. Staff classified 98 of the ingestions (~56%) as "Yes," 54 (~31%) as "Highly Similar," and 24 (~14%) as "Potential."

ESHF staff reviewed each CPSRMS incident report for the following factors: victim age, victim sex, number of magnets ingested, magnet size, magnet shape, use scenario, ingestion awareness, delay between ingestion and correct diagnosis, occurrence of misdiagnosis, source of access, presence of packaging when magnets were acquired by the victim or victim's household, and presence of age labels and magnet ingestion hazard warning(s) originally with the product. The magnets involved in the reported incidents typically were 5-millimeter diameter spheres, most

³⁶ In this memorandum, unless otherwise specified, "magnet set" refers to magnet set products manufactured, marketed, intended, or some combination of these factors, consistent with the magnet set product identified by the Petitioner. For the purpose of this memorandum, staff's use of "magnet set" excludes irrelevant magnet set products, such as children's tile building sets with encased magnets, and sets of magnets in jewelry products.

³⁷ The reported incidents in the CPSRMS database do not provide a complete count of all incidents that occurred during the period of interest. However, they do provide a minimum number for the incidents occurring during this period and may illustrate the circumstances involved in the incidents.

often described as “rare-earth” magnets, and commonly sold in sets of 216 to 222 magnets.³⁸ The ages of the victims are known for 165 of the 176 magnet ingestions (Figure 1).

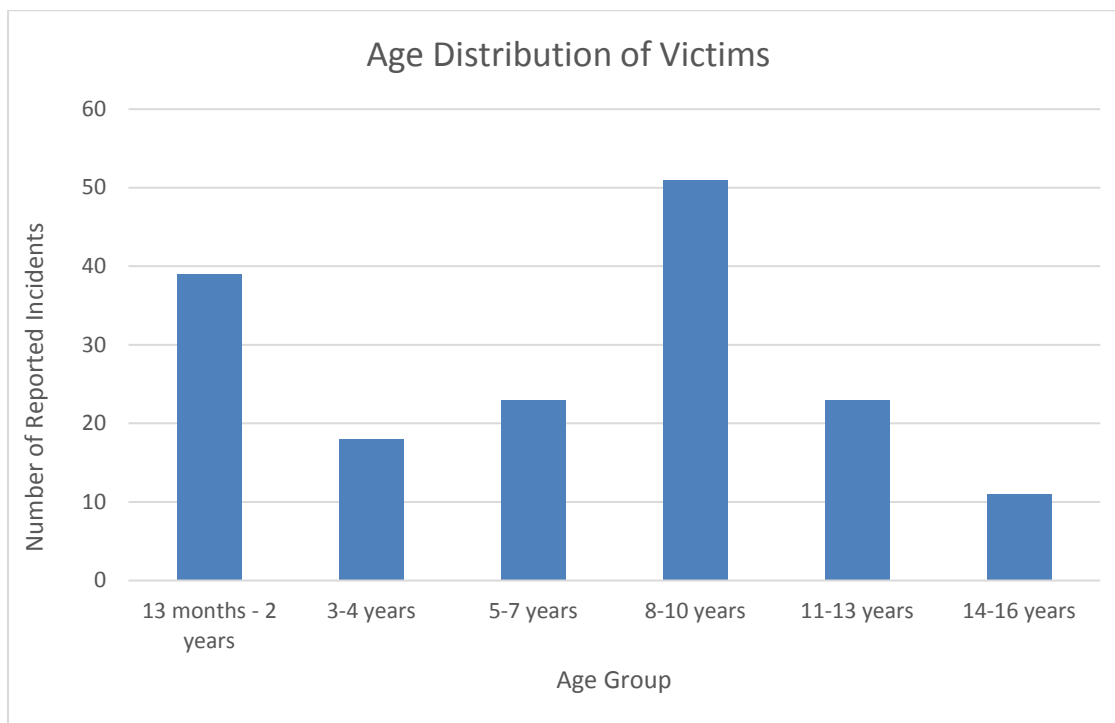


Figure 1. Ages of victims among 165 magnet ingestions (excludes 11 cases in which age was not reported).

Of the 165 victims with known ages, the most common age reported was 2 years (~15% of victims with known ages). Approximately 76 percent of the victims were children 3 years or older, and more than half of the victims (~52%) were children ages 8 years or older, whom caregivers would expect to understand warnings and not ingest inedible objects, such as magnets from magnet sets. Approximately 48 percent of the victims were female, and 47 percent were male (victim’s sex is unknown for ~5% of cases). The reported number of magnets ingested ranged from 1 to 93; however, in some cases, the exact number is unknown. Two of the victims died; one died in 2013, and the other in 2018. Staff is aware of two additional deaths involving magnet ingestion, which were excluded because they occurred outside the United States. All four deaths involved products that are described consistent with staff’s classification for “Highly Similar.” The four deaths are discussed in the HS memorandum.

Use patterns, sources of access, and delays between ingestion and correct diagnosis are discussed below.

a) Use Patterns by Age in Ingestion Incidents

ESHF staff identified several distinct use patterns for different age groupings that can explain

³⁸ The magnet sets involved reportedly included 2-mm to 6-mm diameter spherical and cubical magnets. In many cases, information in the reports is too limited to discern the number of magnets in the set. Staff found sets sold online with upwards of 1,000 magnets.

how these high-powered magnets were used before ingestion. Figure 2 below shows the use patterns by age for known ages. Note: the “Playing” grouping includes accidental ingestion while playing, fidgeting, and orally exploring the magnets; and the “Other” grouping includes accidental ingestion from actions such as: children transporting the magnets in their mouths, hiding the magnets in their mouths, magnets falling from surfaces into their mouths, and magnets being thrown into their mouths.

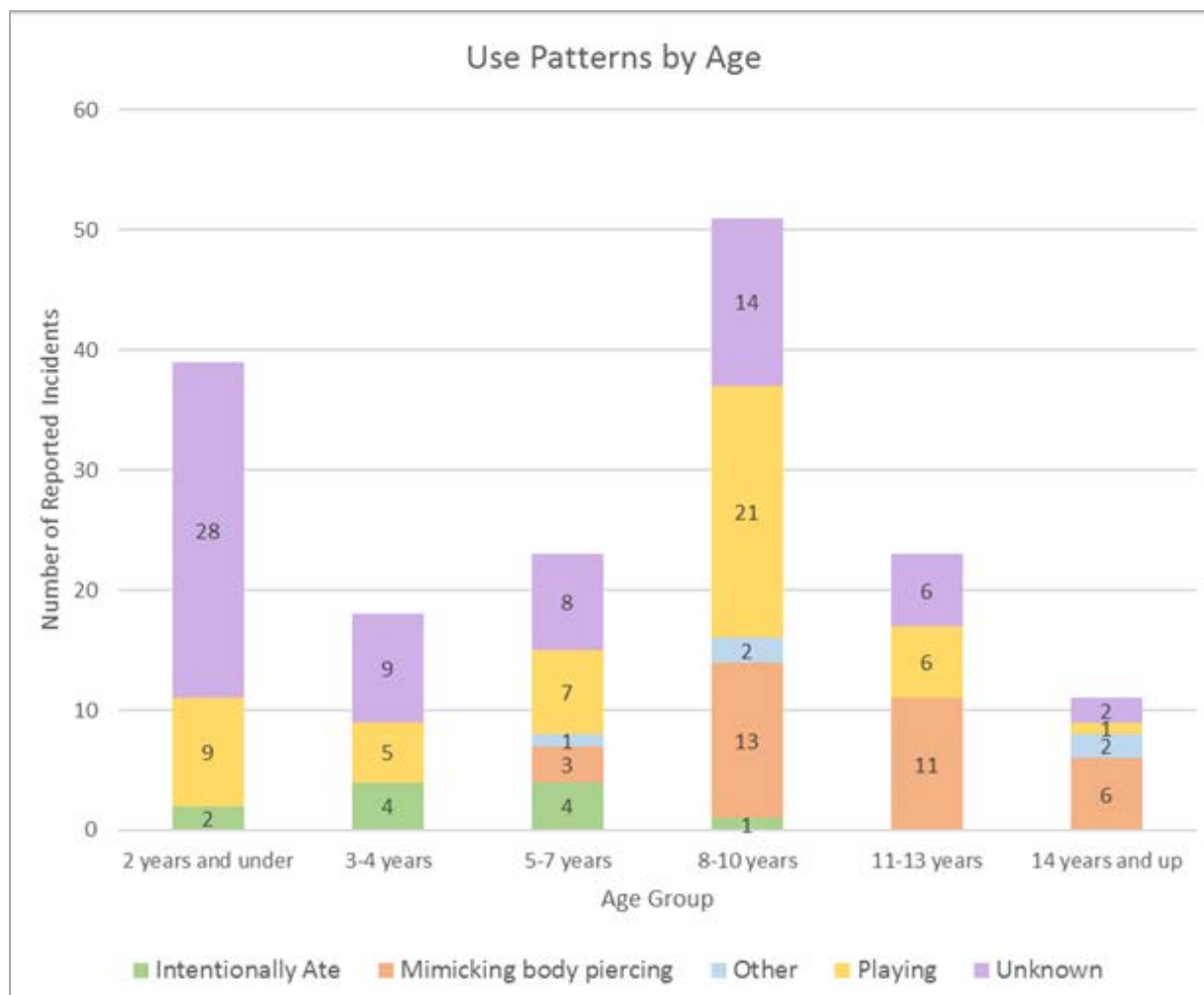


Figure 2. Use patterns by age for the 165 magnet ingestions with a known age.

Staff found that the use pattern often is unknown in cases involving children under 8 years of age. Many reports indicate the ingestion was not witnessed by caregivers; only approximately 36 percent of the reports involving children under 8 years of age indicate the caregivers were aware of the magnet ingestion prior to seeking medical attention. Additionally, the use pattern is unknown in some cases because some of the children lacked the cognitive ability to explain why they ingested the magnet(s). Of the cases for which use pattern is known, about 29 percent indicate that the victims (under 8 years old) intentionally ate magnets. In one case, the victim

reported intentionally eating magnets because she thought the magnets looked like food.³⁹ It is not surprising that the most frequently reported age involved in the incidents is age 2 years, given that foreign body ingestions peak from 6 months to 3 years of age (Green, 2015); and 2-year-olds generally are quite mobile and unlikely to be under direct supervision at all times. Even when supervision is provided, magnet ingestion can be too quick for caregivers to see and intervene. Exploration is a normal aspect of child development, and young children are likely to be drawn to magnets aesthetically, and due to magnets' seemingly "magical" (invisible) attraction and repulsion properties. Younger children are also less likely than older children to understand and anticipate the ingestion hazard.

For victims 8 years of age and older, the majority of the cases involved children accidentally ingesting magnets while using them to mimic body piercings (~48% of cases with a known use pattern), or while playing with the magnets (~44% of cases with a known use pattern). It is typical for this population to fidget with the magnets and orally explore the product's magnetic properties, such as testing the magnetic attraction through their teeth, or using the magnets to simulate lip and tongue rings, resulting in them accidentally swallowing the magnets. These use patterns are consistent with normal development for this age group, for whom experimentation and peer influence are common determinants of behavior.

b) [Source of Access to Magnets in Ingestion Incidents](#)

ESHF staff identified several distinct ways that children from different age groupings accessed magnets from magnet sets, most of which involved children acquiring loose magnets from a set, as opposed to accessing the full set at the time of ingestion. Figure 3 shows the access categories by age for the 165 victims whose ages are known.

³⁹ Staff found that some magnet sets are multicolored, and can reasonably be mistaken for candy.

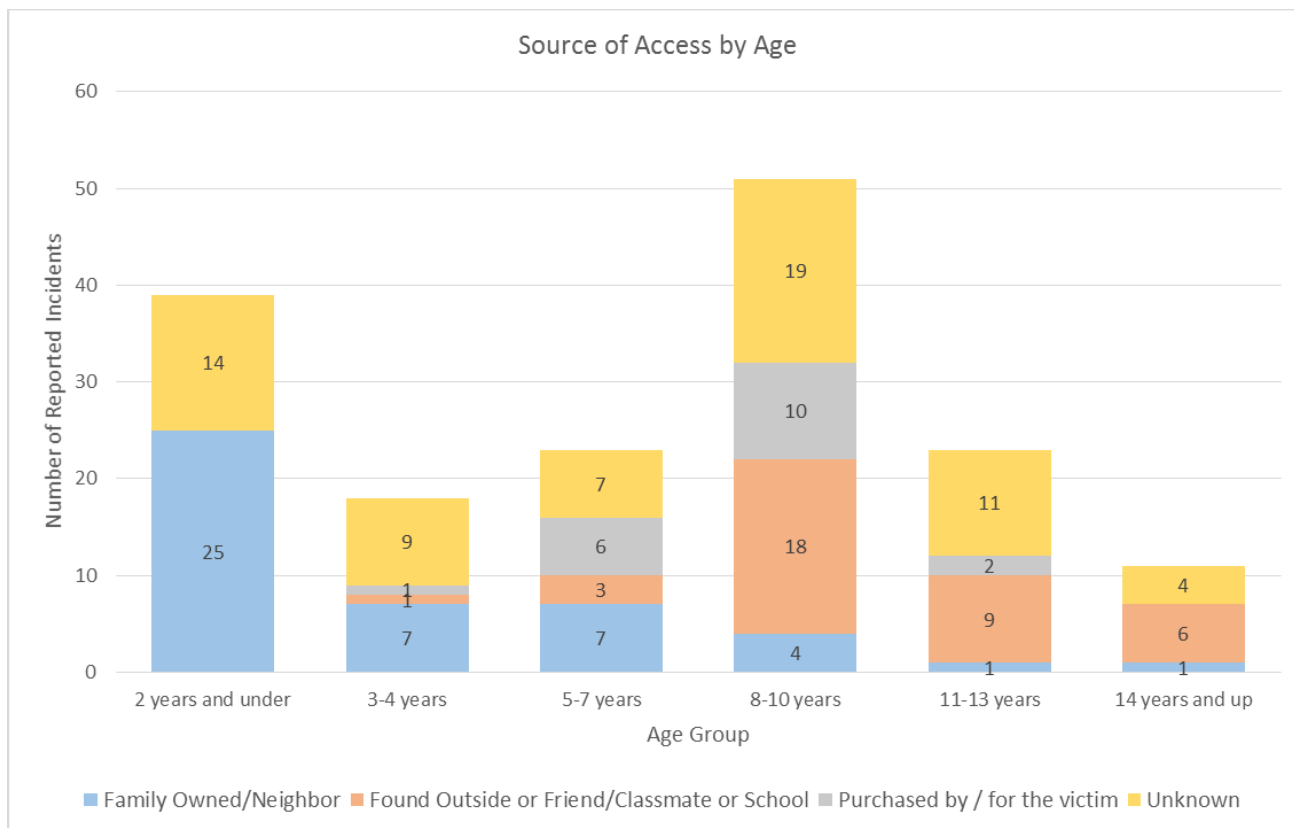


Figure 3. Source of access by age for the 165 magnet ingestions with a known age.

In many cases, it is not known how the magnets were acquired; for example, numerous reports state that the parent was unaware of the magnet ingestion event, or how the victim could have acquired the magnets. Of the cases with a known age of the victim and source of access, staff found that victims under 8 years of age typically gained access to magnets that belonged to family members (~76% of the cases), such as siblings, parents, and relatives. According to the reports, magnets from family members typically were found on floors, on furniture, in bags, and affixed to surfaces (*e.g.*, refrigerators, wallboards), and in some cases, magnets were intentionally shared with the victims by family members. A small number of children under 8 years had the magnet sets purchased for them (~10% of the cases with a known age and source of access). To a lesser extent, there are reports of victims in this age group finding loose magnets outside, receiving magnets from friends or classmates, receiving them from neighbors, and purchasing magnet sets themselves.

In contrast, victims ages 8 years and older typically obtained magnets from friends and classmates (~59% of the cases with a known age and source of access), or had the magnet sets purchased for them (~20% of the cases with a known age and source of access). The high number of cases involving magnets received from friends and classmates is concerning, as the cases typically involved the transmission of loose magnets (absent packaging and any possible warnings or instructions), and caregivers cannot easily manage this source of access. The percentage of cases involving magnet sets purchased for children 8 years and older was twice as high as for children under 8 years, which, based on staff's technical analysis and examination of incident reports and consumer reviews for magnet sets, staff attributes to reasons including:

- caregivers underestimated the potential severity of the hazard;
- caregivers received social pressures from their children, other family members, and friends;
- caregivers saw the magnet set or similar sets marketed to children;
- caregivers saw children handling the magnets without incident and read consumer reviews about children handling the magnets without incident; and
- caregivers underestimated the likelihood that older children and teens would ingest a magnet, let alone multiple magnets, or a magnet and a ferromagnetic object.

To understand the source of access better, staff reviewed the 176 cases for information regarding magnet ingestion warnings, age labels, and packaging. Although most of the cases did not mention this information, staff did observe the following:

- Approximately 19 percent of the cases indicated that the involved magnet sets originally had magnet ingestion warnings (not necessarily seen by the victim or victim's household).
- Approximately 19 percent of the cases indicated that the involved magnet sets originally had age labels of 14 years+, "keep away from children" wording, or both (not necessarily seen by the victim or victim's household).
- Approximately 30 percent of the cases indicated that the victim or household had access to the original packaging.
- Approximately 11 percent of the cases indicated that the caregiver was aware of the hazard prior to the ingestion event(s); some caregivers mentioned not seeing the warning until after the incident, and some reported mistaking the magnet ingestion warning for the common, unrelated "choking hazard" warning.

c) Time Lapse Between Ingestion and Correct Treatment

Incidents often resulted in surgical intervention, in part, because there were significant delays in victims receiving correct treatment. At least 23 percent of the 176 magnet ingestions involved a multiday delay between ingestion and correct treatment (there is insufficient information in most of the reports to know if there was a delay). Common causes of delays included: (1) caregivers being unaware of the ingestion event, resulting in delayed hospital visits and subsequent misdiagnoses, and (2) caregivers, medical professionals, or both, incorrectly expecting that the magnets would pass naturally through the child's body. For example, one case, which involved a 2-year-old swallowing 10 magnets that were purchased for his 7-year-old brother, indicates that several weeks passed between the ingestion and surgery to remove the magnets. The report states that the victim was complaining of stomach pains, and the caregivers incorrectly assumed the magnets would pass naturally. In two of the incidents that resulted in death, the caregivers and medical professionals were not aware of the ingested magnets, and the symptoms were misdiagnosed.

Numerous efforts to raise public awareness have attempted to combat the hazard and misconceptions surrounding the hazard. Since 2006, CPSC has drawn attention to the magnet-ingestion hazard through recalls of children's magnet toys, safety alerts, a public forum, public

safety bulletins, and rulemaking activity.⁴⁰ Campaigns by health organizations, such as the American Academy of Pediatrics (AAP) and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), have endeavored to educate the medical community and the public about the dangers of magnet ingestion.⁴¹ Consumer Reports shared articles and an online video to publicize the hazard and aid in preventing future incidents.⁴² Other efforts, such as outreach from consumer advocacy groups (examples include Consumer Federation of America⁴³ and Kids In Danger⁴⁴) and standard development by ASTM, have also attempted to raise public awareness of the hazard.

Despite public outreach efforts, recent incident reports demonstrate that magnet ingestions are still occurring (43 CPSRMS cases occurred in 2019), and significant delays between magnet ingestion and proper treatment remain common. Based on staff's analysis, many consumers are still unaware of the hazard, they fail to appreciate the likelihood of accidental ingestion, or both. One major contributor to delays is that parents and children often fail to make the connection between the magnet ingestion and the symptoms, in part, due to the frequently seen time lapse between magnet ingestion and symptoms, and because the preliminary symptoms typically are similar to common illnesses. In some incidents, the victims were unable or unwilling to tell caregivers and medical professionals about the magnet ingestion. Many cases detail victims only seeking treatment after experiencing significant discomfort, at which point substantial internal damage occurred. For example, one report indicates that in January 2017, a 3-year-old victim was found playing with her older brother's magnet set, and she told her father that she had not swallowed any magnets. Days following the incident, she became ill and was misdiagnosed with a stomach virus. Eventually, x-rays were taken, revealing three magnets in her small intestine. The victim lost a portion of her digestive tract and was hospitalized for approximately 2 weeks to recover after the surgery.

III. Examination of Product Marketing Information and Consumer Reviews

The majority of magnet sets are purchased online. When consumers make purchases in brick-and-mortar stores, as opposed to purchases online, potentially there are more sources to inform their purchasing decision, such as the section where the product is displayed and surrounding products, store representatives, retail packaging, and the physical product. However, when consumers make purchases online, their examination typically is limited to the product name, description, photographs, age labels, consumer reviews, and other information on the website.

⁴⁰ Examples of efforts from the CPSC: in 2007, the CPSC developed a public safety alert about powerful magnets (<https://www.cpsc.gov/s3fs-public/5221.pdf>). In October 2014, the CPSC published its final rule, Safety Standard for Magnet Sets, 79 Fed. Reg. 59,962. Under the rule, if a magnet set contained a magnet that fit within the CPSC's small parts cylinder, each magnet in the magnet set had to have a flux index of 50 kG²mm² or less. In November 2016, the rule was vacated and remanded by the U.S. Court of Appeals for the Tenth Circuit.

⁴¹ See the AAP website: <https://services.aap.org/en/search/?k=magnets>, and NASPGHAN website: <https://www.naspghan.org/content/72/en/Foreign-Body-Ingestion>, for articles discussing the hazard.

⁴² Example of 2017 Consumer Reports magnet hazard awareness-raising material on the Consumer Reports website: <https://www.consumerreports.org/product-safety/magnets-marketed-as-toys-could-be-dangerous-to-kids/>.

⁴³ Example of 2012 public outreach article from Consumer Federation of America: <https://consumerfed.org/testimonial/cfa-comments-cpsc-notice-proposed-rulemaking-safety-standard-magnet-sets/>.

⁴⁴ Example of 2011 public outreach article from Kids In Danger: <https://kidsindanger.org/2011/11/cpsc-warns-about-high-powered-magnets/>.

By the time they receive the package, consumers may feel confident regarding the suitability of the product for their children, regardless of marketing and safety information on the package.

For years, ESHF staff has reviewed numerous magnet sets obtained through online sellers to assist Compliance staff efforts. ESHF staff examined magnet sets that were very similar or identical in form and function (*e.g.*, typically 216 individual cubes or spheres measuring 5 mm on each side or 5 mm in diameter), yet notably marketed to different user populations. Some sets primarily targeted children, providing online information including:

- product names, such as: “Children’s puzzle” and “Educational Toys for Kids”;
- product descriptions, such as: “Exercise children's ability, let the children develop imagination”;
- age labeling, such as: “10 and up,” “8 and up,” “1 year,” and “3 years and up”; and
- photographs showing children playing with the set, or opening a gift box.

Other sets did not target children primarily, and some specifically targeted adults, providing online information including:

- product names, such as: “216pcs 5mm Magnetic Balls Puzzle,” “Neodymium Magnet Executive Toys Puzzle,” and “Magnetic Toy Adults' Gift”;
- product descriptions that appeal to adults and do not mention children, such as: “Activate your imagination and creativity. Great for releasing stress or pressure from daily life and improve your hand flexibility,” and “Perfect for testing your mental skills and challenging your patience”;
- age labeling, such as: “Keep out of reach from children,” and “14 years and Up”; and
- product photographs showing detailed and complex structures and no images of children.

Staff found that some sets sold online had conflicting marketing information, such as warnings to keep the magnets away from young children; yet they also included photos of young children playing with the product. Many webpages had consumer reviews indicating use of magnet sets by young children and recommending the sets for children, despite prominent warnings and age labels against use of the product by children under 14 years.

In 2019, Compliance and ESHF staff jointly conducted a magnet set consumer review study. Staff examined 56 magnet sets sold online to determine how the products were being marketed, what kind of warning information was provided, and if consumer reviews mentioned use of the magnet sets by children. Staff’s examination included evaluating the product webpages, and, for all but two of the magnet sets, evaluation of exemplar samples. The magnet sets were selected from international and domestic online sources. Staff found that the international online sources, which were international online marketplaces (including service to the U.S.), were less likely to have relevant warnings, and more likely to directly market the products to children (typically 8+ years). Compliance staff had difficulty analyzing consumer reviews from the international online sources, due, in part, to the multiple languages, and, consequently, the potential for translation errors. The summary of staff’s findings from the domestic online sales channels is provided below.

Compliance and ESHF staff examined 41 magnet sets from a domestic online marketplace and a domestic online retailer. Staff noted the following observations regarding safety information

online, on package, or both⁴⁵:

- 617 out of 1,752 consumer reviews (~35%) mentioned use by children⁴⁶;
- 28 out of 41 magnet sets (~68%) had a magnet ingestion hazard warning similar to the warning proposed by the Petitioner;
- 39 out of 41 magnet sets (~95%) had an age label of 14+ years, a warning to keep the product away from children, or both;
- 28 out of 41 magnet sets (~68%) had a magnet ingestion hazard warning and either an age label of 14+ or a warning to keep the product away from children;
- 9 out of 41 magnet sets (~22%) had marketing directly targeting children under 14 years, such as in the titles, descriptions, photos, or a combination of these;
- 6 out of 41 magnet sets (~15%) had at least 50 percent of the consumer reviews mentioning use by children;
 - 4 of these 6 magnet sets (~67%) had a magnet ingestion hazard warning similar to the warning proposed by the Petitioner⁴⁷;
 - 5 of these 6 magnet sets (~83%) had an age label of 14+ years, a warning to keep the product away from children, or both; and
 - 4 out of these 6 magnet sets (~67%) had a magnet ingestion hazard warning and either an age label of 14+ or a warning to keep the product away from children.

In summary, the majority of the domestically sold magnet sets had magnet ingestion warnings similar to the warning proposed by the Petitioner, as well as age labels for 14+ years, warnings to keep the product away from children, or both. Marketing to children under 14 years was relatively rare. Despite these factors, consumer reviews commonly mentioned use of the product by children.

IV. Analysis of Petitioner Requests

This section discusses the requirements the Petitioner requests, and ESHF staff's assessment of those requirements. The Petitioner requests rulemaking based on how the magnet sets are marketed:

Magnet sets marketed to children under 14 years of age:

Regarding magnet sets *designed, marketed, or manufactured for children under the age of 14* with individual magnets that are small enough to fit entirely within the "small parts cylinder" described in 16 CFR § 1501.4, the Petitioner requests a mandatory standard that the individual magnets shall have a flux index of 50 kG²mm² or lower.

⁴⁵ Note: These observations do not account for potential on-package safety information for the two magnet sets that staff did not examine in person; therefore, the counts of warnings and age labels may be higher than noted.

⁴⁶ Compliance staff included the following terms in the "use by children" count: child, children, kid, grandchild, grandkid, grandson, granddaughter, son, daughter, boy, girl, specified ages under 14, and similar terms.

⁴⁷ Two of the magnet sets were not examined in-person; consequently, staff is unaware if there were on-package warnings or age labels.

As noted in the Engineering Sciences memorandum (Tab E), 16 CFR part 1250 already requires compliance with ASTM F963 – 17, *Standard Consumer Safety Specification for Toy Safety*, for products intended for children under 14 years of age. ASTM F963 – 17 requires that toys with loose magnets that are small enough to fit entirely within the “small parts cylinder” must have a flux index less than but not equal to 50 kG²mm². As such, 16 CFR part 1250 imposes a requirement nearly identical to what the Petitioner requests, but is slightly stricter (prohibiting a flux index of 50 kG²mm² from loose magnets in children’s toys).

Magnet sets marketed to individuals 14 years of age and older:

If the product is a “general purpose” magnet set, *i.e.*, for individuals 14 years of age and older, the Petitioner requests that the Commission establish mandatory requirements regarding labeling, instructions, and packaging, such as conspicuous warnings and age labels, safety instructions for returning the entire set to its package after use, CR packaging, and visual confirmation that all magnets are returned to their original container. For reasons discussed below, ESHF staff is concerned that Petitioner’s proposed requirements for “general purpose” magnet sets may have limited effectiveness.

a) **Safety Information**

The effectiveness of the proposed safety information in labels and instructions for magnet sets depends on: (1) educating consumers regarding the magnet ingestion hazard, and (2) encouraging consumers to perform actions they otherwise might not perform to avoid the hazard. The Petitioner proposes requiring a label for age 14 years and older, instructions to ensure that all magnets are returned to the packaging after use, and a warning label, such as exhibited in Figure 4 below.

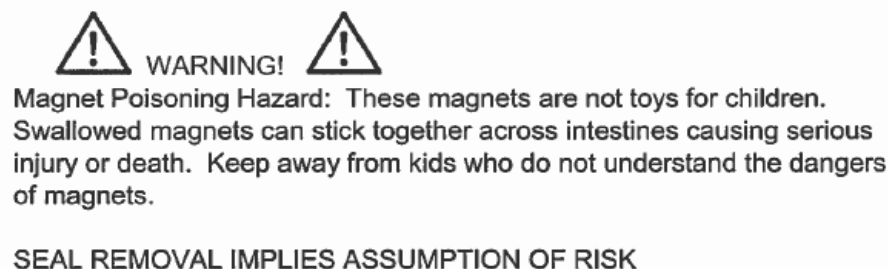


Figure 4. Magnet warning label example provided by the Petitioner.

ESHF staff has concerns regarding the proposed warning label, which include, but are not limited to, the following:

- The label has two safety alert symbols, one on each side of the signal word, when it should only have one symbol per ANSI Z535.4 – 2011, *Product Safety Signs and Labels*.
- The label identifies the hazard as a “poisoning” hazard, which is inaccurate and misleading.
- It may be inferred that the product should only be kept away from “kids who do not understand the dangers.” As discussed above, it is common for consumers, both caregivers and children, to misunderstand the accidental nature of the hazard, and that the

vulnerable populations include children who do not have a history of mouthing or ingesting inedible objects.

- The label does not indicate that ingestion of magnets has resulted in deaths and serious injuries.
- The label does not identify the actions likely to lead to ingestion.
- The label does not include actions to take if ingestion occurs.

In addition to addressing these specific concerns regarding Petitioner's proposed warning label, staff also assessed a warning-only approach to address the hazard in general. Staff concludes this approach is inadequate because safety literature has shown that warnings are the least effective strategy for addressing a hazard, relative to designing out the hazard or guarding against the hazard (Sanders and McCormick, 1998). Based on staff's analysis, there are numerous factors, discussed below, which hinder the effectiveness of safety information, especially for magnet sets.

Consumer common perception of low risk associated with magnet sets

Consumers are unlikely to consult and heed warning information for this product because the product appears simple, familiar, and non-threatening. Incident data and consumer reviews of magnet sets demonstrate that consumers commonly recognize magnet sets as suitable playthings for children; this hinders the perceived credibility of warning information that they are hazardous for children. Studies have found that the more familiar consumers are with a product, the less likely they are to look for, or read, warnings (Wogalter et al., 1999) and instructions (Inaba, Parsons, & Smillie, 2004; Robinson, 2009; Schriver, 1997); consequently, it is more likely consumers will discredit or ignore the warnings (Ayres et al., 1986). Furthermore, Sedney and Smith (2012) posited that if caregivers have observed either their child, or their child's peers using the product or a similar product without incident, caregivers may conclude that their child can use the product safely, regardless of what the warnings state (*cf.* Vredenburg & Zackowitz, 2006). Similarly, recommendations from others, including online reviews of magnet sets, can influence the likelihood of consumers disregarding the hazard.

Misunderstood hazard

The magnet ingestion hazard is a hidden hazard, and consumers are unlikely to anticipate and appreciate the vulnerability of children, especially teens, who do not have a history of mouthing or ingesting inedible objects. Therefore, consumers are unlikely to keep the magnets away from these populations, regardless of warning information, which consumers are likely to perceive as not pertaining to these children. Furthermore, as shown in incident reports, many consumers assume wrongfully that when ingested without any apparent choking episode, magnets may pass through the body without causing any harm.

Source of access

As discussed in "Findings from Magnet Ingestion Incident Data" above, magnets from magnet sets are often acquired by children without the packaging and instructions, such as from children sharing sets and children finding loose magnets in their environment. In such cases, any warning

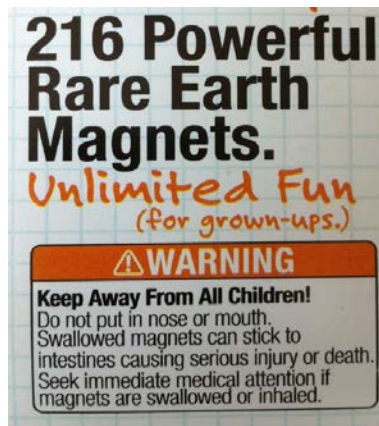
information displayed on packaging or instructions, as well as packaging characteristics (*e.g.*, CR packaging or packaging that indicates whether all magnets are in the package), becomes immaterial.

Use by older children

Older children and teens may knowingly choose to disregard 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 (Brown & Beran, 2008; Vredenburg & Zackowitz, 2006). Therefore, warnings about keeping magnet sets away from children could have the unintended effect of making the product more appealing to some of these children. Additionally, age labels for 14 years and older may mislead consumers to believe that children ages 14 years and older are immune to the hazard, which is not the case.

Historical inadequacy of similar efforts

Some magnet sets are sold without age labels and warnings regarding the magnet ingestion hazard. However, incidents and consumer reviews indicate that young children in the past have accessed and continue to access magnet sets, even when there are prominent warnings, age labels, instructions, marketing, and packaging that attempt to identify the appropriate user population as adults, and warn about the ingestion hazard. There are CPSRMS reports dating back to 2010, which indicate that the involved magnet sets had marking and labeling similar to what the Petitioner requests; warnings about the hazard; and identifying adults as the appropriate user population. The following image is an example of product marketing and warnings included in one incident report from 2011:



In this example, the product was marketed to “grown-ups”; it had a warning to keep the product away from all children; and it included a clear magnet ingestion warning. Nonetheless, the product was involved in a magnet ingestion incident involving a 9-year-old child. This case is

not unique; staff has found numerous incident reports and consumer reviews that indicate use by children, which display nearly identical marketing and warnings.⁴⁸

b) Packaging

The Petitioner proposes requiring that “general purpose” magnet sets include a packaging structure that affords visual verification that all of the pieces have been returned to the packaging after use. In addition, the Petitioner proposes requiring CR packaging that prevents children from gaining access to magnets that are in the packaging.

Repackaging and visual verification

CPSRMS reports demonstrate that consumers are unlikely to repackage the sets in their entirety after each use, which would be necessary to limit children’s access to the sets and individual magnets. Incident reports demonstrate that children often acquire magnets from magnet sets that are not in their packaging. In addition, magnet sets are designed and marketed to make complex sculptures, and for other purposes that discourage consumers from dismantling, repackaging, and keeping the entire set together after each use.

Even if the user intends to repackage the entire set after every use, it may be infeasible for consumers to locate the magnets and account for the full set, as sets can include hundreds, even thousands, of tiny magnets. Although staff agrees with the Petitioner that individual, separated spherical magnets tend to self-orient and attract more easily than other shapes, staff found that grouped, separated magnets, including spherical magnets, often repel rather than reorient. This results in separated groups of linked magnets repelling one another, making it difficult to repackage the set. Staff also found that it was common for magnets to be flicked away from one another when handling, such as when separating magnets with one’s thumb, resulting in the magnets being dropped. The flicking motion may explain incident reports that describe magnets suddenly jumping into children’s mouths while children were handling them. In examining samples, staff found that cube-shaped magnets were particularly likely to be flung during this motion, possibly because the cube shape requires more force to fit one’s finger between individual magnets. Fidgeting, for which magnet sets are commonly marketed, can also contribute to the likelihood of pieces being liberated, unbeknownst to the user, if their attention is directed elsewhere. Once these tiny magnets become liberated from the set, it can be especially difficult to locate spherical magnets, because the round shape increases the likelihood of dropped magnets rolling out of sight. Staff found that many sets sold online include extra pieces, in part, because losing the magnets is expected. Staff also found many incident reports and consumer reviews that mentioned lost magnets.

Repackaging, especially if it requires constructing specific shapes, can be challenging and time-consuming, and not all consumers will have the time and inclination to do it. In examining sample 216-piece magnet sets, staff found that even combining and orienting the magnets into a

⁴⁸ Another example of marketing and warnings, as well as packaging, similar to those proposed in the petition, can be found on SaferProducts.gov: <https://saferproducts.gov/ViewIncident/1911835>. The report is dated October 14, 2019, and it describes the ingestion of 2.5 mm diameter spherical magnets by a 5-year-old child.

6 x 6 x 6 cube proved to be a laborious task. Research shows that increased costs of compliance with a warning (e.g., time and effort) can quickly drive compliance rates to zero (Dingus et al., 1991). Therefore, packaging that enables visual confirmation that the set has been collected in its entirety would need to be quick and simple; and even then, it would be fallible because it would depend on consumers finding all the pieces and choosing to repackage them after every use, which is unrealistic.

CR packaging

CR packaging makes it difficult for children under 5 years of age to open a container.⁴⁹ It can serve as a physical reminder that the contents of the packaging are hazardous. Its effectiveness at preventing children under 5 years from opening the packaging depends, in part, on the magnet sets being repackaged properly after every use. As discussed above, there are many reasons consumers may not repackage magnet sets in their entirety after every use. In addition to those reasons, consumers are unlikely to reliably use CR packaging for magnet sets because the products are largely marketed as toys and stress relievers, making them appear less threatening than the products often involved in chemical and pharmaceutical poisonings, for which inconsistent use of CR packaging by consumers has been documented.

Furthermore, CR packaging would not be effective for children 5 years and older, whose cognitive and motor skills overlap those of adults. The majority of victims with a known age in both NEISS estimates and CPSRMS data were 5 years or older, making CR packaging an inherently inadequate approach for preventing the subject hazard for the majority of the victims. CR packaging can also be perceived as a nuisance, making users less likely to store the magnets in the packaging after every use.

V. Responses to Comments

CPSC received 21 comments in response to the petition. Comments related to the human factors issues and ESHF staff's responses are provided below.

1. Foreseeable use

CPSC received a comment noting that magnet set ingestion is a foreseeable misuse because magnets should be expected to separate from sets, and it is normal developmental behavior for toddlers and children to put magnets into their mouths.

Response:

Staff agrees that magnet set ingestion is a foreseeable misuse. Detailed in the "Discussion" and "Petitioner Requests" sections above, there are numerous reasons why children are likely to acquire loose magnets and ingest them.

2. Design restrictions: Flux index and size

CPSC received comments about the types of magnet sets that should be subject to limits on

⁴⁹ More information about CR packaging can be found here: <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/PPPA>

magnet size and strength. One commenter stated that flux index limits only should apply to products intended for children under 14 years old, to allow consumers to choose between stronger products and safer products. Another commenter stated that size and strength restrictions should apply to all magnet sets because they are attractive to children, regardless of the intended user age.

Response:

Staff considers that size and strength restrictions should apply to all of the subject magnet sets, regardless of the intended user age. Detailed in the “Discussion” and “Petitioner Requests” sections above, there are many reasons that magnet sets marketed as “general purpose” are likely to be acquired by children, and the hazard is not limited to children under 14 years of age. Staff notes that loose magnets intended as toys for children under 14 years old already are subject to the Commission’s toy standard in 16 CFR part 1250, which includes size and strength restrictions. However, there is still a need to ascertain whether magnets having flux index values below the 50 kG² mm² “hazardous magnet” limit can cause ingestion injuries.

3. CR packaging

CPSC received a comment supporting the petition request for CR packaging because it would limit toddlers’ access to the product. CPSC also received a comment stating that CR packaging would be ineffective at reducing magnet set injuries because the product may not remain in its original packaging.

Response:

As detailed in the “Packaging” section above, staff considers that relying on CR packaging is unlikely to effectively mitigate the magnet ingestion hazard.

4. Repackaging

CPSC received a comment supporting the petition request that the subject product’s packaging show whether all of the magnets in a set are returned to the package. Another comment suggested a similar alternative that would require packaging made of magnetized material to ensure magnets are held in place for storage. Another comment stated that packaging requirements would be effective at reducing injuries because most injuries involved a toddler finding misplaced magnets. Additionally, CPSC received a comment that it may not be possible to develop packaging that shows whether hundreds of magnets in a set have been repackaged.

Response:

For the reasons detailed in the “Packaging” section above, staff considers that the packaging concepts are unlikely to effectively mitigate the magnet ingestion hazard.

5. Warning labels

CPSC received comments supporting the petition request for warning labels. Commenters stated that warnings should be in a visible location, and warning language should be uniform, stern, warn of potential injuries, state the danger of ingestion, and include age recommendations. One commenter advocated pairing warnings with additional requirements, noting that warnings alone would not eliminate injuries because incidents involve children finding misplaced magnets.

Another commenter stated that warning labels alone would be adequate to address the hazard because warnings would advise adults to supervise children's access to the product.

CPSC also received comments stating that warning labels would not adequately reduce injuries because labels may be discarded after users open the product, young children and non-neurotypical children may not understand package warnings, and older children and teens unintentionally ingest magnets from magnet sets, despite package warnings. Commenters noted that since entering the market in 2008, most magnet sets have been marketed as adult desk toys, included age recommendations of 13 or 14 years, and included warnings to keep the products away from children; however, these warnings did not reduce ingestions and injuries. Commenters also noted that, by concluding that certain magnet sets pose a "substantial product hazard," CPSC has determined that no labeling can sufficiently mitigate the hazard associated with magnet sets.

Response:

Detailed in the "Labeling and Instructions" section above, staff considers that relying on warnings is unlikely to effectively mitigate the magnet ingestion hazard. Regarding the comment about supervision, in most of the incidents reported in CPSRMS, the young children gained access to magnets that were owned by older family members. Constant supervision is unrealistic, and older toddlers and preschool children (2 through 5 years old) are regularly out of view of a supervising parent for about 20 percent of their awake time at home, and they are completely unsupervised (*i.e.*, the parent is not listening to or watching what the child is doing at all) for about 4 percent of their awake time in the home (Morrongiello et al., 2006).

6. Instructions

CPSC received comments stating that instructions would be ineffective in reducing the hazard associated with magnet sets. CPSC also received one comment supporting instructional requirements. Commenters noted that instructions have limited effectiveness, for reasons similar to labeling, including that users may discard instructions after opening the product, and children may not comprehend instructions. One commenter stated that if consumers need to be told how to use magnet sets without ingesting them, then the product should be banned.

Response:

Detailed in the "Labeling and Instructions" section above, staff considers that relying on instructions is unlikely to effectively mitigate the magnet ingestion hazard.

7. Age restrictions

CPSC received comments stating that age restrictions would not be effective at reducing the magnet sets hazard. CPSC also received one comment supporting age restrictions. Commenters noted that it is unrealistic to think that age recommendations would keep magnet sets away from children, that existing age recommendations have not reduced ingestions or injuries, that labels or instructions bearing age restrictions may be discarded, that children would not comprehend age restriction warnings, and that age recommendations would not address teens unintentionally ingesting magnets.

Response:

Detailed in the “Labeling and Instructions” section above, staff considers that relying on age labels is unlikely to effectively mitigate the magnet ingestion hazard.

8. Education Campaign as an Alternative:

A commenter stated that CPSC should pursue a public awareness campaign to encourage responsible adult use. However, one commenter noted that education campaigns are unlikely to be as effective as other alternatives, such as recalls.

Response:

Public awareness-raising campaigns associated with magnet sets may have limited or temporary effectiveness in mitigation of the magnet ingestion hazard. As detailed in the “Hazard Patterns” section above, the past decade has witnessed numerous public awareness-raising efforts by many organizations, and incident reports and consumer reviews of magnet sets continue to demonstrate that many consumers remain unaware of the hazard, fail to appreciate the likelihood of accidental ingestion, or both.

VI. Voluntary Standard Efforts for “Adult” Magnet Sets⁵⁰

Since March 2019, CPSC staff has participated in the ASTM F15.77 subcommittee on “adult” magnet sets, which has been working on a draft voluntary standard, titled: *Specification for Marketing and Labeling Adult Magnet Sets Containing Small Loose, Powerful Magnets with a Flux Index 50 kG2mm2 WK68963*. Thus far, the draft standard has been focused on magnet sets with a flux index of greater than or equal to 50 kG²mm², and it includes requirements similar to those requested by the Petitioner for “general purpose” magnet sets. As described in Section 1.1 of the draft standard,

This specification covers marketing, packaging, labeling, and warning requirements for adult magnet sets containing small, powerful magnets. It is aimed at minimizing the identified hazards to children and teens associated with ingesting small, powerful magnets that are intended for adults, *i.e.*, those persons 14 years of age and older.

The draft standard does not include performance requirements. Staff concludes that performance requirements, such as limiting magnet size, strength, or both, are necessary to reduce significantly or eliminate the hazard. The draft standard relies only on consumers altering their behavior in some way to avoid the hazard, which the data show is insufficient to address the hazard. Accordingly, staff has the same concerns with the draft standard as with the Petitioner’s proposed requirements. Staff submitted two letters to the subcommittee, which detailed various factors that explain why the proposed requirements are insufficient, and encouraged the subcommittee to consider performance requirements (Appendices A and B). Additionally, in subcommittee meetings, staff requested that the subcommittee investigate the suitability of the current magnet testing methodology and flux index limit.

⁵⁰ This section does not include voluntary standards activity beyond May 27, 2020.

The draft standard was balloted in late 2019.⁵¹ A significant number of negative votes were received on the ballot. All negative votes, including CPSC staff's vote, were accompanied by an explanation regarding the ineffectiveness or limited effectiveness of the proposed requirements for addressing the hazard. For example, the majority of non-CPSC negative voters argued that parents and children are unlikely to follow warnings and instructions for the product, and that caregivers are unable to adequately manage access to magnet sets by children. Several of the voters also raised concern regarding whether the flux index of 50 kG²mm² is a suitable boundary for establishing hazardous magnets.

VII. Conclusion

Based on ESHF staff's technical expertise and their examination of magnet sets, incident reports, consumer reviews, and the available literature, staff concludes that relying only on the Petitioner's proposed requirements for labeling, instructions, and packaging is unlikely to effectively mitigate the magnet ingestion hazard. The effectiveness of the proposed requirements depends on persuading consumers to consistently and reliably take unrealistic actions to avoid the hazard. Staff examined incident reports dating back to 2010, which demonstrate the inadequacy of prominent warnings, age labels, instructions, marketing, and packaging that attempt to identify adults as the appropriate user population and warn about the hazard. There have also been numerous public awareness raising campaigns over the past decade, led by multiple organizations, which have attempted to communicate the magnet ingestion hazard to caregivers, children, and medical professionals. However, recent incidents and consumer reviews demonstrate that caregivers and children continue to underestimate the likelihood and severity of the magnet ingestion hazard. There has been an increase in incidents since the CPSC regulation was vacated, and staff concludes that absent performance requirements, magnet sets will continue to present a 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.

References

- Ayres T. J., Gross M. M., Wood C. T., Horst D. P., Beyer R. R., & Robinson J. N. (1989). What is a warning and when will it work? *Proceedings of the Human Factors Society Annual Meeting*, 33, 426-430.
- Brown, T., & Beran, M. (2008). Developmental stages of children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for Children: Designing Products and Places for Toddlers to Teens* (pp. 13–30). New York: Taylor & Francis.
- Inaba, K., Parsons, S.O. & Smillie, R. (2004). *Guidelines for developing instructions*. Boca Raton, FL: CRC Press.
- Inkster, S. (2020). *Petition requesting rulemaking on magnet sets: Health sciences considerations and response to public comments*. CPSC memorandum to Susan Bathalon, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Green, S. S. (2015). Ingested and aspirated foreign bodies. *Pediatrics in Review*, 36(10), 430–437. doi: 10.1542/pir.36-10-430.

⁵¹ ASTM Ballot F15.77 19-01, item #1, WK68963. Of the 24 official votes, 13 were “affirmative,” eight were “negative,” and three were “abstain.”

- Mordecai, B. (2020). *Existing standards and analysis of magnetic strength of magnet sets*. CPSC memorandum to Susan Bathalon, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Morrongiello, B. A., Corbett, M., McCourt, M., & Johnston, N. (2006). Understanding unintentional injury-risk in young children I. The nature and scope of caregiver supervision of children at home. *Journal of Pediatric Psychology*, 31(6), 529–539.
- Robinson, P. A. (2009). *Writing and designing manuals and warnings* (4th ed.). Boca Raton, FL: CRC Press.
- Sanders, M.S. & McCormick, E. J. (1993). *Human factors in engineering and design*. McGraw-Hill, Inc., New York, NY.
- Schrivier, K. A. (1997). *Dynamics in document design*. New York City, NY: Wiley.
- Sedney, C. A., & Smith, T. P. (2012). *Human factors assessment of strong magnet sets*. CPSC memorandum to Jonathan D. Midgett, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Topping, J. (2020). *NEISS estimates and analysis of reported incidents related to ingestion of magnets of various shapes and sizes from, or possibly from, magnet sets*. CPSC memorandum to Susan Bathalon, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Vredenburg, A. G., & Zackowitz, I. B. (2006). Expectations. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 345–354). Mahwah, NJ: Lawrence Erlbaum Associates.
- Wogalter, M.S., DeJoy, D., & Laughery, K. R. (Eds.). (1999). *Warnings and risk communication*. Philadelphia, PA: Taylor & Francis.

Appendix A
October 18, 2019 Staff Letter to ASTM F15.77 Explaining Staff's Position



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Stephen Harsanyi
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October 18, 2019

TRANSMITTED VIA EMAIL

Ms. Nancy Nord
Subcommittee Chairman for ASTM F15.77,
Magnet Sets Containing Small Loose, Powerful Magnets with a Flux Index ≥ 50
c/o ASTM International
100 Barr Harbor Drive, P.O. Box C700
West Conshohocken, PA 19428-2959

Dear Ms. Nord:

U.S. Consumer Product Safety Commission (CPSC) staff appreciates the effort of the 15.77 subcommittee members to mitigate the hazard associated with children swallowing or inhaling small, powerful magnets.¹ CPSC staff is writing to explain its participation in the development of the ASTM F15.77 standard, *Magnet Sets Containing Small Loose, Powerful Magnets with a Flux Index ≥ 50* , and state its position regarding the effectiveness of warning information concerning the magnet ingestion hazard.

Staff believes that relying only on warning information will not effectively reduce the hazard associated with the ingestion of small, powerful magnets from magnet sets.

Warning information, in general, has limited effectiveness because it depends on persuading consumers to alter their behaviors in some way to avoid the hazard. This is in contrast to an engineering solution, such as a performance requirement, which could prevent the hazard or access to the hazard. Magnet sets, in particular, present unique challenges to persuading consumers to alter behavior to avoid the hazard.

CPSC staff's concerns are listed below:

- Staff estimates that there have been thousands of emergency department-treated ingestions since 2009, involving, or possibly involving, magnets from magnet sets. There have been at least two deaths involving magnets possibly from magnet sets. More specifically, staff is aware of two

¹ The views expressed in this letter are those of CPSC staff and have not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

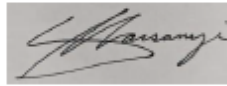
deaths involving magnets with characteristics similar to magnets typically found in magnet sets, but in each case, the source of the magnets was not reported.

- 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. Studies have found that the more familiar consumers are with a product, the less likely they are to look for, or read, a warning (Wogalter et al., 1999); consequently, it is more likely consumers will discredit or ignore the warning (Ayres et al., 1986). Sedney and Smith (2012) posited that if caregivers have observed either their child, or their child's peers using the product or a similar product without incident, caregivers may conclude that their child can use the product safely, regardless of what the warnings state (*cf.* Vredenburg & Zackowitz, 2006). Similarly, recommendations from others, including online reviews of magnet sets, can influence the likelihood of consumers disregarding the hazard.
- Consumers are unlikely to repack the sets in their entirety after each use. Magnet sets are designed and marketed to make complex sculptures and jewelry, and for other purposes that dissuade consumers from dismantling, repackaging, and keeping the entire set together. Magnet sets can have upwards of 1,000 tiny magnets, making finding and collecting each magnet after every use, difficult and time-consuming to accomplish. Research shows that increased costs of compliance with a warning (*e.g.*, time and effort) can quickly drive compliance rates to zero (Dingus et al., 1991).
- Magnets are often acquired without packaging, which makes any warning information on the package irrelevant. The incident data include many cases of victims acquiring magnets that were found in their environment or received from their friends and school mates.
- 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 (Brown & Beran, 2008; Vredenburg & Zackowitz, 2006). Therefore, warnings about keeping magnet sets away from children could have the unintended effect of making the product more appealing to some of these children.
- 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. Staff is participating in this subcommittee, in part, to make these concerns known to the subcommittee. Although staff is assisting the subcommittee in making the warnings as strong and credible as possible, staff continues to believe that warning information, alone, is unlikely to effectively alleviate the hazard. Instead, the hazard should be eliminated, perhaps through a performance requirement, thereby preventing the hazard, rather than attempting to persuade consumers to avoid it.

Thank you for the opportunity to participate in ASTM F15.77 activities. CPSC staff looks forward to continuing to work with ASTM to improve the safety of magnet sets.

Sincerely,



Stephen Harsanyi
Engineering Psychologist,
Division of Human Factors

CC: Molly Lynyak, Manager, Technical Committee Operations, ASTM International
Susan Bathalon, Magnet Sets Project Manager, CPSC
Patricia L. Edwards, CPSC Voluntary Standards Coordinator

References

- Ayres T. J., Gross M. M., Wood C. T., Horst D. P., Beyer R. R., & Robinson J. N. (1989). What is a warning and when will it work? *Proceedings of the Human Factors Society Annual Meeting*, 33, 426-430.
- Brown, T., & Beran, M. (2008). Developmental Stages of Children. In R. Lueder & V. J. B. Rice (Eds.), *Ergonomics for Children: Designing Products and Places for Toddlers to Teens* (pp. 13-30). New York: Taylor & Francis.
- Sedney, C. A., & Smith, T. P. (2012). *Human factors assessment of strong magnet sets*. CPSC memorandum to Jonathan D. Midgett, Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.
- Vredenburg, A. G., & Zackowitz, I. B. (2006). Expectations. In M. S. Wogalter (Ed.), *Handbook of Warnings* (pp. 345-354). Mahwah, NJ: Lawrence Erlbaum Associates.
- Wogalter, M.S., DeJoy, D., & Laughery, K. R. (Eds.). (1999). *Warnings and risk communication*. Philadelphia, PA: Taylor & Francis.

Appendix B
January 9, 2020 Staff Letter to ASTM F15.77 Explaining Staff's Negative Ballot Vote



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January 9, 2020

TRANSMITTED VIA EMAIL

Ms. Nancy Nord
Subcommittee Chairman for ASTM F15.77,
c/o ASTM International
100 Barr Harbor Drive, P.O. Box C700
West Conshohocken, PA 19428-2959

Dear Ms. Nord:

This letter responds to ASTM ballot F15.77 (19-01), item #1, *Specification for Marketing and Labeling Adult Magnet Sets Containing Small Loose, Powerful Magnets with a Flux Index 50 kG2mm2 WK68963*. Staff of the U.S. Consumer Product Safety Commission (CPSC) is voting negative on the ballot item.¹

Based on CPSC staff's technical expertise and its examination of magnet sets, incident reports, consumer reviews, and the available literature, staff concludes that relying only on the draft standard's proposed requirements for warnings, instructions, marketing, and packaging ("proposed requirements"), is unlikely to mitigate effectively the hazard associated with the ingestion of small, powerful magnets from magnet sets. The proposed requirements are inadequate because they depend on warnings to override the perception of the product as a suitable plaything for children. In addition, the proposed requirements depend on persuading consumers to consistently perform actions they otherwise might not perform to avoid the hazard. We expand on these points below. As an alternative to the proposed requirements, staff urges the subcommittee to continue efforts to expand the scope of the draft standard to include performance requirements that effectively mitigate the magnet ingestion hazard.

As discussed in staff's letter to the subcommittee on October 18, 2019, explaining staff's participation in the development of this standard, there are numerous factors that render the proposed requirements insufficient.

1. *Consumer Common Recognition*: Studies show that consumers are unlikely to consult and heed warning information for products and features they perceive as simple, familiar, and non-threatening, such as the subject magnet sets. Incident data and consumer reviews of magnet sets

¹16 C.F.R. part 1031, as amended in 2016, permits CPSC staff to vote and hold leadership positions on an optional basis, provided that such activities have the prior approval of CPSC's Office of the Executive Director. CPSC staff sought and received approval to vote in October 2019 on matters pertaining to ASTM subcommittee F15.77.

demonstrate that consumers commonly recognize magnet sets as suitable for children; warning information that suggests the contrary is unlikely to be perceived as credible. In addition, studies demonstrate that the more familiar consumers are with a product, the less likely they are to look for and read a warning; in contrast, consumers are more likely to discredit or ignore the warning. If caregivers have observed their child, or their child's peers, using the product, or a similar product, without incident, caregivers may conclude that their child can use the product safely, regardless of what the warnings state. Similarly, recommendations from other consumers and caregivers, including online reviews of magnet sets by others who have purchased these sets, can lead consumers to disregard the hazard.

2. *Required Repackaging:* Consumers are unlikely to repackage the sets in their entirety after each use, which is likely to be required to limit children's access to the sets and individual magnets. Magnet sets are designed and marketed to make complex sculptures, and for other purposes that discourage consumers from dismantling and repackaging the entire set. Magnet sets can have upwards of 1,000 tiny magnets, making the task of finding and collecting every individual magnet, after every use, difficult and time-consuming. Even small increases in time, effort, and other "costs," can have a substantial effect on compliance with a warning, and can quickly drive compliance rates to zero.
3. *Accessibility:* As evidenced in incident reports, magnets from magnet sets are often acquired by children without the packaging and instructions, such as from children sharing sets and children finding loose magnets in their environment. In such cases, any warning information limited to these sources, as well as packaging characteristics, are ineffective. Additionally, the proposed requirement for added complexity for opening the packaging is unlikely to be effective for older children.
4. *Misunderstood Hazard:* Consumers are unlikely to anticipate and appreciate the vulnerability of teens and children 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, which are likely to be perceived as not pertaining to these children.
5. *Access by Older Children:* Older children are unlikely to comply with the warnings. Although older children presumably would be capable of understanding the danger posed by magnet ingestion, they are likely to give in to peer pressure, test limits, bend rules, and underestimate the risk and consequences. In fact, warnings about keeping magnet sets away from all children could have the unintended effect of making the product more appealing to these older children.
6. *Historical Inadequacy of Similar Efforts:* While some magnet sets are sold absent warnings regarding the ingestion hazard, incidents and consumer reviews indicate that young children are continuing to access magnet sets even when there are prominent warnings, 14+ age labels, instructions, marketing, and packaging that attempt to communicate the appropriate user population and warn about the ingestion hazard.

Additionally, in the appendix below, CPSC staff lists other concerns with the draft standard; however, resolution of these concerns would not, in staff's technical opinion, adequately address the hazard.

Magnet ingestion is a significant concern to CPSC staff, primarily due to the hidden nature of the hazard and the difficult-to-control chain of events that lead to injury and death. In staff's briefing package, *Final Rule on Safety Standard for Magnet Sets*, dated September 3, 2014, a multidisciplinary team of CPSC staff concluded that warnings, even strengthened warnings, as well as other methods of addressing consumer behavior (e.g., bitterants, child resistant packaging, and sales restrictions), will not

Appendix

Additional Concerns with the Proposed ASTM F15.77 Draft Standard

In addition to staff's above comments, staff notes the following concerns:

- The draft standard's title is limited to marketing and labeling; however, there are other requirements in the draft standard.
- Ambiguous language is used, which leaves important requirements open to interpretation. For example, regarding designs and techniques for assuring that all magnets have been collected, staff notes that some structures, such as cubes, can be challenging and time-consuming for consumers to construct.
- "Adults" are defined in the draft standard as including children 14 years of age or older. The legal age of adulthood is not below 18 in any U.S. state. Furthermore, staff notes that there have been incidents of magnet ingestion involving children 14 years of age and older.
- The minimum type size for the warning label is too small (*i.e.*, 0.06 inches for the warning text and 0.15 inches for the signal word) for this product; a product that is non-threatening in appearance and has a hidden hazard.
- The requirements in section 8 do not match the example warning label (Figure 3). The language in Figure 3 was recommended by the Marking and Labelling task group.
- Contacting the Poison Control Center should be considered for the warning label.⁵
- Aside from instructional literature, the draft standard does not address statements that contradict or confuse the meaning of the information required by the standard.
- The product can be marketed as a toy, which can reduce the perception of the product, which is non-threatening in appearance, as potentially hazardous, and support common recognition of the product as a suitable plaything for children.

⁵ Several members of the Instructional Literature task group voiced arguments in favor of contacting the Poison Control Center. For example, on October 30, 2019, one subcommittee member of the Instructional Literature task group stated the following points:

"1- We may not need to refer every child in. Ingestion of one high powered magnet may not be a problem. Ingestion of multiple is where we get concerned.

2- Telling the family member to seek immediate care also doesn't mean that the appropriate care (x-ray, serial abd exams, or surgery) will be done in the ED. There's probably a higher chance of appropriately recognizing the severity of the exposure if poison control is involved as compared to an average rural/community ED. Plus, the ED often calls poison control (esp in peds cases/peds EDs), so it doesn't obviate the need for us to have high confidence that poison control will appropriately manage these cases.

3- There is better public health tracking of data through poison centers."

adequately reduce the hidden hazard and risk of injury associated with magnet sets.² CPSC has an open petition regarding magnet sets, Petition CP 17-1.^{3,4} Although staff appreciates the efforts of the ASTM F15.77 subcommittee, staff does not believe that this hazard can adequately be addressed by methods that rely only on encouraging consumers to alter their behavior in some way to avoid the hazard, especially given the unique challenges discussed above. Thus, CPSC staff cannot support the current ballot item. Staff looks forward to working with ASTM to develop requirements that effectively alleviate the hazard associated with the subject magnet sets.

Sincerely,

Stephen Harsanyi
Engineering Psychologist,
Division of Human Factors

CC: Molly Lynyak, Manager, Technical Committee Operations, ASTM International
Susan Bathalon, Magnet Sets Petition Project Manager, CPSC
Patricia L. Edwards, CPSC Voluntary Standards Coordinator
Ben Mordecai, CPSC Toy Program Lead Testing Engineer

² https://cpsc.gov/s3fs-public/pdfs/foia_SafetyStandardforMagnetSets-FinalRule.pdf

³ <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RDN=3041-AD67>

⁴ <https://cpsc.gov/s3fs-public/Petition-CP-17-1-Requesting-Rulemaking-to-Establish-Safety-Standards-for-Magnet-Sets-September-20-2017.pdf?dl7e0H9QZHp2Vdi65og6udi3W2IApab>

TAB E: Economic Analysis



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
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TO: Susan M. Bathalon, Project Manager
Children's Program Area Risk Manager
Office of Hazard Identification and Reduction (EXHR)

THROUGH: Gregory B. Rodgers, Ph.D., Associate Executive Director
Directorate for Economic Analysis

Robert L. Franklin, Senior Staff Coordinator
Directorate for Economic Analysis

FROM: Charles L. Smith, Economist, Directorate for Economic Analysis

SUBJECT: Petition Requesting Rulemaking on Magnet Sets: Economic Considerations

I. Introduction

On August 17, 2017, Zen Magnets, LLC (Zen or Petitioner), submitted a petition requesting that the Consumer Product Safety Commission (CPSC) initiate a rulemaking to adopt a safety standard for high-powered magnet sets under Sections 7 and 9 of the Consumer Product Safety Act to address hazards associated with these products when they are ingested, aspirated, or otherwise inserted into the body.

For this briefing package, staff considered magnet sets to generally consist of numerous identical, small, powerful magnets. Magnet sets vary in the number of magnets, and the size, shape, and strength of magnets. The Petitioner does not define "magnet sets," but describes the product as small rare earth magnets of various shapes, sizes and flux indices that are commonly sold as magnet sets for the purpose of making sculptures, providing therapeutic value, or to serve as educational or research tools. Zen states that the marketplace offers magnet sets comprised of individual magnets, approximately 5 millimeters (mm) in diameter, each having a flux index⁵² greater than 50 kG²mm². In its petition, Zen reports that it markets spherical magnets having a flux index of between 400 and 550 kG²mm².

The Petitioner notes that high-powered magnet sets present a risk of injury if misused such that the magnets are ingested, aspirated, or otherwise inserted into the body. Ingested magnets can cause damage to gastrointestinal tissue when the magnets attract across sections of the intestinal tract.

This memorandum assesses economic considerations related to the Petition on high-powered magnet sets.

⁵² The flux index (magnetic force) of a magnet is calculated by multiplying the square of the magnet's surface flux density (in KGauss) by its maximum cross sectional area (in mm²).

II. Recommendation of the Petitioner

For magnet sets *designed, marketed, or manufactured for children under the age of 14*, the Petitioner proposes that the individual magnets shall have a flux index of $50 \text{ kG}^2\text{mm}^2$ or lower,⁵³ if the individual magnets are small enough to fit entirely within the “small part cylinder” described in 16 CFR § 1501.4. The Petitioner claims this requirement will effectively limit the strength of magnets purchased for younger children, such that the magnets will not attach across internal tissue if ingested.

For *general use* magnet sets intended for individuals 14 years of age and older, the Petitioner requests different requirements, including packaging, warnings, age restrictions, and instructions.⁵⁴ Zen requests a standard for magnet set packaging, such as requiring that the packaging be difficult for children to open and that the packaging enable users to determine whether all magnets are returned to the package after use. The Petitioner also requests that magnet set packaging provide warnings regarding the ingestion hazard and that the product is not intended for children under 14. Finally, Zen requests that magnet sets include instructional information on how to avoid using the product in such ways that ingestion or aspiration can occur, and how to confirm that all magnets have been returned to the packaging after use.

III. Background

In recent years, the CPSC has taken actions intended to address hazards associated with the products that are the subject of the petition. These prior actions included: 1. agreements entered into by CPSC in mid-2012 with most of the larger manufacturers/importers to stop sales of the subject small, high-powered magnet sets; 2. administrative actions taken by CPSC against firms that initially refused to stop selling the subject magnet sets; 3. CPSC recalls of the magnet sets that had previously been sold to the public; 4. CPSC actions to prevent retailers from selling the subject magnet sets in “brick-and-mortar” stores; and, 5. CPSC issuance of a mandatory standard (16 CFR Part 1240) that went into effect in April 2015.⁵⁵ In a decision issued by a panel of the United States Court of Appeals for the Tenth Circuit (the Court) on November 22, 2016, the magnet sets standard was vacated and remanded to the Commission.⁵⁶ The rule was removed from the CFR, effective March 7, 2017.

The mandatory rule, while it was in effect from April 2015 until November 2016, specified that if the individual magnets were small enough to fit into the small parts cylinder (*e.g.*, a spherical magnet with a diameter of less than 31.7 mm, or 1.25 inches), then the individual magnets must have a flux index of less than $50 \text{ kG}^2\text{mm}^2$, as measured by the

⁵³ In several instances within the petition, the Zen describes the requested magnetic flux index value as less than ($<$) $50 \text{ kG}^2\text{mm}^2$ and equal to or less than (\leq) $50 \text{ kG}^2\text{mm}^2$. For this briefing package, staff assumes that the petitioner’s request is for the flux index to be less than $50 \text{ kG}^2\text{mm}^2$ because that is consistent with ASTM F963, *Standard Consumer Safety Specification for Toy Safety*.

⁵⁴ The petitioner does not seek limitations on the flux index of magnets in *general use* magnet sets.

⁵⁵ Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. 59,962 (Oct. 3, 2014), codified at 16 CFR § 1240.1-1240.5.

⁵⁶ *Zen Magnets, LLC v. Consumer Product Safety Commission*, 841 F.3d 1141 (10th Cir. 2016)

procedures for determining the flux index described in ASTM F963-17 *Standard Consumer Safety Specification for Toy Safety*. Petitioner's proposed requirements reference the strength and size requirements that are nearly identical to the hazardous magnets determinations for children under the age of 14 in ASTM F963.

IV. Description of the Product and Market

The Product

The petition describes small, powerful magnets that are most often made of magnetized alloys of neodymium, iron and boron (commonly referred to as NIB), or other rare earth metals. Before they are magnetized, the NIB cores are typically electroplated with thin metallic layers (such as nickel, copper and gold) or coated with other materials (such as colored epoxy). The coatings make the magnets more attractive to consumers and protect the brittle alloy materials from breaking, chipping and corroding. Nearly 100 percent of neodymium and other rare earth metals are mined in China, which also reportedly holds a nearly worldwide monopoly on the production of NIB magnets (Dent, 2012). Based on available information, all of the small magnets used in magnet sets, and perhaps most of the finished and packaged products that are addressed by the petition, are produced by manufacturers located in China.⁵⁷

Based on information obtained by the CPSC staff, magnet sets typically have been sold in sets of 216 or 224 spheres⁵⁸; although some firms sold sets of 125 spheres, some just a few spheres as extras or replacements, and others have sold large sets of more than 1,000 magnetic spheres. Magnets in sets have most-commonly been spheres with diameters of about 5 mm, although spheres as small as about 2.5 mm have been (and continue to be) sold, as have sets of larger magnet spheres.⁵⁹ In addition to magnetic sphere sets, sets of small magnetic cubes have also been available to consumers, although magnetic cubes have comprised a relatively small share of the market.

The Magnet Sets Market in the United States before the 2015 Mandatory Rule

Before turning to the current status of the magnet sets market, this section provides a brief overview of the history of magnet sets on the U.S. market to provide an idea of the changes that have occurred in the market over time. The year 2009 was the first year with significant sales of magnet sets to U.S. consumers. As noted above, CPSC's magnet set actions commenced in mid-2012 when the CPSC requested manufacturers to stop producing and selling the magnet sets, and initiated a series of recalls of the magnet sets already sold to the public. Based on information reviewed on product sales, including reports by firms to the Office of Compliance and Field Operations, the number of such magnet sets that were sold to U.S. consumers from

⁵⁷ One importer reported that some of the magnet sets it sells and ships to U.S. consumers are made from bulk magnets received from its supplier in China that it packages for sale.

⁵⁸ Packaged as 6x6x6 cubes (216 total) or 6x6x6 cubes with 6 spare magnets (224 total).

⁵⁹ One firm's larger magnet spheres were reportedly made with cores of strontium ferrite ($\text{SrO} \cdot 6\text{Fe}_2\text{O}_3$), rather than neodymium-iron-boron. Some sets of a few magnets larger than would fit into the CPSC's small part test cylinder have also been marketed.

2009 through mid-2012 may have totaled about 2.7 million sets, or an average of about 800,000 annually. Total unit sales were much lower from mid-2012 until the mandatory rule took effect April 2015, since nearly all firms stopped selling the products, including the firm with, by far, the largest share of the market, Maxfield & Oberton Holdings, LLC, marketer of the brand “Buckyballs” (which ceased operations in December 2012).

Status of the Market since the Mandatory Rule was Vacated

Following the November 2016 Court decision that vacated 16 CFR Part 1240, Zen reportedly began taking orders for the types of magnet sets that it marketed prior to the effective date of the rule. The firm reported that shipments filling these orders would begin at the end of March 2017,⁶⁰ and it is still marketing magnet sets as of March 2020. We also note that a company reportedly formed by the founders of Zen magnets and Maxfield & Oberton (Retrospective Goods LLC) sells sets of 2.5 mm magnet spheres under the Speks brand name (Douglas, 2018). These magnets were purported to have a flux index of less than 50 kG²mm², and the sets were marketed as being in compliance with the mandatory rule while it was in effect. We are not aware of other U.S. importers currently selling magnet sets which also marketed the products before the mandatory rule went into effect.⁶¹ However, a firm reportedly based in Canada, and previously involved in the market, Nano Magnetics, also resumed shipments to U.S. retailers and consumers, and is currently marketing sets of 5 mm magnetic spheres.

At this time, it appears that nearly all of the current marketers (firms or individuals) sell their magnet sets through Internet sites, rather than through “brick-and-mortar” retailers such as book stores, gift shops and other outlets (which commonly sold magnet sets during 2009 through mid-2012).⁶² Some of these Internet sites are operated by the importers (e.g., Zen and Nano Magnetics), but the great majority of sellers (in terms of distinct firms or individuals, if not unit sales) appear to sell through their “storefronts” or “stores” operated on the sites of other Internet retailers and marketplaces, such as Amazon and eBay.

In late 2018, Industrial Economics, Incorporated (IEc) conducted a supplemental examination of the market for magnet sets for the CPSC. IEc’s review of magnet sets offered for sale on these (and other) Internet platforms late in 2018 found a total of 39 Amazon and 30 eBay sellers (IEc, 2019, p. 5). IEc also identified 10 manufacturers and two retailers.⁶³ The Directorate for Economic Analysis (EC) staff provided IEc with a spreadsheet of its research, which identified at least 28 sellers of magnet sets on Amazon and at least 93 sellers on eBay. IEc reviewed these sellers with the intention of merging EC’s research with newer information. IEc

⁶⁰ Zen Magnets email update, March 2017 (<http://us6.campaign-archive2.com/?u=3b1101969991ca7b1b93c864c&id=6335350576>).

⁶¹ A firm doing business as Rival Brothers Manufacturing began online marketing of magnet sets in the spring of 2017 using the product name “Bucky*.” The product packaging was very similar to that used for the brand, “Buckyballs,” previously sold by the firm Maxfield & Oberton Holdings, LLC. Further, the website for Bucky* (Buckyforever.com) included statements such as “Bucky is back” which could have indicated a connection between Bucky* and Buckyballs. However, it appears that sales ceased in February or March of 2018, and the website no longer exists.

⁶² Internet searches on February 3, 2020, found that magnet sets were being offered for sale on Internet sites operated by retailers with brick-and-mortar stores, such as Target and Walmart. However, a subsequent review of such sites on March 4, 2020, did not find the magnet sets were being offered for sale.

⁶³ IEc classified manufacturers as firms producing and selling their own magnet set products, and retailers as firms that typically sell magnets from multiple manufacturers (IEc, 2019, p. 4).

“... discovered that the vast majority of eBay sellers recorded by CPSC were no longer selling relevant magnet set models. Further, more than half of the Amazon storefronts no longer sold relevant magnet set models. [IEc’s] review confirms that Amazon and eBay marketplaces have high turnover rates for magnet set products offered on their sites” (IEc, 2019, p. 8).

More recently, in February and March of 2020, EC staff’s follow-up review of the status of sellers of magnet sets on Amazon and eBay identified by IEC found further evidence of the high turnover rates for these platforms: most of the sellers identified in late 2018 have either ceased selling magnet sets, or have abandoned their “storefronts” or “stores.” EC staff found that only 6 of 39 previous sellers on Amazon are still selling magnet sets, and only 3 of 30 previous sellers on eBay are still offering the products. The remaining 60 sellers either no longer offer magnet sets (51) or no longer operate on the platforms (9). However, staff did identify 10 sellers on Amazon and 15 sellers on eBay that IEC did not identify as being active in the market in late 2018. This gives further evidence of the high turnover rate among retail sellers of magnet sets.

Although the locations of the sellers on Amazon were not always clear, many appeared to have been located in China. The 2018 review of the market by staff of the Directorate for Economic Analysis (EC) found that about 57 percent of magnet set sellers on Amazon (foreign and domestic) had their orders fulfilled by Amazon, a service in which products are stored in Amazon’s domestically-located fulfillment centers, and Amazon personnel pick, pack, ship, and provide customer service for these products. Our recent review found 16 current Amazon sellers, most of which appear to be located in China; 4 of these current Amazon sellers (25%) have orders fulfilled by Amazon. Our recent review of magnet sets of interest on eBay found that of 18 current sellers, 13 (87%) are located in the United States.⁶⁴ This is an apparent shift from 2018, when we found that a substantial majority of sellers on eBay (75%) were located in China or Hong Kong.

In addition to the use of Internet retailers based in the United States, U.S. consumers may also purchase a wide variety of magnet sets using online retailers based in China, such as LightInTheBox.com (and the affiliated website, MiniInTheBox.com), Banggood.com, and AliExpress.com. Magnet sets purchased from foreign Internet retailers may be shipped to U.S. consumers directly from China or from warehouse facilities located domestically.

Magnet sets currently offered for sale are comprised of spheres or cubes in a range of dimensions and numbers of individual magnets. Magnet sets seen in our review of the market mainly were comprised of 216 magnetic spheres, with diameters of 5 mm.⁶⁵ Retail prices average under \$20 per set. IEC’s market review in late 2018 had similar findings.⁶⁶ Magnet sets comprised of spheres or cubes with smaller dimensions (2.5 mm to 3 mm) are also marketed, typically at lower prices. At least some of these smaller magnets are reported to comply with

⁶⁴ Several “stores” selling magnet sets on eBay appeared to have been operated by the same individuals, based on locations and prices. In these cases, multiple storefronts were not counted as distinct sellers.

⁶⁵ Our 2018 review of the market found high-powered magnet sets for sale ranging from 20 or fewer spheres up to 1,728 spheres.

⁶⁶ IEC found that magnet sets with 216 magnets accounted for approximately one-third of the models in their market research, with an average price of \$16.67 (IEc, 2019, p. 7). However, sets of 216 magnet spheres that measured 5 mm in diameter averaged \$18.60.

ASTM, EN71 and CPSIA requirements or advertised as having flux indices of less than 50 kG²mm².⁶⁷

Staff also reviewed currently offered products for compliance with the petitioner's suggested packaging requirements, and age restrictions for *general use* magnet sets intended for individuals 14 years of age and older. EC staff's review of product offerings online found that, when stated or displayed, current packaging generally does not appear to offer much resistance to being opened by young children. Packaging commonly consists of metal cans or plastic cubes, with easily-removable tops. Staff of the CPSC's Engineering Sciences Division of Human Factors (ESHF) and Compliance (CRE) jointly conducted a comprehensive review of magnet set labeling, warnings, and packaging (Harsanyi, 2020). That review found that suggested age limits are commonly stated on online product offerings, but staff found many products that had no suggested age limits. While suggested age limits, when present, typically were 14 years and older, staff found products with lower suggested age limits, such as 8 years and older, which were often not stated on online product offerings.

Staff currently does not have information to estimate magnet sets sales for the period since the Court vacated the mandatory rule. Although a large number of sellers have offered the products online, nearly all of them also offer a wide variety of other products for sale, and most probably have sold relatively few magnet sets.⁶⁸ It is likely that magnet set sales will continue to be largely through Internet sites from small sellers, with a substantial share of sales being comprised of direct-to-consumer sales. These unusual aspects of the magnet set market complicate the task of acquiring reliable information on unit sales.

V. Injuries and Societal Costs

The CPSC has collected information regarding numbers of injuries with, and hazards posed by, sets of small, powerful magnets intended for adult use since about 2009. Some of these injuries required surgical removal of individual magnets from magnet sets that were ingested by children. Reported magnet ingestions have ranged from young children, who put the magnets in their mouths and intentionally ingested them, to adolescents and teens who experimented with the sensation of magnets (*e.g.*, attached magnets to their braces) or paired magnets to mimic tongue or lip piercings. These behaviors have led to the intentional and accidental swallowing of the powerful magnets, with sometimes severe medical consequences that were unexpected by the victims and their families, including, for example, significant damage to the gastrointestinal tract resulting from pressure necrosis injuries when the strong magnets attract each other through intestinal walls. Interaction of ingested magnets is also known to have caused serious injuries and deaths due to twisting and obstruction of the intestine (Inkster, 2020).

⁶⁷ When the Commission voted to issue the safety standard in 2014, staff had not identified any complying magnet sets in the market that served the same niche as the sets of larger and stronger magnets, such as the sets of smaller (2.5 mm to 3 mm) magnets having a flux index of 50 kG²mm² or less.

⁶⁸ At the time of EC's 2018 review of the market, about half of the sellers found on eBay reported the numbers of magnet sets they had sold; the average number of sets reportedly sold by these sellers was 57 and the median number of sets sold was 13.

Magnet ingestions collected in the Consumer Product Safety Risk Management System (CPSRMS) database with incident dates from January 1, 2009, through December 31, 2019, included 176 reports of magnet ingestion *involving or possibly involving* magnet sets; 2 incidents in the United States reportedly resulted in death (Topping, 2020).

Directorate for Epidemiology staff reviewed incident narratives coded from hospital emergency department medical records for magnet ingestion cases obtained from NEISS hospitals. During 2017 and 2018, which is the most-recent period with sufficient data for CPSC's Division of Hazard Analysis to be able to report an estimate, there were 61 such ingestion cases treated in NEISS hospitals' emergency departments, of which 8 were categorized as involving the subject magnet sets and 53 were categorized as possibly involving the subject magnet sets. In addition to injuries initially treated in hospital emergency departments, many product-related injuries are treated in other medical settings, such as physicians' offices, clinics, and ambulatory surgery centers. Some injuries also result in direct hospital admission, bypassing hospital emergency departments entirely. The number of magnet ingestion injuries treated outside of hospital emergency departments is estimated with the CPSC's Injury Cost Model (ICM), which uses empirical relationships between the characteristics of injuries (diagnosis and body part) and victims (age and sex) initially treated in hospital emergency departments and the characteristics of those initially treated in other settings.

The ICM is fully integrated with NEISS and provides estimates of the societal costs of injuries reported through NEISS, as well as the societal costs of other medically treated injuries estimated by the ICM. The major aggregated components of the ICM include: medical costs; work losses; and the intangible costs associated with lost quality of life or pain and suffering.⁶⁹

Table 1 below provides *annual* estimates of the injuries and the societal costs associated with "high-powered and/or ball-shaped magnet ingestions" categorized as either *involving*, or *possibly involving*,⁷⁰ the magnets that are the subject of the petition.

⁶⁹A detailed description of the cost components, and the general methodology and data sources used to develop the CPSC's Injury Cost Model, can be found in Lawrence et al. (2018).

⁷⁰ Our use of the terms, "involve, or possibly involve" corresponds to the designations "Yes" and "Possible" for NEISS incidents used by the Division of Hazard Analysis in the evaluation of magnet set injuries (Topping, 2020, p. 3).

Table 1.

Estimated Average Annual Medically-Treated Injuries and Associated Societal Costs for High-Powered and/or Ball-Shaped Magnet Ingestions that were Determined to Involve, or Possibly Involve, the Magnets of Interest from 2017–2018

| | Total | | Magnet Injuries Determined to Involve Magnets of Interest | | Magnet Injuries Possibly Involving Magnets of Interest | |
|--|-----------------------------------|--------------------------------------|--|--------------------------------------|---|--------------------------------------|
| Treated at: | Medically Treated Injuries | Societal Costs* (Millions \$) | Medically Treated Injuries | Societal Costs* (Millions \$) | Medically Treated Injuries | Societal Costs* (Millions \$) |
| Doctor/Clinic | 197 | \$5.2 | 5 | \$0.1 | 192 | \$2.5 |
| Treated & Released from Hospital EDs | 374† | \$15.9 | 10† | \$0.2 | 364† | \$7.7 |
| Admitted to the Hospital through the ED | 264† | \$91.3 | 51† | \$7.6 | 213† | \$38.1 |
| Direct Hospital Admissions, bypassing the Eds | 127 | \$44.0 | 25 | \$3.7 | 103 | \$18.3 |
| Total | 962 | \$78.2 | 91 | \$11.5 | 872 | \$66.6 |

* In 2018 dollars.

† According to the Directorate for Epidemiology, separately reporting the estimated numbers of emergency department-treated injuries that are hospital-admitted or treated and released, may not be reliable estimates because of the small number of cases upon which the estimates are based.

In Table 1, we have presented separate ICM estimates for NEISS cases determined to involve magnet sets (“yes” category), and those which possibly involved magnet sets (“possible” category). This modeling found an annual average of 91 medically-treated injuries involving magnets of interest (the “yes” category) with average annual estimated societal costs of \$11.5 million in 2017 – 2018. These estimates account for about 9 percent of the average estimated medically-treated injuries (962) and about 15 percent of the average estimated societal costs (\$78.2 million) over those years that involved or possibly involved magnets of interest (“yes” and “possible,” combined).

For the “yes” and “possible” categories, combined, the average estimated societal costs per injury was about \$13,000 for injuries treated in physician’s offices, clinics, and other non-hospital settings; about \$21,000 for injuries that were treated and released from emergency departments; and about \$173,000 for injuries that required admission to the hospital for treatment. Average societal costs were about \$81,000 per incident based on ICM estimates.

Medical costs and work losses (including work losses of caregivers) accounted for about 46 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 54 percent of the estimated injury costs.

Estimated medically-treated injuries (and their societal costs) for the years 2017 – 2018 are considerably greater than for the years 2015 – 2016. Estimated medically-treated injuries averaged 268 annually for the years 2015 – 2016, which is only 28 percent of the average estimated for 2017 – 2018. The average estimated societal costs of injuries during 2015 and 2016 was just 15 percent of that during 2017 and 2018. The difference could largely be attributable to the CPSC compliance activities in early 2015, and the presence of the mandatory rule for magnet sets for most of 2015 and 2016. The two-year period of 2011 – 2012 was the last time when estimated average annual medically-attended injuries (987) were higher than that estimated for 2017 – 2018.

VI. Summary

The current market for magnet sets appears to be comprised of many small firms or individuals who market magnet sets they obtain from suppliers located in China. The products are also offered by many foreign manufacturers and sellers to be imported directly by U.S. consumers. However, no sales estimates or estimates of the number of the subject magnet sets in use are available. Consequently, the unusual nature of the market for magnet sets and the lack of information on magnet set sales and the number of magnet sets in use would complicate any assessment of the hazards associated with current sales for the purpose of determining the potential benefits of a rule, though staff has identified that at least \$11.5 million in societal costs were incurred from magnet sets in incidents in 2017 – 2018, with an additional \$66.6 million estimated in societal costs for products that may have been magnet sets, but for which we have not determined conclusively whether they were magnet sets.

References

- Mordecai, B. (2020). Memorandum, subject: *Existing standards and analysis of magnetic strength of magnet sets*. Bethesda, MD: Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission.
- Dent, P.C. (2012). Rare earth elements and permanent magnets, *J of Applied Physics* 2012; 111(7), 07A721-1.
- Douglas, N. (2018, January 3). I'm Buckyballs inventor Craig Zucker, and this is how I work. *How I Work* (lifehacker.com). Available at: <https://lifehacker.com/im-buckyballs-inventor-craig-zucker-and-this-is-how-i-1821747489>
- Inkster, S.E. (2020). Memorandum, subject: *Petition requesting rulemaking on magnet sets: Health Sciences considerations and response to public comments*. Bethesda, MD: Directorate for Health Sciences, U.S. Consumer Product Safety Commission.
- Israel, J., Cahill, A., and Baxter, J. (2019). Report: Final high-powered magnet set market research report. Cambridge, MA: Industrial Economics, Incorporated (IEC).
- Lawrence B.A., Miller, T.R., Waehrer G.M., Spicer R.S., Cohen M.A., and Zamula, W.W. (2018). *The Consumer Product Safety Commission's revised injury cost model: Final report to the U.S. Consumer Product Safety Commission*. Calverton, MD: Pacific Institute for Research and Evaluation. Available at: <https://www.cpsc.gov/s3fs-public/icm-2018-documentation.pdf?ywuww4jn0eb2hexea0z68b64cv6lluyoe>.
- Harsanyi, S. and Balci-Sinha, R. (2020). Memorandum, subject: *Human Factors assessment of the petitioner's proposal and response to public comments*. Bethesda, MD: Division of Human Factors, Directorate for Engineering Sciences, U.S. Consumer Product Safety Commission.
- Topping, J. (2020). Memorandum, subject: *NEISS estimates and analysis of reported incidents related to ingestion of magnets of various shapes and sizes from or possibly from magnet sets*. Bethesda, MD: Division of Hazard Analysis, Directorate for Epidemiology, U.S. Consumer Product Safety Commission.

TAB F: Engineering Analysis



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Date: June 3, 2020

TO : Susan Bathalon
Magnet Sets Petition Project Manager
Office of Hazard Identification and Reduction

THROUGH: Michael Nelson
Director, Division of Mechanical Engineering
Directorate for Laboratory Sciences

FROM : Benjamin Mordecai
Mechanical Engineer
Directorate for Laboratory Sciences

SUBJECT : Existing Standards and Analysis of Magnetic Strength of Magnet Sets

I. Introduction

On August 17, 2017, Zen Magnets, LLC (petitioner) petitioned the Consumer Product Safety Commission (CPSC) to issue a rule to mandate a safety standard for high-powered magnet sets. The petitioner described the product as small rare earth magnets of various shapes, sizes and flux indices that are commonly sold in magnet sets for the purposes of making sculptures, providing therapeutic value, or to serve as educational or research tools. The petitioner noted that high-powered magnet sets present a risk of injury if misused such as if the magnets are ingested, aspirated, or otherwise inserted into the body. Ingested magnets can cause damage to gastrointestinal tissue when the magnets attract across sections of the intestinal tract.

To address these hazards, the petitioner proposed two distinct safety standards for magnet sets: (1) for magnet sets designed, marketed, and manufactured for children younger than 14 years of age, and (2) for magnet sets designed, marketed, and manufactured for individuals 14 years of age and older.

For magnet sets marketed to children under 14 years of age, the petitioner recommended a performance standard requiring that each small part magnet in a magnet set (*i.e.*, small enough to fit within the small parts cylinder⁷¹) have a flux index of 50 kG²mm² or lower⁷². The petitioner

⁷¹ The dimensions and test procedures for assessing whether something fits in the small parts cylinder are in 16 CFR § 1501.4. The small parts cylinder has a diameter of 1.25 inches (31.7 mm).

claims that this will effectively limit the strength of magnets so that they will not attach across internal tissue if ingested.

For magnet sets intended for “general purpose” rather than children, specifically, consumers 14 years of age and older, the petitioner proposes warning and age labeling, instruction, and packaging requirements to mitigate the magnet ingestion hazard, without setting a maximum flux index limit. For “general purpose” magnet sets, the petitioner requests a safety standard that focuses on the following:

- magnet set packaging that provides warning statements regarding the ingestion hazard;
- instructional literature with directions on how to avoid using the product in ways that can result in ingestion or aspiration and how to ensure all of the magnets are returned to the package after use;
- age recommendations on packaging, warnings, and instructional literature, indicating that the product is for users age 14 and older;
- magnet set packaging that is difficult for children to open;
- and magnet set packaging that enables users to determine whether all magnets are returned to the container after use.

This memorandum provides an assessment of existing standards and practices related to high-powered magnet sets, and briefly discusses the petitioner’s proposed requirements.

II. Product Description

For this briefing package, staff considered magnet sets to generally consist of numerous identical, small, powerful magnets. Magnet sets vary in the number, size, shape, and strength of magnets.

In 2010, the CPSC began investigating incidents involving small, powerful, magnet sets marketed for adults as puzzles, desk toys, sculptures, stress reducers, visualization of micro-structures, or for other similar purposes. These sets, as shown in Figure 1, are typically comprised of numerous identical, spherical, or cuboid magnets, approximately 4 to 6 mm in size, and most commonly composed of NdFeB (Neodymium-Iron-Boron or NIB), though other permanent magnet material compositions such as: Iron-Oxide (ferrite), Aluminum-Nickel-Cobalt (AlNiCo), and Samarium-Cobalt (SmCo), and high grade ceramic ferrite ($\text{SrO } 6\text{Fe}_2\text{O}_3$) exist.

⁷² In several instances within the petition, the Petitioner describes the requested magnetic flux index value as less than ($<$) $50 \text{ kG}^2\text{mm}^2$ and equal to or less than (\leq) $50 \text{ kG}^2\text{mm}^2$. For this briefing package, staff assumes that the petitioner’s request for the product intended for users younger than 14 years old to have a flux index less than $50 \text{ kG}^2\text{mm}^2$ because that is consistent with ASTM F963, *Standard Consumer Safety Specification for Toy Safety*.



Figure 1: Typical Magnet Set

Permanent magnets maintain their magnetic field after being removed from the magnetizing source. NIB and SmCo magnets are often referred to as “rare earth” magnets because Neodymium and Samarium are 2 of the 17 so-called “rare earth” elements found in the periodic table. Magnet sets commonly sold on the market, having a 2.5 mm to 5 mm major dimension, are almost exclusively NIB magnets. Table 1 shows the relative strength of the most common permanent magnet materials.

Table 1: Relative Strength of Magnetic Materials

| Magnet Material* | Relative Strength |
|-------------------------|--------------------------|
| Sintered FeO (ferrite) | Low |
| Sintered AlNiCo | Low to Moderate |
| Bonded NdFeB, NIB | Moderate |
| Sintered SmCo | High |
| Sintered NdFeB (NIB) | Very High |

* Bonded magnets are manufactured by melting the raw materials into a ribbon. The ribbon is pulverized into tiny particles, mixed with a polymer, and either compression or injection molded into shape. Sintered magnets are manufactured by melting the raw materials, which are cooled to form ingots. The ingots are pulverized into tiny particles which are compacted under pressure and heated at high temperature to fuse the particles together. Magnets are cut to shape, surface treated and magnetized.

III. Voluntary Standard and Mandatory Regulation for Toys Containing Magnets

Although ASTM is working on developing a standard for “general purpose” magnet sets intended for users age 14 and older, currently, there is no voluntary standard or regulation for such magnet sets. The Division of Human Factors memorandum, (Tab D) discusses the development process for this voluntary standard. However, there are voluntary and mandatory standards that address magnet sets manufactured, designed, or marketed for children under 14 years old.

Voluntary/Mandatory Standards for Toys Containing Magnets

In June 2006, the ASTM Toy Safety subcommittee began development of voluntary standard requirements to address hazards seen with the ingestion and inhalation of small magnets found in toys intended for children under 14 years of age. The requirements for toys containing magnets were first published in ASTM F963-07, *Standard Consumer Safety Specification for Toy Safety*, and were later strengthened in the 2008 version by incorporating specified magnet use and abuse testing. On February 10, 2009, these requirements were adopted as mandatory regulations by the CPSC, as mandated by Section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). The voluntary standard and the mandatory standard have since been updated; the current version of the standard is ASTM F963-17, which the Commission incorporated by reference in the mandatory toy standard at 16 CFR part 1250.

ASTM F963-17 applies to “toys intended for use by children under 14 years of age.” ASTM F963-17 prohibits toys from containing a loose as-received “hazardous magnet” or a loose as-received “hazardous magnetic component,” and prohibits toys from liberating a hazardous magnet or hazardous magnetic component after specified use and abuse testing. A “hazardous magnet” is a magnet that is small enough to fit entirely within the small parts cylinder⁷³ and that has a flux index of 50 kG²mm² or more. A “hazardous magnetic component” is any part of a toy that fits in the small parts cylinder and contains a hazardous magnet. The *flux index* of a magnet is a novel empirical value chosen by the ASTM magnet toy working group as a way to estimate the relative attraction force of a magnet. The flux index of a magnet is calculated by multiplying the square of the magnet’s surface flux density (in kGauss or kG) by its maximum cross sectional area (in mm²). The prescribed procedure in ASTM F963 uses a Gauss meter⁷⁴ with a probe that measures the surface flux density at 0.015 inches (0.38 mm) above the magnet’s surface, by use of a probe which measures flux density at 0.015 in (0.38 mm) from the tip which is in contact with the magnet. The flux index is calculated by multiplying the area of the pole surface of the magnet by the square of the maximum flux density, with the area of the pole surface calculated as the largest cross section of the magnet that is perpendicular to the axis of its magnetic poles.

⁷³ The small parts cylinder is depicted in ASTM F963, and is identical to the small parts cylinder in 16 CFR § 1501.4.

⁷⁴ A Gauss meter is used to measure the strength of the magnetic field at a specific location and orientation above the magnet surface. The magnetic field strength is measured in units of Gauss. A kiloGauss (kGauss or kG) is 1,000 Gauss units.

As indicated above, the current version of the toy standard is ASTM F963-17, which the Commission incorporated by reference in the mandatory standard⁷⁵, and which applies only to toys intended for children under 14 years of age. However, the standard has an exception specifically for magnetic/electrical experimental sets intended for children 8 years of age and over that contain loose as-received hazardous magnets or loose as-received hazardous magnetic components, provided they comply with requirements for safety labeling described in the standard.⁷⁶

International Voluntary Standards for Toys Containing Magnets

Staff is unaware of any international standards specific to magnet sets intended for children 14 years and older. The following international standards for toys include requirements for children's toys containing magnets.

EN 71-1:2014 Safety of Toys – Part 1: Mechanical and Physical Properties - This European standard applies to toys for children, with toys defined as any product or material designed or intended, whether or not exclusively, for use in play by children of less than 14 years. The requirements for toys containing magnets are similar to those in ASTM F963-17. The EN 71-1 requirement states that any loose as-received magnet(s) and magnetic component(s) shall have either a flux index less than 50 kG²mm², or shall not be a small part. The magnet flux index is calculated the same way as in ASTM F963-17. EN 71-1 has similar use and abuse testing to ensure that hazardous magnet(s) or hazardous magnetic component(s) are not liberated from the toy. EN 71-1 also contains a similar exemption for magnetic/electrical experimental sets containing hazardous magnets intended for children 8 years of age and older.

ISO 8124-1:2018 Safety of Toys – Part 1: Safety Aspects Related to Mechanical and Physical Properties – This international standard applies to all toys, meaning any product or material designed or clearly intended for use in play by children under 14 years of age. The requirements for toys containing magnets are essentially identical to those in ASTM F963-17.

IV. Discussion

Staff reviewed the petitioner's recommendation for a mandatory performance standard requiring that each small part magnet in a magnet set has a flux index $\leq 50 \text{ kG}^2\text{mm}^2$, if the product is designed, marketed, or manufactured for children under 14 years of age. As explained above, toys with magnets that are intended for children under 14 years of age are subject to the requirements in the mandatory toy standard at 16 CFR part 1250, which incorporates by

⁷⁵ The Commission incorporated by reference ASTM F963-17 with one exception regarding sound testing of push and pull toys, which is not relevant to magnets.

⁷⁶ Magnetic/electrical experimental sets are defined as "toy[s] containing one or more magnets intended for carrying out educational experiments involving both magnetism and electricity." The standard states: "The packaging and instructions of magnetic/experimental sets shall carry safety labeling. The labeling shall consist of the safety alert symbol followed by the signal word "WARNING" and contain, at a minimum, the following text or equivalent text which clearly conveys the same hazard alerting message: 'This product contains (a) small magnet(s). Swallowed magnets can stick together across intestines causing serious infections and death. Seek immediate medical attention if magnet(s) are swallowed or inhaled.'"

reference ASTM F963-17. ASTM F963-17 contains performance requirements for toys with magnets that are the same as the requirement the petitioner requests. The current regulation satisfies the petitioner's request.

In 2007, the ASTM working group determined that all the magnets that were likely to have been involved in incidents had flux indices over $70 \text{ kG}^2\text{mm}^2$; therefore, the working group chose a flux index value of $50 \text{ kG}^2\text{mm}^2$ in order to provide what they considered at the time to be a reasonable safety factor. The selection of a magnet's flux index value as a way to assess the magnet's potential hazard was based solely on incident data available at that time. Staff is aware of a number of experimental studies that attempt to determine the effects of magnetic compression forces on gut tissue, none of which use ASTM's flux index of the magnet to make such an assessment. Staff has neither conducted nor is aware of any studies confirming that magnets with a flux index $\leq 50 \text{ kG}^2\text{mm}^2$ will not attract across gastrointestinal tissue.

The ASTM working group originally selected a flux index less than $50 \text{ kG}^2\text{mm}^2$ as a cutoff for what meets the requirements of the standard, based on measurements of a number of toys on the market at the time of the original incidents. Most of the magnets analyzed were cylindrical in shape, some of which had been involved in known incidents. When the ASTM F963 magnet working group graphed the measurements, it showed a fairly linear relationship between calculated flux index and measured attraction force for a majority of the magnets, as shown in Figure 2. Based on this graph, the flux index method was considered a reliable way to gauge a magnet's relative attraction force.

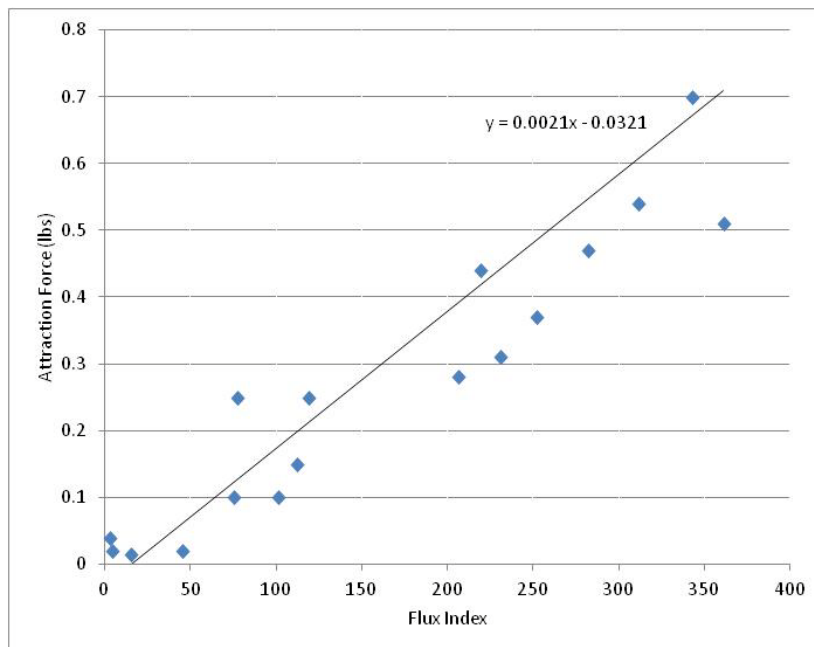


Figure 2: Flux Index versus Attractive Force of Various Sample Magnets
(As measured by ASTM Magnetic Toy Working Group)

The petitioner's recommendation for standard packaging, warnings, and instructions for magnet sets that are marketed for users 14 years of age and older is addressed in the Human Factors staff memorandum (Tab D) in this briefing package.

V. Conclusion

Staff believes the requirements for toys containing magnets in ASTM F963-17 and the current mandatory standard for toys, which specify that each small part magnet in a toy must have a flux index $< 50 \text{ kG}^2\text{mm}^2$, address the petitioner's recommendation to mandate a performance standard for magnet sets intended for children under 14 years old. Moreover, staff is not aware of any voluntary or mandatory standard which addresses hazards related to magnet set products that are marketed to consumers 14 years of age and older, but staff believes that performance requirements addressing magnet ingestion hazards should be considered in future standard development.

TAB G: Compliance Activities



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

MEMORANDUM

Date: June 3, 2020

To: Susan Bathalon, Project Manager
Children's Program Risk Manager
Office of Hazard Identification and Reduction

Through: Robert S. Kaye, Assistant Executive Director
Office of Compliance and Field Operations

Jennifer Timian, Director, Regulatory Enforcement Division
Office of Compliance and Field Operations

From: Joseph Tsai, Compliance Officer, Children's and Durable Product Team
Office of Compliance and Field Operations

Subject: Petition for Rulemaking by Zen Magnets, LLC
(Docket No. CPSC-2017-0037)

INTRODUCTION

This memorandum describes enforcement activities involving magnet sets by the Office of Compliance and Field Operations (Compliance) since January 1, 2008. Since 2008, we have engaged in enforcement activities under Section 15 of the CPSA; the Safety Standard for Magnet Sets, 16 CFR part 1240 (vacated); and ASTM F963 (Standard Consumer Safety Specification for Toy Safety) Section 4.38. We also address a comment made by the petitioner, Zen Magnets, LLC, regarding enforcement activities.

ENFORCEMENT ACTIVITY ON MAGNET SETS

Section 15 of the CPSA

From January 1, 2008 to March 31, 2015, six firms conducted recalls of magnet sets, in conjunction with CPSC, under Section 15 of the CPSA. In addition, on April 12 and 15, 2013, eight retailers recalled magnet sets manufactured by a single firm. Furthermore, we issued a Notice of Non-Compliance and ultimately obtained an order from the U.S. District Court for the

District of Colorado requiring a firm to recall and destroy magnets which had been previously recalled and were later sold by the firm.

On October 26, 2017, in an administrative proceeding conducted pursuant to CPSA Section 15, CPSC issued a Final Decision and Order requiring one firm to recall magnet sets. That firm appealed the Commission's recall order, and the matter is currently pending in the 10th Circuit Court of Appeals.

Safety Standard for Magnet Sets, 16 CFR part 1240 (Vacated)

The Safety Standard for Magnet Sets (Standard), 16 CFR part 1240, which covered general use magnet sets, was in effect from April 1, 2015 to November 22, 2016. During this period, Compliance collected a total of 7 magnet sets. Compliance determined that 5 of the magnet sets were not in compliance with the Standard. The non-compliant magnet sets were distributed by three firms. We issued a Notice of Non-Compliance to all three firms. One firm removed the magnet sets from its website; another agreed to stop the sale and importation of magnet sets; and the website that listed the third firm's magnet sets removed the magnet sets from its listing after it received our Notice of Non-Compliance.

Standard Consumer Safety Specification for Toy Safety, ASTM F963, Section 4.38

The Standard Consumer Safety Specification for Toy Safety (Toy Standard) became mandatory on February 10, 2009. Section 4.38 has been revised twice to address the ingestion hazard associated with strong magnets; currently, ASTM F963-17 is the mandatory standard. Toys that contain a hazardous magnet or a hazardous magnetic component and that are designed or marketed for children under 14 years of age are subject to the magnet requirements under ASTM F963 Section 4.38. A hazardous magnet is defined in ASTM F963 as a magnet which is a small object (completely fits inside the small parts test cylinder) and has a flux index equal to or higher than $50 \text{ kG}^2 \text{ mm}^2$. A hazardous magnetic component is any part of a toy that is a small object and which contains an attached or imbedded magnet with a flux index equal to or higher than $50 \text{ kG}^2 \text{ mm}^2$. ASTM F963 requires that toys intended for children under the age of 14 years shall not contain a loose, as-received, hazardous magnet or magnetic component, nor shall they liberate a hazardous magnet or magnetic component under specified performance testing.

Since early 2018, Compliance has pursued corrective measures from 19 different magnet set sellers whose products violated the Toy Standard. These sellers, the majority of which are located in China, marketed their magnet sets online through e-market platforms. Sixteen of the 19 sellers marketed their products on Amazon.com, two on Walmart.com, and one on Ebay.com.

Compliance issued a Notice of Violation (NOV) to each of the sellers. Compliance did not issue an NOV to the Ebay seller because Compliance was unable to ascertain the Ebay seller's contact information.

Twelve of the 18 sellers did not respond. Of the 6 sellers that did respond, three domestic sellers agreed to conduct recalls. For those sellers that did not respond or were otherwise not available for purposes of executing a corrective action (e.g., the seller was no longer in business or refused to cooperate), Compliance approached the internet platform provider. Both Amazon and Walmart removed the products from their sites, rendering them unavailable for purchase. Additionally, at Compliance's behest, Amazon notified purchasers of the violation and offered refunds to their known purchasers.

Compliance has also identified magnet sets being marketed or recommended as toys for children under 14 years of age on international e-marketing sites. These international sites distribute products globally, including shipping products directly to U.S. consumers; Compliance was unable to ascertain whether these magnet sets were being distributed by third-party sellers as well. Compliance collected and evaluated magnet sets from these international sites and determined they were in violation of the magnet requirements under the Toy Standard because they were small enough to fit entirely within the small parts cylinder and had flux indexes of 50 kG² mm² or greater. Compliance issued NOV's directly to three of these international sellers; however, Compliance did not get responses.

RESPONSE TO COMMENT

On November 28, 2017, Zen Magnets submitted a comment concerning its own petition. In the comment, Zen Magnets alleged that "CPSC's absence of enforcement has encouraged sales of high-powered magnet spheres designed and marketed as toys for children, many of which are without any warnings and/or instructions. These magnets are available from thousands of listings on Amazon, eBay, and hundreds of independent sites. The enforcement of ASTM F963 would eliminate or improve approximately 90% of these listings."

Magnet sets marketed as children's toys must meet mandatory magnet toy requirements under ASTM F963; Compliance will continue to enforce the requirements of ASTM F963. We are aware of some resurgence of e-retail offerings of magnet sets since the Standard was vacated. However, the existing mandatory standard, ASTM F963, applies only to those magnet sets marketed as children's toys.