UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
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BETHESDA, MD 20814

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BALLOT VOTE SHEET

Date: August 8, 2012

TO : The Commission
Todd A. Stevenson, Secretary

THROUGH: Kenneth R. Hinson, Executive Director
Cheryl A. Falvey, General Counsel

FROM : Patricia M. Pollitzer, Acting Assistant General Counsel, RAD

SUBJECT : Safety Standard for Magnet Sets; Notice of Proposed Rulemaking

BALLOT VOTE DATE: August 23, 2012

Staff is forwarding to the Commission a briefing package recommending that the Commission issue a notice of proposed rulemaking (NPR) addressing the risk of injury associated with magnet sets. A draft *Federal Register* notice is provided for your consideration.

Please indicate your vote on the following options:

I. Approve publication of the draft NPR in the *Federal Register*, without changes.

_____ _____
Signature Date

II. Approve publication of the draft NPR in the *Federal Register*, with changes (please specify changes):

_____

_____

_____

_____ _____
Signature Date

III. Do not approve publication of the draft NPR in the *Federal Register*.

_____ _____
Signature Date

IV. Take other action (please specify):

_____

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_____

_____ _____
Signature Date

DRAFT 8/8/12

[Billing Code 6355-01-P]
CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1240

Safety Standard for Magnet Sets; Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of Proposed Rulemaking

SUMMARY: Based on available data, the U.S. Consumer Product Safety Commission (the Commission, the CPSC, or we) has determined preliminarily that there may be an unreasonable risk of injury associated with children ingesting high-powered magnets that are part of magnet sets. These magnet sets are aggregations of separable, permanent, magnetic objects intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. In contrast to ingesting other small parts, when a child ingests a magnet, the magnetic properties of the object can cause serious, life-threatening injuries. When children ingest two or more of the magnets, the magnetic forces pull the magnets together, and the magnets pinch or trap the intestinal walls or other digestive tissue between them, resulting in acute and long-term health consequences. Although magnet sets have only been available since 2008, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments between January 1, 2009 and December 31, 2011.

To address the unreasonable risks of serious injury associated with these magnet sets, the Commission is issuing this notice of proposed rulemaking (NPR), which would prohibit such

magnet sets. Under the proposal, if a magnet set contains more than one magnet that fits within the CPSC's small parts cylinder, magnets from that set would be required to have a flux index less than 50, or they would be prohibited. The flux index would be determined by the method described in ASTM F963-11, Standard Consumer Safety Specification for Toy Safety.

The Commission solicits written comments concerning the risks of injury associated with these magnet sets, the regulatory alternatives discussed in this NPR, other possible ways to address these risks, and the economic impacts of the various regulatory alternatives. This proposed rule is issued under the authority of the Consumer Product Safety Act (CPSA).

DATES: Written comments in response to this document must be received by the Commission no later than [**insert date that is 75 days after publication**].

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2012- _____, by any of the following methods:

Submit electronic comments in the following way:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. To ensure timely processing of comments, the Commission is no longer accepting comments submitted by electronic mail (e-mail), except through www.regulations.gov.

Submit written submissions in the following way:

Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions), preferably in five copies, to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number

for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to http://www.regulations.gov. Do not submit confidential business information, trade secret information, or other sensitive or protected information electronically. Such information should be submitted in writing.

FOR FURTHER INFORMATION CONTACT: Jonathan D. Midgett, Ph.D, Project Manager, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814-4408; telephone: (301) 504-7692, or e-mail: jmidgett@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background

The Commission is proposing a safety standard that would prohibit magnet sets that have been involved in serious injuries. The Commission believes that this proposed rule is necessary to address an unreasonable risk of injury and death associated with these magnet sets.

1. History with magnetic toys

In the mid-2000s, construction toys for children featuring small, powerful magnets were introduced into the toy market. Several children's magnetic construction toys were recalled because the magnets detached from the plastic housing of the toy. (Release #07-164). We received reports of incidents in which children and infants had swallowed the small magnets that had detached from such toys. In some incidents, children swallowed intact magnetic

components that were small parts.[1] These incidents revealed that if a child swallows more than one small, powerful magnet or one such magnet and a ferromagnetic object, the objects can attract each other across tissue inside the stomach and intestines and cause perforations and/or blockage, which, if not treated immediately, can be fatal. We are aware of one death and numerous cases requiring intestinal surgery following ingestion of multiple small, powerful magnets from these toys.

To address the hazard in toys, the CPSC worked with ASTM to develop voluntary standard requirements for toys containing magnets. These requirements became part of ASTM F963, *Consumer Safety Specification for Toy Safety,* which is now a mandatory CPSC standard. ASTM F963-11 defines a "hazardous magnet" and a "hazardous magnetic component" (*i.e*., a toy piece that contains an embedded hazardous magnet) as one that has a flux index greater than 50 and that is a small object. ASTM F963 applies to toys intended for children under 14 years of age. The flux index of a magnet is an empirical value developed by ASTM as a way to estimate the attraction force of a magnet. The ASTM working group established a flux index of 50 as a cutoff for what it considered to be a "safe" magnet, based on measurements of toys on the market. Most of the measured magnets were cylindrical in shape, and some had been involved in known incidents. When the ASTM graphed their measurements, they showed a good correlation (fairly linear relationship) between calculated flux index and measured attraction force for a

[1] The requirements of 16 CFR part 1501 are intended to minimize the hazards from choking, ingestion, or inhalation to children under 36 months of age created by small objects. The requirements state, in part, that no toy (including removable, liberated components, or fragments of toys) shall be small enough without being compressed to fit entirely within a cylinder of the specified dimensions.

majority of the magnets. Based on this graph, ASTM considered the flux index a reliable way to gauge a magnet's relative attraction force. Since the magnets from toys involved in incidents had flux index measurements greater than 70, the ASTM working group chose a flux index of 50 as a cutoff because it was significantly below the values for the incident magnets.

2. Introduction of Magnetic Sets

In 2008, a new type of magnet product came onto the market. The basic product was an aggregated mass of 216 BB-size powerful magnets, generally marketed as adult desk toys for general amusement. These magnet sets were introduced in 2008, but 2009 was the first year with significant sales to U.S. consumers. The products are described more fully in section B of this preamble.

In February 2010, CPSC staff received its first incident report involving this product. No injury resulted from this incident. Shortly after receiving this report, CPSC staff collected and evaluated samples of magnet sets.

In December 2010, we received our first consumer incident report involving the surgical removal of magnets that were part of a magnet set. Information about incidents involving magnet sets is discussed in section C of this preamble.

3. Prior Compliance Actions Concerning Magnet Sets

The CPSC has been warning consumers about the hazards of magnet ingestion since 2006, because of the injuries that have occurred to children from hazardous magnets that were part of construction toys intended for children. Several recalls have been issued for toys containing magnets.

In December 2009, we received a consumer complaint that the magnet sets intended for adults posed hazards similar to magnets in toys. As a follow-up to that complaint, during that month, a sample was collected by staff and age graded by the Directorate for Engineering Sciences, Division of Human Factors to be, in developmental terms appropriate for children ages 9 years old and up.

In February 2010, the CPSC received its first consumer incident report involving a child and a set of magnets intended for adults. A 9-year-old boy swallowed 7 spherical magnets while mimicking body piercings. He was not injured because the magnets passed through his system as a single mass. The magnets had been purchased for a 13-year-old.

Samples of the product were detained and collected at the Customs and Border Protection site in February 2010. At the time of collection, the product was labeled for use by children 13+ years of age. Because of the age grade on the product and the manufacturer's intent, it was subject to the requirements of the toy standard. The Office of Compliance and Field Operations (Compliance) issued a Notice of Noncompliance to the firm in March 2010. At the time, there was very little incident data associated with this product. The firm agreed to a corrective action that included, in part, new warnings to keep the product away from children, a change in the appropriate age for use of the product, and requests to retailers to list the product as appropriate only for consumers over 14 years of age. The firm also removed inventories labeled "13+." The firm also agreed to ask retailers who market products primarily, though not exclusively, to children to execute a Responsible Sellers Agreement prohibiting marketing and sales to children; stop the sale of these magnets to retailers that market products exclusively to children; and

providing a Responsible Sellers Agreement to general use stores for their information.

In December 2010, we received the first report of the surgical removal of magnets from a child who had ingested multiple magnets that came from a magnet set intended for adults. During 2011, Compliance activity included evaluation of the marketing and labeling of the product category, collecting product marketed to children under 13 and evaluating compliance with ASTM F963. In addition, where products did not have labeling or marketing information, the agency encouraged those firms to develop marketing and labeling to ensure that they were not marketed to children. More firms were issued Notices of Noncompliance for marketing to children younger than 14 years.

In response to continuing injuries associated with the products and children of various ages, we published a public service announcement (PSA) in November 2011, concerning the hazard in cooperation with two manufacturers. Reported incidents involving children continued to increase unabated from 8 cases in 2010, 17 cases in 2011, and 25 cases in 2012 (as of July 8, 2012). Twenty two incidents were reported before the PSA; 28 more followed during the eight months after it. A high percentage of the injuries resulted in surgeries or other invasive procedures. Of the 50 reports known to staff, 22 required surgery, and 10 required either invasive procedures such as endoscopies or colonoscopies. In 2011, and into spring 2012, staff continued to identify additional firms offering this product on the internet with labeling and marketing violations.

Given the continued injuries to children, Compliance began negotiation of corrective action plans with 11 of 13 magnet set importers that voluntarily agreed to cease the importation,

distribution, and continued sale of their magnet sets. Two of the importers did not agree to stop sale and are the subject of administrative actions recently initiated by the Commission. As those complaints allege, among other things, CPSC staff experts do not believe warnings will ever be effective in protecting children from this hidden hazard.

B. The Product

1. Description of the Product

The magnet sets covered by this proposed rule typically are comprised of numerous identical, spherical, or cube-shaped magnets, approximately 3 to 6 millimeters in size, with the majority made from NdFeB (Neodymium-Iron-Boron or NIB). These magnets exhibit strong attractive qualities. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding.

Often referred to as "magnet balls" or "rare earth magnets," the products currently are marketed as: adult desk toys, the "puzzles of the future," stress relievers, science kits, and educational tools for "brain development." As shown in product instructions and in videos on related websites, these products can be used and reused to make various two- and three-dimensional forms, jewelry, and toys, such as a spinning top.

The products are sold in sets of varying size, from as few as 27 magnets to more than 1,000. Most of the magnets have been sold in sets of either 125 balls or sets of 216 to 224 balls, although some firms have sold just a few balls as extras. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter, although balls

as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter). In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets recently added small magnetic rods—intended to be used with balls to make geometric shapes—to its desk toy product line.

The most common color of these magnets is a glossy, highly reflective silver, with the spheres often described as similar in appearance to BBs or ball bearings. Some firms now include sets in a wide range of colors, or combinations of colors, ranging from bright pink, green, and blue, to darker shades, such as purple and black. Most, with the exception of the smaller sets, are sold with a container, such as a square plastic cube, a metal tin, and/or a soft pouch. Most brands are sold in nondescript containers, such as metal tins or black fabric boxes. The largest seller uses colorful, transparent packaging that simulates the cube floating within.

The age labeling of hazardous magnet sets varies; currently, most products carry an age label and are marked "14+." Some sets have no specific age recommendation on the package, even though retail websites may identify them as intended for ages "13+" or "14+." The small parts warning[2] is sometimes included on the packaging (*i.e.*, "choking hazard, not for children under 3"), as are warnings to keep the product away from all children.

The proposed rule would define magnet sets as: "any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment,

[2] See 16 CFR §1500.19 (b)(1).

such as puzzle working, sculpture, mental stimulation, or stress relief."

2. Use of the Product

Although firms that sell magnet sets state that they intend them as desk toys for adults, these sets are found in offices and homes and in locations within the home beyond desk tops, such as on refrigerators. Magnet sets have some appeal for virtually all age groups. They tend to capture attention because they are shiny and reflect light. They are smooth, which gives them tactile appeal, and they make soft snapping sounds as they are manipulated. They have the properties of a novelty, which arouses curiosity; incongruity, which tends to surprise and amuse; and complexity, which tends to challenge and maintain interest. Their strong magnetic properties cause them to move in unexpected ways, with pieces snapping together suddenly, and moving apart—occasionally quite quickly. These properties or characteristics of magnets are likely to seem magical to younger children and may evoke a degree of awe and amusement among older children and teens. These features are the foundation of the product's appeal as a challenging puzzle or as a manipulative or jewelry. They may also be used as a stress ball and as a way to hold things in place.

Children from toddlers through teens have been exposed to these products in the home setting and elsewhere. Ingestion incidents have been reported to involve children 5 years of age and younger and follow similar scenarios as other ingestion incidents among this age group. Mouthing and ingestion of non-food items is a normal part of the exploratory behavior of preschool children. Caregivers, in a few cases, said they had intended to keep the sets away from the victims, but did not realize they had failed to do so, until after the child became ill and the

magnets had already caused internal injuries. In other incidents, the child reportedly had never mouthed or ingested objects previously, and as a result, they were permitted by the caregiver to play with the magnets. As might be expected, in a number of cases, the magnets were not in their original containers, and caregivers were unaware that some were missing from the set and in the child's possession. Several importers sell sets of spares, small numbers of balls to replace those lost or missing from a larger set.

These products would also be appealing to children of early-to-middle elementary school age, who might be capable of controlling the magnetic forces exhibited by the pieces while constructing various forms depicted in the product instructions and on the related websites. Simple three-dimensional puzzles begin to interest children as they approach 8 and 9 years of age; and 9 through 12 year olds are interested in highly complex puzzles. Children in the 9 through 12 year age group have the reading skills to follow directions for three-dimensional puzzles, and they have the fine motor skills required to handle small, abstract, or interlocking pieces. Nine-year-olds can complete puzzles with 100 to 500 pieces; and 10 through 12 year olds enjoy the challenge of puzzles with 500 to 2,000 pieces. Children in this age group also can engage in activities that require the type of meticulous work and attention that would be needed to create the complex patterns and structures found in the paper and video instructions related to the magnet sets. Additionally, magnets typically are included in elementary school (ages 6 through 12) science curricula, the age at which children are taught the basic concepts of magnetism.

For all of these reasons, magnet sets are sometimes purchased for children under the age

of 14, despite the warnings or labeling. This is consistent with reviews on retail websites, which indicate that these products are being purchased for children. Approximately one-third of 53 adults reviewing one manufacturer's product on Amazon.com reported purchasing them for children 8 through 11 years of age.

Thus, it is foreseeable that some portion of these products will be purchased for elementary school children and teens. Given the relatively low cost for some sets, children in these age groups also may purchase the magnet sets themselves. The incident reports reflect behaviors that are beyond the intended use of the product, but that are foreseeable for the groups using them. The mouthing of objects, common among younger children, develops into less obvious and more socially acceptable oral habits, which may continue through childhood and adolescence and into adulthood (*e.g.*, mouthing or chewing a fingertip, fingernail, knuckle, pen, pencil, or other object, especially while concentrating or worrying). This tendency toward mouthing behavior involving magnets could account for some reported ingestions, where incident details are lacking.

Where details are provided, the incident reports describe scenarios that are consistent with the behaviors of children in this age range. Although exploratory play is generally associated with very young children, people of all ages use their senses to explore unfamiliar phenomena. More discussion of the hazard scenarios involving these products is provided in section C.2 of this preamble.

3. The Market

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 have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. This reflects a combination of retail sales directly to consumers (through company websites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggests prices typically ranging from about $20 to $45, with an average price of about $25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of neodymium, iron, and boron. They are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.

All of the firms that have marketed the products are believed to import them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers, and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. Firms often have sales arrangements with Internet retailers who hold stock for them and process orders.

We have identified about 25 U.S. firms and individuals who have recently imported magnetic sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps more than 98%) of units sold. One firm is

believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own websites or other Internet shopping sites. In addition to products offered for sale by U.S. importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China; many that market products through "stores" on a leading Internet shopping site.

C. Risk of Injury

The risk addressed in this proceeding concerns damage to intestinal tissue caused by the ingestion of more than one magnet from a magnet set, magnets that are attracted to each other in the digestive system, damaging the intestinal tissue trapped between the magnets. In rare cases, there can be interaction between magnets in the airways and digestive tract (esophagus). Serious injury and death are likely consequences when children ingest strong magnets.

1. Incident Data

NEISS data. CPSC staff reviewed data from the National Electronic Surveillance System (NEISS) database of magnet-related ingestion cases treated in emergency departments from January 1, 2009 to December 31, 2011.[3] To derive estimates, CPSC staff considered all cases reported through NEISS from January 1, 2009 to December 31, 2011, which mentioned "magnet" in the narrative field of NEISS reports. This review produced an estimated 6,100

[3] The Commission collects information on hospital emergency room-treated injuries through the NEISS database. This data can be used to provide national estimates of product-related injuries treated in U.S. hospital emergency departments. Incidents reported to the Commission represent a minimum count of injuries. To account for incidents that are not reported to the Commission, the staff calculates an estimated number of such injuries.

magnet-related ingestions for that period of time (note that this includes incidents involving all types of magnets, not just magnet sets). This excludes cases with descriptions such as "kitchen magnet" or "plastic-covered magnet." Staff further analyzed cases that possibly involved magnets that were from magnet sets. This review also yielded a count of 72 magnet ingestion cases during this time period, which staff determined (based on a review of narratives in the NEISS reports) to involve or possibly involve magnets from magnet sets. Based on the magnet ingestion cases treated in NEISS hospital emergency departments, staff determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in U.S. emergency departments during this time period. NEISS cases are coded from medical records so brand name is rarely available, but descriptions of the products from the NEISS narrative suggests that the magnets involved in these cases are magnets from magnet sets. For more information about the process for developing the estimates of incidents, see the memorandum from the Directorate for Epidemiology at Tab A of staff's briefing package [INSERT link to website]. It is possible that some number of the estimated 4,400 magnet ingestion-related injuries not classified as high-powered magnets could be attributable to the ingestion of magnets from high powered magnet sets. However, the information provided in the NEISS reports did not provide sufficient detail to place them into that category.

Staff reviewed the NEISS data to obtain more information about incidents involving magnet sets. With regard to age, the largest portion of these incidents involved children 4 through 12 years of age. Of the estimated 1,700 ingestion incidents related to magnet sets, 1,200 of the victims are in the 4- through 12-year-old age group (70.6 percent). It is quite possible that

some portion of the estimated 4,400 "magnets, type unknown/other type" category of incidents also involved magnet sets and children in the 4- through 12-year-old age group. Of the estimated 1,700 ingestions, most (approximately 1,600) were treated and released from the hospital.

Databases other than NEISS. In addition to reviewing NEISS data, staff also reviewed incidents reported through other CPSC databases, such as the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP). These databases provided more detailed descriptions, and thus, included more information about the products involved and the incident scenarios. In reviewing the initial set of incidents from these databases, staff considered all reported incidents from January 1, 2009 through June 30, 2012, that involved a magnet and an ingestion or injury was reported. Excluded from this review were magnets in children's toys, as well as magnets that were determined to be a different type other than small, strong magnets from sets of magnets. Staff focused on one hazard pattern: ingestion of magnets. Other reported hazard patterns, such as allergic reactions, ear injuries, and a hand injury were excluded.

From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012 involving the ingestion of magnets by children between the ages of 1 and 15. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets contained in products that meet the definition above of "magnet set"; and 5 of those 50 incidents possibly involved ingestion of this type of magnet. We discuss these 43 incidents (the 38 incidents, plus the 5 possible incidents) in more detail below.[4]

[4] Six of the remaining seven incidents (out of the 50 incidents) involved ingestion of magnets that were part of, or designed to be, part of jewelry, including beads, faux tongue rings, and earrings. One incident involved the

In 35 of the 43 incidents, two or more magnets were ingested. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old or between the ages of 4 and 12 years.

In 20 of the 43 incidents, the victims reportedly put the magnets in their mouth because they thought the magnets were edible; they wished to emulate jewelry piercings; or they simply mouthed the magnets while playing with them. In 23 of those 43 incidents, there is insufficient information to determine how the magnets were being used at the time of the ingestion.

In 30 of the 43 incidents, the reports indicate the source of the magnets ingested. In 10 of the incidents, the magnets were owned by a relative and were obtained, presumably by the victim, without the relative's knowledge. In 5 incidents, the magnets were given to the child by an adult; and in 12 incidents, the magnets were obtained from a friend or classmate. In three instances, the magnets were purchased by the victim. The number of ingestion incidents involving magnets from magnet sets has increased over time, from 7 in 2010, to 16 in 2011, and 20, as of June 30, 2012.

2. Hazard Scenarios

The incident reports describe scenarios that are consistent with behaviors of children in the age range described in the incidents. In the incidents reported among the 8- through 12-year-

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ingestion of a magnetic rock. The rock magnet and magnets in jewelry would not meet the proposed definition of "magnet set" and would not be covered by this proposed rulemaking.

old age group, one child described wanting to feel the force of the magnets through his tongue; one was trying to see if the magnets would stick to her braces; and another wanted to see if the magnets would stick together through her teeth. Another common scenario accounted for half of the reported ingestion incidents among 8 to 15 year olds. Children used at least two and as many as seven magnets to simulate piercings of their tongue, lips, or cheeks. On the tongue or lip, children sometimes used more than two magnets to form the appearance of a ring. This is a type of role-play behavior, particularly for the younger children in the group, and the magnets serve as highly realistic props.

In this section, we summarize some of the incident reports to demonstrate a few of the hazard scenarios that have been reported in incidents involving ingestion of magnets from magnet sets.

In one incident, a 10-year-old girl simulating a tongue piercing, accidentally swallowed two magnetic balls. That same day, her mother took her to the local emergency room, and she was admitted for 5 days; during that time, the movement of the magnets was monitored by 10 x-rays, 3 CT scans, and an endoscopy. Ultimately, the magnets were manipulated from their eventual position in the colon into the appendix via laparoscopic surgery and removed by an appendectomy.

In another incident, a 13-year-old girl accidentally swallowed five small, spherical, high-powered magnets when they suddenly snapped together while she was mimicking a lip piercing. Although her abdominal pains began and worsened over the next 2 days, she did not tell her mother of the ingestion until 3 days later. She was then taken to hospital, where abdominal x-

rays confirmed ingestion of five magnetic balls. Medical staff initially tried unsuccessfully to remove the magnets using an oral bowel cleansing solution and then a colonoscopy procedure. Eventually she underwent surgery, and the magnets—located in three different places in her small intestine—were removed during a surgical procedure that involved resection of damaged bowel tissue and removal of her appendix. The victim's complicated recovery resulted in hospitalization for 14 days, and the surgery left a 4-inch abdominal scar.

In another incident, an 18-month-old boy sustained life-threatening intestinal injuries and will have lasting adverse health effects after ingesting three small, spherical magnets. The boy exhibited symptoms of diarrhea and vomiting and was clutching at his right side. When his mother took him to the local hospital, he was diagnosed with an ear infection. When his symptoms did not resolve a few days later, she took him to a second hospital where, reportedly, he was diagnosed with bronchitis, given some medication, and released. One or 2 days later, his mother noticed that his stomach was distended and took him to a third hospital. Abdominal x-rays revealed three small balls, requiring immediate surgical intervention to remove the foreign objects. The procedure required resection of 6 inches of the child's small intestine and resection of 3 inches of his large intestine. The victim remained in intensive care for 1.5 weeks before being released. He continued to have diarrhea and other intestinal problems (at least 2 months post-surgery when the IDI was completed).

In another incident, a 3-year-old girl swallowed eight small spherical magnets from a magnet set, which she found on a refrigerator door. An x-ray revealed two joined magnets that appeared to be located in the victim's esophagus, plus another six magnets that appeared to be

joined together in the victim's stomach. A second x-ray image, taken the next day at a different hospital, showed that the magnets had not moved. A third x-ray at a Children's Hospital showed no movement of the magnet pair (described as 3mm beads) in the esophageal area, and some movement of the group in the abdomen. Pre-intervention, the treating physicians correctly recognized that she might have aspirated a magnet into her airways that was interacting through tissues with a magnet located in the esophagus. The girl underwent three coordinated procedures: (1) a bronchoscopy that removed one "magnetic bead" from her right bronchus; (2) an esophagogastro-duodenoscopy (endoscopy) that removed one magnetic bead from the mid-esophagus, and five magnetic beads from the stomach; and (3) a diagnostic laparoscopy, followed by laparoscopic-assisted removal of the remaining magnet, plus laparoscopic repair of a gastric perforation and a small bowel perforation.

In another incident, a 23-month-old male ingested eight small spherical magnets from a product described as a "magnetic puzzle." He started vomiting overnight and worsened the next day. He was taken to an urgent care facility, where a bilateral ear infection initially was suspected. A few hours later, as the child's condition worsened and he lost consciousness intermittently, an abdominal x-ray indicated six small balls that the mother recognized immediately, and informed the staff, were magnets from the puzzle. He was transferred to a Children's Hospital where an x-ray revealed some slight movement of the magnets. According to the mother, the doctors thought the magnets would pass naturally. An x-ray taken the following day showed the magnets to be located between the small and large intestine; therefore, surgery was undertaken to remove them. During surgery, two balls were found in the small

intestine and six balls were found outside of the bowel in the abdominal cavity. These were removed and a small intestine perforation repaired. Staff does not have access to the full medical records, but according to the parents, extremely serious complications ensued after the first surgery. The child underwent several sequential surgeries over the next 10 days to repair leaks (unclear if this involved missed perforations/failure of repairs/new perforations) and treat a blood clot, ischemic necrotic bowel, and serious infection stemming from the initial magnet injury. Ultimately, after what appears to be at least five or six operations, the child was stabilized but was still retained in an intensive care unit for more than a month, having lost all but 10 to 15 centimeters of small intestine (*HS staff notes the small intestine is about 600 to 700 centimeters long)*. He is being fed intravenously and has a colostomy bag to remove waste products. He will require a bowel transplant and his long-term prognosis is poor.

As these scenarios demonstrate (and further discussed in the next section), parents and caregivers may not realize that the child has ingested magnets. Thus, diagnosis and treatment is delayed, and the severity of the resulting injuries increases.

3. Details Concerning Injuries

As indicated in the previous section describing some of the incident scenarios, diagnosis of injury from magnet ingestion is complicated by multiple factors, and the resulting injuries can be very serious. Medical professionals may not be aware of the dangers posed by ingestion of high-powered magnets and the corresponding need for immediate evaluation and monitoring. Standard diagnostic tools, such as x-rays, may not demonstrate fully that the ingested item is a magnet and they may not allow medical professionals to identify the number of magnets

ingested. Moreover, magnets may appear in an x-ray to be other nonmagnetic items that children commonly ingest, such as beads, which typically are monitored without surgical intervention and are allowed to pass through the child's gastrointestinal tract. Furthermore, treatment for injuries resulting from the ingestion of these magnets often is delayed, much to the serious detriment of the patient because the symptoms associated with damage to intestinal tissue resulting from the ingestion of these magnets frequently resemble the symptoms associated with less serious conditions, such as the stomach flu.

Accurate and timely diagnoses also are complicated by the fact that children and teens may not attribute their gastrointestinal symptoms to prior ingestion of magnets, and they may be unable or unwilling to communicate to their parents, caregivers, or medical personnel that they have ingested magnets. Accordingly, the delay of surgical intervention due to the patient's presentation with non-specific symptoms and/or medical personnel's lack of awareness of the dangers posed by multiple magnet ingestion can exacerbate life-threatening internal injuries and has resulted in the need for a bowel transplant.

In medical terms, the magnet injuries are pressure necrosis injuries. The unique mechanism of injury involving harmful tissue compression by strong magnets has become established in recent years. Ingested magnets residing in relatively close proximity to one other are mutually attracted through intestinal walls. The magnets interact rapidly and forcefully. The magnetic attraction can occur over distances of about 10 to 20 mm for a pair of magnets, to distances much greater than that, as the number of magnets involved increases. The attraction forces 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 gastrointestinal tissues (GI) (peristaltic or mixing motions), as well as the intermittent turbulent flow of the considerable volumes of gastrointestinal fluid in the small intestine, or the passage of semisolid contents in the large intestine. The magnets remain coupled, exerting strong bilateral compression forces on the trapped GI tissues, sufficient to block their blood and nutrient supply. The extreme pressure exerted on the trapped tissues ultimately is directly responsible for the progressive tissue injury, which starts with local inflammation and ulceration, progressing to tissue death, then perforation, or fistula formation.

Fistulas (abnormal connections or passageways between two organs or vessels that normally do not connect) cause serious, debilitating symptoms, but generally are not as acutely urgent as perforations. Perforations present a serious risk of leakage of gut contents into the abdominal cavity which, within hours, can escalate quickly from an area of local infection, to peritonitis (an inflammation of the peritoneum, the thin tissue that lines the inner wall of the abdomen and covers most of the abdominal organs), then life-threatening systemic infection (sepsis).

In some rare cases, ingested magnets have caused loops of the bowels to become twisted; this obstructs passage of gut contents and deprives the twisted gut segment of blood. It is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped segment from becoming necrotic, and/or from rupturing and causing contamination of the abdominal cavity. Magnets have also 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.

Once attracted magnetically to each other through intestinal walls, the magnets involved in GI injuries are unlikely to disengage spontaneously or to move position until they are removed by clinicians. A pair of magnets might be uncoupled by stronger attraction forces exerted by a larger number of magnets in a separate GI location (which then could cause further injury, perhaps unrecognized, in a different GI location). If magnets fall through perforations into the peritoneal cavity, they are expected to require surgical intervention and to have a relatively high associated morbidity.

Complications after these abdominal surgeries include bleeding, infection, and ileus (temporary paralysis of gut motility). Adhesions (where bands of intra-abdominal scar tissue form that can interfere with gut movement and can cause obstruction) may occur as a short-term or long-term (years) complication, frequently resulting in bowel obstructions requiring additional surgeries, and thus, creating a cycle. In females, there also can be future fertility concerns related to abdominal scar tissue and adhesions. 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, total parental nutritional feeding (and consequent frequent bouts of sepsis), need for a bowel transplant, and even death.

D. Statutory Authority

This proceeding is conducted pursuant to the Consumer Product Safety Act (CPSA). Magnet sets are "consumer products" that can be regulated by the Commission under the authority of the CPSA. *See* 15 U.S.C. 2052(a).

The Commission is authorized, under section 7 of the CPSA, to promulgate a mandatory consumer product safety standard that sets forth certain performance requirements for a consumer product or that sets forth certain requirements that a product be marked or accompanied by clear and adequate warnings or instructions. 15 U.S.C. 2056. A performance, warning, or instruction standard must be reasonably necessary to prevent or reduce an unreasonable risk or injury. In addition, if the Commission finds that no feasible consumer product standard under section 7 would adequately protect consumers from an unreasonable risk or injury associated with hazardous magnet sets, the Commission may promulgate a rule under section 8 of the CPSA declaring hazardous magnet sets to be banned products. 15 U.S.C. 2057.

Section 9 of the CPSA specifies the procedure the Commission must follow to issue a consumer product safety standard under section 7. In accordance with section 9, the Commission may commence rulemaking by issuing an NPR including the proposed rule and a preliminary regulatory analysis in accordance with section 9(c) of the CPSA and requesting comments with respect to the risk of injury identified by the Commission, the regulatory alternatives being considered, and other possible alternatives for addressing the risk. *Id*. 2058(c). Next, the Commission will consider the comments received in response to the proposed rule and decide whether to issue a final rule and a final regulatory analysis. *Id.* 2058(c)-(f).

According to section 9(f)(1) of the CPSA, before promulgating a consumer product safety rule, the Commission must consider, and make appropriate findings to be included in the rule, concerning the following issues: (1) the degree and nature of the risk of injury that the rule is designed to eliminate or reduce; (2) the approximate number of consumer products subject to

the rule; (3) the need of the public for the products subject to the rule and the probable effect the rule will have on utility, cost, or availability of such products; and (4) means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices. *Id.* 2058(f)(1).

According to section 9(f)(3) of the CPSA, to issue a final rule, the Commission must find that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product" and that issuing the rule is in the public interest. *Id.* 2058(f)(3)(A)&(B). In addition, if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that: (1) the voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or that (2) substantial compliance with the voluntary standard is unlikely. *Id.* 2058(f)(3(D). The Commission also must find that expected benefits of the rule bear a reasonable relationship to its costs and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E)&(F).

The Commission seeks input on whether it should be regulating under section 7 and 9 of the CPSA or seeking a ban under section 8 of the CPSA or under similar provisions of the Federal Hazardous Substances Act.

E. Relevant Existing Standards

Currently, there is no voluntary or mandatory standard applicable to magnet sets. ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, precludes the inclusion of a "hazardous magnet component" in a toy primarily intended for use by children 14 years of age or

younger. The Consumer Product Safety Improvement Act of 2008 (CPSIA) mandated ASTM F963 as a consumer product safety standard. Section 106 of the CPSIA. The ASTM standard defines "hazardous magnet component" as any part of a toy that is a small object and which contains an attached or imbedded magnet which has a flux density greater than 50. The vast majority of the hazardous magnet sets currently on the market are primarily intended for children over the age of 14, based on the labeling and marketing materials associated with these products, and as such, they are not subject to the ASTM voluntary toy standard.

A group of magnet set importers and distributors have requested that ASTM International develop a voluntary standard for the labeling and marketing of these products. Specifically, these companies have requested the formation of a voluntary standard to: (1) provide for appropriate warnings and labeling on packages of these magnet sets; and (2) establish guidelines for restricting the sale of these magnet sets to children, by not selling to stores that sell children's products exclusively and not selling the magnet sets in proximity to children's products. At this time, however, no applicable voluntary standard exists.

F. Description of the Proposed Rule

The Commission is proposing a rule that would prohibit certain high-powered magnet sets. As described in previous sections of this preamble, we are aware of serious injuries resulting from children ingesting such magnets. Magnets that do not have the prohibited characteristics and magnets that are not parts of magnet sets would still be allowed.

1. Scope, Purpose, and Effective Date - § 1240.1

This section of the proposed rule would state that the proposed requirements in 16 CFR part 1240 are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. The standard would apply to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after the date 180 days after publication of a final rule.

2. Definitions - § 1240.2

This section of the proposed rule would define the term "magnet set" to mean "any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." This definition would not include other magnetic products that do not meet the definition, such as toys intended for children and jewelry. Magnets that are part of a toy intended for children are already covered by the requirements in ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, which is a mandatory CPSC standard. The Commission seeks comment on the scope of the products proposed to be covered by this proposed rule and, in particular, whether risks are presented by magnets in science kits or craft and hobby kits no matter how they are age graded and labeled.

3. Requirements - § 1240.3

This section would set forth the requirements for magnet sets. If a magnet set contains more than one magnet that fits within the small parts cylinder that CPSC uses for testing toys, magnets from that set would be required to have a flux index of 50 or less. The proposed rule

would specify that the requirements apply to magnet sets with more than one magnet because ingesting a single magnet would not produce the serious injuries that have been reported with magnet sets. The small parts cylinder referenced in the proposed rule is specified in 16 CFR part 1501 – Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts. If an object fits completely within the small parts cylinder, this indicates that the object is small enough to be ingested. If a magnet that is part of a magnet set is too large to fit within the small parts cylinder, it would not be prohibited, regardless of the magnet's flux index. Thus, it might be possible for manufacturers to make magnet sets that contain strong magnets so long as the magnets are sufficiently large, although the large size could reduce their utility.

Small magnets (*i.e.*, those that fit within the small parts cylinder) that are part of a magnet set must have a flux index less than 50. This limit is based on the level that is specified in ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, which is a mandatory CPSC standard. As discussed in section A.1 of this preamble, the flux index of a magnet is an empirical value developed by ASTM as a way to estimate the attraction force of a magnet.

The flux index limit of 50 was developed by ASTM, with CPSC staff's participation, to address injuries resulting from strong magnets that separated from toys. The limit was based on an analysis of magnets that were involved in incidents. The Commission seeks input on the limit particularly as to whether there may be health risks should a large number of magnets be ingested even if such magnets are below the flux limit of 50.

4. Test Procedure for Determining Flux Index - § 1240.4

This section of the proposed rule would describe how to determine the flux index of magnets that are part of a magnet set. If the magnet set contains more than one shape or size of magnet, at least one of each shape and size would be selected for testing. The flux index of the selected magnets would be measured in accordance with the procedure set forth in section 8.24.1 through 8.24.3 of ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*. The flux index of the magnet is calculated by multiplying the square of the magnet's surface flux density (in KGauss) by its maximum cross-sectional area (in mm^2). The ASTM standard uses a gauss meter and probe that measures the surface flux density at 0.015 inches (0.38 mm) above the magnet's surface. The area is measured at the largest cross-section of the magnet that is perpendicular to the axis of its magnetic poles.

We are proposing to use the methodology specified in ASTM F963-11 to measure the flux index of magnets that are part of a magnet set. The test method was developed to address hazards posed by magnets that are part of a toy. Such magnets are likely to be individual magnets that separate from a toy. Magnet sets may contain hundreds of magnets. Thus, such magnets are more likely to be aggregated than magnets separated from toys. When magnets are aggregated, their magnetic strength may increase. Children exposed to magnets from these magnet sets may ingest more magnets than they would if a magnet separates from a toy. Thus, it may be desirable to develop a method for testing the strength of aggregated magnets. We are interested in receiving comments that would address this issue.

5. Findings - § 1240.5

In accordance with the requirements of the CPSA, we are proposing to make the findings

stated in section 9 of the CPSA. The proposed findings are discussed in section N of this preamble.

G. Alternatives

The Commission has considered alternatives to reduce the risk of injuries related to the ingestion of magnets contained in magnet sets. However, as discussed below, the Commission does not believe that any of these would adequately reduce the risk of injury.

1. Voluntary Recalls

Although several of the companies that manufacture or import magnet sets have voluntarily agreed to recall (and in some cases, stop selling) these products, and several retailers have agreed to stop sale, the Commission has been unsuccessful in negotiating voluntary recalls and stop sales with several companies that control a significant portion of the magnet set market, including the company that sells more than 70 percent of the magnet sets purchased in the United States. It is extremely unlikely that all manufacturers/importers will voluntarily agree to stop selling and recall their magnet sets. Moreover, recalls would not prevent new entrants into the market in the future.

2. Voluntary Standard

Currently, there is no applicable voluntary standard in effect. As mentioned previously, a group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The voluntary standard they are interested in developing would provide for warnings and labeling and would establish guidelines for restricting the sale of these magnet sets. However, despite companies'

marketing and labeling to attempt to limit children's exposure to magnets, ingestion incidents involving children continue to occur and the labeling does not change the attractiveness of the product to children or the intrinsic play value of the magnet sets. From the date that the firm with the largest share of the market undertook certain labeling enhancements and marketing restrictions through June of 2012, the Commission has learned of 47 additional incidents involving ingestion of magnets from hazardous magnet sets, 26 involving ingestion of the company's hazardous magnets. As discussed more fully in the next section of this preamble, we do not believe that warnings would adequately reduce the injuries associated with this product.

3. Warnings

It is unlikely that additional or different warnings on the packages of magnet sets would significantly reduce the ingestion-related injuries caused by high-powered magnets. Safety and warnings literature consistently identifies warnings as a less effective hazard-control measure than designing out the hazard or guarding the consumer from a hazard. Warnings do not prevent consumer exposure to the hazard, but rely on persuading consumers to alter their behavior in some way to avoid the hazard. With this product, warnings are particularly unlikely to adequately reduce or eliminate the ingestion of these magnets.

Warnings are especially unlikely to be effective among children because children may lack the cognitive ability to appraise a hazard or appreciate the consequences of their own actions and may not understand how to avoid hazards effectively. In addition, warning design guidelines and literature commonly recommend that the text of warnings intended for the general public be written at no higher than the 6th grade reading level, which is equivalent to a child

about 11 years old. A warning that met this guideline presumably would not be understood by many children younger than 11.

Older children, more advanced cognitively, are able to appreciate better the hazards described in a warning. However, these children value peer acceptance more than parental guidelines, and social influences and peer pressure can drive adolescent behavior more strongly than their own independent thought processes. Furthermore, adolescents are at a developmental stage in which they test limits and bend rules. Therefore, warnings about keeping the product away from children could have the unintended effect of making the product more appealing to some children. Older children might view such warnings as attempts to restrict personal freedom or self-expression, which could result in responses that are contrary to the warning's recommendations. For example, warnings about not using the product in the specific ways that might place them at risk, such as mimicking piercings, might have the unintended effect of encouraging this behavior among these children. Repeated use of the product in this way, without ingesting the magnets, most likely will convince these children that the hazard is not especially likely or is not relevant to them.

The ingestion warnings that currently accompany these products appear to be aimed at adults, primarily parents and other caregivers. Staff generally found the content of these warnings to be lacking in the following ways. The warnings often refer to children swallowing the magnets, without describing the incident scenarios that might lead to ingestion among older children and adolescents, whom caregivers may not believe are likely to put magnets into their mouths. Some warnings refer to the potential for swallowed magnets to stick to intestines,

without referring to other magnets or ferromagnetic objects. Other warnings refer to magnets sticking together or attaching to other metallic objects inside the body, but they fail to explain that the magnets can attract through the walls of the intestines and forcefully compress these tissues. Without detailed information such as this, consumers may not understand how swallowing magnets differs from swallowing other small parts, or how magnets sticking together could pose a hazard rather than simply pass through the child's system. In sum, without a clear, explicit, and accurate description of the nature of the hazard and its consequences, consumers may have difficulty developing an accurate mental model of the hazard scenario and might find the warning implausible. In such situations, consumers are unlikely to comply with the action recommended in the warning.

Even if warnings could communicate the ingestion hazard, its consequences, and appropriate hazard-avoidance measures in a way that would be understood by most parents and other caregivers, the resulting warnings may not be effective at substantially reducing the incidence of magnet ingestions if consumers do not concur with what the warning states. Avoiding the ingestion hazard requires consumers to keep the product away from all children, or at least children in the incident age group, which is 15 years old and younger. Caregivers who read and understand the warnings may attempt to keep this product out of the hands of young children, but are not likely to be so diligent about heeding the warning with older children and adolescents. Unless caregivers are convinced that their child is likely to mimic lip, nose, or similar piercings or to perform other activities that might lead them to place magnets into their mouth or nose, caregivers may doubt that the warnings are relevant to their child, despite the

warnings' assertions to the contrary.

Even if caregivers believe the warnings, several factors may prevent compliance. Some children, especially those who are older, may have peers who already own and use magnets from magnet sets. Some personally may have used the product before. Knowing this, caregivers might feel significant social pressure from the child, other family members and friends, to purchase the product for their children, or allow their children to use the product, especially if magnet sets are very popular among the child's peers. Caregivers who own the product and attempt to heed the warnings might find it quite difficult to prevent their child's access to the magnets and still keep the product reasonably accessible for their own use.

Moreover, securing the product from a child after every use requires time and effort, and warnings research has shown that even small increases in time and effort can prevent compliance with warnings. If the caregiver cannot secure the product properly—without dismantling the shapes and forms created during use—and the caregiver has created especially challenging or interesting designs with the magnets, the caregiver might feel compelled to keep the forms intact and, as a result, fail to secure the product properly. In addition, the difficulty of attempting to identify an appropriate location to store the magnet sets may dissuade consumers from doing so, particularly for a product often marketed to be for "stress relief." Attempts to secure the product also may fail because the caregiver underestimates the abilities of their child and places the product in locations that seem secure but are still accessible to the child. Teens may have cognitive and motor skills similar to an adult's, making it extremely challenging to keep the magnet sets out of their hands. Furthermore, if caregivers know that their children have friends

who own and use magnet sets, caregivers are likely to conclude that securing their magnet set will not prevent exposure to other identical or similar products. This may lead caregivers to reject the warning message.

Based on these concerns about the likely effectiveness of warnings for magnet sets, we do not believe that warning labels would adequately reduce the risk of injury presented by these products. We are interested in receiving comments on the warnings issues.

4. Packaging Restrictions

Theoretically, magnet sets could be sold with special storage containers to reduce the likelihood that children would access the magnets. Possible storage might include: a container that would clearly indicate when a magnet is missing from the set, or a package that is child resistant. Aside from the evident challenges in developing such containers, their effectiveness at reducing ingestions is doubtful. Such approaches would depend on consumers securing the packaging after each use. As discussed above, consumers may be reluctant to place the product back in its packaging after they have created designs with the magnets.

5. Restrictions on Sales of Magnet Sets

Another possible alternative to address the hazard of children ingesting magnets from magnet sets might be to limit the places where magnet sets are sold, keeping them away from toy stores, children's sections of stores, and other such locations. It is not clear that the Commission would have the regulatory authority to impose such sales restrictions by rule. In any event, such restrictions are unlikely to reduce ingestions significantly. As discussed in section B.2 of this preamble, children access these magnets from sources other than stores. The magnet sets may be

available in the home after a caregiver has purchased them. Such sales restrictions are unlikely to deter teens. Moreover, restrictions on in-store sale of magnet sets would not affect Internet sales.

6. No action

Another option is for the Commission to take no regulatory action to address the risk of injury posed by magnet sets. It is possible that, over time, increased awareness of the hazard could result in some reduction in ingestions. The magnitude of any such reduction in incidents is uncertain, but would likely be smaller than if the Commission issues the proposed rule.

H. Preliminary Regulatory Analysis

The Commission is proposing to issue a rule under sections 7 and 9 of the CPSA. The CPSA requires that the Commission prepare a preliminary regulatory analysis and that it be published with the text of the proposed rule. 15 U.S.C. 2058(c). The following discussion is extracted from staff's memo, "Preliminary Regulatory Analysis of a Proposed Rule that Would Prohibit Certain Small Powerful Magnet Sets."

1. Introduction

The Commission has preliminarily determined to issue a rule prohibiting magnet sets that have been involved in incidents resulting in serious injuries to children who have ingested magnets that are part of these magnet sets. Some of these incidents have required surgery to remove individual magnets ingested by children. Reported incidents of magnet ingestion involved young children who put the magnets in their mouth and adolescents and teens who paired magnets to mimic tongue or lip piercings. This behavior has led the powerful magnets being swallowed ,

resulting sometimes in severe medical consequences, including significant damage to the gastrointestinal tract.

The proposed rule would prohibit magnet sets that do not meet the requirements of the proposed rule. Thus, for magnet sets that contain more than one magnet, if any of the magnets would fit within the small parts cylinder, the magnet set would be prohibited, unless the small magnets meet the specified flux index limit. This performance standard for magnet sets would effectively ban current designs of magnetic desk sets of the type that have become popular in recent years.

2. Description of the Product and Market

Magnetic desk sets that would be affected by the scope of the proposed rule are comprised of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. These magnet sets were introduced in 2008, but the first year with significant sales to U.S. consumers was 2009.[5] Most have been sold in sets of either 125 balls or sets of 216 to 224 balls, although some firms have sold just a few balls as extras, and others have sold large sets of more than 1,000 magnetic balls. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter; although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15 mm to 25 mm in diameter).[6] In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the

[5] However, small neodymium-iron-boron magnets previously have been, and continue to be, marketed by firms, such as magnet suppliers and distributors of educational products.

[6] One firm's larger magnet balls are reportedly made with cores of strontium ferrite ($SrO{\cdot}6Fe_2O_3$), rather than neodymium-iron-boron.

market. The leading marketer of such magnet sets has recently added small magnetic rods—intended to be used with balls to make geometric shapes—to its desk toy product line.

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 have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. This value range reflects a combination of retail sales directly to consumers (through company websites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggest prices typically ranging from about $20 to $45, with an average price of about $25.

The small powerful magnets most likely to be affected by this proposed rule are made from alloys of neodymium, iron, and boron. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Nearly 100 percent of neodymium and other rare earth metals now are mined in China, which also reportedly holds a nearly worldwide monopoly on the production of neodymium-iron-boron magnets. Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.[7]

As noted above, none of the magnetic sets within the scope of the proposed rule are

[7] 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 repackages in its U.S. office.

produced domestically. All of the firms that have marketed the products are believed to import them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers; and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. For example, some of the firms with smaller sales volumes reported to Compliance staff that they mainly marketed products (sourced from manufacturers in China) through sales arrangements with a leading Internet retailer, which held stock for them and processed orders. A review of the product listings of the Internet retailer found that several other firms have similar business models. Other U.S. firms and individuals sell magnetic sets they have imported from China through "stores" they maintain on another major Internet shopping site.

To date, the Directorate for Economic Analysis has identified about 25 U.S. firms and individuals who have recently imported magnetic desk sets for sale in the United States. The combined sales of the top seven firms have probably accounted for the great majority (perhaps over 98%) of units sold. Due to resource constraints, the compliance division targeted 13 firms for corrective action. Eleven agreed to stop sale pending negotiations for a corrective action plan, two are now the subject of administrative cases recently initiated by the Commission. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own websites or other Internet shopping sites. In addition to products offered for sale by U.S.

importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China, many of which market products through "stores" on a leading Internet shopping site.[8]

3. Evaluation of the Proposed Rule

Societal Costs and the Potential Benefits of a Rule Prohibiting Certain Magnetic Desk Sets

Estimated Societal Costs of Injuries

The purpose of the proposed rule is to prevent serious intestinal injuries that can result when children ingest two or more of the magnets in the subject magnet sets (or one magnet and another ferromagnetic object) (Inkster, 2012). The draft proposed rule would prohibit magnet sets that do not meet specified performance requirements. Therefore, benefits of the proposed rule would be the resulting reduction in injuries. Based on a review of magnet ingestion incidents reported through CPSC databases that include the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP), CPSC staff is aware of 38 confirmed incidents involving ingestion of one or more powerful magnets from a subject magnetic desk set since the product was introduced in 2008 (Garland, 2012). An additional five incidents possibly involved magnets from such magnet sets. No fatalities involving the products are known to the CPSC.

Our analysis of the potential benefits of the proposed rule focuses on injuries reported through the National Electronic Injury Surveillance System (NEISS), a probability sample of U.S. hospital emergency departments that can be used to provide national estimates of product-

[8] More than 40 such stores shipping magnetic desk toys directly from Hong Kong or China were identified in a brief review of product offerings on the Internet site.

related injuries initially treated in U.S. hospital emergency departments. Based on a review of incident narratives coded from emergency department medical records for magnet ingestion cases obtained from NEISS hospitals, the Directorate for Epidemiology staff has identified 72 magnet ingestions from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Although manufacturer or brand name information is rarely available in the medical records extracted for NEISS, three of the 72 NEISS-reported cases (4.2%) did mention a brand name of magnet sets that are the magnets of interest; 69 cases (95.8%) were determined to have possibly involved the magnets of interest because the case narratives included terms such as "high powered," "magnetic ball," "magnetic marble," "BB size magnet," or "magnetic beads" (Garland, 2012).

Based on the 72 NEISS-reported magnet cases, there were an estimated 1,716 injuries treated in U.S. hospital emergency departments during the 2009 through 2011 study period. Roughly 6 percent were hospitalized injuries, as opposed to being treated and released. The benefits of the proposed rule can be estimated as the reduction in the societal costs associated with the injuries that would be prevented by the proposed rule. The Directorate for Economic Analysis bases estimates of the societal costs of emergency department-treated magnet injuries on the CPSC's Injury Cost Model (ICM) (Miller et al., 2000). The ICM is fully integrated with NEISS, and it estimates the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between the number of medically attended injuries treated in emergency departments and the number of injuries treated in other settings, the ICM also estimates the number and societal costs of medically attended injuries treated outside of

emergency departments, such as in doctors' offices and clinics. The estimates of societal costs provided by the ICM depend upon (and vary by) the injury diagnosis, the body part affected, the injury disposition (*i.e.*, treated in a doctor's office, treated and released from a hospital emergency department, or hospitalized), and the age and sex of the victim.

Table 1 provides *annual* estimates of the injuries and the societal costs associated with "high-powered and/or ball-shaped magnet ingestions" that *involve*, or *possibly involve*, the magnets that are the subject of the proposed rule. As shown in the table, the 2009 through 2011 NEISS estimates suggest an estimated *annual* average of about 572 emergency department-treated injuries, including 537 injuries that were treated and released and 35 injuries that were hospitalized. About 70 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Just over half of the magnet cases from the emergency departments of the hospitals that comprise the NEISS sample appear to have involved the ingestion of more than one magnet.[9] Additionally, based on estimates from the ICM, there were another 870 injuries treated annually outside of hospital emergency departments.

After including the injuries treated outside of hospital emergency departments, there was an annual average of about 1,442 medically attended injuries involving ingestions of magnets that were defined as at least "possibly of interest." These injuries resulted in annual societal costs of about $24.8 million (in 2011 dollars) during the 2009–2011 time period. The average

[9] In contrast to the available evidence on the number of magnets ingested from the NEISS estimates, 37 of 40 non-NEISS incidents reported to the CPSC involved the ingestion of more than one magnet (see Garland, Table 10). The difference may be related to the number of cases upon which the NEISS estimate was based, which may have been too small to provide reliable estimates. Alternatively, it is possible that the non-NEISS injury reports to the CPSC tended to involve the more serious cases with multiple magnets.

estimated societal costs per injury were about $13,000 for injuries treated outside of emergency departments and hospitals (such as in a doctor's office or clinics), about $17,000 for those that were treated and released from emergency departments, and about $112,000 for those that were admitted to hospitals for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 25 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 75 percent of the estimated injury costs (Miller et al., 2000).

Table 1.
Estimated average annual medically attended 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, 2009–2011.

Injury Disposition	Estimated Number	Estimated Societal Costs ($ millions)*
Treated and Released from Hospital Emergency Department (NEISS)	537	$ 9.1
Admitted to Hospital Through the Emergency Department (NEISS)	35†	$ 3.9
Medically Treated Outside of Hospital Emergency Department (ICM)	870	$11.7
Total Medically Attended Injuries	1,442	$24.8

* In 2011 dollars.
† According to the Directorate for Epidemiology, the estimated number of hospital-admitted emergency department-treated injuries is a not a reliable estimate because of the small number of cases upon which the estimate was based.

It should be noted that there is uncertainty concerning these estimates. Some of the cases described as "possibly" involving the magnet injuries that were included in Table 1 may not have

involved the magnets that are the subject of the NPR. As noted above, about 95.8 percent of the cases upon which the table was based were described as only possibly involving the magnets of interest because NEISS narratives are not required to list manufacturer or brand name. Hence, it is possible that Table 1 overstates the societal costs associated with the magnets that would be included in the proposed rule.

On the other hand, in addition to the magnet cases upon which the table was based, there were also 175 NEISS cases (representing about 1,440 emergency department-treated injuries annually) in which the magnet type was unknown. These cases included those in which the case narrative mentioned that a magnet was involved, but presented insufficient information to classify the magnet type. Consequently, to the extent that the unknown magnet types involved those that would be covered by the proposed rule, the Table 1 results would tend to understate the societal costs associated with the magnets subject to the proposed rule.

Estimated Benefits of the Proposed Rule

As noted above, the benefits of a proposed magnet rule would be the reduction in the societal costs of the injuries that would be prevented. In general, because the proposed rule would effectively ban certain types of magnet sets, all ingestion injuries that would have involved magnets that, in the absence of the proposed rule, would have been sold after the effective date of the proposed rule, will be prevented. However, if children, adolescents, and teens cannot play with or use the prohibited magnets, they could play with or use substitute products that may also result in injury. Hence, the overall benefits of the proposed rule should be measured as the *net reduction* in injuries, and the concomitant reduction in societal costs, that

would result.

These issues make it difficult to estimate with much certainty the prospective benefits of a proposed rule. However, if we assume that the injuries presented in Table 1 provide a generally accurate estimate of the annual injuries that would be prevented by the proposed rule, and that the risk associated with the use of substitute products is small, the expected benefits might amount to roughly $25 million annually.

Potential Costs of a Rule Prohibiting Certain Magnetic Desk Sets

The profits of firms represent a measure of the benefits to businesses that result from the production and sale of products. Similarly, the use value or "utility" that consumers receive from products represent the benefits of product use by the consuming public. Consequently, the costs of a proposed rule that effectively bans certain magnetic sets would consist of: (1) the lost profits of firms that would be barred from producing and selling the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price.

Market Wide Profits

First consider "profits," which would be defined as the total revenue (TR) received by firms resulting from the sale of the subject magnets, less the total costs (TC) needed to produce, distribute, and market them. We do not have firsthand knowledge of the profits of firms marketing the magnetic desk sets, but we do have information that may help us provide an upper limit.

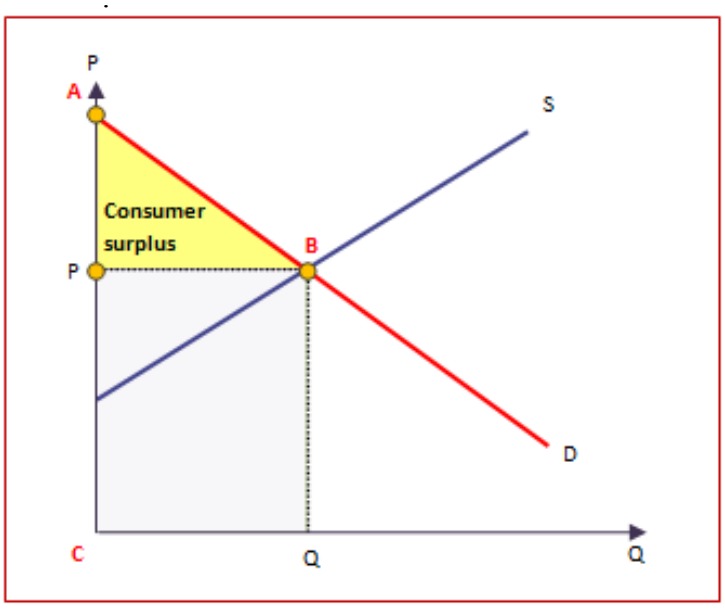
Based on the available information described earlier, sales of the magnetic desk sets may

have averaged roughly 1 million annually during the 2009−2011 study period, with an average retail price of about $25 per set. Thus, total industry revenues may have averaged about $25 million annually (*i.e.,* 1 million sets × $25 per set). Additional information provided by firms to the Office of Compliance and Field Operations suggests that the average import cost of the magnets to U.S. importers may have amounted to about $10 per set, or an annual average of about $10 million (*i.e*., 1 million sets × $10 import cost per set). Thus, total revenues, less import costs, might have averaged about $15 million annually (*i.e*., $25 million−$10 million). While the share of profits from this $15 million in net revenues is unknown, it seems unlikely that profits would amount to more than about half, or about $7.5 million annually. Thus, the costs of a proposed rule in terms of reduced profits might amount to as much as $7.5 million on an annual basis.[10]

Lost Utility to Consumers

We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe it conceptually. In general, use value includes the amount of: (1) consumer expenditures for the product, plus (2) what is called "consumer surplus." In the case of the magnetic desk sets, given sales of about 1 million sets annually, and an average retail price of about $25 per set, consumer expenditures would amount to about $25 million annually. This $25 million represents the minimum value that consumers would expect to get from these products. It is represented by the area of the rectangle CPBQ in the standard supply and demand graph below, where P equals $25, and Q equals 1 million units.

[10] While most of these potential profits would accrue to importers, who also sell the magnetic desk toys directly to consumers, some portion would accrue to other retailers.



The consumer surplus is given by the area of the triangle PAB under the graph's demand function, and represents the difference between the market clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they had to pay. For example, while tickets to a concert or football game might sell for $100 each, some consumers who buy them for $100 would have been willing to pay $150 per ticket. In other words, they paid $100 and received benefits that they value at $150. Hence, each of these consumers would receive a *consumer surplus* of $50.[11]

In general, the use value for the magnetic desk sets obtained by consumers is represented by the area of the trapezoid CABQ. However, the prospective *loss* in use value associated with

[11] If the above graph represents the market for tickets, the demand curve (AD) describes the quantity of tickets demanded at each price (*i.e.*, the quantity of tickets consumers are willing and able to purchase at each price). In this example, the $150 the consumer would have been willing to pay for the ticket is represented on the demand curve at a point to the left of point B. The consumer surplus is given by the relevant point on the demand curve (*i.e.*, where price = $150), minus the market clearing price of $100.

the proposed rule prohibiting certain magnetic desk sets would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the prohibited product, but they would, nevertheless, still have the $25 million (represented by the rectangle CPBQ) that they would have spent on magnetic sets in the absence of a ban. While they can no longer purchase magnetic desk sets, which would have been their first choice, they can use this money to buy other products providing use value.

We have no information regarding aggregate consumer surplus, and hence, the amount of utility that would be lost from a ban of magnetic sets. While the magnetic desk sets clearly provide "utility" to purchasers, they are not necessities. Consequently, the demand for magnetic desk sets is probably *not* price inelastic, a factor that would tend to reduce estimates of utility losses.[12] Additionally, if the magnetic sets are "faddish," they may not be the type of product that will be used intensively by consumers over long periods of time. However, if, for example, consumers who purchased the magnetic sets at an average price of $25 would have been willing to spend, on average, $35 per set, the lost utility from the desk sets might amount to about $10 million on an annual basis (*i.e.*, [$35−$25] × 1 million units annually).

Finally, it should be noted that the loss in consumer surplus just described represents the maximum loss of consumer utility from the proposed rule; the actual loss is likely to be lower. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased in the place of magnetic desk sets. If, for example, there were close

[12] To say that the demand for a product is "price inelastic" means that the quantity demanded tends to be insensitive to changes in the price of the product. Gasoline is an example of a product with an inelastic demand, meaning consumers are not likely to reduce substantially their purchase of gasoline (at least in the short run) even if the price increases substantially.

substitutes for magnetic desk sets (*i.e.*, desk sets that are almost as satisfying and similarly priced), the overall loss in consumer surplus (and hence, the costs of the proposed rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the proposed rule would tend to be higher. Nevertheless, the proposed rule will result in some level of lost utility. By purchasing magnetic desk sets rather than other products, consumers are revealing that they have a preference for the magnetic desk sets that are likely to provide more utility than a substitute purchase.

Sensitivity of Results to Product Life Assumptions

Implicit in this analysis has been the assumption that the expected useful life of the magnetic desk sets is about 1 year. Because this product has only been in widespread consumer use since 2009, this assumption is made without extensive knowledge about the actual use of the magnetic sets by consumers. Magnetic desk sets are relatively durable products, purchased at an average price of about $25. However, many consumers may find them to be novelties that soon lose much of their appeal. Thus, even if some of the products remain in homes or offices longer than a year, the risk of ingestion by children may be much higher in the first month or two after they are purchased. On the other hand, the magnets may be put away in a place accessible by children at some later date. Although it is somewhat speculative, it seems reasonable to assume that the effective useful product life of magnetic desk sets is, on average, no more than about a year.

However, it should also be noted that the results of our analysis are not particularly sensitive to this product life assumption. For example, had we assumed that the average product

life was about 2 years, rather than 1 year, estimates of the number of sets in use at any given time would approximately double, reducing the estimated *annual* risk of injury, per magnetic desk set in use (and hence, reduce estimated societal costs per set) by about half. However, this reduced estimate of annual societal costs would itself be offset by the fact that the sets remain in use for 2 years, rather than 1 year. Thus, annual benefits would be halved, but benefits would be accrued over a 2-year period rather than 1 year. Consequently, even if we had doubled the assumed product life, the relationship between benefits and costs would have remained about the same.

Alternatives to the Proposed Rule

There are several possible alternatives that the Commission might consider instead of a proposed rule prohibiting certain magnetic desk sets.

Alternative Performance Requirements

As an alternative to the proposed rule, the Commission could consider promulgating an alternative set of requirements that could reduce the risk of injury from magnetic desk sets. Performance requirements might allow a different flux index for the magnets sold as manipulative desk sets; different specifications regarding shapes and sizes of magnets within the scope of the standard; or some other criteria that have not yet been developed (but not as stringent as in the proposed rule). The advantage of such an approach is that it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets and at the same time allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults. Additionally, the expected injury reduction would depend upon the

parameters of the performance requirements that are established.

Safer Packaging

A possible alternative might be for magnetic desk sets to be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such an approach might prevent injuries resulting from a small number of magnets being separated from a set without the owner knowing. In reality, though, many consumers may not use such containers because it could require time to form the magnets into a shape (*e.g.*, a cube) to make them fit in the containers; or they might want to keep the magnets out of their container in a shape or structure that took time and effort to construct.

Alternatively (or in combination), the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may result in several practical problems. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the child-resistant packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnetic desk sets because of the level of inconvenience it would involve (Sedney & Smith, 2012). Also, for the reasons described above, consumers may leave magnets outside of their container.

Warnings

The Commission could require strong warnings on labels and on product instructions designed to prevent the use of the magnetic desk sets by children. The Division of Human

Factors, Directorate for Engineering Sciences (HF) memorandum contains an extensive discussion concerning warnings and their potential effectiveness (Sedney & Smith, 2012). Based on HF staff's examination, the ingestion warnings that currently accompany magnetic desk sets are generally aimed at adults, but appear to be deficient in terms of their content. For example, some warn against children swallowing the magnets without describing the incident scenarios. Some warnings refer to the propensity for swallowed magnets to stick to intestines without referring to the presence of other magnets or metal objects. Others warnings did refer to magnets sticking together or attaching to other metallic objects inside the body, but without explaining that the magnets can attract through the walls of the intestines and forcefully compress these tissues, resulting in serious injuries. According to CPSC staff, without detailed information in the warnings, consumers may not really understand how swallowing magnets differs from swallowing other small parts or how magnets sticking together could pose a hazard.

CPSC staff believes that it may be possible to develop warnings that could adequately communicate the ingestion hazard, the consequences of ingestion, and how to avoid the hazard. To the extent that the subject magnets present a "hidden" hazard about which consumers are unaware, explicit and adequate warnings could reduce ingestions and allow adults to continue to enjoy the use of the product. However, the effectiveness of such warnings is unknown, and CPSC staff doubts that even well-written warnings would substantially reduce the incidence of magnet ingestions. Some caregivers who read and understand the message may attempt to keep the magnets out of the hands of young children, but staff doubts many caregivers would attempt to keep the product away from older children and adolescents. Additionally, staff is doubtful

that children old enough to understand the warnings would abide by them.

Restrictions on the Sale of Magnetic Desk Sets

Another option for the Commission to consider might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Sales limitations or requirements for strong warnings might also be required on websites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings could be developed although the staff has expressed serious concern as to whether such warnings can ever overcome the attractiveness of the magnets and their intrinsic play value.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce the number of ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging, even if parents try to restrict the use of the desk sets. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a product that they apparently enjoy. We are interested in receiving comments that would address this issue.

Address Through Corrective Actions Rather than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While staff believes this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

Summary

Based on reports to the CPSC, ingestions of small magnets contained in magnetic desk sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. However, because of the lack of definitive information on the number of injuries involving magnetic desk sets that would be prevented by a proposed rule, there is uncertainty concerning the benefits that would result. If we assume that the NEISS cases identified by the Directorate for Epidemiology staff as involving high-powered and/or ball-shaped magnet ingestions actually involved the magnets that would be prohibited, then the estimated benefits of the rule might amount to about $25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009−2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility.

There are alternative regulatory actions that the Commission could consider that might allow the magnetic desk sets to continue to be marketed. For example, the Commission, by regulation, could issue alternative performance requirements or require warnings that explicitly describe the hazard and how to avoid it. Other options might be to develop requirements for the packaging of the magnetic desk sets (*e.g.*, develop requirements for child-resistant packaging);;

and/or place limitations on how and where the magnetic desk sets can be sold. These alternative actions—which might be considered alone, or in combination—would have varying levels of effectiveness.

I. Paperwork Reduction Act

The proposed rule would not require manufacturers (including importers) to perform testing or require manufacturers or retailers to keep records. For this reason, the proposed rule does not contain "collection of information requirements" as that term is used in the Paperwork Reduction Act, 44 U.S.C. 3501–3520. Therefore, the proposed rule need not be submitted to the Office of Management and Budget (OMB) in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.

J. Initial Regulatory Flexibility Analysis

1. Introduction

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed rules for their potential economic impact on small entities, including small businesses. Section 603 of the RFA calls for agencies to prepare and make available for public comment an initial regulatory flexibility analysis describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. The initial regulatory flexibility analysis is to contain:

1) a description of the reasons why the action is being considered;

2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for the preparation of the report or record; and

5) an identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

Accordingly, staff prepared an initial regulatory flexibility analysis, which is summarized below.

2. Description of the Proposed Rule and Reasons for Considering It

As discussed previously, the proposed rule would prohibit magnet sets that do not meet the specified requirements described in section F of this preamble. Some of the incidents that have come to the attention of the Commission involving ingestions of magnets from desk sets have resulted in severe medical consequences, including significant damage to the stomach or intestines. Based on a review of emergency department-treated magnet ingestions obtained through the NEISS, the Directorate for Epidemiology staff has identified 72 magnet ingestions from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Based on these injuries, staff estimates that there has been an *annual* average of about 572 emergency department-treated injuries involving the products, including 537 injuries that were treated and released and 35 injuries that were hospitalized.[13] Additionally, based on estimates from the CPSC's Injury Cost Model (ICM), which is integrated with NEISS, there were 870 other injuries treated annually outside of hospital emergency departments, such as in doctors' offices and clinics. The estimated total of 1,442 medically attended injuries involving

[13] Average annual estimates are from the Injury Cost Model evaluation of 72 emergency department-treated injuries during 2009–2011 determined to have involved, or possibly having involved, magnets of interest (Garland, 2012).

magnet ingestions, which were defined as at least "possibly of interest," resulted in average annual societal costs of nearly $25 million during 2009 through 2011, based on estimates provided by the ICM.

3. Products Within the Scope of the Proposed Rule

This proposed rule would cover magnet sets that are comprised of sets of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. The products have been described as desk toys, games, puzzles, and stress relievers. The small powerful magnets most likely to be affected by the proposed rule are made from alloys of neodymium, iron, and boron. We are interested in receiving comments that would address this issue both as to the type of products that should be covered and the composition of the magnets. More information concerning the product and the market is provided in section B of the preamble.

4. Small Businesses Subject to the Proposed Rule and Possible Economic Impacts

The proposed rule would impact U.S. importers and retailers of manipulative desk sets that are comprised of small powerful magnets of the size and magnetic force proscribed by the proposed rule. None of the magnetic desk sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import them from manufacturers in China, packaged and labeled for sale to U.S. consumers. The Directorate for Economic Analysis has indentified about 25 firms and individuals in the United States who have

recently imported the product for sale to consumers. All of the importers are small businesses under U.S. Small Business Administration (SBA) size standards (SBA, 2012).[14]

Based on information on product sales reviewed by the Directorate for Economic Analysis staff, including reports by firms to the Office of Compliance and Field Operations (Compliance), the number of manipulative magnetic desk sets that have been sold by U.S. importers since the products were introduced in 2008 may total about 2.7 million sets, with a value to the firms of roughly $50 million. This value range reflects a combination of retail sales directly to consumers (through company websites and other Internet retail sites) and sales to retailers who market the products.

Although there are about 25 U.S. importers of magnet sets that would fall within the scope of the rule, the economic impact of the rule will be most severe for the seven firms that account for the great majority (perhaps over 98%) of units sold. Perhaps five of these larger importers derive most or all of their revenues from the sale of magnetic desk toys falling within the scope of the rule, or related products, such as books and surfaces upon which magnetic designs are constructed. These firms would be severely affected by the proposed rule, which would effectively ban the magnet sets that they have been importing and selling. Consequently, they may go out of business. Two of the other leading importers of magnetic desk sets apparently have fairly broad product offerings, which could lessen the severity of the economic

[14] The SBA size standard for "Other Miscellaneous Nondurable Goods Merchant Wholesalers" (which includes importers) is 100 employees and the size standard for "Non-store Retailers – Electronic Shopping" is $30 million in average annual receipts (SBA, 2012).

impact of a rule. Nevertheless, the impacts of the proposed rule could be considered significant for these small importers.

Nearly all of the perhaps 18 other recent U.S. importers of magnetic desk sets have sold relatively few of the products. These importers sourced the products from manufacturers in China and have marketed the magnet sets through online "stores" maintained on Internet retail sites. Many of these importers are individuals who may also market a variety of other products through the same Internet outlets. For individuals and firms with these business models, the discontinuance of certain magnetic desk sets as a source of revenue as a result of the rule is less likely to cause significant economic hardship, unlike the firms or individuals who derive most, or all, of their revenue from sales of magnetic desk sets and related products.

Although a large share of magnetic desk sets are sold directly to consumers by the importers using their own Internet websites or other Internet shopping sites, a rule prohibiting these products would also affect retailers of the products, whether selling them online or physically in stores. However, these retailers are not likely to derive significant proportions of total revenues from sales of affected desk sets, and the impacts on individual firms should be minimal.

5. Objectives of, and Legal Basis for, the Proposed Rule

The purpose of the proposed rule is to reduce the risk of injury from ingestion of one or more small, powerful magnets that comprise the subject consumer products. As noted above, the estimated total of 1,442 medically attended injuries involving magnet ingestions that were defined as at least "possibly of interest" resulted in annual societal costs of about $25 million

during the 2009 to 2011 time period. These incident numbers may change over the course of the rulemaking because the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) has provided the Commission with some additional incident data and is currently surveying their members regarding any additional incident data they may have to share with the Commission. After receiving this data the Commission may conduct its own survey to collect additional data similar to the exposure surveys the Commission has conducted in the ATV rulemaking. However, it is expected that the proposed rule would substantially reduce the future incidence and cost to society of ingestions of the subject magnetic desk sets. As discussed in section D of this preamble, the rule is being proposed under the authority of the CPSA.

6. Other Federal Rules

We are not aware of any federal rules that may duplicate, overlap, or conflict with the proposed rule.

7. Alternatives to the Proposed Rule

There are possible alternatives to the proposed rule that would reduce the impact of a rule on small businesses. These alternatives would include the following:

a. Adoption of a Performance Standard with Different Provisions

As an alternative to the proposed rule, the Commission could consider promulgating a different set of performance requirements to reduce the risk of injury from magnetic desk sets. Performance requirements might require a different flux index for the magnets sold as manipulative desk sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have not been developed yet. The advantage of

such an approach is that, theoretically, it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets, and at the same time, allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially reduce the physical qualities of the products that make them enjoyable for adults.

b. Safer Packaging Options

In theory, magnetic desk sets could be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such a requirement might prevent injuries that result from a small number of magnets becoming separated from a set without the owner knowing. In reality, though, many consumers might be unlikely to use such containers because using a container could require consumers to take time to form the magnets into a shape (e.g., a cube) in order for the magnets to fit back into the container, or consumers might wish to keep the magnets in a formation that took time and effort to construct.

Alternatively, the magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may suffer from several practical problems. Child-resistant packaging would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product such as the magnetic desk set because of the level of inconvenience it would involve.

It is not clear that the Commission would have the authority to require either of these

approaches through regulation.

c. Warnings/Labeling Requirements

The Commission could require labeling on affected magnetic desk sets to warn consumers in lieu of a rule that prohibits the products. Following its evaluation of this alternative, the Division of Human Factors, Directorate for Engineering Sciences, concluded: "it may be possible to develop warnings that could inform parents and other caregivers better about the ingestion hazard, its consequences, and appropriate hazard-avoidance measures. Nevertheless, the resulting warnings may not be effective at motivating caregivers to comply, and therefore, they may not reduce substantially the incidence of magnet ingestions."

d. Restrictions on the Sale of Magnetic Desk Sets

Another option might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Advertising and sales limitations or requirements for strong warnings might also be required at websites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out (and the legal authority to impose such restrictions by regulation is uncertain), but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings of the sort that CPSC staff has suggested could be developed.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce ingestions. Some parents would still

allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some young children will get into the packaging even if parents try to restrict the use of the products. Nevertheless, combining sales limitations with explicit warnings might educate parents about the hidden nature of the hazard, while at the same time allow adults to continue to use a product that apparently they enjoy.

e. Address Through Corrective Actions Rather than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While we believe this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

f. Taking No Action

The Commission could take no regulatory action to reduce the risk of ingestion injuries associated with magnetic desk sets. Under this alternative, future societal losses would be determined by the numbers of products in use, other factors that affect the likelihood that young children, adolescents, and teens will ingest the magnets, and the awareness and response of the medical community to the hazards presented by ingested magnets. Theoretically, over time, increased awareness of the hazards by caregivers could make it more likely that the magnets will be kept away from young children and older children, and school personnel could be made more aware of the hidden dangers of using strong magnets to mimic tongue or lip piercings. Also, the medical community seems to be taking steps to become better educated about the risks of ingested magnets, which should lead to monitoring of patients' medical status more quickly, which would reduce the adverse medical consequences of magnet ingestions.

8. Summary

The results of this initial regulatory flexibility analysis suggest that the proposed rule would likely have a significant adverse impact on seven of the small importers of magnetic desk sets, and perhaps five of these firms that derive most or all of their revenue from the sale of magnetic desk sets might go out of business. Some possible alternatives to a rule prohibiting the products have been identified. All of these alternatives would reduce the expected impact of the rule on small businesses. However, these alternatives might not achieve the same level of benefits as the proposed rule.

K. Environmental Considerations

Usually, CPSC rules establishing performance requirements are considered to "have little or no potential for affecting the human environment," and environmental assessments are not usually prepared for these rules (see 16 CFR 1021.5 (c)(1)). This proposed rule falls within the categorical exemption.

L. Executive Order 12988 (Preemption)

As required by Executive Order 12988 (February 5, 1996), the CPSC states the preemptive effect of the proposed rule as follows:

The regulation for hazardous magnet sets is proposed under authority of the CPSA. 15 U.S.C. 2051–2089). Section 26 of the CPSA provides that "whenever a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any

requirements as the performance, composition, contents, design, finish, construction, packaging or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal Standard". 15 U.S.C. 2075(a). Upon application to the Commission, a state or local standard may be excepted from this preemptive effect if the state or local standard: (1) provides a higher degree of protection from the risk of injury or illness than the CPSA standard, and (2) does not unduly burden interstate commerce. In addition, the federal government, or a state or local government, may establish and continue in effect a non-identical requirement that provides a higher degree of protection than the CPSA requirement for the hazardous substance for the federal, state or local government's use. 15 U.S.C. 2075(b).

Thus, with the exceptions noted above, the magnet set requirements proposed in today's Federal Register would preempt non-identical state or local requirements for magnet sets designed to protect against the same risk of injury.

M. Effective Date

The Commission proposes that this rule would become effective 180 days from publication of a final rule in the Federal Register and would apply to all magnet sets manufactured or imported on or after that date. The CPSA requires that consumer product safety rules take effect not later than 180 days from their promulgation unless the Commission finds there is good cause for a later date. 15 U.S.C. 2058(g)(1).

N. Proposed Findings

The CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. Specifically, the CPSA requires that the Commission consider and make findings about the degree and nature of the risk of injury; the number of consumer products subject to the rule; the need of the public for the rule and the probable effect on utility, cost, and availability of the product; and other means to achieve the objective of the rule, while minimizing the impact on competition, manufacturing, and commercial practices. The CPSA also requires that the rule must be reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product and issuing the rule must be in the public interest. 15 U.S.C. 2058(f)(3).

In addition, the Commission must find that: (1) if an applicable voluntary standard has been adopted and implemented, that compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be substantial; (2) that benefits expected from the regulation bear a reasonable relationship to its costs; and (3) that the regulation imposes the least burdensome requirement that would prevent or adequately reduce the risk of injury. *Id*. These findings are discussed below.

*Degree and nature of the risk of injur*y. Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-

shaped magnets that were contained in products that meet the above definition of "magnet set," and 5 of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 10 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children younger than 4 years old, or between the ages of 4 and 12.

Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly intestinal twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury, but as few as two magnets can cause serious internal damage in a very short period of time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences to the treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel

transplant; and possible impediments to fertility with girls. Even those children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus, exposing children to repeated dosages of radiation.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost, and availability. We cannot estimate, in any precise way, the use value that consumers receive from these products. In general, this would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e*., the difference between the market price and the maximum amount consumers would have been willing to pay for the product). Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose of the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, the circumstances associated with this product limit the likely effectiveness of warning labels.

Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not appreciate the hazard associated with magnet sets, and as a result, they will continue to allow children access to the product. Children may not appreciate the hazard and will continue to mouth the items, swallow them, or, in the case of young adolescents and teens, mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; the small size of the individual magnets precludes the addition of such a warning. Because individual magnets are shared easily among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to $25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits to firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer

available. We estimate these costs to be about $7.5 million in lost profits and some unknown quantity of lost utility. Considering the injuries associated with magnet sets—and the resulting societal costs, balanced against the likely impact that the proposed rule would have on firms producing and selling the product, and on consumers who would lose the utility of the product—we preliminarily conclude that magnet sets pose an unreasonable risk of injury and that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it would reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries. The Commission seeks comment on this issue and also whether similar actions regarding lawn darts and dive sticks have had the effect of reducing injuries by reducing the access to the product.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) provide for appropriate warnings and labeling on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as: not selling to stores that sell children's products exclusively, and not selling the magnets in proximity to children's

products. Such a voluntary standard would have many of the same limitations as would a labeling standard.

Relationship of benefits to costs. Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about $25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, also are uncertain. However, based on annual estimates available for the 2009−2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. We conclude that none of these alternatives would adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets. Theoretically, this might allow some current products to continue to be produced. However, it is unclear that a different flux index would permit products that have the desired physical qualities to make them sufficiently enjoyable to adults while adequately reducing the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape

they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. It is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings may still not abide by them. Some type of sales restriction, limiting the location where magnet sets could be sold, might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or other locations when adults have bought them and they are available to children. The Commission could continue to address the hazard from magnet sets through corrective actions, *i.e*., recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission has the option of taking no regulatory action. Although it is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than if the Commission issues the proposed rule.

O. Request for Comments

We request comments on all aspects of this proposed rule. We ask for comments concerning the risks of injury associated with these magnet sets; the regulatory alternatives discussed; other possible ways to address these risks; and the economic impacts of the various regulatory alternatives. We specifically seek comments concerning the following issues:

- The proposed definition of "magnet sets" that would be covered by the rulemaking and other issues related to scope of the proposal
- The appropriateness of the proposed flux index limit of 50 or less
- The adequacy of the proposed test procedure for determining the flux index, particularly whether it would be sufficient to account for the strength of aggregated magnets
- Alternatives to the small parts cylinder that limits the size of the magnets at issue
- The likelihood that a magnet set could function as entertainment for adults and meet the proposed requirements
- All alternatives to the proposed regulatory action
- Issues related to warnings for these products
- The options of conducting the rulemaking under section 8 of the CPSA or under provisions of the FHSA

P. Conclusion

For the reasons stated in this preamble, the Commission preliminarily concludes that magnet sets that do not meet the specified proposed requirements present an unreasonable risk of injury.

List of Subjects in 16 CFR Part 1240

Consumer protection, Imports, Infants and children, Labeling, Law enforcement.

For the reasons stated in the preamble, the Commission proposes to amend Title 16 of the Code of Federal Regulations as follows:

1. Add part 1240 to read as follows:

PART 1240 — SAFETY STANDARD FOR MAGNET SETS

Sec.

AUTHORITY: 15 U.S.C. 2056 and 2058.

§ 1240.1 Scope, purpose, and effective date.

This part 1240, a consumer product safety standard, prescribes requirements for magnet sets, as defined in § 1240.2. These requirements are intended to reduce or eliminate an unreasonable risk of injury to children who ingest magnets that are part of hazardous magnet sets. This standard applies to all magnet sets, as defined in § 1240.2, that are manufactured or imported on or after [180 days after publication of a final rule].

§ 1240.2 Definitions.

(a) The definitions in section 3 of the Consumer Product Safety Act (15 U.S.C. 2052) apply to this part 1240.

(b) *Magnet set,* means any aggregation of separable, permanent, magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief.

§ 1240.3 Requirements.

(a) *Small parts*. Magnet sets containing more than one magnet that fits completely within the cylinder described in 16 CFR 1501.4, must meet the requirement in paragraph (b) of this section.

(b) *Flux index*. When tested in accordance with the method described in § 1240.4, small magnets, as determined in paragraph (a) of this section, must have a flux index of 50 or less.

§ 1240.4 Test procedure for determining flux index.

(a) Select at least one magnet of each shape and size that the magnet set contains.

(b) Measure the flux index of the selected magnets in accordance with the procedure in sections 8.24.1 through 8.24.3 of ASTM F963-11, *Standard Consumer Safety Specification for Toy Safety*, approved December 1, 2011. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box 0700, West Conshohocken, PA 19428; telephone 610-832-9585; www.astm.org. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA,

call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

§ 1240.5 Findings.

(a) *The degree and nature of the risk of injury*. Based on a review of NEISS data, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period from January 1, 2009 to December 31, 2011. From review of INDP and IPII databases, we are aware of 50 reported incidents occurring from January 1, 2009 through June 30, 2012, involving the ingestion of magnets by children between the ages of 1 and 15 years. Of those 50 incidents, 38 involved the ingestion of high-powered, ball-shaped magnets that were contained in products that meet the above definition of "magnet set," and five of those 50 incidents possibly involved ingestion of this type of magnet. Hospitalization was required in order to treat 29 of the 43 incidents, with surgery necessary to remove the magnets in 20 of the 29 hospitalizations. In 9 of the 29 hospitalizations, the victim underwent colonoscopic or endoscopic procedures to remove the magnets. In 37 of the 43 incidents that likely involved magnets from hazardous magnet sets, the magnets were ingested by children who were less than 4 years old or between the ages of 4 and 12 years old.

Once ingested, these strong magnets begin to interact in the gastrointestinal tract, which can lead to tissue death, perforations, and/or fistulas, and possibly bowel twisting and obstruction. If left untreated, these injuries can lead to infection of the peritoneal cavity and other life-threatening conditions. The number of magnets swallowed increases the risk of attraction and injury; however, as few as two magnets can cause serious internal damage in a

very short period of time. The fact that many medical professionals do not appreciate the health consequences of magnet ingestion increases the severity of the risk because a doctor who is unfamiliar with these strong magnets may send a child home and expect the magnets to pass naturally. There are also health consequences associated with treatment and surgery for removal of ingested magnets. There may be a risk of gastrointestinal bleeding; leakage of holes that were repaired; rupturing of resectioned bowels; temporary paralysis of the bowels; use of a colostomy bag; IV feeding, initially, or for some longer time period; and compromise of nutrition and digestive function. Long-term health consequences can be severe as well: loss of intestinal tissue; compromised nutrition absorption; adhesions and scarring of intestines; need for a bowel transplant; and possible impediments to fertility with girls. Even those children who pass the magnets naturally and do not require surgery still need close observation by doctors and may undergo sequential x-rays, thus exposing children to repeated dosages of radiation.

Number of consumer products subject to the rule. The market has increased substantially since magnet sets were first introduced. We estimate that the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million.

The need of the public for magnet sets and the effects of the rule on their utility, cost and availability. We cannot estimate in any precise way the use value that consumers receive from these products. In general, this would be the amount of money that consumers expend on the product, plus the consumer surplus (*i.e*., the difference between the market price and the maximum amount of money that consumers would have been willing to pay for the product).

Although the proposed rule would prohibit the magnet sets currently on the market, it is conceivable that a similar product that meets the requirements of the proposed rule could be developed that would serve a similar purpose as the magnet sets that the proposed rule would prohibit.

Other means to achieve the objective of the rule, while minimizing the impact on competition and manufacturing. Various alternatives to the proposed rule are discussed in previous sections of this preamble. We do not believe that options other than the proposed rule prohibiting certain magnet sets would sufficiently reduce the number and severity of injuries resulting from the ingestion of magnets from these magnet sets. As discussed above, the circumstances associated with this product limit the likely effectiveness of warning labels. Despite existing warning labels and market restrictions, ingestion incidents have continued to occur. Parents and caregivers may not appreciate the hazards associated with magnet sets, and as a result, they will continue to allow children access to the product. Children may not appreciate the hazards, and they will continue to mouth the items, swallow them, or, in the case of young adolescents and teens, mimic body piercings. Once the magnets are removed from their carrying case, the magnets bear no warnings to guard against ingestion or aspiration; and the small size of the individual magnets precludes the addition of such a warning. Because individual magnets are easily shared among children, many end users of the product are likely to have had no exposure to any warning.

Unreasonable risk. As noted previously, we have determined that an estimated 1,700 ingestions of magnets from magnet sets were treated in emergency departments during the period

from January 1, 2009 to December 31, 2011. Injuries resulting from such ingestions of magnets can be severe and life-threatening. The risk posed by these magnets may not be appreciated by caregivers and children, as they may assume, mistakenly, that the consequences of ingesting magnets would be similar to ingesting any other small object. However, once ingested, these strong magnets are mutually attracted to each other and exert compression forces on the trapped gastrointestinal tissue.

We estimate that the societal costs of resulting injuries could amount to $25 million annually. This would be the expected benefits that could result from the proposed rule. The costs of the proposed rule would consist of the lost profits of firms that produce and sell magnet sets, plus the lost use value that consumers would experience when the product is no longer available. We estimate these costs to be about $7.5 million in lost profits and some unknown quantity of lost utility. Considering the injuries associated with magnet sets and the resulting societal costs, balanced against the likely impact that the proposed rule would have on firms producing and selling the product, and the impact on consumers who would lose the utility of the product, we conclude, preliminarily, that magnet sets pose an unreasonable risk of injury. Additionally, we conclude that the proposed rule is reasonably necessary to reduce that risk.

Public interest. This proposed rule is in the public interest because it may reduce magnet-related deaths and injuries in the future. A rule prohibiting certain magnet sets from the chain of commerce will mean that children will have less access to this product, thereby reducing the number of incidents of children swallowing the magnets and the resulting cost to society of treating these injuries.

Voluntary standards. Currently, there is no voluntary standard for magnetic sets. A group of magnet set importers and distributors have requested the formation of a voluntary standard by ASTM International for the labeling and marketing of these products. The companies have requested the formation of a voluntary standard to: (1) provide for appropriate warnings and labeling on packages of these magnet sets, and (2) establish guidelines for restricting the sale of these magnet sets to, or for the use of children, such as by not selling to stores that sell children's products exclusively, and by not selling magnet sets in proximity to children's products. Such a voluntary standard would have many of the same limitations as a labeling standard.

Relationship of benefits to costs. Based on reports to the CPSC, ingestions of small magnets contained in magnet sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. Although there is some uncertainty concerning the benefits that would result from the proposed rule, we estimate that benefits of the rule might amount to about $25 million annually. The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009−2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility. We believe that there would be a reasonable relationship between the anticipated benefits and costs of the proposed rule.

Least burdensome requirement. We have considered several alternatives to the proposed rule prohibiting certain magnet sets. We conclude that none of these alternatives would

adequately reduce the risk of injury. Alternative performance requirements might allow a different flux index for magnets contained in magnetic sets. Theoretically, this might allow some current products to continue to be produced. However, it is unclear whether a different flux index would permit products that have the desired physical qualities to make them enjoyable to adults would reduce adequately the characteristics that make these strong magnets hazardous to children. Some type of special storage containers or other packaging requirements might be possible. However, it is unlikely that consumers would use such containers, particularly if they wish to keep the magnets out of the container and maintain whatever shape they have constructed with the magnets. We have considered the possibility of requiring rigorous warnings on the products or in the instructions for the products. However, magnet sets currently on the market provide warnings concerning the potential hazard to children. It is unlikely that even strengthened warnings would substantially reduce the incidence of magnet ingestions. This is particularly true for incidents involving older children and adolescents. Moreover, children who are old enough to understand the warnings still may not abide by them. Some type of sales restriction limiting the location where magnet sets could be sold might be possible. However, even with restrictions on sales, ingestions are still likely to occur as children encounter these magnets in the home, at school, or in other locations when adults have bought them and they are available to children. Finally, the Commission could continue to address the hazard from magnet sets through corrective actions, *i.e.*, recalls of the product. However, such action would do nothing to prevent additional companies from continuing to enter the market and import magnet sets into the country. The Commission has the option of taking no regulatory action. Although it

is possible that, with increased awareness of the hazard over time, some reduction in ingestions could occur, the magnitude of any such reduction in incidents is uncertain and would likely be smaller than if the Commission issues the proposed rule.

Dated: _____

_____
Todd A. Stevenson, Secretary
U.S. Consumer Product Safety Commission

Staff Briefing Package

Notice of Proposed Rulemaking for
Hazardous Magnet Sets
August 8, 2012

For further information, contact:

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EXECUTIVE SUMMARY

Made in China, certain small, powerful magnets have been imported into the United States for sale as desk sets, and children are using these products and ingesting multiple small hazardous magnets. Once in the gut, the magnets can clamp together with body tissues trapped in between them as the magnets attract each other through the walls of different areas of the gastrointestinal tract. Once affixed, the magnets cannot pass through the body, and the pressure between the two magnets can cause severe and fatal injuries.

This hazard pattern is difficult for caregivers and health care professionals to envision, hard to diagnose, difficult to treat, potentially life-threatening, and it can have debilitating, lifelong health effects.

The magnet sets are highly attractive to children and promote activities that are well within their mental and physical capabilities. Warnings to keep the products away from children, sales restrictions, and other public education approaches to injury prevention seem unable to affect current injuries in a reliable manner given the intrinsic play value of the magnets and their attractiveness to children of all ages.

To prevent injuries, and the resulting pain and suffering and potential deaths within a vulnerable population, staff recommends a proposed rule that would effectively ban the sale of the kinds of sets of strong magnets intended for adult manipulative play that are currently producing injuries.

The number of magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. The average estimated societal costs per injury ranged from about $13,000 to $112,000, depending on whether the injuries sustained resulted in the patient being treated and released, or hospitalized. Making some assumptions about the information, staff estimates that the expected benefits of a rule addressing sets of strong magnets might amount to roughly $25 million annually.

The costs of the proposed rule would consist of: (1) the lost profits to firms that would be unable to import and sell the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price. Neither of these costs can be estimated with much certainty. However, based on available information, these costs could amount to about $7.5 million in lost profits annually, along with some unknown value for lost utility.

Briefing Memo

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

Memorandum

This document has been electronically approved and signed.

Date: August 8, 2012

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Cheryl A. Falvey, General Counsel
Kenneth R. Hinson, Executive Director

FROM: DeWane Ray, Assistant Executive Director
Office of Hazard Identification and Reduction

Jonathan Midgett, Project Manager
Office of Hazard Identification and Reduction

SUBJECT: Briefing Package: Notice of Proposed Rulemaking for Hazardous Magnet Sets

Introduction

In the past few years, sets of small, powerful magnets have been marketed as construction toys, desk toys, sculpture, or stress relievers. Children are playing with the magnets and ingesting them. Toddlers and preschool children ingest them as they do other small objects and hazardous substances; among older children, ingestion is usually by accident. Parents have also reported that children and teens attempt to simulate jewelry piercings, by placing a pair of magnets on opposing sides of their tongues or lips, thereby leading to accidental ingestions. Once swallowed, magnets can attract together from different sections of the gastrointestinal tract, forcefully clamping together with gastrointestinal tissues trapped between them, causing life-threatening injuries. This briefing package explains the injury patterns associated with sets of strong magnets and the facts that support a proposed rule for these products.

Product Description

Sometimes called "fidget toys," these aggregated masses of strong magnets are intended to be manipulated in a playful manner for recreation and entertainment. People playing with the sets of magnets can explore magnetic attraction and repulsion while forming the magnets into structures and sculptures. Users face certain intriguing challenges akin to jigsaw puzzles or other games

when attempting to form the magnets into specific shapes. Additionally, the tactile, auditory, and visible features of the products have pleasing aesthetic properties.

Common sets include hundreds of spherical magnets with diameters from 3 mm to 6 mm or larger, but many models are available with magnets of different sizes, colors, and shapes. Most products are sold with some kind of storage container. Some sets have more than 1,000 magnets. Some consumers share photos of their intricate creations online.

Typical sets of magnets

Magnet sets contain magnets that are small parts, have very high attractive forces, and are capable of attracting and holding onto other magnets in their sets across distances of 1 to 2 centimeters or more.

Some products have warnings on their packaging and/or on their storage cases. The warnings often claim that the product is not intended for children, and some attempt to explain the hazards presented after an ingestion of multiple magnets. Some products have no warnings.

The products have been sold in many different kinds of retail outlets, including toy stores, department stores, gift shops, novelty stores, and online shops. At least one major manufacturer refuses to sell the products to toy stores.

Are these products covered by voluntary standards?

If these products were considered toys intended for children, they would be banned under the toy standard. Because these types of products are generally marketed to consumers older than 14 years, they arguably fall outside the scope of the toy standard, ASTM F963. Yet the age grading label cannot overcome the intrinsic play value and attractiveness of the product. Under the mandatory toy standard, magnetic toys intended for children younger than 14 years cannot contain small, strong magnets, unless they pass rigorous abuse testing to prevent magnet loss and are encapsulated in objects that are too large to be swallowed easily. The toy standard exempts science kits and craft kits[1] due to the functional necessity of having a strong magnet for these uses.

[1] It should be noted that the exception for craft and hobby kits in the mandatory toy standard is quite limited and the language of 4.38.3 of the toy standard would indicate a singular "loose as-received" hazardous magnet or magnetic component, or both. In short, these kits would contain no more than 2 magnetic items.

Five manufacturers recently asked the ASTM International (ASTM) to create a subcommittee to draft a standard for the labeling and marketing of loose, small magnets of a certain strength that are intended for consumers over 14 years old. During a conference call held on August 7, the attendees decided to begin working on a draft.

Injuries and Incidents

Who are the victims?
Staff is aware of 72 incidents involving or possibly involving strong magnet ingestions occurring from 2009 through 2011, via information obtained through the National Electronic Injury Surveillance System (NEISS) (Tab A). Estimates using these NEISS cases predict that 1,700 ingestions have occurred during this time, about 70 percent involving *children ages 4 through 12 years*.

The cases reported to the agency through other CPSC databases such as IPII and INDP include 50 cases of magnet-related ingestions. From these 50 cases, 38 involved magnets from a set of strong magnets similar to the products described above and 5 more cases that possibly involved this type of product. For the 43 ingestion cases involving or possibly involving sets of strong magnets, most of the reported incidents involved more than one magnet (35 incidents; 81.4%). Victims usually swallowed two to nine magnets in those incidents (29 incidents; 82.9%). The agency also has records of incidents involving ingestions of magnets from other product categories, including faux tongue rings, other jewelry, and toys intended for children under the age of 14 years that are covered by toy regulations, but these incidents are excluded from this discussion because these other product categories have different use patterns.

It should be noted that the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) has provided the Commission with some incident data and is currently surveying their members regarding any additional incident data they may have to share with the Commission. One option the Commission might consider with regard to possible rulemaking would be whether to do its own survey to collect additional data similar to the exposure surveys the Commission has conducted in the ATV rulemaking.

What were victims doing?
For the 43 ingestion cases reported to the agency involving or possibly involving sets of strong magnets, nearly half (46.5%) of the victims intentionally placed the magnets in their mouths for one reason or another. Older victims in the 4- through 12-year-old and the 13+ age groups specifically reported having the magnets in their mouths to simulate piercings or mouthing them for other reasons (25 of 35 incidents from those age groups; 71.4%) (Tab A).

Staff reports that shiny, colorful, strong magnets have some appeal for virtually all age groups (Tab B). As children approach 8 and 9 years of age, they are interested in three dimensional puzzles, and 9 through 12-year-olds can engage highly complex puzzles. The reading skills of children in these age groups allow them to follow directions. Their fine motor skills allow them to handle interlocking pieces. This means that many sets of strong magnets currently being marketed for ages 14 years and older are actually, in developmental terms, appropriate for consumers beginning at younger ages. Staff notes that some reviewers of the magnet sets on a

major online retailer, and one-third of those reviewing the biggest seller, reported purchasing the products for children younger than 14 years old.

Reported incident scenarios involve common, expected exploratory behaviors. Sometimes victims were exploring the magnetic properties of the magnets. Others were separating the magnets with their teeth while they built something with them. The youngest victims were mouthing and ingesting the magnets in the characteristic manner of early childhood exploration. In the 8- to 12-year-old age group, victims describe wanting to feel the force of the magnets on their tongue, teeth, or braces. In another common scenario, children used two or more magnets to simulate piercings of their tongues, lips, or cheeks in their role play of celebrities in the fashion and entertainment industries. Since real piercings may be forbidden or considered unacceptable, strong magnets offer a fun, seemingly safe means to try such fashions.

How did victims get the magnets?

For the 4- through 12-year-old age group, 19 of the 29 individuals (65.5%) were either given the magnets by an adult, purchased by the victim, or obtained at school and/or by a friend (Tab A). Anecdotal evidence in agency investigation reports suggests that children generously dispense magnets to peers. These methods of acquisition suggest that some adults are not aware of the warnings on the product, do not believe them, or do not think they are relevant to their children. The injury mechanism is unusual, unforeseen, and complex, similar to what the Commission dealt with in the dive sticks performance standard and unlike predictably hazardous products like skateboards, balloons, or knives. Caregivers are unlikely to imagine the hazards of ingesting magnets until after witnessing an injury, potentially contributing to a lack of supervision of children wanting to use the products. Even if caregivers have seen, believed, and tried to heed the warning labels on the products, their children could easily gain access to the products without their knowledge at school or from their peers.

Injury Severity

When someone ingests more than one magnet, they can experience a range of outcomes (Tab C). The initial nonspecific symptoms of a magnet trapped in the gut (nausea, vomiting, abdominal pain) are easily confused with common gastrointestinal upsets and x-rays are not always taken. Some magnets may be merely monitored by health care professionals using one or more serial x-ray images. This wait-and-see approach occurs because doctors may not be aware of the magnetic properties of the objects seen on the x-ray images. It is difficult to see the tissues clamped between magnets, which would alert doctors to the fact that the objects will not void naturally. There are cases of delayed recognition of the magnets that resulted in much greater injury severity and complications. When the Commission met with NASPGHAN, the presenters explained that despite efforts to educate health professionals on this hazard, there is not widespread understanding of this phenomenon. The hazard presented by magnets was described as a silent bullet hole in the abdomen with no entry wound and no exit wound.

Once the objects are identified as being arrested in the gastrointestinal tract, depending on location, doctors may choose to remove the magnet using a fiber optic scope inserted down the throat or through small incisions in the abdomen (laparoscopy). In this intervention, the doctor still may not be aware that the object is a magnet or that there could be tissues trapped between multiple magnets. The likelihood of more invasive surgery (laparotomy) and the risk of

complications are influenced by the length of time that the magnets have been trapped, how many magnets were swallowed, and the relative awareness of the medical professionals regarding the magnet ingestion hazard and the fact that that multiple gastrointestinal walls may be involved. A laparotomy entails a much larger abdominal incision allowing for a more thorough inspection, assessment, and repair of the damaged tissues. If the magnets interact through intestinal tissues and become fixed in place for some time, so called "pressure necrosis injuries" result, in which the intervening tissues become damaged and can die from lack of blood flow, causing holes to be opened in the gut (perforations). Holes in the intestines allow bowel contents to leak into the abdominal cavity, leading to sepsis and death. Intestines may also twist into loops (volvulus) causing an obstruction or form a new channel between adjacent sections of intestines (fistula).

To repair perforations in the gut, some damaged segments of bowel tissue may have to be removed. In one severe case, a child had so much small intestine removed that he is in need of a bowel transplant and needs to be fed intravenously. More serious complications can result when, after finding and repairing two perforation sites, surgeons overlook other perforations, which results in leakage of bowel contents into the abdominal cavity and worsening risk of local infection, which can lead to systemic infection (septicemia).

Post-operative complications of abdominal surgeries to remove magnets and repair the holes made by them can have life-long effects on victims' health. Complications include, bleeding, infection, and temporary paralysis of gut motility. Bands of scar tissue in the gut form after the surgery. These scars can interfere with gut movement and can cause obstructions as both a short- and long-term (years) complication, frequently resulting in bowel obstructions requiring additional surgeries, and thus, creating a painful cycle of abdominal surgery. In girls, future fertility can be affected by internal scarring. Digestive function of victims can be *permanently* affected, hindering absorption of food, causing diarrhea, and cramping. Victims might need total intravenous feeding.

To date, staff is not aware of any fatalities associated with sets of strong magnets labeled for teens and adults, but a 20-month-old boy was killed in 2005 by similarly strong magnets that fell out of a toy intended for children. The magnets used in the magnet sets labeled for teens and adults are as strong, or stronger, than the magnets in that fatal case, and each set contains many more loose magnets than the toy involved in the fatality.

Compliance Actions

The agency has been warning consumers about the hazards of magnet ingestion since 2006, because of the injuries that have occurred to children from hazardous magnets in construction toys intended for children. Several recalls have been issued for toys containing magnets (Tab G-Restricted Use Document). Provisions in the voluntary standard for toys containing hazardous magnets were developed in subsequent years to address the hazard and became mandatory in August 2009.

In December 2009, the agency received a consumer complaint that the magnet sets intended for adults posed hazards similar to magnets in toys. As a follow-up to that complaint, during that

month, a sample was collected by staff and age graded by the Directorate for Engineering Sciences, Division of Human Factors to be, developmentally appropriate for children ages 9 years old and up.

In February 2010, the agency received its first consumer incident report involving a child and a set of magnets intended for adults. A 9-year old boy swallowed 7 spherical magnets while mimicking body piercings. The boy was not injured because the magnets passed through his system as a single mass. The magnets had been purchased for a 13-year-old.

Samples of the product were detained and collected at the Customs and Border Protection site in February 2010. At the time of collection, the product was labeled for use by children 13+ years of age. Because of the age grade on the product and the manufacturer's intent, it was subject to the requirements of the toy standard. The Office of Compliance and Field Operations ("Compliance") issued a Notice of Noncompliance to the firm in March 2010. At the time, there was very little incident data associated with this product. The firm agreed to a corrective action that included, in part, new warnings to keep the product away from children, a change in the appropriate age for use of the product, and requests to retailers to list the product as appropriate only for consumers over 14 years of age. The firm also removed inventories labeled "13+." The firm also agreed to ask retailers who market products primarily, though not exclusively, to children to execute a Responsible Sellers Agreement prohibiting marketing and sales to children; stop the sale of these magnets to retailers that market products exclusively to children; and providing a Responsible Sellers Agreement to general use stores[2] for their information.

In December 2010, the agency received the first report of the surgical removal of magnets from a child that had ingested multiple magnets that came from a magnet set intended for adults. During 2011, Compliance activity included evaluation of the marketing and labeling of the product category, collecting product marketed to children younger than 13 and evaluating compliance with ASTM F963. In addition, where products did not have labeling or marketing information, the agency encouraged those firms to develop marketing and labeling to ensure that they were not marketed to children. More firms were issued Notices of Noncompliance for marketing to children younger than 14 years.

In response to continuing injuries associated with the products and children of various ages, the agency published a public service announcement (PSA) in November 2011, concerning the hazard in cooperation with two manufacturers. Reported incidents involving children continued to increase unabated from 8 cases in 2010, 17 cases in 2011, and 25 cases in 2012 (as of July 8, 2012). Twenty two incidents were reported before the PSA; 28 more followed during the eight months after it. A high percentage of the injuries resulted in surgeries or other invasive procedures. Of the 50 reports known to staff, 22 required surgery, and 10 required either invasive procedures such as endoscopies or colonoscopies. In 2011, and into spring 2012, staff continued to identify additional firms offering this product on the internet with labeling and marketing violations.

[22] General use stores means stores that sell to both adults and children.

Options to Reduce Risk

Larger Magnets
Increasing the size of the magnets so that they cannot be ingested may reduce the risk, but probably at the expense of the purported utility of the product for its intended purpose. Making the magnets larger would require significant product redesign and such an option may or may not be viable and would be something on which the Commission seeks comments.

Weaker Magnets
Weaker magnets would not clamp together as often or as powerfully as strong magnets. This might alleviate some of the likelihood of injury if the magnets were ingested, or it could potentially increase the time available for getting the appropriate medical responses. Weaker magnets may or may not be viable option for redesign and would be something on which the Commission seeks comments.

Child-Resistant Packaging
Child-resistant packaging for a toy, even a toy intended for teens and adults, is unlikely to be effective, given the lack of awareness of the hazard, the desire to display sculptures using the magnets, and the increased inconvenience of such packaging for the intended users. Even if consumers could be convinced of the need for special packaging, many victims were old enough to open common child-resistant packages.

Warnings
Warnings and other forms of public education are the least effective strategies to reduce injuries with consumer products. Staff found that many warnings used on sets of strong magnets fail to meet the minimum guidelines for being understood (Tab B). The warnings are also found on packaging; so the warnings are unlikely to be seen by users who did not purchase the product. Warnings on storage cases are more likely to stay with a product longer than the packaging; but the storage case is not always used or kept because the sculptures made with the magnets are put on display. Furthermore, the warnings may not be believed by consumers who predict that their children would not ingest magnets, not knowing about the temptation to use the magnets to simulate piercings. Strong warnings can also be interpreted by teens as an inappropriate limit on their personal freedom or self-expression and actually increase risk taking, contrary to the warning message.

While staff believes that warnings could be composed with all of the necessary components (hazard statement, consequences, and avoidance measures), the resulting warnings would not be effective at substantially preventing injuries if consumers do not believe the warnings. Staff doubts that many caregivers are likely to heed the warning when they have older children because they view older children as more responsible. Unless they understand the motivation to simulate piercings or other known scenarios that lead to accidental ingestions, caregivers may doubt that the warnings are relevant to their children. If caregivers observe children using the product without incident, they can conclude that their child can use the product safely.

If caregivers believe the warnings and try to heed them, several factors can counteract their efforts to keep magnet sets away from their children. For instance, older children may have

peers who already own the product and can exert significant social pressure on caregivers to purchase the product. Caregivers might find it difficult to keep the product accessible for their own use but secure from children. Compliance with the warning requires time and effort, which hinders its effectiveness. Caregivers may not want to secure the product after creating an interesting design. The sets contain so many magnets that keeping track of missing magnets is very difficult. Even if a caregiver goes to the trouble of finding a secure place, children can be very clever and motivated to get into things that are off limits. Keeping products from older children would be particularly challenging. Furthermore, children can obtain the product from other children at school. If caregivers realize this, it can further sap their motivation to comply with warnings.

Aversives

The use of foul odors or bitter coatings on the magnets might not reduce the appeal of the product, but these strategies are unlikely to prevent ingestion (Tab B). Bitter coatings on magnets might prevent some children from placing more than one magnet in their mouth, but incident reports indicate that serious injury is possible when one ingests as few as two magnets, and children might ingest multiple magnets before they detect the aversive agent.

Sales Restrictions

A major distributor of sets of strong magnets has agreed not to sell the sets to stores that sell exclusively to children for safety reasons. Unfortunately, competitors seem to have capitalized on this marketing strategy and other brands have been available in those child-oriented outlets where children purchase them and where caregivers can easily confuse the magnet sets with children's products. It seems that consumers and manufacturers of the product found the "14+" age label to be unconvincing. If the strategy of restricting sales of these products was enforced across all of the firms selling sets of strong magnets, staff believes that some effect might be expected; but, given that children have been gaining access to products not purchased in toy stores, this strategy would likely be inadequate to eliminate children's access to the product and the potential for serious injuries associated with this type of product.

Summary

Staff recommends that the Commission issue a notice of proposed rulemaking for hazardous magnet sets labeled for teens and adults because the sets create a severe, hidden hazard that is highly attractive to a vulnerable population because of the intrinsic play value of these items. The products provide play activities that are perceived by caregivers to be appropriate for children, as well as present use patterns that are difficult for caregivers to predict. The injury mechanism is not intuitive, surprising victims and their caregivers. The injuries are serious, life-threatening, difficult to diagnose, and they may have painful, debilitating long-term health effects. Continued reliance on warning labels, various market restrictions, and public education seems unlikely to reduce the number of incidents adequately. Staff predicts that injuries to children will continue without significant product redesign. Staff believes that injuries and fatalities will be averted by the proposed rule.

Preventing Injuries Caused by Hazardous Magnet Sets

Staff believes that relying on the previous work of the ASTM F963 toy standard subcommittee is a prudent choice for defining the features of a hazardous magnet. The toy standard uses two features of a magnet to define a "hazardous magnet": the size of the magnet and the strength of the magnet (flux index). The following discussion describes the rationale for this injury-prevention strategy.

Magnet Size

A simple method to prevent ingestion of objects is to limit their size: large objects cannot be swallowed easily. This method is used worldwide to prevent choking incidents with toys intended for children younger than 3 years old. Staff recommends using the small parts cylinder to screen for hazardous magnetic components. The small parts cylinder was invented to prevent choking and ingestion of toys and toy parts, based on incident samples from agency records. All of the incidents known, to date, appear to have involved magnets and magnetic components that would fit into the small parts cylinder.

A possible objection to this strategy is that the small parts cylinder may not restrict the size of toys that teens could swallow because the cylinder was based on incidents involving younger children. Unfortunately, deriving the proper dimensions for the older groups may require considerable study. In defense of the cylinder, its dimensions are large enough that even adults would have a difficult time swallowing something that barely fits inside. Additionally, the cylinder has the advantage of industry familiarity and widespread availability. The toy standard has defined a hazardous magnet using a size limit based on the small parts cylinder.

Magnet Strength

The toy standard uses a measure of magnetic attraction force called the "flux index" (see Tab D for details on properties of magnetism). Any magnet fitting within the small parts cylinder would be deemed hazardous, if it also had a flux greater than 50. This limit was selected by the ASTM F963 subcommittee from a non-statistical, convenience sampling of the weakest magnets known to have been involved in an incident, plus a factor of safety.

Employing the current toy standard restrictions on magnet sets intended for adults raises a question. The flux index measurement in the toy standard method is made on a single magnet. Unfortunately, in numerous incidents involving magnet sets for adults, the swallowed magnets line up together in a row. If several magnets attract together in a row, the resulting aggregation can have a higher attraction force than each individual magnet. The exact increase in attraction force is dependent upon the shapes and material of the individual magnets. This additive effect on magnet strength can endow a grouping of several lower strength magnets (magnets with a flux index just under 50) with a potentially hazardous strength.

We are proposing to use the methodology specified in ASTM F963-11 to measure the flux index of magnets that are part of a magnet set. The test method was developed to address hazards posed by magnets that are part of a toy. Such magnets are likely to be individual magnets that separate from a toy. Magnet sets may contain hundreds of magnets. Thus, such magnets are more likely to be aggregated than magnets separated from toys. When magnets are aggregated, their

magnetic strength may increase. Children exposed to magnets from these magnet sets may ingest more magnets than they would if a magnet separates from a toy. Thus, it may be desirable to develop a method for testing the strength of aggregated magnets. We are not aware of magnet sets comprised of individual magnets sets that are comprised of magnets with a flux index under 50. The flux index of the magnet sets currently in the market are generally in the range of 400 to 600. We are interested in receiving comments that would address this issue.

Recommendations for a Proposed Rule

Staff recommends using the term "magnet set" to mean "any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy for general entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." If a magnet set contains more than one magnet that can individually fit completely within the small parts cylinder described in 16 CFR part 1501, then those small magnets must have a flux index of 50 or less as determined by the method described in ASTM F963-11.

Economic Impacts

The number of magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million (Tab E). Prices for a set of magnets typically ranged from about $20 to $45, with an average price of about $25. Based on the available information, all of the magnets have been manufactured in China and imported to the United States. Staff has identified about 25 U.S. firms and individuals who have recently imported magnet sets. All of these firms fall into the category of "small businesses."

The combined sales of the top seven firms have probably accounted for the great majority of units sold. Five of these larger importers appear to derive most or all of their revenue from the sales of magnet sets falling within the scope of the rule. These firms would be severely affected by the proposed rule, which would effectively ban the magnet sets that they have been importing and selling. Consequently, they may go out of business. Two of the other leading importers of magnetic desk sets appear to have fairly broad product offerings, which could lessen the severity of the economic impact of a rule. Nevertheless, the impacts of the draft proposed rule could be considered to be significant for these small importers.

Based on the 72 NEISS cases during 2009–2011 identified by staff as involving or possibly involving the magnets of interest, staff estimates that there has been an *annual* average of about 572 emergency department-treated injuries involving the magnets. Additionally, based on the CPSC's Injury Cost Model, there were another 870 injuries annually that were initially treated outside of hospital emergency departments, such as in doctors' offices and clinics. The societal costs associated with these injuries are estimated to be nearly $25 million annually for the years 2009 to 2011, based on estimates derived from the agency's Injury Cost Model. The average estimated societal costs per injury ranged from about $13,000 to $112,000, depending on whether the injuries sustained resulted in the patient being treated and released or hospitalized. Making some assumptions about the information, staff estimates that the expected benefits of a rule addressing sets of strong magnets might amount to roughly $25 million annually. Medical

costs and work losses (including work losses of caregivers) accounted for about 25 percent of these injury cost estimates; the intangible costs of injury associated with pain and suffering accounted for about 75 percent.

The costs of the proposed rule would consist of: (1) the lost profits to firms that would be unable to import and sell the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price. Neither of these costs can be estimated with much certainty. However, based on available information, these costs could amount to about $7.5 million in lost profits annually, along with some unknown value for lost utility. (The costs of the proposed rule are discussed more fully at Tab E).

There are alternative regulatory actions that the Commission could consider that might allow the magnet sets to continue to be marketed. For example, the Commission, by regulation, could: issue alternative (*e.g.*, less stringent) performance requirements or require warnings that explicitly describe the hazard and how to avoid it. Other possible options might be to develop requirements for the packaging of the magnetic desk sets (*e.g.*, develop requirements for child-resistant packaging); and/or place limitations on how and where the magnetic sets can be sold. These alternative actions—which might be considered alone or in combination—would have varying levels of effectiveness but would not achieve the same level of benefits as a rule effectively banning the types of magnetic desk sets that have been imported and sold in recent years.

Conclusion

Staff recommends that the Commission publish an NPR in the *Federal Register*. The rule would become effective 180 days after publication of a final rule in the *Federal Register*.

TAB A: NEISS Estimates and Analysis of Reported Incidents Related to Ingestion of Small, Strong Magnets that Aare Part of a Set of Magnets of Various Sizes

TAB A

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

Memorandum Date: July 9, 2012

TO : Jonathan Midgett, Ph.D.
Magnet NPR Team Lead
Division of Human Factors

THROUGH : Kathleen Stralka, M.S.
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway, M.S.
Director
Division of Hazard Analysis

FROM : Sarah Garland, Ph.D.
Mathematical Statistician
Division of Hazard Analysis

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*

Introduction

In support of the notice of proposed rulemaking (NPR) effort for small, strong magnets that are part of a set of magnets of various sizes, this memorandum provides analysis of incidents from different sources. This memo provides estimates for emergency department-treated, magnet-related ingestions obtained through the National Electronic Injury Surveillance System (NEISS). Also provided in this memo are summaries of the reported incidents of magnet ingestions available through other CPSC databases, which include the Injury or Potential Injury Incident database (IPII) and the In-depth Investigation database (INDP). Due to the difficulty in identifying specifically the strong magnets that are considered adult desk toys, especially in the NEISS, this memo considers a larger range of magnets. The details of what is included and excluded are provided later in this memo.

Although more details are provided in the report, some findings are summarized below:

NEISS Estimates

- There are an estimated 6,100 emergency department-treated, magnet-related ingestions from 2009 to 2011.
- Of the estimated 6,100 ingestions, an estimated 1,700 are attributed to being high-powered and/or ball-shaped magnet ingestions. Note that the remaining 4,400 estimated ingestions could include small, strong magnets from magnet sets, but the NEISS narrative coded from the medical record did not provide manufacturer name or model to make this distinction.

*It should be noted that this memo reflects the opinions of CPSC staff and has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

- Of the estimated 6,100 emergency department-treated, magnet-related ingestions, an estimated 3,500 victims are in the 4- through 12-year-old age group (57.4%). For the estimated 1,700 ingestions attributed to high-powered and/or ball shaped magnets, an estimated 1,200 victims are in the 4- through 12-year-old age group (70.6%). Of the remaining 4,400 estimated ingestions, an estimated 2,300 victims are in the 4- through 12-year-old age group (52.3%).

Reported Incidents

- Fifty magnet-related ingestion incidents have been reported to CPSC staff, of which 43 were identified as small, strong magnets from a magnet set or possibly this type of magnet.
- The most commonly reported age group of victims is the 4- through 12-year-old age group, with 29 of the 50 (58.0%) reported victims in this group.
- For the 43 incidents reported to involve (or possibly involve) small, strong magnets, 24 victims are in the 4- through 12-year-old age group (55.8%).
- For the 4- through 12-year-old age group, 19 of the 29 victims (65.5 percent) were reported to be using the magnets to simulate piercings or to be mouthing the magnets for other reasons, such as attempting to stick the magnets to their braces. For the remaining 10 victims in this age group, the use pattern is either unknown or fits into another category.

NEISS Estimates

Magnet-related cases within the NEISS database from January 1, 2009 to December 31, 2011, were considered for the initial dataset. To gather all possible data related to the magnets of interest, a keyword search was implemented and any case that mentioned "magnet" in the narrative field was included. This was completed across all products. Unless otherwise noted, all estimates span the 2009–2011 timeframe. From this master set, cases were *excluded* from the analysis if any of the following applied:

- Any case known to have involved a magnet from a child's toy, such as a magnet from a "princess set" or a magnet from a "fish toy";
- Any case determined to involve a different type of magnet than that in question, such as reports of "kitchen magnets";
- Any case in which it was most likely that the magnet reported was not the item of interest; for example, "swallowed a plastic-covered magnet . . .";
- Any case that could not be determined to be magnet-related was excluded; for example, "5YOF, acc swallowed dog toy vs. magnet . . .";
- Any case that did not involve ingestion or possible ingestion of at least one magnet.

Each case was placed in a category that identifies the type of magnet involved. Magnet categories are as follows:

- Yes/Possible – This category includes cases where a small, strong magnet was mentioned, specifically the type known as adult desk toys and identified by mention of the manufacturer or model in the NEISS narrative. However, since there is no requirement for hospitals in the NEISS to collect manufacturer or model names, this was rarely available. Thus, this category also includes cases that mention "high-powered," "magnetic ball," "magnetic marble," "BB-size magnet," or "magnet beads" (where no jewelry is mentioned). Excluded are faux tongue rings, jewelry beads, and other jewelry.
- Magnet, type unknown/Other type—This category includes cases were the magnet was part of jewelry, such as a faux tongue ring, magnetic rocks, and cases where the narrative did not provide enough information to classify the magnet in the "Yes/Possible"

category. It should be noted that it is possible that a small or large portion of these could include the small, strong magnets from a magnet set. However, because this remains unknown for these cases, they are reported in this category throughout this section.

As noted above, the type of magnet could only be identified based on information the NEISS narrative provides, where manufacturer and model information is most often unavailable. It is possible that if more information were available on the cases classified in the "Magnet, type unknown/Other type" category, part of the estimate from the group could be moved to the "Yes/Possible" magnet category, increasing the estimate. **Table 1** provides the number of cases for each category. **Table 2** provides the overall estimates of emergency department-treated ingestions for these collapsed groups.

Table 1: Count of Magnet Ingestion Cases Treated in NEISS Hospitals Emergency Departments by Magnet Category, 2009–2011

New Magnet Category	N
Yes/Possible, small, strong magnet	72
Magnet, type unknown/Other type	190
Total	**262**

Table 2: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2009–2011

Magnet Category	Estimate[3]	CV[4]
Yes/Possible, small, strong magnet	1,700	0.19
Magnet, type unknown/Other type	4,400	0.16
Total	**6,100**	**0.14**

Table 3 provides the total estimates for emergency department-treated, magnet-related ingestions for each of the years 2009 to 2011. This collapses both of the categories reported in **Table 2**, so estimates would be possible. No statistically significant trend was detected across these years, p-value = 0.29. All remaining tables collapse the years 2009–2011, so each estimate corresponds to that timeframe.

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

Year	Estimate	CV[3]
2009	1,600	0.22
2010	1,900	0.17
2011	2,600	0.18
Total	**6,100**	**0.14**

[3] Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding.
[4] The coefficient of variation (CV) is a measure of the standard deviation relative to the estimate itself.

To explore the estimates further, **Table 4** provides the overall age breakdown for all cases by magnet category. The age groups are as follows: less than 4 years of age; 4 through 12 years of age; and 13 years of age or more. Notice that the largest proportions are in the 4- through 12-year-old age group, for the total estimates and for each magnet category. The 4- through 12-year-old age group in the "Magnet, type unknown/Other type" category has an estimate of 2,300 ingestions, which consists of 52.3 percent of the total estimate for that category. This age group for the "Yes/Possible" category contributes to 70.6 percent of the total estimated 1,700 ingestions. Since there is such a large proportion of ingestions in the "Magnet, type unknown/Other type" category for the 4- through 12-year-old age group, it is quite possible that cases classified in the "Magnet, type unknown/Other type" category could be reclassified in the "Yes/Possible" category if more information were available. This would result in larger estimates for the "Yes/Possible" category.

Table 4: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Age Group, 2009–2011

	Magnet Category					
	Yes/Possible, small, strong magnet		Magnet, type unknown/Other type		**Total**	
	Estimate	**CV[3]**	**Estimate**	**CV**	**Estimate**	**CV**
Age Group						
Less than 4 years	*	*	1,800	0.18	**2,200**	**0.16**
4 through 12 years	1,200	0.22	2,300	0.19	**3,500**	**0.16**
13+ years	*	*	*	*	*	*
Total	**1,700**	**0.19**	**4,400**	**0.16**	**6,100**	**0.14**

*Indicates an estimate that could not be determined with a level of precision that is deemed reportable.

The estimated number of magnet-related, emergency department-treated ingestions for each sex is provided in **Table 5**. A breakdown of sex by magnet category was not possible, due to low estimates in the "Yes/Possible" group.

Table 5: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Sex, 2009–2011

Sex	Estimate	CV[3]
Female	2,500	0.16
Male	3,600	0.17
Total	**6,100**	**0.14**

The estimated numbers of emergency department-treated, magnet-related ingestions by disposition and category are provided in **Table 6**. Note that most are treated and released from the hospital, for both the overall estimate (5,600; 91.8%) and the "Yes/Possible" estimate (1,600; 94.1%) and the "Magnet, type unknown/Other type" estimate (4,000; 90.9%).

Table 6: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Disposition, 2009–2011

	Magnet Category					
	Yes/Possible, small, strong magnet		Magnet, type unknown/Other type		**Total**	
	Estimate	**CV[3]**	**Estimate**	**CV**	**Estimate**	**CV**
Disposition						
Treated and Released	1,600	0.20	4,000	0.16	**5,600**	**0.14**
Hospitalized /Transferred	*	*	*	*	*	*
Total	**1,700**	**0.19**	**4,400**	**0.16**	**6,100**	**0.14**

*Indicates an estimate that could not be determined with a level of precision that is deemed reportable.

For each case, CPSC staff recorded the number of magnets that were swallowed based on the narrative provided. **Table 7** provides the estimated number of emergency department-treated ingestions associated with the number of magnets involved for both magnet categories. The numbers of magnets involved are in one of three groups: 1 magnet, more than 1 magnet (or 1 magnet with a piece of metal), or unknown. Notice that most incidents involved one magnet.

Table 7: Estimated Number of Magnet-Related Ingestions Treated in Hospital Emergency Departments by Magnet Category and Number of Magnets Swallowed in Each Case, 2009—2011

	Magnet Category					
	Yes/Possible, small, strong magnets		Magnet, type unknown/Other type		**Total**	
	Estimate	**CV[3]**	**Estimate**	**CV**	**Estimate**	**CV**
Number of magnets swallowed						
1 magnet	*	*	3,200	0.18	**4,000**	**0.15**
More than 1 magnet	*	*	1,100	0.24	**2,000**	**0.18**
Unknown	*	*	*	*	*	*
Total	**1,700**	**0.19**	**4,400**	**0.16**	**6,100**	**0.14**

*Indicates an estimate that could not be determined with a level of precision that is deemed reportable.

Reported Incidents Analysis Results

This section summarizes incident information available in the INDP and IPII databases. Due to more descriptive product information available in the INDP and IPII databases, which can include the manufacturer, model, and other information, the specific products of interest are more readily identifiable from these sources than in the NEISS. There is often more information about the victim and the incident. As such, this section characterizes the reported 50 incident scenarios in more detail than in the NEISS section.

All reported incidents from January 1, 2009 through June 30, 2012, involving a magnet where an ingestion or injury was reported, were considered to be part of the initial set of incidents. Excluded from this set were magnets in children's toys and magnets determined to be a different type than small, strong magnets from sets of magnets. Only one hazard pattern is detailed in this section, which is, ingestions concerning magnets. Other reported hazard patterns include an allergic reaction, ear injuries, and a hand injury. All of the tables in this section correspond to incidents with an ingestion hazard pattern.

It should be noted that the summary of information in this section is based on anecdotal data. The data collected for this study is based on information reported to the CPSC through various sources. It is not a complete set of all incidents that have occurred; nor is it a statistical sample representing all magnet-related ingestion incidents. Also, reporting is ongoing for magnet-related ingestion incidents occurring in the specified timeframe. CPSC staff is expecting additional reports and information of magnet-related ingestion incidents occurring in the given period.

Also, note that one report includes a list of 15 victims reported to involve the ingestion of high-powered, ball-shaped magnets. Little other information is provided. As a result, only the most severely injured victim is reported throughout this section. All others are omitted. If one were to add the remaining 14 victims, then the "Yes" category would increase by 14 throughout the remainder of this memo. All other information would remain unknown. Another report lists two victims, but the details are only available for one victim; thus, only that victim is included in the counts below. If this other victim was included, then the "Yes" category would increase by one, and all other information would be unknown. Finally, one report lists two victims; however, full information is available on both. Thus, both victims are included in the counts provided in this section.

The magnet categories in this section are similar to those defined in the NEISS section; however, some differences exist. The following describes the magnet categories used throughout this section:

- Yes – includes incidents where small-strong magnets from a set of magnets were reported. This includes various sizes of these magnets. Generally, positive identification was made through the reported manufacturer of the magnets. This excludes faux tongue rings, jewelry beads, and other jewelry because these are classified in their own category.
- Possible – includes incidents describing magnets like those of the "Yes" magnet category, but could not be identified absolutely as the "Yes" category.
- Jewelry, beads – includes incidents where the magnet was part of, or is designed to be part of, jewelry as small, magnetic beads.
- Jewelry, tongue ring – includes reports of magnets that are described to function as faux tongue rings.

- Jewelry, earrings – includes jewelry that uses the magnets as a means to attach the earring to the ear.
- Rock – includes incidents that report a magnetic rock.

Table 8 provides the number of reported magnet-related ingestions where each incident is assigned to a category. The most commonly reported magnet ingestion category is the category reporting small, strong magnets from a set of magnets ("Yes" and "Possible" categories account for 43 of the 50 reported incidents). It cannot be concluded that there are more of these incidents than another. It can only be stated that 43 incidents of ingestions in those magnet categories have been reported.

The magnets classified as jewelry and rock are included in this report due to the possibility that the magnets involved are similar to the type of magnets that are in the "Yes" and "Possible" categories.

Table 8: Magnet Category for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Frequency
Yes, involves small, strong magnets	38
Possible, possibly involves small, strong magnets	5
Jewelry, beads	3
Jewelry, tongue ring	2
Jewelry, earrings	1
Rock	1
Total	**50**

*Reporting for this period is ongoing.

Table 9 shows the year of incident by magnet category. The majority of ingestion incidents were reported to have occurred in 2011 and 2012, with none in 2009.

Table 9: Magnet Category by Year for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Year*			
	2010	*2011*	*2012*	**Total**
Yes, involves small, strong magnets	7	15	16	**38**
Possible, possibly involves small, strong magnets	0	1	4	**5**
Jewelry, beads	0	0	3	**3**
Jewelry, tongue ring	0	0	2	**2**
Jewelry, earrings	0	0	1	**1**
Rock	0	0	1	**1**
Total	**7**	**16**	**27**	**50**

*Reporting for this period is ongoing.

Table 10 summarizes the number of magnets swallowed in each incident by magnet category. For the 43 ingestions in the "Yes" and "Possible" categories, most of the reported incidents involved more than one magnet (35 incidents; 81.4%); two to nine magnets was the most common number of magnets swallowed in those incidents (29 incidents; 82.9%).

Table 10: Magnet Category by Number of Magnets for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Number of Magnets				
	Unknown	1 magnet	2–9 magnets	10+ magnets	**Total**
Yes, involves small, strong magnets	5	2	25	6	**38**
Possible, possibly involves the small, strong magnets	0	1	4	0	**5**
Jewelry, beads	3	0	0	0	**3**
Jewelry, tongue ring	1	0	1	0	**2**
Jewelry, earrings	1	0	0	0	**1**
Rock	0	0	0	1	**1**
Total	**10**	**3**	**30**	**7**	**50**

*Reporting for this period is ongoing.

Table 11 provides the number of reported incidents by disposition and magnet category. For the 43 in the "Yes" and "Possible" categories, 29 reported a hospitalization as a result of the magnet ingestion (67.4%).

Table 11: Magnet Category by Disposition for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Disposition		
	Injured, not hospitalized	Hospitalized	**Total**
Yes, involves small, strong magnets	12	26	**38**
Possible, possibly involves small, strong magnets	2	3	**5**
Jewelry, beads	0	3	**3**
Jewelry, tongue ring	2	0	**2**
Jewelry, earrings	0	1	**1**
Rock	0	1	**1**
Total	**16**	**34**	**50**

*Reporting for this period is ongoing.

Table 12 provides the summary of the number of individuals ingesting magnets by victim age group and magnet category. For the 43 reported incidents in the "Yes" and the "Possible" incidents, 24 are reported for victims in the 4- through 12-year-old age group (55.8%).

Table 12: Magnet Category by Victim Age Group for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Age Group				
	Unknown	Less than 4 years	4 through 12 years	13+ years	**Total**
Yes, involves small, strong magnets	1	13	19	5	**38**
Possible, possibly involves the magnets of interest	0	0	5	0	**5**
Jewelry, beads	0	0	3	0	**3**
Jewelry, tongue ring	0	0	1	1	**2**
Jewelry, earrings	0	0	1	0	**1**
Rock	0	1	0	0	**1**
Total	**1**	**14**	**29**	**6**	**50**

*Reporting for this period is ongoing.

Table 13 gives the reported magnet use patterns at the time of the incident. For the 43 in the "Yes" and "Possible" incidents, 20 victims are reported (46.5%) to have had the magnets in their mouth intentionally for one reason or another, while 23 had an "unknown" or "another use" pattern. **Table 14** provides the reported use at the time of the incident by victim age group. The 4- through 12-year-old and the 13+ age groups specifically reported having the magnets in their mouth to simulate piercings or mouthing them (25 of 35 incidents from those age groups; 71.4%).

Table 13: Magnet Category by Use for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Use			
	Jewelry in mouth	Playing with in mouth, not as jewelry	Unknown/Other	**Total**
Yes, involves small, strong magnets	11	8	19	**38**
Possible, possibly involves small, strong magnets	1	0	4	**5**
Jewelry, beads	2	0	1	**3**
Jewelry, tongue ring	2	0	0	**2**
Jewelry, earrings	1	0	0	**1**
Rock	0	0	1	**1**
Total	**17**	**8**	**25**	**50**

*Reporting for this period is ongoing.

Table 14: Victim Age Group by Use for Reported Magnet-Related Ingestions, January 2009–June 2012*

Age Group	Use			
	Jewelry in mouth	Playing with in mouth, not as jewelry	Unknown/Other	**Total**
Unknown	0	0	1	**1**
Less than 4	0	0	14	**14**
4 through 12	11	8	10	**29**
13+	6	0	0	**6**
Total	**17**	**8**	**25**	**50**

*Reporting for this period is ongoing.

Table 15 summarizes the reported source of the magnet(s). That is, who owned the magnet(s) or how the victim obtained the magnet(s). **Table 16** breaks down the source by the age group of the victim. For the 4- through 12-year-old age group, only one magnet was reported to be owned by a relative, while this was the most commonly reported group for the less than 4-year-old age group. For the 4- through 12-year-old age group, 19 of the 29 individuals (65.5%) were either given the magnets by an adult, purchased by the victim, or obtained at school and/or by a friend.

Table 15: Magnet Category by Source for Reported Magnet-Related Ingestions, January 2009–June 2012*

	Source					
Magnet Category	Unknown	Owned by relative**	Given to child by adult	Purchased by victim	School/Friend	**Total**
Yes, involves small, strong magnets	10	10	5	3	10	**38**
Possible, possibly involves small, strong magnets	3	0	0	0	2	**5**
Jewelry, beads	0	1	0	0	2	**3**
Jewelry, tongue ring	1	0	0	1	0	**2**
Jewelry, earrings	1	0	0	0	0	**1**
Rock	1	0	0	0	0	**1**
Total	**16**	**11**	**5**	**4**	**14**	**50**

*Reporting for this period is ongoing.
**This includes incidents where the victim had access to the magnets because they were located on the refrigerator.

Table 16: Victim Age Group by Source for Reported Magnet-Related Ingestions, January 2009–June 2012*

	Source					
Age Group	Given to child by adult	Owned by relative**	Purchased by victim	School/Friend	Unknown	**Total**
Unknown	0	0	0	0	1	**1**
Less than 4	0	9	0	0	5	**14**
4 to 12	5	1	3	11	9	**29**
13+	0	1	1	3	1	**6**
Total	**5**	**11**	**4**	**14**	**16**	**50**

*Reporting for this period is ongoing.
** This includes incidents where the victim had access to the magnets because they were located on the refrigerator.

Finally, **Table 17** summarizes the sex of the victim and by magnet category for reported incidents. **Table 18** gives the age group breakdown by sex. For the 4- through 12-year-old age group, there are 14 reported incidents for males and 15 for females.

Table 17: Magnet Category by Victim Sex for Reported Magnet-Related Ingestions, January 2009–June 2012*

Magnet Category	Sex			
	Unknown	Female	Male	**Total**
Yes, involves small, strong magnets	1	23	14	**38**
Possible, possibly involves small, strong magnets	0	1	4	**5**
Jewelry, beads	0	2	1	**3**
Jewelry, tongue ring	0	0	2	**2**
Jewelry, earrings	0	1	0	**1**
Rock	0	1	0	**1**
Total	**1**	**28**	**21**	**50**

*Reporting for this period is ongoing.

Table 18: Age Group by Victim Sex for Magnet-Related Ingestions, January 2009–June 2012*

Age Group	Sex			
	Unknown	Female	Male	**Total**
Unknown	1	0	0	**1**
Less than 4	0	8	6	**14**
4 through 12	0	15	14	**29**
13+	0	5	1	**6**
Total	**1**	**28**	**21**	**50**

*Reporting for this period is ongoing.

Discussion

An estimated 6,100 magnet-related ingestions were treated in hospital emergency departments between 2009 and 2011. Of these cases, an estimated 1,700 were identified as involving a high-powered and/or ball-shaped magnet of interest for this NPR. For the “Yes/Possible” magnet category, an estimated 1,200 of the 1,700 estimated ingestions (70.6%) were victims 4 through 12 years of age. And of the 4,400 estimated magnet ingestions for “Magnet, type unknown,” 2,300 (52.3%) are estimated for victims in the 4- through 12-year-old age group. It is possible that if more information were available on these cases, part of the estimate from this group could be moved to the “Yes/Possible” magnet category, increasing the estimate.

For incidents reported to CPSC staff, a majority of the ingestions were classified into the “Yes” category (38 of the 50 incidents; 76.0%). The most commonly reported age group of victims is the 4- through 12-year-old age group, making up 29 of the 50 (58.0%) of the total incidents and 24 of the 43 in the “Yes” and “Possible” categories (55.8%). This age group was reported to have been using the magnets as jewelry in their mouth or playing with the magnets in their mouth in 19 of the 29 reported ingestions (65.5%). An example of “playing with the magnets in their mouth” comes from two reports of ingestions occurring while the victims were attempting to stick the magnets to their braces. This age group of victims most commonly had reported access to the magnets through school and/or a friend or through an adult (16 of the 29 incidents; 55.2%).

TAB B: Human Factors Assessment of Strong Magnet Sets

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

DATE: August 2, 2012

TO: Jonathan D. Midgett, Ph.D., Project Manager
Office of Hazard Identification and Reduction (EXHR)

THROUGH: George A. Borlase, Ph.D., P.E., Associate Executive Director
Directorate for Engineering Sciences

Robert B. Ochsman, Ph.D., CPE, Director
Division of Human Factors, Directorate for Engineering Sciences

FROM: Catherine A. Sedney, Engineering Psychologist
Division of Human Factors, Directorate for Engineering Sciences

Timothy P. Smith, Engineering Psychologist
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of Strong Magnet Sets

BACKGROUND

This memorandum provides a Human Factors (HF) assessment in support of staff's effort to evaluate the risks associated with products that consist of small, strong magnets sold in sets. This effort is a follow-up to investigations initiated by the Office of Compliance and Field Operations that were prompted by magnet ingestion incidents, many of which resulted in serious injuries.

GENERAL PRODUCT DESCRIPTION AND LABELING

The products are collections of strong magnets, usually spherical in shape and typically measuring 3 to 5 millimeters in diameter. Based on staff assessments[5] of samples of the most common brands, these magnets are an alloy of neodymium, iron, and boron (NIB) made with various coatings; may be capable of attracting across a distance of 1.5 or more centimeters (0.6 in); and would be considered hazardous under the ASTM toy standard.[6]

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[5] V. Amodeo, Directorate for Engineering Sciences, Division of Mechanical Engineering (ESME), personal communication, June 21, 2012.

[6] Section 3.1.37 of ASTM F 963-11 *Standard Consumer Safety Specification on Toy Safety,* defines a "hazardous magnet" as one with a flux index greater than 50 that is also a small object (*i.e.*, a small part per 16 CFR 1501).

Often referred to as "magnet balls," the products are marketed currently as adult desk toys, the "puzzles of the future," stress relievers, and as "science kits" and educational tools for "brain development." As shown in product instructions and in videos on related websites, they can be used and re-used to make various two- and three-dimensional forms, jewelry, and toys, such as a spinning top.

The products are sold in sets of varying size, from as few as 27 to more than 1,000 magnets. Most typically, sets consist of 216 spheres (6^3) that form a cube, and a number of brands include spare spheres with some of their sets. The most common color is a glossy, highly reflective silver, with the spheres often described as similar in appearance to BBs or ball bearings. Some firms now include sets in a wide range of colors, or combinations of colors, ranging from bright pink, green, and blue, to darker shades, such as purple and black. Most, with the exception of the smaller sets, are sold with a container, such as a square plastic cube, a metal tin, and/or a soft pouch. Most brands are sold in fairly low-key, nondescript containers, such as metal tins or black fabric boxes. The largest seller uses colorful transparent packaging that simulates the cube floating within.

The age labeling of strong magnet sets varies; currently, most products that carry an age label are marked "14+." Some have no specific age recommendation on the package, even though retail websites may identify them as intended for ages "13+" or "14+." The small parts warning[7] is sometimes included on the packaging (*i.e.*, "choking hazard, not for children under 3"), as are warnings to keep the product away from all children.

INCIDENT DATA AND INJURIES

Staff from the Directorate for Epidemiology's Division of Hazard Analysis (EPHA) searched the Commission's databases (IPII and INDP) for incidents involving magnets, and EPHA provided national estimates for magnet ingestions treated in emergency departments from the CPSC's National Electronic Injury Surveillance System (NEISS).[8] EPHA staff reported that there were an estimated 6,100 emergency department-treated, magnet-related ingestions for the years 2009 through 2011. Of these, 1,700 were attributed to high-powered and/or ball-shaped magnets; 70.6 percent of those treated are estimated to be in the age range of 4 to 12 years.

From January 1, 2009 through June 30, 2012, the CPSC received 50 reports of magnet ingestion incidents involving children ages 15 and younger; one report was submitted by a physician who referenced 15 cases without detail except for magnet type and treatment. Unlike NEISS data, which are drawn from a national sample of emergency departments, these 50 reports from the IPII and INDP databases are anecdotal, and EPHA considers them a minimum number of incidents. These incidents do not constitute a random sample, nor are the incidents assigned for CPSC investigation (*i.e.*, INDP assignments) randomly chosen. This set of reports, therefore, may not be representative of other incidents for which the staff has no information. For example,

[7] See 16 CFR §1500.19 (b)(1).
[8] S. Garland, Ph.D., EPHA. Draft memorandum to J. Midgett, (EXHR) dated July 9, 2012.

those who experienced little or no negative effects from swallowing strong magnets, and those who experienced a "near miss" by mouthing but not swallowing magnets, would have had little or no reason to report to CPSC. Conversely, those who were unfamiliar with the CPSC would not have reported despite having had severe effects. Thus, the numbers presented here are provided only to describe this sample of investigated incidents and cannot be applied to the incidence of magnet ingestion in general. Despite this limitation, they are a valuable source of information because they include details that are not available in the brief reports provided by emergency room staff in the NEISS data (?). HF staff reviewed the spreadsheet summaries of these incidents provided by EPHA staff and selected incident reports when additional information was needed to identify the incident scenario. EPHA staff identified 38 of the reported incidents as involving the subject magnet sets, and an additional five as possibly involving them. The remaining incidents involved magnetic beads reportedly designed for use as earrings (1), tongue rings (2), or other types of jewelry (3), and a set of magnetic toy rocks (1). EPHA staff reported that hospitalization was required in 34 of the 50 reported incidents.

Of the incidents for which age was provided (49), 17 children were 5 years of age or younger; 26 were 8 to 12 years of age, and 6 children were 13 to 15 years of age. Incidents occurred at about the same frequency between males and females in the two younger age groups, while all but one of the children older than 12 were females. Ingestion incidents among preschoolers, such as those involving small objects, medications, and household chemicals are commonplace; the scenarios are similar regarding magnet ingestions. Only one is mentioned here because it is peculiar to the product in question: The child, a 4-year-old, had seen candies that looked similar to the product used to decorate a cake. Among the older groups, four of the males, half of the 8- to 12-year-olds, and all of the 13- to 15-year-olds were using, or pretending to use, the magnets as tongue or lip rings or piercings when they swallowed them unintentionally. Other scenarios that led to ingestion were described as children feeling the sensation of the magnetic force against the tongue or braces, and simply as playing with the magnets in the mouth. The products sometimes were purchased for or by the child who ingested the magnet(s); in some cases, the magnets were taken from sets and shared with friends at school.

Details copied from one report highlight factors that increase the potential for serious injuries when children ingest two or more magnets of the type that comprise these sets (In-Depth Investigation 110310CCC1393). A fourth-grader received a gift consisting of "bead-like" magnets identified as a "building set" and took it to school to share the magnets with his friends. On consecutive days (Thursday and Friday) at school, one of his friends unintentionally swallowed two magnets as he used them to simulate a lip piercing. He became ill, and over the weekend admitted to his parents that he had swallowed the magnets. His mother assumed that they would pass through his digestive system, but the child's pain had increased by Monday, and he was taken to a local emergency department. X-rays revealed the magnets in his lower intestine. The first physician to treat the child thought that the magnets would pass through the digestive system without problems. Another physician researched the issue and apparently identified references that elucidated the injury mechanisms peculiar to strong magnets. The child was subsequently transferred to a trauma center where he underwent surgery to repair damage to his large and small intestines.

As described by Health Sciences (HS) staff,[9] because of the strong magnetic forces exerted by these products, the individual magnets may attract each other through the walls of different areas of the gastrointestinal tract after they are swallowed. The magnetic forces operating between the magnets can trap, compress, and damage the tissues, ultimately resulting primarily in perforations or fistula[10] that require surgical intervention. Post-surgical complications and permanent adverse health effects are also possible. The injury risk appears to be exacerbated, as suggested above, by three factors: (1) children, depending on their age, may be unable or unwilling to tell anyone that they have ingested magnets; (2) given the small size of the magnets, caregivers seem likely to assume that they are harmless and will pass through the digestive tract; and (3) there is a lack of awareness of the nature of the hazard among medical professionals,[11] resulting in delayed diagnosis or treatment. This persists despite continued incidents that have generated product recalls, safety alerts, and articles in professional journals.[12]

DISCUSSION

AGE APPROPRIATENESS OF THE PRODUCTS[13]

As objects, the magnet sets have some appeal for virtually all age groups. First, they tend to capture attention because they are shiny and reflect light. Physically, they are smooth, which gives them tactile appeal, and they make soft snapping sounds as one manipulates them. As a stimulus set, they have the properties of novelty, which arouses curiosity; incongruity, which tends to surprise and amuse; and complexity, which tends to challenge and maintain interest. Their strong magnetic properties cause them to behave in unexpected ways, with pieces suddenly snapping together, and moving—occasionally quite quickly—apart. Such behavior is likely to seem magical to younger children and to evoke a degree of awe and amusement among older children, teens, and even adults who understand its source. This characteristic is the foundation of the product's appeal as a challenging puzzle and as jewelry. It may also make it a source of annoyance or frustration for those who have little time or patience for puzzles. They may be more likely to use the collection of magnets as a unique stress ball, and as an unusually effective way to hold things in place.

Learning to counteract and control the magnetic forces exhibited by the pieces in order to construct the various forms displayed in the product instructions and on the various websites would be an inherently appealing and challenging activity beginning in the early to middle elementary school years. Simple three-dimensional puzzles begin to interest children as they approach 8 and 9 years of age, and 9 through 12-year-olds are interested in highly complex

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[9] S. E. Inkster, Ph.D., HS. Personal communication, June 27, 2012.
[10] An abnormal opening or connection between two internal organs, or an internal organ and the body surface.
[11] S. E. Inkster, Ph.D., HS, personal communication, July 9, 2012.
[12] For example, the simplest of Internet searches produces numerous links that identify the hazard of magnet ingestions: http://www.google.com/#hl=en&safe=active&sclient=psy-ab&q=magnet+ingestion&oq=magnet+ingestion&gs_l=serp.3..0l3j0i30.37199.37199.0.37870.1.1.0.0.0.0.140.140.0j1.1.0...0.0.23X13cmspJI&pbx=1&bav=on.2,or.r_gc.r_pw.r_qf.,cf.osb&fp=3ddc6ee7f452a242&biw=917&bih= (produced 7/11/12).
[13] Portions of this section are copied verbatim from author S.R. White, HF, personal communication, March 26, 2010.

puzzles (Therrell, Brown, Sutterby, & Thornton, 2002). Children of this age have the reading skills to follow directions for puzzles with three dimensions, and they have the fine-motor skills required to handle small, abstract, or interlocking pieces. Nine-year-olds can complete puzzles with 100 to 500 pieces, and 10- through 12-year-olds enjoy the challenge of puzzles with 500 to 2,000 pieces.

Children in these age groups also can engage in activities that require the type of meticulous work and attention that would be needed to create the complex patterns and structures found in the paper and video instructions related to the magnet sets. Additionally, magnets typically are included in elementary school (ages 6 through 12) science curricula. During these years, children are taught the basic concepts of magnetism, such as how to locate the opposite and like poles of magnets by observing how they attract and repel each other, as would be required to use these sets effectively. In short, in developmental terms, these products are particularly appropriate for children as puzzles beginning at younger ages than commonly recommended by the manufacturers.

FORESEEABLE USE AND MISUSE

Although firms that sell magnet sets state that they intend them as desk toys for adults, the sets and magnets from them are found in both offices and homes and in locations within the home beyond desk tops, such as on refrigerators. Children from toddlers through teens have been exposed to magnet sets in the home setting, and ingestion incidents have occurred over a number of years. Magnet ingestion incidents reported (*i.e.,* in the IPII and INDP databases) among those ages 5 years and younger do not appear to differ substantially from other childhood ingestion scenarios for this age group. Caregivers in a few cases said they intended to keep the sets away from the victims, and did not realize they had failed until after the child became ill and the magnets had already caused internal injuries. In other incidents, the child reportedly had never mouthed or ingested objects before, and was permitted to play with the magnets. As might be expected, in a number of cases, the magnets were not in their original containers, and caregivers were unaware that some were missing.[14] For example, in one report, the complainant had purchased two sets of magnets. The family used some as refrigerator magnets that were within reach of a three-year-old. The child ingested several of them over two days before their absence was noted. Mouthing and ingestion of non-food items is a normal part of children's exploratory behavior that contributes to similar incidents, such as choking and poisoning. Incidents of both types peak in early toddlerhood and decline markedly thereafter.

In reported magnet ingestion incidents among children who were older, but still younger than the manufacturer's recommended age, the product sometimes was purchased for them despite warnings or labeling. This is consistent with reviews that customers post on retail websites that indicate that these products are being purchased for children. As discussed in HF staff's original evaluation of one brand for the Office of Compliance,[15] approximately one-third of 53 adults

[14] As described in the introduction, typical sets have at least 216 magnets; larger sets include over 1,000. Some sets include separate small packages of spare magnets.
[15] S.R. White, HF, personal communication, March 26, 2010.

reviewing the products on Amazon.com reported purchasing them for children 8 through 11 years of age. Other brands have fewer reviews, but mention of pre-teens and young teenagers as avid users of these products is common.

Thus, it is foreseeable that some portion of these products will be purchased for elementary school children and teens. Given the relatively low cost for some sets, children in these age groups also may purchase the magnet sets themselves. The incident reports reflect behaviors that are beyond the intended use of the product, but that are foreseeable for the groups using them. The mouthing of objects and typical thumb-sucking behaviors common among younger children develops into less obvious and more socially acceptable oral habits that, for many people, continue through childhood and adolescence into adulthood. For example, it is common to see an adult mouthing or chewing a fingertip, fingernail, knuckle, pen, pencil, or other object, especially while concentrating or worrying. This tendency toward mouthing behaviors involving magnets could account for some reported ingestion incidents for which no details are available.

Where there are details provided, the incident reports offer scenarios that are consistent with the behaviors of the age range. Although exploratory play is generally associated with very young children, normal healthy people use their senses—which requires use of body parts—to explore unfamiliar phenomena throughout the life span. In the incidents reported among the 8- to 12-year-olds, one child described wanting to feel the force of the magnets through his tongue, one was trying to see if they would stick to her braces, and another wanted to see if they would stick together through her teeth. These are normal and foreseeable behaviors of curious children exploring a new stimulus whose properties are both unfamiliar and entertaining.

Another common scenario accounted for half of the reported ingestion incidents among the 8- to 15-year-olds. Children used at least two and as many as seven magnets to simulate piercings of their tongues, lips, or cheeks. On the tongue or lip, children sometimes used more than two magnets to form the appearance of a ring. This is a type of role-play behavior, particularly for the younger children in the group, and the magnets serve as a highly realistic prop.

Both preteens and teens are influenced by popular—or merely famous—figures in the fashion and entertainment industries, and piercings are part of the current trend. For young teenagers as a group, *real* lip, tongue, or nose piercings may be a possibility to consider. However, for some, piercings may be forbidden or considered unacceptable within the peer or family group, or may be thought to be painful. Yet piercings may still hold appeal as the child explores various means of self-expression and self-assertion. The products offer a fun, seemingly safe means to try out such fashions, even for children who would not seriously consider the real alternative.

The issues related to preteen and teen use of magnets from sets for simulated piercings, because they appear so prominently in the incident data, are discussed further below.

OPTIONS TO REDUCE RISK

The Human Factors profession offers a standard hierarchy of approaches to address product hazards (*e.g.,* Sanders & McCormick, 1993):

- Design out the dangerous features of the product.
- Protect against the hazards by guarding or shielding.
- Provide adequate warnings and instructions for proper use and foreseeable misuse.

The design of these products cannot be made substantially safer without also altering their performance characteristics. Guarding or shielding approaches attempt to separate those at risk from the hazard. In principle, packaging could be devised to make the product inaccessible to most young children in much the same way that lighters and certain pharmaceutical and household chemical containers are designed to be child-resistant (CR). In practice, however, this approach is unlikely to be effective because compliance is likely to be low. Even CR packaging that is effective at preventing a child's initial exposure to the product would be effective against future exposures only if the caregiver secures the product in the packaging after every use. This seems unrealistic with magnet sets. Non-use and incorrect use of CR closures due to perceived inconvenience and difficulty of use results in many chemical and pharmaceutical poisonings annually among children younger than 5. These occur despite a general recognition of the risk, the physical presence of the CR packaging as a cue that the substance inside is hazardous, the display of warnings, and annual public education programs. In comparison, the subject products are marketed in terms of their entertainment value as "amazing" desk toys, puzzles, science kits, and stress relievers. The likelihood that consumers will be motivated to return them to their containers after every use seems low. For example, older teens or adults may wish to display a completed puzzle, or leave a partially solved puzzle in place for later completion. Further, CR packaging is an impractical approach for older children, whose cognitive and motor skills overlap those of adults. It is highly unlikely that adults would accept such an approach because of the level of inconvenience it would involve. Even small costs in terms of time and effort have been shown to reduce behavioral compliance with warnings, such as those that would accompany CR packaging (*e.g.*, Ingestion hazard. Always put magnets in box and close latch). Because neither design nor guarding alternatives are practical, the final approach to consider is warning consumers about the potential hazard and the actions they can take to avoid the hazard. The following section discusses this in detail.

POTENTIAL EFFECTIVENESS OF WARNINGS

Safety and warnings literature consistently identify warnings as a less effective hazard-control measure than either designing out a hazard or guarding the consumer from a hazard (Zackowitz & Vredenburgh, 2005; Wogalter, 2006; Wogalter & Laughery, 2005). Warnings are less effective primarily because they do not prevent consumer exposure to the hazard. Instead, they rely on persuading consumers to alter their behavior in some way to avoid the hazard.

Child Compliance

Warnings are especially unlikely to be effective among children because children may lack the cognitive ability to appraise a hazard or appreciate the consequences of their own actions and may not understand how to avoid hazards effectively (Kalsher & Wogalter, 2008; Rice & Lueder, 2008). In addition, warning design guidelines and literature commonly recommend that the text of warnings intended for the general public be written at no higher than the 6th grade reading level (Leonard, Otani, & Wogalter, 1999), which is equivalent to a child about 11 years

old. HF staff has found that many warnings fail to meet this guideline, and even a warning that did meet this guideline presumably would not be understood by many children younger than 11.

Older children, who are cognitively more advanced, are able to appreciate the hazards described in a warning better. However, these children value peer acceptance more than parental guidelines (Brown & Beran, 2008), and social influences and peer pressure can drive adolescent behavior more strongly than their own independent thought processes (Zackowitz & Vredenburgh, 2005). For example, the product offers a seemingly safe and reversible way to try out lip, tongue, and nose piercings, and if children see their peers performing this activity, they will feel compelled to act similarly, even if alerted to the risks. Repeated use of the product in this way without ingesting the magnets most likely will convince these children that the hazard is not especially likely or is not relevant to them. Furthermore, adolescents are at a developmental stage in which they test limits and bend rules (Zackowitz & Vredenburgh, 2005); therefore, warnings about keeping the product away from children could have the unintended effect of making the product more appealing to some of these children, who might see it as "forbidden fruit" (Kalsher & Wogalter, 2008). Older children also might view such warnings as attempts to restrict personal freedoms or self-expression, which could result in responses that are contrary to the warnings' recommendations (Kalsher & Wogalter, 2008). For example, warnings about not using the product in the specific ways that might place them at risk, such as mimicking piercings, might have the unintended effect of encouraging this behavior among these children.

It might be possible to employ a warning that makes use of sensory modalities other than vision to make the product less appealing to children. Making the product emit an unpleasant odor might dissuade children from playing with it; however, such a feature would not be effective universally, and most likely, it would dissuade adults from using the product too. Making the magnets especially bitter or foul tasting (*i.e.*, adding an aversive agent) may not reduce the product's appeal, but this approach seems unlikely to be very effective because aversive agents will not deter or prevent ingestions (*cf.* CPSC, 1992). Although the use of aversive agents might discourage some children from placing additional magnets in the mouth, incident reports indicate that serious injury is possible when one ingests as few as two magnets, and children might ingest multiple magnets before they detect the aversive agent.

Caregiver Compliance

Based on HF staff's examination of several magnet products, the ingestion warnings that currently accompany these products appear aimed at adults, primarily parents and other caregivers. Staff generally found these warnings to be lacking in terms of their content. The warnings tended to refer to children swallowing the magnets, without describing the incident scenarios that might lead to ingestion among older children and adolescents, who caregivers may not believe are likely to put magnets into their mouths. Some warnings refer to the potential for swallowed magnets to stick to intestines, without referring to other magnets or ferromagnetic objects. Other warnings refer to magnets sticking together or attaching to other metallic objects inside the body, but they fail to explain that the magnets can attract through the walls of the intestines and forcefully compress these tissues. Without detailed information such as this, consumers may not understand how swallowing magnets differs from swallowing other small parts or how magnets sticking together could pose a hazard and simply not pass through the

child's system. In sum, without a clear, explicit, and accurate description of the nature of the hazard and its consequences, consumers may have difficulty developing an accurate mental model of the hazard scenario and might find the warning implausible. In such a situation, consumers are unlikely to comply with the action recommended in the warning.

Although doing so might be very difficult and time-consuming, staff believes that it may be possible to develop warnings that could communicate the ingestion hazard, its consequences, and appropriate hazard-avoidance measures in a way that would be understood by most parents and other caregivers. Nevertheless, the resulting warnings may not be effective at substantially reducing the incidence of magnet ingestions if consumers do not concur with what the warning states. Avoiding the ingestion hazard requires consumers to keep the product away from all children, or at least children in the incident age group, which is 15 years old and younger. Caregivers who read and understand the warnings may attempt to keep this product out of the hands of young children, but HF staff doubts that many caregivers are likely to be so diligent about heeding the warning with older children and adolescents. For example, caregivers may question how likely it would be for their child to swallow more than one magnet or swallow a magnet and another metallic object, especially if the child is older, seemingly responsible, and not known to mouth toys and other objects frequently. Unless they are convinced that their child is likely to mimic lip, nose, or similar piercings or to perform other activities that might lead them to place magnets into the mouth or nose, caregivers may doubt that the warnings are relevant to their children, despite the warnings' assertions to the contrary. If the caregiver has seen the child or the child's peers use the product or similar products before, without incident, or knows that children of that age have used the product successfully, they may conclude that their child can use the product safely, regardless of what the warnings state (*cf.* Vredenburgh & Zackowitz, 2006).

Even if caregivers believe the warnings, several factors may prevent compliance. Some children, especially those who are older, may have peers who already own and use the product. Some personally may have used the product before. Knowing this, caregivers might feel significant social pressure from the child, other family members, and friends to purchase the product for their children or allow their children to use the product, especially if the product is very popular among the child's peers (*cf.* Kalsher & Williams, 2006; Vredenburgh & Hemlock-Rich, 2006). Caregivers who own the product and attempt to heed the warnings might find it quite difficult to prevent child access and still keep the product reasonably accessible for their own use. Securing the product from a child after every use requires time and effort, and warnings research has shown that even small increases in time and effort can prevent compliance (Riley, 2006). If the caregiver cannot secure the product properly without dismantling the shapes and forms created during use, and the caregiver has created especially challenging or interesting designs, the caregiver might feel compelled to keep the forms intact and, as a result, fail to secure the product properly. In addition, the difficulty of attempting to identify an appropriate location to store the product may dissuade consumers from doing so, particularly for a product often marketed for "stress relief." Attempts to secure the product also may fail because the caregiver underestimates the abilities of their child and places the product in locations that seem secure but are still accessible to the child. Teens may have cognitive and motor skills similar to those of an adult (Brown & Beran, 2008), making it extremely challenging to keep the product out of their hands. Furthermore, if caregivers know that their children have friends that own and use the

product, the caregivers are likely to conclude that securing their product will not prevent exposure to other identical or similar products. This may lead caregivers to reject the warning message.

CONCLUSIONS

Manufacturers identify magnet sets as adult desk toys, puzzles, science kits, educational tools for "brain development," and as stress relievers. As objects, these products have some appeal for virtually all ages. In terms of developmental stages, typical sets are appropriate as puzzles for children beginning at about 9 years of age, although younger children can handle smaller sets successfully. Product reviews on retail websites indicate that at least some proportion of sales is for preteens and young teenagers, despite labeling and warnings. Foreseeable use of the products make it likely that they will be brought into the home, that children ranging from toddlers to teenagers will handle them, and that some ingestions will occur. Impediments to prompt treatment of magnet ingestions seem likely. Children may fail to report the ingestion for various reasons, and even when alerted, adults may fail to appreciate the hazard the magnets pose. Despite continued incidents that have generated product recalls, safety alerts, and articles in professional journals, there appears to be ongoing lack of awareness of the nature of the hazard even among medical professionals.[16]

Of the standard approaches to reducing risk, neither design changes nor guarding approaches appear practical, leaving only warnings and instructions as an option. Although doing so might be very difficult and time-consuming, staff believes that it may be possible to develop warnings that could better inform parents and other caregivers about the ingestion hazard, its consequences, and appropriate hazard-avoidance measures. Nevertheless, the resulting warnings may not be effective at motivating caregivers to comply, and therefore, may not substantially reduce the incidence of magnet ingestions.

[16] S.E. Inkster, Ph.D., HS, personal communication, July 9, 2012.

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TAB C: Assessment of injuries, complications, and acute and long-term health effects related to ingestion of magnets from magnet sets

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814

MEMORANDUM

Date: August 6, 2012

TO Jonathan Midgett, Ph.D., Project Manager - Magnet NPR,
Directorate for Hazard Identification and Reduction (EXHR)

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director,
Directorate for Health Sciences (HS)
Lori E. Saltzman, M.S., Division Director, HS

FROM: Sandra E. Inkster, Ph.D., Pharmacologist, HS

SUBJECT: Assessment of injuries, complications, and acute and long-term health effects related to ingestion of magnets from magnet sets.

Introduction

CPSC staff is engaged in notice of proposed rulemaking (NPR) activity to address the rising number of serious internal injuries in children related to ingestion of small, extremely powerful magnets found in various novelty items that recently have entered the consumer market. These particular products, which are typically described by their various distributors as: desk toys, games, puzzles, and/or manipulative stress relief-type products, share a generic design. Typically, they consist of aggregated masses of identical magnets, with the number of individual magnets supplied in the various sets ranging from about 72 to more than 1,000. The majority of currently marketed products consist of multiple, small, bead-like spheres (of approximately 5 mm diameter). Newer variants on this theme include, but are not limited to, sets of similarly sized, cube-shaped magnets, and larger, marble-sized spheres (at least 15 mm diameter), which CPSC's Health Sciences (HS) staff believes, based on accumulated knowledge and experience of magnetic force-related injuries, are also capable of causing similar magnet ingestion injuries as have been reported for the 5 mm diameter magnetic spheres.[17] This HS staff memorandum summarizes the range of injuries, medical interventions,

[17] The very small magnetic spheres and cubes (sides or diameters ranging approximately from 4 to 5 mm) are generally composed of a rare earth magnet material (a neodymium iron boron [NIB] composite), whereas larger spheres appear to HS staff to be composed of a slightly lower strength magnetic material that is not necessarily a rare earth formulation. It is possibly a high-grade ferrite magnet material, based on available information on magnets found in different types of magnetic products that are known to have caused previously reported GI-MSIs.

and outcomes that are possible, consequent to ingestion of these strong magnets. It also describes the serious complications that can arise, particularly in cases where the caregivers' and/or medical professionals' lack of awareness, or incomplete understanding, of the unique magnet injury mechanisms, results in delayed recognition of an urgent need for medical intervention, and/or failure to appreciate the full extent of internal injuries during initial medical procedures.

Background

Beginning in 2005, the CPSC first began receiving reports of serious life-threatening gastrointestinal (GI) injuries in children, caused by ingestion of small, powerful magnets found in children's toy products. The first and only magnet ingestion fatality involving magnetic forces that HS staff is aware of occurred in late 2005; it involved a 20-month-old boy who ingested 9 small cylindrical neodymium-iron-boron (NIB) rare earth magnets (approximately 6 mm diameter x 4 mm height) that fell out of his older sibling's new magnetic construction toy *(IDI 051213CCC3192).* Within 40 hours of first vomiting, the boy died from severe internal injuries caused by the magnetic interaction of the powerful magnets within his gastrointestinal (GI) tract, less than an hour after presenting at a hospital emergency department *(see mechanism of magnet injury details below)*. HS staff refers to these types of injuries as gastrointestinal-magnet specific injuries (GI-MSIs), because they involve unique attraction (and repulsion) forces of the strong magnets, rather than being due simply to the physical dimensions of the magnets. Following this death, the hazard severity of the unique MSI pattern (which was first reported sporadically in the medical literature from 1989 through 2002, [Oestreich, 2009]) and the sudden, rapid increase in NIB magnet ingestion injury data involving toy products, lead to development and incorporation of magnet performance requirements for children's toys in ASTM F963, *Consumer Safety Specification for Toy Safety* (activity began in 2006; current requirements are found in ASTM F963-11).

Information provided by CPSC Epidemiology, Division of Hazard Analysis (EPHA) staff (S. Garland, 2012) demonstrates that since 2009, the CPSC has received a growing number of reports that document similar life-threatening GI injuries in children and teenagers, who, for various reasons described by Human Factors (HF) staff, have ingested multiple, small, spherical, rare earth magnets from this new "aggregated magnet set" product class. Similar incidents involving magnetic spheres have also been reported in the media and are beginning to appear in the medical literature.

Information from product manufacturers/distributors or CPSC Laboratory Sciences, Chemistry Division (LSC) staff has confirmed that the magnetic material in the majority of the various magnetic sets staff has examined, to date, consists of the rare earth NIB composite. Various sources identify NIB as the most powerful magnet material currently available. [18] Staff is aware that other particularly strong magnet materials that are considered capable of causing similar injuries, and, which do not appear to be rare earth formulations, are also being sold in sets of multiple, larger, magnets.

HS Staff's Review of Incidents

[18] See weblink at http://www.aacg.bham.ac.uk/magnetic_materials/history.htm, History of Magnetism, University of Birmingham, UK, Applied Alloy Chemistry Group, and, Coey, 2006.

HS staff reviewed numerous reports found in the CPSC databases of magnet ingestions involving small spherical magnets. The majority of the incidents involve ingestion of two or more magnets, and two cases involve toddlers who reportedly ingested 37 and 39 magnets, respectively. In some cases, the specific product and/or manufacturer of the magnets involved was clearly identified; in other cases, the term "buckyballs" was used as a generic descriptor of the involved spherical magnets, but the specific product/manufacturer was not clearly established. In recent months, it has become increasingly common for incident reports submitted by health care professionals to refer generically to any small, spherical NIB magnet as a "buckyball," regardless of whether the magnets involved were confirmed to be brand name products. (See IPII I1240485A (04/05/12) from a pediatric gastroenterologist reporting 15 patients seen in one facility since 2010, *"who have ingested multiple "Buckyballs" or rare-earth metal magnets."*) HS staff also notes its review of findings in some reports, that medical records refer to the spherical magnetic balls as "magnetic beads," and they describe arrangements of magnets seen in x-ray images as "rings" or "bracelets," even when the product is identified as a specific product/brand name desk toy, puzzle, and/or manipulative stress relief-type product.

HS staff's review of selected reported incidents reveals that the incidents can be categorized by outcome into several groups:

1. Ingestion of a single magnet that passes through the GI tract uneventfully, but which may be monitored by health care professionals, using one or more serial x-ray images.
2. Ingestion of two or more joined magnets that pass through the GI tract uneventfully, but which may 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 via endoscopy shortly after ingestion and prior to causing any serious internal injuries.
4. Ingestion of two or more magnets that presents to health care professionals when the patient has nonspecific GI symptoms some time after serious internal injury has started, and which is recognized immediately as an urgent situation requiring surgical intervention. Surgical intervention typically involves an initial laparoscopic approach, where removal of the magnets is achieved by enterectomy (a small incision made in the bowel wall), and which sometimes entails an appendectomy, and/or repair of damaged intestinal/stomach walls that might require removal (resection) of damaged segments of bowel tissue. In some of the more serious cases, findings during initial examination, or laparoscopy, indicate a need for a more invasive open laparotomy.[19] In the less serious cases, laparoscopic assistance can facilitate removal of some, or all, of the magnets, by endoscopy or colonoscopy.
5. In worst cases, ingestion of two or more magnets, present to health care professionals some time after the patient first becomes 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

[19] In laparoscopic surgery, a few small incisions are made in the abdominal wall (the largest is typically in the navel), and the field of view of internal organs is limited to the visual field of the laparoscope instrument. In open laparotomy, a much larger incision is made to open up the abdominal cavity in order to thoroughly inspect, assess, and repair or resect, damaged tissues, as is necessary. The risk of short- and long-term complications is significantly greater with a laparotomy as compared to a laparoscopy.

believe incorrectly that the objects (which may or may not be understood to be magnets) will be voided naturally and so they delay necessary surgical intervention, allowing significant worsening of life-threatening internal injuries (primarily perforations), which increases the risk of serious complications. More 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, they can overlook other perforations sites, which results in continued leakage of bowel contents into the abdominal cavity and much worsening risk of local infection, which can lead to systemic infection (septicemia). Higher severity injuries tend to involve more invasive surgical intervention (open laparotomy).

Unlike GI-MSI involving toys, where a single magnet sometimes interacted with a ferromagnetic steel ball that was not a magnet, HS staff's review of selected incidents indicates that in every case involving the magnet sets discussed in this briefing package, all involved magnets were identical (*i.e.,* they came from the same product unit available to the victim). As detailed in the injury mechanism section, the magnet sets' common general physical properties (material, size, shape), rather than any brand-specific characteristic, are the cause of the injury because they ultimately determine the amount of pressure exerted on trapped tissues. Some examples of magnet ingestion incidents involving multiple magnet set products are highlighted in the following summaries of selected incident reports:

IDI 120130CNE1512: A 10-year-old girl simulating a tongue piercing accidentally swallowed two small magnetic balls. That same day, her mother took her to the local emergency room, and she was admitted for 5 days, during which time, the movement of the magnets was monitored by 10 x-rays, 3 CT scans, and an endoscopy. Ultimately, the magnets were manipulated from their eventual position in the colon into the appendix via laparoscopic surgery, and then removed by an appendectomy. There is no indication that any GI-MSI occurred, and reportedly, the total medical costs incurred during the girl's treatment exceed $22,000.

IDI 110112CBB2269: Over a 2-day period, a 3-year-old girl swallowed eight small spherical magnets, from a magnet set, which she found on a refrigerator door. The victim's father, an MD, reported that an x-ray he ordered revealed two joined magnets that appeared to be located in the victim's esophagus, plus another six magnets that appeared to be joined together in the victim's stomach. Originally, the father thought the magnets would be voided naturally, but he became concerned when a second x-ray image, taken the next day at a different hospital, showed that the magnets had not moved. A third x-ray at a Children's Hospital showed no movement of the magnet pair (described as 3mm beads) in the esophageal area, and some movement of the group in the abdomen. Pre-intervention, the treating physicians correctly recognized that she might have aspirated a magnet into her airways that was interacting through tissues with a magnet located in the esophagus. The girl underwent three coordinated procedures: (1) a bronchoscopy that removed one "magnetic bead" from her right bronchus; (2) an esophagogastro-duodenoscopy (endoscopy) that removed one magnetic bead from the mid-esophagus, and five magnetic beads from the stomach; and (3) a diagnostic laparoscopy, followed by laparoscopic-assisted removal of the remaining magnet, plus laparoscopic repair of a gastric perforation and a small bowel perforation. Concerns for any broncho-esophageal fistula injury were ruled out by subsequent esophogram days after removal of the pair of magnets, and the girl was discharged in good health 4 days after surgery. HS staff notes that, although surgeons were on standby, it was not clear prior to gastro-endoscopy that one of the six magnets thought to be co-located in the stomach was actually located in the second segment of the small intestine (jejunum).

IDI 120130CBB2294: A 13-year-old girl accidentally swallowed five small spherical high-powered magnets when they snapped together suddenly while she was mimicking a lip piercing. Although her abdominal pains began and worsened over the next 2 days, she did not tell her mother of the ingestion until 3 days later. She was then taken to hospital where abdominal x-rays confirmed ingestion of five magnetic balls; medical staff initially tried unsuccessfully to remove the magnets using an oral bowel cleansing solution (three attempts), and then a colonoscopy procedure. Eventually she underwent surgery, during which time the magnets—in three different locations within her small intestine—were removed via surgery, involving enterectomy and resection of damaged bowel tissue, including removal of her appendix and ileo-cecal valve. The victim's complicated recovery resulted in hospitalization for 14 days and left a 4-inch abdominal scar.

IDI 110311HCC3475: According to information provided by the mother of an 18-month-old boy, her son sustained serious life-threatening intestinal injuries, and he has lasting adverse health effects, consequent to ingestion of three small, spherical magnets. The mother reports that after her son had exhibited symptoms of diarrhea and vomiting (duration not specified) and was clutching at his right side, she took him to the local hospital where he was diagnosed as having an ear infection. Although it is not actually specified, it appears that he was treated and released the same day. His symptoms did not resolve, so a *"few"* days later, she took him to a second hospital where, reportedly, he was diagnosed as having bronchitis, given some medication, and then released. "*One or two days later,*" upon noticing that his stomach was distended, she took him to a third hospital where she was advised that he was lethargic and extremely septic. Abdominal x-rays revealed three small balls and immediate surgical intervention ensued to remove these foreign objects. It is not clear from the mother's report whether the doctors learned the balls were magnetic before or during surgery, but she did not understand that magnets were involved until after surgery. The repair of the boy's GI-MSIs involved resection of 6 inches of small intestine and 3 inches of large intestine. The victim was kept in an intensive care unit for 1.5 weeks before being released, and he continued to have diarrhea and other intestinal problems (at least 2 months post-surgery when the IDI was completed). It is noted that, although the mother signed a medical release, the child's medical records are not yet available to CPSC staff to verify the specific injuries, treatment, complications, outcome, and long-term health impact of the GI-MSIs, particularly with regard to the reported misdiagnoses at two hospitals, and consequent delays in appropriate intervention. However, based on the mother's initial incident report to the CPSC, which indicated that the magnets inside her child's intestines had "rusted through," HS staff surmises that the likely injuries included multiple bowel perforations, quite likely with magnets falling out of the GI tract into and contaminating the abdominal cavity, plus possible loss of the important ileo-cecal valve.

IDI 120419CBB3615: On an unknown date (thought to be after 3/26/12), a 23-month-old male ingested eight small spherical magnets from a product described as a "magnetic puzzle." He started vomiting overnight on 4/2/12, and worsened the next day. As a result, he was taken to an urgent care facility, where a bilateral ear infection initially was suspected. A few hours later, as the child's condition worsened and he lost consciousness intermittently, an abdominal x-ray indicated six small balls that the mother recognized immediately, and informed the staff, were magnets from the puzzle. He was transferred to a Children's Hospital where a subsequent x-ray revealed some slight movement of the magnets. According to the mother, the doctors thought the magnets would pass naturally. An x-ray taken the following day showed the magnets to be located between the small and large intestine; therefore, surgery was undertaken to remove them. During surgery, two balls were found in the small intestine and six balls were found outside of the bowel in the abdominal cavity. These were removed and a small intestine

perforation repaired. Staff does not have access to the full medical records, but according to the parents, extremely serious complications ensued after the first surgery. The child underwent several sequential surgeries over the next 10 days to repair leaks (unclear if this involved missed perforations/failure of repairs/new perforations) and treat a blood clot, ischemic necrotic bowel, and serious infection stemming from the initial magnet injury. Ultimately, after what appears to be at least five or six operations, the child was stabilized but was still retained in an intensive care unit for more than a month, having lost all but 10 to 15 centimeters of small intestine (*HS staff notes the small intestine is about 600 to 700 centimeters long)*. He is being fed intravenously and has a colostomy bag to remove waste products. He will require a bowel transplant and his long-term prognosis is poor. Staff notes that this case recently has been reported in the medical literature (Gilger, Noel, 2012), and it is also reported on a podcast at the website of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). It was also described to HS staff and others at a recent open meeting with CPSC staff requested by NASPGHAN (06/05/12), where representatives also informed CPSC staff about an ongoing NASPGHAN survey on magnet ingestion injuries.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Survey

Some preliminary information on eighty-six incidents, from the ongoing NASPGHAN survey of magnet ingestion cases treated by medical professionals, was provided to CPSC staff by Dr R Adam Noel.[20] The information reports that at least twenty-six cases required surgical intervention procedures (as opposed to endoscopy or and colonoscopy procedures that are less complicated, but not without risk). Notwithstanding the fact that several survey cases lack key details, at least 6 laparoscopies, 19 laparotomies, 1 appendectomy and 1 thoracotomy are reported. A thoractomy procedure is a highly invasive surgery that involves cutting through the chest wall; this case reportedly involved a perforation injury caused by interaction between magnets located in the esophagus (GI tract) and the airway (in the mediastinal chest level) of a 9 month-old girl who had swallowed five magnets. Another atypical NASPGHAN survey case reports a perforation injury as a complication of “trans adhesion press” caused by two magnets located in one victim’s esophagus and “cardia”; from the limited details available, it is not clear whether this is a duplicate report of the thoracotomy case reported by another doctor, or another similar case.

Mechanism of Injury

In medical terminology, the magnet injuries are pressure necrosis injuries. The unique mechanism of injury involving harmful tissue compression by extremely strong magnets (primarily, but not exclusively, NIB magnets) has become established in recent years. When ingested, strong magnets (in close or fairly distant proximity of one another) are mutually attracted to each other through intestinal walls and interaction occurs rapidly and forcibly.[21] The

[20] Personal communication to CPSC staff, Dr. R Adam Noel, July 12, 2012

[21] HS staff notes observations that once attracted to each other, identical cylindrical and cube-shaped NIB magnets tend to align in chains, where their opposite poles contact each other and their edges lie flush with each other, making it difficult to uncouple them or to discern individual magnet outlines in x-rays. Spherical magnets also interact preferentially pole-to-pole, aligning like a string of beads, where the free ends may or may not interact to form a circular “bracelet-”like structure. Also, when like poles of individual NIB magnets are brought together gradually, the strong repulsion forces cause the magnets to flip and become reoriented momentarily, with their opposite poles facing each other before quickly and forcefully, colliding as a result of their mutual attraction forces. HS staff’s observations, based on the handling of numerous multiple NIB magnet samples and other strong magnets, suggests that repulsion forces operating between a pair of magnet can cause movement and reorientation and subsequent

magnetic attraction can occur over distances ranging from as little as 10 to 20 mm for a pair of magnets, to distances much greater than that as the number of involved magnets increases. The attraction forces 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 gastrointestinal tissues (peristaltic or mixing motions), as well as the intermittent turbulent flow of the considerable volumes of gastrointestinal fluid in the small intestine, or the passage of semi-solid contents in the large intestine. The magnets remain coupled, exerting strong bilateral compression forces on the trapped GI tissues, sufficient to block the blood and nutrient supply. The extreme supra-physiological pressure exerted on the trapped tissues ultimately is directly responsible for the progressive tissue injury, which starts with local inflammation and ulceration, progressing to tissue death, then perforation or fistula formation.

When two separate areas of the GI tract are involved, the perforation tends to occur first in the section with the thinner muscular wall, *e.g.,* in gastro-ileal or gastro-colonic magnet interactions, the ileum or colon will likely sustain a perforation before the thicker stomach wall is perforated completely. Evidence from MSIs at other body sites shows that perforation of considerably stronger cartilaginous tissues of the nasal septum, or the scrotal skin, can occur within a day or so of magnet application. This suggests that magnet perforations of thinner gut walls can develop within similar timeframes, likely faster, depending on the material composition, and the relative size, shape, and number of magnets ingested. 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 open channel between two previously unconnected gut areas.[22] Fistulas cause serious, debilitating symptoms, but generally are not as urgent acutely as perforations. Perforations present a serious risk of leakage of gut contents into the abdominal cavity that, within hours, can escalate quickly from an area of local infection, to bacterial infection and inflammation of the membrane lining the abdominal cavity and its organs (secondary peritonitis), then life-threatening systemic infection (sepsis). It is noted that cases of GI-MSIs have been reported where magnet interaction and attraction occurred between two or more magnets that were located in only two separate GI sites, but which also trapped additional segments or loops of bowel tissue between them so that pressure necrosis injuries involved multiple bowel walls. HS staff is aware of cases where a single interaction between magnets caused damage to six or more bowel walls, leaving behind multiple perforations. In some cases, these additional perforation sites have gone unrecognized by medical professionals who were unfamiliar with the GI-MSI hazard; they initially repaired injuries from what they at first believed to be just two perforation sites, which resulted in much greater injury severity and associated complications. Interactions between ingested magnets have caused GI obstructions and hernias, and in some rare cases, have caused loops of the bowels to become twisted (volvulus); this obstructs passage of gut contents and deprives the twisted gut segment of blood. It is considered an extremely urgent situation, requiring immediate surgical intervention to prevent the trapped segment from becoming necrotic, and/or from rupturing and causing contamination of the abdominal cavity. The

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attraction of magnets at slightly greater distances than the distances at which opposite poles of magnets attract spontaneously.

[22] Some recent clinical trials have used novel magnetic devices that apply controlled pressure, allowing for tissue remodeling, to achieve sutureless connections (magnetic compression anastomoses) between blood vessels in cardiac by-pass surgeries and between GI segments (resection of colon, or stomach and small intestine), or to unblock bile ducts of liver transplant or pancreatic cancer patients.

relatively short mesentery[23] connections of the duodedum and ileo-cecal areas appear to predispose them to being sites of volvulus injuries. Magnets have also 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.

Given the number of variables involved, it is not possible for HS staff to describe definitively the timing and rate of injury for cases involving desk toy-type products. However, in comparison to the hazardous cylindrical NIB magnets (6.0 mm diameter x 4.1 mm) that are typically found in children's magnetic construction sets, and that exert pressure on a larger area of gut wall between their circular pole surfaces and that have stronger attraction forces as reported by ESME staff, the pressure level (force per unit area) exerted between two spherical magnets of near-equal mass to the cylindrical magnets is much greater due to the much smaller contact point between two spheres. HS staff notes it is pressure applied on the tissues, rather than force, which is the ultimate determinant of the injury. According to information provided to HS staff during the public meeting with NASPGHAN doctors (6/5/12), for the same location of GI tissue involved, the rate of injury from sphere-shaped magnets apparently is faster that the rate of injury from cylindrical magnets typically found in children's construction toys. HS staff is not aware that any volvulus injuries have been reported involving small sphere-shaped magnets, but cannot rule this out as a future possibility. At least one case of GI-MSI involving trapped intestine and mesentery tissue and spherical magnets has been reported, but full details could not be obtained by CPSC staff (H1140074A).

Once attracted magnetically to each other through intestinal walls, the magnets involved in GI injuries are unlikely to disengage spontaneously or move position until they are removed by clinicians. A pair of magnets might be uncoupled by stronger attraction forces exerted by a larger number of magnets in a separate GI location (which then could cause further injury, perhaps unrecognized, to a different GI location). In a few rare cases, after completing the process of fistula or perforation formation, magnets separated by a thin layer of dead tissue may pass through the openings and continue passage along the GI tract to ultimate voiding. A case report, in which healing of a magnet-created fistula without surgical intervention was observed, has raised an intriguing question concerning how often magnet fistula injuries might be missed (Hwang et al, 2007). If magnets fall through perforations into the peritoneal cavity, they are expected to require surgical intervention and to have a relatively high associated morbidity.

Post–operative complications of abdominal surgeries for GI-MSIs include, bleeding, infection, and ileus (temporary paralysis of gut motility). Adhesions (where bands of intra-abdominal 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 resulting in bowel obstructions requiring additional surgeries, and thus, creating a cycle. Doctors from NASPGHAN recently indicated to CPSC staff that, particularly in females, there also can be future fertility concerns related to such abdominal scar tissues and adhesions. 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, 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 ileo-cecal valve, located at the junction of the small and large intestine, which controls flow of bowel

[23] The mesentery tissues are specialized connective tissues folds of the peritoneal lining that connect the intestines to the posterior abdominal wall and loosely maintain the position of the intestines within the abdominal cavity; they also contain the nerves and blood and lymph vessels of the intestines.

contents, and hence, greatly impacts digestive function. As noted in one of the selected cases summarized above, GI-MSIs have resulted in the need for a bowel transplant.

HS Staff Conclusions

HS considers that all of the spherical and cube shaped NIB magnets it has examined (that are generally of approximately 4.7 to 5 mm diameter or length) have similar properties and can apply extreme supra-physiological pressure to trapped gastrointestinal tissues. As such, they all present a similar risk of pressure-necrosis injury, regardless of the brand of product involved. Other larger magnets sold as sets, and, which are composed of different non-NIB material(s) not quite as strong as NIB, are also considered powerful enough to cause GI-MSIs. (Injuries documented in the literature and in CPSC's EPIR databases confirm that GI-MSIs have resulted from strong, non-rare earth magnets).[24] Clearly, small spherical NIB magnets have caused multiple high-severity injuries that in the most extreme cases have caused serious life-threatening damage to trapped tissues of the gastrointestinal tract, requiring resection of damaged bowel, and in once case, the need for a bowel transplant. Although just a pair of magnets can cause serious injuries, the relative risk of injury presented by the products is increased as the number of magnets ingested increases; this is obviously a function of the large number of individual magnets found in each product.

Other sites of MSI compression injuries of concern have been reported, particularly involving nasal tissue (septum), and they have necessitated the use of general anesthesia to remove the deeply embedded magnets.

One of the biggest concerns with magnet ingestion injuries is that the medical community (particularly pediatricians, pediatric gastroenterologists, pediatric surgeons and emergency medicine specialists) is still not fully aware of this new unique injury mechanism, which aptly has been compared to hidden bullet wounds, without entry and exit wounds. The nature of the initial nonspecific GI symptoms (nausea, vomiting, abdominal pain) is easily confused with common gastrointestinal upsets, and imaging studies are not always sought immediately. The incident reports involving ingestion of small powerful magnets for multiple magnet sets show that this concern continues today, since there are several cases of delayed recognition of the magnet injuries that resulted in much greater injury severity and complications.

References

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Garland S. (2012) Directorate for Epidemiology, Hazard Analysis (EPHA), CPSC staff Memorandum to Jonathan Midgett, NEISS estimates and analysis of reported incidents related to ingestion of high-powered, ball-shaped magnets of various sizes.

[24] The physical dimensions of larger, non-NIB, strong magnets (ellipsoid shapes and irregular "rock" shapes) can reach the stomach and intestines of older children to cause GI-MSIs (Vijaysadan, Perez, Kuo, 2006; Garland, 2012); individually, they can also present an acute choking hazard and/or a non-magnet specific esophageal or intestinal obstruction hazard, particularly to young children.

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TAB D: Analysis of Magnetic Strength of Small Powerful Magnets

TAB D

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

Memorandum

Date:

TO : Jonathan Midgett, Ph.D.
Magnet NPR Team Lead
Division of Human Factors

THROUGH: George A. Borlase, Ph.D., P.E.
Assistant Executive Director
Directorate for Engineering Sciences

Mark Kumagai, P.E.
Director, Division of Mechanical Engineering
Directorate for Engineering Sciences

FROM : Vincent J. Amodeo
Mechanical Engineer
Directorate for Engineering Sciences

SUBJECT : Analysis of Magnetic Strength of Small Powerful Magnets

Background: In the past few years, small, powerful, multiple-magnet sets marketed for adults as a puzzle, desk toy, sculpture, stress reducer, or for similar entertainment, have become popular. Figure 1 shows an example of a typical magnet set of this type.

Figure 1. Typical Magnet Set

It should be noted that this memo reflects the opinions of CPSC staff and has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission

The sets are typically comprised of numerous identical, spherical, or cube-shaped magnets, approximately 4 to 6 millimeters in size, with the majority being made from NdFeB (Neodymium-Iron-Boron or NIB).

Permanent Magnets

There are several different types of permanent magnets that are currently available. A permanent magnet is one that maintains its magnetic field after being removed from the magnetizing source. The most common are: Iron-Oxide (ferrite), Aluminum-Nickel-Cobalt (AlNiCo), Samarium-Cobalt (SmCo), and Neodymium-Iron-Boron (NIB). NIB and SmCo magnets are often referred to as "rare earth" magnets because Neodymium and Samarium are two of the 17 so-called "rare earth" elements found on the periodic table. Table 1 shows the relative cost and strength of the most common permanent magnet materials.

Table 1. Relative Cost and Strength of Magnetic Materials

Magnet Material**	Cost	BHmax (kJ/m^3)***
Sintered FeO (ferrite)	Low	10-40
Sintered AlNiCo	Moderate	10-88
Bonded NdFeB (NIB)	High	60-100
Sintered SmCo	Very High	120-240
Sintered NdFeB (NIB)	Moderate High	200-440

**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 is cooled to form ingots. The ingots are pulverized into tiny particles which are compacted under pressure and heated at high temperature to fuse the particle together. Magnets are cut to shape, surface treated and magnetized.
*** BHmax is a measure of the density of magnetic energy from the magnet material.

While the multiple-magnet sets are marketed to adults, the individual magnet size and strength, and the hazard they present, are similar to those found in children's magnetic toys. However, ASTM has developed requirements to minimize liberation and ingestion of small powerful magnets found in toys for children 14 and under.

In the mid-2000s, construction toys for children featuring small, powerful magnets were introduced into the toy market. Due to poor quality and design, several children's magnetic construction toys were recalled because the NIB magnets detached from the plastic housing. (Release #07-164). The small magnets, which were often hidden to the parents, were ingested by children and infants. Some children even swallowed intact magnetic components that were small parts[25]. If more than one small, powerful magnet or one such magnet and a metallic object are

[25] The requirements of 16 CFR 1501 are intended to minimize the hazards from choking, ingestion, or inhalation to children under 36 months of age created by small objects. The requirements state, in part, that no toy (including removable, liberated components, or fragments of toys) shall be small enough without being compressed to fit entirely within a cylinder of the specified dimensions.

swallowed, the objects can attract to each other across tissue inside the stomach and intestines and cause perforations and/or blockage, which, if not treated immediately, can be fatal (See Tab C). CPSC is aware of one death and numerous cases requiring intestinal surgery following ingestion of multiple small powerful magnets (see Tab A). To address the hazard in toys, CPSC requested that ASTM International develop voluntary standard requirements for toys containing magnets.

Voluntary Standard and Mandatory Regulation for Magnetic Toys:

In June 2006, the ASTM F15.22 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 up to 14 years of age. The original requirements for toys with magnets were published in ASTM F963-07, "*Standard Consumer Safety Specification for Toy Safety,"* and they were strengthened in the 2008 version. These requirements were adopted as mandatory regulations by the CPSC as mandated by the Consumer Product Safety Improvement Act of 2008 (CPSIA). There is no similar voluntary standard for "adult" magnet sets, which are not covered by the ASTM F963 standard.

ASTM F963-11 defines a "hazardous magnet" and a "hazardous magnetic component" (*i.e.*, a toy piece that contains an embedded hazardous magnet) as one that has a flux index greater than 50 and that is a small object. The *flux index* of a magnet is an empirical value developed by the ASTM F15.22 magnet toy working group as a way to estimate the 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) by its maximum cross sectional area (in mm^2). ASTM used a gauss meter and probe that measured the surface flux density at 0.015 inches (0.38 mm) above the magnet's surface. The area is measured at the largest cross section of the magnet that is perpendicular to the axis of its magnetic poles.

The ASTM working group established a flux index of 50 as a cutoff for what is considered a "safe" magnet, based on measurements of a number of toys on the market (see Table 2). Most of the measured magnets were cylindrical in shape, and some had been involved in known incidents. When the ASTM graphed their measurements, they showed a good correlation (fairly linear relationship) between calculated flux index and measured attraction force for a majority of the magnets (see Figure 2).

Based on this graph, the flux index was considered a reliable way to gauge a magnet's relative attraction force. Since the magnets from toys involved in incidents had flux index measurements over 70, the working group chose a flux index of 50 as a cutoff because it was significantly below the values for the incident magnets. Per ASTM F963, magnets (in toys) with a flux index over 50 must not be small parts or be imbedded in components that are small parts and must not liberate after specific use and abuse testing requirements.

As a comparison, the 5 to 6 mm diameter spherical magnets in the magnet sets that are the subject of this memo had a flux index generally in the 400-600 range. Directorate for Engineering Sciences (ES) staff found that small part magnets with a flux index of 50 and lower exist, but has not seen such magnets used in existing toys or as adult magnet sets. The flux index of a 2.0 mm diameter by 2.0 mm height NIB cylinder magnets is about 33.

Table 2. ASTM Magnet Data

Item	Shape	Dim. 1 (mm)	Dim. 2 (mm)	Height (mm)	Flux Density (kG)	Attraction Force (lb)	Flux Index (kG^2 mm^2)	Magnet Type
1	Bar	4.3	15.4	5.5	0.22	0.04	3	Non-NIB
2	Bar	4.4	12	4.4	0.29	0.02	4	Non-NIB
3	Block	14.2	15.7	0.6	0.26	0.014	15	Non-NIB
4	Disk	25.3	-	0.5	0.3	0.02	45	Non-NIB
5	Disk	4.1	-	1.2	2.4	0.1	75	NIB
6	Bar	8.3	10.5	4.1	0.94	0.25	77	Non-NIB
7	Disk	11.8	-	4	0.96	0.1	101	Non-NIB
8	Cylinder	3	-	4.1	4	0.15	112	NIB
9	Cylinder	11	-	4.6	1.12	0.25	119	Non-NIB
10	Disk	5	-	2.1	3.24	0.28	206	NIB (?)
11	Disk	6	-	2	2.8	0.44	219	NIB (?)
12	Cylinder	4	-	4	4.26	0.31	231	NIB (?)
13	Cylinder	5	-	3.1	3.61	0.37	252	NIB (?)
14	Cylinder	4.9	-	3	3.85	0.47	282	NIB (?)
15	Cylinder	6	-	3	3.34	0.54	311	NIB (?)
16	Cylinder	11	-	2	1.88	1.2	336	NIB
17	Cylinder	6	-	4.1	3.5	0.7	343	NIB
18	Cylinder	5	-	4	4.29	0.51	361	NIB (?)

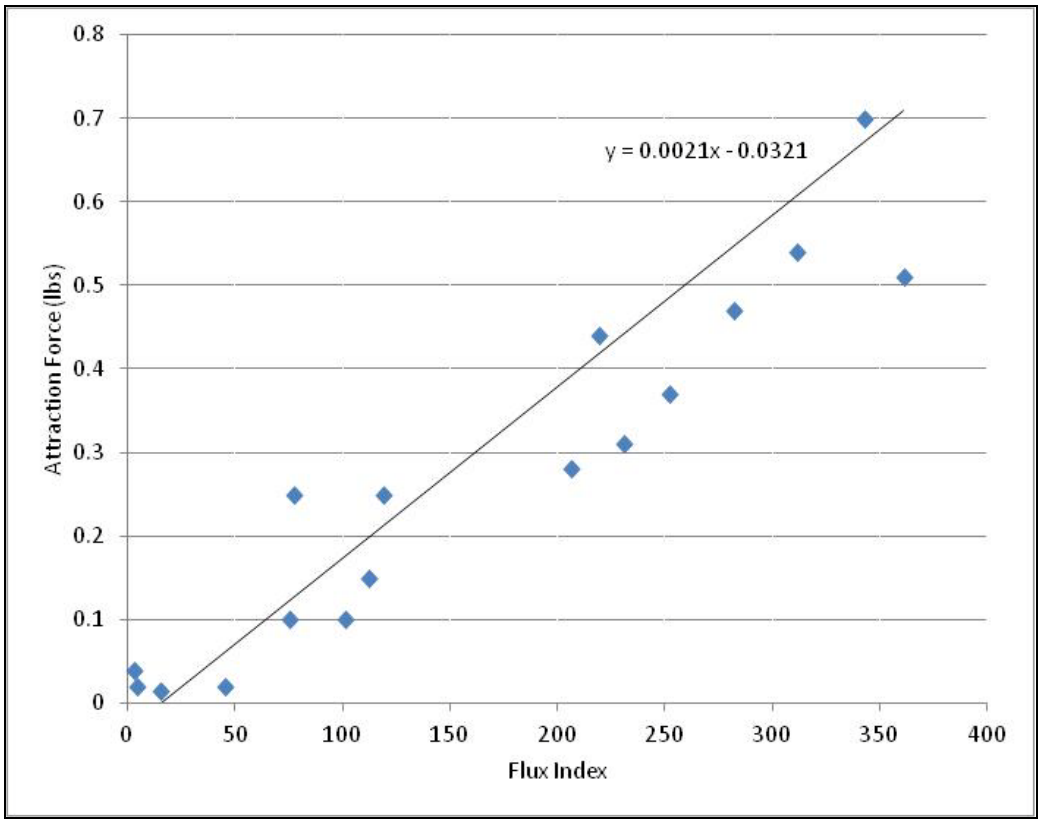


Figure 2. Flux Index Versus Attractive Force of Various Sample Magnets
(As measured by ASTM Magnetic Toy Working Group)

ASTM F963 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 1,000 cycles of intended use, followed by an impact with a 2.2 lb (1.0 kg) metallic mass dropped onto the magnetic component from a height of 4 inches. The 1,000 cycle test is then repeated to ensure that a hazardous magnet will not be liberated.

Concerns with the Existing Toy Standard

ES staff believes that manufacturers have made their toys containing powerful magnets more robust (that won't liberate magnets) and with larger components (that can't be swallowed), rather than using weaker magnets, to comply with the voluntary standards and CPSC regulations for magnet toys. This strategy minimizes the likelihood of powerful small part magnet ingestion in toys. Alternately, to meet the toy standard requirements, manufacturers could use weak small part magnets with flux index of 50 and lower, but this would reduce the attraction force of the magnets to the point where they might no longer hold toy parts together as desired.

A toy with multiple weak small part magnets could present an issue that the existing ASTM F963 magnet requirements do not address, namely: stacking or stringing of magnets. Stacked magnets act like a magnet of the combined size and therefore the stack has a higher attraction force and flux index. The amount of added attraction force created by stacking depends on the

magnet material, size, and shape. A toy could have small part magnets under 50 flux index, which would be acceptable in the existing toy standard. However, when these small part magnets are combined, they could create a magnet with an effective flux index over 50 depending upon their characteristics.

Measuring Magnetic Field

The material type, mass, and shape of a magnet determine its magnetic field. This field is aligned with its north and south magnetic poles (see Figure 3). Surface flux density is a measurement of how intense the magnetic field is at a given distance (dimension "x" in Figure 4) above the magnetic pole surface. As indicated previously, stacked magnets will act like a magnet of the combined size, which the poles of the magnets aligning themselves.

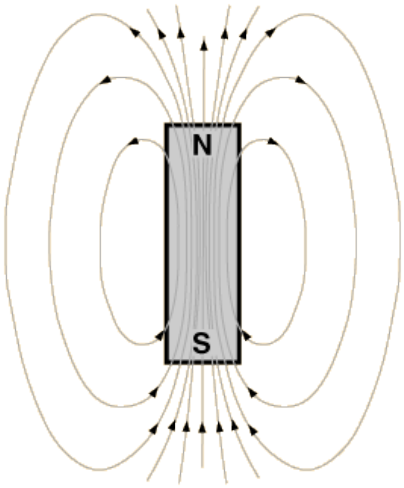


Figure 3. Magnetic Field of Magnet

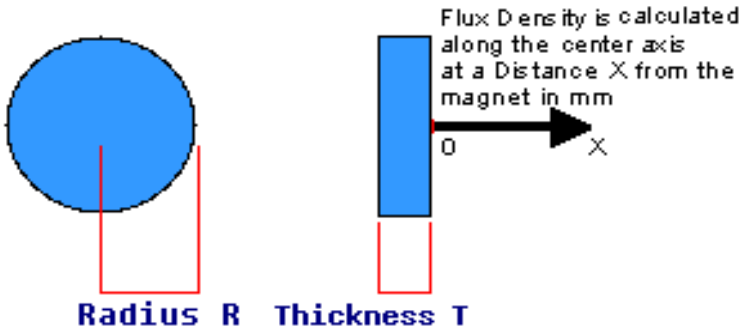


Figure 4. Disc Magnet

Per ASTM F963, the surface flux density is measured with a gauss meter using an axial probe with the following specifications (see Figure 5).

Flux Density Measurement:

Test Equipment—direct current field gauss meter with a resolution of 5 gauss (G) and an axial type probe.

"A" is the distance between the active area and the probe tip.
"B" denotes the probe tip.
"D" is the probe diameter.

Figure 5. Axial Probe Example

(Lakeshore axial probe: http://www.lakeshore.com/mag/hlp/n_axialp.html)

The probe tip is moved across the surface of either pole of the magnet in order to locate the highest surface flux density point, as shown in Figure 6. The peak value is difficult to locate, especially on spherical magnets. This can result in 5 to 20 percent variability in measurement depending upon the ability of the technician. To minimize inaccuracy, ES staff averages surface flux density measurements from several magnets. The value is used to calculate the magnet's Flux Index, by multiplying the square of the peak surface flux density (KGauss), by its cross sectional area (mm^2). Since the flux density measurement is imprecise, the Flux Index calculation in not an exact value. The ASTM F963 method specifies a gauss meter and an axial probe with a distance between the active area (diameter of 0.76 +/- 0.13 mm) and probe tip of 0.38 mm (0.015 inches) (dimension "A" in Figure 5). This means the magnetic flux density is measured at a distance of 0.38 millimeters above the magnet surface. A probe with a different probe tip will measure a different surface flux density which would result in a different Flux Index value.[26]

[26] Lakeshore axial probes are available with a probe tip to active area distances of 0.005, 0.010, 0.015, and 0.025 inches.

Figure 6. Gauss Meter and Axial Probe Used to Locate Magnet Surface Flux Density

A magnet's surface flux density decreases with the distance from the magnet's surface; the farther away from the surface, the lower the flux density. The general trend is shown in Figure 7.

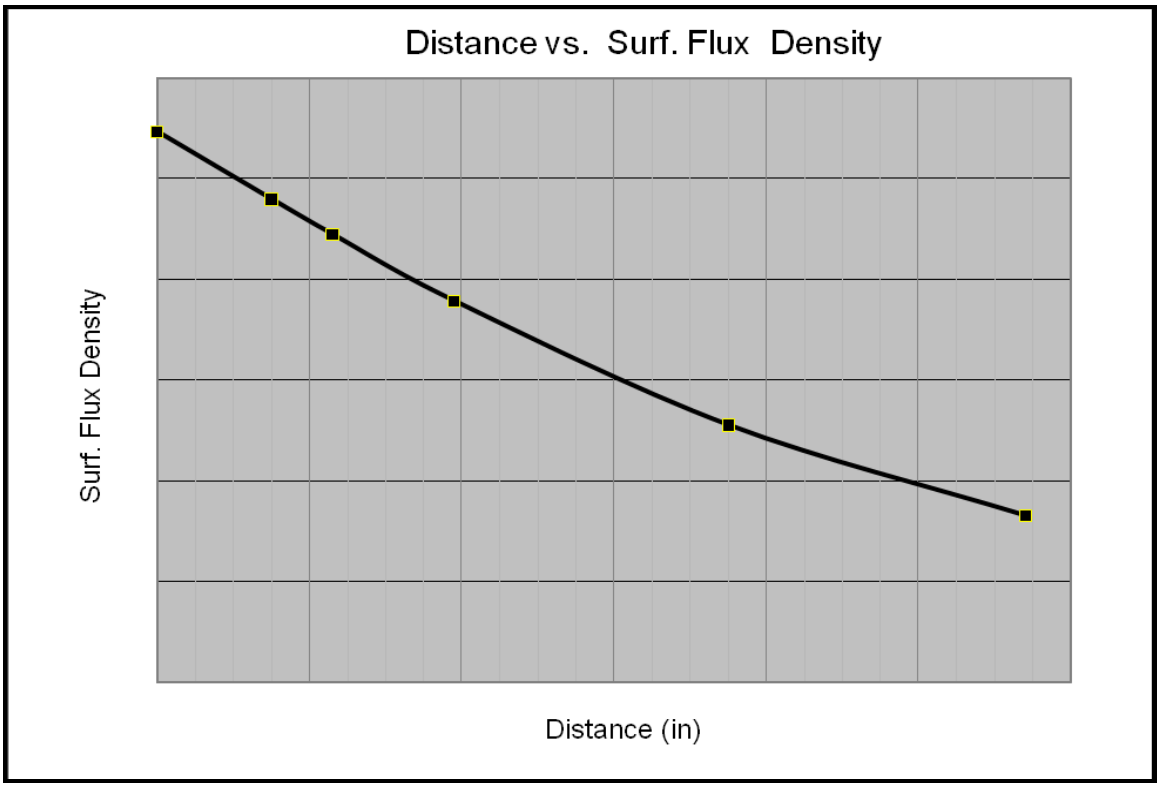


Figure 7. Example of Surface Flux Density vs. Distance From Magnet Surface

Comparison of Magnet Strength

ES staff has gathered considerable data on magnets of various materials, sizes and shapes, so that these values would be available to assess the injury mechanism.

ES staff measured magnet to magnet attraction forces using a calibrated Quantrol digital force gage (see Figure 8). The load cell used in the force gage is capable of measuring to the nearest 0.001 pound (0.454 gram-force). To gain an understanding of how a magnet's attraction force changes with separation distance, ES staff measured attraction force between two identical magnets at separation distances of 0.00, 0.34, 0.50, 1.0, 1.5, 1.9, 3.0, 3.8 and 5.0 millimeters. The distances were chosen to establish a set of attraction force data points from 0 to 5 millimeters so that a plot could be drawn. Each magnet was glued onto plastic threaded rods with their magnetic poles aligned and threaded into the force gage stand, as shown in Figure 9. Stacks of note paper were used to set the separation distances as the magnets were moved toward each other. Each stack height was determined using a caliper to the nearest 0.03 mm. Attraction force was measured when the magnets contacted each side of the paper stack.

Figure 8. CPSC Digital Force Gage Setup

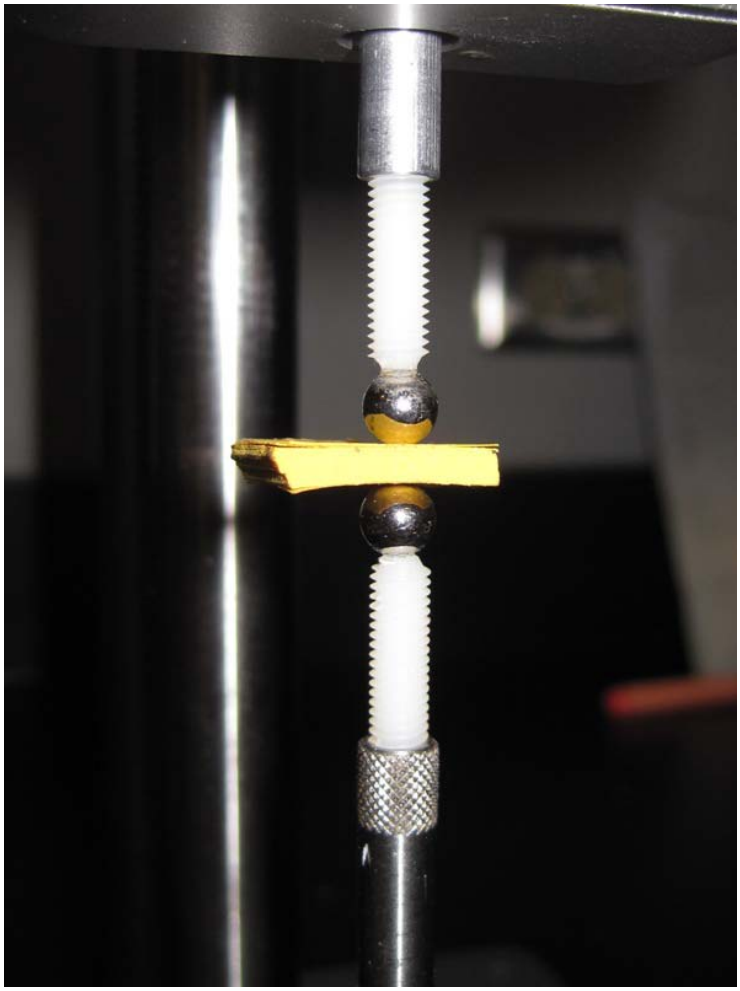


Figure 9 – Close-up View of Magnets Mounted in Force Gage

Properties for a select number of magnets measured by ES staff are shown in Table 3. Magnets 1, 4, and 6 are cylindrical NIB magnets from recalled children's magnetic construction sets. Magnet 2 is a cylindrical ferrite magnet from a science kit. Magnets 3, 5, 7, 8, and 9 are spherical and cube NIB magnets from typical adult multiple-magnet sets. Magnet to magnet attraction force values at separation are shown in Table 4. Table 3 is sorted by the last column on the right, Flux Index, and Table 4 data is given in the same order. As can be seen in Table 4, the Flux Index values do not necessarily align with the attraction force values for the magnets because the magnet samples are more diverse in shape and size than those that were measured by ASTM. The relative scale of the magnets tested (in Tables 3 and 4) is shown in Figure 10. A plot of the Flux Index versus the attraction force at a separation of 0.34 mm (column 5 in Table 4), for magnets 1 through 9, is shown in Figure 11. This can be compared to the plot for the ASTM data in Figure 2. A graph of the attraction force versus separation distance from Table 4, for magnets 1 through 9, is shown in Figure 12.

Table 3. Magnets Properties

	Magnet Material	Shape	Diameter (mm)	Height (mm)	Cross Section Area (mm^2)	Volume (cm^3)	Mass (g)	Density (g/cm^3)	Surface Flux Density (Gauss)	Surface Flux Index (kG^2 mm^2)
1	NIB	Cylinder	4.04	1.19	12.8	0.015	0.117	7.67	2.54	82.7
2	Ferrite	Cylinder	12.0	5.0	113.1	0.565	2.78	4.92	1.35	206.1
3	NIB	Cube	4.01	4.01	16.1	0.065	0.480	7.36	4.23	288.2
4	NIB	Cylinder	5.05	4.19	20.1	0.084	0.546	6.49	4.30	371.0
5	NIB	Sphere	4.72	n/a	17.5	0.055	0.413	7.49	5.18	470.4
6	NIB	Cylinder	5.99	4.09	28.2	0.115	0.797	6.91	3.92	433.7
7	NIB	Sphere	5.00	n/a	19.7	0.066	0.480	7.32	5.32	556.6
8	NIB	Sphere	5.05	n/a	20.1	0.068	0.501	7.41	5.46	598.2
9	NIB	Sphere	5.99	n/a	29.2	0.113	0.837	7.42	5.72	923.4

Table 4. Magnet to Magnet Attraction Force (lbs) vs. Separation Distance (mm)

	Magnet Material	Shape	Separation Distance (mm)								
			0.0 mm	0.34 mm	0.5 mm	1.0 mm	1.5 mm	1.9 mm	3.0 mm	3.8 mm	5.0 mm
			Attraction force (lbs)								
1	NIB	Cylinder	0.308	0.192	0.170	0.102	0.072	0.048	0.022	0.012	0.004
2	Ferrite	Cylinder	0.668	0.554	0.528	0.438	0.368	0.310	0.228	0.168	0.116
3	NIB	Cube	1.394	0.908	0.820	0.564	0.414	0.296	0.164	0.102	0.052
4	NIB	Cylinder	1.602	1.134	1.036	0.724	0.560	0.404	0.234	0.150	0.078
5	NIB	Sphere	0.650	0.482	0.450	0.304	0.218	0.166	0.090	0.058	0.032
6	NIB	Cylinder	1.846	1.312	1.220	0.884	0.688	0.506	0.304	0.204	0.116
7	NIB	Sphere	0.764	0.576	0.524	0.358	0.272	0.202	0.114	0.070	0.036
8	NIB	Sphere	0.802	0.610	0.566	0.386	0.298	0.216	0.120	0.074	0.042
9	NIB	Sphere	1.160	0.926	0.876	0.646	0.496	0.362	0.224	0.148	0.086

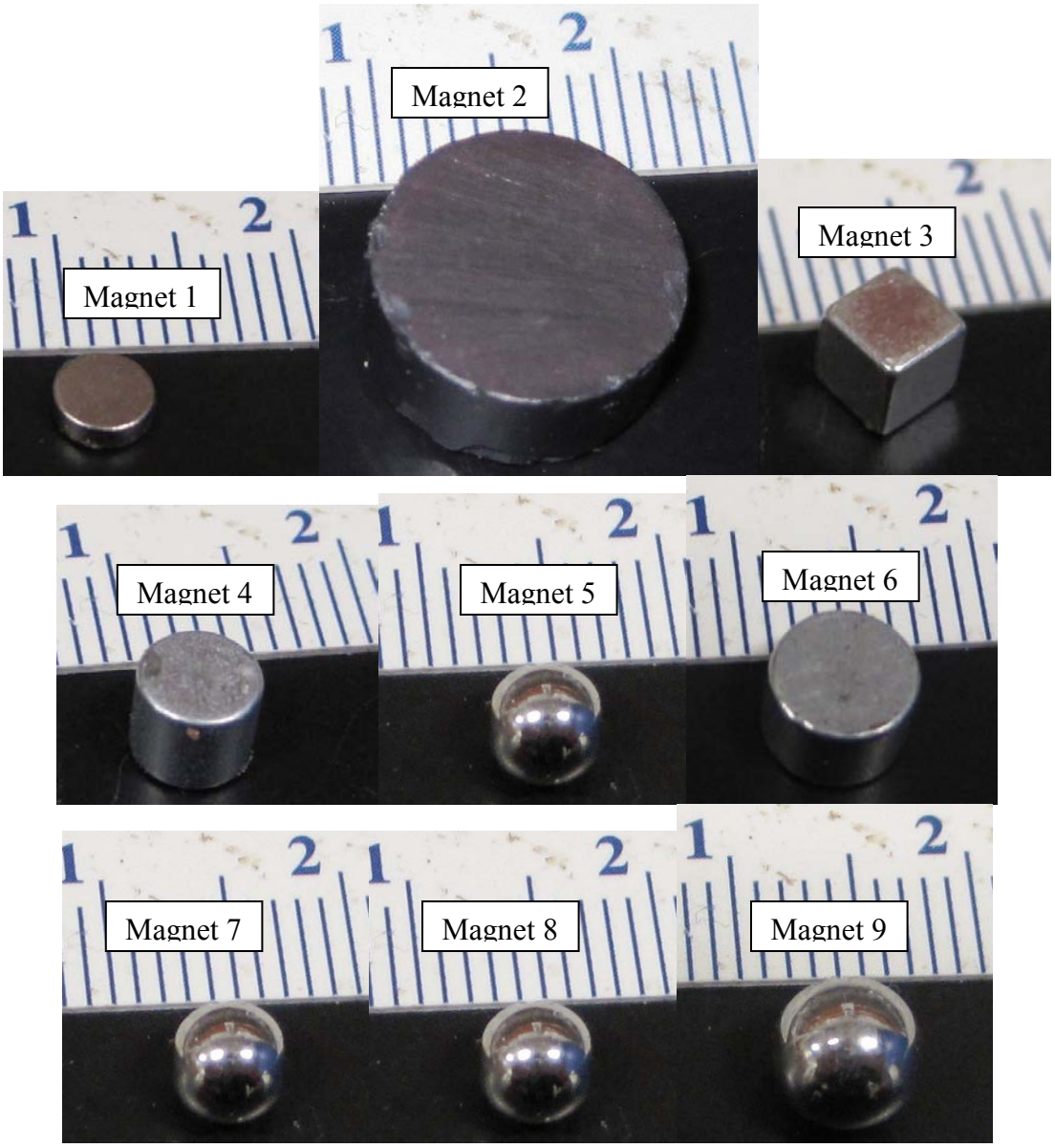


Figure 10. Magnet Pictures

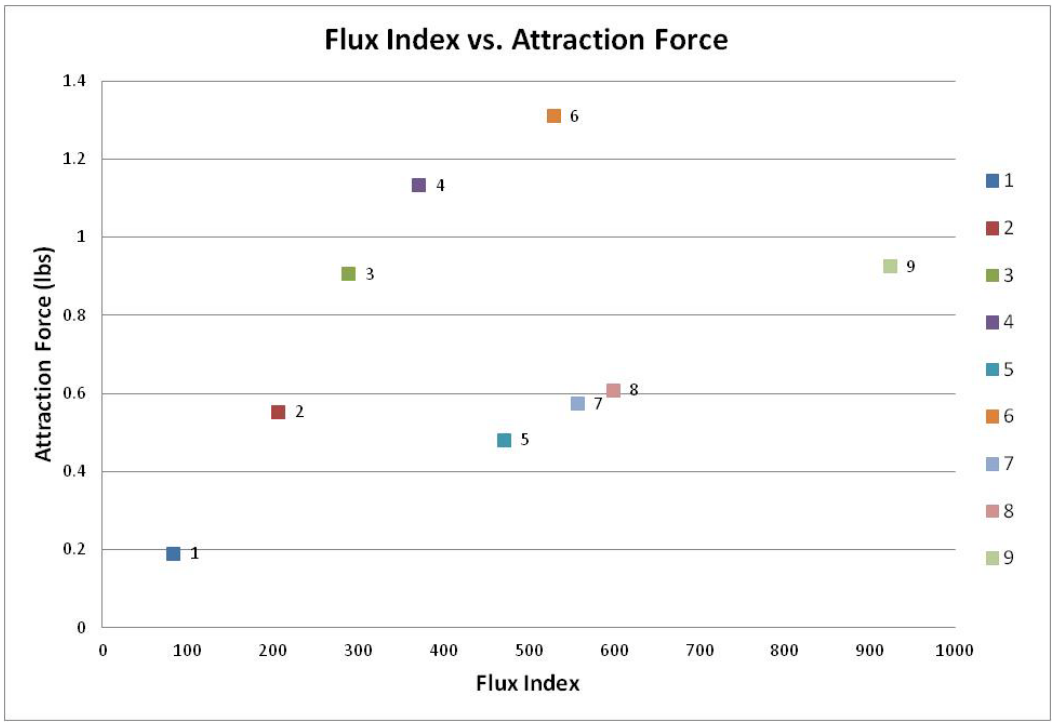


Figure 11. Attraction Force vs. Flux Index at 0.38 mm Magnet Separation

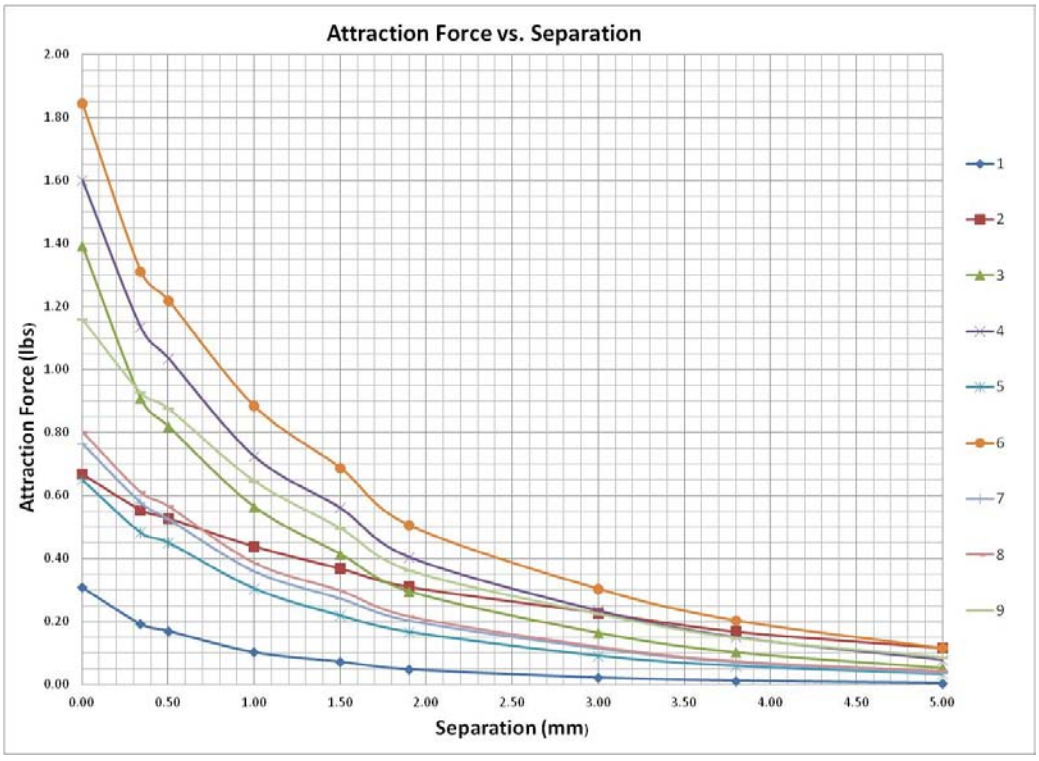


Figure 12. Attraction Force versus Separation Distance for Measured Magnets

Magnet Interaction

Magnet to magnet attraction force for the magnets shown in Table 4 is significant at separations of 5 millimeters and less. However, as magnet separation increases, the attraction force decreases. Though powerful, magnets must be within a few centimeters of each other in order to attract toward each other depending upon the size of their magnetic field. The larger the mass, the greater the magnetic field and the farther apart two magnets can be and still attract. As such, a larger magnet made from a weaker magnet material can have a higher attraction force than a smaller magnet made from a stronger magnet material.

In order for a magnet to move towards another magnet at a distance, the attraction force between the two must overcome the forces opposing the movement of the magnets. These opposing forces include gravity, friction, and intervening material. This distance is increased by stacking or stringing multiple magnets.ES staff determined the number of like magnets in a string that are required to pick up a single magnet at distances of 1.5 cm, 2.0 cm, and 2.5 cm, as shown in Figure 13, using a stack of cards to separate the magnets. These values are show in Table 6. This experiment shows that two similar magnets will clearly interact and stay strongly attracted to each other at separations of 1.5 cm or more. As distance increases and attraction force decreases, however, magnets can be combined in a stack or string to increase the net attraction force in order to attract at greater distances. Once magnets do attract, the forces to separate them are quite high.

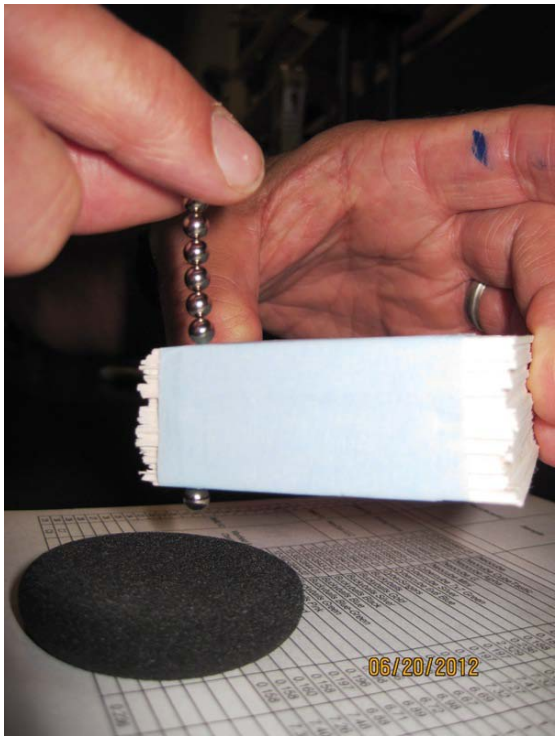


Figure 13. Magnet String to Magnet Attraction

Table 5. Magnet String to Magnet Attraction

	Magnet Material	Shape	Number of Strung Magnets to Pick up Single Magnet Across Distance		
			1.5 (cm)	2.0 (cm)	2.5 (cm)
1	NIB	Cylinder	2	5	>16
2	Ferrite	Cylinder	1	2	3
3	NIB	Cube	1	2	3
4	NIB	Cylinder	1	1	2
5	NIB	Sphere	1	2	9
6	NIB	Cylinder	1	1	2
7	NIB	Sphere	1	2	5
8	NIB	Sphere	1	2	4
9	NIB	Sphere	1	2	2

Summary

Sets of small, powerful magnets sold as adult magnet sets contain magnets of similar size and strength to those found in children's toys that have been recalled. ASTM developed requirements in F963 "*Standard Consumer Safety Specification for Toy Safety"* to effectively minimize the likelihood of toys containing or liberating small, powerful magnets. F963 establishes small part magnets with flux indexes over 50 to be hazardous. All toys containing magnets are subject to rigorous testing to ensure hazardous magnets do not fall out. Adult magnet sets are not covered by F963 but would fail the requirements if they were subject to the standard. The adult magnet sets include magnets measured by ES staff are small parts, have flux index values in the 400-600 range, and are capable of attracting across distances of 1 to 2 centimeters or more.

TAB E: Preliminary Regulatory Analysis of a Proposed Rule that Would Prohibit Certain Small Powerful Magnet Sets

TAB E

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

Memorandum

August 1, 2012

TO: Jonathan D. Midgett, Ph.D., Project Manager
Office of Hazard Identification and Reduction (EXHR)

THROUGH: Gregory B. Rodgers, Ph.D., Associate Executive Director
Directorate for Economic Analysis
Deborah V. Aiken, Ph.D., Senior Staff Coordinator
Directorate for Economic Analysis

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

SUBJECT: Preliminary Regulatory Analysis of a Proposed Rule that Would Prohibit Certain Small Powerful Magnet Sets

Introduction

The U.S. Consumer Product Safety Commission (CPSC or Commission) has received information regarding incidents with, and hazards posed by, certain small, powerful magnets contained in desk sets. Some of these incidents have required surgical removal of individual magnets ingested by children. Reported incidents of magnet ingestion involved young children who put the magnets in their mouths, and adolescents and teens who paired magnets to mimic tongue or lip piercings. This behavior has led to the accidental swallowing of the powerful magnets, with unexpected and, sometimes, severe medical consequences, including significant damage to the gastrointestinal tract (Inkster, 2012). The purpose of this preliminary regulatory analysis is to evaluate the possible benefits and costs of a proposed rule prohibiting hazardous magnet desk sets.

Description of the Proposed Rule

The draft proposed rule would prohibit the manufacture, import, and sale of certain magnet sets. It would apply to any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy that uses the magnets for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief. Magnet sets that do not meet the specified flux index limit and that have two or more magnets that would fit within the small parts cylinder would be prohibited.

Although characterized as a performance standard for magnets, it is important to note that the standard would effectively ban current designs of magnetic desk sets of the type that have become popular in recent years.

Description of the Product and Market

Magnetic desk sets that would be affected by the scope of the draft proposed rule are comprised of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. These magnet sets were introduced in 2008, but the first year with significant sales to U.S. consumers was 2009.[27] Most have been sold in sets of either 125 balls or sets of 216 to 224 balls, although some firms have sold just a few balls as extras, and others have sold large sets of more than 1,000 magnetic balls. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter, although balls as small as about 3 mm have been sold, as have sets of larger magnet balls (perhaps 15mm to 25 mm in diameter).[28] In addition to magnetic ball sets, desk sets of small magnetic cubes have also been sold, although they have comprised a relatively small share of the market. The leading marketer of such magnet sets has recently added small magnetic rods intended to be used with balls to make geometric shapes to its desk toy product line.

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 have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets, with a value of roughly $50 million. This value reflects a combination of retail sales directly to consumers (through company websites and other Internet retail sites) and sales to retailers who market the products. A review of retail prices reported by importers and observed on Internet sites suggest prices typically ranging from about $20 to $45, with an average price of about $25.

The small powerful magnets most likely to be affected by a possible CPSC rule are made from alloys of neodymium, iron, and boron. This composition has been confirmed in analyses of product samples by CPSC staff from the Directorate for Laboratory Sciences. The magnetized neodymium-iron-boron cores are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding. Nearly 100 percent of neodymium and other rare earth metals now are mined in China, which also reportedly holds a nearly worldwide monopoly on the production of neodymium-iron-boron magnets (Dent, 2012). Based on available information, all of the small magnets used in magnet sets, as well as most of the finished and packaged products that would be subject to CPSC regulation, are produced by manufacturers located in China.[29]

[27] However, small neodymium-iron-boron magnets previously have been, and continue to be, marketed by firms such as magnet suppliers and distributors of educational products.

[28] One firm's larger magnet balls are reportedly made with cores of strontium ferrite ($SrO{\cdot}6Fe_2O_3$), rather than neodymium-iron-boron.

[29] 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 repackages in its U.S. office.

Importers of Magnetic Desk Sets

As noted above, none of the magnetic sets within the scope of the prospective CPSC rule are produced domestically. All of the firms that have marketed the products are believed to import them packaged and labeled for sale to U.S. consumers. Several Chinese manufacturers have the facilities and production capacity to meet the orders of U.S. importers, and there are no major barriers to market entry for firms wishing to source products from China for sale in the United States. For example, some of the firms with smaller sales volumes reported to Compliance staff that they mainly marketed products (sourced from manufacturers in China) through sales arrangements with a leading Internet retailer, which held stock for them and processed orders. A review of the product listings of the Internet retailer found that several other firms have similar business models. Other U.S. firms and individuals sell magnetic sets they have imported from China through "stores" they maintain on another major Internet shopping site.

The Directorate for Economic Analysis has identified about 25 U.S. firms and individuals who have recently imported magnetic desk sets for sale in the United States.[30] The combined sales of the top seven firms have probably accounted for the great majority (perhaps over 98%) of units sold. One firm is believed to have held a dominant position in the market for magnetic desk sets since it entered the market in 2009. That firm, and a few of the larger firms (including a firm based in Canada with a branch office in the United States), have marketed the products through accounts with retailers, in addition to selling directly to consumers on the Internet, using their own websites or other Internet shopping sites. In addition to products offered for sale by U.S. importers, consumers also have the ability to purchase magnetic sets directly from sources in Hong Kong or China, many of which market products through "stores" on a leading Internet shopping site.[31]

Evaluation of the Proposed Rule

Societal Costs and the Potential Benefits of a Rule Prohibiting Certain Magnetic Desk Sets

Estimated Societal Costs of Injuries

The purpose of the proposed rule is to prevent serious intestinal injuries that can result when children ingest two or more of the magnets in the subject magnet sets (or one magnet and another metallic object) (Inkster, 2012). The draft proposed rule would prohibit magnet sets that do not meet specified requirements. Therefore, benefits of the proposed rule would be the resulting reduction in injuries. Based on a review of magnet ingestion incidents reported through CPSC databases that include the Injury or Potential Injury Incident database (IPII) and the In-

[30] Compliance targeted only 13 of these firms for corrective action because some of the firms sell so few magnets that it became a resource issue to pursue these matters on a case by case basis. Of the 13 firms targeted for compliance action, 11 agreed to stop sale voluntarily and the compliance division is continuing to negotiate a corrective action plan with each of these firms. The Commission voted to institute administrative action seeking a recall with regard to the two firms that refused to stop sale.

[31] More than 40 such stores shipping magnetic desk toys directly from Hong Kong or China were identified in a brief review of product offerings on the Internet site.

depth Investigation database (INDP), CPSC staff is aware of 38 confirmed incidents involving ingestion of one or more powerful magnets from a subject magnetic desk set since the product was introduced in 2008 (Garland, 2012). An additional five incidents possibly involved magnets from such magnet sets. No fatalities involving the products are known to the CPSC.

Our analysis of the potential benefits of the proposed rule focuses on injuries reported through the National Electronic Injury Surveillance System (NEISS), a probability sample of U.S. hospital emergency departments that can be used to provide national estimates of product-related injuries initially treated in U.S. hospital emergency departments. Based on a review of incident narratives coded from emergency department medical records for magnet ingestion cases obtained from NEISS hospitals, the Directorate for Epidemiology staff has identified 72 "high-powered and/or ball shaped magnet ingestions" from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest. Although manufacturer or brand name information is rarely available in the medical records extracted for NEISS, three of the 72 NEISS-reported cases (4.2%) did mention a brand name of magnet sets that are the magnets of interest; 69 cases (95.8%) were determined to have possibly involved the magnets of interest because the case narratives included terms such as "high powered", "magnetic ball", "magnetic marble", "BB size magnet" or "magnetic beads" (Garland, 2012).

Based on the 72 NEISS-reported magnet cases, there were an estimated 1,716 injuries treated in U.S. hospital emergency departments during the 2009 through 2011 study period. Roughly 6 percent were hospitalized injuries, as opposed to being treated and released. The benefits of the proposed rule can be estimated as the reduction in the societal costs associated with the injuries that would be prevented by the proposed rule. The Directorate for Economic Analysis bases estimates of the societal costs of emergency department-treated magnet injuries on the CPSC's Injury Cost Model (ICM) (Miller et al., 2000). The ICM is fully integrated with NEISS, and estimates the societal costs of injuries reported through NEISS. Additionally, based on empirical relationships between the number of medically attended injuries treated in emergency departments and the number of injuries treated in other settings, the ICM also estimates the number and societal costs of medically attended injuries treated outside of emergency departments, such as in doctors' offices and clinics. The estimates of societal costs provided by the ICM depend upon (and vary by) the injury diagnosis, the body part affected, the injury disposition (*i.e.*, treated in a doctor's office, treated and released from a hospital emergency department, or hospitalized), and the age and sex of the victim.

Table 1 below provides *annual* estimates of the injuries and the societal costs associated with "high-powered and/or ball-shaped magnet ingestions" that involve, or possibly involve, the magnets that are the subject of the proposed rule. As shown in the table, the 2009 through 2011 NEISS estimates suggest an estimated *annual* average of about 572 emergency department-treated injuries, including 537 injuries that were treated and released and 35 injuries that were hospitalized. About 70 percent of these emergency department-treated ingestions involved children ages 4 through 12 years. Just over half of the magnet cases from the emergency departments of the hospitals that comprise the NEISS sample appear to have involved the

ingestion of more than one magnet.[32] Additionally, based on estimates from the ICM, there were another 870 injuries treated annually outside of hospital emergency departments.

After including the injuries treated outside of hospital emergency departments, there was an annual average of about 1,442 medically attended injuries involving ingestions of magnets that were defined as at least "possibly of interest." These injuries resulted in annual societal costs of about $24.8 million (in 2011 dollars) during the 2009–2011 time period. The average estimated societal costs per injury were about $13,000 for injuries treated outside of emergency departments and hospitals (such as in a doctor's office or clinics), about $17,000 for those that were treated and released from emergency departments, and about $112,000 for those that were admitted to hospitals for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 25 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 75 percent of the estimated injury costs (Miller et al., 2000).

Table 1.
Estimated average annual medically attended 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, 2009–2011.

Injury Disposition	Estimated Number	Estimated Societal Costs ($ millions)*
Treated and Released from Hospital Emergency Department (NEISS)	537	$ 9.1
Admitted to Hospital Through the Emergency Department(NEISS)	35†	$ 3.9
Medically Treated Outside of Hospital Emergency Department (ICM)	870	$11.7
Total Medically Attended Injuries	1,442	$24.8

* In 2011 dollars.
† According to the Directorate for Epidemiology, the estimated number of hospital-admitted emergency department injuries is a not a reliable estimate because of the small number of cases upon which the estimate was based.

It should be noted that there is uncertainty concerning these estimates. Some of the cases described as "possibly" involving the magnet injuries that were included in Table 1 may not have involved the magnets that are the subject of the NPR. As noted above, about 95.8 percent of the

[32] In contrast to the available evidence on the number of magnets ingested from the NEISS estimates, 35 of 43 non-NEISS ingestions reported to the CPSC that involved, or possibly involved, the magnets of interest, involved the ingestion of more than one magnet (see Garland, Table 10). The difference may be related to the number of cases upon which the NEISS estimate was based, which may have been too small to provide reliable estimates. Alternatively, it is possible that the non-NEISS injury reports to the CPSC tended to involve the more serious cases with multiple magnets.

cases upon which the table was based were described as only possibly involving the magnets of interest because NEISS narratives are not required to list manufacturer or brand name. Hence, it is possible that Table 1 overstates the societal costs associated with the magnets that would be included in the proposed rule.

On the other hand, in addition to the magnet cases upon which the table was based, there were also 175 NEISS cases (representing about 1,440 emergency department-treated injuries annually) in which the magnet type was unknown. These cases included those in which the case narrative mentioned that a magnet was involved, but presented insufficient information to classify the magnet type. Consequently, to the extent that the unknown magnet types involved those that would be covered by the proposed rule, the Table 1 results would tend to understate the societal costs associated with the magnets subject to the proposed rule.

Estimated Benefits of the Proposed Rule

As noted above, the benefits of a proposed magnet rule would be the reduction in the societal costs of the injuries that would be prevented. In general, because the rule would effectively ban certain types of magnet sets, all ingestion injuries that would have involved magnets that, in the absence of a ban, would have been sold after the effective date of the proposed rule, will be prevented. However, if children, adolescents, and teens cannot play with or use the prohibited magnets, they could play with or use substitute products that may also result in injury. Hence, the overall benefits of the proposed rule should be measured as the *net reduction* in injuries, and the concomitant reduction in societal costs, that would result.

These issues make it difficult to estimate with much certainty the prospective benefits of a proposed rule. However, if we assume that the injuries presented in Table 1 provide a generally accurate estimate of the annual injuries that would be prevented by the proposed rule, and that the risk associated with the use of substitute products is small, the expected benefits might amount to roughly $25 million annually.

Potential Costs of a Rule Prohibiting Certain Magnetic Desk Sets

The profits of firms represent a measure of the benefits to businesses that result from the production and sale of products. Similarly, the use value or "utility" that consumers receive from products represent the benefits of product use by the consuming public. Consequently, the costs of a proposed rule that effectively bans certain magnetic sets would consist of: (1) the lost profits to firms that would be barred from producing and selling the product in the future, and (2) the lost use value experienced by consumers who would no longer be able to purchase the prohibited magnets at any price.

Market Wide Profits

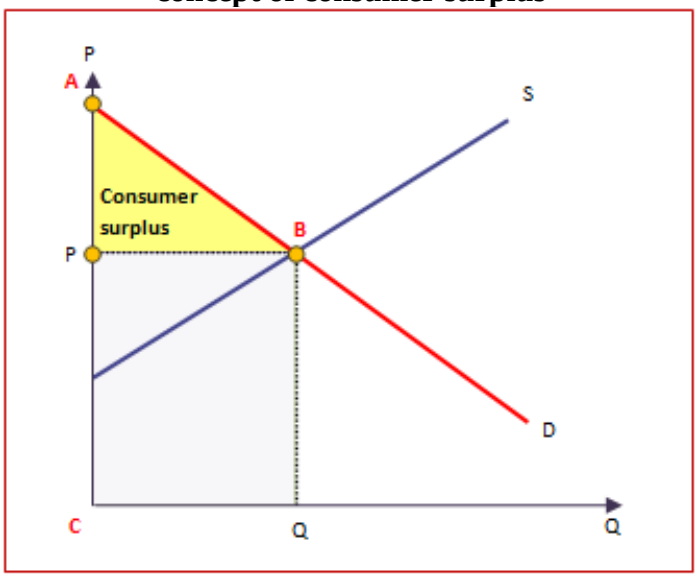
First consider profits, which would be defined as the total revenue (TR) received by firms resulting from the sale of the subject magnets, less the total costs (TC) needed to produce, distribute, and market them. We do not have firsthand knowledge of the profits of firms marketing the magnetic desk sets, but we do have information that may help us provide an upper limit.

Based on the available information described earlier, sales of the magnetic desk sets may have averaged roughly 1 million sets annually during the 2009−2011 study period, with an average retail price of about $25 per set. Thus, total industry revenues may have averaged about $25 million annually (*i.e.*, 1 million sets × $25 per set). Additional information provided by firms to the Office of Compliance and Field Operations suggests that the average import cost of the magnets to U.S. importers may have amounted to about $10 per set, or an annual average of about $10 million (*i.e.*, 1 million sets × $10 import cost per set). Thus, total revenues, less import costs, might have averaged about $15 million annually (*i.e.*, $25 million − $10 million). While the share of profits out of this $15 million in net revenues is unknown, it seems unlikely that profits would amount to more than about half, or about $7.5 million annually. Thus, the costs of a proposed rule in terms of reduced profits might amount to as much as $7.5 million on an annual basis.[33]

Lost Utility to Consumers

We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe it conceptually. In general, it includes the amount of: (1) consumer expenditures for the product, plus (2) what is called "consumer surplus." In the case of the magnetic desk sets, given sales of about 1 million annually, and an average retail price of about $25, consumer expenditures would amount to about $25 million annually. This $25 million represents the minimum value that consumers would expect to get from these products. It is represented by area of the rectangle CPBQ in the standard supply and demand graph below, where P equals $25, and Q equals 1 million units.

Figure 1. Supply and demand graph illustrating the concept of consumer surplus



[33] While most of these potential profits would accrue to importers, which also sell the magnetic desk toys directly to consumers, some portion would accrue to other retailers.

The consumer surplus is given by the area of the triangle PAB under the graph's demand function, and represents the difference between the market clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they had to pay (McCloskey, 1982; OMB, 2003).[34] For example, while tickets to a concert or football game might sell for $100 each, some consumers who buy them for $100 would have been willing to pay $150 per ticket. In other words, they paid $100 and received benefits that they value at $150. Hence, each of these consumers would receive a *consumer surplus* of $50.[35]

In general, the use value for the magnetic desk toys obtained by consumers is represented by the area of the trapezoid CABQ. However, the prospective *loss* in use value associated with the proposed rule prohibiting certain magnetic desk sets would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the prohibited product, but they would, nevertheless, still have the $25 million (represented by the rectangle CPBQ) that they would have spent on magnetic sets in the absence of a ban. While they can no longer purchase magnetic desk sets, which would have been their first choice, they can use this money to buy other products providing use value.

We have no information regarding aggregate consumer surplus, and hence, the amount of utility that would be lost from a ban of magnetic sets. While the magnetic desk sets clearly provide "utility" to purchasers, they are not necessities. Consequently, the demand for magnetic desk sets is probably *not* price inelastic, a factor that would tend to reduce estimates of utility losses.[36] Additionally, if the magnetic sets are "faddish," they may not be the type of product that will be used intensively by consumers over long periods of time. However, if, for example, consumers who purchased the magnetic sets at an average price of $25 would have been willing to spend, on average, $35 per set, the lost utility from the desk sets might amount to about $10 million on an annual basis (*i.e.*, [$35−$25] × 1 million units annually).

Finally, it should be noted that the loss in consumer surplus just described represents the maximum loss of consumer utility from the proposed rule; the actual loss is likely to be lower. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased in the place of magnetic desk toys. If, for example, there were close substitutes for magnetic desk sets (*i.e.*, desk toys that are almost as satisfying and similarly priced), the overall loss in consumer surplus (and hence the costs of the proposed rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the

[34] The concept of consumer surplus has been discussed in several CPSC staff analyses, including Tohamy (2006) and Rodgers (2004).

[35] If the above graph represents the market for tickets, the demand curve (AD) describes the quantity of tickets demanded at each price (*i.e.*, the quantity of tickets consumers are willing and able to purchase at each price). In this example, the $150 the consumer would have been willing to pay for the ticket is represented on the demand curve at a point to the left of point B. The consumer surplus is given by the relevant point on the demand curve (*i.e.*, where price = $150), minus the market clearing price of $100.

[36] To say that the demand for a product is price inelastic means that the quantity demanded tends to be insensitive to changes in the price of the product. Gasoline is an example of a product with an inelastic demand. Consumers are not likely to reduce substantially their purchase of gasoline (at least in the short run) even if the price increases substantially.

proposed rule would tend to be higher. Nevertheless, the proposed rule will result in some level of lost utility. By purchasing magnetic desk sets rather than other products, consumers are revealing that they have a preference for the magnetic desk sets that are likely to provide more utility than a substitute purchase.

Sensitivity of Results to Product Life Assumptions

Implicit in this analysis has been the assumption that the expected useful life of the magnetic desk sets is about 1 year. Since this product has only been in widespread consumer use since 2009, this assumption is made without extensive knowledge about the actual use of the magnetic sets by consumers. Magnetic desk sets are relatively durable products purchased at an average price of about $25. However, many consumers may find them to be novelties that soon lose much of their appeal. Thus, even if some of the products remain in homes or offices longer than a year, the risk of ingestion by children may be much higher in the first month or two after they are purchased. Consequently, it seems reasonable to assume that the effective useful product life of magnetic desk toys is, on average, no more than about a year.

However, it should also be noted that the results of our analysis are not particularly sensitive to this product life assumption. For example, had we assumed that the average product life was about 2 years, rather than 1 year, estimates of the number of sets in use at any given time would approximately double, reducing the estimated *annual* risk of injury, per magnetic desk set in use (and hence, reduce estimated societal costs per set) by about half. However, this reduced estimate of annual societal costs would itself be offset by the fact that the sets remain in use for 2 years, rather than 1 year. Thus, annual benefits, per magnetic set in use, would be halved, but benefits would be accrued over 2 years rather than one year. Consequently, even if we had doubled the assumed product life, the relationship between benefits and costs would have remained about the same.

Alternatives to the Proposed Rule

There are several possible alternatives to the proposed rule prohibiting certain magnetic desk sets that the Commission might consider.

Alternative Performance Requirements

As an alternative to the draft proposed rule, the Commission could consider promulgating an alternative set of requirements that could reduce the risk of injury from magnetic desk toys. Such requirements might allow a different flux index for the magnets sold as manipulative desk sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have not yet been developed (but are not as stringent as in the proposed rule). The advantage of such an approach is that it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets and at the same time allow adults to continue to use the product. One practical question, however, is whether such a standard would eliminate or substantially affect the physical qualities of the products that make them enjoyable for adults. Additionally, the expected injury reduction would depend upon the parameters of the requirements that are set.

Require Safer Packaging

The Commission could require magnetic desk sets to be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such a requirement might prevent injuries resulting from a small number of magnets being separated from a set without the owner being aware. In reality, though, many consumers may not use such containers because it could require time to form the magnets into a shape, such as a cube, which the containers would require, or they might wish to keep the magnets out of their container in a shape or structure that took time and effort to construct.

Alternatively (or in combination), the Commission could require the magnets to be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may suffer from several practical problems. It would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnetic desk sets because of the level of inconvenience it would involve (Sedney & Smith, 2012). Also, for the reasons described above, consumers may leave magnets outside of their container.

Warnings

The Commission could require strong warnings on labels and on product instructions designed to prevent the use of the magnetic desk toys by children. The Division of Human Factors, Directorate for Engineering Sciences (HF) memorandum contains an extensive discussion concerning warnings and their potential effectiveness (Sedney & Smith, 2012). Based on HF staff's examination, the ingestion warnings that currently accompany magnetic desk sets are generally aimed at adults, but appear to be deficient in terms of their content. For example, some warn against children swallowing the magnets without describing the incident scenarios. Some warnings refer to the propensity for swallowed magnets to stick to intestines without referring to the presence of other magnets or metal objects. Others warnings did refer to magnets sticking together or attaching to other metallic objects inside the body, but without explaining that the magnets can attract through the walls of the intestines and forcefully compress these tissues, resulting in serious injuries. According to HF, without detailed information in the warnings, consumers may not really understand how swallowing magnets differs from swallowing other small parts or how magnets sticking together could pose a hazard.

HF staff believes that it may be possible to develop warnings that could adequately communicate the ingestion hazard, the consequences of ingestion, and how to avoid the hazard. To the extent that the subject magnets present a "hidden" hazard about which consumers are unaware, explicit and adequate warnings could reduce ingestions and allow adults to continue to enjoy the use of the product. However, the effectiveness of such warnings is unknown, and HF doubts that even well-written warnings would substantially reduce the incidence of magnet ingestions. Some caregivers who read and understand the message may attempt to keep the magnets out of the hands of young children, but HF staff doubts many caregivers would attempt to keep the product away from older children and adolescents. Additionally, HF staff is doubtful that children old enough to understand the warnings would abide by them.

Restrictions on the Sale of Magnetic Desk Sets

Another option for the Commission to consider might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Sales limitations or requirements for strong warnings might also be required on websites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings of the sort that HF staff has suggested could be developed.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard, and possibly reduce the number of ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk sets despite the warnings. Also, some children will get into the packaging, even if parents try to restrict the use of the desk sets. Nevertheless, combining sales limitations with explicit warnings might help some parents understand the hidden nature of the hazard, while at the same time allowing adults to continue to use a product that they apparently enjoy.

Address through Corrective Actions Rather than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While the staff believes this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

Summary

Based on reports to the CPSC, ingestions of small magnets contained in magnetic desk sets have caused multiple, high severity injuries that require surgery to remove the magnets and repair internal damage. However, because of the lack of definitive information on the number of injuries involving magnetic desk sets that would be prevented by a proposed rule, there is uncertainty concerning the benefits that would result. If we assume that the NEISS cases identified by the Directorate for Epidemiology staff as involving high-powered and/or ball-shaped magnet ingestions actually involved the magnets that would be prohibited, then the estimated benefits of the rule might amount to about $25 million annually.

The costs of the proposed rule, in terms of reduced profits for firms and lost utility by consumers, are also uncertain. However, based on annual estimates available for the 2009−2011 study period, these costs could amount to about $7.5 million in lost profits and some unknown quantity of lost utility.

There are alternative regulatory actions that the Commission could consider that might allow the magnetic desk toys to continue to be marketed. For example, the Commission could, by regulation issue alternative requirements or require warnings that explicitly describe the hazard and how to avoid it. Other options might be to develop requirements for the packaging of the magnetic desk sets (*e.g.*, develop requirements for child-resistant packaging) and/or place

limitations on how and where the magnetic desk sets can be sold. These alternative actions—which might be considered alone or in combination—would have varying levels of effectiveness.

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TAB F: Initial Regulatory Flexibility Analysis of a Rule that Would Prohibit Certain Small Powerful Magnetic Sets

TAB F

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

Memorandum

August 2, 2012

TO: Jonathan D. Midgett, Ph.D., Project Manager, Magnetic Desk Toys NPR
Office of Hazard Identification and Reduction (EXHR)

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

Deborah V. Aiken, Ph.D., Senior Staff Coordinator
Directorate for Economic Analysis

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

SUBJECT: Initial Regulatory Flexibility Analysis of a Rule that Would Prohibit Certain Small Powerful Magnetic Sets

Introduction

The U.S. Consumer Product Safety Commission (CPSC or Commission) has received information regarding incidents with, and hazards posed by, sets of small powerful magnets. Some of these incidents have required surgical removal of individual magnets contained in the sets that were ingested by children. Reported magnet ingestions have ranged from young children who put the magnets in their mouths to adolescents and teens who experimented with the sensation of magnets (*e.g.,* on their braces) or paired magnets to mimic tongue or lip piercings. These behaviors have led to the accidental swallowing of the powerful magnets, with unexpected and, sometimes, severe medical consequences, including significant damage to the gastrointestinal tract (Inkster, 2012). Based on these incidents, and the nature of the hazard, CPSC staff has prepared analyses in support of the possible issuance of a notice of proposed rulemaking (NPR) that would prohibit certain magnetic desk sets.

The Regulatory Flexibility Act (RFA) requires that rules proposed by the Commission be reviewed for the potential economic impact on small entities, including small businesses. Section 603 of the RFA requires the Commission to prepare and make available for public comment an Initial Regulatory Flexibility Analysis (IRFA) describing the impact of the proposed rule on small entities and identifying impact-reducing alternatives. The IRFA is to contain:

1) a description of the reasons why the action is being considered;

2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

4) a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities that will be subject to the requirement and the types of professional skills necessary for the preparation of the report or record; and

5) an identification, to the extent possible, of all relevant federal rules that may duplicate, overlap, or conflict with the proposed rule.

In addition, the IRFA must contain a description of any significant alternatives to the proposed rule that would minimize any significant economic impact of the proposed rule on small entities. Suggested alternatives for discussion include: different compliance or reporting requirements for small entities; classification, consolidation, or simplification of compliance or reporting requirements for small entities; the use of performance rather than design standards; and partial or total exemptions from coverage for small entities.

Description of the Proposed Rule

The draft proposed rule would prohibit the manufacture, import, and sale of certain magnet sets. It would apply to any aggregation of separable, permanent magnetic objects that is a consumer product intended or marketed by the manufacturer primarily as a manipulative or construction desk toy that uses the magnets for general entertainment, such as puzzle working, sculpture, mental stimulation, or stress relief. Magnet sets that do not meet the specified flux index limit and that have two or more magnets that would fit within the small parts cylinder would be prohibited.

Although characterized as a performance standard for magnets, it is important to note that the standard would effectively ban current designs of magnetic desk sets of the type that have become popular in recent years.

Reasons for Considering the Proposed Rule

As noted above, some of the incidents involving ingestions of magnets from desk sets that have come to the Commission's attention have resulted in severe medical consequences, including significant damage to the stomach or intestines. Based on a review of emergency department-treated magnet ingestions obtained through the National Electronic Injury Surveillance System (NEISS), the Directorate for Epidemiology staff has identified 72 magnet ingestions from 2009 through 2011, which were determined to involve, or possibly involve, the magnets of interest (Garland, 2012). Based on these injuries, staff estimates that there has been an *annual* average of about 572 emergency department-treated injuries involving the products, including 537 injuries that were treated and released and 35 injuries that were hospitalized (Smith, 2012). Additionally, based on estimates from the CPSC's Injury Cost Model (ICM), which is integrated with NEISS, there were 870 other injuries treated annually outside of hospital emergency departments, such as in doctors' offices and clinics. The estimated total of 1,442

medically attended injuries involving magnet ingestions that were defined as at least "possibly of interest," resulted in average annual societal costs of nearly $25 million during 2009 through 2011, based on estimates provided by the ICM.[37]

The Commission is required to consider whether appropriate voluntary standards could adequately address the problem rather than the imposition of a mandatory rule. The Commission is unaware of any voluntary standard that addresses the risks presented by the subject products. Deferring to a voluntary standard, therefore, is not an alternative to the draft proposed rule. Other regulatory alternatives available to the Commission that could reduce the economic impact on small businesses are discussed below.

Products within the Scope of the Proposed Rule

Manipulative desk sets that are within the scope of the proposed rule are comprised of sets of small powerful magnetic balls, cubes, and/or cylinders that can be arranged in many different geometric shapes. The products have been described as desk toys, games, puzzles and stress relievers. These products were introduced in 2008, but the first year with significant sales to U.S. consumers was 2009.[38] Most have been sold in sets of either 125 balls or sets of 216 to 224 balls. Some firms have also sold sets with fewer than 100 balls or have sold just a few balls as extras, and others have sold large sets of over 1,000 magnetic balls. Based on product information provided by marketers, the most common magnet size is approximately 5 mm in diameter, although balls as small as about 3 mm have been sold, as well as sets of larger magnet balls (perhaps 15 mm or larger in diameter).[39] In addition to magnetic ball sets, sets of small magnetic cubes are also sold, although they have comprised a relatively small share of the market. The leading marketer of magnetic desk toys has recently added to its desk toy product line small magnetic rods intended to be used with balls to make geometric shapes.

The small powerful magnets most likely to be affected by the proposed rule are made from alloys of neodymium, iron and boron. This composition has been confirmed in analyses of product samples by personnel of the CPSC's Directorate for Laboratory Sciences. The magnetized neodymium-iron-boron cores are coated with metals (*e.g.,* nickel, silver, and gold) and other materials to make them more attractive to consumers, to provide a range of colors, and to protect the brittle magnetic alloy materials from breaking, chipping, and oxidizing.

[37] In addition to medical costs, the societal costs of injuries estimated by the ICM include costs related to work losses, legal and liability expenses, and costs associated with pain and suffering (Miller et al, 2000).
[38] However, small spherical neodymium-iron-boron magnets previously have been marketed, and continue to be marketed, by firms such as magnet suppliers and distributors of educational products.
[39] One firm's larger magnet balls are made with cores of strontium ferrite ($SrO{\cdot}6Fe_2O_3$), rather than neodymium-iron-boron.

The Market for Magnetic Desk Sets, Small Businesses Subject to the Proposed Rule, and Possible Economic Impacts

The draft rule would impact U.S. importers and retailers of manipulative desk sets that are comprised of small powerful magnets of the size and magnetic force proscribed by the rule. None of the magnetic desk sets within the scope of the proposed rule are produced domestically. All of the firms that have marketed the products are believed to import them from manufacturers in China, packaged and labeled for sale to U.S. consumers. The Directorate for Economic Analysis has indentified about 25 firms and individuals in the United States that have recently imported the product for sale to consumers. All of the importers are small businesses under U.S. Small Business Administration (SBA) size standards (SBA, 2012).[40]

Based on information on product sales reviewed by the Directorate for Economic Analysis staff, including reports by firms to the Office of Compliance and Field Operations (Compliance), the number of manipulative magnetic desk sets that have been sold by U.S. importers since the products were introduced in 2008 may total about 2.7 million sets, with a value to the firms of roughly $50 million. This value range reflects a combination of retail sales directly to consumers (through company websites and other Internet retail sites) and sales to retailers who market the products.

Although there are about 25 U.S. importers of magnet sets that would fall within the scope of the rule, the economic impact of the rule will be most severe for the seven firms that account for the great majority (perhaps over 98%) of units sold. Perhaps five of these larger importers derive most or all of their revenues from the sale of magnetic desk toys falling within the scope of the rule, or related products, such as books and surfaces upon which magnetic designs are constructed. These firms would be severely affected by the proposed rule, which would effectively ban the magnet sets that they have been importing and selling. Consequently, and they may go out of business. Two of the other leading importers of magnetic desk sets apparently have fairly broad product offerings, which could lessen the severity of the economic impact of a rule. Nevertheless, the impacts of the draft proposed rule could be considered to be significant for these small importers.

Nearly all of the perhaps 18 other recent U.S. importers of magnetic desk sets have sold relatively few of the products. These importers sourced the products from manufacturers in China and have marketed the magnet sets through online "stores" maintained on Internet retail sites. Many of these importers are individuals who may also market a variety of other products through the same Internet outlets. For individuals and firms with these business models, the discontinuance of certain magnetic desk sets as a source of revenue as a result of the rule is less likely to cause significant economic hardship, unlike the firms or individuals who derive most, or all, of their revenues from sales of magnetic desk sets and related products.

[40] The SBA size standard for "Other Miscellaneous Nondurable Goods Merchant Wholesalers" (which includes importers) is 100 employees and the size standard for "Nonstore Retailers – Electronic Shopping" is $30 million in average annual receipts (SBA, 2012).

Although a large share of magnetic desk sets are sold directly to consumers by the importers using their own internet websites or other internet shopping sites, a rule prohibiting these products would also affect retailers of the products, whether selling them online or physically in stores. However, these retailers are not likely to derive significant proportions of total revenues from sales of affected desk sets, and the impacts on individual firms should be minimal.

Objectives of and Legal Basis for the Draft Proposed Rule

The purpose of the draft proposed rule is to reduce the risk of injury from ingestion of one or more small, powerful magnets that comprise the subject consumer products. As noted above, the estimated total of 1,442 medically attended injuries involving magnet ingestions that were defined as at least "possibly of interest" resulted in annual societal costs of about $25 million during the 2009 to 2011 time period. It is expected that the draft proposed rule will substantially reduce the future incidence and cost to society of ingestions of the subject magnetic desk sets. The rule is being proposed under the authority of the Consumer Product Safety Act (CPSA). Under Section 8 of the CPSA [15 U.S.C. § 2057]:

> *. . . whenever the Commission finds that (1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and (2) no feasible consumer product safety standard under this Act would adequately protect the public from the unreasonable risk of injury associated with such product, the Commission may, in accordance with section 9, [15 U.S.C. § 2058], promulgate a rule declaring such product a banned hazardous product.*

Other Federal Rules

Staff is not aware of any federal rules that may duplicate, overlap, or conflict with the draft proposed rule.

Alternatives to the Draft Proposed Rule

There are possible alternatives to the draft rule, which would reduce the impact of a rule on small businesses. These alternatives would include the following:

a) Adoption of a Standard with Different Provisions

As an alternative to the proposed rule, the Commission could consider the promulgation of a different set of performance requirements that could reduce the risk of injury from magnetic desk sets. Performance requirements might require a different flux index for the magnets sold as manipulative desk sets, different specifications regarding shapes and sizes of magnets within the scope of the standard, or some other criteria that have not yet been developed. The advantage of such an approach is that it could reduce the potentially unreasonable risk of injury associated with magnetic desk sets and, at the same time, allow adults to continue to use the product. One practical consideration, however, is whether such a standard would eliminate or substantially reduce the physical qualities of the products that make them enjoyable for adults.

b) Requiring Safer Packaging

In theory, magnetic desk sets could be sold with special storage containers that are fitted to the product so that consumers would be able to determine whether any of the magnets were missing from the sets. Such a requirement might prevent injuries resulting from a small number of magnets being separated from a set without the owner being aware. In reality, though, many consumers might be unlikely to use such containers because it could require time to form the magnets into a shape, such as a cube, that the containers would require, or they might wish to keep the magnets in a shape they took time and effort to construct.

Alternatively, magnets could be sold in child-resistant packaging. Such an approach has the potential to reduce ingestion injuries, but it may suffer from several practical problems. It would not prevent teens and adolescents (and even some younger children) from opening the packaging. Additionally, the packaging would have to be secured after each use. According to the Division of Human Factors, it is unlikely that adults would accept child-resistant packaging for a product like the magnetic desk toy because of the level of inconvenience it would involve (Sedney & Smith, 2012).

c) Warnings/Labeling Requirements

The Commission could require labeling on affected magnetic desk sets to warn consumers in lieu of a rule that prohibits the products. Following its evaluation of this alternative, the Division of Human Factors, Directorate for Engineering Sciences, concluded: "it may be possible to develop warnings that could inform parents and other caregivers better about the ingestion hazard, its consequences, and appropriate hazard-avoidance measures. Nevertheless, the resulting warnings may not be effective at motivating caregivers to comply, and therefore, they may not reduce substantially the incidence of magnet ingestions" (Sedney & Smith, 2012).

d) Restrictions on the Sale of Magnetic Desk Sets

Another option might be to prohibit sales of magnetic desk sets in toy stores, children's sections of general purpose stores, and near cash registers of stores that sell any children's products. Advertising and sales limitations or requirements for strong warnings might also be required at web sites advertising the sale of magnets on the Internet.

The details for developing a set of sales limitations and requirements would need to be worked out, but the idea would be to make sure that magnetic desk sets, to the extent possible, are not sold at locations where children are likely to be present. Sales requirements might also be combined with strong and explicit warnings of the sort that HF staff has suggested could be developed.

Such sales limitations, in combination with adequate and explicit warnings, may increase consumer awareness of the hazard and possibly reduce ingestions. Some parents would still allow their children (especially older children and adolescents) to play with the magnetic desk

sets despite the warnings. Also, some young children will get into the packaging even if parents try to restrict the use of the products. Nevertheless, combining sales limitations with explicit warnings might help parents understand the hidden nature of the hazard, while at the same time allowing adults to continue to use a product that they apparently enjoy.

e) Address through Corrective Actions Rather than Regulatory Action

Alternatively, the Commission could continue to address the hazard by means of Corrective Action Plans. While the staff believes this approach may be deficient, such a strategy might be combined with other actions described above to achieve some reductions in the hazard.

f) Taking No Action

The Commission could determine that no rule is reasonably necessary to reduce the risk of ingestion injuries associated with magnetic desk sets. Under this alternative, future societal losses would be determined by the numbers of products in use, other factors that affect the likelihood that young children, adolescents, and teens will ingest the magnets, and the awareness and response of the medical community to the hazards presented by ingested magnets. Over time, increased awareness of the hazards by caregivers could make it more likely that the magnets will be kept away from young children and older children, and school personnel could be made more aware of the hidden dangers of using strong magnets to mimic tongue or lip piercings. Also, the medical community seems to be taking steps to become better educated about the risks of ingested magnets, which should lead to quicker monitoring of patients' medical status that would reduce the adverse medical consequences of magnet ingestions.

Summary

The results of this IRFA suggest that the proposed rule would likely have a significant adverse impact on seven of the small importers of magnetic desk sets; perhaps five of these firms that derive most or all of their revenues from the sale of magnetic desk sets might go out of business. Some possible alternatives to a rule prohibiting the products have been identified. All of these alternatives would reduce the expected impact of the rule on small businesses. However, these alternatives might not achieve the same level of benefits as the proposed rule.

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TAB G: Small, Powerful Magnets - Summary of Compliance Action