



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

This document has been electronically
approved and signed.

Memorandum

Date: August 20, 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: Staff Responses to Questions about the Notice of Proposed Rulemaking for
Hazardous Magnet Sets

This memorandum provides staff responses to questions from Commissioner Nord about the Notice of Proposed Rulemaking for sets of small, powerful magnets.

Questions:

1. *Staff states that “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.” Draft Federal Register Notice p.34.*
 - a. *Has Staff drafted any warnings in an attempt to create a “clear, explicit, and accurate description of the nature of the hazard and its consequences”? If so, please provide drafts of the warnings.*
 - b. *If Staff has not yet attempted to draft a “clear, explicit, and accurate” warning, please describe the contours of one—including pictograms (or descriptions of pictograms) if appropriate.*

Staff has not drafted any warning language intended to describe the ingestion hazard associated with strong magnet sets, and the potential consequences of that hazard, in a clear, explicit, and accurate manner. As noted in the NPR briefing package, staff believes that developing an understandable warning that could communicate the ingestion hazard, its consequences, and appropriate hazard-avoidance measures may be possible, but to be effective, warnings must be seen, believed, and heeded. Staff believes that even the most carefully designed warning would

be inadequate to prevent the injuries associated with magnet sets because the warning is unlikely to be seen, believed, or heeded by consumers.

Many current warnings that accompany strong magnet sets describe the hazard as swallowing or ingesting magnets, and staff agrees that this information should be included in a warning. Staff also believes that additional text that describes the primary incident scenarios that might lead to ingestion among older children and adolescents (*e.g.*, simulating piercings), whom caregivers otherwise are unlikely to believe would put magnets into their mouths, should be considered. However, staff recognizes that adding such text may inspire older children to perform these behaviors if they had not already considered the possibility of using the magnets in these ways. In addition, older children warned against performing these activities might view such warnings as attempts to restrict their personal freedoms or self-expression, which could have the unintended and opposite effect of encouraging the behaviors the warnings were intended to prevent.

A warning about the magnet ingestion hazard should describe the specific mechanisms of the hazard. For example, it might include the idea that magnets can move suddenly and unexpectedly inside the mouth, thereby causing the victim to swallow them unintentionally. It should describe that the hazard exists upon ingestion of two or more magnets, or that it could occur upon ingestion of one magnet and another ferromagnetic object, even if there has been a delay between ingestions. It also should describe how these items can attract one another through the tissues of the gastrointestinal tract, can forcefully compress and damage these tissues, and may not pass through the victim's system without surgical intervention.

The warning should describe explicitly actions that consumers should take to prevent exposure to the hazard. Current warnings pertaining to magnet ingestions tend to instruct consumers to keep the product away from children, but the warnings neither state specific ages at risk nor indicate the level of protection required (*e.g.*, lock in a secure place when not in use). Caregivers may differ in how they define "children" and may have difficulty determining the age at which a child can safely use the product. Lastly, a warning about the ingestion hazard must communicate all of this information concisely at an approximate sixth grade reading level.

Staff recognizes that supplementary graphics or pictograms can help communicate the hazard, its consequences, or appropriate avoidance behaviors. However, the design of effective graphics can be difficult. Some seemingly obvious graphics have been found to be understood poorly, and some may give rise to interpretations that are opposite the intended meaning. Thus, at this point, staff is uncertain about the types of graphics or pictograms that might be appropriate for use in a warning.

All of these difficulties conspire against the creation of an effective warning for this product category.

2. *The Commission's regulations specify warnings for many products—including balloons, small parts, and small balls—that may be present only on the product's package, not*

affixed directly to the product. Please identify those products or product categories for which warnings only on the package are acceptable.

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.

Generally, warnings about significant hazards should be located so that they communicate the necessary information to affected consumers in time to avoid the hazard. If the sole purpose of a warning is to influence the consumer's decision to purchase the product, then placing such a warning only on the packaging may be appropriate. Such an approach also might be suitable if the exterior packaging is highly likely to be retained and used repeatedly over the life of the product, if the warning remains conspicuous and legible.

However, if the product continues to present a significant hazard when separated from its packaging, and if people other than the purchaser are likely to interact with the product or to be exposed to the hazard, the warning typically should be affixed to the product. Staff recognizes that certain product features, such as space constraints on small products, may make the presence of a warning on the product itself impractical. Nevertheless, the impracticality of an on-product warning does not necessarily make a warning only on the packaging "acceptable" in terms of addressing the hazard if a significant hazard remains and affected consumers are unlikely to receive the warning.

In addition, warnings only on the product packaging are only useful in cases in which the product is received in its original packaging (*e.g.*, if the product is purchased new). If the product were acquired without its original packaging, the recipient would not receive the relevant warning information.

3. *Is it correct that many products or product categories when first introduced to the market pose hazards that may be unfamiliar to many users (generators and infant monitors, for example)?*
 - a. *Is it reasonable to conclude that greater familiarity with the products may better instruct the public as to the hazards and that injuries associated with the products will likely descend from an early peak?*

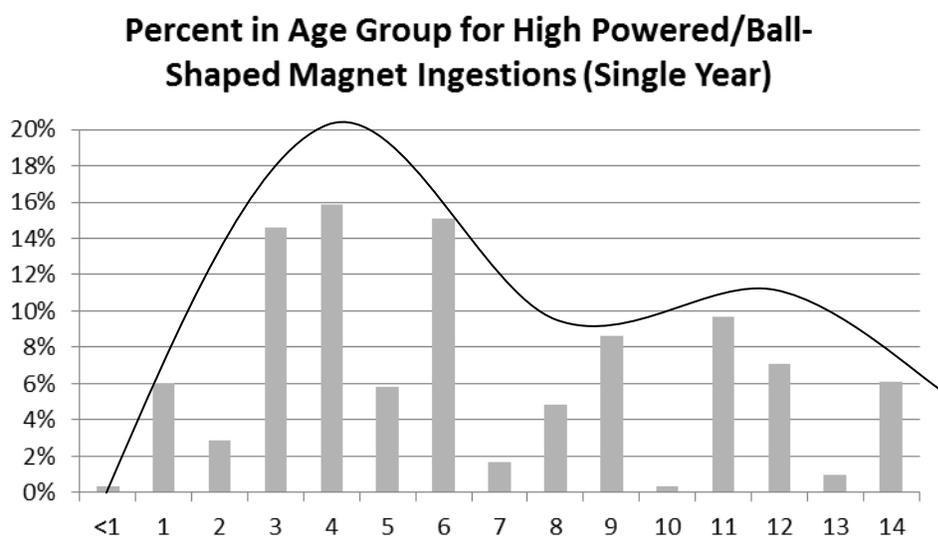
Staff agrees that when a product is introduced to the market, it may pose hazards that are unfamiliar to consumers. However, it does not necessarily follow that greater familiarity with the product would result in fewer injuries. Research has found that consumers generally are more likely to seek out warnings and other safety information on *unfamiliar* products, and are *less* likely to seek out and comply with this information as familiarity with the product increases. That being said, consumers who are more familiar with the hazards associated with a product and believe that they—or those whose safety they are responsible for—are susceptible to the hazard, are more likely to engage in hazard-avoidance behaviors than those who are not. In addition,

increased familiarity with activities that consumers perceive as being highly risky can increase compliance with warnings.

These findings suggest that with increased exposure to, and familiarity with, magnet sets, consumers may be less likely to seek out and read the warnings that accompany these sets and that supplemental hazard-communication efforts would be needed to improve consumer awareness of the ingestion hazard. With increased knowledge about the hazard, consumers may be more likely to attempt to keep the product out of the hands of children they perceive to be at risk. Whether this would result in a reduction in injuries is unclear, because such a reduction would require: (1) that caregivers are convinced that their children, even if older, are at risk, and (2) that caregivers are capable of preventing access to the product by at-risk children.

4. *Staff stated that magnet-set ingestions have a bi-modal distribution, but the NEISS-based estimates only describe a very broad distribution of ingestions (70% involve children aged 4 to 12). Please indicate the age ranges at each mode, and state the percentage of incidents occurring at each mode. If data is unavailable to draw a statistically sound conclusion, please provide estimates using the data that forms the basis of the staff's conclusion that the distribution is bi-modal.*

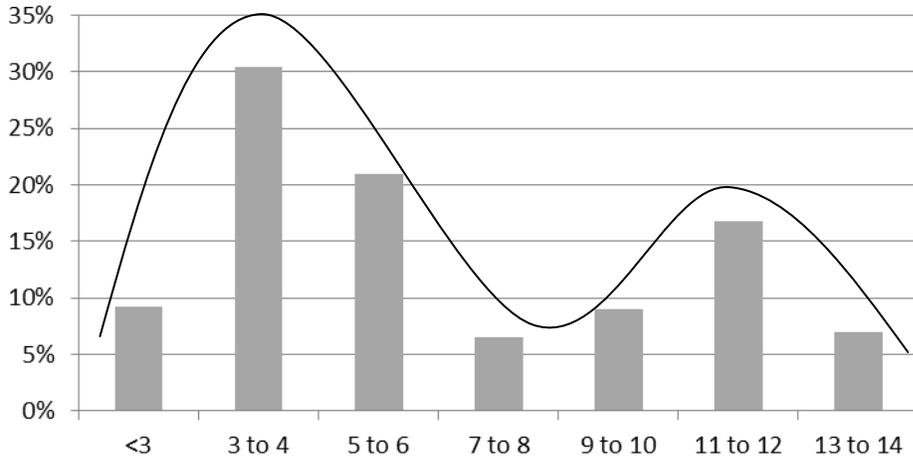
CPSC staff adhered to the established standards for reporting NEISS estimates, which is to refrain from releasing estimates of fewer than 1,200 (see Table 4 in the Epidemiology memo titled, "NEISS estimates and analysis of reported incidents related to ingestion of small, strong magnets that are part of a set of magnets of various sizes"). However, we appreciate that such a reporting restriction can make it a bit difficult to understand the relationship between age and these magnet set ingestions. The following graph shows the distribution of the 1,700 high-powered and/or ball-shaped magnet ingestions by single year of age:



Source: NEISS 2009-2011

A bimodal age distribution becomes more apparent with some aggregation of these age groups:

Percent in Age Group for High Powered/Ball-Shaped Magnet Ingestions (2-year aggregations)

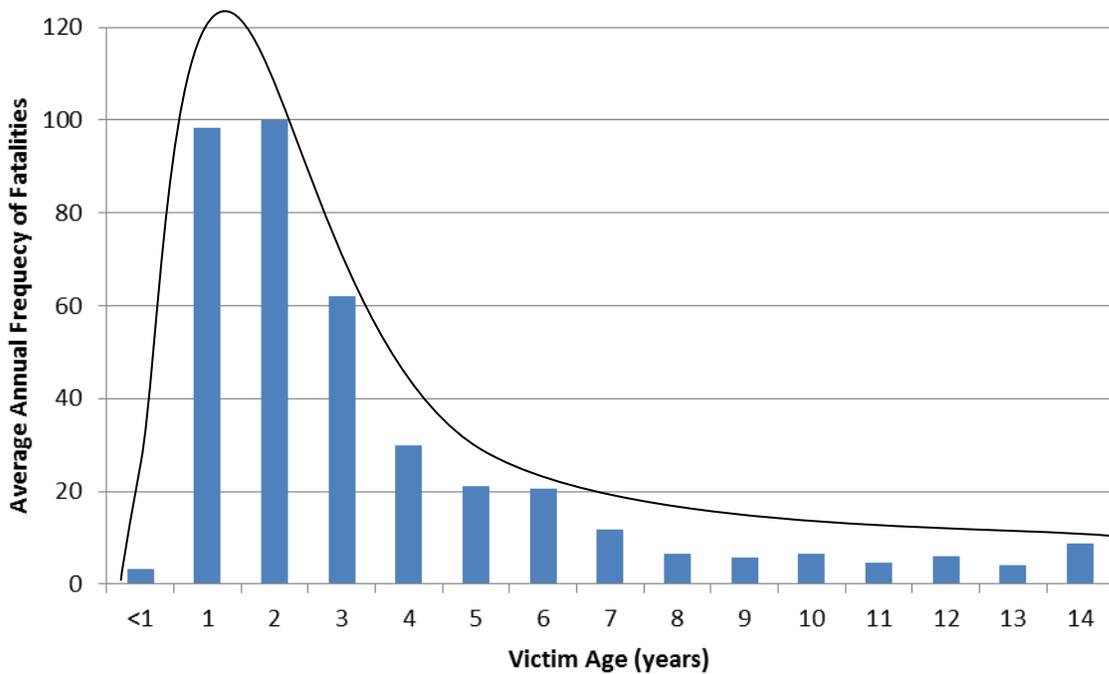


Source: NEISS 2009-2011

Seen this way, there is a peak in emergency department visits around ages 3–4, as well as an additional smaller peak around ages 11–12. This distinguishes it somewhat from a unimodal distribution with a single peak in the example below.

Example of a Unimodal distribution:

Average Annual Fatalities for Children Younger than 15 Years of Age by Age.



It is important to note, however, that the distribution by age for magnets does not meet the strictest statistical definition of a “bimodal distribution.” Strictly speaking, the mode is the number appearing most often among a set of numbers. The peak around age 11 is smaller than the one observed around age 4. Also, when viewed by single year of age, the small number of observations for particular ages (*e.g.*, 2, 5, 10, 13) means the shape of the distribution is not as smooth as one would expect with more data. More observations would likely provide a smoother distribution; however, it is unclear whether more data would provide a more classically bimodal distribution or one that is more unimodal and positively skewed.

5. *What combination of alternative actions described in staff’s Briefing Package, items 2 through 5, (see Draft Federal Register Notice pp. 31-7), would be the most effective at addressing the hazard covered by the proposed rule?*

As stated in staff’s briefing package, staff does not believe that any of these alternatives by itself or in combination would adequately reduce the risk of injury.

6. *What is Staff’s basis for concluding that magnets in magnet sets—other than those that are 3-to-6-millimeter spheres—pose the same hazard as the 3-to-6-millimeter spheres? Please describe your basis for at least the following three elements of the hazard posed by the alternative designs currently being marketed, and describe it for each of the two groups primarily involved in ingestions (see Question 5):*

- i. attractiveness,*
- ii. pattern of use or misuse, and*
- iii. the consequences of swallowing two or more magnets.*

Staff notes it is well recognized in the medical literature that young children, particularly up to 3 years of age, can and do intentionally, though inappropriately, ingest objects of various shapes and sizes, not just smooth shaped objects. In comparison to small spherical magnets, small 4 to 5 mm cube-shaped magnets will not feel “as comfortable” for a young child to mouth, but they can readily be swallowed in one “gulp.” As such, staff considers the relative risk of magnet ingestion injuries is only slightly reduced in young children with cube-shaped magnets of a similar size to small spheres.

For older children simulating tongue piercings, the pressure exerted on the tongue at the edges of a cube will likely feel somewhat less comfortable than the pressure applied by a sphere. However, even if used just one time to mimic a tongue piercing, the strong attraction-repulsion forces of cube shaped (or other shaped) strong magnets can cause them to interact in unexpected ways within the mouth, which can lead to unintentional swallowing. As magnets (and any other objects) increase in size, they become increasingly less easy to swallow and ingest, particularly if they have straight, angled edges rather than being smooth and curved. Larger, marble-sized, spherical objects can present an immediate airway occlusion choking hazard, particularly in younger children.

Once ingested, with regard to magnet ingestion pressure necrosis injuries involving different shaped magnets, staff notes that it has previously seen injuries requiring surgical intervention resulting from various magnet shapes and high strength magnet materials, including:

1. multiple neodymium-iron-boron NIB cylindrical magnets used in construction toys, (diameter from 4 to 6 mm);
2. multiple NIB disc magnets used in small playsets;
3. multiple irregular- shaped non-rare earth “sticky stone” magnets;
4. a pair of large elliptical non-rare earth “rattlesnake egg” magnets¹;
5. combinations of a cylindrical magnet with a stainless steel ball (non-magnet ferromagnetic object); and
6. combinations of a cylindrical magnet with a button battery.

All have resulted in similar injuries because, once ingested, two or more strong magnets, or one strong magnet and a ferromagnetic object, can interact in the same way within the digestive tract. For a specific location in the gastrointestinal tract, the size and relative strength of the individual magnet(s) and the number of magnets interacting can determine how much pressure is applied to the intestinal wall (which influences the rate at which tissue damage occurs). For the most common types of magnet injury, the contact area between the magnets can determine the size of a perforation (or fistula). The size of a GI perforation does not limit the potential severity of injury; even a perforation caused by a small fish bone can present a risk of peritonitis and sepsis if not treated quickly. Staff notes it has not yet seen any of the relatively rare volvulus injuries with desk set magnets, but reasons that the risk of such injuries seen with magnets in toys is likely to be presented by similarly strong magnets of any shape, if ingested.

a. To Staff's knowledge, are any new designs contemplated by any manufacturer? If so, please provide the answers to Question 6 for those designs.

Staff is aware of ellipsoid magnets, some of which fit within the small parts test cylinder and sold in pairs; spherical magnets the size of marbles and sold in sets of 30 and 64; spherical magnets measuring just under 1 inch and sold in sets of eight; and cylindrical magnets measuring approximately .94 inch x .21 inch and sold in sets of 36. Staff has evaluated only the ellipsoid and marble-sized magnets; the opportunity to examine the larger spheres and the cylinders was brief.

The ellipsoid magnets are distinct from the other types in that they are not a construction toy. Classified as a novelty “finger-fidget” toy, they are used by striking them together so that they vibrate and produce a distinct buzzing sound. They have general appeal as smooth, shiny, magnetic objects that make an interesting noise when manipulated correctly. Staff notes a GI pressure necrosis injury involving such products has been documented in the medical literature (see footnote for previous question).

¹ Revisiting Swallowed Troubles: Intestinal Complications Caused by Two Magnets—A Case Report, Review and Proposed Revision to the Algorithm for the Management of Foreign Body Ingestion *Viju Vijaysadan, MD, Maria Perez, DO, and David Kuo, MD, 2006, J Am Board Fam Med. 2006 Sep-Oct;19(5):511-6*

The marble-sized spherical magnet sets are marketed as “mega constructor” magnets and are sold with images of numerous forms or puzzles for the user to reproduce. The cylinders are shown on a video on the firm’s website, in combination with small spheres (presumably the firm’s 5-mm spheres) to form various geometric figures. The figures generally appear simplistic in comparison to the complicated and often detailed structures produced with spherical magnet sets. Expected use patterns with these two types of sets are similar to magnet sets of small spheres—that is, for use as puzzles, stress relievers, creative media, and as strong magnets to hold other metal objects and paper. However, the size of the larger spheres, the size and shape of the cylindrical magnets, the number of pieces in the sets, and the lower complexity of the forms associated with the products, suggest that they would likely be purchased for, and used by, children younger than 9 years old, the age at which staff graded the sets with small spheres.

The large (0.97 in) spherical magnets are displayed in still images on the firm’s website as what appears to be a desk accessory to hold paperclips and cards, or as a novelty item. The YouTube video² by the firm that introduces the product is more lively, and as with their other products, the packaging emphasizes how much fun they are. Use of the product by what may be a younger consumer demonstrates their use as what is typically referred to as a “finger-fidget toy” in the video at this link: http://www.youtube.com/watch?v=0Rw_bu7Syh8. The product seems likely to be used in this way as manipulative stress relievers as well, and they may be used as a base in combination with strong magnets of other sizes and shapes to form structures.

The products described, particularly the large spheres, are unlikely to be used frequently to mimic lip, tongue, or cheek piercings because of their size; however, despite the magnets’ large size, some children may use them this way, or try to, as a form of horseplay. As with the smaller magnets, children also may place one or more of the magnets in their mouths to explore the feel of the magnetic force or simply to satisfy an oral habit. It is possible that the size and shape of these magnets may make them somewhat easier to control in the mouth than the small spheres, thus, reducing the risk of unintentional ingestion; staff has insufficient information to make this assessment with any certainty. Young children (*i.e.*, those at risk from choking and ingestion hazards in general) would be as likely to mouth the pieces of these sets as the small spheres, perhaps more so because the size makes for easier handling, and the risk of exposure within the home setting may be higher. Further, ingestion among these younger children may be intentional.

7. At the August 8, 2012 briefing, staff explained that industry believed that a maximum flux index of 50 would protect magnet users against the hazards under review here. Does staff agree with that conclusion, given that staff expressed concern about the additive attractive and repulsive strength of magnets with a flux index of 50 in the Briefing Package? (See Staff Briefing Package, Tab D: Analysis of Magnetic Strength of Small Powerful Magnets, pp. 54-5)

The ASTM requirement of 50 flux index was based on ingestion incidents with individual bare magnets and magnets housed in components. CPSC staff is unaware of any incidents associated

² <http://www.youtube.com/watch?NR=1&feature=endscreen&v=9yGgEVdIUTo>

with toys or magnet sets with individual magnets with a flux index lower than 50 that have led to internal injuries. There are small NIB magnet discs that are 0.125 inches (3.2 mm) in diameter x 0.032 inches (0.79 mm) in height and have a flux index less than 50. When two to three of these magnets are stacked together, the flux index of the aggregated magnets can exceed 50. Staff purchased these small magnets through an Internet site that marketed various individual magnets. Staff has not seen any toys or “magnet sets” marketed with individual magnets of this size. Play value of magnets this small may be limited. This is why staff has sought comment in the draft federal register notice on this issue.

8. *Are any magnet sets that would meet the proposed rule – whether marketed to adults or children – sold today?*

Staff is unaware of any “magnet sets” on the market that that would meet the proposed rule. However, there are magnets available online that are not marketed as “magnet sets” that would meet the 50 flux index requirement. These are very small (around 2mm major dimension for NIB magnets) and play value may be limited.

9. *Staff says that magnet sets’ primary utility is in their entertainment value, as desk toys. Are there other uses, either actual or potential (for example, education, art and design, or modeling)? Please describe any non-entertainment uses.*

As described in the briefing package, magnets are used in school curricula to demonstrate the principles of magnetism. In general, this entails use of only one or a small number of magnets that are larger than those that typically are sold in magnet sets. Some firms claim educational benefits of simply using their magnet sets, such as improving math and geometry SAT scores, although they provide no evidence. The magnets in magnet sets, however, can be used to create and demonstrate simple and complex geometric forms and for more advanced educational pursuits.

For purposes other than education, staff is uncertain that there is a clear line between entertainment and non-entertainment as defined within the question. For example, the question suggests that use of magnet sets as two- or three-dimensional puzzles (*i.e.*, copying an existing form) would be entertainment, and that use of them as a medium to produce original art forms, or to explore designs or models of various types, would serve purposes other than entertainment. However, the latter examples would seem to fit as well into the category of arts and crafts, hobbies, or similar leisure activities. Examples observed on the Internet appear to fit largely in that category, although staff concedes that the short timeframe prevented extensive research of other uses of these products.

Staff notes that magnets are also sold in bulk and are available from online wholesale suppliers. These magnets are sold without packaging or marketing that promotes their use for any specific purpose. They could be used in any of the ways mentioned in your question, but could also be used as component parts of products, such as cabinet hardware, general fasteners, or for other purposes.