

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of)	CPSC Docket No. 12-2
ZEN MAGNETS, LLC,)	
Respondent.)	Hon. Dean C. Metry
)	Administrative Law Judge

COMPLAINT COUNSEL'S MOTION FOR SUMMARY DECISION
REDACTED

Pursuant to 16 C.F.R. § 1025.25, Complaint Counsel hereby moves this Court for summary decision on the grounds that there is no genuine issue of material fact and Complaint Counsel is entitled to judgment as a matter of law.

The motion is based upon the accompanying memorandum of points and authorities, statement of facts, exhibits, and the records of this case.

Pursuant to paragraph eight of the Protective Order entered on January 8, 2014, Complaint Counsel is filing this Motion and accompanying documents *in camera*. Complaint Counsel will timely serve on the Secretary, the Presiding Officer, and the Respondent a redacted version of the Motion and accompanying documents with confidential information redacted, so that the non-confidential portions of such documents may be part of the public record.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mary B. Murphy".

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September 26, 2014

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COMPLAINT COUNSEL'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR SUMMARY DECISION

REDACTED

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I. INTRODUCTION

Complaint Counsel filed an administrative enforcement proceeding pursuant to Section 15 of the Consumer Product Safety Act (CPSA) seeking a determination by the Court that small rare earth magnets (SREMs) known as Zen Magnets® Rare Earth Magnetic Balls (Zen Magnets) and Neoballs (collectively the Subject Products) present a substantial product hazard. The Subject Products are imported and distributed by Zen Magnets, LLC (Zen or Respondent).

The record establishes that there is no genuine dispute as to the material facts in this matter. The parties agree that the Subject Products are consumer products and that the matter is subject to the jurisdiction of the Commission.¹ The parties further agree that the Subject Products consist of small, rare earth magnets with a significant magnetic strength that are designed as manipulatives. (Facts, ¶¶ 8-9, ¶¶ 16-17, ¶ 19, ¶ 25). The parties agree that individual magnets in the Subject Products can and do become separated from the sets, and that children can and do access the individual magnets.² Finally, the parties agree that the Subject Products

¹ Under Sections 15(c), (d) and (f) of the CPSA, the Commission has jurisdiction over consumer products, defined as “any article or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of the consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise” 15 U.S.C. § 2052(a)(5). Zen admits the Subject Products are consumer products. (Complaint Counsel’s Statement of Material Undisputed Facts (“Facts”) ¶ 6), that it is an “importer” and “retailer” of Zen Magnets and Neoballs (Facts, ¶ 3), and that the Subject Products were “distributed in commerce.” (Facts, ¶ 7.)

² Facts, ¶¶ 30, 32-33, 37-38, 42, 44-46. When deposed, Zen’s president Shihan Qu testified that “by definition if you keep [magnets] away from pets and children who don’t understand them, then you wouldn’t lose them.” But when asked: “But the point is you know it happens right?” Mr. Qu answered “Yes. We know it can happen.” Ex. 4, Excerpts from Dep. of Shihan Qu at 150.

Zen representatives also corresponded with children using magnets and congratulated them on their use. In a June 13, 2010, email from a middle-school student titled “Wow,” the student wrote: “I’ve started a new middle school trend. [A]lmost every person in middle school has Zen Magnets . . . they’re everywhere, girls where [sic] them as necklaces, guys where [sic] them as bracelets it [sic] just AWESOME!” Zen’s president reacted not with alarm, but with congratulations: “Jonathan, That’s completely awesome to hear. :-) Good to hear our magnets are liked by trend-setters such as yourself.” Ex. 4, Qu Dep. at 565-66 & Ex. 4A, Ex. 40 to Qu Dep., June 13, 2010 email to Zen Magnets titled “WOW,” and Zen President Shihan Qu’s Feb. 17, 2010 response. Discovery revealed many communications between Zen and children discussing magnet use, parents discussing purchases of magnets for young children, or consumers writing to ask about the use of SREMs for costume jewelry. In a typical response,

pose a deadly risk of injury to children if ingested. (Facts, ¶¶ 50-56). Indeed, the President of Zen Magnets, Shihan Qu, admits in correspondence with CPSC staff that:

If two or more magnets or magnetic components or a magnet and another metal object (such as a small metal ball) are swallowed separately, they can attract to one another through intestinal walls. This traps the magnets in place and can cause holes (perforations), twisting and/or blockage of the intestines, infection, blood poisoning (sepsis), and death. When multiple magnets are ingested surgery is required to remove the magnets and sometimes sections of the intestine need to be removed.³

The Subject Products consist entirely of small, rare earth magnets designed specifically to be separated. Because consumers can separate the magnets and given their small size, magnets can easily be lost. (Facts, ¶¶ 23, 30). Consumers can also easily share subsets of the small, powerful magnets. (Facts, ¶ 45). Zen Magnets accommodates lost magnets by providing “spares” and encouraging users to separate individual magnets to share with others. Zen admits to furnishing to consumers tens of thousands of “spare” magnets. (Facts, ¶¶ 13, 30). Although the Subject Products do not appear hazardous, as few as two small magnets separated from sets as large as 1,728 contaminate any space they are in, creating a risk of injury or death to young children who find them and ingest them, and to tweens and teens who obtain them and use them to attach to braces or simulate tongue piercings and accidentally swallow them. The risk posed by these types of SREMs has been demonstrated repeatedly – one child has died as a result of SREM ingestion and dozens have been hospitalized or required surgery when ingested magnets have connected across gastrointestinal tissue within the body. (Facts, ¶¶ 50-56). There have been at least two known incidents involving the Subject Products and dozens more caused by unknown brand magnets that are virtually identical to the Subject Products. (Facts, ¶¶ 37-38, ¶¶

when asked whether “a really neat bracelet for my sister” was “a smart idea,” and “[w]ould it be unhealthy,” Zen’s president responded that using magnets as a bracelet is “a great idea. They won’t fall off easily.” Ex 4. Qu Dep. at 545-46 & Ex. 4B, Exh. 34 to Qu Dep., Feb. 17, 2010 email to Zen Magnets, titled “health question,” and Zen President Shihan Qu’s Feb. 17, 2010 response.

³ Ex. 34, Respondent Zen Magnet’s Full Report (dated May 29, 2012) at 4.

48-49). The condition creating the risk, i.e., loose, separable, accessible SREMs, constitutes the basic character of the Subject Products, and this amounts to a design defect that creates a substantial risk of injury to the public.

Warnings do not and cannot mitigate this risk. As a threshold matter, no warnings can attach to separated magnets because the small size of individual magnets precludes the addition of a warning. (Facts, ¶ 24). Moreover, no warning would be adequate to address the fundamental risk—injury caused by lack of containment—because the essence of the Subject Products as loose, separable magnets make containment impossible regardless of a warning.

The undisputed facts demonstrate that the Subject Products contain a defect which creates a substantial risk of injury to the public and therefore present a substantial product hazard. Accordingly, Complaint Counsel is entitled to judgment as a matter of law.

II. FACTUAL BACKGROUND

A. The Subject Products – Zen Magnets and Neoballs

Beginning in 2009, a number of manufacturers began to import and distribute aggregated masses of high-powered, small rare earth magnets. These manufacturers included former Respondent Maxfield & Oberton, LLC, which manufactured and sold 5 mm high-powered magnets under the name “Buckyballs,” and former Respondent Star Networks, Inc., which sold nearly identical magnets as “Magnicubes.”⁴

In September 2009, Respondent, manufacturer of the Subject Products, entered the SREM market, selling and distributing aggregated masses of high-powered shiny, metallic-colored

⁴ See Ex. 37, CPSC Release No. 14-172, Buckyballs and Buckycubes High-Powered Magnet Sets Recalled Due to Ingestion Hazard; Craig Zucker To Fund A Recall Trust, Settles With CPSC (dated May 12, 2014); Ex. 38, CPSC Release No. 14-248, Star Networks USA Recalls Magnicubes Due to Ingestion Hazard; Firm Settles Administrative Lawsuit, (dated Aug. 4, 2014). See also Ex. 4, Qu Dep. at 53 (Buckyballs are 5 mm spheres). In a letter to the Commission, Zen President Qu admits that “our competitors’ magnets . . . are similar in size and shape to ours.” See Ex. 9, Letter from Qu to “CPSC” titled “Re: your letter requesting us to shut down” (dated August 2, 2012).

magnets under the brand name Zen Magnets. (Facts, ¶¶ 4, 8). In 2011, Zen began distributing SREMs under the “Neoballs” brand name in a variety of colors. (Facts, ¶¶ 5, 9). The Subject Products are 5 mm spherical magnets. (Facts, ¶¶ 8-9). The Subject Products are not permanently encased in a storage container, but rather are an aggregation of individual 5 mm magnets that are made to be separated from each other. (Facts, ¶ 23). The Subject Products are designed as manipulatives that are intended to be made into various objects, including jewelry, artistic designs, models, sculptures and other structures. (Facts, ¶¶ 25-26).

Magnet strength is measured by flux index. The Subject Products have a flux index⁵ over 400 kG² mm² and are capable of attracting SREMs across a distance of 1.5 cm or greater. (Facts, ¶¶ 16-17). Thus, the Subject Products are “30 Times more powerful than the average fridge magnet.”⁶ The Subject Products can connect in configurations such as strings, rings or clumps and can also attract to nonmagnetic ferrous items such as steel ball bearings. (Facts, ¶¶ 20-21).

The Subject Products are about the same size as Buckyballs with magnetic forces “about the same” as Buckyballs. (Facts, ¶ 22). Both Buckyballs and Zen Magnets have been sold as metallic-colored spheres, and both Buckyballs and Neoballs have been sold in a variety of colored spheres, such as blue and red. (Facts, ¶¶ 8-10). Neither Buckyballs nor the Subject Products contain any brand identifiers or other markings on their individual magnets. (Facts, ¶ 24).

⁵ Flux index (kG² mm²) is calculated by multiplying the area of the pole surface (mm²) of the magnet by the square of the maximum flux density (kG²). Flux index is used to measure the strength of a magnet. Any magnet that is a small object with a flux index >50 is considered a hazardous magnet. See Ex. 8, F963-11 Standard Consumer Safety Specification for Toy Safety (2011) at 8.24.3.

⁶ Ex. 48, Ex. 13 to Qu Dep., Screenshots of Zen Magnets home page, <http://www.zenmagnets.com/>.

B. Sale of the Subject Products to Consumers

Zen Magnets and Neoballs are sold on Respondent's websites, www.Zenmagnets.com and www.Neoballs.com. (Facts, ¶ 62). The Subject Products can be purchased on these websites by anyone with a PayPal account, credit card, or the anonymous currency bitcoin. (Facts, ¶ 63). Zen Magnets have also been sold in retail stores, including in marijuana dispensaries and game stores. (Facts, ¶ 62). Zen plans to expand its distribution of the Subject Products to additional retail game stores and hobby stores, as well as other stores that previously sold Buckyballs brand magnets. (Facts, ¶ 64).

Zen-brand magnets are sold in sets of 72, 216, or 1,728 magnets. Zen Magnets also can be purchased individually, at a cost of approximately \$0.20 each. (Facts, ¶ 8). Neoballs, which were sold in 216-magnet sets from 2011 to September 2012, are now sold individually at a cost of \$0.06-0.10 per magnet. (Facts, ¶ 9). By October 2013, Zen had sold more than 50,000 sets of Zen-brand magnets to consumers in the United States. (Facts, ¶ 11). As of July 2013, in addition to selling more than 1,700 Neoball sets containing 216 magnets, Zen had "sold individually" 678,253 Neoballs. (Facts, ¶ 12).

Since 2009, Zen has used a variety of warnings on its websites and in its packaging. (Facts, ¶¶ 67-73). For example, from 2009 through mid-2011, the Zen Magnets website warned: "Be cautious with open chains. Can cause serious problems if swallowed. Do not give to kids under the age of 12, and keep them away from pets. Call poison control if more than 1 magnet is swallowed." (Facts, ¶ 67). In 2011, on the "buy" page of www.zenmagnets.com, Zen stated: "Magnets cause fatal intestinal pinching if swallowed. Keep from animals and children who don't understand this." (Facts, ¶ 68).

Beginning in November 2012, www.neoballs.com added a warning stating, “High power magnets may cause fatal intestinal pinching if swallowed. Keep away from all orifices [sic] If magnets are ingested or aspirated to the lungs, immediate medical attention is required. (Facts, ¶ 70). A similar “pop up” warning appears on the Neoballs purchase screen, stating in part: “Warning: Keep Away From Mouth. Practice responsible magnet usage!” (Facts, ¶ 72). Zen Magnets currently are sold with the following warning:

Warning: **DO NOT SWALLOW MAGNETS.** How old do you have to be to play with these? Dunno. 14 years old in the U.S. for a strong magnetic toy, unless it’s not a toy, then no age limit, but they’re fun magnet spheres, aren’t they a toy? Unless it’s a “science kit” then the government age recommendation is 8+. But really, it’s whatever age at which a person stops swallowing non-foods. Strong magnets can cause fatal intestinal pinching. Place swallowing magnets on your don’t do list along with breathing water, drinking poison, and running into traffic. Call poison control if more than one is swallowed. And keep these away from kids (and pets) who don’t understand these dangers. BTW, this is a “science kit” for sure. (Facts, ¶ 70).

Neoballs also includes a written product warning:

OMFG

READ ME

This is serious. The grumpy CPSC is about to BAN magnet spheres in the US because they are an ingestion hazard. They don’t trust that you are capable of understanding and following warnings. Prove them wrong, or we all can’t have nice magnets. Zen Magnets LLC, the producer of Neoballs, has had no record of ingestion and we’d like to keep it that way. High powered magnets can cause potentially fatal intestinal pinching if swallowed. Keep magnet spheres away from all orifices, especially the mouth and nose. High powered magnets are not a toy. Keep away from anybody who does not understand these dangers. SRSLY. Sorry about the lecture. We had to. Hope you understand. (Facts, ¶ 73).

These warnings do not and cannot appear on individual magnets due to the small size of the magnets. (Facts, ¶ 24). Moreover, these warnings do not warn users about any risks specifically associated with magnets that become separated from a set, and do not advise owners that they must find any lost magnets. (Facts, ¶ 31). Similarly, the warnings also do not advise owners that they should not share magnets. (Facts, ¶ 46).

C. How Children Obtain the Subject Products

Because the Subject Products are sold in containers from which they are meant to be removed, and because of the nature of the magnets, each individual magnet can be separated from the set and not returned to the storage container. Individual magnets may become lost or a Subject Product's owner may share them with others. Shihan Qu, who has personally lost magnets, states that "commonly magnets can be lost when sharing with friends. Sometimes they take some without intentionally doing so."⁷ Zen Magnets also indicates on its website that its magnets are likely to become separated from a set, responding to a customer who reported losing magnets: "Stories like this we hear all the time. Understandably. The magnets are small, easy to separate, and often stick where you may not expect."⁸

Magnets that have been lost or separated from a set come with no attached warnings and appear substantially the same as SREMs made by other manufacturers. (Facts, ¶¶ 24, 28). Because the individual magnets, which are sold in sets containing as many as 216 or 1,728 magnets, are so small and numerous, it may also be difficult for a Subject Product's owner to know that magnets have been lost unless the owner counts all of the magnets after each use. (Facts, ¶¶ 31-33).

Because use of the Subject Products requires removal from the container in which they are sold and because individual magnets become separated from the set, either through loss or purposefully, Zen sells great numbers of spares to replace Neoballs or Zen Magnets. (Facts, ¶ 13). In fact, recognizing that consumers likely will need replacement magnets for lost ones,

⁷ Ex. 4, Qu Dep. at 241-42. Mr. Qu admits that sometimes he is unsure whether magnets have been lost: "[I]f magnets are missing from one set, I generally assume that they're now part of another set or they have been placed somewhere else or slipped somewhere else." *Id.* at 242.

⁸ Ex. 5B, Expert Report of J. Paul Frantz, Ph.D., CPSC, CPE (dated July 16, 2014) at 12, Exhibit B to Declaration of J. Paul Frantz.

Zen provides spare SREMs in most of its magnet sets.⁹ Zen has provided its customers with more than [REDACTED] spares. (Facts, ¶ 13).

D. Young Children Are Able to Obtain the Subject Products

Young children can obtain the Subject Products either by removing them from a set to which they gain access, by finding individual magnets that have become separated from the set, or by being given magnets that already have been separated from a set.¹⁰ Such access can and does lead to ingestion by young children. A baby or toddler will likely intentionally put the magnet in his or her mouth to learn more about it. (Facts, ¶ 35). Babies, toddlers, and preschoolers learn about objects in their world through sensory exploration. (Facts, ¶ 34). Babies and toddlers especially learn about the world by putting things they want to learn about in their mouth. (Facts, ¶ 34). Their tongues, lips, and mouths are parts of their body over which they have the most control, and they use these parts of the body to explore the world around them.¹¹ In addition to being the result of such developmentally expected behavior, ingestion may occur because the magnets appear to some children to be pieces of candy.¹²

Children under the age of five are attracted to the Subject Products because the magnets are reflective, shiny and smooth. (Facts, ¶ 34). This age cohort wants to play with the Subject Products and are drawn to them.¹³ Children under the age of five are especially likely to be

⁹ See *id.* Ex. 5B, Frantz Report at 13 (Zen provides 6 spares with each set of 216 magnets and 8 spares with each set of 1,728 magnets).

¹⁰ See, e.g., Ex. 18, Decl. of S [REDACTED] A [REDACTED]; Ex. 21, Decl. of J [REDACTED] H [REDACTED]; Ex. 26, Decl. of M [REDACTED] J [REDACTED]; Ex. 27, Decl. of K [REDACTED] L [REDACTED]; Ex. 28, Decl. of A [REDACTED] C [REDACTED].

¹¹ Ex. 16, Decl. of Dr. Laurence Steinberg at ¶ 10.

¹² See, e.g., Ex. 27, Decl. of K [REDACTED] L [REDACTED] at ¶ 5.

¹³ See *id.* Ex. 16, Steinberg Decl. ¶ 9.

attracted to and want to play with Subject Products that are displayed as sculptures of commonly-recognized characters or objects.¹⁴

Caregivers acting with reasonable care are not able to prevent children under the age of five from playing with or using the Subject Products in ways that can result in ingestion. (Facts, ¶ 32-33). Caregivers who have not purchased the Subject Products are likely to have no way of knowing the risk that SREMs pose because such a risk is not obvious and individual magnets contain no warnings. Because of the small size and great number of magnets in a set, and the lack of warnings advising owners that they must account for all magnets in a set, even caregivers who purchased the Subject Products are highly unlikely to count the number of individual magnets in a set after each use to ensure that individual magnets have not become separated from the set or lost. (Facts, ¶ 32). Similarly, a caregiver acting with reasonable care likely will not search for magnets that have become separated from the set, and the Subject Product's warnings do not advise caregivers to do so. (Facts, ¶¶ 31-33, 67-72). Even if the caregiver does search for lost magnets, he or she may not be able to find them because of their small size. These scenarios provide access to the magnets by young children.¹⁵

E. Tweens and Teens Are Able to Obtain the Subject Products

Tweens and teens are also likely to gain access to the Subject Products and use them in ways that can lead to accidental ingestion. (Facts, ¶¶ 39-49). The Subject Products are easy to break apart and share without substantially altering the play value of remaining magnets in a set. (Facts, ¶¶ 45-46). Because they are easily replaced if shared, tweens and teens who obtain the Subject Products are likely to share them with other friends. Neither those who receive separated

¹⁴ See *id.* Ex. 16, Steinberg Decl. ¶ 13. See, e.g. Ex. 18, Declaration of S█████ A█████ at ¶ 7.

¹⁵ Ex. 16, Steinberg Decl. ¶ 12.

magnets from the Subject Products nor their parents and caregivers are provided with any warnings that may have been initially provided with the Subject Products.

Unlike infants and toddlers, tweens and teens generally do not intentionally swallow magnets.¹⁶ Adults therefore may not consider Subject Products dangerous because adults believe that older children are able to avoid intentionally swallowing nonfood objects. (Facts, ¶ 42). Older children and teenagers, however, can and do play with or use the Subject Products in ways that can lead to accidental ingestion. (Facts, ¶ 39-49).

Older children who have braces may want to test the magnetic properties of the Subject Products with the metal of their braces. (Facts, ¶ 44). Similarly, they may be looking for a way to experiment with behavior, such as facial piercing, that may be disapproved by their parents, believing that mimicking tongue piercings with the Subject Products is a safe way to experiment.¹⁷ Additionally, online videos of children or adults using magnets in such a manner may lead this age group to believe such behavior is safe to do themselves.¹⁸ All of this behavior is foreseeable and representative of behavior engaged in by children of this age. (Facts, ¶ 44).

F. Children Who Obtain SREMs May Suffer Severe Injury or Death

Incident reports obtained by CPSC staff and reviewed by Complaint Counsel's experts, including Dr. Adam Noel and Dr. Paul Frantz, contain approximately 100 reports of ingestions of SREMs.¹⁹ These reports include at least two incidents of ingestions of the Subject Products (Facts, ¶ 37, 48) and at least one death and dozens of incidents associated with SREMs made by other manufacturers or SREMs virtually identical to the Subject Products but whose brand was

¹⁶ Ex. 5B, Frantz Report at 48 (teens and tweens "do not intentionally swallow separated SREMs.")

¹⁷ *Id.* Ex. 16, Steinberg Decl. ¶ 17.

¹⁸ *Id.* Ex. 16, Steinberg Decl. ¶ 17.

¹⁹ Ex. 5B, Frantz Report at 35.

unknown to the child ingesting them or the caregivers and medical staff treating them.²⁰ A survey of pediatric gastroenterologists likewise reported 123 SREM ingestions.²¹ Many of these ingestion incidents required hospitalization or surgery to remove the ingested magnets. (Facts, ¶ 54).

The nature of the risk of injury posed by the Subject Products is unique and extraordinarily dangerous. In contrast to many other small objects young children ingest routinely, SREM ingestion has proved to be “a different type of foreign body ingestion” with a much higher rate of surgical intervention and a much higher rate of serious injury than other foreign body ingestions. (Facts, ¶ 54). If swallowed, SREMs are powerful enough to attract to another object or magnet through body tissue, causing pressure necrosis or “tissue death” if tissue is trapped between the two objects and the magnets are not removed. (Facts, ¶ 51). Children who have ingested SREMs have been treated for intestinal blockage, perforated intestines, infections, peritonitis (contamination of the body cavity when bowel contents leaks), and necrosis (tissue death) necessitating removal of sections of bowel.²² Some children have suffered the removal of most of their small bowel, rendering them unable to absorb sufficient nutrition through their digestive system, and requiring daily intravenous or stomach-tube feedings that bring with them a risk of infection or liver damage. (Facts, ¶ 55).

²⁰ In many reported cases of SREM ingestion, the brand name is undetermined because ingested 5 mm SREMs appear the same as the Subject Products, regardless of brand name. A technical assessment of the Subject Products by Complaint Counsel expert Vincent Amodio concurs that there is no meaningful technical differences between Zen Magnets, Neoballs, and Buckyballs. (Facts, ¶¶ 16-18). Dr. Adam Noel, Complaint’s Counsel’s expert witness, concludes that with respect to the injuries which are caused by the SREMs, the brand of magnet is “inconsequential.” (Facts, ¶ 58). The record establishes that if Zen Magnets or Buckyballs were swallowed, they would react identically in the human body. When asked “Do you have any reason to believe, given our conversation[,] that Buckyballs and Zen Magnets have about the same magnetic strength and very similar size, that they would react differently in the human body upon being swallowed?” Zen’s president answered “Upon being swallowed, no.” Ex. 4 Qu Dep. at 296-97.

²¹ Ex. 15, Noel Decl. ¶ 8.

²² Ex.15, Noel Decl. ¶¶ 9-10; Ex. 29, Dep. of Dr. R. Adam Noel at 84-85, 214.

Treatment of SREM ingestions is complicated by a lack of immediate medical intervention. (Facts, ¶ 52-53). Parents often are not aware that a child has ingested a magnet until much later, often sometime after the child begins exhibiting symptoms of stomach pain or vomiting, or after the magnets have been identified on an X-ray or in an autopsy.²³ Even if parents are timely advised of the ingestion by their child, they may believe that the magnets will pass, and do not seek immediate medical attention. (Facts, ¶53). Medical professionals often misdiagnose an ingestion because the symptoms frequently mirror those of a flu or stomach virus.²⁴ Even in cases where medical professionals have been advised that a child had ingested magnets, immediate surgical intervention has not been taken due to a lack of understanding of the mechanism of injury set forth above.²⁵ As Dr. Noel states: “[I]n a case where a child is sent home after ingesting magnets and they’re in there more than 12 hours, the possibility of having intestinal perforation is quite high.”²⁶ As a result, children who ingested SREMs suffered catastrophic injuries when separated magnets used their strong attractive power to pull together through bands of tissue in a child’s digestive tract. (Facts, ¶¶ 50-51, 54-56).

Even when children did not suffer long term injury, children who were treated for SREM ingestion may be subjected to multiple X-rays, CT scans, or endoscopy procedures to remove magnets from their digestive systems. (Facts, ¶ 57). Medical intervention necessitated by magnet ingestion is significant and expensive, even where no surgery is required.²⁷ Endoscopies for children usually require general anesthesia, and both of these procedures carry risks of injury or

²³ Facts, ¶ 52. *See, e.g.*, Ex.18, A [REDACTED] Decl. ¶¶ 12-13, Ex. 28, C [REDACTED] Decl. at ¶ 10.

²⁴ Facts, ¶ 52. *See e.g.*, Ex. 18, A [REDACTED] Decl. ¶¶ 12, 13, Ex. 28, C [REDACTED] Decl. ¶ 8.

²⁵ Facts, ¶ 53. *See, e.g.*, Ex. 23, B [REDACTED] Decl. at ¶ 5; Ex. 24, R [REDACTED] Decl. at ¶ 6; Ex. 25, A [REDACTED] Decl. ¶ 6.

²⁶ Ex. 29, Noel Dep. at 78.

²⁷ Ex. 15, Noel Decl. at ¶¶ 18-19; *see e.g.* Ex. 22, G [REDACTED] Decl. at ¶¶ 7- 11.

death.²⁸ X-rays and CT scans result in a cumulative increased risk of radiation, and children treated for SREM ingestions may require repeated scans during and after treatment.²⁹

A survey conducted by The North American Society of Pediatric Gastroenterology, Hematology, and Nutrition (NASPGHAN) documented SREM injuries and treatment of such ingestions (the NASPGHAN Study).³⁰ Dr. Noel, who was the author and primary researcher for the NASPGHAN Study,³¹ found that SREM ingestions, which might have been expected to decline as children got older, actually were reported to have peaked for children 3-6, declined slightly for children aged 6 to 9, then peaked again with a significant increase for children 9 to 12.³² Notably, the rates of treatment for ingestion of SREMs for children ages 12 to 15 were essentially equal to those of children ages 6 to 9.³³ This extraordinary increase in injuries for older children is unique to SREM ingestion.³⁴

The NASPGHAN Study also addressed clinical management of SREM ingestions and revealed that most children in the survey who ingested magnets had to undergo some type of medical intervention. Of the 123 SREM ingestion cases reported with clinical detail, 52% resulted in an endoscopy, 21% involved both endoscopy and surgery, and 6% of the cases involved only surgery. Only 21% of the reported cases required no invasive medical intervention.³⁵

²⁸ Ex.15, Noel Decl. ¶ 19.

²⁹ Ex. 15, Noel Decl. ¶ 19.

³⁰ Ex. 15, Noel Decl. at ¶ 5; Ex. 15A, Curriculum Vitae of Complaint Counsel Medical Expert Dr. R. Adam Noel, Ex. 15B, Neodymium Magnet Ball Ingestion Survey Results (NASPGHAN Study Results).

³¹ Ex. 15, Noel Decl. at ¶ 5.

³² Ex. 15, Noel Decl. at ¶ 7; Ex.15B, NASPGHAN Study Results at 4.

³³ *Id.*

³⁴ Ex. 15, Noel Decl. at ¶ 7.

³⁵ Ex. 15, Noel Decl. at ¶ 8; Ex. 15B, NASPGHAN Study Results at 8.

Among the children in the NASPGHAN Study who were exposed to endoscopy or surgery, 48% had intestinal perforation or fistula as a result of the magnet ingestion, 26% had deep pressure lesions caused by the SREMs, and 5% had mucosal erythema (redness and inflammation) or shallow erosion (eating away of the mucosal surface).³⁶ Of the children who underwent surgery, 16% required bowel resections (removal of portions of the intestines), and, tragically, 9% of the cases involving surgical intervention required long-term care.³⁷

In summary, SREMs create a serious and substantial medical risk to children if swallowed, as demonstrated by the increasing number of children undergoing procedures after ingesting the magnets from a set.³⁸ SREM ingestion injuries can be “a very quiet type of injury” because the child exhibits outward symptoms that can be easily confused with gastrointestinal virus or infection.³⁹

The difficulty in diagnosing ingestion of magnets adds to their risk.⁴⁰ Delays in diagnosis can exacerbate the seriousness of SREM-related injuries as magnets move beyond the reach of non-surgical interventions such as endoscopy, become fixed in the gastrointestinal tract of a child, and continue to cause injuries such as intestinal perforations and fistulas.⁴¹ Teenagers, who are not usually at appreciable risk of foreign body ingestions, are at higher risk for SREM ingestion because they use magnets as tongue jewelry and decorations on braces, which puts them at increased risk of accidental ingestion.⁴² Because doctors do not see the branding or

³⁶ Ex. 15, Noel Decl. ¶ 9; Ex.15B, NASPGHAN Study at 11.

³⁷ Ex. 15, Noel Decl. at ¶ 10; Ex. 15B, NASPGHAN Study at 13.

³⁸ Ex. 29, Noel Dep. at 219.

³⁹ Facts, ¶ 52. Ex. 29, Noel Dep. at 219.

⁴⁰ Ex. 29, Noel Dep. at 225.

⁴¹ Facts, ¶ 53. Ex. 15, Noel Decl. at ¶ 16.

⁴² Ex. 29, Noel Dep. at 205, 220-221 (“They are doing something to fit in and they use them as decorating jewelry . . . And I don’t think they realize what can happen when they swallow that little tiny metal ball.”)

warnings of SREMs, but only the damage that the SREMs have done, they consider all 5 mm SREMs “pretty much the same,” and consider the magnet brand “inconsequential.” (Facts, ¶ 58). Thus, their incident reports generally do not include reference to the specific brand of SREMs.

G. Case Studies of Children Who Have Ingested SREMs and Suffered Severe Injury and Death

Children who have been injured or have died as a result of ingesting SREMs have obtained and used the magnets in the ways described by Drs. Frantz, Noel, and Steinberg. The following case studies describe how young children, tweens and teens obtained and ingested SREMs, including two cases of ingestion which involved Zen Magnets.

Infants and toddlers have obtained magnets that have become separated from SREM sets and suffered severe injury and death. The death of 19-month-old A■■■■ C■■■■ shows the risks to infants and toddlers who may obtain SREMs that are separated from a larger set.

A■■■■ C■■■■, 19 Months Old, SREM Ingestion

On August 20, 2013, the 11-year-old brother of A■■■■ C■■■■ received a necklace made of approximately 20 multicolored SREMs from a 10 or 11-year-old neighbor.⁴³ The SREM necklace was not in any type of packaging and had no warnings.⁴⁴ A■■■■’s brother made a small bracelet for A■■■■ out of some of the magnets, but kept it in his room.⁴⁵ A■■■■’s mother did not know of the risks posed by the magnets.⁴⁶

Two days later, A■■■■ began vomiting and became lethargic.⁴⁷ A■■■■’s mother took her to the hospital, and was told A■■■■ probably had a stomach virus. A■■■■’s mother asked the medical professionals whether they should take an X-ray, but they declined because the symptoms appeared to be caused by a stomach virus.⁴⁸ She was advised to take A■■■■ to her family doctor if A■■■■ did not improve.⁴⁹ Upon returning

⁴³ Ex.28, C■■■■ Decl. at ¶ 3.

⁴⁴ *Id.* ¶ 4.

⁴⁵ *Id.* ¶ 6.

⁴⁶ *Id.*

⁴⁷ *Id.* ¶ 7.

⁴⁸ *Id.* ¶ 8.

⁴⁹ *Id.*

⁵⁰ *Id.*

home, A [REDACTED] was able to hold down some water, so her mother thought she was improving. In bed, her mother held A [REDACTED] to help her fall asleep. A [REDACTED] fell asleep shortly after midnight.⁵¹

On August 23, 2013, A [REDACTED]'s mother awoke at 7:30 a.m. to ready her two other children for school. She went to wake A [REDACTED] after sending her other children to school, and found that A [REDACTED] was not breathing and could not be resuscitated.⁵² A [REDACTED] was taken to a medical center where she was pronounced dead.⁵³

As part of an autopsy, X-rays were taken that showed a string of seven small round objects in A [REDACTED]'s body.⁵⁴ During the autopsy, seven green and gold 5 mm round magnets were found in A [REDACTED]'s small intestine.⁵⁵ After the autopsy, on August 23, 2013, the [REDACTED] Coroner concluded that A [REDACTED]'s death was caused by "ischemic bowel" due to "spherical magnets found in small intestine."⁵⁶

Children under the age of five are also highly likely to be attracted to and want to play with SREMs that are displayed as sculptures of commonly-recognized characters or objects. (Facts, ¶ 34). This scenario may make the magnets additionally enticing to young children. The case of M [REDACTED] M [REDACTED] illustrates this scenario.

M [REDACTED] M [REDACTED], 22 Months Old, SREM Ingestion

M [REDACTED] was 22 months old when his 15 year old brother received a set of SREMs. M [REDACTED]'s mother, a schoolteacher, did not believe the products were any more dangerous than other types of small toys that were in the household. M [REDACTED]'s brother built models with the magnets from the set and displayed them for days on a cabinet that he had in his room. M [REDACTED]'s mother would occasionally find missing magnets on the floor in his brother's room, and would return them to the set.⁵⁷

On December 8, 2011, M [REDACTED] began vomiting, and his mother suspected that he had contracted a bad virus. She took him to the doctor three days later, and the doctor ordered an X-ray. The X-ray revealed the presence of something that looked like a bracelet in M [REDACTED]'s abdomen. Doctor's hospitalized M [REDACTED] for 24 hours.⁵⁸

⁵¹ *Id.* ¶ 9.

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.* ¶ 10.

⁵⁵ Ex. 39, [REDACTED] Coroner's Report.

⁵⁶ *Id.*; Ex. 19, Declaration of Dr. Somerset at ¶ 11.

⁵⁷ A [REDACTED] Decl. ¶ 5, 7, 9.

⁵⁸ *Id.* ¶¶ 11-13, 15.

review of Zen's customer list [REDACTED]

When SREMs become separated from the sets, they pose a danger to children because parents and caregivers are not likely to appreciate that they have lost a magnet or that there is a risk associated with a lost magnet. If the parent does realize they have lost a magnet, they are not likely to look for it. (Facts, ¶ 33). Loose magnets pose a danger to toddlers who may find and ingest the magnets and suffer severe, life-altering injuries. The case of B [REDACTED] J [REDACTED], who was seriously injured after ingesting SREMs which had become separated from the set, illustrates this risk.

B [REDACTED] J [REDACTED], 22 Months Old, SREM Ingestion

In February 2012, B [REDACTED] J [REDACTED] was 22 months old. That same month, B [REDACTED]'s mother bought a set of SREMs for B [REDACTED]'s father. B [REDACTED] discovered and swallowed at least eight of the magnets, which his mother believes may have gotten lost on the floor and rolled under the couch.⁶⁹

On April 2, 2012, B [REDACTED] began vomiting. Believing that he was suffering from a stomach virus, B [REDACTED]'s mother took him to an urgent care facility and then a hospital. An X-ray revealed eight magnets in his stomach. After waiting two days to see if the magnets would pass through B [REDACTED]'s system, B [REDACTED]'s doctors performed surgery to remove the magnets. Surgery revealed that the magnets had caused a perforated intestine.⁷⁰

Several days after initial surgery, B [REDACTED] developed a high fever, and additional emergency surgery disclosed an additional intestinal perforation. The new surgery necessitated creation of an ostomy (artificial bowel opening) to carry stool outside B [REDACTED]'s body. During this process, B [REDACTED] was kept in an induced coma, and breathed through a respirator.⁷¹

During a third surgery, dead tissue was discovered in B [REDACTED]'s small intestine. A blood clot had cut off the blood supply to the small intestine, and much of his small intestine

⁶⁷ See Ex. 40, IDI [REDACTED] at 3.

⁶⁸ See Ex. 6, Sales Records for Zen Magnets.

⁶⁹ See Ex. 26, Declaration of M [REDACTED] J [REDACTED] at ¶ 5.

⁷⁰ See Ex. 26, J [REDACTED] Decl. at ¶¶ 7-10.

⁷¹ See Ex. 26, J [REDACTED] Decl. at ¶¶ 11-12, 14.

had to be removed. Over months, B [REDACTED] underwent nine additional surgeries to clean the wound, maintain his ostomy, and remove dead and infected issue.⁷²

Since swallowing eight magnets in 2012, B [REDACTED] has required constant care. He had to re-learn how to sit up, how to walk, and how to use his hands. His mother had to provide him with nutrition intravenously and by tube to his stomach.⁷³

B [REDACTED] can eat food, but cannot receive sufficient nutrition from it because he is missing most of his small intestine. Rather, he takes nutrition intravenously and through a stomach tube, which places him at risk of both infection and liver damage. He awaits a bowel transplant, which may be years in the future, and his medical expenses to date exceed \$1.5 million.⁷⁴

Ingestions of SREMs by children also occur because children use them in ways that require they be separated from the sets, such as those promoted by Zen. Zen has advertised its magnets as “fun to play with,” stating that they “look good on cute people” and may form a “wrist-worthy chain,” and are good for “self-adornment.” (Facts, ¶ 59). The case of E [REDACTED] H [REDACTED] demonstrates the risk when children use SREMs as a bracelet or jewelry.

E [REDACTED] H [REDACTED], 2 Years Old, SREM Ingestion

E [REDACTED] H [REDACTED] was 2 years old when he ingested SREMs obtained by his sister. E [REDACTED]’s sister played with a set of Buckyballs at a friend’s house. She made a bracelet out of some of the magnets, and placed the bracelet in a bag and brought it home with her. The bracelet consisted of approximately 20 to 30 magnets. Her parents did not count the magnets, and did not appreciate that they could be dangerous.⁷⁵

E [REDACTED]’s sister kept the magnets in her room with her other jewelry, and would take them out occasionally to play with them. In November of 2013, E [REDACTED]’s father was advised by E [REDACTED]’s sister that she had seen E [REDACTED] put one of the magnets in his mouth. E [REDACTED]’s sister removed the magnet from the child’s mouth. E [REDACTED]’s father did not believe that the child was at risk because he thought he had retrieved the only magnet the child had placed in his mouth, and thought that even if he had ingested more, they would likely pass.⁷⁶

⁷² See *id.* at ¶¶ 12-13.

⁷³ See *id.* at ¶ 15-17.

⁷⁴ See *id.* at ¶¶ 17-20.

⁷⁵ Ex. 21, H [REDACTED] Decl. at ¶¶ 4-8.

⁷⁶ See *id.* at ¶¶ 8-12.

Two days later E [REDACTED] began to complain of stomach pain, and his father believed he had a virus. E [REDACTED] was taken to the doctor's office, where X-rays were performed. The X-rays showed three of the magnet balls in his stomach. An endoscopy was performed but the magnets could not be retrieved. Surgery was eventually performed. Doctors removed the magnets and repaired the hole that had occurred when the magnets attracted to each other through E [REDACTED]'s stomach and small intestines.⁷⁷

Young children may also swallow SREMs because they may look like candy. SREM ingestion by four-year-old S [REDACTED] L [REDACTED] illustrates a case where a young child swallowed SREMs because they looked like the candy decorations on his mother's wedding cake.

S [REDACTED] L [REDACTED], 4 Years Old, SREM Ingestion

In 2010, K [REDACTED] L [REDACTED] bought a set of SREMs as a Christmas present for her ten-year-old son N [REDACTED]. In late December 2010, she flew from [REDACTED] to [REDACTED] with N [REDACTED] and her four-year-old son S [REDACTED] for her wedding. N [REDACTED] brought the SREMs with him to play with on the airplane.

At the wedding, on December 31, 2010, the cake was decorated with small, silver, round candies that were almost identical in appearance to SREMs. S [REDACTED] ate a piece of cake at the wedding, and ate more leftover cake in the days after the wedding.⁷⁹

On January 6, 2010, S [REDACTED] began screaming in pain and dry heaving. His pain continued the next day, and he was very lethargic and refused to eat or drink. On January 8, 2010, S [REDACTED] and his family flew home from [REDACTED] to [REDACTED]. On the final leg of the flight, S [REDACTED] was in so much pain that he tore his hair out and screamed for three hours. A doctor and nurse who were on the flight tended to him, and a flight attendant asked if the plane should make an emergency landing, although the plane ultimately continued to [REDACTED].⁸⁰

After landing in [REDACTED], S [REDACTED]'s parents drove him directly from the airport to the hospital, where an X-ray showed SREMs lodged in his intestines. He was transported by medevac airplane to another [REDACTED] hospital, and then transferred to a third hospital where surgery was eventually performed after S [REDACTED] had gone many days without eating. When speaking with S [REDACTED], K [REDACTED] L [REDACTED] determined that he had eaten SREMs because they looked like the candy on her wedding cake. Doctors repaired major

⁷⁷ Ex. 21, H [REDACTED] Decl. at ¶¶ 13-22.

⁷⁸ Ex. 27, L [REDACTED] Decl. at ¶¶ 2, 4.

⁷⁹ *Id.* at ¶ 5.

⁸⁰ *Id.* at ¶¶ 6-9.

intestinal damage, and S [REDACTED] still experiences stomach and digestive problems even though the surgery was over three years ago.⁸¹

Older children and teenagers with access to the Subject Products are likely to want to share the Subject Products with friends at school or otherwise away from caregiver supervision. (Facts, ¶ 45). The Subject Products are small, portable, easily hidden, and easily shared. (Facts, ¶ 46). Older children, teenagers and “tweens” have unintentionally swallowed magnets from the Subject Products after finding a small number of magnets or by having received them from friends or at school. (Facts, ¶¶ 47-49).

Thus, even if a caregiver is extremely vigilant in preventing access to the Subject Products in his or her own household, it is likely that children or teenagers will be exposed to the Subject Products in other places such as a school, playground, or friend’s home. (Facts, ¶ 46). Teens who swallow magnets from the Subject Products may need surgery and may lose part of their gastrointestinal tract due to magnet ingestion. The case of C [REDACTED] R [REDACTED] illustrates this scenario.

C [REDACTED] R [REDACTED], 14 Years Old, Zen Magnets Ingestion

C [REDACTED] was 14 years old when she obtained six loose Zen Magnets from a friend at church on November 18, 2013. Her mother believed the magnets could be dangerous and told her to discard them; however, C [REDACTED] kept two of the magnets. While at school, C [REDACTED] accidentally swallowed two of the magnets after she had placed them in her mouth while she was in the restroom. Her mother took her to the emergency room, but her daughter was sent home and told to wait for the magnets to pass.⁸²

Later that evening, after researching high powered magnets on the internet, C [REDACTED]’s mother took her daughter to another emergency room. X-rays revealed that the magnets had passed out of her stomach and could not be retrieved by oral endoscope. She was transported to a local Children’s Hospital, where she was given

⁸¹ Ex. 27, L [REDACTED] Decl. ¶¶ 10, 13, 15-17.

⁸² Ex. 24, R [REDACTED] Decl. ¶¶ 2-6.

laxatives to encourage the magnets to pass. C █████ remained in the hospital during this time.⁸³

After several days in the hospital, C █████ underwent surgery. The surgeons removed the magnets as well as part of C █████'s colon and intestines and her appendix. She was released from the hospital three days later.⁸⁴

C █████ obtained the magnets from a friend.⁸⁵ Customer records obtained from Zen indicate that █████ before C █████'s friend gave her the six Zen Magnets.

Parents also reasonably may not appreciate the risk posed by the Subject Products or may not believe that their child will intentionally put the products in his or her mouth. (Facts, ¶ 42). Thus, when an older child requests that a parent purchase the Subject Product after seeing them in a retail setting, the parent likely will do so. The case of B █████ B █████ illustrates a reasonable parent's actions that led to serious health consequences.

B █████ B █████, Ten Years Old, SREM Ingestion

B █████'s mother visited a gift shop in July 2011 with B █████, his brother P █████, and a family friend, M █████. B █████ was eight years old, M █████ was 11, and P █████ was four years old. The children saw a set of Buckyballs magnets displayed on the counter of the gift shop and asked their mother to purchase a set. The mother saw no warnings on the packaging or display. She was concerned that they might contain small parts so she kept the set out of reach of her four-year-old child. She did not, however, think that the magnets posed a risk to her eight-year-old child, B █████. After they were bought, the family rarely played with them, and the mother kept them out of reach of her younger child, P █████, but not her older child, B █████.⁸⁷

Two years later, in January 2013, B █████, who was then ten, woke up with intermittent abdominal cramps. He was well enough to go to school, but by nightfall was in serious pain and eventually began vomiting. His mother brought him to the emergency room. Initially the doctors thought he might have the flu, but his inability to drink fluids without vomiting caused the doctors to order a CT scan. The CT scan showed metal objects in his belly, but the doctor sent them home and told them to call their pediatrician in the

⁸³ Ex. 24, R █████ Decl. ¶¶ 7-14.

⁸⁴ *Id.* at ¶ 11.

⁸⁵ *Id.* at ¶ 14.

⁸⁶ Facts, ¶ 15; Ex. 6.

⁸⁷ Ex. 20, B █████ Decl. ¶¶ 2-4.

morning. When confronted by his mother, B ■■■ initially denied ingesting any magnets. After some discussion, he admitted he had put some in his mouth. The pediatrician then admitted B ■■■ to the hospital.⁸⁸

B ■■■ was given a colonoscopy which was unsuccessful in removing the magnets. The doctors then realized that the magnets were cutting off the blood supply to his intestinal tissue and admitted him to surgery. During six hours of surgery, the doctors removed a portion of B ■■■'s small intestine, large intestine, and appendix to remove the magnets. B ■■■ experienced tremendous pain for many days after the surgery and has permanent scars. The total costs of medical care were \$80,000.⁸⁹

Even parents who closely monitor health risks to children may not know the risks posed by a SREM product that they have never purchased and whose warnings they have never seen. The case of S ■■■ A ■■■ illustrates this scenario.

S ■■■ A ■■■, 10 Years Old, SREM Ingestion

S ■■■ was ten years old in September 2011 when she was given four high-powered spherical magnets by a friend at school. She took them home and played with them.

S ■■■'s mother is a medical doctor who has specialized in family practice, but she had never heard of the risks to children posed by small, high-powered magnets and did not realize her daughter would be at risk if she played with them. She had never purchased high-powered magnets and had never seen warnings related to them.⁹⁰

While playing with the magnets in her hand, S ■■■ brought the magnets close to her mouth. S ■■■ felt something in her mouth and swallowed. She then realized that three magnets had been attracted to her braces when the magnets were near her mouth and that she accidentally swallowed the three magnets.⁹¹

S ■■■'s mother took S ■■■ to the emergency room but they were told to go home and wait for the magnets to pass. S ■■■ asked the doctor to consult with a specialist. He was reluctant but ultimately agreed to consult with a specialist. The specialist sent S ■■■ to another hospital for emergency surgery, but she was then transferred to a third hospital where the only surgeon specializing in pediatric gastroenterology was on call.⁹²

⁸⁸ Ex. 20, B ■■■ Decl. ¶¶ 5-7.

⁸⁹ *Id.* at ¶¶ 9-14.

⁹⁰ Ex. 25, A ■■■ Decl. ¶¶ 5, 12-13.

⁹¹ *Id.* at 5.

⁹² Ex. 25, A ■■■ Decl. ¶¶ 5-8.

S ■ was taken for laparoscopic surgery and doctors were able to remove the magnets. S ■ was hospitalized for two days after the surgery and unable to attend school again for several more days while she continued to recover from her surgery.⁹³

Tweens and teens may also experiment with the Subject Products by trying to attach them to their braces, not realizing that this may cause them to inadvertently swallow magnets. (Facts, ¶ 44). In many such instances, this exposure will take place in the absence of adult supervision. (Facts, ¶ 45). Medical intervention to retrieve ingested SREMs comes with serious risks and can lead to severe complications. The case of J ■ B ■ illustrates this scenario.

J ■ B ■, 10 Years Old, SREM Ingestion

J ■ was 10 years old in 2011 when a friend at school gave her four SREMs from a set of magnets that were Buckyballs or similar to Buckyballs. J ■'s family had never purchased SREMs or seen any warnings related to SREMs. While playing, J ■ attached SREMs to her braces, and accidentally swallowed them.⁹⁴

At the hospital, J ■ was given fluid to help the magnets pass. The fluid passed into her lungs, causing pneumonia, and J ■ had to be transferred to pediatric intensive care. Her mother was informed of the risks of anesthesia and intubation, and then J ■ was intubated under general anesthesia so that she could breathe, while doctors continued to X-ray her to monitor the ingested magnets.⁹⁵

After several days in pediatric intensive care, J ■'s lungs recovered sufficiently to allow the doctors to perform a colonoscopy to remove four magnets lodged in J ■'s colon.⁹⁶

Older children and teenagers looking for a way to experiment with non-parent-approved behavior, such as piercings, are likely to use the Subject Products for that purpose.⁹⁷ Caregivers of older children are not likely to adequately warn tweens and teens about putting the Subject

⁹³ *Id.* at ¶¶ 9-10.

⁹⁴ Ex. 23, B ■ Decl., ¶¶ 3-4.

⁹⁵ *Id.* at ¶¶ 5-8.

⁹⁶ *Id.* at ¶¶ 6-8.

⁹⁷ Ex. 16, Steinberg Decl. ¶ 17.

Products in their mouths because they do not believe they would engage in such behavior. (Facts, ¶ 43). Caregivers acting with reasonable care are not able to prevent children over the age of five, including pre-teens and teenagers, from playing with or using the Subject Products in ways that can lead to ingestion of the Subject Products. (Facts, ¶ 46). The case of M■■ G■■ illustrates this risk.

M■■ G■■, 9 Years Old, SREM Ingestion

In May 2012, M■■ G■■, then 9 years old, was given four SREMs at school, which she used to simulate tongue piercings. While drinking water, she accidentally swallowed the magnets.⁹⁸

M■■ was taken to the hospital, where X-rays indicated four small magnet spheres in her stomach. By the time the doctors were able to attempt an endoscopy, they were not able to remove the magnets because the magnets had moved out of her stomach. After several days and additional X-rays, the magnets passed through her system.⁹⁹

The case studies described above illustrate the type of incidents reported to the Commission and to NASPGHAN. Dr. Paul Frantz examined approximately 100 cases in which the ingestion of an SREM was reported to the Commission and found that in 45 percent of the cases where it could be determined how a child gained access to the magnets, the facts showed that the child gained access from a “peer, friend, or other child.”¹⁰⁰ These children used the SREMs as bracelets, necklaces and faux ear and nose piercings, or otherwise held SREMs in their mouths, and then unintentionally ingested them. The majority of ingestion reports made to Commission staff resulted from imitation mouth piercing (47%), sticking magnets to braces (6%), or storing/holding magnets in the mouth

⁹⁸ Ex. 22, G■■ Decl. ¶¶ 2-3.

⁹⁹ *Id.* at ¶¶ 5-11.

¹⁰⁰ Ex. 5B, Frantz Report at 37, Figure 21.

(4%).¹⁰¹ Additionally, the NASPGHAN Study of its membership found that 24% of magnet ingestions reported by NASPGHAN members resulted from “pretend body art and piercing.”¹⁰²

III. SUMMARY DECISION STANDARD

Under the Commission’s Rules of Practice, any party may file a motion, with supporting memorandum, for a Summary Decision and Order in its favor upon all or any of the issues in controversy. 16 C.F.R. §1025.25(a). Such a motion “shall be granted if the pleadings and any depositions, answers to interrogatories, admissions, or affidavits show there is no genuine issue as to any material fact and that the moving party is entitled to a Summary Decision and Order as a matter of law.” 16 C.F.R. §1025.25(c).

The Commission’s Summary Decision standard is similar to Rule 56(a) of the Federal Rules of Civil Procedure,¹⁰³ which states:

A party may move for summary judgment, identifying each claim or defense — or the part of each claim or defense — on which summary judgment is sought. The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.

In cases interpreting Rule 56, *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986), *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), and *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986), the United States Supreme Court set forth the standard applicable to motions

¹⁰¹ Ex. 5B, Frantz Report at 42, Figure 22. An additional 27% of ingestions reclassified simply as “accidental swallowing.”

¹⁰² Ex. 15B, NASPGHAN Study Results at 6.

¹⁰³ Where the Federal Rules of Civil Procedure do not conflict with an agency’s rules of practice, judicial interpretation of the Federal Rules of Civil Procedure may guide the Presiding Officer’s decision making. *See, e.g., In re Spring Grove Resource Recovery, Inc.*, 1995 EPA ALJ LEXIS 28 at *2 (Sept. 8, 1995) (noting that Federal Rules “often guide decision making in the administrative context” and relying upon the Federal Rules where the EPA’s Rules of Practice merely stated that amendments were available only upon motion granted by the Administrative Law Judge with no further guidance); *see also In re Hoechst Celanese Corp.*, 1990 FTC LEXIS 121 at *3 (May 14, 1990) (where federal rule similar to FTC’s Rules of Practice, “judicial constructions of the federal rule can be useful in interpreting the [FTC’s] rules”).

for summary judgment. In *Celotex*, the Court made clear that under Rule 56, a court is obliged to grant summary judgment if the evidence shows that there is no genuine issue as to any material fact and the moving party is entitled to summary judgment as a matter of law. *Celotex*, 477 U.S. at 322-323. Moreover, as *Anderson* makes clear, the appropriate inquiry on summary judgment is not whether issues of fact exist, but rather whether any issue of “material fact” exists: “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.” *Anderson*, 477 U.S. at 248.

The standard is “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” *Anderson*, 477 U.S. at 251-52. If “the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no ‘genuine issue for trial.’” *Matsushita Electric Industrial Co.*, 475 U.S. at 587. “When the moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts.” *Id.* at 586. The mere existence of a “scintilla of evidence” is insufficient to defeat summary judgment. *Anderson*, 477 U.S. at 252.

Because there is no to dispute as to the material facts demonstrating that the Subject Products present a substantial product hazard, Summary Decision for Complaint Counsel is appropriate.

IV. ARGUMENT

The Subject Products Are a Substantial Product Hazard Under Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2) Because They Contain Product Defects Which Create a Substantial Risk of Injury to the Public

The CPSA provides that the Commission may order a firm to stop sale of a consumer product, recall the product, and provide notice to the public about the recall if the product “presents a substantial product hazard.” CPSA § 15(c), (d); 15 U.S.C. § 2064(c), (d). Under CPSA Section 15(a)(2), a “substantial product hazard” is “a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.” 15 U.S.C. § 2064(a)(2).

A “defect” may include a defect in the product’s design or warnings. 16 C.F.R. § 1115.4. A design defect may be present “if the risk of injury occurs as a result of the operation or use of the product,” 16 C.F.R. § 1115.4, and a “risk of injury” includes “a risk of death, personal injury, or serious or frequent illness.” CPSA Section 3(a)(14); 15 U.S.C. § 2052(a)(14). In determining whether a risk of injury renders a product defective, the Commission considers the following factors, as appropriate:

The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination.

16 C.F.R. § 1115.4.

Because the Subject Products contain a design defect which creates a substantial risk of injury to the public, the Subject Products present a substantial product hazard within the meaning

of CPSA Section 15(a)(2). Accordingly, this Court should order the Respondent to stop sale of the Subject Products and implement a corrective action, including a recall.

A. The Subject Products Contain a Design Defect Because A Risk of Injury Occurs as a Result of Their Operation and Use

A design defect may be present if a risk of injury occurs as a result of the operation or use of a product. 16 C.F.R. §1115.4. Here, the operation and use of the Subject Products produces a risk of injury to young children and adolescents. Specifically, the Subject Products contain SREMs that are frequently separated from sets while the product is in intended use. Designed as a manipulative in which hundreds of small magnets can be arranged in countless formations, the loss and separation of individual magnets occur as part of the expected operation and use of the Subject Products, resulting in a risk of injury from ingestion by young children and toddlers. *See supra* at 7-9. Similarly, foreseeable uses of separated magnets by older children and teens produces a risk of injury from accidental ingestion by that population. *See supra* at 9-10.

The risk of injury that occurs as a result of the use and operation of the Subject Products is rooted in a number of factors. Dr. Laurence Steinberg, a nationally-renowned expert in developmental psychology, has opined on the developmental reasons for these risks, indicating that the risks vary with a child's age. Children younger than five are attracted to magnets because the magnets are reflective, shiny, and smooth.¹⁰⁴ They want to play with SREMs and are drawn to them.¹⁰⁵ Because babies, toddlers, and preschoolers learn about objects through sensory exploration, it is normal for them to explore magnets with their tongues, lips, and mouths, areas of the body over which they have the most control.¹⁰⁶ Therefore, a baby or

¹⁰⁴ Ex. 16, Steinberg Decl. ¶ 9.

¹⁰⁵ Ex. 16, Steinberg Decl. ¶ 9.

¹⁰⁶ Ex.16, Steinberg Decl. ¶ 10.

toddler who is exposed to one or more of the Subject Products separated as a result of normal operation and use will likely examine the magnets, and, as part of that examination, put the magnets in his or her mouth.¹⁰⁷ As Dr. Noel has demonstrated, this natural behavior can result in catastrophic injury.¹⁰⁸

Children older than five are also highly likely to play with the Subject Products in ways that can lead to accidental ingestion.¹⁰⁹ Children of this age are enticed and fascinated by the features of the magnets and will want to be around them and play with them.¹¹⁰ In this context, it is foreseeable that older children, who know the difference between food and magnets and do not desire to swallow them, nevertheless will use the magnets in a way that may result in ingestion. For example, children who have braces may experiment with the attractive magnetic force, as 10-year-old J. [REDACTED] B. [REDACTED] and S. [REDACTED] A. [REDACTED] did, to their significant injury. Likewise, older children and teenagers looking for a way to experiment with body piercings are likely to use the magnets for that purpose, as 9-year-old M. [REDACTED] G. [REDACTED] did.

As demonstrated by Dr. Noel, ingestions of magnets are far more likely to result in medical intervention and serious injury than ingestions of other foreign bodies. (Facts, ¶ 55.)

Because of the attractiveness of the magnets to older children, SREM ingestions, after decreasing in children aged 6-9, then increase significantly in children 9-12.¹¹¹ As Dr. Frantz shows, much of this risk arises from the use of SREMs as pretend piercing, accounting for nearly half of the

¹⁰⁷ Ex. 16, Steinberg Decl. ¶¶ 9-10.

¹⁰⁸ Ex. 15, Noel Decl. ¶ 7; *See, e.g.* Ex. 18, A. [REDACTED] Decl. at ¶ 13; Ex. 21, H. [REDACTED] Decl. at ¶ 11.

¹⁰⁹ Ex. 16, Steinberg Decl. ¶ 13.

¹¹⁰ Ex. 16, Steinberg Decl. ¶ 15.

¹¹¹ Ex. 15, Noel Decl. ¶ 7; Ex. 5B, Frantz Report at 36 & Fig. 20.

ingestions for which he was able to document a cause, while another 10% resulted from sticking magnets to braces or storing/holding magnets in the mouth.¹¹²

These ingestions—whether by toddlers who access magnets that separate during the normal operation and use of the Subject Products or by older children and teens who foreseeably use magnets for piercings and other experimental behaviors—demonstrate a design defect in the Subject Products because, as explained in 16 C.F.R. §1115.4, “a risk of injury occurs as a result of the operation or use of the product.”

1. The Risk of Injury Associated with the Subject Products Renders them Defective

In addition to the design defect identified above, the Subject Products contain a defect as a result of the risk of injury associated with the product. As Commission regulations recognize, not all products that present a risk of injury are defective. 16 C.F.R. § 1115.4. To determine whether the risk of injury associated with a product renders the product defective, the factors set forth in § 1115.4 should be considered, as appropriate. These factors are: the utility of the product; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of the warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission’s own experience and expertise; and other factors relevant to the determination. *Id.* Taken together, these factors, analyzed below, demonstrate that the risk of injury associated with the Subject Products renders them defective.

¹¹² Ex. 5B, Frantz Report at 42 & Figure 22. An additional 27% of ingestions reclassified simply as “accidental swallowing.” *Id.*

a. Utility of the Product

The Subject Products offer some utility. For example, some adults enjoy using them as a “desk toy” or “fidget toy.” Children may use the Subject Products to “make great bracelets,” as suggested by Zen’s president.¹¹³ The Subject Products, which are intended to be manipulated into shapes or figures,¹¹⁴ also may provide entertainment to both adults and children. Additionally, Respondent’s experts opine that the Subject Products may be useful to illustrate scientific principles. SREMs are a simple novelty akin to Rubik’s Cubes, hula hoops, Slinkys and Pet Rocks,¹¹⁵ products with similarly limited utility but without the hazards associated with the Subject Products. Unlike a knife with a sharp blade whose sharpness is necessary for the knife to function and whose risk of injury is outweighed by the usefulness of the product, SREMs offer only limited utility.

For purposes of this motion, Complaint Counsel does not dispute that the facts show that the Subject Products have some limited utility for either amusement and recreational purposes or for educational purposes. However, this factor alone is not singularly determinative in evaluating the risk of injury posed by the Subject Products. The discussion of these additional factors below demonstrate such risk.

b. Nature of the Risk of Injury

Ample evidence of the serious nature of the injuries associated with the Subject Products is demonstrated by the 100 SREM ingestion incidents reported to and evaluated by Commission staff. This evidence is further underscored by data in the NASPGHAN Study which details the

¹¹³ Ex.4, Qu. Dep. at 265 & Ex. 4B, Qu Dep. Exhibit 34.

¹¹⁴ (Facts, ¶25), Ex. 2 at ¶ 40 (Zen Magnets and Neoballs have an “intended use as a medium for sculpture building, and manipulation.”)

¹¹⁵ Indeed, Buckyballs were specifically marketed as a toy akin to the Rubik’s cube. *See* Ex. 2 at ¶ 37 (citing Buckyball advertisement comparing SREMs to “a Rubik’s Cube that actually makes you smarter.”)

significant injuries that have been sustained by young children and teenagers as a result of magnet ingestion. Those injuries include deep pressure lesions, intestinal perforations, and fistulas. According to the survey, 48% of the children who were treated surgically or endoscopically for magnet ingestion had intestinal perforations or fistulas; 26% had deep pressure lesions.¹¹⁶ Of the surgical cases, 16% required bowel resections and 9% required long term care.¹¹⁷ B [REDACTED] J [REDACTED], who lost most of his small intestine and now must be fed through tube in his veins and stomach, is a tragic example of the serious injury that can result from ingestion as is the death of 19 month old A [REDACTED] C [REDACTED] who died from ischemic bowel caused by the ingestion of seven SREMs.

The grave risk of injury associated with the Subject Products is beyond dispute as even Zen's President admits in his full report to the Commission that ingestion of multiple magnets "can cause holes (perforations), twisting and/or blockage of the intestines, infection, blood poisoning (sepsis) and death."¹¹⁸ Furthermore, it is without consequence that the number of incidents attributable directly to the Zen brand is small. The record establishes, and Respondent admits, that no qualitative difference exists between the Zen brand and other rare earth magnets that have higher established incident rates, such as Buckyballs, and that the injury mechanism is identical to such magnet sets.

c. Necessity

Children and adults may enjoy manipulating the Subject Products into shapes or figures, but the products do not serve a necessary function. Many other products, such as Rubik's Cubes, hula hoops, Slinkys and Pet Rocks provide amusement and entertainment, thus rendering the

¹¹⁶ Ex. 15, Noel Decl. ¶ 9.

¹¹⁷ Ex.15, Noel Decl. ¶ 10.

¹¹⁸ Ex. 34, Zen Full Report at 4.

Subject Products an additive product of amusement, rather than a necessary one. Similarly, even if it is possible to use the Subject Products to create models of quadrillions and other mathematical principles or principles of physics as attested to by Respondent's witnesses, Dr. Boyd Edwards and Dr. David Richter, the facts in the record do not demonstrate that these centuries old principles of math and physics cannot be effectively communicated and taught without the use of a product which has been only the market since 2009.

d. Population Exposed to the Product and its Risk of Injury

The NASPGHAN Study, the opinions of Dr. Noel and Dr. Frantz, and the case studies identified in this brief all prove beyond dispute the Subject Products have caused serious life threatening injuries to our most vulnerable population: children. The undisputed evidence shows that the youngest, most vulnerable children, who with age-appropriate behavior explore their environments with their mouths, sometimes find and ingest magnets.¹¹⁹ The undisputed evidence shows that "tweens" and teens use the products as pretend jewelry and piercings.¹²⁰

As Dr. Steinberg opines, children are enticed by the features of SREMs, and even older children are attracted by them and likely to put them in their mouths. Moreover, as demonstrated by the incident involving B [REDACTED] B [REDACTED], and as both Dr. Frantz and Dr. Steinberg confirm in their expert opinions, it is highly unlikely that users of the Subject Products will secure the magnets or count them continuously while in use, making it virtually impossible for caregivers acting with reasonable care to prevent young children or teenagers from accessing, playing with, or using SREMs in ways that can lead to ingestion.¹²¹

¹¹⁹ Facts at ¶ 35. *See, e.g.* Ex. 18, A [REDACTED] Decl.; Ex. 21, H [REDACTED] Decl.; Ex. 26, J [REDACTED] Decl.; Ex. 27, L [REDACTED] Decl.; Ex. 28, C [REDACTED] Decl.

¹²⁰ *See, e.g.* Ex. 22, G [REDACTED] Decl.; Ex. 23, B [REDACTED] Decl.; Ex. 24, R [REDACTED] Decl.; Ex. 25, A [REDACTED] Decl.

¹²¹ Ex. 16, Steinberg Decl. ¶ 11.

e. Obviousness of Risk

Not only do the Subject Products present a serious risk of injury, the nature of that risk is hidden. As our experts indicate, neither older children who have used the magnets as jewelry or fake piercings, nor their parents, have a good understanding of the potential risks. As Dr. Steinberg explains, reasonable caregivers are likely to believe that the only risk of SREMs is intentional ingestion. (Facts, ¶ 42). Even then, caregivers are apt not to appreciate the risks associated with ingestion, believing that magnets will likely pass through the digestive tract without complication. (Facts, ¶ 53). Furthermore, caregivers are unlikely to believe a warning concerning ingestion risks if they think their own child or teenager would not intentionally ingest SREMs and also are unlikely to believe that older children and teenagers would engage in behavior such as mimicking piercing or sticking magnets to their braces. (Facts, ¶¶ 43). Even if adults were aware of such behavior, they may regard such actions as silly or immature but not hazardous given that older children usually avoid swallowing nonfood objects.¹²² Finally, a child who reads a warning or is told about the risks of ingestion of magnets is likely to disregard the risk, even if she believes the risk applies to her because the future consequences of such actions appear vague.¹²³

Indeed, the nature of the risk is sufficiently opaque that reasonable caregivers are unlikely to search intensely for a lost magnet or magnets. (Facts, ¶ 33). In fact, the Subject Products may appear so benign, such as when they are in the form of a colorful bracelet, that caregivers may knowingly give them to young children without appreciating the hidden risks. Such a lack of understanding on the part of caregivers is foreseeable given that even experienced medical

¹²² Ex. 5B, Frantz Report, at 48; Ex. 25, A [REDACTED] Decl. ¶13.

¹²³ Ex. 16, Steinberg Decl. ¶ 24; Ex. 41, Deposition of Lawrence Steinberg at 62 (compared to adults, adolescents are less likely to consider the potential harms of risky activity).

personnel are often unaware of the hazards associated with SREM ingestion, leading to misdiagnoses or improper care. (Facts, ¶ 52).

In summary, the potentially catastrophic risks of the Subject Products are largely obscure to caregivers, to children, and even to medical personnel.

f. Adequacy of Warnings and Instructions to Mitigate Risk

The undisputed serious risk associated with the Subject Products cannot be adequately mitigated through the use of warnings and instructions. Warnings presented with the Subject Products and similar magnets have been demonstrably ineffective in preventing injuries. As a threshold matter, warnings associated with the Subject Products are ineffective because the warnings are separated from the Subject Products once the product is taken out of the packaging for use. Thus, in most cases, the Subject Products have no warnings at all, nor can this be remedied by an on-product warning because the small size of the magnets preclude such an approach. (Facts ¶ 24).

Even if warnings were present for each and every use of the Subject Products, a comprehensive study by Dr. Frantz of the warnings used with the Subject Products and other virtually identical magnets demonstrates the Subject Product warnings do not and cannot adequately warn against the basic risk of magnets—injury cause by lack of containment.

Dr. Frantz, who has more than 25 years of practice in “warnings, safety engineering, and human factors engineering/ergonomics,”¹²⁴ performed a survey of injury patterns arising from small magnet exposure, and demonstrated that several injury patterns correspond to the risks of SREMs. First, injuries occur to younger children – babies, toddlers and preschoolers – who

¹²⁴ Ex. 5A, Curriculum Vitae of J. Paul Frantz.

swallow separated magnets as part of exploring their environment with their mouths.¹²⁵ Second, older children do not intentionally swallow magnets, but put magnets in or near their mouths for “pretend” lip and tongue piercings, or stick magnets to their braces as part of their play, exploration, and socializing.¹²⁶ In most cases, these older children received SREMs from a peer or friend.¹²⁷ In both scenarios, Dr. Frantz identified the risk as involving the separation of the SREMS from their sets, intentionally or by accident, and that such “loose” SREMS cause injuries to children.

Prior to the introduction into the market of the Subject Products and similar magnet sets, magnet injuries typically occurred when SREMs embedded in toys became separated from the toy. These loose or separated SREMs created a serious risk of injury.¹²⁸ In the instant case, the Subject Products contain SREMs that *by design* are constantly separated from sets while in intended use. As such, they are, when sold, “like a broken product that has created a hazardous condition.”¹²⁹ This primary risk – separation and loss, with no containment strategy – is not addressed in Respondents’ current warnings. That is because the condition creating the risk, i.e., loose, separable, accessible and manipulable SREMs – constitutes the basic character of the Subject Products.¹³⁰ In fact, Zen’s warnings and marketing assume, expect, and accommodate that magnets will be lost in the normal course of use.¹³¹ Not only has Zen sold “spare” magnets

¹²⁵ Facts, ¶¶ 34-35; Ex. 5B, Frantz Report at 28.

¹²⁶ Ex. 5B, Frantz Report at 48.

¹²⁷ Ex. 5B, Frantz Report at 42 & Fig. 22.

¹²⁸ Ex. 5B, Frantz Report at 48-49 (*citing* 2006 and 2007 CPSC recalls of Magnetix Building set after separated SREMs caused one death, one aspiration and 27 intestinal injuries, and 2006 and 2007 CPSC recalls of Polly Pocket Playsets after SREMs became detached).

¹²⁹ *Id.*

¹³⁰ Ex. 5B, Frantz Report at 50-51.

¹³¹ Ex. 5B, Frantz Report at 50-51. Shihan Qu, who admits to losing magnets himself, admits that “commonly magnets can be lost when sharing with friends. Sometimes they take some without intentionally doing so.” Ex. 4, Qu Dep. at 241-42. Mr. Qu admits that at times he is unsure whether magnets have been lost: “If magnets are

on the Zen and Neoballs web sites, each of the Zen sets (except the Mini) comes packed with spare magnets to replace lost ones.¹³² This is consistent with the response of Zen's President when asked what a magnet owner should do if he lost ten magnets in the park. He said: "If hypothetically a person said they lost ten magnets in the park, I would assume that he should buy ten more because the magnets lost are unlikely to be found."¹³³

Even if Respondent were to warn that containment of the magnets is necessary to prevent injury, that warning would be ineffective because complete containment itself is an impossibility: magnets from these sets get lost, magnets separate, magnets get shared at school, magnets roll under couches. When a product contains 1700 individual pieces, as a Zen product does (or even 200 pieces for that matter), containment is not practical or possible, making an effective warning on containment equally impossible. Thus, even comprehensive warnings, were Respondent to adopt such an approach, about the nature of injuries caused by magnet ingestion do not and cannot address the fundamental risk—injury caused by lack of containment—associated with the Subject Products.¹³⁴ The serious risk associated with the Subject Products thus cannot be mitigated through the use of warnings and instructions.

g. Role of Consumer Misuse and Foreseeability of Such Misuse

Although the Subject Products are designed for manipulative and construction purposes, behaviors that Respondent may characterize as misuse are highly foreseeable. As set forth in the

missing from one set, I generally assume that they're now part of another set or they have been placed somewhere else or slipped somewhere else." *Id.* at 242.

¹³² Ex. 4, Qu Dep. at 84.

¹³³ Ex. 4, Qu Dep. at 252. Likewise, Dr. Boyd Edwards, a magnet enthusiast and physics professor who is proposed expert for Zen, admits to having lost magnets in his kitchen, notwithstanding his practice of counting them after each use. Ex. 11, Dep. of Boyd Edwards at 53. "We had the visitors over and the – that [sic] played with the magnets, and when they left, I was four short." *Id.* Dr. Edward also has "misplaced" magnets that were later found in his carpet, and temporarily lost magnets when he created a "spinning top" SREM video, only to find missing magnets "On the floor [and] stuck to the dishwasher." *Id.* at 57-58.

¹³⁴ Ex. 5B, Frantz Report at 50; Ex. 10, Frantz Dep. at 27-28.

previous paragraphs, it is clear that young children are attracted to magnets and are likely to find them and ingest them and older children are likely to want to use magnets as piercings or to stick them to their braces, even if they have no intention of swallowing them.¹³⁵ Dr. Steinberg also opines that older children and teenagers seeing videos online of children or adults using magnets in such ways will be more likely to believe that it is safe for them to do so themselves.¹³⁶ Dr. Steinberg's expert analysis concluded that "there is a high risk that a child or teenager will play with or use the product in a way that might lead to ingestion of the product."¹³⁷ Accordingly, the use of SREMS for these purposes, whether or not the behaviors are appropriately characterized as misuse, is likely and therefore foreseeable.

h. Commission Experience and Expertise

Commission staff has investigated the properties and hazards caused by SREMs for many years. Since approximately 2006, Commission staff has investigated the release of SREMs from certain children's toys, evaluated incidents and injuries (including a child's death) resulting from SREM ingestions arising from magnet separation, and issued recalls.¹³⁸ Since February 2010, Commission staff also has investigated hundreds of reports of injuries caused by Buckyballs, Zen Magnets and other, similar SREMs.

¹³⁵ See *supra* at 7-10. See also Facts, ¶¶ 34-39, 44-45.

¹³⁶ Exh. 16, Steinberg Decl. at ¶ 17.

¹³⁷ Ex. 41, Steinberg Dep. at 54.

¹³⁸ The Commission announced the recall of Polly Pocket Magnetic Play Sets in 2006 following 170 reports of SREMs being released from the toy and three serious injuries, and re-announced the recall following additional incidents. See Ex. 42, CPSC Release No. 07-039, *Serious Injuries Prompt Recall of Mattel's Polly Pocket Magnetic Play Sets*, (Nov. 21, 2006). See also Ex. 43, CPSC Release No. 07-273, *Additional Reports of Magnets Detaching from Polly Pocket Play Sets Prompts Expanded Recall by Mattel*, (Aug. 14, 2007).

The Commission announced the recall of Magnetix Building Sets in 2006, following a death and four serious injuries caused by SREMs that became separated from a toy, and re-announced the recall following additional incidents and injuries. See Ex. 44, CPSC Release 06-127, *Child's Death Prompts Replacement Program of Magnetic Building Sets*, (Mar. 31, 2006); see also Ex. 45, CPSC Release No. 07-164, *Magnetix Magnetic Building Set Recall Expanded Serious Injuries Continue to be Reported to CPSC*, (Apr. 19, 2007).

To address the issues in this Proceeding, Complaint Counsel has relied on its technical staff, and also has engaged experts from crucial disciplines to study and opine on the risks of SREMs. Dr. Noel, Complaint Counsel's medical expert, conducted the most extensive study of SREM injuries and treatment, and continues to study and publish on this matter as one of the nation's experts on medical issues arising from SREM ingestion.¹³⁹ Dr. Frantz, an experienced expert on human factors, human engineering and warnings, has studied how magnet ingestions occur and what role the design, labeling, and warning of the magnets has played in the current blizzard of serious injuries to children. Dr. Steinberg, a renowned developmental psychologist, has studied how both younger and older children access and interact with SREMs, and addressed the nature of potentially hidden risks. Declarations from parents of children who have ingested loose or separate magnets further demonstrate that the magnets do in fact separate and are accessed and ingested by children. Commission staff is well-equipped to evaluate and report on the hazards of SREMs, including the Subject Products.

Based on the foregoing, the Subject Products provide limited utility, no necessity, and pose a hidden serious risk to a vulnerable population. Moreover, the risk of injury cannot be mitigated by warnings and any consumer misuse is highly foreseeable. Accordingly, under the factors set forth in 16 C.F.R. § 1115.4, the risk of injury associated with the Subject Products renders the products defective.

B. The Subject Products Present a Substantial Product Hazard Because They Contain Defects Which, Based on the Patterns of Defect, the Number of Defective Products, and the Severity of the Risk, Creates a Substantial Risk of Injury to the Public

Not only do the Subject Products contain a defect, they present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA. Under section 15(a)(2), a

¹³⁹ Ex. 15A Curriculum Vitae of Dr. R. Adam Noel.

substantial product hazard means:

a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.

Thus, the statute sets forth three factors to be considered in determining whether a substantial product hazard exists as the result of a defect which creates a substantial risk of injury: pattern of defect, the number of defective products distributed in commerce, and the severity of the risk. These factors are disjunctive: any one of the factors could create a substantial product hazard. 16 C.F.R. § 1115.12(g)(1). Here, all three factors are satisfied, clearly establishing the existence of a substantial product hazard in this case.

1. Pattern of Defect

Under 16 C.F.R. § 1115.12(g)(1)(i), a “pattern of defect” analysis requires consideration of whether the defect arises from the “design, composition, contents, construction, finish, packaging, warnings, or instructions of the product. . .” A pattern of defect is established here both with respect to the design of the Subject Products and the warnings that accompany them.

As established in section A above, the Subject Products contain a design defect because the operation and use of the products, whereby loose magnets are meant to separate from and re-attach to one another, results in a risk of injury to children and teens through ingestion of separated magnets.

In addition to containing a design defect, the warnings for the Subject Products are inadequate and therefore defective. Respondent's warnings do not identify the primary risks of the magnets, which is that they become separated, lost, and scattered. What is more, even if such a warning were to accompany the Subject Products, the warning would be insufficient because containment of magnets that come in sets of hundreds and even thousands, is not possible. The

warnings therefore are defective in their current formulation, nor can they be modified to warn adequately of the risks presented by a failure to contain the magnets because containment is not possible.

Thus, the pattern of defect here, which arises from both the operation and use of the product and its inadequate warnings, creates a substantial risk of injury to the public and therefore presents a substantial products hazard under section 15(a)(2) of the CPSA.

2. Number of Defective Products

Even one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination if the injury is serious and/or if the injury is likely to occur. 16 C.F.R. §1115.12(g)(1)(ii). Zen admits to selling more than 50,000 sets of magnets, with the most popular sets containing 216 magnets and six spares to replace lost magnets. In terms of total numbers of magnet spheres distributed, Zen's president admits that "[w]e've sold millions."¹⁴⁰ It is beyond dispute that the injuries that result from magnet ingestion are extremely serious and even fatal, and can occur if only two magnets are ingested. (Facts, ¶¶ 50-57).¹⁴¹ Accordingly, the sale of millions of individual magnets that can cause such grave injuries creates a substantial risk of injury to the public and therefore provides a clear basis for a substantial product hazard determination under the statute.

3. Severity of the Risk

A risk is severe if the injury which might occur is serious and/or the injury is likely to occur. 16 C.F.R. §1115.12(g)(1)(iii). As set forth above, the undisputed evidence, provided in the NASPGHAN Study and illustrated by the specific injuries to children such as A [REDACTED]

¹⁴⁰ Ex. 4, Qu Dep. at 605.

¹⁴¹ See also Ex. 34, Zen Full Report at 4 ("Magnets can cause injury or death if more than one are [sic] swallowed.")

C [REDACTED] and other children harmed after ingesting SREMs,¹⁴² demonstrates the severity of this risk presented by the Subject Products. As a result of the severe risks to children, the defect creates a substantial risk of injury to the public and therefore presents a substantial product hazard.

Together, the pattern of defect, the number of products, and the severity of the risk associated with the Subject Products, establish conclusively that the Subject Products present a substantial product hazard within the meaning of section 15(a)(2).

V. CASE LAW

Although a proceeding such as this to determine whether a product presents a “substantial product hazard” occurs infrequently, the matter before this Court falls squarely within the framework for making such a determination set forth in two previous administrative cases. In *In re P & M Enterprises*, CPSC Docket No. 88-1 (Initial Decision Mar. 30, 1989, Unanimously Upheld By Commission Jul. 17, 1991) (“*P & M Enterprises*”), a copy of which is attached hereto as Exhibit 35, Complaint Counsel argued that an electric worm probe known as the “WORM GETT’R” created a substantial product hazard.¹⁴³ The product, which conducted electricity into the ground to force earthworms to the surface, was alleged to create a risk of electric shock.

The Administrative Law Judge (ALJ) found that the risk of electrocution and death from the Worm Gett’r created a “patent product defect.” *P & M Enterprises*, Initial Decision, Mar. 30, 1989 at 20. The court found that even though “strictly and consistently” followed warnings were likely to allow consumers to avoid injury, the evidence showed that “users have not followed and are not likely to follow” such a scenario strictly and consistently. *Id.*

¹⁴² See 15B, NASPHGAN Study Results, *See also* Declarations at Exs. 18 through 28.

¹⁴³ The Presiding Officer’s Initial Decision was upheld unanimously by the Commission. *See* CPSC, *P&M Worm Probes Found Hazardous; Electrocution Risk Cited In CPSC Order To Halt Manufacture And Sale Of Worm Probes*, Jul. 26, 1991, available at <http://www.cpsc.gov/en/Recalls/1991/PM-Worm-Probes-Found-Hazardous-Electrocution-Risk-Cited-In-CPSC-Order-To-Halt-Manufacture-And-Sale-Of-Worm-Probes/>.

The ALJ also found that where, as here, warnings “have failed and continue to fail to convey adequately . . . the latent hazard in and the lethal nature of” the product risk, or where (as here) the warnings failed to “warn convincingly against permitting children of any age” to use the product, the warnings “in and of themselves constitute a product defect.” *Id.* Because of the pattern of product defects, the number of defective products distributed, the severity of the risk involved, the latent (*i.e.*, hidden) hazard of the product, and the risk of injury or death, the ALJ determined that a substantial product hazard existed. *Id.* at 21-23. The undisputed evidence in this case compels a similar result: the pattern of product defects arises from the operation and use of the product; the risk of injury is severe; the hazard is hidden; millions of SREMs have been sold; and the warnings do not and cannot mitigate the risk.

A finding that the Subject Products create a substantial product hazard also is supported by *In re Francis Alonso, Jr. d/b/a Mylar Star Kites*, CPSC Docket No. 75-16 (Initial Decision, June 21, 1976, Decision and Order, *findings of fact affirmed; order set aside on jurisdictional grounds*, Sept. 16, 1977), copy attached hereto as Exhibit 36. In *Mylar Star Kites*, the ALJ considered whether kites constructed with “aluminized polyester film” presented a substantial product hazard due to the risk of electric shock or other injury if the kite should touch or become entangled in overhead power lines. The ALJ found the aluminized kite was an “attractive recreational device” which because of the risk of contact with high voltage lines, “has proven to be extremely hazardous.” Initial Decision at 11. The ALJ also found that the proposal by the Respondent to “label the kites and distribute warning literature,” was “insufficient by itself to eliminate the hazard,” as there was no guarantee that the instructions would invariably be obeyed. *Id.* at 11. As such, the risk of additional incidents was “clearly foreseeable” unless the aluminized kites were banned. *Id.*

Although the Commission ultimately set aside the ALJ's order on procedural grounds, *Mylar Star Kites*, Decision and Order at 3-5, the Commission affirmed the ALJ's findings of fact, including the determination that the product presented a substantial product hazard. *Id.* at 3. Moreover, the Commission dismissed the Respondent's argument that other airborne objects, such as wire-controlled model airplanes, posed a similar hazard. Noting that the record did not support such a contention, the Commission declared that, even if the record had been sufficient, "we do not believe that we are obligated to act against every product that may pose a similar hazard in order to act against one that the record establishes is a hazard." *Id.* at 2. Similarly, in the instant matter, to the extent that Respondent contends that other products, such as marbles or balloons, present serious risks to children, and that the Commission's treatment of the Subject Products should be commensurate with its treatment of those, those arguments have no merit. As in the *Mylar Star Kites* case, those arguments are not supported by the record but even if they were, there is no requirement, as the Commission made clear, to act against every product that may pose a hazard.

Not only did the Commission indicate that action on one product did not necessarily require action on another, the Commission emphasized that the type of product at issue, an amusement such as a kite, was relevant to its consideration. The court found that "because of the nature and severity of the risk without an offsetting benefit sufficient to justify the risk, a product such as this [if properly before the Commission] would present a substantial product hazard." *Id.* at 3.¹⁴⁴ Applying the Commission's analysis to the case at hand leads to an identical conclusion. Not only is the nature of the risk severe, there is no "offsetting benefit" from an amusement that would justify the risk of injury and death associated with the Subject Products.

¹⁴⁴ Adopting the ALJ's finding of fact, the Commission set aside the ALJ's decision on jurisdictional grounds, finding that under now-repealed CPSA section 30(d), the action was required to be brought under the Federal Hazardous Substances Act.

Under the framework set forth in *P&M Enterprises* and *Mylar Star Kites*, the Subject Products constitute a substantial product hazard as they indisputably contain defects which, because of the pattern of defect, the number of defective products, and the severity of the risk, create a substantial risk of injury to the public.

VI. CONCLUSION

Because the record establishes that there is no genuine dispute as to material fact, Complaint Counsel is entitled to judgment as a matter of law. Based on the pattern of defect arising from the operation and use of the Subject Products and their inadequate warnings, the large number of defective products, including millions of individual magnets, and the severity of the hidden risk of serious injury to a vulnerable population, the Subject Products create a substantial risk of injury to the public and therefore present a substantial product hazard under section 15(a)(2) of the CPSA. Accordingly, the Court should enter judgment in favor of Complaint Counsel; find that the Subject Products constitute a substantial product hazard; and order Respondent to cease the sale and distribution of the Subject Products, give public notice, and issue full refunds to consumers.

Respectfully submitted,



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U.S. Consumer Product Safety Commission

September 26, 2014

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of)	
)	
ZEN MAGNETS, LLC,)	CPSC Docket No. 12-2
)	
)	Hon. Dean C. Metry
Respondent.)	Administrative Law Judge
)	

**[PROPOSED] ORDER GRANTING COMPLAINT COUNSEL'S MOTION FOR
SUMMARY DECISION**

Having considered Complaint Counsel's Motion for Summary Decision, and any responses, it is ORDERED that Complaint Counsel's Motion is GRANTED.

This Court issues this Order pursuant to Section 15 of the Consumer Product Safety Act and finds that the Subject Products present a substantial product hazard. Accordingly, Respondent is ordered to cease sale and distribution of the Subject Products, issue full refunds to consumers, and give notice to the public of the defect and remedy.

Dated: _____

The Honorable Dean C. Metry
Presiding Officer