UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

COMPLAINT COUNSEL'S PREHEARING BRIEF

Complaint Counsel submits this Prehearing Brief pursuant to 16 C.F.R. § 1025.22, containing a summary of the facts expected to be proved and the anticipated order of proof, a statement of issues presented, a summary of the legal arguments in support of Complaint Counsel's contentions, and a table of authorities attached as Exhibit A.

INTRODUCTION

Complaint Counsel will prove by a preponderance of the evidence that small rare earth magnets (SREMs), sold by Respondent under the brand names Zen Magnets and Neoballs (collectively the Subject Products), present a substantial product hazard pursuant to Section 15 of the Consumer Product Safety Act (CPSA). The evidence will show that the Subject Products present a substantial product hazard because they have "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). The condition creating the risk – loose, separable, accessible SREMs – constitutes the basic character of the Subject Products, and this amounts to a design defect because a risk of severe injury to children "occurs as a result of the operation or use of the product." 16 C.F.R. § 1115.4. The evidence will also show that the Subject Products present a substantial product hazard because they fail to comply with a consumer product safety standard that limits magnetic strength in toys

that contain loose as-received magnets, which creates a substantial risk of injury to the public. *See* 15 U.S.C. § 2064(a)(1).

I. STATEMENT OF FACTS AND ORDER OF PROOF

Complaint Counsel hereby presents a summary of the facts it will prove by a preponderance of the evidence at the hearing. Complaint Counsel intends to present these facts in approximately the order in which they are described here.

A. The Subject Products – Zen Magnets and Neoballs

In September 2009, Respondent, manufacturer of the Subject Products, began selling and distributing to consumers aggregated masses of high-powered, shiny, metallic-colored SREMs under the brand name Zen Magnets. In 2011, Respondent began distributing SREMs under the Neoballs brand name in a variety of colors.

The Subject Products are 5 mm spherical SREMs. The Subject Products are not permanently encased in a storage container, but rather are an aggregation of individual 5 mm SREMs that are made to be separated from each other. 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.

Magnet strength is measured by flux index. The Subject Products have a flux index[1] over 400 $kG^2\,mm^2$ and are capable of attracting SREMs across a distance of 1.5 cm or greater. The Subject Products are at least thirty times more powerful than an average refrigerator magnet. The Subject Products have a flux index greater than 50.

The size and flux of the Subject Products are approximately the same as Buckyballs. Both Buckyballs and Zen Magnets have been sold as metallic-colored spheres, and both

[1] Flux index ($kG^2\,mm^2$) is calculated by multiplying the area of the pole surface (mm^2) of the magnet by the square of the maximum flux density (kG^2). Flux index is used to measure the strength of a magnet.

Buckyballs and Neoballs have been sold in a variety of colored spheres, such as blue and red. Neither Buckyballs nor the Subject Products contains any brand identifiers or other markings on their individual magnets.

B. Sale of the Subject Products to Consumers

Respondent sells Zen Magnets and Neoballs on its websites, zenmagnets.com and neoballs.com. The Subject Products can be purchased on these websites by anyone with a PayPal account or credit card, and Zen Magnets can also be purchased by anyone with the anonymous currency bitcoin. Respondent has also sold Zen Magnets in retail stores, including marijuana dispensaries and game stores. Zen plans to expand its distribution of the Subject Products to additional game stores and hobby stores, as well as other stores that previously sold Buckyballs brand magnets.

Zen 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. 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. By October 2013, Zen had sold more than 50,000 sets of Zen-brand magnets to consumers in the United States. As of July 2013, in addition to selling more than 1,700 Neoball sets containing 216 magnets, Zen had sold individually 678,253 Neoballs.

Zen has used a variety of warnings on its websites and in its packaging. These warnings do not and cannot appear on individual magnets due to the small size of the magnets. 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. Similarly, the warnings also do not advise owners that they should not share magnets.

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, has stated that "commonly magnets can be lost when sharing with friends. Sometimes they take some without intentionally doing so." Zen Magnets also has indicated 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."

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. Because the individual magnets, which are sold in sets containing as many as 216 or 1,728 SREMs, are so small and numerous, it also may 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.

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

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. Such access can and does lead to ingestion by young children. A baby or toddler likely will intentionally put the magnet in his or her mouth to learn more about it. Babies and toddlers learn about objects in their world through sensory exploration. Babies and toddlers especially learn about the world by putting things they want to learn about in their mouth. 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. 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.

Children under the age of five are attracted to the Subject Products because the magnets are reflective, shiny and smooth. They want to play with the Subject Products and are drawn to them. Children under the age of five are especially likely to be attracted to and want to play with Subject Products that are displayed as sculptures of commonly-recognized characters or objects.

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. 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. 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. 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 represent the type of situations in which young children gain access to magnets.

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. The Subject Products are easy to break apart and share without substantially altering the play value of remaining magnets in a set. Tweens and teens who obtain the Subject Products are likely to share them with other friends because the magnets are easily replaced if shared. When magnets have been separated from the sets, neither the recipients who obtained magnets from a friend nor their parents or caregivers are provided with any warnings that may have initially accompanied the Subject Products.

Unlike infants and toddlers, tweens and teens generally do not intentionally swallow magnets. Adults therefore may not consider the Subject Products to be dangerous, because they believe that older children are able to avoid intentionally swallowing non-food objects. Older children and teenagers, however, can and do play with or use the Subject Products in ways that can lead to accidental ingestion.

Older children who have braces may want to test the magnetic properties of the Subject Products by sticking them to their metal braces. 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. Additionally, online videos of children or adults using magnets to simulate facial piercings may

lead this age group to believe that it is safe to engage in such behavior. All of this behavior is foreseeable and representative of behavior engaged in by children of this age.

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

CPSC staff obtained approximately 100 reports of ingestions of SREMs. CPSC staff conducted In Depth Investigations (IDIs) for these incidents, obtaining witness statements and records to confirm that these incidents involved ingestions of 5 mm SREMs. These reports include at least two incidents of ingestions of the Subject Products, and at least one death and dozens of incidents associated with SREMs made by other manufacturers. In some of the ingestion incidents, the brand of the SREMs could not be determined; however, the SREMs involved in those incidents were 5 mm SREMs like the Subject Products. Because the Subject Products do not contain any brand identifiers, any incidents where the SREM brand could not be determined also could have involved the Subject Products. Apart from the incidents obtained by CPSC staff, a survey of pediatric gastroenterologists reported 123 incidents of SREM ingestions. Many of these ingestion incidents required hospitalization or surgery to remove the ingested magnets.

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. 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. 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. 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.

Treatment of SREM ingestions is complicated by a lack of immediate medical intervention. 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. 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. Medical professionals often misdiagnose a magnet ingestion because the symptoms frequently mirror those of a flu or stomach virus. Even in cases where medical professionals have been advised that a child has ingested magnets, immediate surgical intervention has not been taken due to a lack of understanding of the mechanism of injury set forth above. 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. This injury can occur in as little as eight hours after ingestion.

Even when children do 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 identify the presence of magnets and remove them from their digestive systems. Medical intervention necessitated by magnet ingestion is significant and expensive, even where no surgery is required. Endoscopies for children usually require general anesthesia, and both of these procedures carry

risks of injury or death. 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.

A survey conducted by the North American Society of Pediatric Gastroenterology, Hematology, and Nutrition (the NASPGHAN Study) documented SREM injuries and treatment of such ingestions. The Study showed that SREM ingestions, which might have been expected to decline as children got older, actually were reported to have peaked for children 3-6 (toddlers), declined slightly for children aged to 6 to 9, then peaked again with a significant increase for children 9 to 12 (tweens and teens). 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. This extraordinary increase in injuries for older children is unique to SREM ingestion.

The NASPGHAN Study also addressed clinical management of SREM ingestions and revealed that most children in the survey who ingested magnets were required 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.

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). 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.

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

The difficulty in diagnosing ingestion of SREMs adds to their risk. 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. Teenagers, who are not usually at appreciable risk of foreign body ingestions, are at higher risk for SREM ingestion because they use SREMs as tongue jewelry and decorations on braces. This behavior places teenagers at increased risk of accidental ingestion. Because doctors do not see the branding or warnings of SREMs, but only the damage that the SREMs have done, they consider all 5 mm SREMs the same and consider the magnet brand to be inconsequential to the mechanism of injury. Thus, physicians' incident reports which were included in the NASPGHAN study generally do not include reference to the specific brand of SREMs.

G. Children Have Ingested SREMs and Suffered Severe Injury and Death

Children who have been injured or died as a result of ingesting SREMs have obtained and used the magnets in the ways described above. Infants and toddlers have obtained magnets that have become separated from SREM sets and suffered severe injury and death. 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. Loose SREMs pose a danger to toddlers who may find and ingest the magnets and suffer severe, life-altering injuries.

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." Young children may also swallow SREMs because the SREMs may look like candy.

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. The Subject Products are small, portable, easily hidden, and easily shared. Older children, teenagers and tweens have unintentionally swallowed magnets from the Subject Products after finding a small number of magnets or after receiving them from friends or classmates. Even if a caregiver is extremely vigilant in preventing access to the Subject Products in his or her 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. Teens who swallow magnets from the Subject Products may need surgery and may lose part of their gastrointestinal tract due to magnet ingestion.

Parents also reasonably may not appreciate the risk posed by the Subject Products or may not believe that their child will intentionally put SREMs in his or her mouth. Even parents who closely monitor health risks to children may not know the risks posed by SREM products that they have never purchased and whose warnings they have never seen.

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 inadvertently to swallow magnets. In

many such instances, this exposure will take place in the absence of adult supervision. Medical intervention to retrieve ingested SREMs comes with serious risks and can lead to severe complications.

Older children and teenagers looking for a way to experiment with non-parent-approved behavior, such as facial piercings, are likely to use the Subject Products to mimic that behavior. Caregivers of older children are not likely to adequately warn tweens and teens about putting the Subject Products in their mouths because they do not believe they would engage in such behavior. Caregivers acting with reasonable care are not able to prevent children, pre-teens and teenagers, from playing with or using the Subject Products in ways that can lead to ingestion of the Subject Products.

II. STATEMENT OF ISSUES

Complaint Counsel may submit the following issues for the Court's determination:

1. Do the Subject Products contain "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 presenting a "substantial product hazard" under 15 U.S.C. § 2064(a)(2)?

2. Do the Subject Products fail to comply with the Toy Standard (presented at ASTM International Standard F963-08, Standard Consumer Safety Specification for Toy Safety, and its most recent version, ASTM 963-11), because they are toys which contain "hazardous magnets" (loose as-received magnets with a flux index greater than 50 and that are "small objects"), and does this failure to comply with the Toy Standard create "a substantial risk of injury to the public" under 15 U.S.C. § 2064(a)(1)?

III. LEGAL ARGUMENTS

A. Complaint Counsel Must Prove Its Case By a Preponderance of the Evidence

Complaint Counsel must prove its case by a preponderance of the evidence. The rules governing this proceeding require that the Court's "Initial Decision shall be based upon a consideration of the entire record and shall be supported by reliable, probative, and substantial evidence." 16 C.F.R. § 1025.51(b). Section 15(f)(1), 15 U.S.C. § 2064(f)(1), adopts the hearing standards of section 554 of the Administrative Procedure Act, which in turn applies the provisions of section 556 of the APA to adjudicatory proceedings. 5 U.S.C. §§ 554, 556.

The U.S. Supreme Court has held that where a statute requires "substantial evidence," "adjudicatory proceedings subject to the APA satisfy the statute where determinations are made according to the preponderance of the evidence." *Steadman v. SEC*, 450 U.S. 91, 101-02, 104 (1981). The preponderance of the evidence burden of proof "simply requires the trier of fact 'to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence.'" *Concrete Pipe & Products of California, Inc. v. Constr. Laborers Pension Trust for S. California*, 508 U.S. 602, 622 (1993), *quoting In re Winship*, 397 U.S. 358, 371–372 (1970) (Harlan, J., concurring) (citation omitted).

B. 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.

1. 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 used as intended. 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. Similarly, foreseeable uses of separated magnets by older children and teens produces a risk of injury from accidental ingestion by that population.

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. Children younger than five (babies and toddlers) are attracted to magnets because the magnets are reflective, shiny, and smooth. They want to play with SREMs and are drawn to them. Because babies and toddlers 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. Therefore, babies or toddlers who are 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 their mouth and ingest the magnet. This natural behavior can result in catastrophic injury.

Children older than five are also highly likely to play with the Subject Products in ways that can lead to accidental ingestion. Children of this age are enticed and fascinated by the features of SREMs and will want to be around them and play with them. 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. Children who have braces may experiment with the attractive magnetic force of SREMs, 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.

Ingestions of magnets are far more likely to result in medical intervention and serious injury than ingestions of other foreign bodies. 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. 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."

2. 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. *See* 16 C.F.R. § 1115.4. To determine whether the risk of injury associated with a product renders it defective, the factors set forth in section 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.

a. Utility of the Product

The Subject Products offer only limited 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. The Subject Products, which are intended to be

manipulated into shapes or figures, also may provide entertainment to both adults and children. SREMs are a simple novelty akin to Rubik's Cubes, hula hoops, Slinkys and Pet Rocks, 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.

Although the Subject Products have some limited utility for amusement and recreational purposes, this factor alone is not singularly determinative in evaluating the risk of injury posed by the Subject Products. The discussion of additional factors below demonstrates 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 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 study, 48% of the children who were treated surgically or endoscopically for magnet ingestion had intestinal perforations or fistulas; 26% had deep pressure lesions. Of the surgical cases, 16% required bowel resections and 9% required long term care.

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 (perforation) twisting and/or blockage in the intestines, infection, blood poisoning (sepsis) and death." 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. Similarly, even if it is possible to use the Subject Products to create models of scientific or mathematical principles, the facts 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 on the market since 2009.

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

The Subject Products have caused serious life threatening injuries to our most vulnerable population: children. The youngest, most vulnerable children, who with age-appropriate behavior explore their environments with their mouths, sometimes find and ingest magnets. Tweens and teens use the products as pretend jewelry and piercings.

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, 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.

e. Obviousness of Risk

Not only do the Subject Products present a serious risk of injury, the nature of that risk is hidden. Neither older children who have used the magnets as jewelry or fake piercings, nor their parents, have a good understanding of the potential risks. Reasonable caregivers are likely to believe that the only risk of SREMs is intentional ingestion. 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. Furthermore, caregivers are unlikely to heed a warning concerning ingestion risks if they believe 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. 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. 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.

Indeed, the nature of the risk is sufficiently opaque that reasonable caregivers are unlikely to search intensely for a lost magnet or magnets. 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 personnel are often unaware of the hazards associated with SREM ingestion, leading to misdiagnoses or improper care.

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. This deficiency cannot be remedied by an on-product warning because the small size of the magnets precludes such an approach. Even if warnings were present for each and every use of the Subject Products, the Subject Product warnings do not and cannot adequately warn against the basic risk of magnets—injury caused by lack of containment.

A survey of injury patterns arising from small magnet exposure shows that several injury patterns correspond to the risks of SREMs. First, injuries occur to younger children – babies, toddlers and preschoolers – who swallow separated magnets as part of exploring their environment with their mouths. 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 play, exploration, and socializing. In most cases, these older children received SREMs from a peer or friend. In both scenarios, the risk involves the separation of the SREMs from their sets, intentionally or by accident, and 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. 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. 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. In fact, Zen's warnings and marketing assume, expect, and accommodate that magnets will be lost in the normal course of use. Not only has Zen sold spare magnets on the Zen and Neoballs web sites, each of the Zen sets (except the Mini) comes packed with spare magnets to replace lost ones. 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."

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 impossible: magnets from these sets get lost, magnets separate, magnets get shared at school, and magnets roll under couches. When a product contains more than 1700 individual pieces, as a Zen product does (or more than 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. 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 previous paragraphs, 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. 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. Thus, 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. 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. Since February 2010, Commission staff also has investigated hundreds of reports of injuries caused by Buckyballs, Zen Magnets and other, similar SREMs.

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. R. Adam Noel, Complaint Counsel's medical expert, conducted an 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. Dr. J. Paul 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. Laurence 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. Testimony from parents of children who have ingested loose or separate magnets will further demonstrate that the magnets do in fact separate and are accessed and ingested by children.

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.

C. 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, Create 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 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 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 or more is not possible. The warnings therefore are defective in their current formulation, and they cannot 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." 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. 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). According to Commission regulations, "serious injury" includes not only grievous bodily harm, but also injuries necessitating hospitalization requiring medical or surgical treatment, injuries to internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day. *Id.* at §1115.6(c). As set forth above, the evidence will demonstrate that serious injuries have occurred as a result of ingestion of the Subject Products. Because 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 will show by a preponderance of the evidence that the Subject Products present a substantial product hazard within the meaning of section 15(a)(2).

D. The Subject Products Are a Substantial Product Hazard Under Section 15(a)(1) of the CPSA, 15 U.S.C. § 2064(a)(1) Because They Do Not Comply With the "Toy Standard," Creating a Substantial Risk of Injury to the Public

ASTM is an international standards organization that develops and publishes voluntary consensus technical standards for a wide range of consumer products and services.[2] ASTM Standard F963-11, the Standard Consumer Safety Specification for Toy Safety (Toy Standard), sets out basic safety standards for toys. The Toy Standard sets safety standards for magnets that are toys or component parts of toys, and prohibits toys from containing loose as-received "hazardous magnets."[3] A hazardous magnet is a magnet which has a flux index greater than 50 and which is a small object.[4] The Consumer Product Safety Improvement Act of 2008 made this standard a mandatory consumer product safety rule.[5]

CPSA Section 15(a)(1) defines a "substantial product hazard" as "a failure to comply with an applicable consumer product safety rule … which creates a substantial risk of injury to the public…." The Subject Products are toys that contain loose as-received hazardous magnets as defined by the Toy Standard, and thus they fail to comply with the Toy Standard and create a

[2] ASTM used to be called the American Society for Testing and Materials and shortened its name to ASTM in 2001.

[3] *See* ASTM F963-11 at §§ 3.1.81 (defining "toy" as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age"), 4.38 (stating magnet standard).

[4] *See* ASTM F963-11 at § 3.1.37 (defining "hazardous magnet"). A small object fits within a small parts cylinder, which 2.25 inches long by 1.25 inches wide, about the size of the throat of a child under three years old. *See* 16 C.F.R. § 1501.4.

[5] Section 106 of the Consumer Product Safety Improvement Act of 2008, Public Law 110–314 (not codified in U.S. Code, available at http://www.cpsc.gov/PageFiles/129663/cpsia.pdf), provided for this standard to be a mandatory consumer product safety standard under CPSA section 9.

substantial risk of injury to the public, making them a substantial product hazard under CPSA Section 15(a)(1).

The Subject Products are toys pursuant to the Toy Standard because they were designed, manufactured, or marketed as a plaything for children under 14 years of age. The Subject Products have a flux greater than 50, and thus are hazardous magnets under the Toy Standard. The Toy Standard prohibits toys from containing a loose-as-received hazardous magnet. The Subject Products consist of and contain loose-as-received hazardous magnets. As a result, the Subject Products fail to comply with the Toy Standard.[6]

As explained above, the Subject Products create a substantial risk of injury to the public. Because the Subject Products fail to comply with the Toy Standard and create a substantial risk of injury to the public, they are a substantial product hazard pursuant to CPSA Section 15(a)(l), 15 U.S.C. § 2064(a)(l).

E. The Case Law Demonstrates That the Subject Products Present a Substantial Product Hazard

Although a proceeding 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"

[6] The Toy Standard contains an exception for science kits, but the evidence will show that this exception does not apply to the Subject Products.

created a substantial product hazard.[7] 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 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*.

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

[7] 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/.

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.[8] 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.

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.

IV. CONCLUSION

Complaint Counsel will prove by a preponderance of the evidence that the Subject Products present a substantial product hazard. 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 SREMs, 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. In addition, the Subject Products present a substantial product hazard because they do not comply with the Toy Standard, which creates a substantial risk of injury to the public pursuant to CPSA Section 15(a)(1), 15 U.S.C. § 2064(a)(1). Accordingly, the Court should enter

[8] 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.

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,

DVice

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November 10, 2014

EXHIBIT A - TABLE OF AUTHORITIES

FEDERAL CASES

Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986)

Celotex Corp. v. Catrett, 477 U.S. 317 (1986)

Concrete Pipe & Products of California, Inc. v. Constr. Laborers Pension Trust for S. California, 508 U.S. 602 (1993)

In re Francis Alonso, Jr. d/b/a Mylar Star Kites, CPSC Docket No. 75-16, (Initial Decision, June 21, 1976, Decision and Order, Sept. 16, 1977) (attached to Motion for Summary Decision, Exhibit 36)

In re Hoechst Celanese Corp., 1990 FTC LEXIS 121 at *3 (May 14, 1990)

In re P & M Enterprises, CPSC Docket No. 88-1 (Initial Decision Mar. 30, 1989, Unanimously Upheld By Commission Jul. 17, 1991) (attached to Motion for Summary Decision at Exhibit 35)

In re Spring Grove Resource Recovery, Inc., 1995 EPA ALJ LEXIS 28 at *2 (Sept. 8, 1995)

In re Winship, 397 U.S. 358 (1970)

Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574 (1986)

Steadman v. SEC, 450 U.S. 91 (1981)

FEDERAL STATUTES

5 U.S.C. § 554

5 U.S.C. § 556

15 U.S.C. § 2052

15 U.S.C. § 2064

FEDERAL REGULATIONS

16 C.F.R. § 1025.25

16 C.F.R. § 1025.51

16 C.F.R. § 1115.4

16 C.F.R. § 1115.12

CERTIFICATE OF SERVICE

I certify that I have provided on this date, November 10, 2014, Complaint Counsel's Prehearing Brief to the Secretary, the Presiding Officer, and Respondent in these proceedings in the following manner:

Original and three copies by hand delivery to the Secretary of the U.S. Consumer Product Safety Commission: Todd A. Stevenson.

One copy by electronic mail to the Presiding Officer:

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