UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	CPSC Docket No. 12-2
ZEN MAGNETS, LLC,	)	
Respondent.	)	

COMPLAINT COUNSEL'S APPEAL BRIEF

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I. STATEMENT OF THE CASE

On August 6, 2012, Complaint Counsel, on behalf of the U.S. Consumer Product Safety Commission, filed an administrative complaint under Section 15 of the Consumer Product Safety Act ("CPSA"), alleging that Zen Magnets and Neoballs ("Subject Products") present a substantial product hazard ("SPH"). A hearing was held from December 1-17, 2014, with the Honorable Dean C. Metry presiding, and the parties filed Post Hearing Arguments on March 16, 2015. On March 25, 2016, Judge Metry issued an Initial Decision and Order. Complaint Counsel filed a timely Notice of Appeal. Respondent Zen Magnets ("Zen") did not file a Notice of Appeal or Cross Appeal.

The Subject Products are two brands of powerful, small, rare-earth magnets ("magnets" or "SREMs") – shiny, silver-colored, "fun to play with" Zen Magnets and "colorful" Neoballs.[1] Zen Magnets are sold in sets of 72, 216 or 1,728 loose, separable magnets.[2] Neoballs may be purchased individually from Respondent's website, allowing purchasers to mix and match colors and form their own sets.[3]

Magnets that become separated from their set can cause severe injury or death when as few as two of them are ingested. Between 2009 and 2013, one toddler died and an estimated 2,900 children were treated in emergency rooms after ingesting magnets. *See* CC-27A at 8-13; Trial Transcript (Tr.) 913:8-17, 931:17-22. Nearly 80 percent of children in a study by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition ("NASPGHAN") who ingested SREMs required invasive medical intervention to remove the SREMs and/or repair

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[1] Zen Magnets home page, www.zenmagnets.com, CC-51; Exh. A to Complaint Counsel's Post Hearing Argument (Exh. A), ¶¶ 23-25, 32, 41, 57; Neoballs home page, www.neoballs.com; Exh. A at ¶¶ 60, 80-84.

[2] Exh. A at ¶¶ 34-42.

[3] Exh. A at ¶¶ 60, 71, 80, 81, 85, 86, 96.

gastrointestinal injuries. *See*; CC-24; CC-27A at 8; CC-28; Tr. 742:8-20. These injuries can occur when SREMs attract through tissue in as little as eight hours after ingestion. *See* CC-24; CC-27A at 8; CC-29; Tr. 748:1-16. Children who survive SREM ingestion may suffer lifelong, debilitating injuries. *See* CC-27A at 7; CC-28; Tr. 754:1-755:14.

The Subject Products present a substantial product hazard pursuant to section 15 of the CPSA. 15 U.S.C. § 2064. They present this hazard because they create a substantial risk of injury due to multiple defects and due to their failure to comply with ASTM F963 ("Toy Standard"). The Subject Products are defective pursuant to § 2064(a)(2) for three distinct reasons, each of which, alone, is sufficient to satisfy the defect element of an SPH. Specifically, the Subject Products contain a defect because: 1) a risk of injury occurs as a result of the use, including foreseeable misuse, of the Subject Products; 2) they have inadequate warnings that do not and cannot mitigate the risk of injury; and 3) application of the factors in 16 C.F.R. § 1115.4 shows that the risk of injury associated with the Subject Products renders them defective. An analysis of each of these defects is provided below, followed by a discussion of why these defects create a substantial risk of injury to the public, thereby presenting a substantial product hazard.

A. The Subject Products Are Defective for Three Distinct Reasons

1. A Risk of Injury Occurs as Result of Their Operation and Use

A product 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. Here, individual magnets separate from their set, leading to ingestion by children who obtain separated magnets, which causes injury or death:

- *Separation* – Magnets easily become separated from a set; the basic design of the Subject Products requires that individual magnets be manipulated and separated from each other. *See* CC-10A at 7, 13-16; Tr. 343:5-344:3, 385:19-386:2;

- *Ingestion* – Once magnets separate from their set, children foreseeably obtain and ingest magnets that are lost or that are shared by friends or family members. Infants and toddlers are attracted to and ingest magnets as a normal method of exploring their surroundings, which includes mouthing items. Tweens and teens accidentally ingest SREMs when they attach them to braces or mimic tongue piercings and the SREMs suddenly snap together and repel down their throat. *See* CC-19A at 3-16; CC-21; CC-22; Tr. 377:12-379:3, 419:4-8, 420:17-421:2, 423:8-11.

- *Injury* – In as little as eight hours, ingested SREMs that attract through intestines can result in tissue injuries and death (necrosis) and perforate the gastrointestinal tract leading to peritonitis (contamination of the body cavity due to leakage of bowel contents). Immediate intervention is necessary; however, diagnosis is often delayed because children who ingest SREMs have nonspecific symptoms often mistaken by parents and medical professionals as the flu or stomach infection. These painful injuries can cause permanent damage to a child's gastrointestinal tract or can result in death. *See* CC-27A at 8, 10-13; CC-24; CC-25: CC-26; Tr. 748:1-755:14, 761:21-762:9.

Because the operation and use of the Subject Products, which requires manipulation and separation of individual magnets, leads to a risk of serious injury to young children who find and ingest them and to adolescents who experiment with them, the Subject Products are defective. That such ingestion can be characterized as misuse is of no consequence because foreseeable misuse falls within the meaning of use set forth in Commission regulations. 16 C.F.R. § 1115.4.

2. ***Inadequate Warnings Render the Subject Products Defective***

The Subject Products are also defective because they have inadequate warnings. *See* 16 C.F.R. §1115.4 (warnings may create a defect if they allow "[r]easonably foreseeable consumer use or misuse [that] could result in injury"). Respondent sold many products with no warnings through at least May 2012. CC-55; Tr. 2333:11-15, 2351:17-21, 2352:1. When Zen finally added various iterations of warnings, the warnings were defective because they did not, and could not, adequately address the risk of separation, ingestion, and injury:

- although Zen eventually added in-package language about the risk of ingestion and injury, Zen designed the Subject Products such that individual magnets separate from their sets, an inherent feature of the product that precludes an effective warning from accompanying it. Thus, warnings never reach children or their

caregivers who obtain innocuous-looking, lost or shared magnets that have been separated from their sets, *see* CC-10A at 14; CC-19A at 12, 15; Tr. 381:16-382:10;

- the in-package warnings do not warn users about the risk posed by separated magnets, namely, that the loss or sharing of even two magnets out of dozens or hundreds could lead to the death or injury of a child who later obtains them, *see* CC-10A at 9, 46-47; Tr. at 253:6-254:17, 255:4-14; and

- even if Respondent changed the warnings to warn of the risk posed by separated magnets (*i.e.,* that users must never lose or share them), it would be nearly impossible to use the Subject Products – loose, separable magnets – in a way that consumers could successfully heed such a warning to prevent magnets from becoming separated from their sets. *See* CC-10A at 7, 9-10; Tr. at 255:14-256:1.

Because no warning could adequately mitigate the risk posed by the Subject Products, the warnings are defective.

3. Under the Factors in 16 C.F.R. § 1115.4, the Risk of Injury Renders the Subject Products Defective

In addition to being defective due to the operation and use (including reasonably foreseeable misuse) of the product and due to of its inadequate warnings, the factors in 16 C.F.R. § 1115.4 provide a third basis for establishing a defect in the Subject Products. Under the regulation, a product may contain a defect if its design presents a risk of injury to the public. To determine whether the risk of injury is the type of risk that renders a product defective, 16 C.F.R. § 1115.4 sets forth a multi-pronged inquiry. Under that framework, the Subject Products are defective because: a) SREMs have low utility; b) they can cause severe injury or death when separated and ingested; c) they are not a necessity; d) they injure a vulnerable population (children); e) they appear innocuous and present a non-obvious risk; f) the warnings do not and cannot mitigate the risk: g) any "misuse" of the product by children is foreseeable; h) the Commission's own experience has shown the dangers posed by SREMs; and i) case law supports a defect finding here.

As the above analysis shows, the Subject Products are defective for three distinct reasons: a risk of injury occurs by virtue of their operation or use, including reasonably foreseeable misuse; the warnings are inadequate and that inadequacy cannot be cured; and an analysis of the regulatory factors compels a defect finding. Although only one reason would have provided a sufficient basis for a finding of defect in this matter, Complaint Counsel, by a preponderance of the evidence, established the Subject Products contained a defect for each of these separate reasons.

B. The Subject Products Are a Substantial Product Hazard Because the Defects Create A Substantial Risk of Injury

The Subject Products contain a defect which creates a substantial risk of injury to the public, thereby presenting a substantial product hazard under section 15(a)(2) of the CPSA. Specifically, the pattern of defect, the number of products, and the severity of the risk create a substantial risk of injury to the public. *See* 15 U.S.C. § 2064(a)(2); 16 C.F.R. § 1115.12(g)(1) (explaining that these three factors "are set forth in the disjunctive" so "the existence of any one of the factors could create a substantial product hazard.")

1. The Pattern of Defect

The pattern of defect arises from the product's design, warnings, and instructions, which require the separation of individual magnets that leads to the reasonably foreseeable ingestion of those magnets by toddlers and adolescents who can never be properly warned about the risks posed by the Subject Products. *See* CC-10A at 7, 9-10, 13-16, 18-19, 44-47; CC-27A at 7-10.

2. The Number of Products

Respondent distributed millions of individual Zen Magnets and Neoballs and a child can suffer serious injury or death after ingesting as few as two magnets. *See* CC-10A at 23-24; CC-16; CC-57A at 4.

3. Severity of the Risk

The severity of the risk of injury is high as debilitating injury and even death can result from exposure to the Subject Products. *See* CC-10A; CC 18.1-18.95; CC-27A at 6, 7, 10-13; CC-28 at 14; CC-29 at 5, 7; Joint Notice Regarding Witness Stipulations ("Joint Notice"), Dec. 8, 2014, Exh. K at ¶11-12.

C. The Subject Products Are a Substantial Product Hazard Because Their Failure to Comply With the Toy Standard Creates a Substantial Risk of Injury to the Public

In addition to presenting a substantial product hazard due to defects that create a substantial risk of injury to the public, the Subject Products are also substantial product hazards because their failure to comply with the Toy Standard creates a substantial risk of injury to children. *See* 15 U.S.C. § 2064(a)(1). A product violates this standard if it contains a loose as-received "hazardous" magnet and is a "toy." ASTM F963 § 4.38.1 (CC-2); CC-1A at 5-6; Tr. 97:13-18. The Subject Products are "hazardous" because they have a flux index over 50. ASTM F963 §§ 3.1.37 (CC-2), 4.6, 8.24.1; CC-1A at 5-6; Tr. 97:13-18. They are "toys" because Zen designed, manufactured, or marketed them as playthings for children under age 14.[4] For example, Zen specifically marketed them as a "fun toy" for children to "play with" at age 12 and up.[5] Because the products have been sold and marketed as playthings for children under 14, they are toys containing a hazardous magnet that violate the Toy Standard. That violation creates a substantial risk of injury to children for the reasons discussed above and throughout this brief.

[4] *See* ASTM F963 § 3.1.81 (CC-2); CC-10A at 10-13, 26-27; CC-11-CC-13; CC-17; CC-19A at 4; CC-45, CC-46; CC-58; CC-63 at 2, 4; CC-65; Tr. 429:15-22, 431:2-20, 1953:20-1954:5, 2228:15-2231:14, 2411:11-2412:4, 2425:3-7, 2570:7-14.

[5] *See* CC-44 (describing Zen Magnets as a "fun toy"); Tr. 2570:11-14, CC-48 at 2, CC-50 at 2 (Zen's website stating that children can "play with" Zen Magnets at age 12); Qu testimony, Tr. at 2570:11-14.

II. STATEMENT CONTAINING THE REASONS WHY THE INITIAL DECISION IS INCORRECT

The Initial Decision (ID) is incorrect because the Administrative Law Judge (ALJ) misconstrued, misapplied, and misunderstood the law and the regulations governing this matter, resulting in strained legal conclusions not supported by the record in this case. Although the ALJ made generally correct factual conclusions, he erred in applying the law to those facts and, as a result, reached an incorrect decision in failing to find that the Subject Products contained a defect on even one of the three strong theories of defect Complaint Counsel presented. At bottom, the Initial Decision rests on two flawed conclusions: that the Subject Products were not defective because injuries occurred as a result of misuse, and that, in any event, warnings are sufficient to mitigate the risk of injury. Neither conclusion is supported by law or fact. Ingestion, even accepting the characterization of misuse, was reasonably foreseeable and a defect arises from such foreseeable misuse. Additionally, the warnings could not mitigate the risk because users were either unlikely to see them or could not appreciate the warnings because of the non-obvious nature of the risk. Having found no defect based on a faulty understanding of the law, the ALJ was compelled to reach the erroneous conclusion that the products did not present a substantial product hazard.

A. The Initial Decision Incorrectly Found That the Subject Products Do Not Contain a Defect

The ALJ erred in finding that the Subject Products do not contain a defect and thus do not present a substantial product hazard pursuant to CPSA section 15(a)(2).

1. The ALJ Erred in Concluding That a Defect is Not Present as a Result of the Operation and Use of the Product

Complaint Counsel established a strong factual record–and the ALJ agreed–that ingestion of SREMs creates a "real risk of injury and can result in severe injury or death." ID at 8.

Because ingestion was not an "intended" use of the product, however, the ALJ concluded that the admittedly "real risk" of ingestion did not occur as a result of use of the product but rather as a result of misuse. ID at 8. Because of such misuse, the ALJ concluded the risk of injury did not occur as a result of magnet operation or use. Such a conclusion does not comport with the law.

According to the regulations, 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. The uncontroverted evidence shows that use of the Subject Products, and those of virtually identical products, causes severe injury and death. *See* CC-24; CC-25; CC-26; CC-27A at 4, 6-8, 10-13, 15; CC-28 at 8; CC-29 at 4. The regulations do not state that a defect arises only if the risk of injury occurs as a result of the "proper" use of the product or that misuse negates a finding of defect. To the contrary, the regulations contemplate foreseeable misuse. *See* 16 C.F.R. § 1115.4(d) (defect may be present based on "[r]easonably foreseeable consumer use or misuse"). The ALJ's conclusion, therefore, that "it cannot be said the risk of injury occurs as a result of SREM use or operation" is premised on the flawed legal understanding that such "use" only encompasses "proper use" or advertised use. Thus, the ALJ incorrectly concluded that the ingestion hazard only could support a defect finding if the Subject Products were "marketed for oral ingestion" or "advertised for oral ingestion . . . ." ID at 8, 18-19. The ALJ's conclusion that the Subject Products did not present a defect as a result of their operation and use was erroneous because Complaint Counsel established, Respondent admitted, and the ALJ agreed, that ingestion of the Subject Products by toddlers, young children and adolescents was foreseeable. The regulations confirm that foreseeable misuse does not remove a product from beneath the defect umbrella, and the ALJ erred in concluding otherwise. *See* 16 C.F.R. § 1115.4; CC-19A at 2-4, 13-17; CC-21; CC-22; Tr. 377:12-379:3, 419:7-8, 420:20-421:2, 423:8-11, 2411:16-2412:10; ID at 26.

Had the ALJ applied the law correctly in this instance, the defect inquiry would have ended and the ALJ would not have had to reach the question of whether the warnings were also defective and whether an analysis of the factors in 16 C.F.R. § 1115.4 showed that the risk of injury was of the type to render the Subject Products defective. There too, however, the ALJ applied a flawed legal analysis to reach a conclusion at odds with the record.

2. *The ALJ Erred in Finding That the Warnings Are Not Defective*

The ALJ's embrace of warnings as a cure-all for the risk of egregious injury presented by the Subject Products is not supported by the record or the law. Complaint Counsel established that regardless of the warning –even one that instructs users not to ingest the product and informs them of the catastrophic consequences of ingestion–those warnings would never be adequate to address the risk of injury because the warnings could not travel with separated magnets. *See* CC-10A at 14, 45-47; CC-19A at 12, 15; Tr. 381:16-382:10, 2605:14-2606:16. The ALJ, however, sidestepped the well-developed record on this point, positing instead a straw man argument that Zen's warnings "do not contain a fault, flaw, or irregularity which causes a weakness, failure, or inadequacy." ID at 12. The ALJ concluded that no such flaw or weakness existed because Zen warned consumers about the ingestion hazard and because there was "no credible evidence consumers were harmed despite these warnings . . . ." ID at 15. Leaving aside that this conclusion ignores that Zen provided no warnings for a long period and that its warning against ingestion only evolved over time, this conclusion fails to address Complaint Counsel's main contention that the content of the warnings ultimately is without consequence because users and their caregivers are unlikely ever to see those warnings. The warnings could therefore never be adequate because, as the evidence showed, most children who ingest SREMs obtained lost or

shared SREMs without ever seeing any warnings. *See* CC-10A at 14, 27-28, 31-33, 37-38; CC-19A at 12, 15; Tr. 381:16-382:10, 2604:3-2606:6.

Moreover, the ALJ's conclusion is based on the misguided understanding that warnings alone can be sufficient to mitigate risk. The regulations state that a product defect may result from a product's warnings, but the regulations do not sanction all risk simply because the warnings do not have a fault, flaw or irregularity that causes a weakness or failure. Such a view mistakenly assumes that any level of risk may be mitigated provided a product contains warnings. Nothing in the statute, regulations, or case law supports the view, suggested by the ALJ's reasoning, that any manner of hazard would be permissible provided a manufacturer slaps a warning on its product. Testimony adduced at the hearing, and supported by academic analysis of the Subject Products, demonstrates that even fulsome warnings are not, as here, sufficient to adequately address the risk of injury. Because of their inherent limitations, confirmed by documented evidence, warnings are not always appreciated or understood, particularly when associated with benign-looking items like the Subject Products. Parents and children therefore routinely disregard such warnings. *See* CC-19A at 11-12,16-18. Despite this evidence, the ALJ placed undue emphasis, without support in the record, on the value of warnings and Zen's ability to warn away even the most severe risks.

The ALJ also erred in concluding that the low number of documented incidents associated with the Subject Products compelled a conclusion that the warnings were effective to deter ingestion, and wrongly dismissed as irrelevant injury and incident information associated with ingestions of substantially similar magnets. As an initial matter, the ALJ simply ignored credible evidence that the Subject Products caused specific injuries to identified individuals. *See* ID at 16. Moreover, he failed to consider that the differential in injury data between Zen and

Buckyballs was the product of their enormous differential in market share. That more injuries were associated with Buckyballs than Zen Magnets is entirely consistent with Buckyballs market dominance. *See* Tr. 1474:3-8, 1478:19-1479:2, 1484:19-1485:1. His dismissal of documented injuries caused by virtually identical products also reveals a lack of understanding of the governing regulations and precedent that should have guided his legal analysis. Not only is a showing of injury unnecessary to establish a defect because the CPSA requires only evidence of a risk of injury and not proof of actual injury, the evidence of injury caused by identical products such as Buckyballs was precisely the type of information the ALJ should have relied on to inform his decision instead of waiting for a "body count," an approach Commission precedent has specifically instructed against. *Dye* at 11.

The ALJ also erroneously credits the efficacy of Zen warnings and, at the same time, over emphasizes Buckyballs advertisements for oral uses of its product. Although the ALJ repeatedly references such Buckyballs advertisements (neglecting to mention any other Buckyballs advertising content), the evidence does not show that Buckyballs in fact advertised its products mainly for oral purposes and nothing in the record suggests that those who suffered injuries from Buckyballs were aware of any such advertisement. *See* ID at 18, 25. There is simply nothing in the record to support the ALJ's finding on this point, which amounts to rank speculation. So too is his conclusion that the Zen warnings were efficacious. No evidence, let alone a preponderance of the evidence, supports the ALJ's conclusion that Zen's warnings sufficiently deterred ingestion. *See* ID at 16. In fact, the record showed that that most SREM users were unlikely to ever see warnings. *See* CC-10A at 14, 27-28, 31-33, 37-38; CC-19A at 4,11-12,16-18; Tr. 2604:3-2606:1; 2480:1-12. Zen presented no evidence showing that

consumers saw and heeded its warnings. The ALJ's conclusion, therefore, that the warnings were efficacious in preventing injuries from the Subject Products finds no support in the record.

3. The ALJ Erred in Finding That the 16 C.F.R. § 1115.4 Factors Did Not Demonstrate that the Subject Products Are Defective

The ALJ improperly disregarded Complaint Counsel's evidence in considering the "defect" factors specified in 16 C.F.R. § 1115.4, and failed to properly weigh all of the factors, completely ignoring one factor (necessity) and mistakenly giving undue weight to the product's utility. ID at 28. A reasoned analysis of the defect factors demonstrates that the Subject Products are defective because they separate from their sets, resulting in children ingesting them, causing potentially severe injury or death.

The ALJ found that the magnets separate from their sets and that when ingested, all similar magnets, regardless of brand, create a risk of serious injury. ID at 7- 10, 16-17 . Where the ALJ erred, however, was in concluding that the separation of magnets does not pose a risk of injury. Instead, the ALJ incorrectly found that "the risk of injury associated with SREMs does not derive from the severability of the magnets, but emanates from ingestion." *Id.* at 14. Thus, the ALJ concluded that separated magnets "are *harmless*," "do not result in *any exposure* to danger," and thus do not "create *any* threat to *any* individual." ID at 7-10 (emphasis added). This conclusion shows a fundamental misunderstanding of ingestion hazards. A consumer product can create a "threat" and "exposure to danger" precisely because a portion of the product separates from the rest of the product and then can be ingested. Indeed, under the ALJ's reasoning, the Commission would have no reason to require child-resistant packaging on medicine containers because the medicine, when properly used, does not cause a hazard, as the hazard would only emanate from the improper ingestion by a toddler. So too would small parts

regulations be unnecessary to prevent a choking hazard because the risk of injury does not derive from a product containing a small part but from the ingestion of that small part.

Taken to its logical conclusion, the ALJ's reasoning would allow any manner of hazard to go unaddressed if actions by a child contributed to the resulting injury from a product. Inadequate furniture prone to tipping over would be acceptable in this view because the injury hazard emanates from a child climbing on that furniture. Pool drains that eviscerate children would not need to be addressed because the hazard results from children improperly sitting on or coming into contact with those drains. Laundry pods that poison children would be acceptable because the risk of injury only occurs when a child is able to access the product and ingest it. The list goes on, showing the flawed analysis at the heart of the ALJ's fundamental conclusion that the risk derives not from the product, but from "improper" use (however foreseeable) of that product by a vulnerable population.

The definition of "defect" in 16 C.F.R. § 1115.4 rejects this absurd result, recognizing that a product may be defective if its design creates a "risk of injury." Zen designed its products so that hazardous magnets would separate and, foreseeably, be ingested when used. Accordingly, the Subject Products are defective because "the design presents a risk of injury to the public" due to SREMs that become separated and pose an ingestion risk. 16 C.F.R. § 1115.4.

4. The ALJ Erred in Disregarding the Significance of Severe Injuries and Death of Children Caused by SREMs

Although the ALJ correctly found that SREMs can cause severe injury or death, he erred in characterizing serious, life-threatening injuries to children, including the emergency room treatment of an estimated 2,900 children, as "insignificant." ID at 23. The ALJ further erred in blaming SREM injuries generally on parents and children who lacked "intelligence" or "education," and specifically blaming the death of a 19-month-old girl on her mother, even

though her daughter obtained innocuous-looking shared SREMs that were unaccompanied by any warnings. ID at 18-19, 23. The ALJ ignored unrebutted testimony from an expert with 40 years of experience in child and adolescent developmental psychology that SREM ingestion generally is a result of natural childhood behavior and not the result of parental neglect or an absence of diligent supervision. CC-19A at 8-12, 15; Tr. 472:8-13, 473:4-8.

5. The ALJ Improperly Applied Commission Precedent

The ALJ wrongly applied Commission precedent. In *In re Dye and Dye*, CPSC Docket No. 88-1, 1989 WL 435534 (Initial Decision, Mar. 30, 1989, unanimously upheld by Commission Jul. 17, 1991), the Commission determined that the Worm Gett'r electric worm-catching probe presented a substantial product hazard. The facts and analysis supporting *Dye* compel a defect finding here. In *Dye*, it was "readily foreseeable" that children could be exposed to the Worm Gett'r's electrical charge by wandering into the area where the product was used, and thus "even proper use of the Worm Gett'r would expose a user or bystander to a substantial risk of harm." ID at 9, quoting *Dye* at *2. Similarly, it is reasonably foreseeable that young children will be exposed to the risk of magnets in areas where magnets are used, when they find SREMs that become separated during "proper use," or receive shared SREMs.

In re Francis Alonso, Jr. d/b/a Mylar Star Kites, CPSC Docket No. 75-16 (Initial Decision, June 21, 1976, rev'd on other grounds, Sept. 16, 1977) (*Mylar*) also supports a defect finding. There, the Commission found that electrically conductive kites "presented a danger through normal use" because they could accidentally contact power lines, posing an electrocution hazard. ID at 11. Similarly, when magnets are used, they can become lost or separated from the set and accidentally swallowed by a small child or adolescent, posing a risk of serious injury or death. Both *Dye* and *Mylar* support a defect finding here.

B. The Initial Decision Incorrectly Found That Some Subject Products Do Not Violate the Toy Standard

The Initial Decision correctly found that Subject Products that were either sold without warnings or labeled for use by children under age 14: a) are "toys;" b) were sold in violation of the Toy Standard; c) are "substantial product hazards;" and d) must be recalled. ID at 16 n.6, 34. Zen did not file a cross appeal challenging this finding, and thus has waived any claim that its products sold without warnings or with age labels of 12 and up are not substantial product hazards. *See* 16 C.F.R. § 1025.53(e); *El Paso Nat. Gas Co. v. Neztsosie*, 526 U.S. 473, 479 (1999) (absent a cross-appeal, an appellee may not seek "either to enlarge[e] his own rights" or "lessen[] the rights of his adversary").

Having found that Zen advertised, marketed, and sold such "toys" for years, the ALJ then erred in finding that those same products suddenly were not "toys" simply because Zen tweaked its age recommendation or added an in-package or online warning. ID at 31-33. Whether a product is subject to the Toy Standard is based on a review of the product's design, manufacturing and marketing; it is not simply a semantic exercise that can be coyly evaded with a packaging makeover. Zen specifically marketed its products with an "appropriate usage age as 12 years and older." ID at 34. It still does so to this day.[6] The ALJ wholly failed to consider how Zen's years of advertising and marketing its "toys" that were "compatible" with Buckyballs could so suddenly be undone by a simple label change. CC-10A at 14. Thus, the ALJ erred in finding that Subject Products with these new age limits or warnings were not "toys" even though: a) Zen had previously sold the exact same product with a label explicitly providing for use by children under 14; b) Zen has "suggested and marketed" its products with "an appropriate usage age as 12 years and older" on its website, and in fact intended to market the product to

[6] *See* Zen Magnets website at http://zenmagnets.com/relations/#FAQ, accessed May 4, 2016.

such age group; c) Zen itself has "classified the product as a toy" and "recognized that the product might be used by children under the age of 14;" and d) Zen's products were in fact used by children under 14. ID at 31, 34. The evidence shows that the Subject Products are "toys" with hazardous magnets that violate the Toy Standard, creating a substantial risk of injury to the public.

The ALJ also erred in limiting a recall of products sold without warnings to products sold prior to May 2010. ID at 34. The evidence shows that Zen continued selling many magnet sets without warnings through at least May 2012. *See* CC-55; Tr. 2351:17-2352:1.

III. COMPLAINT COUNSEL'S EVIDENCE

A. The Subject Products Are High Flux Magnets

The Subject Products are 5 mm spherical magnets with a flux index greater than 50. CC-1A at 5, 6; CC-7; CC-8; Tr. 97:13-18. Zen Magnets are shiny, silver-colored SREMs sold in sets of 72, 216 or 1,728 magnets. *See* Exh. A to Complaint Counsel's Post Hearing Argument at ¶¶ 4, 12-16, 34-39, 57, 77; Tr. 1467:4-1468:7. Zen Magnets were mainly sold at zenmagnets.com, and a small number were sold in about 18 retail stores. Tr. 1543:8-17; 1548:12-19; Tr. 1563: 4-11; 1717:13-22; 1718:1-7: 1733:5-1734:22. Zen provided free spare SREMs with most of its Zen Magnets sets, offered spares for sale online, and included a packaging insert describing them as a "fun toy." *See* CC-10A at 13, 16, 19, 22-24; CC-44. Neoballs are shiny, brightly colored SREMs sold exclusively online since 2012 where consumers can purchase one or multiple magnets. *See* Exh. A to Complaint Counsel's Post Hearing Argument at ¶¶ 4, 60, 78-80, 83, 85; CC-5; CC-5A; CC-10A at 23; Tr. 1469:4-6, 11-13.

B. Warnings on the Subject Products

None of the Zen Magnets sold prior to May 2010 contained warnings. Tr. 2333:11-15. On May 24, 2011, a CPSC investigator inspected Zen's facility in Colorado and obtained samples of Zen Magnets from Shihan Qu, the owner of Zen Magnets. Tr. 1716:3-15; 1951:6-1952:11; 1963:20-1964:19. The investigation established that Zen Magnets were advertised on the Firm's website with a warning not to give them to children under the age of 12, but the products themselves did not contain in-package warnings. CC-54. Based on the staff's determination that Zen Magnets offered for sale by the Firm were toys with a hazardous magnet in violation of the Toy Standard, staff issued Zen Magnets a "Notice of Non Compliance." CC-54. Because the Subject Products at that time lacked warnings about the hazards of magnet ingestions, the Notice stated, "consumers may have unknowingly purchased this product for children under the age of 14 years or for use in households with children under the age of 14." *Id.* Staff requested that the Firm stop sale and recall products sold with the 12+ age limit. Zen, however, refused to recall the products and continued to sell them. CC-16; Tr. 1995:2-6.

On May 15, 2012, a CPSC investigator again inspected Zen's facility and found that Zen was still selling the Zen 72 piece Mini Set and 216 piece Original Set without in-package warnings. *See* CC-55; Tr. 2348:21-2350:21, 2351:17-2352:1. Zen had sold thousands of sets by that date, all without any warnings. *See* CC-16, entries 1-16945. The only warnings that consumers encountered were those displayed on the website at the time of purchase, advising that children ages 12 and up could use the Subject Products. *See* CC-55. Subject Products sold after May 2012 had a variety of in-package warnings; however, none of the warnings addressed the risks posed by separated SREMs that are lost or shared with others. Instead, some of the in-package warnings referred to the product as a "fun toy" and suggested that the product could be

appropriate for children 8+, 12, or 14. CC-11 at 17, 18; CC-44; Tr. 2356:6-2358:12; Exh. A to Complaint Counsel's Post Hearing Argument at ¶¶ 44-50.

The Zen Magnets website advertised the Subject Products as "fun to play with" and recommended their use by children ages 12 and up. Tr. 2245:3-2247:1. However, through a few simple clicks on the website, a user could purchase Zen Magnets without seeing any warning or age label. Tr. 2253:11-2254:2. Products bought on Zen's website could be shipped directly to a person of any age, and then placed into the hands of a young child without the child or a parent seeing a warning. Tr. 2247:15-2254:2. The Neoballs website allows users to bypass a warning with one click. Tr. 2218:7-15. Although Shihan Qu testified that Zen Magnets required retailers to check identification and provide warnings to buyers prior to a sale, within hours of that testimony an undercover CPSC investigator purchased Zen Magnets from two of Zen's retailers without either protocol being followed. Tr. 2621:11-2622:15, 2624:2-2629:19.

C. The Subject Products Separate From Their Set

Dr. Paul Frantz, an expert in the field of human factors, examined the Subject Products and their warnings. He studied the Subject Products to determine how easily SREMs may separate from their sets. Dr. Frantz found that if a user drops SREMs, they "separate so quickly that it is nearly impossible to see them separate without a slow motion replay . . . ." CC-10A at 18. The only way to ensure that no individual SREMs are lost is to count each magnet after each use; however, the instructions do not advise consumers that such a protocol should be followed and, Dr. Frantz testified, consumers would be highly unlikely to do so in any event. CC-10A at 20. According to Zen, it would take two people working "at least ten minutes each to refine a 2 pound glob of [1,728] knotty magnets back into a useful construction chain" to see if any were lost. CC-10A at 10, 18-19; CC-63 (Zen website). Dr. Frantz determined that it was

unreasonable to expect consumers to account for separated SREMs, especially given Zen's failure to warn users that SREMs pose a risk of injury if separated from their set. Indeed, Zen did not expect its users to keep track of all their SREMs. CC-10A at 9-10, 19-22.

Zen knew from the first year it began selling SREMs, in 2009, that consumers lost them "all the time." CC-10A at 22; CC-11 at 53; Tr. 305:8-13. Knowing that SREMs would become separated and lost, Zen accommodated the loss by providing free and low cost spares – 220,000 spares in total. *See* CC-10A at 23-25; Tr. 349:20-350:13. Spares were provided without any on-product warnings. *See* CC-11 at 52. Dr. Frantz testified that the ease of separating and losing SREMs means that anywhere SREMs are used may become a "contaminated space" if as few as two SREMs are lost. CC-10A at 4, 20-21. Any child who enters that space in the future may find and ingest those SREMs. CC-10A at 33 (citing CC-18.16, 18.27)Tr. 394:9-18, 399:7-400:2. In fact, Dr. Frantz examined an In-Depth Investigation (IDI) of the case of toddler Braylon Jordan, who ingested magnets that his parents believe had been lost under a couch. CC-10A at 33; CC-18.27.

Zen designed the Subject Products to be separated during normal use. Indeed, recognizing that SREMs need to be separated to use them, Zen provided a free PVC card tool with many of its sets to aid in separating magnets. CC-57 at 2-3. Because the Subject Products are designed to be separated when used as intended, Zen acknowledged that magnets from its sets will be separated, shared with friends, or in some cases lost altogether. *See* CC-10A at 19, 2-23: CC-33 at 1; CC-34 and CC-35. Shihan Qu stated that he has personally lost magnets and that "commonly magnets can be lost when sharing with friends." CC-11 at 30. Users reported to Zen that SREMs became lost, sometimes within hours of purchase. CC-33 to CC-35. Zen stated on its website that the loss of SREMs was expected and routine – "Stories like this we hear all

the time. Understandably. The magnets are small, easy to separate, and often stick where you may not expect." CC-10A at 22; CC-11 at 12.

Zen's own experts similarly reported losing the Subject Products. Dr. Boyd Edwards stated that children visited his home, played with his SREMs, "and when they left, I was four short." Tr. 1404:8-1405:9, 1436:22-1437:4. He also had "maybe 10" SREMs that "flew in all directions" when he was using them; he found them on the floor and stuck to the dishwasher. Tr. 1407:9-1409:6. Dr. Edwards also stated that his son lost three SREMs while playing with them. CC-10A at 21. Similarly, Zen witness Dr. Anthony Pelletier stated that he lost SREMs in his classroom; despite searching for them, he never found nine SREMs. R-189 at 44:3-15.

Dr. Frantz also examined Commission staff's incident reports and IDIs which explained how children obtained SREMs. Dr. Frantz found that 45% of those children obtained SREMs from another child and 12% found lost SREMs. CC-10A at 30; CC-11; Tr. 380:10-22. Importantly, these children (and their caregivers) were unlikely to have seen any of Zen's in-package warnings. CC-11 at 48*;* Tr. 381:1-18. Accounts and testimony from parents whose children ingested SREMs without ever seeing warnings corroborated these findings. Joint Notice Exhs. B, D, F, J.

D. Separation of SREMs Leads to Ingestion by Infants, Toddlers, Tweens and Teens

Dr. Laurence Steinberg, a psychologist specializing in children and adolescence for over 40 years, examined the evidence in this case, including reports and medical records of children accessing and ingesting SREMs. Dr. Steinberg testified that infants and toddlers are drawn to the Subject Products' shiny metallic features, and will touch, mouth, and ingest the products as they explore their environment. CC-19A at 2-4, 6; Tr. 418:3-14, 419:7-8, 420:20- 421:2, 423:8-11. Some of these children gain access to SREMs which are lost, unbeknownst to the child's

caregiver. CC-19A at 11; Joint Notice, Exh. H. In other cases, infants or toddlers gain access to SREMs purchased for older siblings. The stipulated testimony regarding Emilyano Hoeft, who ingested magnets his older sister was using as jewelry, and Muneeb Mokhtar, who ingested magnets his older brother was using to create sculptures, illustrate these scenarios. Joint Notice Exhs. A, G. Stryder Licata suffered devastating injuries after swallowing SREMs he thought resembled candy. Joint Notice Exh. I; CC-19A at 5-6, 10; CC-20.

Tweens and teens are drawn to SREMs, Dr. Steinberg testified, because they see celebrities and others using them to simulate tongue piercings and jewelry. CC-19A at 13-14, CC-21, CC-22. Zen supports this usage by marketing the magnets for "self-adornment." Tr. 2411:16-2412:10; CC-64; CC-65. In many cases, children bring them to school where they share SREMs with friends and imitate behavior they see on the internet. CC-19A at 13-17; Tr. 431:16-432:6. Tweens and teens who use the Subject Products to mimic piercings can accidentally ingest SREMs when the SREMs suddenly snap together and repel down their throats. CC-19A at 15, 16; Tr. 377:15-378:19. Sara Andelin, Jocelyn Bustamante, and Marin Gold accidentally ingested SREMs in this manner. Joint Notice, Exhs. B, D, F. Similarly, Christin Rivas obtained six Zen Magnets from a friend without ever seeing warnings and accidentally swallowed two of them. CC-19A at 14; Joint Notice, Exh. J.

E. Ingestion of SREMs Causes Injuries

Dr. Adam Noel, a pediatric gastroenterologist, was qualified as an expert in the field of pediatric gastroenterology, and as an expert in the diagnosis and treatment of SREM ingestions by children. CC-27A at 5. Dr. Noel testified that ingested SREMs can attract through intestinal tissue and clamp together. *Id.* at 7. The SREMs compress gastrointestinal tissue with sufficient force to cause tissue necrosis or death. *Id.* In as little as eight hours, SREMs that attract through

gastrointestinal tissue can burrow through intestinal walls, creating fistulas or holes through which bowel contents can escape and cause serious infection and sepsis. *Id.* at 8, 10. SREMs also can attract through two separate portions of intestines and cut off blood flow to the lower portion, resulting in ischemic bowel. *Id.* at 9; CC-24; CC-25; Tr. 748:1-755:14, 761:21-762:9.

Dr. Noel's expert opinions are based on his review of an extensive body of medical data, including 95 incident reports prepared by CPSC staff. CC-27A at 4; Tr. 615:6-14, 609:10-18. Dr. Noel noted that children who ingested SREMs suffered serious injuries and required invasive medical intervention that ranged from x-rays, to endoscopies and surgeries. *Id.* at 8, 10-13 citing, *e.g.*, CC-18.35 and CC-30 (Patient M In-Depth Investigation (IDI) and medical records); CC-18.7 and CC-31 (Bruski incident report and medical records); CC-18.15 (Child A IDI and medical records); CC-18.48 (Rivas IDI and medical records); CC-18.9 and CC- 32 (Bustamante IDI and medical records); CC-28 at 8; CC-29 at 4; CC-39. Surgical procedures were performed to remove magnets when endoscopies were not successful, to repair holes in the bowels, or remove damaged intestines. Tr. 588-90; CC-27A at 7-10. As with all surgeries, a risk of injury or death is possible; however, even non-surgical procedures to remove swallowed SREMs can result in life-threatening injuries, such as the trauma suffered by Jocelyn Bustamante when doctors attempted to flush ingested SREMs from her digestive system but mistakenly introduced fluid into her lungs, resulting in respiratory distress. Joint Notice at Exh. D, ¶¶ 5-7; CC-27A at 13; Tr. 768:8-770:13.

The diagnosis and treatment of SREM ingestions is impeded by the fact that the cases present with symptoms that mirror those of a stomach bug or flu; as a result, parents may not seek immediate medical attention. Medical professionals who do not know that an ingestion has occurred or who may not appreciate the risk of harm presented by the ingested SREMs may

follow standard "wait and see" protocol. This standard approach, however, can allow the injuries to worsen. CC-24; CC-25; CC-27A at 10-12; Tr. 763:13-766:21.

Dr. Noel's testimony about the mechanism of injury was further informed by a NASPGHAN study of 481 cases of magnet ingestion by children, 123 of which were reported in clinical detail. The study revealed that children who ingest SREMs are at a higher risk of medical intervention than children who ingest other foreign bodies. CC-27A at 6, 7. Nearly 80% of children who ingest SREMs require medical intervention, compared to 10-20% who ingest other foreign bodies. *Id.*; Tr. 742:8-743:12. A significant percentage of children in the study needed invasive medical intervention or surgery: 52% needed endoscopies; 21% needed both endoscopy and surgery, sometimes because of unsuccessful endoscopies, and an additional 6% needed surgery to remove magnets or repair holes in their intestines. CC-27A at 6, 7; CC-28 at 8; CC-29 at 4; Tr. 589:1-22; 742:8-20. Dr. Noel also testified that the safe removal of SREMs can be impeded by the attraction force between surgical equipment and the magnet. Tr. 588:13-589:9, 775:6-776:1.

Although physicians commonly see foreign body ingestions in children under three, the risk presented by SREMs is unique because SREM ingestions span a wider population. The NASPGHAN study, which was approved by the LSU Health Science Center Institutional Review Board, Tr. 557:8-19, revealed many cases in which infants and toddlers suffered SREM ingestion, but the injury patterns associated with SREM ingestions also evidenced a second peak among tweens and teens. CC-27A at 7; CC-28 at 4; CC-29 at 3; Tr. 733:22-7367. This injury pattern is unique to SREMs and places a different category of children at risk. CC-27A at 7; Tr. 735:10-736:2.

In addition to data from IDIs and NASPGHAN, Kathleen Stralka, a CPSC expert in epidemiology and statistical analysis, testified that staff had projected approximately 2,900 incidents of ingestions that were treated in hospital emergency rooms between 2009 to 2013, using data in the National Electronic Injury Surveillance System (NEISS). Tr. 885:18-22; 887:1-10; 913:10- 17; CC-39 at 1. NEISS data were collected from emergency rooms, coded and analyzed, to project nationwide SREM incidents. Tr. 894:12-896:1-4, 902-906. The projections are based on a hospital coder's summary of medical data sent to CPSC staff. Tr. 890:8-17, 902:6-19, 1143:6-15. Staff consulted with in-house experts to review the data to determine if an incident involved SREM ingestion. Tr. 889:5-10, 916:13-15, 1007:5-1008:13, 1047:10-22, 1048:1-6. Technical staff who reviewed NEISS data also reviewed anecdotal evidence of ingestions, identifying SREMs in the NEISS data not by a specific product code or keyword, but through an analysis of narratives in ingestion reports. Tr. 1161:20-1162:19. Staff incorporated a dynamic range of descriptors based on terminology that evolved considerably from 2009 to 2013. *Id.* Ms. Stralka used her expertise to assess the NEISS incident data and compute the nationwide projection of 2,900 cases. Tr. 889:1-13, 912:1-913:4.

Respondent presented no expert testimony from engineers, human factors experts, child psychologists, medical doctors, or epidemiologists to rebut any of Complaint Counsel's expert evidence.

IV. ARGUMENT

A. Legal Standard

1. Standard of Review

The Commission considers the whole record, but shall "exercise all the powers which it could have exercised if it had made the Initial Decision," and is free to "adopt, modify or set

aside" any or all of the ALJ's findings and conclusions. 16 C.F.R. § 1025.55. Although CPSC's adjudication rules do not specify a standard of review, courts have interpreted similar rules as providing for *de novo* review. *See, e.g., Landry v. FDIC*, 204 F.3d 1125, 1138 (D.C. Cir. 2000), *cert. denied*, 531 U.S. 924 (2000) (in administrative proceedings, ALJ has "purely recommendatory power" subject to *de novo* review). Under *de novo* review, the Commission "review[s] the matter anew, the same as if it had not been heard before, and as if no decision previously had been rendered." *Freeman v. Directv, Inc.*, 457 F.3d 1001 (9th Cir. 2006).

2. Burden of Proof

The Administrative Procedure Act, 5 U.S.C. § 551 et seq., and the case law interpreting it, establish the standard of proof that a proponent must meet to prevail in an administrative adjudicative proceeding. That level of proof, applicable in this case, is the preponderance of the evidence standard. *See Steadman v. S.E.C.*, 450 U.S. 91, 104 (1981) (determinations in agency adjudicatory proceedings "are made according to the preponderance of the evidence"), *reh'g denied*, 451 U.S. 933 (1981). This standard applies in CPSA Section 15 proceedings. *See Dye* at *4 (Complaint Counsel must meet its burden by "a preponderance of the evidence").

A preponderance of the evidence standard "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 [court] of the fact's existence.'" *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993), quoting *In re Winship*, 397 U.S. 358, 371–372 (1970) (Harlan, J., concurring). The Commission may accept Complaint Counsel's evidence if a fact is "more likely to be true than untrue," which "is a less stringent standard of proof than the 'clear and convincing' or 'beyond a reasonable

doubt' standards.'" *Dye* at *4. Complaint Counsel has satisfied this burden with respect to each element necessary to find that the Subject Products are a substantial product hazard.

B. The Subject Products Constitute a Substantial Product Hazard Under Section 15(a)(2)

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). The Subject Products are defective for three distinct reasons and those defects create a substantial risk of injury, thereby presenting a substantial product hazard. The Subject Products are defective because: 1) a risk of injury occurs as a result of its operation and use, including reasonably foreseeable misuse; 2) the warnings are defective and no warning adequately addresses the risk; and 3) application of the factors under 16 C.F.R. § 1115.4 shows that the risk of injury associated with the Subject Products renders them defective.

1. The Subject Products Are Defective Because They Present a Risk of Injury That Occurs As a Result of Their Operation and Use

The Subject Products are defective because they present a risk of injury that occurs as a result of their operation and use. That is, the Subject Products are designed to be separated, allowing them to be ingested by children, causing severe injury or death. The design defect is inherent in the product because the condition creating the risk–loose, separable, accessible SREMs that are easily lost or shared–constitutes the basic character of the Subject Products. CC-10A at 7, 13-16, 25; Tr. 343:5-344:3, 385:19-386:2. The creation of figures and sculptures advanced by Zen is not possible unless the magnets are separated. Tr. 2536:15-21. Zen encourages consumers to build such creations to enter Zen-sponsored online contests. R-195; R-196; Tr. 1688:6-8, 1692:1-9.

Zen admits that some SREMs may be lost or given away and never returned to the set. CC-10A at 19, 22-23; CC-11 at 52, 53; CC-33 at 1; CC-34; and CC-35. Expecting that consumers will lose or share magnets, Zen accommodates this by including free spares with the 216 piece Gift Set and 1,728 piece Mandala Set, and by offering low-cost spares online. CC-10A at 23-25; Tr. 255:18-256:1, 305:8-13, 346:5-348:15. Severe injury caused by the operation and use of the Subject Products occurs because the space in which a magnet is lost becomes "contaminated." CC-10A at 4, 20-21; CC-11 at 51; Tr. 254:9-17. Magnets that become separated or lost can be propelled into unknown places on the floor, to the bottom of chairs and underneath couches, where infants and toddlers are likely to discover them. CC-10A at 4, 20-21; Tr. 1407:9-1409:6. Young children who later enter areas contaminated by lost magnets have accessed and ingested separated magnets and suffered serious injury. CC-10A at 29-30, 32-33, 35-36, 39-40; CC-27A at 9 (22-month-old severely injured and put in induced coma after finding and swallowing eight SREMs); Tr. 394:9-18, 399:7-400:2. Ample testimony showed that such behavior is foreseeable. CC-19A at 2-4, 13-17; CC-21; CC-22; Tr. 377:12-379:3, 419:7-8, 420:20-421:2, 423:8-11, 2411:16-2412:10; ID at 26.

Because the Commission was well aware of the risks posed by liberated magnets, the Commission worked for years to keep children safe by ensuring that products containing SREMs not allow magnets to escape. Prior to the introduction of high-powered magnet sets in 2009, magnet injuries typically occurred when magnetic components separated from a product–in other words, when a product broke. CC-10A at 5-6; CC-11 at 32-33; Tr. 252:9-254:17. The hazard posed by such liberated magnets led to recalls of the products because children could and did ingest magnets which became separated from the product, resulting in serious injury and death. CC-10A at 5-6.

Here, the Subject Products are made of hundreds of individual SREMs but they have no "containment system" to keep them from becoming separated–they are *designed* to be broken apart– and in that sense are identical to products recalled due to SREM separation. *Id.* at 5-7; (discussing recalls of toys that broke and released magnets); CC-11 at 49; Tr. 251:18-252:5. However, the risk posed by the Subject Products is even greater because the Subject Products do not look "broken"; to the contrary, as the ALJ acknowledged, a few separated magnets appear to present no risk at all to parents or children who come across them, or to medical professionals who later treat ingestions. *See* ID at 24 (their danger is "something medical professionals, let the alone the average consumer, would not realize"); CC-10A at 6-7; CC-19A at 12-13; CC-24; CC-25; CC-27A at 10-12.

The ALJ erroneously held, however, that the Subject Products could be defective only if "ingestion was part of the product's 'use' or 'operation.'" ID at 8. In other words, Zen had to advertise that children should place SREMs in their mouth or eat them; otherwise, ingestion would constitute "misuse." *Id.* at 10, 17. The ALJ concluded that because a risk of injury must occur from a product's intended *use*, not from *misuse*, the Subject Products do not present a risk of injury. *Id.* at 8. This conclusion is directly contrary to the language of the applicable regulation, 16 C.F.R. § 1115.4, and is erroneous for two reasons.

First, separation of SREMs is a direct result of the intended use of the product and it is that separation that exposes children to a risk of injury from magnet ingestion. Just as with small parts, medicine, laundry pods or nearly any other ingestion hazard, it is the separation of the hazard from the product that creates a risk of injury due to ingestion. This is particularly true for separated shiny and colorful SREMs, which are enticing to young children who, as Dr. Steinberg testified, want to mouth them and may mistake them for candy. *See* CC-19A at 5 (describing 4-

year-old who mistook SREMs for candy resembling chocolate balls he saw on a wedding cake). A handful of SREMs also seem innocuous to tweens and teens, who may receive them from a friend and attach them to their braces or use them to mimic piercings and then inadvertently swallow them when they suddenly snap together and repel down their throat. *See* CC-10A at 36-37; CC-19A at 13. Complaint Counsel presented unrefuted evidence that ingestion by children who obtain lost or separated SREMs without seeing warnings and then use them to engage in age appropriate behavior is not "misuse." *See* CC 10-A at 40, 42; CC-19A at 12-15.

Second, even if ingestion is characterized as "misuse," it is evidence of a defect because it is foreseeable misuse. A defect may result both from "[r]easonably foreseeable consumer use or misuse" of a product. 16 C.F.R. § 1115.4(d). Complaint Counsel's unrebutted expert testimony proved such use was foreseeable. Dr. Steinberg, whose analysis was informed by more than 40 years of experience in developmental psychology, stated that infants and toddlers foreseeably would be attracted to and intentionally ingest SREMs. *See* CC-19A at 8. This likelihood of attraction and ingestions is enhanced when the product is used by an older sibling to create playful figures, and if the end product is displayed. *See* CC-19A at 9-11; Joint Stipulation Exhibit A, Hoeft Decl. (describing injuries to 3-year-old who swallowed magnets given to his older sister by a friend). Zen Magnets encourages the creation of figures in contests, including a Monopoly themed contest and others in which cartoon characters are featured. *See* R-195, R-196; Tr. 1704:8-16.

Dr. Noel, an expert in pediatric gastroenterology, and Dr. Frantz, a human factors and warnings expert, each testified that infants and toddlers in fact did ingest SREMs that had been lost, used to build figures or create jewelry, or brought into the house for an older sibling. CC-27A at 10-13. Similarly, Dr. Steinberg established that tweens and teens foreseeably will use

SREMs in ways that can lead to accidental ingestion, and that such behavior is entirely age appropriate. CC-19A at 12-13. Moreover, parents do not caution against such use, believing that their tween or teen is old enough to know not to intentionally swallow non-foods. CC-10A at 27. Dr. Noel and Dr. Frantz testified that tweens and teens engaged in exactly such expected behavior. CC-10A at 36-38; CC-27A at 12-13. Thus, even if ingestion is considered "misuse," it is evidence of a defect because it is reasonably foreseeable. *See* 16 C.F.R. § 1115.4. It was error for the ALJ to disregard ample evidence in the record demonstrating that ingestion resulted from foreseeable use (whether or not it is characterized as misuse), and that error was compounded by his failure to apply the appropriate legal standard which contemplates that a defect may arise from foreseeable misuse.

Because the ALJ wrongly determined that SREM separation creates no risk of injury and that misuse could not be evidence of a defect, the ALJ also wrongly applied Commission precedent. In *Dye*, it was "readily foreseeable" that children could be injured by the Worm Gett'r, and it is similarly foreseeable that young children will be exposed to the risk posed by separated magnets. Complaint Counsel submits that it is even more foreseeable that children will be exposed to separated or lost SREMs because users may not appreciate that SREMs have been lost in a particular space, so there is even more potential for children to be exposed to the hazard posed by SREMs. *See* CC-10A at 45.

In *Dye*, the Commission also noted that the CPSA requires only a risk of injury and no "proof of actual injuries." Thus, the Commission found the Worm Gett'r to be defective even though it caused no fatalities, because it shared the same "functional characteristics" as other brands that did cause injuries. *Dye* at *6. Here, the ALJ properly determined that the Subject Products are "nearly identical" to other SREMs that have also caused injuries to children. *See* ID

at 18. In finding that SREMs do not pose a risk of injury, however, the ALJ improperly considered that the fatality rate of products that were substantially similar to the Subject Products "far exceed[ed] that of the SREMs at issue here." ID at 9. Just as the Worm Gett'r could not be readily distinguished from brands that had been associated with incidents and injuries to consumers, the Subject Products cannot be distinguished from Buckyballs and other SREM brands associated with incidents and injuries. CC-10A at 29; CC-27A at 13. Zen Magnets and Neoballs have no identifying marks or labels when outside the packaging; thus, many consumers and medical professionals were not in a position to identify the brand of ingested SREM. As the *Dye* court noted, the absence of incident and injury data is not determinative:

> It is a major function of the [CPSC] to prevent injury and death from consumer products, and [CPSC] regulations make it clear, as noted, that identification of actual injuries or deaths do not stand as an absolute prerequisite to corrective actions by the CPSC.

Dye, at 20.[7]

However, unlike *Dye* where the Commission was unable to present evidence of a single injury or incident associated with a Worm Gett'r, Complaint Counsel proved that Zen Magnets did in fact cause injuries*, see infra* at 36-38; however, it appears that the ALJ ignored that evidence. Even if there were no injuries, however, the risk posed by the Subject Products is established by their similarity to other magnet products that have resulted in injuries and death. *See* ID at 18 (finding that the Subject Products are "nearly identical" to Buckyballs); CC 1-A at 8 (Subject Products and other brand SREMs have "no functional difference in magnetic strength or size"); CC-10A at 13, 29 (Zen marketed its products for use as jewelry, similar to Buckyballs).

[7] Quoting an argument advanced by Complaint Counsel in that case, the Dye court noted: "[T]he Agency was established by Congress to prevent injuries and deaths from consumer products and not just to react to injuries and deaths from these products. . . . **[T]he Agency is not limited to 'body counts'** but may use any available means to seek out and identify product hazards." *Dye* at 16. (emphasis added).

S*ee also U.S. v. Zen Magnets, LLC*, 2016 WL 1114560, at *3-4 (D. Colo. Mar. 22, 2016) (finding Neoballs "indistinguishable" from a competitor's SREMs). Evidence of 2,900 projected ER visits for SREM ingestions was also instructive, but was disregarded by the ALJ. Such evidence should have been considered, just as the court in *Dye* relied on projections by a Commission expert who testified that there was a high probability that three or more persons may be electrocuted by P&M Worm probes over the course of the useful life of the products, with a projection of 7.5 electrocutions possible. *Dye* at 11. Thus, contrary to the ALJ's finding, the reasoning underlying the decision in *Dye* supports a finding that the Subject Products are defective.

The *Mylar* case also supports a defect finding. The ALJ here attempted to distinguish the risk from "normal use" of electrically-conductive kites from a similar risk caused by use of magnets by finding that the kites' conductivity was merely aesthetic while SREM's strong magnetism is functional. The ALJ concluded that if the kites' electrical conductivity "improved functionality" then "there is no question" it would not be defective. ID at 11. Complaint Counsel disputes the ALJ's conclusion that a design feature that adds functionality to a consumer product cannot be the basis for a defect finding. Neither the regulations nor the statute provides a basis for that conclusion. The ALJ's interpretation of *Mylar* evidences a fundamental misunderstanding of the CPSC statute and regulations, for even if a kite had greater "functionality" at the cost of electrocuting any child who allowed it to touch overhead wires, it would still present a substantial product hazard. The presence or absence of enhanced functionality simply does not inform an SPH inquiry under the statute, notwithstanding the ALJ's unsupported assertion to the contrary.

In fact, the reasoning in *Mylar* compels a finding that the Subject Products contain a defect that creates a substantial product hazard. Both the kites and SREMs are "attractive recreational devices" that, even when used as intended, can result in an accidental event that poses a risk of injury to children. As noted in *Mylar*, the kites are not intentionally flown into power lines, but come into contact with them "when an aluminized kite breaks it string or otherwise becomes uncontrollable and falls across power lines." *Mylar* at 11. The court held that not only did the instructions that accompanied the product fail to effectively communicate the hazard, it was not likely that they would be obeyed; thus, the risk of incidents was clearly foreseeable. *Id.* at 11.

Similarly, when SREMs are used, they can become lost or separated from the set and accidentally swallowed by a small child or adolescent. In such scenarios, the warnings that may have accompanied the product are no longer present, making it unlikely that a parent or child would ever see the warning or understand the risk; thus, the risk of ingestion incidents is clearly foreseeable. The risk of injury posed by use of the magnets, whether characterized as misuse or not, renders them defective.

2. The Subject Product's Warnings Are Defective

A product may be defective because of inadequate warnings. 16 C.F.R. § 1115.4. By way of example, the regulations note that inadequate instructions and safety warnings may create a defect if they contribute to a risk of injury due to "[r]easonably foreseeable consumer use or misuse" of a product. *Id.* at (d).

The Subject Product's warnings are defective because no warning, even one that fulsomely warned against ingestion, could mitigate the risk that magnets will separate and be lost during use and thus negate the warning. CC-10A at 9-10, 46-47; Tr. 255:14-256:1. Moreover,

that inadequacy cannot be cured because the magnets are too small to carry their own warnings. ID at 15.

The ALJ correctly found that the various iterations of in-product and website warnings that accompanied Zen Magnets and Neoballs "do not address the severability of the magnets," but erred in finding that severability does not create a risk of injury. ID at 14. Complaint Counsel's evidence, presented through Drs. Steinberg and Frantz and 95 IDIs where children accessed and ingested SREMs, established that ingestion is a foreseeable result of severability. CC-10A at 36-37, 40, 42; CC-19A at 5, 12-15. Users separate and lose magnets during normal use of the Subject Products, so the warnings do not, and could not, advise users to exercise the amount of caution required to prevent users from having SREMs separate from their sets. *See* CC-10A at 9-10. Mr. Qu himself, as well as his own witnesses, testified about their own loss of SREMs. *See* CC-10A at 21; CC-33 to CC-35; R-189 at 44:3-15; Tr. 305:8-13, 1404:8-1405:9, 1436:22-1437:4. Indeed, Zen contemplates that sharing and loss will occur even among the most careful of users and accommodates this expected loss by providing spares. *See* CC-10A at 23-25. Complaint Counsel's evidence established that shared or lost SREMs foreseeably will be obtained by children and ingested, and as Dr. Noel testified, ingestion may result in serious injury or death. *See* CC-19A at 5-6, 10-14; CC-20; CC-27A at 7-8. Respondent presented no evidence to the contrary.

The warnings also are defective because they do not accompany the product at all times. Children (and their caregivers) who obtain lost or shared magnets never see any warnings, and because of the design of the products, warnings cannot be placed on the magnets themselves. CC-10A at 14: CC-19A at 12, 15; Tr. 381:16-382:10. Contrary to the ALJ's characterization of Complaint Counsel's argument, it is not an "absurdity" to find a product to be defective because

its design precludes a necessary warning about the risk of severe injury and death. ID at 15. This is particularly true where, as the ALJ acknowledged, "a consumer is not likely to appreciate the full magnitude of the risk associated with SREM ingestion if the product is separated from its packaging and warnings." *Id.* at 24. On-product warnings would provide notice to a consumer during each and every use of the product; warnings contained in the packaging and online warnings may be seen once and disregarded or discarded. CC-10A at 28 (citing CC-18.48), 31 (citing CC-18.24), 32 (citing CC18.37), 34 (citing CC-18.48), 36 (citing CC-18.19), 38 (citing CC-18.33) (mother of four year old bought SREMs for child, believed he would not mouth items; child swallowed nine magnets believing them to be candy, suffered catastrophic injuries).

The ALJ also improperly concluded that the warnings were not defective because there were no injuries linked to the Subject Products. ID at 16. Not only does this conclusion fly in the face of the clear language of the regulations and case law that injuries are not necessary for a finding of defect, the conclusion demonstrates a complete disregard for specific evidence establishing that children in fact were injured by the Subject Products.

The CPSA does not require the Commission to wait until children are harmed before a product is recalled. *See* 16 C.F.R. § 1115.4 (a product may have a defect even if "there are no reports of injury.") Injuries are not required to establish a defect where, as here, experience about an identical product can inform the analysis. Zen designed the Subject Products to be "nearly identical" to other SREMs, ID at 18, directly competed with Buckyballs, and marketed the Subject Products as "compatible" with Buckyballs. Tr. 1778; CC-10A at 14. Additionally, Vincent Amodeo testified that he found the size, strength, and flux of Buckyballs, Zen Magnets and Neoballs to be similar. CC-1A at 8. Because of the similarity of the Subject Products to other SREMs, parents of injured children often did not know the brand of the magnet that injured

their child and medical professionals are also unable to identify an magnet's brand, factors that undermine the reliability of the conclusion that "no" injuries resulted from the Subject Products. CC-27A at 13 (most of the brand names of the magnets involved in ingestion incidents cannot be identified"); Tr. 936:20-937:3 (medical records typically do not identify brand names). Furthermore, the hazard presented by SREMs is the same regardless of brand. *See* CC-27A at 13 ("all 5 mm SREMs, regardless of the brand name, behave the same way once ingested, and pose the same risk of serious injury."). In such a case, an evaluation of the risk posed by the products is far more relevant than a tally of children injured or killed by a specific brand. *See, e.g., Dye* at *6. To quote Complaint Counsel in *Dye*, a "body count" is not required for the Commission to find a product to be defective.

Moreover, at least two children *were* seriously injured by the Subject Products, and a third individual reported swallowing a Zen Magnet. *See* Tr. 2563:16-2565:15 (testimony from Mr. Qu that he knew of "two confirmed ingestions" by children where "our subject products . . . led to injury" and an additional report from a third person who said they swallowed a Zen Magnet). In the first incident, Barbara Rivas testified that her 14-year-old daughter obtained six Zen Magnets from a friend and accidentally swallowed two, requiring surgery to remove part of her colon and intestines. Testimony of Barbara Rivas at ¶¶ 4, 11, 14. The ALJ wrongly disregarded this statement as "little more than hearsay." ID at 16 n.5. Ms. Rivas's testimony was "admitted into the record as if the witness[] had testified to such statements at the hearing," Joint Notice at 1, after the ALJ asked the parties to "stipulate to the occurrences without bringing all the details that are probably more emotional than legally required for me to make a decision." Tr. 808:14-18. As such, Ms. Rivas's testimony was admitted as an in-court statement and is not hearsay, and is entitled to the same weight as if she presented live testimony. *See* Fed. R. Evid.

801(c). Conversely, the ALJ quoted at length from a number of Respondent's stipulated, unsworn statements from witnesses who had no personal experience using the Subject Products, yet the ALJ did not consider those hearsay. *See* ID at 21-22.

Furthermore, Ms. Rivas's knowledge about the brand of SREMs that severely injured her daughter is supported by evidence completely disregarded by the ALJ. Ms. Rivas testified that, on November 18, 2013, her daughter Christin received six Zen Magnets from a named friend who bought them online shortly before the incident. Joint Notice Exh. J at ¶ 14. Zen's business records showed that this friend's family purchased 216 Zen Magnets online just three weeks before the incident. CC-16 at entry 32482. Zen's records show that this magnet set came with six free spares, the same number of SREMs shared with Christin. *Id.*; CC-10A at 28. Ms. Rivas testified that she had never seen any warnings with the Zen Magnets, Joint Notice Exh. J at ¶ 13, and indeed Zen's spares had no warnings against sharing them or about any risks posed by shared SREMs. Tr. 2605:14-18 ("Q: So the question was, a child takes the baggy of six spares, hands it to a friend, that friend will not see any warning on that baggy right? A: [Mr. Qu] Yes.") Taken together, this demonstrates by a preponderance of the evidence that the six SREMs given to Ms. Rivas's daughter were Zen Magnets. Respondent did not dispute any of this evidence.

Similarly, the ALJ disregarded evidence of a second ingestion incident involving Zen Magnets. Dr. Noel testified about Patient M, a 15-month-old who suffered severe injuries to her intestines after ingesting SREMs. CC-27A at 11, CC-30A to 30C. Dr. Frantz testified that his review of Zen's business records showed that Patient M's parents had purchased 216 Zen Magnets that also came with six free spares. CC-10A at 28; CC-16. Mr. Qu testified that he also was able to confirm that Patient M's parents bought Zen Magnets prior to their daughter ingesting the SREMs. Tr. 2329:6-11. Importantly, Mr. Qu testified that Patient M's parents

bought the Zen Magnets during the time that Zen distributed its products without any warnings. Tr. 2932:11-19; 2933:11-15. This demonstrates, by a preponderance of the evidence, that Patient M ingested Zen Magnets that came with no warning about any risks posed by the SREMs. Mr. Qu further testified that he learned of a third incident in which a consumer reported that he had ingested a Zen Magnet. Tr. 2565:1-15.

Complaint Counsel established by a preponderance of the evidence that the warnings do not and could prevent SREMs from becoming separated, and therefore do not and could not warn children (and caregivers) who obtained separated SREMs of any risk at all. Accordingly, the warnings are defective.

3. The Subject Products Are Defective Under the Factors in 16 C.F.R. § 1115.4

In addition to containing a design defect and a defect in their warnings, the Subject Products are defective under an application of the factors set forth in 16 C.F.R. §1115.4:

- 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. In analyzing these factors, the ALJ erred by disregarding evidence in the record and misinterpreting the CPSA and Commission precedent. A proper analysis of the defect factors shows that the risk of injury presented by the Subject Products renders them defective.

a. The Subject Products Have Limited Utility

The ALJ improperly found that the Subject Products have "high" utility. ID at 20. In balancing the documented incidents of severe injuries to children against the utility of the Subject Products, the ALJ disregarded affidavits testifying to the grievous injuries caused SREMs, and relied disproportionately on a handful of statements alleging that SREMs have utility. *Id.* at 20-22. Disregarding the death of a toddler, minimizing the permanent injuries and daunting long-term prognosis for several children, and characterizing emergency room treatment by an estimated 2,900 children to be "insignificant," the ALJ improperly placed significant weight on the testimony of eight Respondent witnesses who liked to use SREMs. ID at 21-23.

One of those witnesses, Dr. Edwards, was improperly accepted by the ALJ to be an expert witness (*see infra* at 64-68). Respondent proffered Dr. Edwards as an expert in the "educational utility of the Subject Products." Tr. 1272:15-17. The ALJ allowed Dr. Edwards to speculate about a hoped-for "predicted . . . trend" of using SREMs to teach; a "trend" that has yet to materialize. Indeed, the ALJ noted that even Dr. Edwards conceded that SREMs are not "in widespread use in academia" and that he never actually used or needed SREMs during his many years of teaching. ID at 21 n.8. The ALJ attempted to explain the lack of evidence showing any widespread pattern of SREM use in academia by relying on Dr. Edwards's questionable testimony that there could be a "lag in integrating new teaching techniques"

because "it can take a year or two to change a syllabus," even though SREMs have been sold since 2009. ID at 21 n.8.

Furthermore, Respondent's argument, and the ALJ's finding, that Zen Magnets have utility due to their high magnetic flux are undercut by recent actions taken by Mr. Qu. As of November 2015, Zen has been selling "Compliance Magnets," advertised as small magnet spheres with less magnetic strength than the Subject Products. The Commission may take official notice of this fact. 16 C.F.R. § 1025.43(d) (Commission may "at any time" consider facts generally known within the jurisdiction of the Commission or whose accuracy cannot be reasonably questioned). In promoting the new magnets, Zen states that Compliance Magnets have a similar utility to Zen Magnets – they "will obey, conform, and abide by all CPSC regulations but still be capable of most of the same structures as Zen magnets." U.S. Department of Justice Filing in *Zen Magnets, LLC v. Consumer Product Safety Commission*, No. 14-9610 (D. Colo. Nov. 6, 2015) (attached at Exh. 1).[8] Zen's sale of substitute magnets further demonstrates the error in the ALJ's finding that that the "spherical and magnetic qualities" of the Subject Products have high utility because they are so "unique." ID at 22.

Because Respondent has stated that Compliance Magnets can be used to create the same figures and structures that Boyd Edwards and other Respondent witnesses testified were helpful in an educational setting, the strength of Respondent's utility argument is diminished. Thus, the evidence wholly fails to establish that the Subject Products have high utility.

There was also no evidence that the Subject Products required a flux of over 400. *See* CC-1A; CC-7; CC-8. Although the magnets must have attraction value, Respondent did not demonstrate that a flux in excess of 50 was essential for that purpose. On this point, the

[8] Zen's statements concerning Compliance Magnets are admissible as a party admission. *See* Federal Rule of Evidence 801(d)(2).

reasoning of the court in the *Dye* case is instructive: "Nothing in the record establishes… that in order for the worm prove to function effectively it requires full line voltage, 120 volts of electricity." *Dye* at 21-22.

b. The Subject Products Present a Risk of Serious Injury or Death

Complaint Counsel established, and the ALJ properly recognized, that SREMs can cause serious injury or death to children who ingest them. ID at 17. In as little as eight hours, ingested SREMs may create holes in a child's intestines, causing severe infections, or may clamp intestines together, destroying gastrointestinal tissue. CC-24; CC-27A at 8, 10; Tr. 748:1-16. These injuries can cause, and have caused, permanent damage or death. CC-27A at 7; CC-28: Tr. 754:1-755:14. An estimated 2,900 children sought emergency room treatment due to SREM ingestion, and Commission staff prepared 95 incident reports and IDIs documenting SREM incidents and injuries.CC-27A at 4, 10-13; CC-36; Tr. 913:8-17, 931:17-22. The NASPGHAN study also documented 481 cases of magnet ingestion by children. CC-27A at 6. Children who ingest SREMs are at an increased risk for invasive procedures, with almost 80 percent requiring an endoscopy or surgery, or both. *Id.*

The ALJ properly recognized the types of injuries caused by SREMs, but erred in concluding that the risk of injury is not significant. Indeed, the ALJ concluded a risk of injury would be "significant only when [the Subject Products are] advertised for oral ingestion and/or when combined with a lack of parental supervision." ID at 19. This finding is erroneous. To find a defect, the CPSA does not require proof that a manufacturer advance the very use that leads to the risk of injury. The hazard need not be intended if it is foreseeable. *See* 16 C.F.R. § 1115.4 (defect may be based on "[r]easonably foreseeable consumer use or misuse"). Because

Zen Magnets are designed to be separated and it is foreseeable that children will ingest separated SREMs and suffer severe injury or death, the risk of injury is significant.

The ALJ also erred in finding an insignificant risk of injury based on a deeply flawed conclusion that the risk posed by un-ingested SREMs is "nil" unless there is a lack of parental supervision. ID at 18-19. This conclusion has absolutely no basis in the record. To the contrary, the unrebutted evidence showed that many children who ingested SREMs either obtained them from friends or found lost SREMs, and thus the children and their caregivers had no reason to suspect SREMs were dangerous. See CC-10A at 30 (in CPSC incident reports that described how children obtained SREMs, 45% of them got SREMs from other children and 12% found lost SREMs). Dr. Steinberg's unrebutted expert opinion showed that parents and caregivers of children who receive or find separated SREMs would have no reason to believe that SREMs posed any hazard to their children. CC-19A at 9-12, 17-18. Infants and toddlers may find and swallow separated SREMs in seconds, such that "[a] caregiver acting with reasonable care even may not even see the child put the magnet in his mouth." CC-19A at 8, 9-12.

Similarly, "a caregiver acting with reasonable care could [not] prevent an older child, ages 9-17— commonly referred to as tweens and teens—from accidentally ingesting magnet balls from the Subject Products." *Id.* at 17-18. Dr. Steinberg explained that "a caregiver would likely never see a warning relating to the Subject Products, and may never know about the dangers associated with the magnet balls." *Id.* Even if a caregiver did see Zen's warnings, Dr. Steinberg explained that those flawed warnings stated "that the product is safe for anyone who has reached the age where they have 'stopped swallowing non-foods.' A teenager is an individual who has stopped swallowing non-foods, so a reasonable caregiver would not believe that the warnings apply to children in that age range." *Id.* This testimony was supported by

affidavits from parents, including one pediatrician, whose children suffered severe injuries from SREMs and testified that they had no reason to suspect the SREMs were dangerous, let alone that they could begin to destroy their children's gastrointestinal tract within hours of swallowing them. *See* Joint Notice Exhs. A-J.

Despite this substantial testimony, the ALJ nevertheless concluded that SREMs pose no risk because ingestion results from parental neglect, a conclusion that appears to be based solely on the ALJ's unsupported speculation about the cause of death of Child A. *See* ID at 18-19. In charging that Child A's death was caused by "a more than negligent parent," the ALJ cited an account contained in a non-testifying police officer's notes in which the officer speculated about the child's exposure to an insecticide found inside the child's house. *Id.* The ALJ completely ignored the testimony of Child A's mother about the ingestion of the SREMs and the sworn affidavit of the medical examiner as well as unrebutted expert medical testimony. Child A's mother testified that her 11-year-old son brought SREMs home in the form of a necklace after receiving them from a friend. Joint Notice Exh. E ¶ 3. Child A's brother took apart the SREM necklace to make a bracelet for himself and another bracelet to share with his little sister. *Id.* at ¶ 6. Child A eventually found and swallowed SREMs from her brother's bracelet. *Id.* at ¶ 10. Child A's mother never saw any SREM warnings and did not know about any dangers associated with SREMs. *Id.* at ¶ 4.

Dr. Steinberg's unrebutted, expert opinion concluded that Child A's mother acted reasonably:

> It was reasonable for her to not suspect that the magnet balls were dangerous. She had not seen them before, and they came into her house without any warnings or packaging. … [Child A's mother] had no reason to know that the magnet balls were dangerous because her older child was bringing into the home something that looked like a toy and could be fashioned into jewelry, he was playing with the

> magnet balls like a toy, and he had received the magnet balls from another child his age.

CC-19A at 10. Indeed, Zen had marketed the Subject Products to be used in exactly the way Child A's brother was using them – as a "wrist-worthy chain" to be worn by middle school children and used as "play jewelry." CC-10A at 13, CC-65; Tr. 2425:3-7. The medical examiner conducted an autopsy on Child A and conclusively determined the cause of death to be "ischemic bowel due to spherical magnets in the small intestine and … the manner of death was accidental." Testimony and Declaration of J. Scott Somerset, M.D., Joint Notice at Exh. K. Zen did not challenge Dr. Somerset's conclusions and, indeed, stated that it had no objection to admitting his testimony. *See* Joint Notice at 1. Dr. Noel further testified that his review of the medical records and autopsy reports associated with Child A's death conformed with Dr. Somerset's conclusion. *See* CC-27A at 12. Respondent presented no evidence disputing the factual findings of Dr. Somerset or Dr. Noel.

Despite the conclusive, unrebutted testimony of Dr. Steinberg, Dr. Somerset and Dr. Noel, and the affidavit from Child A's mother, the ALJ speculated that Child A's death actually "resulted from a lack of proper supervision combined with a more than negligent parent." ID at 19. The ALJ based this conclusion solely on notes from an unsworn police officer who speculated that Child A may have died from exposure to the insecticide Sevin (carbaryl). *Id.* The ALJ placed significant weight on the officer's speculation, finding that "Child A's exposure to an insecticide demonstrates a lack of basic custodial supervision." ID at 19.[9] Yet the evidence shows that the officer's belief was entirely wrong. The toxicology report showed no carbaryl was detected in the child's system. Rather, the medical examiner found SREMs in Child A's

[9] In allowing cross examination on this point of Dr. Noel, the Presiding Officer noted: "I understand that many things are said by people who are not professionals or who are not trained and give opinions such as in police reports. And I will assign that the due weight that it is entitled to." Tr. at 695:2-6.

intestine, which had attracted through the intestines, cut off the blood supply to a portion of the bowel, and caused the tissue to die. CC 18-15; CC-36; Somerset Decl. ¶¶ 11-12. He concluded that SREM ingestion was "the only explanation" for her cause of death. Somerset Decl. at ¶ 11.

The ALJ also blamed doctors for misdiagnosing Child A's symptoms, ID at 19, despite testimony from Dr. Noel that it is extremely difficult for doctors to identify SREM injuries because ingestions present with non-specific symptoms that mirror those of a virus or stomach infection. *See* CC-27A at 10 ("[t]he difficulty in diagnosing ingestion of magnets adds to their risk"). This difficulty is exacerbated when infants or toddlers swallow SREMs because such young children cannot explain what they ingested, resulting in delayed treatment and a greater risk of injury or death. *Id.* at 12. Moreover, because young children often suffer from stomach bugs and viruses, doctors do not immediately believe that extraordinary measures are necessary. CC-27A at 10-11 Tr. 763:13-766:10; 766:12-21. The ALJ blamed Child A's mother and her doctors even though the ALJ found that the "obviousness of the risk [posed by SREMs] is low" and their "propensity to cause intestinal pinching [is] something medical professionals, let alone the average consumer, would not realize." ID at 24.

Complaint Counsel showed by more than a preponderance of the evidence that the Subject Products present a risk of serious injury or death. The ALJ properly recognized the serious injuries caused by the Subject Products and the hidden nature of the risk, yet strained to overcome his own findings to reach the unsupported conclusion that blame lies with neglectful parents.

c. The Subject Products Are Not Necessities

Although the ALJ extensively discussed the utility of the Subject Products, the ALJ completely failed to consider whether the Subject Products are necessities. This failure to address one of the elements set forth in the regulation constitutes error.

The evidence shows that the Subject Products are not necessities. Respondent presented no evidence that any science curriculum would be impeded if the Subject Products were not available. Respondent's expert, Dr. Edwards, admitted that he taught chemistry for 24 years before he knew SREMs existed, and he was able to successfully communicate centuries-old scientific principles without them. Tr. 1401:14-1402:14. Respondent's other witnesses were similarly unable to identify more than a few instances in which Zen Magnets have been used in a class. Tr. 1420:10-13, 1423:1-5. Respondent also testified that Neoballs have a greater variability in their dimensions, are less precise, and are even less suited to demonstrating scientific principles than Zen Magnets. Tr. 1542:15-1543:2, 1647:3-20. Respondent admitted that the products are unlike necessities such as food, water, and shelter. Tr. 2210:18-21. Furthermore, the Commission may take official notice of the fact that Respondent has begun marketing Compliance Magnets as alternatives to the Subject Products, which Zen admits are "capable of [being formed into] most of the same structures as Zen magnets," thus undermining the proposition that the Subject Products are necessities because other products cannot perform the same function. *See supra* at 40.

Having failed to examine whether the Subject Products are a necessity, the ALJ then erroneously compared the Subject Products, which Zen began selling in 2009, to knives, a necessity in use since at least the Paleolithic era 2.5 million years ago.[10] *See* ID at 28-29. The

[10] *See* Richard Hartenberg, Hand Tool, Encyclopedia Britannica, http://www.britannica.com/technology/hand-tool.

Commission rightly explains in its defect regulations that necessities such as knives are not defective simply because they are capable of causing harm. A knife's sharpness "is necessary if the knife is to function adequately," 16 C.F.R. § 1115.4, but is also a known and obvious hazard. Yet the Commission still undertakes a defect analysis for knives, and has recalled knives when they present a substantial product hazard.[11] Similarly, analysis of all the defect factors shows that the Subject Products present a risk of injury that renders them defective. The ALJ erred in comparing the Subject Products to knives without analyzing whether SREMs are a necessity, which the evidence shows they are not.

d. A Vulnerable Population Faces a Risk of Severe Injury as a Result of Exposure to the Subject Products

Contrary to the ALJ's conclusion, it is far from "difficult to identify" the population exposed to the Subject Product's risk of injury. ID at 23. The evidence irrefutably demonstrates that the Subject Products place children – a vulnerable population – at risk.

The ALJ correctly found that an estimated 2,900 children have sought emergency room treatment due to SREM ingestion. ID at 23. In addition, Commission staff documented SREM ingestion in 95 incident reports and IDIs, and Complaint Counsel presented the stipulated testimony of parents whose children ingested SREMs, causing severe injury and even death. CC-10A at 27-28; CC-18.1-CC-18.95; CC-19A at 2-3: CC-27A at 4-5; Joint Notice, Exhs. A-J. The evidence documented two distinct age groups at risk of injury from SREM ingestion: infants and toddlers who will touch, mouth, and ingest the products as they explore their environment, CC-19A at 2-4, 6; Tr. 419:7-8, 420:20- 421:2, 423:8-11, and tweens and teens who use them to stick to braces or simulate tongue piercings and jewelry. CC-19A at 13-14, CC-21, CC-22. Dr. Frantz noted that SREMs demonstrated a unique pattern of injuries among a vulnerable

[11] *See, e.g.,* knife recalls at http://www.cpsc.gov/en/Taxonomy/Products/Kitchen/Knives-and-Slicers/Knives.

population – a pattern of injuries in children up to age 4, followed by a decline in injuries until a second spike in incidents among tweens and teens around age 9-17. CC-11 at 36 (Fig. 20).

Despite evidence establishing exactly which age groups are at risk from SREMs, the ALJ found that no identifiable population faced any risk. The ALJ dismissed several thousand estimated injuries to children as mostly affecting those who were careless, uneducated, or had low intelligence, and then ultimately disregarded them all as "insignificant." ID at 23. Additionally, the ALJ improperly concluded that a risk of injury requires evidence that an identifiable population will **always be at risk** due to magnets. Although he acknowledged that the evidence showed that toddlers ingest shiny, colorful, candy-like magnets, he disregarded that evidence because "toddlers will swallow just about anything." *Id.* Having failed to find any particular risk to children, a vulnerable population, the ALJ remarkably concluded that a propensity to "swallow anything" somehow weighed *against* finding a defect. ID at 24.

Complaint Counsel's experts noted that magnets uniquely affect highly identifiable groups of children – infants and toddlers who are attracted to and may intentionally ingest magnets, and tweens and teens who believe they are safely using magnets to stick to braces or mimic piercings and then unintentionally swallow them. The ALJ cited nothing in the record to suggest that these children had low intelligence, less education, were prone to carelessness or had negligent parents, factors the ALJ, incorrectly, suggested were relevant to the case at hand. Those factors, even if present, do not minimize the risk of injury posed by a consumer product.[12]

[12] CPSA Section 2 provides: "The Congress finds that (1) an unacceptable number of consumer products which present unreasonable risks of injury are distributed in commerce: (2) complexities of consumer products and the **diverse nature and abilities of consumers** using them frequently result in an ability of users to anticipate risks and to safeguard themselves adequately; (3) the public should be protected against unreasonable risks of injury associated with consumer products . . . ." (emphasis added).

To the contrary, Complaint Counsel presented expert testimony and testimony from parents that children, ranging from infants to teenagers, ingested SREMs while engaging in reasonable, age-appropriate conduct. Joint Notice Exhs. A-J; CC-10A at 27-28, 31-34, 36-38; CC-18.1-18.95; CC-19A at 4-18; CC-30A-E; CC 31A-C; CC 32. Tweens and teens – including Sara Andelin, Jocelyn Bustamante, and Marin Gold – accidentally ingested SREMs when using them to mimic piercings. Tr. 378:1-6; Joint Notice, Exhs. B, D, F. Christin Rivas obtained six Zen Magnets from a friend without ever seeing warnings and accidentally swallowed two of them. Joint Notice, Exh. J; CC-10A at 28. Fifteen-month-old Child M ingested Zen Magnets that her family had purchased online. Both children who ingested Zen Magnets required invasive surgery to repair injures suffered as a result of the ingested magnets. CC-27A at 11-12; CC-18.35. The evidence demonstrates that the Subject Products present a serious risk to children, a vulnerable population.

e. The Risk Presented By the Subject Products is Not Obvious

Complaint Counsel presented substantial evidence that the risk presented by the Subject Products is not obvious. The ALJ correctly found that SREMs present a non-obvious risk that "militates towards the conclusion that SREMs are substantial product hazards." ID at 24. The ALJ found that "a consumer is not likely to appreciate the full magnitude of the risk associated with SREM ingestion if the product is separated from its packaging and warnings." Further, the ALJ found that doctors also may not realize the dangers posed by ingested SREMs. ID at 24. Despite reaching these conclusions, the ALJ then minimized their importance, stating that "warnings adequately address the issue with consumers." *Id.* For the reasons discussed at pages 9-12 and 33-38, the ALJ's overreliance on the value and efficacy and adherence to warnings is misplaced.

f. The Subject Product's Warnings Fail to Mitigate the Risk

As demonstrated above, the Subject Product's warnings are defective and do not and cannot mitigate the risk because: 1) the warnings do not and could not warn users to never lose SREMs, and 2) children who obtain lost or shared SREMs never see the warnings. *See supra* at 33-38. Specifically, the warnings are not kept with the product and cannot therefore mitigate the risk posed by separation of individual magnets. Tr. 381:16-382:10. Additionally, many Subject Products were sold without any warnings at all through at least May 2012. CC-55; Tr. 2351:17-2352:1. The ALJ erroneously found that the Subject Product's warnings mitigate their risk because there was no "credible evidence" that the Subject Products harmed anyone, disregarding two documented incidents where Zen Magnets were ingested and caused serious injuries and excluding numerous other cases where unknown brand SREMs injured children. Most importantly, by suggesting that injuries are a prerequisite to a defect finding, the ALJ misapprehended the law. ID at 25.

The CPSA does not require the Commission to wait until children are harmed before a defective product is recalled. In elucidating possible defect scenarios "to assist subject firms in understanding the concept of a defect as used in the CPSA," the Commission included an example of a power tool with inadequate warnings and instructions: "*Although there are no reports of injury*, the product contains a defect because of the inadequate warnings and instructions." 16 C.F.R. §1115.4(d). Consistent with that guidance, the ALJ in the *Dye* case found a defect due to inadequate warnings, despite the fact that not a single consumer was injured by the product at issue. *Dye* at 21. Thus, the ALJ erred in pointing to the lack of injury as evidence that the warnings were adequate.

Both cases involving Zen Magnet ingestion also confirm the mistaken reliance on warnings as a means to appropriately safeguard against the risk posed by the Subject Products.

In each case, the children's parents never saw any warnings. *See supra* at 36-38. Even if Respondent improved its in-package warnings, those warnings never reach children who obtain shared or lost magnets. In addition, the warnings that the ALJ credits with successfully deterring ingestions are far from "explicit" and "clear." *See* ID at 13-14. In fact, the record is replete with evidence that thousands of products were sold without any in package warnings; with dense and confusing warnings that contain no age limit, inadequate age limits, or multiple age limits; or with online warnings that can be easily bypassed.[13] The evidence shows that warnings do not and cannot mitigate the risk posed by the Subject Products.

g. The Role of Consumer Misuse of the Product and the Foreseeability of Such Misuse

Complaint Counsel established by a preponderance of the evidence that it is highly foreseeable that children will use the Subject Products in ways that lead to ingestion of SREMs. Once SREMs are separated from their set, children foreseeably obtain and ingest them when they find lost SREMs or receive shared SREMs from friends. Infants and toddlers ingest SREMs as part of their normal mouthing behavior. Tweens and teens do not intend to ingest SREMs and in fact believe they are using them in a safe manner to mimic tongue piercings, yet SREMs still unexpectedly snap together and repel down their throat. The evidence shows that this occurs due to normal, age-appropriate behavior by children who obtain lost or shared SREMs without ever seeing warnings. CC-10A at 40; CC-19A at 8, 12-13. The ALJ deemed ingestion by children to be "misuse," and held that "the misuse is foreseeable even where the warnings are present." ID

[13] CC-10A at 46-47; Tr. at Tr. at 2247-2254 (website had no warnings or warnings that could easily be bypassed); Tr. at 2333:11-15 (no warnings with Zen Magnets before May 2010); CC-55, Tr. at 2350:16-21, 2351:17-2352:1 (no warnings with Zen Mini and Zen original sets through May 15, 2012); Tr. 2480:17 (Zen changed its website warnings during a break in the testimony of Mr. Qu at the hearing), Tr. 2602:10-14 (Mr. Qu acknowledged at the hearing that "the warnings for Zen Magnets keep changing, the paper warnings, website warning, as recent as this week the website warnings have changed"); Tr. 2605:14-18 (Zen's spares have no warnings); Tr. 2606:2:6 (individual Neoballs have no warnings on them); ID at 13-14 (documenting variety of warnings).

at 26. The record does not support this conclusion.

Although Complaint Counsel disagrees that ingestion of magnets by children may be characterized as misuse, the foreseeability of such use or misuse is nevertheless proof of a defect. *See* 16 C.F.R. § 1115.4 (a product may have a defect if "a risk of injury occurs as a result of the operation or use of the product," including "[r]easonably foreseeable consumer use or misuse"). The unrebutted testimony of Dr. Steinberg established that children who swallow SREMs are not misusing them – they are engaging in age-appropriate behavior. *See* CC-19A at 8, 13-14. Dr. Steinberg also established that SREMs are enticing to young children who foreseeably will want to mouth them and may mistake them for edible candy. *Id.* at 5-6. Likewise, Dr. Steinberg testified that tweens and teens foreseeably will attach SREMs to their braces or use them to mimic piercings and then inadvertently swallow them when they suddenly snap together and repel down their throat. *Id.* at 13-14. Complaint Counsel presented unrefuted evidence that ingestion by children who obtain lost or separated SREMs without seeing warnings and then use them to engage in age appropriate conduct is not "misuse." CC-10A at 40, 42; CC-27A at 5-6, 13-14. As stated above, the ALJ erroneously found that the Subject Product's warnings – which do not address severability and never warn children who find lost or shared SREMs – deter misuse to such a degree that it is no longer foreseeable.

h. Commission Expertise and Experience Supports a Finding That the Products Are Defective

The ALJ concluded that the agency's expertise in determining risk and hazards posed by the Subject Products should be afforded little weight. ID at 28. The ALJ relied on *Skidmore v.*

Swift & Co., 323 U.S. 134 (1944), but that case is not instructive here as it concerns the standard of review for a court reviewing agency action. Here, there is not yet any final agency action until the Commission issues a final decision in this adjudication.

Moreover, the court's factual basis for minimizing the value of the Commission's expertise was based on an incomplete assessment of the case. The ALJ noted that "the Agency's judgment is [that] the product is a substantial product hazard under Section 15(a)(2) of the CPSC, because its instruction, packaging and warnings are inadequate for U.S. consumers . . . ." *Id.* at 28. This statement shows that the ALJ failed to comprehend the legal and factual basis of Complaint Counsel's case. Complaint Counsel alleged that the Subject Products presented a substantial product hazard under 15(a)(2) because they contained a defect in design, in warnings and instructions, and because the risk of injury rendered the product defective; in addition, the products presented a substantial product hazard under 15(a)(1) because the product failed to comply with the Toy Standard, ASTM 963. The ALJ disregarded agency expertise based on an incomplete understanding of the bases for relief sought by Complaint Counsel.

Commission expertise is particularly relevant here. The CPSC is charged with protecting consumers from unreasonable risks of injury associated with consumer products. The Commission has tasked its directorates with product assessments of hazards associated with consumer products, including products that liberate hazardous magnets. Those assessments were used by staff to negotiate recalls, between 2006 and 2008, of products that liberated hazardous magnets. It is with the background of expertise on the hazards posed by liberated magnets – specifically, the risk of injury and death to children, our most vulnerable population – that the Commission took steps to understand and address the hazards posed by these new, more powerful SREMs.

Responding to an increase in magnet ingestions, the Commission issued a safety alert in 2011 advising consumers of the risk posed by SREMs. As incident and injury data associated with SREMs continued to increase, Commission staff conducted IDIs and collected incident reports concerning 95 incidents to further inform the agency's understanding of the hazards posed by SREMs. CC-18.1-CC-18.95. Staff also engaged its technical directorates from engineering, human factors and health sciences to analyze the products, assess the efficacy of warnings, and determine the risks of injury posed by the Subject Products and other SREMs. Mechanical engineering expert Vincent Amodeo, who has over 15 years of experience at CPSC in evaluating magnets and was integral in the development of the Toy Standard at issue in this matter, evaluated the Subject Products. CC 1-A. Commission epidemiology expert Kathleen Stralka also testified that the Commission collects data on products from a variety of sources, including NEISS data, which is then analyzed by agency subject matter experts to formulate national projections of injuries. In this case, agency experts projected that an estimated 2900 children were treated for SREM ingestions between 2009 and 2013. Tr. 913:8-17. The agency also considers information from outside entities, such as NASPGHAN, to amass data to further inform the expert's understanding of the hazards posed by SREMs. R-130. The ALJ was in error in devaluing the Commission's decades of consumer safety expertise in evaluating whether the Subject Products presents a substantial product hazard.

i. Case Law Interpreting the CPSA Supports a Defect Finding

The ALJ failed to specifically address this factor in his Initial Decision. As explained above, case law from two prior administrative proceedings supports a finding that the Subject Products present a substantial product hazard. In *Dye*, the Commission found that the Worm Gett'r, an electric probe used to conduct electricity into the ground to force worms to the surface,

created a substantial product hazard. The Worm Gett'r had not been associated with any incidents or injuries, but the evidence demonstrated that it was identical to other brands that had caused serious injury and death to consumers. The manufacturer disputed that the product created a risk of injury and argued that any injured consumers did not follow warnings and instructions. The manufacturer further asserted that the electrical voltage was necessary for the product to operate effectively, so that, like a sharp knife, its utility outweighed the risk posed by the hazardous aspect of the product.

The Administrative Law Judge in that case was not persuaded by Respondent's reasoning, concluding that the lack of injuries did not preclude a finding that a product contained a defect, particularly where it was identical to others which had caused injuries. *Dye* at 22. In addition, the court found, that where, as here, warnings "have failed and continue to fail to convey adequately . . . the latent hazard" of the product risk, or where 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." *Dye* at 15. In the same way, the number of incidents and injuries associated with SREMs generally evidences the risk of injury posed by the Subject Products, and the warnings fail to adequately convey the "latent hazard" caused by separated SREMs.

Mylar Kites also supports a substantial product hazard finding here. In *Mylar Kites*, Commission staff charged that aluminized polyester film kites presented a substantial product hazard due to the risk of electric shock if the kite contacted power lines. The court found that the "recreational device" posed a risk of injury if misuse occurred—the string broke, or the user lost control of the kite and it came into contact with electrical lines—and that such use could not be

cured by instructions or warnings. The court also found that the risk of incidents was "clearly foreseeable." *Id.* at 15

Here, the evidence similarly shows that the use of SREMs—which are also recreational devices—create a risk of injury when they are accidentally ingested by teens or by toddlers or infants who come across lost or separated SREMs. Such incidents are foreseeable, *see* ID at 26, and the warnings do not and cannot address the risk of injury posed by the Subject Products.

j. Product Liability Case Law/Federal and State Public Health and Safety Statutes

Complaint Counsel is unaware of case law involving the Subject Products or analogous federal and state health and safety statutes. Complaint Counsel notes, however, that cases have been filed against the manufacturers of similar magnets. *See, e.g., Jordan v. Maxfield and Oberton Holdings LLC*, 2016 WL 1173100 (S.D. Miss. Mar. 22, 2016) (denying motion to dismiss in case involving toddler who suffered severe injuries due to Buckyballs ingestion, allowing case to proceed against the manufacturer and owner Craig Zucker).

4. The Subject Products Are a Substantial Product Hazard Because Defects Create a Risk of Injury to the Public

Because the ALJ did not find that the Subject Products are defective, the ALJ did not analyze whether defects create a substantial risk of injury to the public "because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise." CPSA § 15(a)(2), 15 U.S.C. § 2064(a)(2). Commission regulations explain that "[t]hese factors are set forth in the disjunctive. Therefore, the existence of any one of the factors could create a substantial product hazard." 16 C.F.R. § 1115.12(g)(1). Here, all three factors support a substantial product hazard finding.

a. The Defects Create a Substantial Risk of Injury Because of a Pattern of Defect

Under 16 C.F.R. §1115.12(g)(1)(i), a "pattern of defect" may be demonstrated by the "design, composition, contents, construction, finish, packaging, warnings, or instructions of the product . . . ." As explained above, a pattern of defect is established with respect to both the design and warnings of the Subject Products. The Subject Products are defective as designed because of the operation and use of the product, whereby loose SREMs are meant to separate from a set, resulting in a risk of ingestion and injury. CC-10A at 7, 9-10, 13, 16, 43; CC-27A at 7-10; Tr. 304:21-305:3, 343:5-344:3, 385:19-386:2. The warnings are also defective because they fail to identify the risk of lost or shared SREMs and cannot be remedied to adequately address this risk. CC-10A at 9, 44-47; Tr. 253:6-254:17, 255:14-256:1, 342:4-11, 367:16-368:14. See discussion at 33-38 for additional discussion of the defective warnings.

Accordingly, the pattern of defect arises from the both the operation and use of the product and its inadequate warnings, creating a substantial risk of injury to the public and a substantial product hazard under Section 15(a)(2) of the CPSA.

b. The Defects Create a Substantial risk of Injury Because of the Number of Products in Commerce

Under 16 C.F.R. §1115.12(g)(1)(ii), 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 is likely to occur. Respondent has sold millions of Zen Magnets and Neoballs, including more than 220,000 free or low cost spare magnets. ID at 23, CC-10A at 24; Tr. 349:20-350:13. The evidence demonstrates that it takes only two ingested magnets to cause serious, life threating injuries to a child. CC-27A at 8, 10-13; CC-24; CC-25; CC-26; CC-57 at 4; Tr. 748:1-755:14,761:21-762:9. The millions of individual Zen Magnets and Neoballs sold by

Respondent and thousands of spares distributed by Respondent create a substantial risk of injury to the public.

c. The Defects Create a Substantial Risk of Injury Because of the Severity of the Risk

Under 16 C.F.R. § 1115.12(g)(1)(iii), a risk is severe if the injury which might occur is serious and/or is likely to occur. A "serious injury" includes "[i]njuries necessitating hospitalization which requires actual medical or surgical treatment, . . . injuries to internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day. . . ." 16 C.F.R. 1115.6(c). An injury may be considered likely based on the number of injuries, the intended use or reasonably foreseeable use or misuse of the product, and whether the risk relates to a vulnerable population such as children. *See* 16 C.F.R. § 1115.12(g)(1)(iii). The evidence, including reports of ingestions contained in Commission incident reports IDIs, the NASPGHAN study, and estimated emergency room treatments based on the NEISS data, demonstrates the severity of the risk presented by the Subject Products. CC- 18.1-18.95; CC-27A at 4, 7, 10-13 (summary of injuries caused by SREMs); CC-28 at 14; CC-29 at 5; CC-39 at 1; Tr. 742:14-20; 913:8-13; 748:1-753:19.

The evidence that the Subject Product pose a serious risk of injury to children who ingest them was uncontroverted. Children who ingest SREMs are at a four times greater risk of medical intervention than children who ingest other foreign bodies. CC-27A at 6, 7; Tr.742:8-743:12. The interventions include X-rays and life-threatening procedures including endoscopies, surgical repair, and bowel resections. Tr. 743:13-745:22,746:3-758:22. Of the children in the NASPGHAN study who had endoscopies plus surgeries, almost half suffered intestinal perforations or fistulas. CC-27A at 7; CC-28 at 11, 13-14; CC-29 at 7; Tr. 705:6-17; 742:8-20. A quarter had deep pressure lesions that occurred when SREMs attracted through intestinal

walls. CC-27A at 7. Of the children who required surgery, 16 percent required bowel resections. *Id.;* CC-28 at 13. Some children, including Patient B, will suffer complications for the rest of their lives. Tr. 753:17-756:17: CC-27A at 9- 10. And while many of the children endured excruciating pain as a result of the ingested magnets, 19-month-old Child A died after ingesting SREMs. CC-27A at 12; CC-18.15; Joint Notice, Exh. E at ¶¶ 6-10, Exh. K at ¶¶ 11-12.

Because the Subject Products create a substantial risk of injury due to: (1) the pattern of defect; (2) the number of products in commerce; or (3) the severity of the risk of injury, they constitute a substantial product hazard.

C. The Subject Products Constitute a Substantial Product Hazard Under Section 15(a)(1)

The Subject Products are substantial product hazards because they fail to comply with the Toy Standard, creating a substantial risk of injury to children. *See* 15 U.S.C. § 2064(a)(1).

1. The Subject Products Do Not Comply With the Toy Standard

The Toy Standard is a mandatory consumer product safety rule pursuant to section 106 of the Consumer Product Safety Improvement Act of 2008. The Toy Standard establishes requirements for toys, which are "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." ASTM F963 § 3.1.81 (CC-2). Written in the disjunctive, this definition of a toy is satisfied if a product meets any of these three criteria.

"Toys must not contain a loose as-received hazardous magnet or a loose as-received hazardous magnetic component." ASTM F963 § 4.38.1. A product violates the standard if it contains a loose as-received "hazardous" magnet and is a "toy." *Id.* There is no question that the Subject Products contain loose as-received small magnets with a flux greater than 50, and thus contain hazardous magnets. ID at 34 n.10; Tr. 2536:8-10. The only disputed issue is whether they are "toys."

The Initial Decision correctly found that Subject Products sold without warnings or labeled for use by children under 14: a) are "toys;" b) were sold in violation of the Toy Standard; c) are "substantial product hazards;" and d) must be recalled. ID at 16 n.6, 34.[14] Thus, "some of Respondent's products constitute toys due to Respondent's marketing tactics and lack of warnings." ID at 30. The ALJ also found that:

- Zen "suggested and marketed" its products with an "appropriate usage age as 12 years and older" on its website,
- Zen "classified the [Subject P]roduct as a toy,"
- Zen "recognized the product might be used by children under the age of 14," and
- Zen acknowledged that "some children under the age of 14 used SREMs."

Id. at 31, 34. The evidence also showed that Zen marketed its products as a "fun toy" that makes great "refrigerator art" and promoted it as play jewelry that "look[s] hot on girls" and "looks good on cute people."[15] Zen stated that its products may be used at "whatever age at which a person stops swallowing non-foods," which Dr. Frantz testified was at least by age five. Tr. 316:1-5. Zen also awarded a "$25 Zen Credit to a 7-year-old Named Little Kev," winner of Zen-sponsored contest. ID at 41 (describing CC-17), CC-10A at 26. Furthermore, warnings that came with the Subject Products, as well as those on zenmagnets.com, flatly recommended that children under 14 may "play with" the Subject Products: Zen's "common sense recommendation is [age] 12." Tr. 2570:15-17; CC-48 and CC-50.[16]

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[14] As stated above, Zen did not appeal this finding and has waived its right to contest this finding. *See* supra at 15.

[15] CC-44 ("Fun Toy"); CC-10A at 10, CC-11 at 12 ("look hot on girls"); Tr. 2421:8-11 ("looks good on cute people"); Tr. 2429:18-20 ("terrific for refrigerator art"); CC-10A at 16 (stating that Zen's marketing its products as refrigerator art "shows that it expects consumers to leave them out and displayed in areas where children can access them, play with them, and ingest them."); CC-63 at 2 (website promoting use as refrigerator art).

[16] *See also* Tr. 2231:2-14, CC-45,CC-46 (from Aug. 2009-Oct. 2011, Zen website warning was for age 12); Tr. 2237:15-19, 2244:3-2247:1, CC-48, CC-52 (in Nov. 2011 and since Nov. 2013, Zen website has had "common sense" age recommendation of 12); Tr. 2584:21-2586:2 (Neoballs advertised at zenmagnets.com); CC-50 at 2.

The evidence shows that Zen: 1) called its products a "fun toy;" 2) suggested its products could be used by children under 14; 3) marketed its products with a "common sense recommendation" for use by children under 14; 4) knew children under 14 might use its products; 5) confirmed that children under 14 did in fact use its products; and 6) awarded a gift certificate to a child under 14 specifically to buy its products. This evidence strongly supports a determination that Zen designed, manufactured, or marketed the Subject Products as a plaything for children under 14, making them "toys."

Despite finding that Zen designed, manufactured, or marketed its products for years as "toys" for use by children under 14, the ALJ found the Subject Products were not "toys" for three reasons: 1) Zen restricted the retail sale of its products only to "adult hobby stores" and "marijuana dispensaries" who followed a "rigorous" sales protocol; 2) Zen sold its products online where no child was able to purchase them; and 3) these sales practices evidence an "intent" for SREM use only by persons age 14 and up. ID at 32-33. The ALJ also held that even if the Subject Products are toys, they do not create a substantial risk to the public, "a conclusion which would preclude the application of the toy standard in and of itself." *Id.* at 33. These findings are not supported by the evidence.

Zen's retailers were not "restricted to 'adult hobby shops' and 'marijuana dispensaries,'" and did not follow a "rigorous protocol" of providing verbal warnings to buyers and obtaining purchaser identification to ensure buyers were over 18. *Id.* at 32. Zen sold Zen Magnets not only at adult shops, but also at toy stores, a bath and body shop, and hobby stores selling both adult and children's toys. CC-69; CC-70; Tr. 2621:18-2622:7, 2625:2-10, 2626:15- 18, 2627:1-2628:19. CPSC investigator Christina Fredrick testified that, on December 12, 2014 – hours after Mr. Qu testified that these "rigorous" protocols were in place in all brick and mortar

locations – she was able to purchase the Subject Products from a Hobby Town store and Soldis, a bath and crystal kiosk without receiving any written or verbal warnings or having to produce identification. Tr. 2621:18-2622:7; 2625:2-10; 2626:15-18; 2628:13-19. In fact, at Soldis – a kiosk selling bath and body products in the middle of a shopping mall – when Ms. Fredrick asked a clerk whether he sold "toys," the clerk took Zen Magnets out of a display case and showed them to her. Tr. 2624:4-9 and 15-17; CC-68; CC-69. She purchased Zen Magnets without receiving any verbal warnings from the clerk, and no warnings were visible on the outside of the packaging. Tr. 2624:18-20; 2625:2-4. She was not asked to show identification or age verification. Tr. 2625:8-10. Similarly, Ms. Fredrick saw Zen Magnets for sale at Hobby Town, which also sold toys and hobby items. Tr. 2627:1-2628:19. She purchased Zen Magnets there without receiving a verbal warning or verifying her age. Tr. 2627:14-2628:19; CC-70. In addition, Respondent admitted that it advertised Zen Magnets to the general public on billboards posted throughout the city of Denver. Tr. 1755:15-18, 1757:13-21 (ads had no warnings); R-132. This evidence refutes the ALJ's finding that Zen limited retail sales to adults, sold its product only at adult retailers, and imposed a rigorous sales protocol to prevent sales to children.

The evidence also shows that Zen had no age restrictions for sales on its websites. Respondent's zenmagnets.com site does not limit purchases by age, and has allowed Zen Magnets to be sent to someone of any age without a buyer seeing a warning or age restriction. Tr. 2247:15-2254:2.[17] Similarly, the neoballs.com site allows a user to click past a warning without reading it. Tr. 2218:7-15. Neither site contains a failsafe that requires users to acknowledge receipt of warnings before ordering. Tr. 2247:15-2254:2; Tr. 2218:7-15. Zen even

[17] Respondent acknowledged the deficiencies in its website after they were elicited through cross examination; within hours of that testimony, Zen's website had been changed to add new warnings. *See* Tr. 2447:12 to 2448:7; Stipulation of Counsel Regarding Images from the Web Site of Zen Magnets, LLC, Dec. 18, 2014.

awarded a gift certificate to purchase Zen Magnets from its website to a seven-year-old who won a Zen-sponsored contest. CC-10A at 26, CC-17.

The ALJ also erred in holding that because Zen did not "intend" to sell and market the Subject Products as toys and to children, they are exempt from the requirements of the Toy Standard. ID at 32. Because the Toy Standard is not based on the "mens rea" of a manufacturer, a simple avowal by Respondent that he did not intend his product as toys for children is insufficient. The proper analysis requires an inquiry into how Zen designed, manufactured, or marketed its products. ASTM F963 § 3.1.81 (CC-2). Zen designed, manufactured, or marketed its products as a "fun toy" for children under age 14 to "play with" for uses such as "self-adornment" and "play jewelry," and Zen has acknowledged that children under 14 do in fact play with its products. For a majority of the time that Zen has been selling magnets, and continuing to this day, Zen *still* states that its age recommendation to "play with" Zen Magnets is age 12.[18] The absence of evidence that a child under age 14 purchased Subject Products online or in a brick and mortar store is not evidence that the product is not a toy. *See* ID at 33. A preponderance of the evidence shows that the Subject Products meet the definition of a "toy" under the Toy Standard.

2. The Failure of the Subject Products to Comply With the Toy Standard Creates a Substantial Risk of Injury to the Public

As demonstrated above, the Subject Products pose a substantial risk of injury to the public. However, the ALJ held that the Subject Products do not create a substantial risk to the public, stating that this conclusion "would preclude the application of the toy standard in and of itself." ID at 33. This conclusion is not supported by the record, as Complaint Counsel

[18] *See* Tr. 2237:15-19, 2244:3-2247:1; CC-48, CC-52; Zen Magnets website, http://zenmagnets.com/relations/#FAQ, accessed May 4, 2016.

established by a preponderance of the evidence that the Toy Standard is applicable to the Subject Products because of their design, manufacture, or marketing to children under 14. Accordingly, Zen's sale of its "toys" constitutes a substantial product hazard because the toys contain hazardous magnets that present a substantial risk of injury to the public for the reasons described amply throughout this brief and the evidentiary record.

The Commission has recognized the substantial risk posed by loose hazardous magnets since at least 2006, when it recalled dozens of toys with liberated hazardous magnets after children swallowed the magnets and suffered serious injuries. CC-10A at 5-6; CC-11 at 32. SREMs present the same risk of injury created by toys recalled during this period due to liberated magnets. CC-10A at 6. That the Subject Products present the same risk is confirmed by incident data collected by CPSC staff about the Subject Products and Buckyballs, which the ALJ found to be "nearly identical" to the Subject Products. ID at 18. This risk of injury is more than speculative; Zen Magnets did in fact cause injury to two children, Christin Rivas and Child M. *See supra* at 36-38. Children foreseeably ingest separated SREMs, and, when ingested, the SREMs can attract through gastrointestinal tissue and cause necrosis, fistulas, intestinal perforations or ischemic bowel, which can lead to sepsis and death, thereby creating a substantial risk of injury to the public. CC-27A at 10; Tr. 749:8-19; 751:3-753:16.

Because the Subject Products violate the Toy Standard and create a substantial risk of injury to the public, they constitute a substantial product hazard.

V. EVIDENTIARY ERROR – THE ALJ ERRED IN QUALIFYING DR. EDWARDS AS AN EXPERT

On October 20, 2014, Complaint Counsel filed a Motion to Strike Dr. Boyd Edwards as Respondent's expert concerning the educational utility of the Subject Products because he did

not possess the necessary knowledge, skill, training, experience or education to qualify as an expert. *See* 16 C.F.R. § 1025.44; Fed. R. Evid. 702. The ALJ denied the pre-hearing motion and reserved for the hearing a decision on whether or not Dr. Edwards was qualified as an expert. Order Denying Agency's Motion to Strike Expert Witnesses, Nov. 26, 2014, at 3. Complaint Counsel again moved to strike Dr. Edwards as an expert at the hearing; however, the ALJ accepted Dr. Edwards as an expert and admitted his expert report into evidence. Tr. 1271:6-10; 1285:21-1286:3; R-155. The ALJ erred in qualifying Dr. Edwards to testify as an expert and in admitting his expert report and the Commission should strike his expert testimony and report.

Under Commission rules, an expert witness is "one who, by reason of education, training, experience, or profession, has peculiar knowledge concerning the subject matter to which his/her testimony relates and from which he/she may draw inferences based upon hypothetically stated facts or offer opinions from facts involving scientific or technical knowledge." 16 C.F.R. § 1025.44. This standard is consistent with the Federal Rules of Evidence which provide that:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Expert testimony is admissible under Rule 702 if it concerns scientific, technical or other specialized knowledge that will aid the trier of fact in understanding or resolving a factual issue. *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 592 (1993). The Court has the task of "ensuring

that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* Expert testimony must be based on "more than subjective belief and unsupported speculation." *Id.* at 590. In general, scientific testimony that is both relevant and reliable must be admitted, while irrelevant or unreliable testimony must be excluded. *Id.* In reviewing the admissibility of potential expert testimony, the Court has a crucial role as "gatekeeper" to exclude unreliable testimony. *See Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 153 (1999).

Dr. Edwards was not properly admitted as an expert because of his lack of academic research in the area, his lack of teaching experience with the Subject Products and his lack of expertise in pedagogy and educational methods. Indeed, Dr. Edwards conceded that:

- He taught physics for more than 20 years, yet never used SREMs in his classes, Tr. 1401:14-17, 1404:4-7, 1260:10-15;
- Students in his classes successfully learned about chemistry, physics, math and magnetism without ever seeing SREMs, Tr. 1401:21-1402:10;
- There are ways to teach about magnetism without using Zen Magnets, Tr. 1402:11-14;
- He has not had any teaching duties since 2010, Tr. 1257:20-1258:4;
- He had not even heard of the Subject Products until after he ceased teaching in the classroom, Tr. 1258:6-14;
- He has not published any peer reviewed journal articles about SREMs, Tr. 1259:22-1260:4; and
- He has no expertise in educational methods of pedagogy, *i.e.*, the methods and practices of teaching, Tr. 1260:4-9.

Instead, Dr. Edwards related that while he lacked experience using SREMs in teaching, he was a magnet enthusiast who was not introduced to the Subject Products until 2012. In early 2013, he twice bought Zen Magnets but returned them to Zen because they were not as precise as

advertised. R-155 at 2. Mr. Qu explained to Dr. Edwards that Zen Magnets did not meet advertised width specifications because Mr. Qu "discovered that the tape measure he was using to determine magnet chain lengths was faulty." *Id.* Mr. Qu then sent Dr. Edwards free booster packs, and Dr. Edwards used Zen Magnets to enter and win a contest sponsored by Zen. *Id.*

Because Dr. Edwards lacks any experience using the Subject Products in teaching, lacks any published peer-reviewed articles concerning the use of the Subject Products in teaching, and lacks any education in pedagogy, his opinions are largely based on his personal, private use of SREMs. *See* R-2 at 1-2. Thus, while Dr. Edwards may have been able to testify as a lay witness about *his* use of the Subject Products, he was not qualified to opine expert opinions about the general educational utility of the Subject Products in classrooms across the nation. Yet because Dr. Edwards was improperly qualified as an expert, he was permitted to testify about the statements, thoughts and opinions of hundreds of other people – many of whom he had never even spoken with (Tr. 1291:2-1292:10) – whose statements would have otherwise been inadmissible hearsay. *See* Tr. 1288:1-7 (allowing Dr. Edwards to testify about non-witness statements "which form the underpinning of Dr. Edwards' opinion" even though the statements were hearsay that the ALJ acknowledged could not be admitted on their own as "substantive evidence of the facts contained in their statements.").

Furthermore, after improperly qualifying Dr. Edwards as an expert, the ALJ then *sua sponte* asked Dr. Edwards numerous leading questions that sought to elicit testimony from the

witness that went well beyond his qualified area of expertise.[19] Specifically, during one of the many instances of questioning by the ALJ, Dr. Edwards was asked whether the use of magnets is a "U.S. phenomenon or is it an international phenomena," Tr. 1422:8-18, and whether he could "foresee a trend in teaching methods to include the subject . . . product . . . ." Tr. 1426:9-18. Complaint Counsel moved to strike the responses to the ALJ's leading questions as lacking foundation and because they were beyond the scope of the witness' expertise. *See* Tr. 1445:19-1448:22. The ALJ granted the request to strike Dr. Edwards's response to the ALJ's questions regarding foreign curricula, *see* Tr. 1447:1-8, but denied the request to strike his predictions about "future trends" in SREM use in education, ruling that "his opinion would be helpful under 702 and 703 to inform me of his opinion as to future trends as to what he sees based on his knowledge and familiarity with the educational field. So as to that, I won't grant the motion to strike." Tr. 1447:9-1448:17. Dr. Edwards was wholly unqualified to testify about "future trends" in "the educational field," yet the ALJ relied heavily on his testimony, expounding at length about Dr. Edward's opinion while virtually ignoring Complaint Counsel's experts. *See* ID at 20-21. For these reasons, Dr. Edwards's expert testimony should not have been permitted.

---

[19] One example of such questioning by the ALJ concerning educational trends was at Tr. 1421:13-22:

> [ALJ] Q: Education is not a static field; is it?
>
> [Dr. Edwards] A: No.
>
> Q It has evolved with new teaching methods and new teaching game plans?
>
> A Yes.
>
> Q Is it your testimony that this, that to learn those principles that you have learned, it would be useful to have these small globs of rare-earth magnets available for classroom use?
>
> A Yes.

Because Dr. Edwards was improperly qualified as an expert, his expert testimony and report should be stricken from the record.

VI. CONCLUSION

By a preponderance of the evidence, Complaint Counsel established that the Subject Products present a substantial product hazard because they 1) contain a product defect which creates a substantial risk of injury to the public and 2) fail to comply with an applicable consumer product safety rule under the CPSA, which creates a substantial risk of injury to the public. Complaint Counsel asks that the Court find that the Subject Products pose a substantial product hazard, and order Respondent to implement a corrective action that includes a stop sale, recall and refund, and notice to consumers.

Respectfully submitted,

_____

Mary B. Murphy, Assistant General Counsel
Daniel R. Vice, Trial Attorney
Division of Compliance
Office of the General Counsel
U.S. Consumer Product Safety Commission
Bethesda, MD 20814
Tel: (301) 504-7809

Complaint Counsel for
U.S. Consumer Product Safety Commission

May 4, 2016

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	CPSC Docket No. 12-2
ZEN MAGNETS, LLC,	)	
Respondent.	)	

[PROPOSED ORDER]

Having considered the entire record, including the March 25, 2016, Initial Decision and Order, the Commission hereby determines that Zen Magnets and Neoballs (Subject Products) present a substantial product hazard pursuant to Section 15(a)(1) and (2) of the Consumer Product Safety Act (CPSA).

The Commission finds that public notification is required in order to adequately protect the public from such substantial product hazard.

The Commission issues this Order pursuant to Section 15 of the CPSA.

Respondent shall not sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any Subject Products.

Respondent shall, within five days of the date of this Order, notify all persons that transport, store, distribute, or otherwise handle the Subject Products, and to which the Subject Products have been transported, sold, distributed or otherwise handled, to cease immediately sale and distribution of the Subject Products.

Respondent shall, within five days of the date of this Order, submit a plan, for approval by the Commission, to provide public notice and institute a recall of the Subject Products. Such

corrective action plan must provide for full refunds to any person who purchased or received the Subject Products.

_____

By Order of the Commission

Dated:

EXHIBIT 1

U.S. Department of Justice
Civil Division, Appellate Staff
950 Pennsylvania Ave. NW, Rm. 7215
Washington, DC 20530

Tel: (202) 514-1838

November 6, 2015

VIA CM/ECF

Clerk of Court
U.S. Court of Appeals for the Tenth Circuit
The Byron White U.S. Courthouse
1823 Stout Street
Denver, CO 80257

RE: *Zen Magnets, LLC v. Consumer Product Safety Commission*, No. 14-9610
Scheduled for Oral Argument on November 18, 2015

We are writing to inform the Court that it has come to our attention that petitioner is now marketing magnet sets that, according to petitioner, "will obey, conform, and abide by all CPSC regulations but still be capable of most of the same structures as Zen magnets." *See* http://zenmagnets.com/compliance-magnets-battle-summary/ (attached); *see also* http://micromagnets.com (attached).

Sincerely,

s/ Daniel Tenny
Daniel Tenny
Counsel for the Consumer Product Safety Commission

cc (via CM/ECF): Counsel of Record

10/2015 Status Update: Compliance Micromagne Final Zens & Neos, Battle Summary .

24
Oct

10/2015 Status Update: Compliance Micromagnets, Final Zens & Neos, Battle Summary

Zen Magnets Public Releases

Sup with Zen Magnets?

Well, we've shipped no sets of magnet spheres for the past seven months And although it's not technically illegal to sell Zen Magnets or Neoballs in the US, we can't import more due to the magnet ban The very last of our supply of Zens and Neos will be available this November (for email notification, click **here**), and after that we won't have more until we succeed in defeating the ban And that's only one of our three simultaneous legal battles

Compliance Magnets

In the meantime, we've begun accepting orders for our new Compliance Magnets They are still magnet spheres that can be used for construction, and they will ship in time for the holiday season Compliance Magnets will obey, conform, and abide by all CPSC regulations but still be capable of most of the same structures as Zen magnets Find details at micromagnets com

But to be clear, these new tiny magnets are designed for ease of use, they are designed to fit inside the regulatory limits set by the CPSC They are not a substitute for Zen Magnets, for which our fight continues Given a choice between Compliance Magnets and no magnets at all, we choose Compliance Magnets But don't get us wrong The CPSC's attempt to remove proper magnet spheres from the US market for all ages, in all states, is still **disproportionately irrational** regulation championed by **unelected** regulators, based on **dishonest data** and **baseless assumptions**, to create **unclear, ineffectual** rules, despite the **greatest historical** public **opposition** Meanwhile Europe is still laughing at the US for banning **Kinder Eggs**

Battle Summary

Our current legal situation is summarized as follows:

Battle 1: Awaiting results This was our December 2014 court battle The judge must decide whether or not we have to recall currently sold products A judgement was to be rendered as early as March 2015, but as of now we're still waiting The results will greatly affect the other two fights

Battle 2: Early stages We are appealing the nationwide all-ages rule that effectively bans magnet spheres This is by far the most expensive battle, and our new product is largely to fund this legal challenge But a product safer than skateboards should not be harder to obtain than guns This is the most important one to win

Battle 3: Just started We get **vindictively** sued for purchasing raw fungible magnets from Magnicube, who was bullied into settling, even though the magnets came from the same factory we use for Neoballs, and we only used the same thing that would have been ok to purchase directly from China They pulled the neat trick of labeling magnet spheres dangerous based on the bullied settlement of a fallen competitor, without any judge evaluating the merits A large portion of our neoballs are now "stained" by recall until the outcome of this battle, which means we will only have a small portion of our Neoballs for sale by the end of year

Magnets must be respected, but need not be feared

Zen Magnets

RECENT STATEMENTS

10/2015 Status Update Compliance Micromagnets, & Neos, Battle Summary
CPSC s Magnet Sphere Ban Lasted 17 hours [Edit I
We Will Fight Until The End
RE Your letter requesting us to shut down

ARCHIVES

October 2015
April 2015
August 2014
August 2012

STOCK STATUS

COMPLIANCE MAGNETS PREORDER @ MICROMAGNETS COM

Final supply of Zen Magnets and Neoballs will be released in November Sign up for email notifications here

You're still reading this?

This server is powered by renewable energy (100% Wind)

Best viewed with Firefox or Chrome

NEWSLETTER SIGNUP

Email Address *

First Name

Are you also interested in:

- ☐ Contests
- ☐ Legal Battle
- ☐ Being our lab rats (Beta Products, Experiments, Job/Collab opportunities, Special Sales)

Subscribe

PUBLIC STATEMENTS

10/2015 Status Update: Compliance Micromagnets, Final Zens & Neos, Battle Summary

October 24, 2015

Sup with Zen Magnets? Well, we've shipped no sets of magnet spheres for the past seven months And although it's not technically illegal to sell Zen Magnets or Neoballs in the US, we can't import more due to the magnet ban The very last of our supply of Zens and Neos will be available this [ ]

EASTER EGG COLLECTION

The Epidemiology Elephant Flagship Contest Savemagnets com Westword Story Art ZenMagnets com Your mov Buckyball Magnetspheres com New Archive

MUCH COMPLY

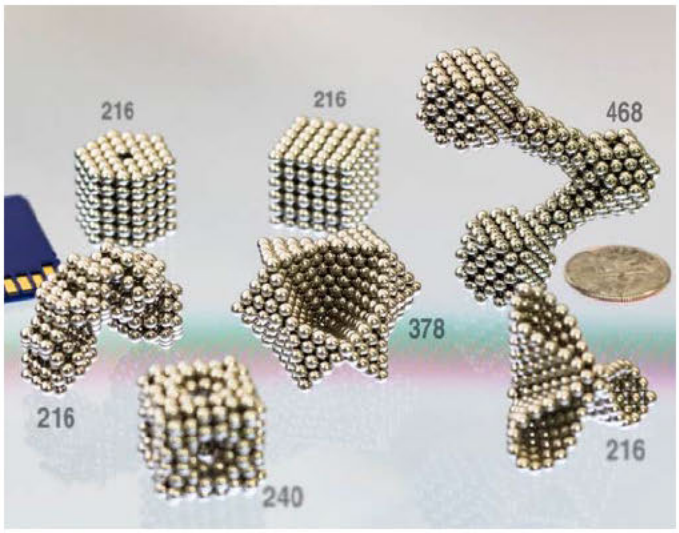
Designed and tested below the CPSC's "hazardous magnet" strength, Micromagnets are 2.5mm nickel plated Neoballs that are twice the challenge, half the diameter, and a third of the cost of Zen Magnets. Young eyes and clean fingernails are strongly recommended for use. Such obey, very conform, wow.

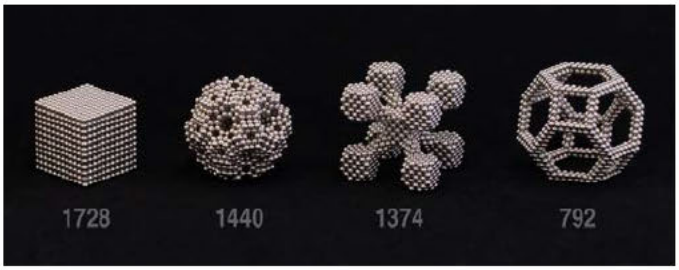
Beta Testers Say:

"I don't hate them nearly as much as I thought I would."
"I'm very impressed! ... almost all Zen Magnet tutorials will work"
"Quite challenging sometimes, and for someone who isn't used to building with magnets at all I think it can be frustrating."

November Shipping

This is not a sometime-maybe-kickstarter-esque preorder. You'll receive the Micromagnets in time for you to enjoy and order more for the holidays. Production is already under way, and packaging is in final design phases. Preorders will ship in the order made. Flat $5 domestic priority shipping.

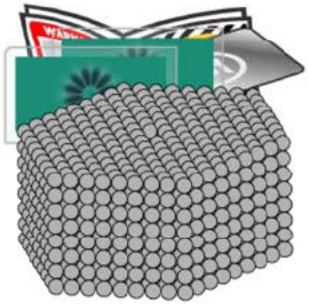




Order

Flat $5 USPS Priority shipping for any quantity within contiguous 48 US states. Shipping begins in November; first come first ship.

WARN NG: Although individual Micromagnets are too weak to be considered "hazardous magnets", the warning we have is the same: Keep away them away from faces! Swallowed magnets may stick together across intestines causing serious injury or death. Keep away from children who don't understand this. Seek immediate medical attention of magnets are swallowed or inhaled.



Micro 432

¢4.6 per magnet

$20.00/set

preorder price

432 Compliance Micromagnets (2.5mm Neoballs)

1 Magnetic Field Viewing Card Tool

Construction Guide

Flat **$5** USPS Priority shipping for any quantity.

Micro 432 Preorder

Micro 1728

¢4.6 per magnet

$80.00/set

preorder price

1728 Compliance Micromagnets (2 5mm Neoballs)

2 Magnetic Field Viewing Card Tool

Extended Construction Guide

Metal Building Plate

Flat **$5** USPS Priority shipping for any quantity.

Micro 1728 Preorder

Micro Experience

The need to make is what makes us.

Once you learn not to crush creations with your giant fingers, Micromagnets are undeniably enjoyable. Like other magnet spheres, Micromagnets have unique and inimitable characteristics so valuable in research, teaching, tactile therapy, and art. Creative energy is flame that can be stoked bigger, or wasted away.

A busy mind will see 432 Micromagnets as a great short-term imagination outlet in the workplace. A focused spirit with a set of 1728 Micromagnets will find countless hours of challenge, and a smart medium of creative expression.

Magnetic Field Viewer

For use as a Micromagnet separation tool and also as a magnetic field viewer.

The thin film will appear lighter when magnetic field lines are parallel to the film, and darker when magnetic field lines are mostly perpendicular to the surface.

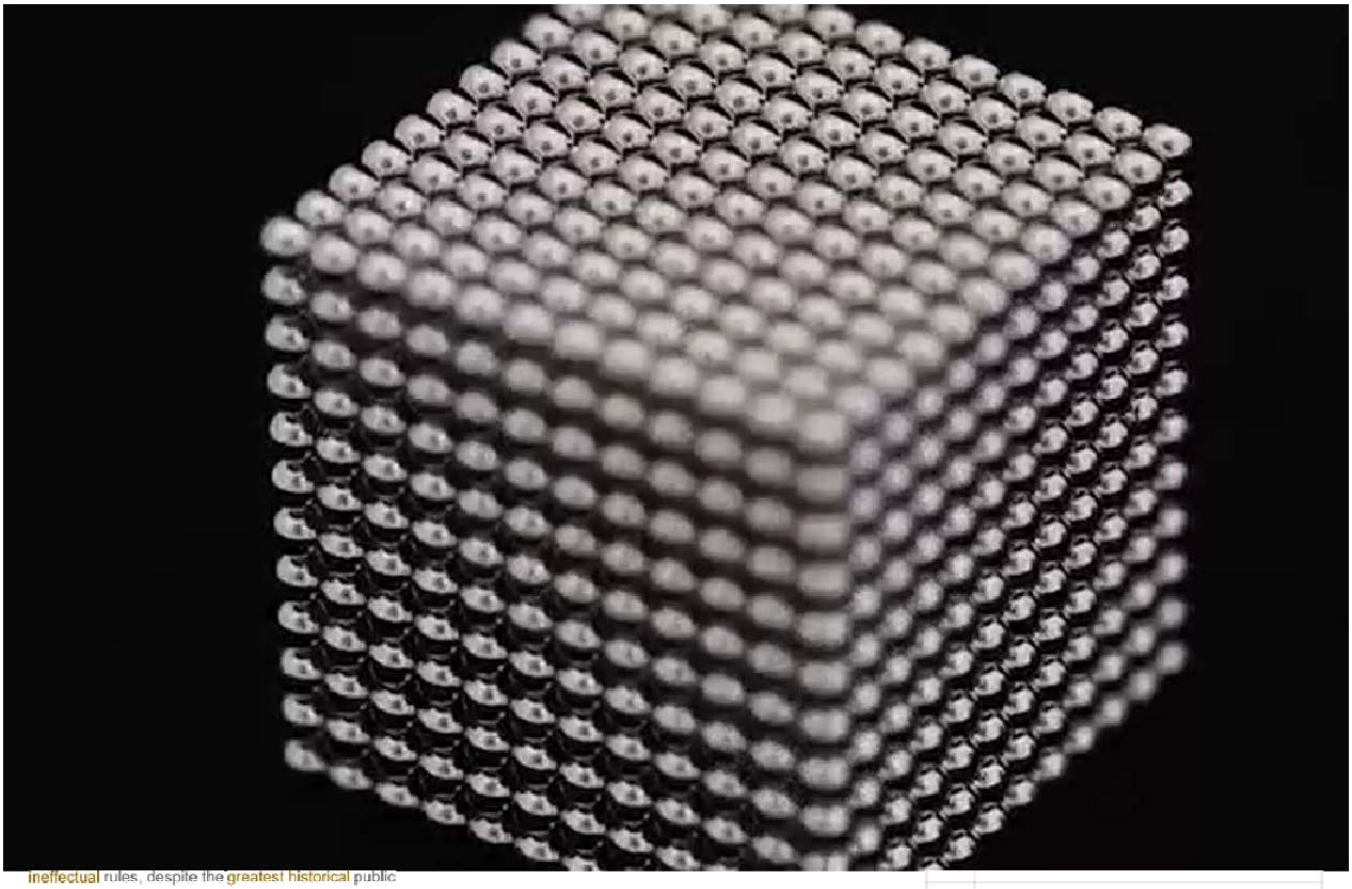
Do NOT use the MFV card for separating full size magnet spheres like Zen Magnets. The green film consists of tiny ferromagnetic oil cells, which will rupture from the pinching pressure of typical magnet spheres. Do not fold or crush the MFV card.

Vs. 5mm Magnets

"What are these? Magnets for ants?"

Those experienced with 5mm magnets (Zen Magnets, Buckyballs, Neoballs, etc) will transition to 2 5mm Micromagnets relatively painlessly. Initial reactions range from pleasant surprise to feeling constrained. Greater mobility and lower price are obvious benefits.

Some manipulation techniques, such as pinching, won't be possible. Fingernails and good near vision are strongly recommended. Most of the same structures are possible, however construction will be more difficult with Micromagnets. Shapes once challenging are now frustratingly difficult; what was once frustrating is now nearly impossible.



ineffectual rules, despite the greatest historical public opposition.

Meanwhile Europe is still laughing at the US for banning Kinder Eggs.

Though even after we're completely out of the top quality Zen Magnets there will always be high-priced industrial magnet sources around..

☐ **Being our lab rats (Beta Products, Experiments, Job/Collab opportunities, Special Sales)**

Subscribe

CERTIFICATE OF SERVICE

I hereby certify that I have provided on this date, May 4, 2016, Complaint Counsel's Appeal Brief:

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

One copy by electronic mail to counsel for Respondent Zen Magnets, LLC:

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Daniel Vice