UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

# COMPLAINT COUNSEL'S REPLY BRIEF

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## I. SUMMARY OF ARGUMENT

Complaint Counsel explained in its Appeal Brief that the Initial Decision is incorrect because the Administrative Law Judge ("ALJ") failed to correctly interpret the law and regulations governing this matter. The ALJ erroneously concluded that the Subject Products do not contain a defect under any of the three theories advanced by Complaint Counsel. The ALJ also erred in finding that Subject Products sold with warnings and age labels comply with ASTM F963 ("Toy Standard").

Zen's response expands upon and compounds these errors, relying on factually unsupported findings and advancing unfounded interpretations and applications of the factors in 16 C.F.R. §1115.4. Complaint Counsel proved by a preponderance of the evidence that the Subject Products are substantial product hazards under sections 15(a)(1) and (2) of the Consumer Product Safety Act ("CPSA"). The Commission should set aside the contrary findings of the ALJ and enter an order requiring the Respondent to undertake remedial actions under Section 15 (c) and (d) with respect to the Subject Products.

## II. LEGAL STANDARD

### *A. Standard of Review*

Respondent argues that the Commission should not undertake *de novo* review because "it is not now appropriate for the Commission to pretend that the hearing never took place." R.Br. at 7. Zen fundamentally misunderstands the role of the ALJ in this proceeding. Although the ALJ exercises powers and duties similar to a trial judge in *administering* a Section 15 proceeding, 16 C.F.R. § 1025.42, the ALJ's role after a hearing concludes is—unlike a trial judge—to "recommend a decision." 5 U.S.C. § 557(b). The Commission reviews that recommendation *de novo.* Although the Commission must base it review on the facts in the

record, the Commission may adopt, modify, or entirely set aside the ALJ's recommendations. 16 C.F.R. § 1025.55(a) (the Commission may "exercise all the powers it could have exercised if it had made the initial decision"). *See also Starrett v. Special Counsel*, 792 F.2d 1246, 1252 (4th Cir. 1986) ("Under administrative law principles, an agency or board is free either to adopt or reject an ALJ's findings and conclusions of law" and ALJ factual findings "are not given the weight of the findings of fact by a district court"); *Mattes v. U.S.*, 721 F.2d 1125, 1129 (7th Cir. 1983) (an "agency is free to substitute its judgment for that of the ALJ" and "independently to weigh the evidence and draw its own inferences"). The plain language of the Commission's rules and the Administrative Procedure Act ("APA") make clear that *de novo* review is the appropriate standard to be applied.

Case law similarly supports application of the *de novo* standard despite Zen's misguided assertion to the contrary. Relying on a footnote in a concurrence in *Landry v. FDIC*, 204 F.3d 1125 (D.C. Cir. 2000), R.Br. at 6, Zen ignores the court's majority holding that the ALJ decision is "purely recommendatory," such that the Commissioners "review[] the ALJ's recommended decision *de novo*." *Id.* at 1130, 1132. Nor does *Cinderella Career & Finishing Schools, Inc. v. FTC*, 425 F.2d 583, 588 (D.C. Cir. 1970), also cited by Respondent, assist Zen. There, the court simply re-affirmed the APA requirement that Commissioners must "consider the evidence adduced at the hearing" and cannot make a "determination without reference to the evidence." *Id.* Complaint Counsel agrees that the Commission must, of course, consider the record, but that consideration nonetheless allows the Commission to "adopt, modify, or set aside the findings, conclusions, and order contained in the Initial Decision…." 16 C.F.R. § 1025.55.[1]

[1] Zen also cites *N.L.R.B. v. Universal Camera Corp.*, 190 F.2d 429 (2nd Cir. 1951), which held that the N.L.R.B. must defer to a hearing examiner's findings concerning witness veracity. R.Br. at 6. That holding was rejected in *F.C.C. v. Allentown Broad. Corp.*, 349 U.S. 358, 364 (1955), where the Supreme Court held that the standard

### *B. Burden of Proof*

The burden of proof that Complaint Counsel must meet to prevail in this proceeding, as in any APA adjudicatory proceeding, is the preponderance of the evidence. *Steadman v. SEC*, 450 U.S. 91, 104 (1981); *In re Dye and Dye*, CPSC Docket 88-1, 1989 WL 435534, at *4 (Initial Decision, Mar. 30, 1989, unanimously upheld Jul. 17, 1991). This standard "simply requires that the trier of fact '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.) Complaint Counsel satisfied this burden with respect to each element necessary to find that the Subject Products are a substantial product hazard.

Zen confuses Complaint Counsel's burden of proof with the type of evidence which must support the Commission's decision – "reliable, probative and substantial evidence." 5 U.S.C. § 556(d). The requirement that the Commission's decision must be based on "substantial evidence" means that the Commission's decision must be supported by a "minimum quantity of evidence" as contained in the record. *Steadman* at 450 U.S. at 98. Unlike the *Cinderella* case cited by Zen, where the F.T.C.'s decision was vacated by the D.C. Circuit because it was made "without reference to the evidence" in the record, *Cinderella* 425 F.2d at 588, here there is substantial evidence in the record to support a Commission finding that the Subject Products present a substantial product hazard.[2]

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articulated in *N.L.R.B.* was incorrect; to the contrary, the APA provides that agencies have the power to substitute their judgment for that of the ALJ. *Id.* In any event, the ALJ here made no findings concerning witness veracity.

[2] Zen also incorrectly states that Commission rules do not require this proceeding to be conducted "in accordance with" the APA, 5 U.S.C. § 551 et seq. R.Br. at 4-5. Commission rules specifically state that adjudicative proceedings "shall be conducted in accordance with" the APA. 16 C.F.R. §1025.2.

## III. ARGUMENT

### *A. The Subject Products Constitute a Substantial Product Hazard Under § 15(a)(2)*

As set forth in Complaint Counsel's Appeal Brief, the Subject Products are defective for three reasons, each of which alone is sufficient to support a defect finding. The Subject Products are defective because:

> 1) a risk of injury occurs as a result of the operation and use, including reasonably foreseeable misuse, of the Subject Products;
>
> 2) the warnings are inadequate because they do not and cannot mitigate 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.

Each of these three theories of defect is supported fully by the evidence in the record, including incident data, stipulated testimony from parents whose children were injured or killed by magnets, medical records, 95 In Depth Investigation and incident reports, testimony from a medical examiner concerning a child who died due to magnet ingestion, and comprehensive opinions by experts in the fields of mechanical engineering, human factors, epidemiology, child psychology, and pediatric gastroenterology. Zen provided no expert testimony to counter this evidence.

#### *1. A Risk of Injury Occurs as a Result of the Operation and Use, Including Reasonably Foreseeable Misuse, of the Subject Products*

As set forth in Complaint Counsel's Appeal Brief, a risk of injury occurs as a result of the operation and use (including reasonably foreseeable misuse) of the Subject Products. Appeal Br. at 2-3, 26-33. 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 magnets that are easily lost or shared—constitute the basic character of the Subject Products.

Rather than respond directly to this argument, Zen mischaracterizes Complaint Counsel's position as charging that "any product that can cause injury, even if only misused, is necessarily defective." R.Br. at 9. Complaint Counsel makes no such charge. Complaint Counsel merely posits, as CPSC regulations instruct, that the reasonably foreseeable misuse of Zen's particular product creates a risk of injury, rendering the product defective. Complaint Counsel makes no claims about "any product," restricting its evidence to Zen's product. Nor does Complaint Counsel assert that injuries caused by all misuse, irrespective of whether misuse was reasonably foreseeable, necessitates a defect finding. As stated in Commission regulations, the question is whether a risk of injury occurs as a result of the operation and use, including foreseeable misuse, of the Subject Products.[3] Complaint Counsel proved, by a preponderance of the evidence, that injuries occurred as a direct result of the operation and use, including foreseeable misuse, of the Subject Products. Notwithstanding Zen's attempt to exaggerate Complaint Counsel's argument, that is all the regulations require and that is all Complaint Counsel asserts.

Complaint Counsel presented physical, documentary, and testimonial evidence that the Subject Products are designed to, and do, easily separate from their sets, and that separated magnets pose an ingestion hazard to children who obtain them. Appeal Br. at 2-3, 26-33. Complaint Counsel's human factors expert, Dr. Paul Frantz, testified that by their very nature, the Subject Products have no "containment system" to keep them from becoming separated. *Id.* at 28-29. Because magnets break apart as result of their operation and use, they are foreseeably lost or shared and, as Dr. Laurence Steinberg testified, are obtained by children who use them in foreseeable and age appropriate ways that create a risk of ingestion, injury and death. *Id.* at 28-30. Zen's products thus create a "risk of injury" as a result of their operation and use.

[3] Zen misinterprets the definition of "defect" as only allowing a defect finding "based *in part* on the foreseeable misuse of the product." R.Br. at 14. The definition of defect has no such restriction. 16 C.F.R. § 1115.4(d).

Zen's meritless and unsupported criticisms of Complaint Counsel's expert witnesses do nothing to alter that amply documented fact. Indeed, the record demonstrates that Dr. Frantz conducted a careful and through analysis of the evidence and concluded that the Subject Product's magnets easily separate from their sets and are ingested by children who obtain lost or shared magnets. Appeal Br. at 18-20. Dr. Frantz further concluded that separated magnets pose a risk of injury because children never see any warnings, as lost or shared SREMs are not accompanied by any warnings. *Id.* at 34-35. Dr. Frantz's conclusions were the product of a thorough analysis of all the evidence in this proceeding and fully support a finding that the Subject Products pose a risk of injury because of their operation and use, rendering them defective pursuant to 16 C.F.R. § 1115.4.[4]

Likewise, Dr. Laurence Steinberg, a psychologist with over 40 years of experience specializing in children and adolescence, thoroughly examined the evidence in this case. Appeal Br. at 20-21. Building on the testimony of Dr. Frantz that magnets separate from sets and are lost or shared, Dr. Steinberg concluded that lost or shared magnets pose a danger to infants and toddlers, who mouth and ingest magnets, as well as tweens and teens, who use them as play jewelry to mimic tongue piercings.[5] Mouthing or swallowing magnets by infants and toddlers is developmentally appropriate, Dr. Steinberg concluded, as is the experimental simulated piercing engaged in by tweens or teens; thus, this conduct is foreseeable. Zen presented no expert evidence to counter Dr. Steinberg's conclusions.

[4] Over relevance objections by Complaint Counsel, Dr. Frantz on cross examination was questioned by Zen's counsel about balloons. R.Br. at 9-10; Tr. 290:18-19, 295:10. Zen now criticizes Dr. Frantz for having "opined" about balloons, when Dr. Frantz made clear that he was not testifying as an expert on balloons, which were not at issue in this proceeding. R.Br. 9-10; Tr. 294:17-19.

[5] Zen concedes that it marketed the Subject Products as appropriate for use as play jewelry. R.Br. at 40 n.24.

Instead, Zen attempts to discredit Dr. Steinberg's expert opinions by faulting him for not conducting "independent research" beyond his systematic review of the evidence in this proceeding and not calculating a precise "probability" of a child ingesting a magnet. R.Br. at 12. Nothing in the Commission's rules or the Federal Rules of Evidence requires an expert to conduct "independent research" rather than drawing scientifically valid conclusions based knowledge, experience, and a review of the evidence in the record. 16 C.F.R. § 1025.44(a); Fed. R. Evid. 702. Dr. Steinberg was provided with ample evidence to review in forming his opinion about how children and caregivers interact with the Subject Products, including the 95 In Depth Investigations and incident reports of ingestions by children. The ALJ admitted Dr. Steinberg as an expert, and Dr. Steinberg's conclusions were made to a "reasonable degree of scientific certainty" based on the evidence and his four decades of experience in developmental psychology. CC-19A at 1-3, 12. Taken together, Complaint Counsel's evidence, including testimony by Dr. Frantz and Dr. Steinberg, established that ingestion by children who obtain lost or shared magnets and use them in age appropriate behavior is not misuse. But even accepting Respondent's argument that such behavior does in fact constitute misuse, that argument is of no consequence because such misuse is foreseeable and therefore gives rise to a defect finding because that reasonably foreseeable misuse results in a risk of injury.

Complaint Counsel proved by a preponderance of the evidence that a risk of injury occurs as a result of the operation and use, including reasonably foreseeable misuse, of the Subject Products. Zen's response, nothing more than an alchemy of unsupported conjecture and misstated law, fails to prove otherwise.[6]

[6] Zen also attempts to defend the ALJ's erroneous interpretation of Commission precedent, arguing that unlike the worm probe in *Dye* and kite in *Mylar*, "the Subject Products are not dangerous when used properly." R.Br. at 14. This argument misses the mark. Magnets, like these other products, cause unintended injury during use because of a

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

As set forth in Complaint Counsel's Appeal Brief, the ALJ erred in finding that the Subject Products' warnings are not defective. Appeal Br. at 33-37. Specifically, the warnings are defective because they do not and cannot prevent magnets from separating from their sets, and the warnings cannot travel with lost or shared magnets. *Id.* at 33-34. In finding that the warnings were not defective, the ALJ erred in restricting his analysis to a narrow portion of the definition of "defect" in 16 C.F.R. §1115.4, concluding that because Zen's warnings addressed ingestion hazards, they "do not contain a fault, flaw, or irregularity which causes a weakness, failure, or inadequacy." Appeal Br. at 9. Zen repeats the error. R.Br. at 18. The definition of defect is significantly more expansive than the language quoted by the ALJ and relied upon by Respondent. A warning may be defective if it contributes to a risk of injury where, as here, it does not warn about the risk of magnet loss and never reaches those who obtain lost or shared magnets. 16 C.F.R. § 1115.4 (d) (citing example of inadequate instructions and warnings creating a defect because they contribute to a risk of injury).

Because Zen offers no expert evidence of its own to counter Complaint Counsel's experts regarding inadequacy of the warnings, Zen instead resorts to misstating and mischaracterizing the record. Although Zen claims that Complaint Counsel's experts "admitted to not testing potential warnings and their efficacy," it cites no such admissions in the record. R.Br. at 19. To the contrary, Dr. Frantz thoroughly considered the evidence in the record, including numerous

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design defect. The worm probe conducted electricity beyond the area necessary to bring worms to the surface and killed people, including children; the aluminum tail on the kite electrocuted consumers, including children, when the tail accidentally made contact with a power line; and the Subject Products are lost or separated when used to make structures or jewelry, are ingested by children and result in serious or fatal injuries. R.Br. at 13-15. Although the ALJ erroneously found that Zen Magnets had not caused injury, such a conclusion, even if true, would not preclude a finding of defect if injuries have been caused by a substantially similar product, as the Commission found in *Dye*. This precedent fully supports a defect finding here. Appeal Br. at 30-33.

potential warnings, none of which would have adequately prevented children from being injured. CC-10A at 43-47.

Relying on the ALJ's findings, Zen asserts that the absence of injuries associated with Zen Magnets is evidence of the efficacy of the warnings. R.Br. at 15-17, 21-22, 29-31. Although Complaint Counsel contends that the ALJ erred in finding that the Subject Products were not shown to have injured consumers, Appeal Br. at 33-37, Respondent's argument also fails because it directly contravenes the plain language of 16 C.F.R §1115.4(d) that warnings can contain a defect *even in the absence of any injury to consumers*. In short, the regulations are unambiguous that the Commission need not wait until children are harmed before requiring a product to be recalled, 16 C.F.R. § 1115.4. Furthermore, stipulated testimony, medical records, and Zen's business records show that two children, Christin Rivas and Patient M, were harmed by the Subject Products. Appeal Br. at 36-38.[7]

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

In addition to containing a design defect such that a risk of injury occurs as a result of their operation and use and a defect in their warnings, the Subject Products are defective under an application of the factors in 16 C.F.R. § 1115.4. Appeal Br. at 38-56. Respondent selectively addresses some of those factors, but for the reasons set forth below, Zen's analysis is neither legally nor factually sound.

[7] Indeed, Mr. Qu admitted, "[W]e are aware of two incidences of our subject products that have led to injury," Tr. 2563:16-22, and conceded that ingestions by Patient M and Christin Rivas were "two confirmed ingestions" of Zen Magnets. Tr. 2565:6-15. Despite these admissions, Zen claims that evidence of these ingestions are improperly based on circumstantial evidence. R.Br. at 17. Circumstantial evidence, however, "is intrinsically no different from testimonial evidence," *Holland v. U.S.*, 348 U.S. 121, 140 (1954), and "can be used to prove any fact, including facts from which another fact is to be inferred." *U.S. v. Kelly*, 527 F.2d 961, 965 (9th Cir. 1976). Likewise, Zen challenges the evidence concerning an ingestion by Christin Rivas, claiming there is no "unassailable proof" she ingested Zen Magnets. R.Br. at 17 n.10. This is not the standard of proof. A preponderance of the evidence demonstrates what Mr. Qu himself confirmed, that not only witness testimony, but also medical records and Zen's business records, show that it is "more likely than not " that Ms. Rivas ingested Zen Magnets. *See supra* at 3.

### *a. The Subject Products Have Limited Utility*

Respondent devotes most of its argument to a discussion of this single factor as it is the only one on which Zen presented evidence at the hearing. Complaint Counsel's evidence demonstrated, however, that the Subject Products have only marginal utility and do not present the unique qualities Zen contends. Appeal Br. at 39-40.[8]

Despite claims that Zen Magnets are uniquely designed to create complex structures, Zen undercut its argument with the introduction of a new product, Compliance Magnets, which it asserts can achieve similar results as the Subject Products. Appeal Br. at 40.[9] Having made those claims, however, Respondent asks the Commission not to believe what it says. Zen argues that, although its laudatory statements about Zen Magnets should be considered as truth, the Commission should not rely on Zen's comparable statements about how "Compliance Magnets" are similar to Zen Magnets for creating structures, because such statements are "puffery" and were made solely to promote sales. R.Br. at 23.

Puffery is defined as "vague, generalized assertions of corporate optimism" that are "so 'exaggerated' or 'vague'" that no reasonable consumer would rely on them. *Gammel v. Hewlett-Packard Co.*, 905 F. Supp. 2d 1052, 1067 (C.D. Cal. 2012). Zen specifically defines its new product as "Compliance Magnets" and markets them as "CPSC Approved" magnets with similar capabilities to Zen Magnets. *See* micromagnets.com. These representations are not vague,

[8] Zen cites *Hale v. Dept. of Transp., F.A.A.*, 772 F.2d 882, 886 (Fed. Cir. 1985), as support for the proposition that the Commission must find that there is "necessarily a preponderance of the evidence that the Subject Product are of high utility." Respondent misconstrues *Hale*, which concerned the rare case when evidence consists solely of unrebutted, self-explanatory documents. This case has far more evidence in the record than that, and ample evidence to support a finding of low utility. Appeal Br. at 39-41.

[9] Complaint Counsel presented ample evidence demonstrating the similarity between the Subject Products and other magnets. Appeal Br. at 31-32. Zen also marketed its products as similar to Buckyballs. CC-11 at 14 (Zen marketed its products as "Bucky compatible"); Appeal Br. at Exh. 1, page 3 of 4 ("Vs. 5mm Magnets" – describing similar 5mm magnets as including "Zen Magnets, Buckyballs, Neoballs, etc.").

generalized statements. They are the essence of the product as defined by Zen. Respondent submitted its products for testing by the Commission and even uses the Commission's test results to sell its products.[10] The Commission may take official notice of Zen's statements about Compliance Magnets because they are "facts generally known within the jurisdiction of the Commission." 16 C.F.R. §§ 1025.43(d), 1025.55(a); Appeal Br. at 40. Zen's statements are also admissible under Federal Rule of Evidence 801(d)(2) (opposing party admissions). The Commission may credit Zen's statements that Compliance Magnets have similar utility to Zen Magnets, and consider it as evidence that the Subject Products do not have the "unique" utility that Respondent advances.

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

Zen does not contest that the Subject Products may cause injury or death when ingested. Instead, Zen reiterates the ALJ's bewildering finding that the magnets cannot pose a risk unless the manufacturer affirmatively advertises that consumers should place them in their mouths. R.Br. at 24-25. Both Respondent and the ALJ have read into the regulations restrictive language that does not exist. As 16 C.F.R. §1115.4 makes clear, the Commission may act to prevent a risk of ingestion even if a product is not advertised for ingestion, but nonetheless is foreseeably used in a manner that presents a risk of ingestion. Appeal Br. at 12-13, 20-21, 42-45.

Compounding Respondent's failure to understand the regulations, Zen also repeats the ALJ's distressing characterization of Child A's mother by asserting that Child A "might not have died" if she "had been better supervised." R.Br. at 26. Nothing in the record supports that

[10] *See* Micromagnets, "Comply Comply Comply" at http://micromagnets.com/cpsc-ul-compliance-tested-cpsa/, visited June 20, 2016.

baseless assertion. Appeal Br. at 44-45.[11] Respondent additionally blames medical professionals who initially treated the toddler, charging that "if doctors . . . had not released her from the hospital, [she] might not have died." R.Br. at 26. Respondent's transparent attempt to shift blame onto victim's families and caregivers ignores the wealth of evidence presented by Complaint Counsel of injuries suffered by children who ingested magnets, including several who required surgery and many who will suffer life-long injuries. Complaint Counsel showed by a preponderance of evidence that the Subject Products pose a serious risk of injury or death, and the ALJ erred in finding otherwise.

***c. The Subject Products Are Not Necessities***

Although the ALJ failed to discuss this factor at all, Complaint Counsel explained why the Subject Products are not necessities. Appeal Br. at 46-47. Moreover, because Respondent concedes that the Subject Products are not "life-sustaining necessities," R.Br. at 28, further discussion of this factor is not required.

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

Identifying the population at risk of injury here is not difficult: it is children, ranging in ages from infants to teenagers. In fact, Zen does not dispute Complaint Counsel's expert testimony describing the age ranges of children at risk of magnet ingestion. Appeal Br. at 47-48. However, Zen repeats the ALJ's erroneous conclusion that a risk of injury requires evidence that an identifiable population be "constantly subjected to the product's risk of injury," putting forth yet another misstatement of the statute and regulations governing this action. R.Br. at 27.

[11] Zen also supports the ALJ's "treatment of Child A's mother's testimony," claiming the ALJ made no error in "assessing that testimony" and that the ALJ's assessment "was a matter of weight to be determined by the trial judge." R.Br. at 18. The Initial Decision never mentions Child A's mother's testimony, let alone contains any assessment of her testimony. Furthermore, the ALJ is not a "trial judge" – even if the ALJ had made any findings about Child A's mother's testimony (which he did not), such findings would be entitled to no deference by the Commission. *See supra* at 1-2.

To the contrary, the regulations require only that the Commission consider "the population exposed to the product and its risk of injury. . . ." 16 C.F.R. § 1115.4. Where, as here, that population is a vulnerable one, this factor demands even greater scrutiny. 16 C.F.R. § 1115.12(g)(1)(iii). Contrary to the ALJ's conclusion the population exposed to this risk is "too amorphous," ID at 23, Complaint Counsel presented unrebutted expert, testimonial, and documentary evidence demonstrating that the Subject Products did indeed present a risk to a vulnerable population: children, including infants, toddlers, and adolescents. Appeal Br. at 20-21, 47-48. What is more, Complaint Counsel presented unrebutted evidence that the risk of injury to this vulnerable population included *serious, catastrophic, potentially fatal gastrointestinal injuries*. *Id.* at 21-24. The record shows that children place the Subject Products in their mouths for age-appropriate reasons and that, within eight hours of ingestion, magnets can result in tissue injuries and tissue death and can perforate the gastrointestinal tract leading to peritonitis. Appeal Br. at 3, 18-24. Children frequently obtain magnets with no warnings against this hidden hazard, and children who ingest them can be severely injured within hours of swallowing them. *Id.* Complaint Counsel demonstrated by a preponderance of the evidence that a vulnerable population faces a risk of severe injury as a result of exposure to the Subject Products, and Respondent fails utterly to contest that evidence.

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

The ALJ found, and Zen does not dispute, that the risk posed by the Subject Products is hidden. R.Br. at 29. Instead, Zen argues that its own warnings, as well as educational campaigns undertaken by NASPGHAN, have increased public awareness, so that the risk is now obvious. *Id.* Respondent offered no evidence to support this claim. *Id.* Indeed, the record belies Zen's unconvincing argument that the latent risk posed by the Subject Product is now

somehow well known. Appeal Br. at 45, 49. Ample evidence shows that Zen's warnings do not and cannot mitigate the risk of harm caused by lost or shared magnets, and Zen's weak claim to the contrary is not unsupported by the record. Appeal Br. at 50-51.

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

In addressing this factor, Respondent repeats the ALJ's erroneous conclusion that no children were injured by the Subject Products as proof that warnings successfully mitigated the risk posed by the products. Even if it were true that no children were harmed by the Subject Products, which Complaint Counsel vigorously contests, the ALJ's faulty conclusion ignores Commission regulations and precedent making clear that a product may contain a defect due to inadequate warnings even absent reports of injury. 16 C.F.R. §1115.4(d); *Dye* at 21. As discussed in the Appeal Brief and above, warnings fail to mitigate the risk posed by the Subject Products because 1) warnings do not and cannot warn users never to lose magnets, and 2) children who obtain lost or shared magnets never see a warning. *See supra* at 8-9, Appeal Br. at 50-51.[12] Moreover, many Subject Products—those sold through May 2012—contained no warnings at all. Appeal Br. at 3, 16. Zen offered no relevant facts to counter Complaint Counsel's evidence, which demonstrates that warnings failed to mitigate the risk of injury.

[12] Respondent challenges the reliability of testimony by Kathleen Stralka, an expert in epidemiology and statistical analysis, that CPSC staff projected approximately 2,900 ingestion incidents treated in emergency rooms. R.Br. at 30. Zen presented no expert to contest these findings and does not claim they lack in scientific rigor. Instead, Zen asserts without explanation that Ms. Stralka's testimony is somehow unreliable because some data was "subjectively binned," which sometimes involved a "judgment call" by CPSC technical staff trained in epidemiology. *Id.* Ms. Stralka employed a thorough and scientifically valid process and the Commission should fully credit her testimony. Appeal Br. at 24. Indeed, the ALJ cited this data without finding that it was unreliable. ID at 23. Moreover, Mr. Qu conceded on cross-examination that his challenges to the CPSC epidemiology staff's methodology were factually flawed. Tr. 2175:2-6 (Mr. Q: "this was actually an error in my methodology"); Tr. at 2177:17-20 (Mr. Q: "that was also a mistake on my part"); Tr. at 2185:10-17, 20-21.

### *g. The Role of Consumer Misuse and the Foreseeability of Such Misuse*

Zen does not dispute the finding that misuse of the Subject Products was foreseeable or the ALJ's finding that the "foreseeability of misuse is a foregone conclusion." R.Br. at 32. Instead, Zen proposes a standard untethered to statute or regulation. That is, Respondent contends that a finding of defect should not attach when there has been foreseeable, but "unreasonable," misuse. R.Br. at 31-32. Zen provides no legal basis, nor can it, for such an interpretation. The regulations contemplate that misuse be reasonably foreseeable, not that the misuse be both reasonable and foreseeable. *Compare* 16 C.F.R. § 1115.4(d) (Commission may consider "[r]easonably foreseeable" misuse) with R.Br. at 25 (arguing that Commission may consider only "reasonable, foreseeable misuse"). Zen's definition of defect finds no basis in the regulations nor in any Commission case law adjudicating Section 15 cases. *See supra* at 7 n.6.

Zen also further attempts to rewrite 16 C.F.R. § 1115.4 to only allow a defect finding "based *in part* on the reasonable, foreseeable misuse of a product." R.Br. at 25. This is not what the regulation states. Nothing in the regulation limits a defect finding by allowing it to be based only "in part" on misuse. 16 C.F.R. § 1115.4(d) (a defect may be based entirely on misuse, and that misuse in turn can be based "in part" on warnings and instructions). The Commission should reject these unfounded arguments and find that foreseeability of misuse weighs in favor of finding a defect.

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

Zen asserts that the ALJ properly "did not give considerable weight" to the Commission's own experience and expertise in evaluating the existence of a defect, because the matter was to be determined on law and fact, not agency expertise. R.Br. at 32. Respondent urges the Commission to ignore the plain language of the regulations which state specifically that

such expertise be taken into account and instead points to a hodgepodge of case law not relevant here. The cases cited by Zen, *Chaney*, *Chevron*, and *Skidmore*, R.Br. at 32-33, do not support the position that an ALJ may ignore agency expertise. Rather, those cases address the deference that must be afforded by a Circuit Court when reviewing final agency action. *Id.* Here, because CPSC has not yet taken final action, those cases are inapposite. 16 C.F.R. § 1025.55(b).[13] Commission regulations specifically allow the Commission to consider its "own experience and expertise" in determining whether a product is defective. 16 C.F.R. § 1115.4.[14] The ALJ erroneously disregarded this factor.

Furthermore, although never raised at the hearing or in pretrial motions, Zen now takes issue with most of Complaint Counsel's experts because they are not employed by the Commission. R.Br. at 33. Zen cites no authority to support this contention. *Id.* To the contrary, this expert evidence is a valid part of the record and should be fully considered by the Commission. 16 C.F.R. § 1025.44.

Zen also attacks the integrity of Commission expert Vince Amodeo for *not* providing testimony outside his area of expertise. R.Br. at 33-34. Mr. Amodeo was qualified as an expert in the physical characteristics and properties of magnets, not as a legal expert on product defects or ASTM standards. CC-1A. To contend that his testimony—which established that Zen Magnets and Neoballs exceeded 50 flux and were nearly identical to other similar magnets in size and attraction force—should somehow be afforded less weight because he did not testify to

[13] Zen admits there has not been final agency action here, but claims "the agency is due even less deference than that owed to it under *Skidmore*." R.Br. at 33 n.20. Zen cites no support for this contention, because none exists.

[14] Zen again criticizes Ms. Stralka's data because it does not identify brand names. Appeal Br. at 33. Zen designed its product without brand identifiers on its magnets, making it extremely difficult for anyone injured by a lost or shared magnet to identify the brand. This does not mean, however, that the Commission is precluded from determining the hazard posed by the Subject Products, which the evidence showed were substantially similar to other magnets in size, flux, and ability to attract across intestinal tissue and cause injuries. Appeal Br. at 31. The record shows that this hazard is the same regardless of brand. *Id.* at 35-36.

matters outside his expertise is puzzling. That Complaint Counsel disputes such an unsupportable position deserves no elaboration.

The Commission's experience and expertise supports a defect finding, and the ALJ erred in concluding otherwise. Appeal Br. at 52-54.

#### *i. Case Law Interpreting the CPSA Supports a Defect Finding*

Respondent justifies the ALJ's failure to specifically address this factor on the basis of "judicial economy." R.Br. at 34. This repeated practice of selectively ignoring factors in 16 C.F.R. §1115.4 is contrary to law, and led to the erroneous findings in the Initial Decision that the Subject Products do not contain a defect. As discussed in the Appeal Brief, both cases—*Dye* and *Mylar Kites*—support a finding of defect here. Appeal Br. at 14, 30-33, 54-55.

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

Respondent objects to Complaint Counsel's reference to a product liability case against a manufacturer of similar magnets (Buckyballs) on the grounds that the products differ from the Subject Products. R.Br. at 36 n.22. As Complaint Counsel's evidence established, however, the Subject Products are nearly identical in size and flux to Buckyballs, and once ingested, react in the same manner. Appeal Br. at 31-32, 35-36, 56. This case is relevant to evaluate the defect presented by the Subject Products, and should be considered by the Commission.

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

The record supports a Commission finding that the Subject Products are defective. Likewise, the record shows that the 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). A defective

product creates a substantial risk of injury, and therefore constitutes a substantial product hazard, if any one of these factors—pattern of defect, the number of products, or the severity of the risk—is present. Here, the Subject Products present all three.

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

Zen largely sidesteps whether its products pose a substantial risk of injury because of a pattern of defect, instead rehashing its criticism of Dr. Frantz by again misrepresenting his testimony. R.Br. at 37-38. However, as Complaint Counsel noted in its Appeal Brief, a pattern of defect is established with respect to both the design and warnings of the Subject Products. The Subject Products are defective because the operation and use of the product, whereby loose magnets are meant to separate from a set, resulting in a risk of ingestion and injury. Appeal Br. at 57. The warnings are also defective because they fail to identify the risk of lost or shared magnets and cannot be remedied to adequately address the risk. *Id.* Complaint Counsel established by a preponderance of the evidence that the Subject Products create a substantial risk of injury because of a pattern of defect.

### *2. The Defects Create a Substantial Risk of Injury Because of the Number of Products in Commerce*

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 likely to occur. 16 C.F.R. §1115.12(g)(1)(ii). Zen concedes that millions of individual magnets remain in circulation. R.Br. at 39. This large number of magnets, just two of which have the potential to cause serious injuries to a vulnerable population, supports a substantial product hazard finding. Appeal Br. at 57-58.

### *3. The Defects Create a Substantial Risk of Injury Because of the Severity of the Risk*

Zen does not contest that ingesting magnets may result in serious and catastrophic injuries, R.Br. at 39, leaving no doubt that the "serious injury" prong of the regulations is satisfied. 16 C.F.R. § 1115.6(c). 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)*

### *1. The Subject Products are Toys That Are Subject to the Toy Standard*

Zen does not dispute that its products sold without warnings a) are "toys;" b) were sold in violation of the Toy Standard; c) are "substantial product hazards;" and d) must be recalled. R. Br. at 31.[15] Yet Zen argues that adding warnings to its product packaging suddenly mean they are no longer toys, even though Zen made no changes to the products themselves and continued to state—even as of the date that Complaint Counsel filed its Appeal Brief—that its products could be "play[ed] with" by children, with a "common sense recommendation" of age 12. Appeal Br. at 60. By marketing its "fun toys" to children as young as 12, Zen brings its product within the definition of toys subject to the Toy Standard. Appeal Br. at 60.

Zen argues that even though it called its products "fun toys" that can be "play[ed] with," it did not *intend* for children under 14 to play with them. R.Br. at 41. As Complaint Counsel's

[15] Zen continued selling many magnet sets without warnings through at least May 2012. Appeal Br. at 16-18. Zen asserts, however, that products sold after May 2010 contained proper warnings, but cites nothing in support of this contention. R.Br. at 35, 40. Because the record shows that Subject Products were sold without warnings through at least May 2012 and Zen presented no evidence to the contrary, the Commission should find that Zen waived any argument that it should not recall products sold through May 2012.

Appeal Brief notes, however, "intent" is not an element of the Toy Standard. Appeal Br. at 63. Advertising a product for children 12 and up speaks for itself.

Despite marketing to 12-year-olds, Zen nevertheless insists that the evidence shows it only intended to market to children 14 and over. Rather than explain how its years of website marketing to 12-year-olds comports with this argument, Zen simply notes "how easily the website can be changed," R. Br. at 42, and actually proved this by changing its website after Complaint Counsel revealed in its Appeal Brief that Respondent was *still* advertising its products as a toy for 12-year-olds. App. Br. at 63. After Complaint Counsel filed its brief, Zen scrubbed its website of Zen's longstanding "common sense recommendation" that children play with its products at age 12, and replaced it with a statement that "Due to legal outcomes, our recommendation is 14." *See* Exh. 1 (comparison of Zen's website before and after filing of Appeal Brief). Screen shots of Zen's website, attached hereto as Exhibit 1, reveal Zen's continued allegiance to marketing its product to 12-year-olds as recently as May 4, 2016. Zen's last-minute effort to remove evidence that it marketed to children under 14 does not change its years-long advertising that its "common sense recommendation is [age] 12," thus demonstrating that the Subject Product were marketed as a toy. Appeal Br. at 60.[16]

### *2. The Subject Products are Not Science Kits Under the Toy Standard*

Although the Toy Standard prohibits the sale of toys with loose as-received hazardous magnets, it includes a narrow exception for "[h]obby, craft, and science-kit type items intended

[16] Zen also makes the inaccurate claim that Dr. Frantz evaluated the Subject Products "based *only* on his reading of the pamphlet found *inside* the packaging of the magnets." R.Br. at 41. Dr. Frantz conducted a thorough examination of Zen's product packaging, warnings and instructions, and sales and marketing practices in determining that Zen's products were marketed to children under age 14. CC-10A at 26-27 (marketing to children), 54-56 (materials considered by Dr. Frantz). In addition, contrary to Zen's assertion, Dr. Frantz made clear that modifications to Zen's packaging did not change the fact that the design and marketing of its products was aimed at children under 14. Tr. 333:15-334:2.

for children over 8 years of age, where the finished product is primarily of play value . . . ." ASTM F963-11 § 4.38.3 (CC-2) ("exempt kits"). Wanting it both ways, Zen contends that its products, which it claims may someday be included in college-level science curricula and were sold in marijuana dispensaries restricted to adult customers, were actually science, craft or hobby kits intended for eight-year-olds. R.Br. at 44-46. The evidence demonstrates that the Subject Products do not fall within this limited exception. *See* Complaint Counsel's Post-Hearing Argument, March 16, 2015, at 7-8.

As a threshold matter, Zen has not met the Toy Standard's strict labeling requirements for exempt kits. Such kits must be "age labeled in a clear and conspicuous manner" only for children over eight. ASTM F963 §§ 4.38.3, 5.2. Respondent's sarcastic age recommendations ("Btw, this product is a 'science kit' for sure," appropriate for "whatever age at which a person stops swallowing non-foods"), CC-44, fall far short of this requirement. Inappropriately labeled warnings "shall be subject to the most stringent applicable requirements" and must be labeled according to the "highest age in the range" allowed; in this case, age 14. ASTM F963 § 5.2. Again, Zen did not meet this standard.

The Commission has significant experience with the packaging and warnings that manufacturers use to sell science, craft and hobby kits to make clear that they are safe for use by eight-year-olds. *See* http://www.cpsc.gov/en/Taxonomy/Products/Toys/Chemistry-Sets-or-Science-Kits. In reviewing the Initial Decision, the Commission may rely on this experience to conclude that the Subject Products are not exempt kits. 16 C.F.R. §§ 1115.4 (Commission may rely on its experience and expertise); 1025.55(a) (Commission may exercise all of the powers it could have exercised if it had made the Initial Decision). The evidence supports a finding by the

Commission that all of the Subject Products are hazardous toys that do not meet the exemption for exempt kits in ASTM F963-11 § 4.38.3, and violate Section 15(a)(1) of the CPSA.

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

The record demonstrates that Zen's sale of its "toys" constitutes a substantial product hazard because the toys contain loose as received hazardous magnets that present a substantial risk of injury to the public. This risk has been recognized by the Commission since at least 2006, when dozens of toys with liberated magnets were recalled after children ingested the magnets and suffered serious injuries. Appeal Br. at 63-64. Zen Magnets and Neoballs pose the same, if not greater, risk. *Id.* Although the ALJ concluded that Subject Products sold without warnings were hazardous toys that should be recalled, ID at 16 n.6, 34, Complaint Counsel had presented evidence that all of the Subject Products sold since 2009 fall into this category.

Because all of the Subject Products, regardless of their warnings, violate the Toy Standard and create a substantial risk of injury to the public, they constitute a substantial product hazard. The Commission should set aside the contrary finding of the ALJ and enter an order requiring the Respondent to undertake remedial actions under Section 15(c) and (d) with respect to all of the Subject Products.

### *D. The ALJ Erred in Qualifying Dr. Edwards as an Expert*

The ALJ improperly admitted Dr. Boyd Edwards as an expert. Appeal Br. at 64-69. In refuting Complaint Counsel's argument, Zen erroneously cites the standard of review applicable when a Circuit Court reviews a trial court judge's decision to allow expert testimony. R.Br. at 47. That standard of review is not applicable here, as the ALJ is not a trial court judge, and the Commission is free to substitute its judgment for that of the ALJ. *See supra* at 1-2.

Although Zen has established that Dr. Edwards is a magnet enthusiast who personally uses Zen's products (including many that Zen gave to Dr. Edwards for free), Zen did not establish that Dr. Edwards had sufficient expertise to opine on the general educational utility of magnets. Appeal Br. at 66-67. Zen concedes that "Dr. Edwards has never used the magnets in a traditional classroom setting," but states that he nonetheless is qualified to be an expert on such use. R.Br. at 49. In support of this contention, Zen advances the circular logic that Dr. Edwards was properly admitted as an expert because it was helpful to the ALJ to hear predictions about future educational use of magnets (predictions that in Dr. Edwards's years as a magnet enthusiast never materialized), and that Dr. Edwards properly made such predictions because he was qualified as an expert. R.Br. at 51-52. In short, the ALJ incorrectly allowed a witness who had no experience using magnets in an educational setting to hypothesize about "future trends" in "the educational field." Appeal Br. at 68. Dr. Edwards may have properly testified about his personal use of magnets, but it was error to allow him to hypothesize about educational utility as an expert.[17]

## IV. CONCLUSION

Complaint Counsel established by a preponderance of the evidence 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 because they 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 respectfully request that the Commission reverse the contrary findings of the ALJ and find that the Subject Products pose a substantial product hazard,

[17] Zen disputes Complaint Counsel's objections to the ALJ's questioning of Dr. Edwards, stating that judges may ask leading questions. R.Br. at 52. Complaint Counsel did not object to these questions because they were leading, but because they sought to elicit testimony that lacked any foundation and were beyond Dr. Edwards's expertise. Appeal Br. at 68.

and order Respondent to implement a corrective action that includes as appropriate a stop sale, recall and refund, and notice to consumers.

Respectfully submitted,

_____

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Complaint Counsel for
U.S. Consumer Product Safety Commission

June 27, 2016

**EXHIBIT 1**

# Relations .

## O HAI!

We are a small company based in the beautiful city of Boulder, Colorado where the sky is always a bit bluer than in pictures you see.

We're more than just another economic establishment poking for capital. We exist to celebrate the arousing poetry of design, commemorate the natural rhythm of geometric shapes, and rouse the dreams of inspired imaginations. Because there are few ventures more worthwhile than stretching the inventive mind, and catalyzing the ingenius intellectual. In addition to our magnet engagement, we hope our social conscience will speak for itself.

Google, Ideo, Chipotle, Blizzard. Respectable companies share many attributes that we like to see in people; honest, creative, dependable and fun.

You can call us Zen Magnets.com. We peddle fun and clarity in the form of strong and shiny rare-earth magnet balls. We gratefully stand atop the shoulders of scientific development.

"We are perishing for want of wonder, not want of wonders"

## FAQ

**+ Q: It looks so easy online, but I can not get them to do what I have seen. Have any tips?**

**+ Q: Have they shipped? Where are they? Are they here yet? Is there tracking? Have they shipped?**

**+ Q: How old do you have to be to play with these?**

A: According to the Consumer Product Safety Commission, 14 years old in the US for a strong magnetic toy. Unless it's not a toy, then no age limit. Unless it's a "Science Kit," then the age regulation is 8+. Zen Magnets are classified as a science kit, so the minimum age as recommended by the US Government is 8. Our common sense recommendation is 12.

**+ Q: Yo, is you guyz still in biziness?**

**+ Q: Payment by Bitcoin?**

**+ Q: How can they be cleaned. I dropped them in the dirt.**

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**+ Q: Yo, is you guyz still in biziness?**

**+ Q: Payment by Bitcoin?**

**+ Q: How can they be cleaned. I dropped them in the dirt.**

**+ Q: Do you ship to XYZ country? How much does it cost.**

**+ Q: What if the magnets weaken? Can they be re-magnetized?**

**CERTIFICATE OF SERVICE**

I hereby certify that I have provided on this date, June 27, 2016, Complaint Counsel's Reply 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 and common carrier to counsel for Respondent Zen Magnets, LLC:

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