UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
ZEN MAGNETS, LLC,	)	CPSC DOCKET NO. 12-2
RESPONDENT	)	

RESPONDENT'S ANSWER BRIEF

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INTRODUCTION

On or about May 16, 2016, Respondent Zen Magnets, LLC ("Zen" or "Respondent") through its counsel, sought an order staying this appellate proceeding pending a ruling by the Consumer Product Safety Commission ("CPSC" or "Commission") on its Motion to Disqualify the Commission or certain members thereof. This Commission has not yet disposed of Zen's Motion to Disqualify, but on May 25, 2016, this Commission issued an Order that denied Zen's Motion for Stay. It is based on that Order that Zen hereby files its Answer Brief. Zen maintains that the Commission should be disqualified from hearing this appeal for all of the reasons set forth in Respondent's Motion.

On March 25, 2016, Administrative Law Judge Dean Metry issued his Initial Decision and Order ("ID") after taking evidence during an administrative hearing in December, 2014. Written closing statements were filed in March 2015. ALJ Metry properly and thoroughly decided the issues raised by CPSC, through its Complaint Counsel, which alleged in a Second Amended Complaint that the Subject Products, as defined in that complaint, sold by Zen, are substantial product hazards pursuant to 15 U.S.C. § 2064(a)(1), (2). Judge Metry ruled that Complaint Counsel failed to meet its burden of establishing that the Subject Products present a substantial product hazard when they are "sold with appropriate warnings, including proper age recommendations." (ID at 36 ¶ 10.) On May 4, 2016, Complaint Counsel submitted its Appeal Brief contesting that finding and nine of the ten other findings of law and fact contained in the Initial Decision.

In addition to contesting the findings of law and fact, Complaint Counsel asserts that Judge Metry made a number of evidentiary errors. Complaint Counsel argues that chief among those errors was the qualification of Dr. Edwards as an expert witness, and the admission of Dr.

Edwards' testimony into the record. (App. Br. at 64-69.) Respondent Zen Magnets, LLC argues herein that Judge Metry properly qualified Dr. Edwards as an expert and accepted his testimony into evidence. Complaint Counsel's sole argument for his disqualification is its misapprehension of Rule 702, F.R.E.

This case is an administrative adjudication conducted pursuant to 5 U.S.C. § 554,[1] the Federal Rules of Civil Procedure, and the Federal Rules of Evidence,[2] and must be decided on the laws and facts presented in the hearing, not on policy considerations or agency discretion. On any review of the record in this proceeding, Judge Metry properly and correctly issued his findings of fact and law (ID at 36 ¶¶ 1-11), and Complaint Counsel has not met its evidentiary burden to show otherwise.

STATEMENT OF THE ISSUES[3]

1. Whether Judge Metry erred in making his findings of fact and law in the Initial Decision.

2. Whether this Commission should adopt the Initial Decision as a Final Decision and Order.

STATEMENT OF THE CASE

This matter originated with a complaint against Zen in 2012. Sometime later, Complaint Counsel filed a Second Amended Complaint, which set forth the issues to be determined by the ALJ. As noted, this matter proceeded to hearing in December 2014. In March 2016, the ALJ issued his ID. This Appeal follows timely.

[1] *See* 15 U.S.C. § 2064(f)(1).
[2] *See* Complaint Counsel's Motion for Official Notice, July 17, 2014.
[3] Although Complaint Counsel presented its arguments through numerous subparts, Zen chooses to address the arguments together, delineating each specific argument within the sections identified below, consistent with the format used by Judge Metry in his ID.

SUMMARY OF THE ARGUMENT

The record amply supports Judge Metry's decision and demonstrates that the Subject Products do not contain a fault, flaw, or irregularity, and are not defective pursuant to 16 C.F.R. § 1115.4 or 15 U.S.C. § 2064. Complaint Counsel was unable to produce credible, reliable evidence that the Subject Products have caused injuries, and failed to account for the substantive differences between the Subject Products and SREMs manufactured by other firms. Further, Complaint Counsel failed to successfully show *how* the Subject Products were defective pursuant to 16 C.F.R. § 1115.4, in either their design, use, or warnings. And lastly, Complaint Counsel did not submit *any* credible evidence that the Subject Products are toys for purposes of ASTM F963-11. As a result, Judge Metry properly concluded that the record did not establish that the Subject Products present a substantial product hazard. His Initial Decision and Order should therefore be adopted by this Commission as a Final Decision and Order pursuant to 16 C.F.R. § 1025.52.

Rather than assert that Judge Metry made incorrect factual conclusions, Complaint Counsel argues that Judge Metry did not understand the law and, as a result, was compelled to reach erroneous legal conclusions. (App. Br. at 7.) That is simply not the case. After reviewing the record as a whole, Judge Metry properly found that the Agency did not meet its evidentiary burden of establishing that the Subject Products present a substantial product hazard for any of the reasons set forth in the Second Amended Complaint.

Respondent challenged the Commission's evidence and expert testimony at hearing and successfully argued the evidence and testimony severely lacked in completeness, thoroughness, and fairness. (ID at 20.) Judge Metry accorded the appropriate *weight* to the CPSC's evidence. Complaint Counsel's overriding argument is that Judge Metry did not accord the weight to the evidence that they wished he had in arriving at his conclusion. Thus, Complaint Counsel cannot

articulate any sufficient legal reason for not adopting the Initial Decision other than mere displeasure with the result.

BURDEN OF PROOF

Complaint Counsel had the burden of establishing that the Subject Products were substantial product hazards by substantial evidence. 16 C.F.R. § 1025.52(b); *id*. at § 1025.43(b)(1) (the burden of proof is on Complaint Counsel); *id*. at § 1025.51(b). Complaint Counsel's and Judge Metry's reliance on *Steadman v. S.E.C.*, 450 U.S. 91, 104 (1981) is misplaced. While it is true that the Supreme Court has deemed a review pursuant to 5 U.S.C. §§ 554 and 556 merely requires a preponderance of the evidence, the CPSC has prescribed a more rigorous burden of proof for its administrative hearings.

Section 7 of the APA, 5 U.S.C. § 556(d), states in relevant part: "A sanction may not be imposed or rule or order issued except on consideration of the whole record or those parts thereof cited by a party and supported by *and in accordance with* the reliable, probative, and substantial evidence." (Emphasis added.) To ascertain what Congress intended by this phraseology, the Court in *Steadman* examined the original text of the statute and the House Report, which expressly adopted a preponderance-of-the-evidence standard. *Steadman*, 450 U.S. at 100-101. This case is different.

In *Steadman*, the only reason the Court turned to sections 5 and 7 of the APA was because the securities laws did not indicate the standard of proof governing SEC adjudications. *Id*. at 96-97. Here, however, the Commission's rules expressly state that decisions in Commission adjudications are to be supported by substantial evidence. 16 C.F.R. § 1025.51(b) ("The Initial Decision shall be based upon a consideration of the entire record and shall be supported by reliable, probative, and substantial evidence"). Of particular importance is the fact that § 1025.51(b) leaves

out the problematic "in accordance with" language that, to the Court, differentiated 5 U.S.C. § 554 from § 706, the latter of which allows a reviewing court to set aside an agency action if it is unsupported by substantial evidence. *Steadman*, 450 U.S. at 99-100. Under the Commission's rules, the Decision must be supported by substantial evidence.

If, *arguendo*, the burden of proof was properly determined by Judge Metry to be a preponderance of the evidence, Complaint Counsel had to show that the existence of a fact is more probable than not. *Concrete Pipe & Prods. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993). Under a preponderance-of-the-evidence standard, if it is close enough to be fifty-fifty as to the existence of a fact, this Commission should decline to find in favor of that fact's existence. *C.f. White v. Halstead Ind., Inc.*, 750 F. Supp. 395, 399 (E.D. Ark. 1990). In addition, this Commission has previously held that a "[p]reponderance of the evidence is a less stringent standard of proof than the 'clear and convincing' or 'beyond a reasonable doubt' standards, *but it is a higher standard than 'substantial evidence*.'" *In re Dye & Dye*, 1989 WL 435534CPSC, CPSC Docket No. 88-1 (1991) at *4 (emphasis added).

STANDARD OF REVIEW

Complaint Counsel is correct in stating that the Commission's rules do not set forth a per se standard of review. (App. Br. at 25.) However, Complaint Counsel's insistence that the review is to be made *de novo* and that the Commission is to free to hear the matter as if it had not been heard in the first place (*id*.) is without merit. The Commission's rules clearly and unequivocally foreclose such an unrestrained *de novo* review. *See* 16 C.F.R. § 1025.55(a) (specifying how the record is to be considered on appeal).

According to the Supreme Court,

> [t]here can be little doubt that the role of the modern federal hearing examiner or administrative law judge within this framework is "functionally comparable" to that

> of a judge. His powers are often, if not generally, comparable to those of a trial judge: He may issue subpoenas, rule on proffers of evidence, regulate the course of the hearing, and make or recommend decisions. See [5 U.S.C.] § 556(c).

Butz v. Economou, 438 U.S. 478, 513 (1978).

Judge Metry's powers in this case are no different. *See* 16 C.F.R. § 1025.42 (powers and duties of the presiding officer). Judge Metry's Initial Decision is not to be set aside by the Commission *as if the case had never been heard in the first place*. *See Landry v. FDIC*, 204 F.3d 1125, 1143 n. 3 (D.C. Cir. 2000) ("*De novo* review does not mean that [Judge Metry's] recommended decisions are without influence") (Randolph, J., concurring), *cert. denied*, 531 U.S. 934 (2000); *NLRB v. Universal Camera Corp.*, 190 F.2d 429, 430 (2nd Cir. 1951) ("an examiner's findings on veracity must not be overruled without a very substantial preponderance in the testimony as recorded"). To the contrary, the Commission's rules require that:

> Upon appeal from or review of an Initial Decision, the Commission *shall* consider the record as a whole or such parts of the record as are cited or as may be necessary to resolve the issues presented and, *in addition*, *shall*, to the extent necessary or desirable, exercise all the powers which it could have exercised *if* it had made the Initial Decision.

16 C.F.R. § 1025.55(a) (emphasis added). The D.C. Circuit has interpreted this language[4] thusly:

> Surely this language makes it clear that the five Commissioners, in reviewing an initial decision, are not to speak as *verbum regis*, but must consider the evidence adduced at the hearing. The regulation makes it clear that the Commissioners *will* consider the record, and that they may *additionally* exercise the powers they *could* have exercised had they made the initial decision.

Cinderella Career & Finishing Schools, Inc. v. FTC, 425 F.2d 583, 588 (D.C. Cir. 1970) (emphasis in original).

[4] The F.C.C.'s regulatory language in 16 C.F.R. § 3.54(a) (1969) is the same as that in 16 C.F.R. § 1025.55(a), save for the substitution of "will" for "shall" in the latter, making the Commission's requirement to consider the record even more clear.

Cinderella explained that when a proceeding involves a prolonged hearing as it did in this case – 13 days of proceedings, 6 expert witnesses, 23 lay witnesses, 2,378 pages of live testimony plus additional written testimony, and 280 admitted exhibits – "the Commissioners are not free to boil over in aggression and completely dismiss those proceedings either because they are dissatisfied with the outcome, or for any other reason. Such procedure is rooted in nothing and places the Commission in the position of being both the instrument and the musician at the same time." *Id*. at 588-589.

The purpose of holding the administrative hearing before Judge Metry was to ensure that the parties received a fair hearing in which they could submit evidence, cross-examine witnesses, disclose facts, and be heard by objection, motion, brief, and argument. 16 C.F.R. § 1025.41(c). It is not now appropriate for the Commission to pretend that hearing never took place. As the D.C. Circuit explained, the Commission "must consider that decision and the evidence in the record upon which it is based, rather than dismissing the proceedings at the hearing out of hand." *Cinderella*, 425 F.2d at 588. "We hardly think it permissible for the Commission to . . . ignor[e] the record and consequently convert[] the entire hearing proceeding into a meaningless exercise." *Id*.

On appeal, this Commission cannot proceed as if the hearing had never taken place and no decision by Judge Metry had previously been rendered, as Complaint Counsel requests. (App. Br. at 25.) Moreover, Complaint Counsel's sole reliance on *Landry* to support its position that an ALJ's initial decision is to be reviewed as if it had never existed is fatal to that argument. *Landry* involved the judicial review of an Appointments Clause claim related to the FDIC's method for appointing ALJs. In that situation, Congress provided that the FDIC must "make its own findings of fact when issuing its final decision." *Landry*, 204 F.3d at 1130 (citing 12 U.S.C. § 1818(h)(1)).

This Commission in the case at bar, on the other hand, has promulgated a rule requiring itself to consider the record established in the administrative hearing. *See* 16 C.F.R. § 1025.55(a); *c.f. Cinderella*, 425 F.2d at 588-590.

As the Supreme Court, and many others, have stated, an agency must follow its own rules. *See e.g. F.C.C. v. Fox Television Stations, Inc.*, 129 S.Ct. 1800, 1830 (2009) ("The agency must follow its own rules"); *U.S. v. Stevens*, 559 F. Supp. 1007, 1015 (D. Kansas 1983) ("The commission must abide by its own rules and regulations, as well as the statutory requirements established by Congress"); *Arizona Grocery Co. v. Atchison T. & S.F. Ry. Co.*, 284 U.S. 370, 389-390 (1932) (an agency must follow its own rules); *Celcom Communications Corp. v. F.C.C.*, 789 F.2d 67, 69 (D.C. Cir. 1986) (stating that it is a "bedrock requirement" that an agency must abide by its own rules); *Reuters Ltd. v. F.C.C.*, 781 F.2d 946, 950 (D.C. Cir. 1986) ("it is elementary that an agency must adhere to its own rules and regulations"). This Commission is therefore required by its own rules to consider the record as it was established in the administrative hearing in issuing a Final Decision and Order, and may not now pretend that no Initial Decision had been issued.

ARGUMENT

I. JUDGE METRY CORRECTLY FOUND THAT THE SUBJECT PRODUCTS DO NOT PRESENT A SUBSTANTIAL PRODUCT HAZARD WHEN SOLD WITH APPROPRIATE WARNINGS.

A. The Subject Products are not Defective Because they Pose no Risk of Injury as a Result of their Operation and Use.

Judge Metry properly found that the operation and use of the Subject Products do not pose a risk of injury. (ID at 12.) It is uncontroverted that the Subject Products can do no physical harm to anyone unless and until they are ingested. (ID at 17); 79 Fed. Reg. 59962, 59964 (Oct. 3, 2014)

(the risk of injury is caused when a person ingests more than one magnet).[5] Complaint Counsel failed to show that the Subject Products are inherently defective because the magnets are designed to be separable. Complaint Counsel's apparent argument is that any product that can cause injury, *even if only* misused, is necessarily defective. The record shows, and as the Commission has acknowledged, separation of magnets does not cause any injury – only ingestion of magnets can cause injury. CC-18; 79 Fed. Reg. at 59964. As Judge Metry explained: "[S]imply because two or more magnets become separated from the primary cluster does not result in any exposure to danger. Instead, it is the separation of two or more magnets, *plus* oral insertion, *followed by swallowing of the magnets that creates the risk of injury*." (ID at 10.) (Emphasis added.) "Because the only proven risk of injury results from ingestion, it cannot be said any consumer could accidentally or unintentionally become exposed to the risk of injury through proper use." (ID at 10.) (*See also id*., contrasting *Dye & Dye* with the current case, noting that the Subject Products pose no danger through accident or inadvertence, and that proper use of the products "create[s] no exposure to danger whatsoever.") It therefore follows that neither the operation nor use of the Subject Products is defective.

Complaint Counsel also advances the theory that any magnet that separates from the rest of a set "contaminates" the environment and creates the mechanism by which a magnet can be ingested, which is itself an alleged defect. (App. Br. at 27.) Any testimony in support of that theory was, however, unreliable[6] and unpersuasive. Neither of the two witnesses that made statements about the risk of magnets that may be lost in the environment and accessed by a child

[5] The Commission's statements about SREMs and the Subject Products are officially noticeable by the Commission pursuant to 16 C.F.R. § 1502.33(a) and Fed. R. Evid. 801(d)(2), as federal courts are required to take judicial notice of the Federal Register. *See* 44 U.S.C. § 1507; *Biodiversity Legal Foundation v. Badgley*, 309 F.3d 1166, 1179 (9th Cir. 2002).

[6] For example, Dr. Frantz opined that balloons are blown up in fewer places than the Subject Products are used. (Tr. 292:21-293:5.)

were able to support their statements with any quantifiable science -- their statements were unsupported hunches. When Dr. Frantz was asked how often he believed Zen Magnets were "lost," his answer was that it was a "frequent occurrence" (Tr. 305:16-306:8), and that Zen "accommodates" its customers' "loss" through the sale of spares (Tr. 348:3-15). Ultimately, Dr. Frantz concluded that a containment risk exists, not based on his own tests or analysis to quantify such a risk, but only on his incorrect understanding about how Zen markets its products – based solely on one customer email Respondent received in 2009. (Tr. 305:8-13; 346:15-16.) In that email, a bar patron lost magnets and emailed Zen, which responded by advertising on its website that Zen "hear[s] stories like that all the time." (Tr. 306:11-12.) This language appeared on Respondent's website only between August 2009 and November 2009, immediately after the company was started (Ex. R-191), and was part of a sales strategy for selling spares.

Dr. Frantz's testimony was also less than entirely credible. When asked to compare the containment risk of magnets to balloons, Dr. Frantz stated that the "[containment hazard is] more limited in terms of where people would blow up a balloon and use a balloon as opposed to where Zen Magnets is suggesting people use their magnets." (Tr. 293:2-5.) Dr. Frantz's conclusion that Zen Magnets are more prevalent than balloons in terms of child accessibility is entirely unfounded, and contrary to the primary documented usage of magnet spheres. (*See e.g.* Ex. R-70.) In addition, use of SREMs require the use of two hands and a flat surface, neither of which are required for balloon usage. (Tr. 2012:5-2013:4.)

Contrary to the notion that Zen's product have an inherent containment problem, Zen's recommended product usage guidelines, which are intended primarily to facilitate ease of use, include recommendations for storage in "Zen Hex" forms (Ex. CC-50; Ex. CC-51; Ex. CC-52; Ex. CC-63), which allow one to easily ensure all magnets are accounted for, while also serving as a

convenient storage method (Tr. 1769:20-1770:8). Dr. Edwards testified about how he provides for the successful and safe containment of his magnets. Despite his owning over 18,000 magnets (Ex. R-154A at 3) and using magnets on hundreds of occasions, Dr. Edwards has lost only four magnets (Tr. 1440:13-19). Dr. Edwards is able to avoid losing magnets by adhering to three easy-to-follow rules: (1) issuing verbal warnings to house guests, including a warning about the ingestion hazard; (2) ensuring that magnets remain on the work surface; and (3) ensuring individual magnets are not separated from one another. (Tr. 1441:19-1442:16.) Consequently, Dr. Edwards has created a viable and simple containment mechanism, albeit one that does not require physical barriers, although Dr. Frantz has shown the latter to also be effective. (*See* Ex. CC-14.) Contrary to Dr. Frantz's testimony about something Zen Magnets had on its website for several months in 2009, Respondent generally expects people to be able to account for, and not lose, their magnets. (Tr. 2011:14-20; 2105:10-15 (based on Mr. Qu's experience routinely handling upwards of tens of thousands of magnets (Tr. 2103:16-22), he believes that the magnets are capable of being kept away from children.))

Additionally, the magnet spheres sold by Zen have a natural propensity for attracting to one another. Such an attraction is not only a barrier to inadvertent loss, it is also a unique quality of the Subject Products, as Dr. Edwards testified. (*See* Tr. 1313:18-20.) Even when Dr. Frantz intentionally abused the Subject Products by dropping them from an unknown height onto a laminate floor, the magnets did not consistently separate. (Tr. 165:3-5; Ex. CC-14.)[7] As Dr. Frantz showed, the Subject Products are not easy to unintentionally "lose" to the environment. Furthermore, Dr. Frantz admitted to never having performed his "drop test" on any other surface

[7] Dr. Frantz's video further proves Respondent's point, and Judge Metry's conclusion, that a separated magnet poses no threat of injury, as neither Dr. Frantz nor anyone else was injured by Dr. Frantz's intentional separation of magnets.

besides kitchen laminate. (Tr. 116:6-8; 332:7-8.) It is therefore unsurprising that Judge Metry did not accord a significant weight to Dr. Frantz's outwardly biased and unreliable testimony.

Dr. Steinberg similarly undertook an incomplete and unpersuasive assessment of the Subject Products. Complaint Counsel, through Dr. Steinberg, asserted that children are "highly likely to play with or use the Subject Products in ways that can lead to ingestion." (Ex. CC-19A at 3.) Dr. Steinberg, however, based his opinion on the colloquial, non-comparative, and non-scientific usage of "likely" (Tr. 416:20-417:2), and did so with the supposition that the SREMs must first be "available to be interacted with" by children (Tr. 477:3-10). Dr. Steinberg explained that his analysis of the incident reports was not conducted with the intent to quantify or qualify the likelihood of misuse by children, and was done exclusively for "illustrative purposes" to "see the range of types of incidents." (Tr. 418:15-419:3.) In fact, Dr. Steinberg provided no opinion on the likelihood of child of any age group actually encountering the Subject Products. (Tr. 477:11-17.) Further, Dr. Steinberg stated that he undertook no independent research regarding the probability of: a child be injured by ingested magnets (Tr. 456:4-9); a magnet not being found after some were dropped on the ground (Tr. 456:14-17); magnet sphere ingestion by a child after being given the magnets by a parent (Tr. 456:18-21); magnets being ingested if they are stored out of the line of sight of a child (Tr. 456:3-7); magnets being ingested if they are found on the ground by a child (Tr. 457:8-11); magnets being ingested if they are not displayed in front of children (Tr. 457:12-16); a magnet being shared by peers leading to ingestion (Tr. 457:17-20); ingestion based on the brand of magnet (Tr. 458:12-459:2); an average person's ability to understand the ingestion hazard mechanism (Tr. 459:13-17); or how marketing may affect magnet ingestion (Tr. 460:14-17). Nor did Dr. Steinberg evaluate how participation in a contest might affect the probability of ingestion. (Tr. 457:21-458:2.)

If the child does not have access to the Subject Products in the first instance, whether a product would appeal to children, generally, is moot; and it is for this reason that Zen undertook sales and marketing strategies to keep its products away from children. (*See* Ex. R-133; Ex. R-197; Ex. R-198; Tr. 2525:9-15.)

Complaint Counsel also relied exclusively on the allegedly "unrefuted" and "unrebutted" opinions of Dr. Frantz and Dr. Steinberg in arguing that children ingesting the magnets is not "misuse." (App. Br. at 28-29.) That testimony is, however, clearly at odds with the record, which showed that the Subject Products were in no way intended, designed, marketed, or manufactured to be either be ingested or used in ways that could lead to unintentional ingestion. (ID at 10; Ex. R-70.) Simply because a child engages in "age appropriate behavior" in no way means that they are not, at the same time, misusing a product.[8] The same is true regarding the Subject Products, which are *only* hazardous when misused, unlike other products that can cause injury in their normal and intended use, such as ATVs, worm probes,[9] *In re Dye & Dye, d/b/a P&M Enterprises*, CPSC Docket No. 88-1 (1991)), and kites with metallic coatings, *In re Francis Alonso Jr., d/b/a Mylar Star Kites*, CPSC Docket No. 75-16 (1977)). (*See also* ID at 9-10.)

[8] Complaint Counsel asserts that, "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." (App. Br. at 28.) Respondent is unclear about what the intended argument is, but maintains that the post-hearing introduction of any evidence regarding small parts, medicine, or laundry pods is improper, particularly without an evidentiary reason for its inclusion in the record. If the Commission does consider such evidence, it certainly cannot be said that ingesting laundry pods (App. Br. at 28) is the intended use for detergent.

[9] Complaint Counsel faults Judge Metry for finding that the fatality rate of worm probes to be much higher than SREMs. (App. Br. at 31.) The record fully supports the conclusion reached by Judge Metry, as only one fatality has been associated with the ingestion of SREMs, according to Complaint Counsel (Ex. CC-18, R-117A), whereas there were 28 confirmed deaths from worm probes, *Dye* at *6. Further, Judge Metry was not able to conclude that the one fatality was solely the result of ingesting SREMS, and that the nature of the risk of injury from SREMs results from more than simple misuse. ID, pp. 18-19.

Complaint Counsel next claims that Judge Metry misapplied the law in finding that no defect existed in the operation and use of the Subject Products. (App. Br. at 30.) That argument must fall for two reasons. First, Judge Metry correctly applied Commission precedent in making his determination. Unlike both Worm Gett'rs and aluminized kites, which were inherently dangerous even when used properly, the Subject Products are not dangerous when used properly. (ID at 9-10.) Also, even though the Subject Products were physically similar to other SREMs that have caused injuries, as was the case in *In re Dye & Dye*, there are fundamental differences in how the Subject Products were designed, manufactured, marketed, and labeled that make them less dangerous than other SREMs. (*See* ID at 10 n. 3, 24-25.) While the ALJ in *Dye* was unconvinced that nothing differed the Worm Gett'r from other worm probes, such was not the case here. (*See e.g. id*.) (noting that Buckyballs marketed its products as oral jewelry, which Respondent did not); (*id*. at 16) (finding that it is unclear whether other products substantially similar to the Subject Products contained warnings similar to those used by Respondent.) Moreover, contrary to their contentions, Complaint Counsel did *not* prove that the Subject Products have caused injuries. (App. Br. at 31.)

The second reason that Judge Metry did not misapply the law in finding that no defect exists in the operation and use of the Subject Products is that the Commission's definition and explanation of what constitutes a defect under 16 C.F.R. § 1115.4(d) is not as expansive as Complaint Counsel insists. Section 1115.4 states, as an example of a defective warning or instruction, a drill that is reasonably, foreseeably misused "*in part* on the lack of adequate instructions and safety warnings." *Id*. (Emphasis added.) The regulations therefore contemplate the finding of defect based *in part* on the foreseeable misuse of a product. The regulations do not contemplate there being a finding of a defect based entirely on the misuse of a consumer product,

i.e., a defect existing solely *because* of misuse, or the *unreasonable* misuse of a product. It would certainly be stifling to hold that a product is defective merely because it can cause injury when unreasonably misused by a consumer. Indeed, the Commission's regulations make clear that not even "all products which present a risk of injury are defective." 16 C.F.R. § 1115.4.

Here, Judge Metry properly found: (1) the warnings were not defective (ID at 36 ¶¶ 3-5); and (2) a review of all the other factors in section 1115.4 led him to the conclusion that the products were not defective (*id*. at ¶ 2). As a result, Judge Metry also properly determined that that the products were not defective in their operation and use, simply because consumers are capable of misusing the products in a way that can cause injury. Moreover, even if, *arguendo*, the misuse is foreseeable, it has been unquestionably *unreasonable* misuse by consumers who have used the Subject Products in ways that have led, or could have led, to ingestion. (*See* Ex. CC-18; stipulated testimony A to J.)

B. Complaint Counsel did not Prove that the Subject Products Have Caused any Injuries.

Judge Metry did not err in finding that Complaint Counsel failed to adduce reliable evidence that the Subject Products resulted in injuries. Although Complaint Counsel couches its argument that Judge Metry improperly found that they did not show the Subject Products have caused injuries in terms of Judge Metry having "ignored [its] evidence" (App. Br. at 31), Complaint Counsel merely takes issue with how Judge Metry weighed the evidence.

Judge Metry properly considered the evidence put forth by Complaint Counsel. Complaint Counsel incorrectly states that Judge Metry "disregarded" statements made by parents who believed their children had been injured by the Subject Products (Zen Magnets). Judge Metry clearly explained that he considered that testimony. (ID at 16 n. 5.) The testimony was neither excluded nor disregarded, but was accorded little weight because Judge Metry determined that the

statements contained hearsay that the magnets involved were in fact Zen Magnets. (*Id*.) Judge Metry's decision to accord such testimony little weight was therefore proper. *See* Fed. R. Civ. P. 52(6) (reviewing court must give due regard to the trial court's opportunity to judge witnesses' credibility); *Imperial Cas. and Indem. Co. v. Carolina Cas. Ins. Co.*, 402 F.2d 41, 44 (8th Cir. 1968) (all reasonable inferences drawn from undisputed fact issues are for the trial court, including matters of the credibility of the witnesses and the weight to be accorded testimony). Respondent never stipulated to the veracity of witness statements. Respondent only stipulated that the statements would be admitted into the record and that, if called, Complaint Counsel's lay witnesses would testify to certain statements. Again, Respondent did not stipulate to the truthfulness of the testimony; nor did the stipulation do anything but admit those statements into the record. The stipulation did not remove from the statements any hearsay, as defined by Fed. R. Evid. 801(c), (d) and 802, that might be contained therein. Complaint Counsel clearly introduced those statements to prove the truth of the matter asserted therein – that the magnets involved in some of those incidents (App. Br. at 36-38) were Zen Magnets. In those statements, however, the declarants were told by someone else that the magnets were Zen Magnets. That is the definition of hearsay. Fed. R. Evid. 801; *see also U.S. v. Comito*, 177 F.3d 1166, 1172 n. 9 (9th Cir. 1999) (hearsay can exist in stipulated testimony). Because Complaint Counsel has not put forth an exception to the hearsay rule in this case, the lay witness statements regarding Zen Magnets having caused injuries was properly deemed to be hearsay by Judge Metry. (ID at 16 n. 5.)[10]

[10] Judge Metry did not find that the entirety of Complaint Counsel's lay witness statements were hearsay. (*See* ID at 16 n. 5.) Rather, only certain parts of the statements were considered hearsay. For example, Barbara Rivas stated that she her daughter's friend had purchased Zen Magnets (¶ 14), but that she had never seen any packaging related to the magnets (¶ 13). Therefore, the only way Ms. Rivas could have suspected the magnets to be Zen Magnets was if someone else had told her so; and when used to prove the magnets were in fact Zen Magnets, that is the very definition of hearsay. Fed. R. Evid. 801. And, most likely, Ms. Rivas' testimony is actually hearsay within hearsay pursuant to Fed. R. Evid. 805. Moreover, Complaint Counsel's insistence that because

Because Complaint Counsel cannot overcome the hearsay included in those witness statements, Complaint Counsel resorts to suggesting that Judge Metry "disregarded" (App. Br. at 37) other evidence that the Subject Products have caused injuries. The other evidence is, however, nothing more than speculation that someone ingested Zen Magnets because someone they knew happened to purchase Zen Magnets. (App. Br. at 37-38.) Such circumstantial evidence, without more, cannot support a finding by the preponderance of evidence that the Subject Products were involved in those ingestions. Complaint Counsel's experts' theory that SREMs are found virtually everywhere in the environment and are constantly lost and shared (Ex. CC-10A) further undercuts the evidence that the magnets involved must have been Zen Magnets. Judge Metry was free to determine what weight to give those statements. Consequently, Judge Metry did not err in finding that the record does not show that the Subject Products have caused any injuries.

Complaint Counsel also complains that Judge Metry did not consider the statements from Respondent's lay witnesses to be hearsay. (App. Br. at 37.) That is because those statements were not hearsay. Respondent's witnesses were testifying about their *own* experiences with SREMs and how they were used in education, research, and the sciences. (ID at 21-22.) The quoted statements from those who had personal experience using the Subject Products and SREMs are not hearsay, which is why they were appropriately accorded more weight by Judge Metry. (ID at 12-22; App. Br. at 37.)

Ms. Rivas' daughter has six magnets in her possession, and Zen Magnets' gift set came with six spare magnets, provides unassailable proof that the magnets must have Zen Magnets, is entirely unfounded. Those facts are probative of nothing more than the fact that her daughter had six magnets, and that the Zen gift set comes with six additional magnets; no relationship between those two facts has ever been established.

C. Judge Metry Properly Found that the Warnings are not Defective.

The Commission's regulations require that a defect take the form of a fault, flaw, or irregularity. Complaint Counsel failed to meet its burden of establishing a defect in Respondent's warnings. Instead of pointing to evidence in the record to show that Judge Metry erred, Complaint Counsel simply states that Judge Metry "sidestepped the . . . record" and posited his own "straw man argument that Zen's warnings 'do not contain a fault, flaw, or irregularity which causes a weakness, failure, or inadequacy.'" (App. Br. at 9.) Complaint Counsel confuses Judge Metry's attempt at understanding its argument, which never enunciated how a fault, flaw, or irregularity existed (*see* Second Amended Complaint), for a misunderstanding of the law. Judge Metry set forth the law very clearly in the ID. Rather than attempt to establish that Respondent's warnings were defective, Complaint Counsel chose to repeat ad nauseam that the warnings were inadequate and could never be made adequate. As Judge Metry summarized: "In the Agency's view, the risk of injury is containment of the SREMs, and the magnets' severability exposes some U.S. consumers to a risk of injury. The Agency argues because the warnings cannot accompany each SREM, given the small and severable nature, the warning are inadequate and defective." (ID at 14.) The evidence presented at the hearing was simply at odds with that theory, as the Initial Decision makes clear, and Judge Metry properly assessed and weighed the evidence on this count.

As a preliminary matter, Judge Metry did not misunderstand or misstate the law regarding warnings. Judge Metry never stated that any level of risk may be mitigated by a warning. Nor was that the question put before Judge Metry. What Complaint Counsel alleged was that the warnings were *defective*, which necessarily requires there to be a fault, flaw, or irregularity with the warnings. 16 C.F.R. § 1115.4. Complaint Counsel simply failed to submit any evidence in

support of its argument that, because magnets are separable, no warning could possibly be adequate. Judge Metry explained:

> The ALJ finds these warnings do not contain a fault, flaw, or irregularity which causes a weakness, failure, or inadequacy, *particularly as argued by the Agency*. . . . [A]s explained above, the risk of injury associated with SREMs does not derive from the severability of the magnets, but emanates from ingestion. Therefore, even though it is true the warnings do not address the severability of the magnets, *the severability does not create the risk of injury*.

(ID. at 14.) (Emphasis added.)

Additionally, Complaint Counsel failed to demonstrate how even "fulsome warnings" (App. Br. at 10) would be insufficient to adequately address the risk of injury. Complaint Counsel's own experts admitted to not testing potential warnings and their efficacy.[11] Dr. Frantz, for example, conducted a "thought experiment" regarding whether an adequate warning could be written. (Tr. 155:22.) Dr. Frantz also concluded it is impossible for users to keep sets intact is based on the unsubstantiated belief that Zen has "said [it] is okay" for people to lose magnets. (Tr. 368:10-14.) As discussed in Respondent's Post-Hearing Argument, Dr. Frantz's belief was a gross mischaracterization of Zen's stance, and he did not have a sufficient basis to conclude that an adequate warning could not be crafted. (*See e.g.* Respondent's Post-Hearing Argument at 9-10.)

Dr. Frantz's conclusion that no adequate warning exists was further undercut by his previous experience writing warnings for products that have caused far more injuries than magnets. For instance, Dr. Frantz, who has worked on ATV warnings, considers those warnings to be adequate, notwithstanding the fact that people still die while operating ATVs. (Tr. 303:17-304:5.) There was therefore a clear disconnect in terms of what Dr. Frantz considered "adequate" when it

[11] Complaint Counsel's expert, Dr. Noel, even stated that there are "many ideas" he and his NASPHGAN colleagues have come up that have already helped to prevent injuries caused by ingesting magnets. (Tr. 803:7-17.)

came to effective warnings, which only served to emphasize that he was nothing more than a mouthpiece for Complaint Counsel, and subsequently reduced the weight and credibility of his testimony. (*See* ID at 20.)

Also contrary to Complaint Counsel's argument that no effective warning could be crafted was Dr. Steinberg's position that there do exist terms, such as "poison" – as was used by Respondent (ID at 13; Ex. R-1) – that could easily communicate an ingestion hazard. (Tr. 455:12-18.) Dr. Steinberg also opined that the Subject Products could be safely used in a scholastic setting under adequate supervision. (Tr. 443:14-16.)

Although Complaint Counsel takes issue with the tenor of some of Zen's warnings, Mr. Qu crafted his warnings the way he did because: (1) it was not clear to him at exactly what age a person should be to use the magnets – on one hand, ASTM said 14 and up, and on the other ASTM and the CPSC's interpretive documentation said 8 and up if it was a hobby, craft, or science-kit type item (Tr. 1978:21-1979:6.); (2) Mr. Qu wanted to make sure that, regardless of what ASTM and the CPSC said, people needed to know what could happen if you swallow a magnet (Tr. 1979:7-14.); and (3) it was a creative and unique way of crafting warnings that would be both memorable and more likely to be read (Tr. 1979:15-17). Complaint Counsel has failed to show how Respondent's warnings are defective.

Complaint Counsel also contends that Zen offered no evidence that people saw and heeded its warnings. Not only was it Complaint Counsel's burden to submit evidence that consumers did not see or heed Respondent's warnings (*i.e.*, it was not Zen's burden, 16 C.F.R. § 1025.43(b)(1), (2)), its contention is also belied by the record. For example, Mr. Qu testified that his warning about the magnets had been viewed several hundred-thousand times. (Tr. 1980:11-16.) Complaint Counsel also submitted no probative, credible evidence that the Subject Product ever caused an

injury (*see* ID at 16 n. 5), a fact that speaks directly to whether or not the warnings were heeded and have been effective. Complaint Counsel now, confusingly, suggests that the lack of evidence of injuries associated with the Subject Products is irrelevant to the question of whether the warnings were defective, and was a fact improperly considered by Judge Metry. (*See* App. Br. at 10-12.) While the regulations do contemplate the existence of a defective warning even when there are no injuries, 16 C.F.R. § 1115.4(d), whether a product has caused injuries is certainly probative of whether a warning has or has not failed to prevent injuries, which is in turn probative of whether a defect exists and whether people have heeded the warnings. Consequently, Zen submitted a plethora of evidence that people have both seen and abided by the warnings it has included with the Subject Products, posted online, and given to retailers. (Tr. 1980:11-16; Ex. R-133; Ex. R-192; Ex. R-193.)

Of particular importance in this case is the fact the Subject Products, especially Zen Magnets, are unique products. (*See* Tr. 19:6-8; *see also* Second Amended Complaint at ¶ 1 (identifying Zen Magnets and Neoballs as the Subject Products.)) The Subject Products *are not* any other SREM, strong magnet, brand of magnet, or product. (*Id*.) Much of Complaint Counsel's case was premised upon the argument that Zen's products share physical similarities to products, such as Buckyballs, that were widely available in retail stores and available for sale to children, and therefore are de facto substantial product hazards because those other products have been linked to injuries. Complaint Counsel did not, however, "sufficiently and credibly correlate any SREM injuries directly to Zen Magnets or Neoballs." (ID at 25.) Additionally, nothing in the record shows that other firms' magnets present substantial product hazards.

Judge Metry properly considered the record as a whole and found that nothing more than hearsay[12] supported Complaint Counsel's unsubstantiated assertion that the *Subject Products* have caused injuries, noting that "[t]he lack of credible evidence here is telling." (*Id*.) Complaint Counsel simply "did not present any credible evidence linking any injury to Respondent's product[s]. The import of this evidence, or the lack thereof, cannot be overstated when considering whether a defect exists in Respondent's warnings, particularly when couched in terms of inadequacy." (ID at 16); (*see also id*. at 25) ("The lack of credible evidence here is telling.") "Because the Agency bears the burden of showing the defective nature of the warnings, and to show the warning's inadequacy, *a dearth of evidence here precludes the ALJ from ruling in the Agency's favor on this issue*." (ID at 16.) (Emphasis added.) Complaint Counsel has cited to nothing in its Appeal Brief to establish that Judge Metry was mistaken.

D. Judge Metry Properly Found that the Subject Products are not Defective Under 16 C.F.R. § 1115.4.

i. Judge Metry Properly Found the Subject Products are of High Utility.

Complaint Counsel admitted that the Subject Products have utility (CC Post-Hearing Br. at 12), and that the magnets have an instructional purpose and artistic value (Tr. 1404:4-7; 1422:1-1423:18). Complaint Counsel did not submit any evidence regarding the low utility of the Subject Products. Because Complaint Counsel did not rebut Respondent's evidence regarding the factor of utility, there was necessarily a preponderance of evidence that the Subject Products are of high utility. *See Hale v. Dept. of Transportation, F.A.A.*, 772 F.2d 882, 886 (Fed. Cir. 1985).

[12] The fact that a friend of someone who ingested magnets also purchased Zen Magnets is evidence of only that fact – not that the magnets ingested were Zen Magnets. That the number of magnets given to the friend was six is also of no consequence absent more information. Complaint Counsel offered nothing more than speculation and innuendo as "evidence" that the Subject Products have caused an injury. Consequently, that "evidence" was appropriately accorded little weight.

Now that the hearing has concluded, Complaint Counsel seeks to introduce new arguments regarding utility. First, Complaint Counsel asks this Commission to take official notice of the fact Respondent started selling "Compliance Magnets" that are capable of making "most of the same structures as Zen Magnets." (App. Br. at 40.) Pursuant to 16 C.F.R. § 1025.43(a), (d), taking official notice of that statement would be clear error for several reasons. First, it is irrelevant, because Compliance Magnets are, by definition, not the Subject Products. (Second Amended Complaint at ¶ 1.) Therefore, it is inadmissible pursuant to section 1025.43(a) and Fed. R. Evid. 401. Second, the statement is not found in a source whose accuracy cannot be questioned – unless the Commission is willing to conclude the information on Respondent's website cannot be questioned. Third, Zen's statement about the capabilities of Compliance Magnets was puffery, *i.e.*, nothing more than an attempt to sell magnets, as was discussed in the Tenth Circuit at oral argument.[13] Moreover, as the statement itself discloses, not *all* of the structures that can be made with Zen Magnets can be made with Compliance Magnets. Therefore, Zen Magnets continue to be unique objects, particularly when it comes to making complex shapes used in art, teaching, and science. The legal conclusion that extends from the statement, of which Complaint Counsel asks the Commission to take official notice, is therefore in reasonable dispute. This Commission should therefore not take official notice of Respondent's statements, as requested by Complaint Counsel.

The second new argument put forth by Complaint Counsel after the conclusion of the administrative hearing is that there is no evidence that the Subject Products require a flux over 400, and that Respondent did not demonstrate a flux over 50 was required for the Subject Products to function. Because this argument was not raised in the hearing, or before, it should not now be considered by the Commission. Assuming, *arguendo*, the Commission reaches the merits of this

[13] *Zen Magnets, LLC v. Consumer Product Safety Commission*, No. 14-9610 (10th Cir.).

new argument, there is ample evidence in the record, and in statements by this Commission, that a flux well over 50 is required for the magnets to function and have a high utility. For example, Dr. Edwards' report discussed using weak magnets for the same purposes and found them to be decidedly inadequate, noting that "magnets that comply with [ASTM F963-11] would fail to fill the educational niche occupied by Zen Magnets." (R-155 at 18-20.) This Commission has similarly stated that having magnets under 50 flux (that are the same size) would "eliminate[] a distinctive product attribute and would limit greatly the magnet sets as candidates for manipulative . . . products." 79 Fed. Reg. at 59977.[14] Complaint Counsel's argument that Judge Metry erred for not considering this argument that was not put before him is unpersuasive and should be rejected by this Commission.

ii. Judge Metry Properly Concluded the Nature of the Risk of Injury is Significant Only in Certain Circumstances.

It is uncontroverted that the Subject Products are only dangerous when ingested. (ID at 17.) Judge Metry therefore properly considered how and why the Subject Products become ingested in making his nature-of-the-risk determination. Specifically, the evidence showed that people ingest SREMs when they are used as "mouth jewelry." (ID at 17.) Respondent, however, never designed, marketed, or manufactured the Subject Products as mouth jewelry. (Tr. 1717:9-12.) The Subject Products do not therefore pose the same risk of injury: "these products are not intended for ingestion and the nature of the risk of injury from an un-ingested SREM is nil." (ID at 18.) Indeed, Complaint Counsel submitted no evidence that a SREM that was not ingested has caused any injury whatsoever. Other products, such as Buckyballs, have previously advertised

[14] The Commission's statements and findings about the Subject Products are admissible pursuant to 16 C.F.R. § 1025.43(a), (d) and Fed. R. Evid. 801 (d)(2).

their products for use as oral jewelry, which, quite logically, resulted in those products being more dangerous.[15] (ID at 18.)[16]

Complaint Counsel's argument that Judge Metry's finding that the risk of injury is lower with the Subject Products as compared to other SREMs is erroneous and unpersuasive. Specifically, Complaint Counsel asserts that because it is foreseeable that people will ingest SREMs, the nature of the risk of injury must be the same for all SREMs. Again, the regulations only contemplate a defect being based *in part* on the reasonable, foreseeable misuse of a product, *based on the lack of adequate instructions and safety warnings*. 16 C.F.R. § 1115.4(d). Because the instructions and warnings were not defective and never advertised his products for oral insertion (ID at 18), Judge Metry properly found that the risk of injury factor did not weigh in favor of finding a defect.

Complaint Counsel's statement that Judge Metry's "conclusion that the risk posed by an un-ingested SREM is 'nil' unless there is a lack of parental supervision" (App. Br. at 42) is a severe misstatement of Judge Metry's findings. First, Judge Metry stated that the risk of an un-ingested SREM is nil – full stop. (ID at 18.) That statement is uncontroverted. Second, Judge Metry did not find that the risk was "nil" *unless* there was a lack of parental supervision. Rather, Judge Metry found that "the nature of the risk of injury of SREM ingestion is significant only when advertised for oral ingestion and/or when combined with a lack of parental supervision. . . . [T]he nature of the risk of injury which the product presents is negligible when accompanied by proper warnings

[15] Complaint Counsel attributes the differential in injury data between the Subject Products and Buckyballs to market share. (App. Br. at 10-11.) However, at the time of the hearing, Respondent's products made up 100 percent of the SREM market share. (Tr. 1480:16-20.)

[16] In [advertising their products for oral insertion], the nature of the risk of injury with Buckyballs is higher than those of Zen Magnets and Neoballs, despite the fact that the two products are nearly identical. Because Zen Magnets and Neoballs are not marketed for oral ingestion, Judge Metry finds the nature of risk of injury is low." (ID at 18.)

and appropriate age restrictions." (ID at 19.) Thus, what Judge Metry found was that (1) an un-ingested SREM is harmless, but that (2) when a SREM is advertised improperly, or contains improper age labels, or when parents fail to supervise children using SREMs, *or* a combination of all those factors exists, the risk of injury increases. Complaint Counsel therefore clearly mischaracterized Judge Metry's findings.[17]

Judge Metry properly found that risk of injury to be negligible when accompanied by proper warnings and age restrictions. Judge Metry did not ignore the evidence in coming to that conclusion, and he properly considered how and why the Subject Products become ingested. Judge Metry further properly deemed that, had Child A been better supervised, and had the doctors who treated her not released her from the hospital, Child A might not have died. (ID at 19; Ex. CC-18.15; Ex. CC-27A.) Complaint Counsel has submitted no evidence to the contrary.[18]

iii. There is not an Identifiable Group that Constantly Subjected to the Subject Products' Risk.

Judge Metry properly determined that the population exposed to the Subject Products are individuals who purchased SREMs and who might encounter SREMs through the purchaser. (ID

[17] Similarly, Complaint Counsel mischaracterizes Judge Metry's analysis of Child A's death by stating that Judge Metry "blamed doctors for misdiagnosing Child A's symptoms." (App. Br. at 45.) Judge Metry handed out no such blame. Instead, Judge Metry noted that misdiagnosis is a problem with magnet ingestions. Complaint Counsel further argued that it offered unrebutted testimony and evidence about the hidden nature of the risk of injury (App. Br. at 42-45), which will be discussed by Respondent under that factor of 16 C.F.R. § 1115.4, *infra*.

[18] Complaint Counsel faults Judge Metry for citing to a police report submitted into evidence by Complaint Counsel, and for "completely ignor[ing]" the medical examiner's testimony and report. (App. Br. at 43.) That allegation is unfounded, as Judge Metry expressly addressed the coroner's findings, relaying that Child A did not test positive for Sevin. (ID at 19.) As for his treatment of Child A's mother's testimony, Judge Metry was not mistaken in assessing that testimony in light of CC-18.15 and the accompanying reports, which showed, among other things, that Child A's death resulted from a number of factors, including a lack of parental supervision and misdiagnosis by doctors. (Ex. CC-18.15; ID at 18-19.) Again, this was a matter of weight to be determined by the trial judge. All of the evidence cited by Complaint Counsel was admitted, but not accorded the weight that Complaint Counsel desires.

at 23.) Judge Metry also properly concluded that the risk of injury is ingesting the magnets. (*Id*.) As a result, the population exposed to the risk of injury is a purchaser of the products, or someone who might encounter the products via the purchaser, *and* who would ingest the magnets. (*Id*.) Based on this information, Judge Metry properly found that "[t]here is no single individual or group of individuals constantly subjected to the product's risk of injury simply because *not all individuals*, no matter the age, will ingest the product." (ID at 23.) (Emphasis added.)

Complaint Counsel misstates that Judge Metry "correctly found that an estimated 2,900 children have sought emergency room ingestion treatment due to SREM ingestion." (App. Br. at 47.) What Judge Metry actually "found" was that the "Agency projects . . . about two thousand nine hundred reported incidents." (ID at 23.) In other words, Judge Metry was simply reciting Complaint Counsel's argument.

Judge Metry properly found that Complaint Counsel's evidence that children will swallow nearly any object to be unpersuasive in finding that a defect exists. Dr. Steinberg, for instance, admitted that he did not make note of the age of individual involved in the reports he was provided (Tr. 418:15-18), believes children are generally drawn to shiny things (Tr. 419:4-16), and that children generally explore the world by putting objects in their mouths (Tr. 420:20-421:2.) Clearly, not every object that a child can put in its mouth is defective, especially when those objects can be kept away from children. (*See* Tr. 425:16-21; Tr. 2105:10-15.)

The evidence also established that no individual has been harmed by using the Subject Products as they were designed, marketed, and manufactured. (*See* Ex. CC-18.) Because the risk of injury only exists when the products are misused, Judge Metry correctly found that, regardless of whether an individual ingests a magnet through "age-appropriate behavior," the population ultimately exposed to the risk of injury is too amorphous. (ID at 23.)

Finally, Judge Metry correctly found that the number of individuals exposed to the risk of the injury is small, especially compared to the millions of magnets that have been sold to consumers. (ID at 23-24.)

iv. The Subject Products are Unique and Irreplaceable Teaching Tools and Artistic Mediums.

Respondent has never held out the Subject Products to be life-sustaining necessities. The Subject Products are, however, inimitable products that provide a unique medium for art, science, research, and teaching. (Tr. 2210:22-2211:3; 1431:12-1432:5; 1428:11-1429:14; 1453:14-18; 1427:7-1428:1; 1419:3-7; 1432:12-1433:7; 1426:14-6; 2555:18-2556:4; 2539:15-2540:13; Ex. R-154A at 3; R-155 at 18-20; Ex. R; Ex. S; Ex. O; Ex. U; Ex. P; Ex. Q; Ex. L; Tr.; T.) The fact that Respondent has *attempted* to build a product that complies with Commission regulations and maintains a *similar*, but not equal, function in no way detracts from the unique characteristics of the products, as discussed *supra* under the "Utility" analysis.

Complaint Counsel bewilderingly faults Judge Metry for using the Commission's example of a knife when weighing the risk of injury against the product's usefulness. (App. Br. at 47.) The knife example is found in 16 C.F.R. § 1115.4 and Judge Metry appropriately quoted that language when conducting his analysis. (ID at 28-29.) Judge Metry did not have to make a finding that the Subject Products are a necessity in order to quote the regulation. Moreover, Judge Metry's analysis was limited to his findings that the strength of the magnets gives them their utility – an uncontroverted fact in these proceedings – and that the strength of the magnets also creates the risk of injury when the magnets are ingested. (ID at 29.) Judge Metry made no error here.

v. Judge Metry's Discussion of the Obviousness of the Risk was not in Error.

Judge Metry correctly found that warnings increase the awareness of the risk of ingesting SREMs. *See* Respondent's discussion of warning defects, *supra*, and its discussion of the ability

of the warnings to mitigate the risk, *infra*. It is only logical that when an otherwise hidden risk is identified and highlighted, that risk becomes better known and apparent. For example, NASPGHAN undertook efforts to educate people about the ingestion risk, and Dr. Noel believes they were successful in preventing injuries by doing so. (Tr. 801:9-803:17.) Additionally, the lack of credible evidence that Zen Magnets have caused injuries, and the lack of evidence that they pose a significant risk of injury given the number of products on the market both support Judge Metry's reasoning that warnings help address the risk, which, as Judge Metry found, may not be fully understood by consumers. Complaint Counsel have failed to show how and why Judge Metry's discussion of the obviousness of the risk was in error.

vi. Respondent's Warning have Successfully Mitigate the Risk.

Judge Metry properly found that, while other firms' SREMs have caused injuries, Complaint Counsel was unable to put forth credible, reliable evidence that the Subject Products have caused injury: "Importantly . . . the Agency was unable to sufficiently and credibly correlate any SREM injuries directly to Zen Magnets or Neoballs. The lack of credible evidence here is telling." (ID at 25.) Complaint Counsel faults Judge Metry for "disregarding two documented incidents where Zen Magnets were ingested." (App. Br. at 50.) However, as discussed above, Judge Metry considered the evidence, then properly exercised his discretion to give it limited weight after determining that the statements provided by parents stating that Zen Magnets had been ingested were hearsay. (ID at 16 n. 5.) Those statements were therefore not relied upon heavily by Judge Metry, which was the proper treatment of that evidence. Again, that evidence was not *disregarded* by Judge Metry, and it was accorded its proper weight.

Respondent properly and clearly identified the risk posed by ingesting magnets, unlike Buckyballs. Judge Metry correctly found that "Buckeyballs did not contain specific warnings

addressing ingestion and intestinal pinching, [but] Zen Magnets and Neoballs do." (ID at 25.) Judge Metry explained:

> Therefore, it is easy to conclude Respondent's warnings adequately deterred consumer ingestion, and deterred purchases by consumers with children that might ingest SREMs. . . . Again, the Agency's inability to provide credible evidence linking injuries to Respondent's products as compared to the plethora of evidence linking injuries to Buckeyballs (which advertised its products as mouth jewelry) shows Respondent's warnings were defective.

(ID at 25.)

Respondent also demonstrated that the NEISS data and estimates were unreliable. For example, Ms. Stralka, the Commission's epidemiology expert, testified that the NEISS data, which the Commission used to arrive at its 2,900 injury estimate, was subjectively binned, which sometimes involved a "complete judgment call by the staff member." (Tr. 1097:6-9; *see also* Tr. 936:17-18.)

Complaint Counsel appears to conflate its argument that the *warnings* are defective (App. Br. at 33-39) with the separate, alternative argument that the *Subject Products* themselves are defective because of the factors enumerated in 16 C.F.R. § 1115.4 (App. Br. at 39-56). Complaint Counsel insists that Judge Metry could not have found that the warnings have not failed to mitigate the risk because they were necessarily defective. That argument puts the proverbial cart before the horse, and is unsupported by both the record and Judge Metry's reasoned findings. As discussed above, Judge Metry properly concluded that Complaint Counsel did not meet its burden of showing how the warnings were defective. (ID at 12-16.) While it is true that 16 C.F.R. § 1115.4 contemplates the finding of a *defective warning* without the existence of an injury (as was the case in *Dye*), neither *Dye* nor any other case cited by Complaint Counsel supports Complaint Counsel's argument that Judge Metry improperly considered the nonexistence of injuries when

analyzing whether the warnings have effectively mitigated the risk. To the contrary, it was entirely reasonable for Judge Metry to have considered whether the warnings had been successful in preventing injuries. And as the record demonstrated, Respondent's warnings were, in fact, successful in preventing injuries. Complaint Counsel has not produced any reliable, credible evidence to the contrary.

Lastly, Complaint Counsel notes that some of Respondent's products were sold without a warning. As Judge Metry made clear in his Order, those products would present a substantial product hazard (ID at 36 ¶ 11) and must be recalled (*id*. at 37).

vii. Judge Metry's Discussion of the Role of Consumer Misuse was not in Error.

Judge Metry properly determined that "misuse is the sole cause of injuries concerning SREMs and misuse's role is significant in that it is the only real source of injury associated with SREMs." (ID at 26.) As discussed above, the use of magnets in ways that could lead to ingestion can be considered to be nothing other than unreasonable misuse, as Respondent did not design, market, manufacture, or intend the Subject Products to be used in any manner that could lead to ingestion. (Tr. 2541:4-14; 2545:12-18; ID at 25; ID at 13-14; Ex. R-1; Ex. R-1D; Ex. R-70; Ex. CC-5(2); Ex. CC-5; Ex. R-193; Ex. R-197; Ex. R-198; Ex. R-199.) While Complaint Counsel's experts said that use of the magnets in ways that could lead to ingestion was something they could foresee, they provided no testimony that such use was not misuse. It does not take the unintended use of the magnets out of the "misuse" category simply because a child can mouth an object found in their environment, or because kids will ignore known risks. (Tr. 440:1-8.) Stated differently, a product can still be misused even if a child is acting in an age-appropriate manner. Complaint Counsel has failed to demonstrate otherwise. Moreover, Complaint Counsel's experts testified, in

essence, that kids cannot be trusted to make good decisions, regardless of the product or risks involved. (Tr. 439:19-440:8.)

Regarding misuse, Judge Metry found that misuse of the Subject Product is foreseeable, but also correctly noted that Respondent's warnings have been successful at deterring misuse. (ID at 26.) Complaint Counsel has submitted no evidence to demonstrate Judge Metry's conclusion was in error.[19] As discussed above, the regulations do not contemplate a finding of defect based solely on the misuse of a product. Because Complaint Counsel did not submit evidence that there was a fault, flaw, or irregularity associated with the products that would create a risk of injury, outside of misuse by consumers, Judge Metry correctly concluded that this factor did not weigh in favor of finding a defect under 16 C.F.R. § 1115.4.

viii. Judge Metry Properly Weighed and Considered Agency Expertise.

After weighing and evaluating the evidence in the record, Judge Metry determined that Complaint Counsel failed to meet their burden of establishing a product defect or a warnings defect in law and fact. (ID at 27-28.) Consequently, Judge Metry did not give considerable weight to Complaint Counsel's plea for considerable deference in finding a product defect, which was a question to be resolved on law and fact, not on the Agency's expertise. *See e.g. Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (agency enforcement decisions involve factors peculiarly within agency expertise); *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 544 (1984) (deference owed to agency's reasonable interpretation of its own statute); *Skidmore v. Swift*

[19] Complaint Counsel has misread Judge Metry's finding that Respondent's warnings mitigate the danger of ingesting SREMs (ID at 26) to mean that the danger of ingesting SREMs "is no longer foreseeable." (App. Br. at 52.) That is not what Judge Metry concluded. To the contrary, Judge Metry stated that the "foreseeability of misuse is a foregone conclusion," but that the record has shown Respondent's warnings to have sufficiently deterred misuse, notwithstanding the existence of foreseeable misuse. (ID at 26.)

& Co., 323 U.S. 134, 140 (1944) (deference to an administrator's conclusions).[20] Because this case was an administrative adjudication pursuant to 5 U.S.C. § 554, Judge Metry's actions were not in error.

Respondent showed how Complaint Counsel's data collection and extrapolation methods, in this case, were unreliable. Notably, their expert witness, Kathleen Stralka, testified that she could not say, within a reasonable degree of statistical certainty, that the magnets binned as "yes/possible" (used to arrive at the 2,900 injury estimate) were the same magnets as those identified as the Subject Products in this case. (Tr. 1094:7-1095:17.) Because of the high degree of uncertainty in the data that was used in this case, it cannot be said that the Commission's own data is reliable. It was therefore proper for Judge Metry to accord it less weight.

Complaint Counsel also relied *entirely* on outside witnesses (Dr. Noel, Dr. Frantz, and Dr. Steinberg) in its attempt to show the Subject Products had defective warnings, a design defect, and/or were violative of ASTM F963-11. (App. Br. at 54.) Accordingly, these witnesses were not entitled to the same deference usually given to a government agency. Essentially, what Complaint Counsel seeks would be tantamount to requiring Judge Metry to defer to all of the Complaint Counsel's allegations, which would be facially improper pursuant to 5 U.S.C. §§ 554 and 556.

As previously discussed, Kathleen Stralka's testimony was unpersuasive and showed the Commission's flawed data collection and analysis in this case. (Resp. Post-Hearing Argument at 16-17; Tr. 1096:15-1097:9; 936:16-19; 1033:18-22; 1095:2-17.) And Vincent Amodeo, the Commission's only other expert, merely testified regarding the physical properties of the magnets and testing methods for size and magnetic strength. (*See* Ex. CC-1A; Ex. CC-7; Ex. CC-8.) Mr.

[20] Complaint Counsel asserts that *Skidmore* is inapplicable because there was not a final agency action. (App. Br. at 52.) Because it is true that there had not been a final agency action in this proceeding yet, the agency is due even less deference than that owed to it under *Skidmore*.

Amodeo did not testify regarding warnings (97:22-98:17) and did not opine on either product defects or whether the Subject Products violated ASTM F-963. Judge Metry therefore properly considered and weighed Complaint Counsel's evidence and witness testimony.

Third, Judge Metry did not "disregard agency expertise based on an incomplete understanding of the bases for relief sought by Complaint Counsel." (App. Br. at 53.) Judge Metry gave a fair and complete hearing and reading of their testimony, then made his ruling based on the fact that he was unpersuaded by the Agency's "positions on law and fact." (ID at 28.) The entirety of the Initial Decision indicates that Judge Metry considered fully each of Complaint Counsel's alternative arguments (*see* ID at 6,[21] 36) and accorded each their due weight.

ix. Judge Metry's Analysis of Case Law was Proper.

As a preliminary matter, Contrary to Complaint Counsel's assertion that Judge Metry "failed to specifically address [their analysis of the case law]" (App. Br. at 54), Judge Metry expressly considered the only two cases cited by Complaint Counsel in Section A(1) of the Initial Decision (ID at 8-12). Rather than "rehash that analysis" (ID at 27) in Section A(3)(viii) of the Initial Decision, Judge Metry referenced his previous analysis of the case law cited by Complaint Counsel. There was no error in exercising sound reason and judicial economy by foregoing repetition of the same legal discussion in two places in his decision.

In his discussion and analysis of the case law, Judge Metry made no error in finding that neither *In re Dye & Dye*, 1989 WL 435534, CPSC Docket No. 88-1 (1991) (Worm Gett'rs), nor *In re Francis Alonso Jr. d/b/a Mylar Star Kites*, CPSC Docket No, 75-16 (1977), supports

[21] "[T]he Agency's Complaint presents two main issues: 1) whether SREMs are a substantial product hazard under CPSA Section 15(a)(2) because they contain defects which create a substantial risk of injury to the public; and 2) SREMs are a substantial product hazard because it violates the toy standard, which creates a substantial risk of injury to the public." (ID at 6.)

Complaint Counsel's position that the Subject Products present a substantial product hazard. The Subject Products are entirely different from worm probes and metallic kites, which can both cause injury during normal operation and use. (ID at 9) ("the injuries and deaths resulting from Worm Gett'r use were caused by accidents or mistakes combined with the intended use of the product.") Additionally, in *Dye*, not even the "best warnings and instructions [could] eliminate the hazard." *Dye* at *3. In *Mylar Star Kites*, the ALJ there similarly found that flying a metallically coated kite could result in not only in severe injury and death to the flier, but also posed a risk to the community because of the risk of taking down power lines. (*Mylar Star Kites*, Initial Decision at 11.) The simple act of flying the metallic kites could result in injury. In the case at bar, however, Respondent demonstrated not only that its warnings were not defective and have been successful in preventing any injuries (ID at 16), but also that misuse of the magnets is the only injury mechanism (ID at 7-8). While an accident could occur when flying the kites that could result in injury, the record clearly shows that an accident while properly using the Subject Products results in no risk of harm whatsoever. (ID at 10 ("simply because two or more magnets become separated from the primary cluster does not result in any exposure to danger.")

Dye is of no assistance to Complaint Counsel's argument that, because other SREM manufacturers have caused injuries, the Subject Products must be defective. (App. Br. at 55.) While the functional characteristics of the Worm Gett'rs were the same as other worm probes, *Dye* at *6, the warnings and instructions were also defective, and failed to point out the seriousness of the hazard, *id*. at *8. Respondent's warnings and instructions in this case were not defective (ID at 36 ¶¶ 3-5); additionally, Respondent's packaging and advertising distinguished the potential hazard posed by the Subject Products from other firms' products (ID at 18, 25). Because of Respondent's proper warnings and advertising of its products after May 2010, Respondent

functionally and critically differentiated its products from more hazardous SREMs that were marketed for use as, for instance, mouth jewelry. (ID at 25.) Because of these differences, Judge Metry properly considered evidence regarding the number of injuries caused by the Subject Products and other SREMs. And, because Complaint Counsel did not submit credible evidence that the Subject Products have caused any injuries, the number of other SREM injuries *did not* evidence the risk of injury posed by the Subject Products, unlike the worm probes in *Dye*.

The ALJ in *Mylar Star Kites* also noted that the aluminized coating on the kites was only for sales and not for performance, unlike the potentially hazardous element of the Subject Products: "In the instant case, the attractiveness of the SREMs to each other is the sine qua non of their essence. Without the ability to attract each other, the product is worthless." (ID at 11.) Judge Metry explained that, like the Commission did in *Mylar Star Kites*, he "balanced the risk of harm with the necessity of the magnetic pull," and, "using the approved analysis of Mylar Star," found that "there is no question that Mylar Star would dictate a different result if the magnetic coating improved functionality, not simply aesthetics." (*Id*.) Due to the disparate facts at issue in *Dye*, *Mylar Star Kites*, and the instant case, Judge Metry properly and reasonably found that both cases were "simply inapposite." (ID at 10.)[22]

Based on all the factors analyzed under 16 C.F.R. § 1115.4,[23] Judge Metry properly found that the Subject Products do not present a substantial product hazard. (ID at 36 ¶ 2.) Complaint

[22] Complaint Counsel's citation to a civil case filed against Buckyballs (App. Br. at 56) is irrelevant to the proceedings against Zen Magnets, LLC. As discussed at length, the risks posed by Buckyballs differed from those posed by the Subject Products in this case. The Commission should not consider that case (*Jordan v. Maxfield & Oberton Holdings, LLC*, 2016 WL 1173100 (S.D. Miss. 2016)) when deciding whether or not the Subject Products present a substantial product hazard.

[23] Complaint Counsel's Appeal Brief does not assert that Judge Metry's weighing of the risk of injury against the product's usefulness was in error. (ID at 28-29.) That analysis should therefore not be addressed by the Commission, pursuant to 16 C.F.R. § 1025.53(b)(4). In the event the Commission entertains an evaluation of that section of Judge Metry's Initial Decision, Respondent

Counsel has shown no error on the part of Judge Metry, but simply contend that the evidence should have been weighed differently, and in its favor. Because no error has been shown, the Commission should affirm Judge Metry's findings under the section 1115.4 factors.

II. THE SUBJECT PRODUCTS ARE NOT DEFECTIVE UNDER 15 U.S.C. § 2064(A)(2).

A. Complaint Counsel did not Establish a Pattern of Defect Related to the Subject Products.

Complaint Counsel did not show that the Subject Products were defective, let alone show that there existed a pattern of defect. As Judge Metry correctly noted, the separability of magnets poses no risk of injury (ID at 10), and is not a defect within in the definition of 16 C.F.R. § 1115.4. Dr. Frantz's contention that separable magnets are per se defective, as if the product is "broken" (Tr. 252:3-5) is particularly unavailing. Dr. Frantz did not consider how magnets were actually used, and to what extent misuse of magnets could result in magnets becoming unaccounted for. (Tr. 269:18-270:12.) Dr. Frantz also stated that he did not determine that the magnets presented a containment problem based on his analysis of the products; rather, that conclusion was one "provided to [him] by Zen Magnets." (Tr. 272:22-273:5.) Further, Dr. Frantz was not asked to opine on the containment issue; he was asked to "answer technical questions about warnings that the implications of the lack of containment that Zen Magnets has acknowledged." (Tr. 273:5-8.) As previously discussed, Dr. Frantz's understanding of what Respondent "acknowledged" was fatally flawed and based on an email to a customer at the outset of the company, and on a misunderstood deposition response about sharing magnets, provided to Dr. Frantz by Complaint Counsel. (Tr. at 276:6-21.) Mr. Qu would later explain that a magnet that is "shared" and

directs the Commission to Respondent's Post-Hearing Argument at 4-7, and Ex. R-155 for a discussion of the products' utility in various applications.

unreturned to the original owner is, in his eyes, a "lost" magnet, which does not also mean that such a "lost" magnet is also "unaccounted for" in the environment. (Tr. 2006:19-2007:7.) In fact, Dr. Frantz provided no credible evidence that the products are defective in design or function that would enable Complaint Counsel to also demonstrate that a pattern of defect existed.

B. Respondent's Warnings did not Fail to Identify the Ingestion Risk and Have Successfully Mitigated the Risk of Injury Through Ingestion.

As discussed in detail above, Complaint Counsel did not show how Respondent's warnings, as they existed after 2010, were defective, and did not show that the warnings failed to mitigate the ingestion risk. Judge Metry correctly found that mechanism for injury is *not* the severability of magnets, but is the ingestion of magnets. (ID at 14.) Consequently, "even though . . . the warnings do not address the severability of the magnets, the severability does not create the risk of injury." (*Id*.) Respondent's warnings clearly notified consumers of the ingestion hazard, as well as intestinal pinching. (Ex. R-1; Ex. R-1D; Ex. CC-5; Ex. CC-5(2); Ex. R-193.) Judge Metry also correctly determined that "the lack of warnings on each individual SREM does not result from a [defect], but [from] a matter of practicality and possibility. It would be near absurdity to fault Respondent for not labeling each individual SREM with a warning." (ID at 15.)

Once again, Complaint Counsel did not submit reliable, credible evidence that the Subject Products have resulted in any injury. (ID at 16.) It is therefore more than reasonable to assume that the warnings have been effective in mitigating injury. Even if, *arguendo*, it is improper to assume otherwise, Complaint Counsel did not submit credible evidence to that effect, which means that this theory of liability cannot have been shown by substantial evidence, let alone by a preponderance of the evidence.

C. The Subject Products Do Not Create a Substantial Risk of Injury Because of their Number.

Complaint Counsel next contends that the defect, which it failed to show exists, creates a substantial risk of injury because of the number of defective products in commerce. While it was shown that Respondent has sold millions of non-defective magnets, Complaint Counsel did not submit any evidence about the expected injuries from those magnets. *See e.g. Dye* at *14 (noting the number of expected injuries based on the number of defective products). Unlike *Dye*, where the evidence established that injuries were *likely* to occur, *id*., in the present case, the evidence showed that injuries were quite unlikely to occur, especially considering the number of products on the market (ID at 5 ¶ 16). The record also established the "dearth of evidence" that Respondent's products have caused injuries. Because of that lack of evidence, there is also no evidence that the Subject Products pose a risk of causing injuries in the future. More importantly, however, because no defect exists, this theory of liability must fall.

D. There is no Defect that Creates a Substantial Risk of Injury.

As Judge Metry correctly found, the risk at issue in this case is remote, especially considering the number of products in commerce. (ID at 5 ¶ 16.) Respondent has never contested that ingesting multiple SREMs could result in injuries. However, because the Subject Products are not defective and injuries are unlikely to occur, this theory of liability does not establish the existence of a substantial product hazard.

III. THE SUBJECT PRODUCTS, AS SOLD AFTER MAY 2010, COMPLY WITH THE TOY STANDARD.

A. The Subject Products Were not Designed, Marketed, or Manufactured as Playthings for Children Under the Age of 14.

Complaint Counsel failed to show that Respondent's products do not comply with ASTM F963-11 (the "Toy Standard") and thereby create a substantial risk of injury to the public. To be subject to the Toy Standard, a product must be a toy that is designed, marketed, or manufactured as a plaything for a child under 14 years of age. Complaint Counsel also had to establish: (1) that the Subject Products are *not* "hobby, craft, and science kit-type items intended for children over 8 years of age, where the finished product is primarily of play value" under ASTM F963-11 § 4.38.3; (2) that the Subject Products do not comply with requirements of § 4.38.3; and (3) that the Subject Products pose a substantial risk of injury to the public as a result. Judge Metry considered all of the evidence put forth by Complaint Counsel (ID at 31) and was unpersuaded that the Agency carried its burden of showing that Respondent's products violate the Toy Standard.

Judge Metry correctly found that Respondent did not design, market, or manufacture the Subject Products as playthings for children under 14 years of age. (ID at 31.) The only evidence adduced by Complaint Counsel established that the Subject Products are toys, generally, and that they *might* be used by someone under the age of 14. (*Id.*; App. Br. At 60.) Neither fact establishes a violation of the Toy Standard.

As purported evidence that Respondent designed, marketed, or manufactured its products for children under the age of 14, Complaint Counsel cites to quotes by Respondent that the magnets make "great refrigerator art," can be used as jewelry,[24] "look hot on girls," and "look[] good on

[24] *In his deposition*, Mr. Qu was first asked if he considered "using the magnets as jewelry to be one of the appropriate uses of Zen Magnets and Neoballs," and after receiving an unsatisfactory response, Mr. Aragon, Counsel to the Commission, followed up: "So I really have to ask again,

cute people." (App. Br. At 60.) None of these statements is remotely probative of whether the Subject Products were designed, marketed, or manufactured for children under the age of 14. Even calling the magnets "fun toys" and stating they can be "play[ed] with" are not probative of whether the Subject Products fall under the purview of ASTM F-963-11. (Tr. 191:19-192:1.)

Complaint Counsel's experts did not provide any probative evidence that the products violated the Toy Standard, either. Dr. Frantz, for example, concluded that the Subject Products were toys based *only* on his reading of the pamphlet found *inside* the packaging of the magnets. (Tr. 191:19-192:1; 328:15-19.) In fact, Dr. Frantz conceded that changing the packaging alone would "move it away from being a children's toy" (Tr. 329:3-7), and when questioned by Judge Metry, admitted that without the inside pamphlet, they would not be "toys," in his expert opinion (Tr. At 335:12-336:1). Dr. Frantz conducted no inquiry into whether the Subject Products were toys based on how they were designed, marketed, or manufactured. Nor did he consider the common uses of the Subject Products. (Tr. 269:18-270:12.) More importantly still, Dr. Frantz admitted that he had not considered or examined Respondent's current packaging when he concluded that the Subject Products were "toys" for the purpose of the Toy Standard. (Tr. 204:7-21.)

According to Dr. Frantz, manufacturers can do things to take products out of the purview of the Toy Standard, such as making language clearer (*e.g.*, "for adults only," or "14 and up"), and by selling the products only to adults. (Tr. 256:13-258:14.) These are both things that Respondent did: the Subject Products clearly state on the *outside* of their current packaging that its magnets "are not children['s] toys" (Ex. R-1; Ex. R-1A), and Respondent sold its products to adults online

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and I'm asking for the second time, do you consider the use as play jewelry an appropriate use of Zen Magnets and Neoballs?" Mr. Qu responded: "Good objection to my last answer by th[e] way, but yes." (Ex. R-199.)

and in dispensaries, head shops, and specialty craft stores (Ex. R-197; Ex. R-198; Tr. 1734:7-1735:5).[25]

Complaint Counsel attempted to show that children can easily purchase the Subject Products by having an investigator, Christina Fredrick, purchase magnets at Soldis, a pipe shop that had then recently moved to a mall. While it is true that Ms. Fredrick, was able to purchase magnets without her ID being checked to verify that she was over the age of 18, Ms. Fredrick was in fact 44 years of age at the time, and admitted that she did not appear to be 18 years of age. (Tr. 2632:17-2633:1.) Of note, Ms. Fredrick was asked for her ID, and did receive verbal warnings about the magnets when she purchased Subject Products from Science Toy Magic. (Tr. 2679:4-9.)

Complaint Counsel also identified flaws in Respondent's website, which allowed consumers to make purchases without seeing warnings, which Respondent quickly corrected. (App. Br. at 62 n. 17.) Respondent's alteration of its website shows how easily the website can be changed to ensure that warnings are seen and understood by consumers prior to purchase. (Tr. 2447:12-2448:3.)

Complaint Counsel correctly notes that an inquiry into whether the Subject Products were designed, marketed, or manufactured as playthings for children under the age of 14 should delve into *how* those things were done (App. Br. at 63), and Judge Metry did just that. The inquiry into Shihan Qu's intent behind his design of and marketing for the Subject Products was entirely proper for determining how the products were made and by whom they were intended to be used. The evidence presented by Complaint Counsel in the administrative hearing is not probative of whether

[25] Complaint Counsel faults Respondent for not placing warnings on billboard advertisements for the Subject Products being sold in dispensaries, and claims such evidence "refutes Judge Metry's finding that Zen limited retail sales to adults." (App. Br. at 62.) However, dispensaries only allow people over the age of majority in their shops. (Tr. 2552:16-2554:12.)

the Subject Products meet the definition of "toys" for purposes of the Toy Standard. To the contrary, the evidence overwhelmingly demonstrates that the Subject Products are designed, marketed, and manufactured for people over the age of 14, not only for fun, but also for art, science, and therapy. Not all things that are fun to play with are toys; not all items used for self-adornment are toys; and not all toys that are fun to play with are those that are designed, marketed, or manufactured for children under the age of 14. Nor does the fact a child under the age of 14 might use an item bring it under the purview of the Toy Standard. (ID at 31-32.) Regarding how Respondent designed, marketed, and manufactured the Subject Products, Judge Metry properly and reasonably found Respondent's methods of sales (online and through restrictive access brick-and-mortar locations) to be "far more compelling" than any of the circumstantial evidence presented by Complaint Counsel to insinuate that, because Respondent knew its products might be used by those under the age of 14, that Respondent designed, marketed, and manufactured the products to be used by children under the age of 14. (ID at 32.)

Respondent also demonstrated that children under the age of 14 were unlikely to have the means to purchase the Subject Product because of Respondent's sales methods, which usually require the use of a credit card. As Judge Metry explained: "This conclusion is most pointedly supported by the Agency's inability to present even a scintilla of evidence that any child under the age of 14 was ever able to purchase SREMs from Respondent's website or in any of the abovementioned stores." (ID at 33.)

In summary, Complaint Counsel submitted evidence that merely addressed the fact the Subject Products are fun to play with, look good on cute people, can be used for self-adornment (Tr. 2422:6-12), and might be used by children (Ex. CC-44). (*See also* ID at 31.) Unless Complaint Counsel is to maintain that anything that is fun to play with and might be used by

someone under the age of 14, even if it is not so intended, is a toy for purposes of ASTM F963-11, the evidence in the record is not nearly sufficient to meet the evidentiary burden required. Respondent, on the other hand, submitted evidence that: Respondent marketed the Subject Products to people between the ages of 15 and 65 (Tr. 2541:4-18); designed Zen Magnets with tighter tolerances to appeal to that same target audience (Tr. 2545:4-2547:7); sold its products to adults online and in dispensaries, head shops, and specialty craft stores (Tr. 1734:7-1735:5); implemented the "Zen Voluntary Standard" to help ensure people knew about the ingestion hazard (Ex. R-197; Ex. R-198); publicly marketed the products sold in dispensaries and head shops (Ex. R-132); and made a flagship video entitled "Never Let Go of Childhood Wonder" (Ex. R-139) – a video clearly not intended for people who were *still* children. Based on this evidence, Judge Metry correctly found that "Respondent did not design, manufacture, or market all SREMs as a plaything for children under 14 years of age." (ID at 33.)

B. If ASTM F963-11 Applies to Either Zen Magnets or Neoballs, Complaint Counsel has not Shown that Respondent is in Non-Compliance with ASTM § 4.38.3.

Contrary to the position taken by Complaint Counsel, simply because Zen produces a magnet of a certain size and flux index does not automatically render the product violative of §§ 4.38.1 and 4.38.2, and subsequently 15 U.S.C. § 2064. Under § 4.38.3, the ASTM standards specifically *exempt* products with loose-as-received hazardous magnetic components when they are hobby, craft, and science kit-type items.

Respondent introduced substantial evidence in the hearing that its products are science-kit type, hobby, or craft items. But for anemic testimony regarding science kits by Dr. Frantz, Respondent's evidence was unrebutted.[26] To wit: Zen's expert and lay witnesses testified at length

[26] Dr. Frantz testified that in his opinion Zen's sales of its products in head shops and dispensaries was inconsistent with Zen's assertion that its products fall under the "science-kit" exemption of §

about the uses of Subject Products in demonstrating and learning principles of science, and Mr. Qu, Dr. Edwards, and Mr. McClive (Ex. Q) all testified to the use of the Subject Products as craft and hobby items. Respondent's Exhibits 195 and 196 show how Zen Gallery users make complex shapes and structures with Subject Products as a form of craft and art. Dr. Edwards' report, R-155, R-2 through R-47, and R-49 through R-54, further showcase the science, hobby and craft uses of the Subject Products – uses for which the magnets were originally designed, marketed, and manufactured (*see* Tr. 2541:4-18; 2545:4-11). Even the Commission's human factors expert, Dr. Frantz, recognized these uses of the Subject Products to be hobbies. (*See* Tr. 157:14-16.) None of the Commission's experts offered arguments against the Subject Products being recognized as a hobby or craft items.

Despite Dr. Frantz's contention that Respondent's products are uniquely hazardous in that they are loose-as-received powerful magnets, such attributes are not unique at all. (*See* Tr. 344:1-3.) Earrings and bracelets intended for children over eight years of have consisted of loose as-received hazardous magnets prior to Zen's existence. Zen has demonstrated that many other products also have loose-as-received magnets defined as "hazardous magnets" under ASTM standards. (*See e.g.* Tr. 2194:10-19; 2190:18-21; Tr. 115:1-9.) Additional proof that ASTM intends that children over eight years of age are expected to safely handle loose as-received hazardous magnets is in the U.S. Standard Specification for Children's Jewelry, ASTM F2923-11, which has an identical definition for "hazardous magnet" (Tr. 115:2-8), and has identical warning language requirements.[27]

4.38.3. This argument is without merit. By Dr. Frantz's own testimony, the location of a product for sale does not have any bearing on it being less or more of a toy. (*See* Tr. 334:11-19 (making it less available by selling it at dispensaries does not "make it less of a toy."))

[27] ASTM F2923-11 is incorporated into law under CPSA, similarly to ASTM F963-11, to which this Commission has taken official notice. (*See* Complaint Counsel's Motion for Official Notice, July 17, 2014.)

Although Zen has never been certain that ASTM F963-11 applied to its Subject Products, Respondent has always acted under the supposition that the most prudent course of action was to assume ASTM labeling requirements were applicable. Consequently, Mr. Qu crafted Respondent's warnings to follow what he interpreted to be incongruous standards: on one hand CPSC staff said 14 and up, and on the other, ASTM and the CPSC interpretive documentation stated 8 and up was a suitable for craft and hobby items. (Tr. 1978:21-1979:6.) Respondent maintains, as it always has, that even if the Subject Products fall under the auspices of the Toy Standard, its products are "hobby, craft, and science kit-type items intended for children over 8 years of age." ASTM F963-11, § 4.38.3. Complaint Counsel failed to show anything to the contrary.

C. Even if, *Arguendo*, the Subject Products are subject to ASTM F963-11, Complaint Counsel has not Established that any Violation of the Toy Standard Creates a Substantial Risk of Injury to the Public.

Again, Complaint Counsel did not prove, by any measure, that Respondent's products have caused any injuries, unlike Buckyballs, which Complaint Counsel repeatedly cites as having the "same risk" as the Subject Products. (App. Br. at 64.) That argument is clearly belied by the record. Because Buckyballs advertised its products for improper uses and contained improper warnings, "the nature of the risk of injury with Buckeyballs is higher than those of Zen Magnets and Neoballs, *despite* the fact the two products are nearly identical." (ID at 18.) (Emphasis added.) Save for a scintilla of circumstantial evidence and complete hearsay, Complaint Counsel has submitted no evidence to refute Judge Metry's finding.[28] Moreover, Complaint Counsel produced no evidence that, even if, *arguendo*, the Subject Products do not comply with the Toy Standard,

[28] For a more complete discussion of the risks associated with the Subject Products, *see* Respondent's discussion of risks, *supra*.

that they thereby create a substantial risk of injury to the public, as is required under 15 U.S.C. § 2064(a)(1). As Judge Metry properly found: "the warnings, utility and proper use demonstrate why the product is not a substantial product hazard." (ID at 33.)

IV. JUDGE METRY PROPERLY QUALIFIED DR. BOYD EDWARDS AS AN EXPERT WITNESS AND ADMITTED DR. EDWARDS' TESTIMONY AND REPORT.

ISSUE RAISED AND RULED UPON

Prior to the commencement of the administrative hearing, Complaint Counsel filed a pre-hearing motion to disqualify Dr. Edwards on October 20, 2014. This motion was denied by Judge Metry in a written order dated November 26, 2104. Complaint Counsel renewed their objection to Dr. Edwards' qualification as an expert and admission of his testimony in the December hearing. (Tr. 1241:17-1253:16.)

STANDARD OF REVIEW

A judge's reliability determination[29] of an expert witness is reviewed for abuse of discretion. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 142 (1999); *General Electric Co. v. Joiner*, 522 U.S. 136, 139 (1997).

SUMMARY OF ARGUMENT

A witness is qualified as an expert based on thier knowledge, skill, experience, *or* education. Fed. R. Evid. 702; 16 C.F.R. § 1025.44. The methods employed, the data used, and the knowledge and experience of Dr. Edwards easily allows him to be an expert witness pursuant to Rule 702. Dr. Edwards' testimony is also reliable, relevant, and helpful, not only to Judge Metry, but also to this Commission, in addressing the use and utility of the Subject Products.

[29] The keystone case addressing the admissibility of *scientific* expert testimony is *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

Because Complaint Counsel has not presented any viable rationale for excluding Dr. Edwards' testimony, for the same reasons that Complaint Counsel's October 20, 2014 motion was denied by Judge Metry, this Commission should reject Complaint Counsel's request that this Commission now strike Dr. Edwards' testimony from the record.

ARGUMENT

Judge Metry did not err in qualifying Dr. Edwards as an expert. Dr. Edwards was and is eminently qualified to offer expert opinions regarding the function of the Subject Products, the general utility of Subject Products, and the potential and actual educational value of Subject Products, as Respondent established before the administrative hearing in its Response to Complaint Counsel's Motion to Exclude Dr. Edwards, and in the hearing itself. Complaint Counsel's entire argument that Dr. Edwards' testimony should be stricken from the record is premised on the fact that Dr. Edwards did not have extensive, first-hand experience using the Subjects Products in a classroom of his own. (App. Br. at 65-69.) Complaint Counsel says nothing of Dr. Edwards' other qualifications, to wit: Dr. Edwards' knowledge gained through 24 years of teaching (Tr. 1263:2-8); his knowledge of SREMs, generally (Ex. R-155); his knowledge of physics and applied physics (Ex. R-155; Ex. R-154; Ex. R-154A); his knowledge of using the Subject Products to demonstrate principles of science, nature, and mathematics (Ex. R-155 at 2-18); his detailed, scientific understanding of how the Subject Products function (*id*. at 1-2); his professional oversight of teachers (Tr. 1262:20-1263:1); his use of the Subject Products in teaching outside of a formal classroom setting (Tr. 1263:9-22); his paper regarding magnet spheres that he was then in the process of getting peer reviewed (Tr. 1264:1-12), which helped inform his opinions about using the magnets in teaching (Tr. 1264:13-20); his review of class methods and teaching

methods as the dean of a university (Tr. 1266:19-22, 1267:3-10, 1268:15-22); and his multiple awards for teaching at the university level (Tr. 1268:1-6).

Each of Complaint Counsel's reasons for why this Commission should strike the testimony of Dr. Edwards is unpersuasive. Complaint Counsel first makes the facile argument, as it did in the hearing (Tr. 1256:7-17), that because Dr. Edwards has not published any peer-reviewed papers on SREMs, he is unqualified as an expert. (App. Br. at 67.) That argument has no legal foundation, and, according to that logic, each one of Complaint Counsel's experts are similarly unqualified. It appears from Complaint Counsel's argument that, to be a qualified expert, one must meet specific, limited criteria in a field to be able to opine regarding that anything in that field. In essence, Complaint Counsel argues that an expert's experience must fill the narrowest niche possible in a given case. Such an argument is inconsistent with Fed. R. Evid. 702, which is intentionally broad: "The fields of knowledge which may be drawn upon are not limited merely to the 'scientific' and 'technical' but extend to all 'specialized' knowledge." Fed. R. Evid. 702, *Advisory Committee Notes* (2000 Amendment).

Complaint Counsel next asserts that Dr. Edwards cannot opine on teaching with the Subject Products because he does not have extensive teaching experience with the Subject Products. Again, that argument has no merit. While it is true that Dr. Edwards has never used the magnets in a traditional classroom setting, that fact has little to no bearing on the question of whether Dr. Edwards' knowledge and experience could help the Presiding Officer (or this Commission) understand the Subject Products, how they are used, and how they could be employed in an educational setting. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993) ("an expert is permitted wide latitude to offer opinions, *including those that are not based on firsthand knowledge or observation*") (emphasis added); *Deutsch v. Novartis Pharmaceuticals*

Corp., 768 F. Supp. 2d 420, 437 (E.D. N.Y. 2011) (same). Dr. Edwards is a professional educator, is an expert in his academic field, and has used the magnets extensively. (Ex. R-154A at 3; Tr. 1440:13-19.) He is also an administrator and physics professor (Ex. R-154), and Dr. Edwards has extensive knowledge of the Subject Products and how they function, not only because he has used them a great deal, but because of his background in physics and applied physics. (*See* Ex. R-155 at 1-4 (explaining his background and principles of magnetism demonstrated by Subject Products); (Ex. R-154 (showing extensive experience in the field of magnetic field theory and conducting numerous research projects on magnets.)) Based on these facts, Dr. Edwards was unquestionably qualified to be an expert in this case.

Complaint Counsel's last argument for striking Dr. Edwards' testimony is the least availing. Complaint Counsel takes issue with Dr. Edwards' opining on the potential use for Subject Products in academia because Dr. Edwards is not an expert on pedagogy, which is the method and practice of teaching. (App. Br. at 66.) Even though Dr. Edwards did not testify about the method and practice of teaching, Dr. Edwards nonetheless has experience in the matters contemplated in a pedagogical degree, and received an award based on his commitment to excellence in pedagogical practices. (Tr. 1269:4-14.) Judge Metry also correctly reasoned that neither Rule 702 nor *Daubert* requires Dr. Edwards to have a degree in pedagogy as a prerequisite to be qualified as an expert. (Tr. 1270:22-1271:2.)

The record clearly shows that Dr. Edwards had the requisite knowledge, experience, training, *and* education to discuss the utility and function of the Subject Products in teaching – which is precisely for what he was admitted as an expert. (Tr. 1273:4-6.) Moreover, the testimony was helpful to Judge Metry in assessing the utility of the Subject Products because, as Complaint Counsel's experts admitted, they all but entirely failed to consider the question of utility. (*See* Tr.

269:18-270:12; 469:15-18; 466:12-15; 469:19-470:1; Ex. CC-10A at 11.) Dr. Edwards was therefore properly admitted as an expert.

Complaint Counsel can point to nothing in the record that even suggests the testimony of Dr. Edwards is unreliable and Judge Merty erred in admitting it. In *Kumho*, the Supreme Court concluded that "a trial court *may* consider one or more of the more specific factors that *Daubert* mentioned when doing so will help determine that testimony's reliability." *Kumho*, 526 U.S. 137, 141 (1999) (emphasis by court). The Court also noted, however, that "the test of reliability is 'flexible,' and *Daubert*'s list of specific factors neither necessarily nor exclusively applies to all experts or in every case. Rather, the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id*. at 141-142 (citing *General Electric Co. v. Joiner*, 522 U.S. 136, 143 (1997)) (emphasis in original). The methods, principles, and facts employed by Dr. Edwards were more than reliable to permit him to opine on the utility and function of Subject Products. Specifically, numerous science disciplines and principles were used to show how Subject Products could be used to demonstrate such principles. (*See e.g.* Ex. R-155 at 3-5 (explaining how mathematics and physics enable Subject Products to function as manipulatives.))

Complaint Counsel further attacks Judge Metry for asking Dr. Edwards questions that were designed to aid the ALJ in making his decision. As an example of allegedly improper questioning, Complaint Counsel cites to the following question: "Is it your testimony that . . . to learn those principles that you have learned, it would be useful to have these small gobs of rare-earth magnets available for classroom use?" (App. Br. at 68; Tr. 1421:18-21.) Complaint Counsel asserts that such a question asked to Dr. Edwards ventures "well beyond his qualified area of expertise." (App. Br. at 68.) Again, this argument has no merit. Dr. Edwards was expressly accepted as an expert

to opine on that exact topic: to help the Presiding Officer understand the usefulness of the magnets in teaching (Tr. 1273:5-6), which also necessarily entails how the magnets could be used in teaching, prospectively. Furthermore, even if the questions by Judge Metry were leading questions, it is the court's prerogative to ask such questions. *See e.g. U.S. v. Wheeler*, 444 F.2d 385, 390 (10th Cir. 1971) (a court may ask a leading question, especially when asked to clarify a point); *U.S. v. Scott*, 529 F.3d 1290, 1297 (10th Cir. 2008) (a court may ask leading question and interrogate a witness in a manner reasonably thought to bring out a just result); *Riley v. Goodman*, 315 F.2d 232, 234-235 (3rd Cir. 1963) (leading questions are within a court's discretion). Complaint Counsel has therefore failed to find any error in Judge Metry's lines of questioning, or in Dr. Edwards' responses.

Complaint Counsel finally takes issue with the weight Judge Metry placed on Dr. Edwards' testimony, and complain that Judge Metry "virtually ignor[ed] Complaint Counsel's experts." (App. Br. at 68.) Again, Judge Metry did not *ignore* Complaint Counsel's experts, but assessed the record as a whole and found those experts' testimony to be lacking, particularly in the area of utility. As Respondent showed in the hearing, Complaint Counsel's experts failed to consider the magnets' utility in a way that was fair, complete, reliable, and, ultimately, persuasive. (ID at 20.) For example, Dr. Frantz testified that he spent hundreds of hours for the Commission analyzing the warnings and the physical properties of the subject products (Tr. 402:17-19), yet, *he did not conduct any research on the utility or use of the magnets* apart from reading litigation materials, looking at YouTube, and visiting a website that did not even belong to Respondent. (*See* CC-10A at 11.) Judge Metry was therefore not in error to accord Dr. Frantz's testimony on the Subject Products' utility less weight than Dr. Edwards', who wrote a report on the subject *and* was admitted as an expert to opine on that very topic. Similarly, Complaint Counsel expert Dr. Steinberg: did

not consider any benefits from the use of magnets in education (Tr. 469:15-18); did not consider the benefits of the use of magnets by children and teens (Tr. 466:12-15); and was not previously aware that the Subject Products could be used in education (Tr. 469:19-470: 1). Unremarkably, then, Dr. Steinberg's testimony about the Subject Products' utility was not persuasive. Judge Metry made no error in his discussion about the magnets' utility when analyzing the various views held by the experts in this case.

This Commission should not re-entertain Complaint Counsel's renewed objection to Dr. Edwards' qualification and his expert testimony. As was established prior to and during the hearing, Dr. Edwards was amply qualified to be an expert, and Judge Metry did not abuse his discretion in admitting his testimony into the record. This Commission should not now strike that testimony from the record.

V. CONCLUSION

Complaint Counsel has not shown that, by either a preponderance of the evidence or by substantial evidence, that Respondent's Subject Products present a substantial product hazard for any of the reasons set forth in the Second Amended Complaint. Complaint Counsel has also failed to show how Judge Metry erred in making his findings of fact and law in the Initial Decision and Order.

WHEREFORE, should this Commission refuse to disqualify itself from hearing this appeal, it should adopt the Initial Decision and Order as a Final Decision and Order pursuant to 16 C.F.R. § 1025.52.

DATED THIS 13th day of June, 2016

Respectfully submitted,

David Japha

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on the 13th day of June, 2016, I served copies of THE RESPONDENT'S ANSWER BRIEF by the service method indicated:

Original and five copies by U.S. mail, and one copy by electronic mail, to the Secretary of the U.S. Consumer Product Safety Commission:
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One copy by electronic mail (by agreement) and one mailed copy to Complaint Counsel:
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