Standard of Review and Burden of Proof

Respondent is in agreement with Complaint Counsel that the Commission can set aside Judge Metry's decision, but that the Commission must base its review *on the record and facts as adduced in the hearing*.

This Commission should clarify what the appropriate burden of proof is for administrative adjudications conducted pursuant to the Consumer Product Safety Act and this Commission's rules.

"The Initial Decision shall be based upon a consideration of the entire record and shall be supported by reliable, probative, and substantial evidence." 16 C.F.R. § 1025.51(b).

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.

The Subject Products are not defective.

The Subject Products are only hazardous if they are misused, unlike other products that can cause injury in their normal and intended use, such as ATVs, worm probes, and kites with metallic coatings.

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. (Contrast Section 1115.4 with 1115.12.)

Utility

- "The Agency admits SREMs have utility." (Initial Decision ("ID") at 20; *see also* Complaint Counsel's Closing Br. at 12.)
- "Dr. Paul Frantz[] did not fairly assess the products. . . ." (ID at 20.)
- "Dr. Frantz did not thoroughly evaluate SREMs. . . ." (*Id.*)
- "Dr. Steinberg similarly performed an incomplete review of the subject products. . . ." (Initial Decision (*Id.*)

> The statements made by Respondent's witnesses 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. As such, these statements were appropriately given more weight by Judge Metry.

Utility

"Complaint Counsel's evidence demonstrated, however, that the Subject Products have only marginal utility and do not present the unique qualities Zen contends. Appeal Br. at 39-40." Reply Br. at 10.

At no point in Complaint Counsel's Appeal Brief at 39-40 does Complaint Counsel cite *any* evidence admitted into the record in this case to rebut Zen's evidence of the magnets' utility. Instead, Complaint Counsel cites to material not in the record and merely criticizes Judge Metry for giving credence to and accepting the veracity of the testimony of Zen's witnesses.

Unique Tools and Artistic Mediums

Q: Are Zen Magnets and Neoballs superior to the traditional method that you learned prior to learning about these magnets in teaching those same principles?

A: Yes, not in teaching the entirety of physics, chemistry, geology, mathematics, but in teaching certain principles in those fields that are outlined in my report, I would say yes.

(Testimony of Dr. Edwards, Tr. 1431:12-1432:5)

The Subject Products help:

- Teach Euclidean geometry
- Students to appreciate Lattices
- Demonstrate principles of magnetism
- Teach about angle strain, lattice defects, platonic solids, slip mechanisms, and demonstrations that require dynamism.

"Regarding the use of Zen Magnets, my four sons engaged in self-directed investigations with magnet spheres. Those investigations and uses have fueled my four sons' interest[s] in careers in math and science." (Ex. L)

"I use magnet spheres in my research in computational meshes, constructing lower-dimensional meshes our of magnet spheres and using these to help mem visualize higher-dimensional meshes, including meshes with dimensionalities greater than three. ¶ These help me choose computational cell geometries and to study various tesselations [sic] of Euclidean space." (Ex. R)

https://www.youtube.com/watch?v=wOv0AkphLhE

R-139

Respondent did not design, manufacture, or market SREMs as a plaything for children under 14 years of age.

Dr. Frantz's Testimony

"It's from my perspective that it is, in fact, a toy. From the – the labeling is what makes it a toy per ASTM 963. That's the problem I'm having." (250:4-7.)

"Can you make it not a toy for children, yes, you can. You can do any number of things, but you have to start with getting rid of that insert. The insert is what makes it technically misbranded, if you will, for lack of a better term." (336:11-16.)

"You can change the packaging. I get that. And then you can move it away from being a children's toy. I totally get that." (329:3-5.)

Dr. Frantz Continued:

JUDGE METRY: Okay. In its most basic form, your testimony is that based upon the written material, including the material on the packaging and on the Web site and in the packaging, you believe those warnings describe the product, either intentionally or unintentionally, as a toy? Is that what I heard your testimony in its most basic form?

DR. FRANTZ: Yes. It means that it's subject to a children's toy standard, which is ASTM F963. ***That's what the packaging inside this means.***

(Tr. 333:15-334:2, cited by Complaint Counsel in its Reply Brief at 20 n. 16 (emphasis added).)

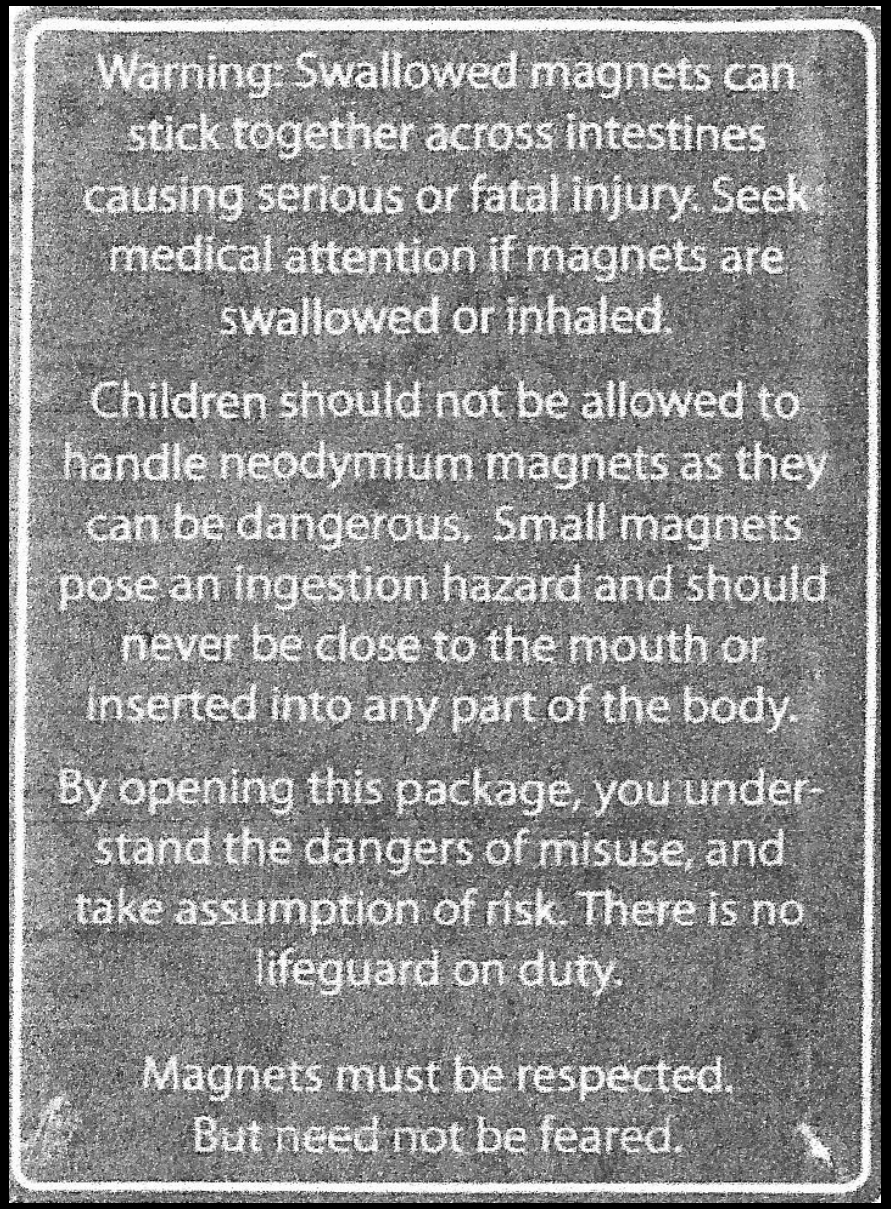
https://www.youtube.com/watch?v=Y_LPhHbMN4U

R-139

The warnings were not inadequate.

"[T]he Agency 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.)

"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.)



R-192

[T]he risk of injury associated with SREMs does not derive from the severability of the magnets, but emanates from ingestion . . . The cause of any risk of injury is from ingestion, an issue roundly, repeatedly, and expressly addressed by Respondent's warnings." (ID at 14-15.)

16 C.F.R. Section 1115.4 requires there to be a fault flaw, or irregularity with the warnings.

"Here, the lack of warnings on each individual SREM does not result from a fault, flaw, or irregularity, but as a matter of practicality and possibility." (ID at 15.)

From the Cross-Examination of Dr. Frantz:

Q You've assisted in writing warnings for ATVs; correct?

A Yes.

Q So can I be assured that you think they're adequate?

A The ones that I know about, I think, reasonably address concerns associated with the product, and I think that they are adequate.

Q Okay. And regardless of that, people still die and have died while using ATVs; correct?

A Yes.

(303:14-304:5)

Testimony of Shihan Qu

“[T]here has been some confusion about my assumptions of where the confusion comes from. I have mentioned that there is some confusion to me regarding the regulations, that's not because of the overlap between the Child Product Safety Act and ASTM in my understanding.” (Tr. 1952:13-18.)

“Previously when you asked me if a child could use magnets safely, my answers were going to be yes, It wasn't about definition of children. So my understanding is that ASTM, from ASTM I gathered that the regulation states for children eight and up, that they can safely read and understand and follow warnings for science, crafts and hobby items. Then I find that to be consistent with other documents from the CPSC, because, for example, under the children's products documents it refers to children who are nine and up being able to use complex manipulatives. . . .” (Tr. 1953:1-12.)

ASTM F963-11 § 5.2

"Toys that are subject to any of the requirements of this specification should be labeled to indicate the minimum age for intended use or have such labeling on any retail packaging. If the toy or toy package is not age labeled in a clear and conspicuous manner or, based on such factors as marketing practices and the customary patterns of usage of the toy by children, is inappropriately age labeled, the toy shall be subjected to the most stringent applicable requirements within this specification."

ASTM F963-11 § 5.17

"*Magnets*—The packaging and instructions of hobby and craft items and science kit-type items for children over 8 years of age which contain a loose as-received hazardous magnet or a loose as-received hazardous magnetic component shall carry safety labeling in accordance with 5.3. The labeling shall consist of the signal word "WARNING" and contain, at a minimum, the following text or equivalent text which clearly conveys the same warning: "*This product contains (a) small magnet(s). Swallowed magnets can stick together across intestines causing serious infections and death. Seek immediate medical attention if magnet(s) are swallowed or inhaled.*"

The Nature of the Risk of Injury

"[T]he 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 and appropriate age restrictions." (ID at 19.)

"There 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.)

"The projection showed that, from 2009 to 2013, an estimated 2,900 SREM nationwide ingestion incidents were treated in hospital ERs." "These numbers are insignificant to show any specific, identifiable population, particularly given the mass amount of magnets purchased and already on the market." (ID at 23.)

The Nature of the Risk of Injury

- "Upon review of the record, the ALJ finds the separation of SREMs does not create a risk of injury occurring as a result of "**the operation or use** of the product." The Agency presented absolutely no evidence that separation, alone, creates any threat to any individual and that consumer has ever been harmed by an un-ingested, liberated SREM. Therefore, the evidence is conclusive; an *un-ingested* SREM is harmless to the U.S. consumer." (ID at 7-8.) (Emphasis in original.)

- "The record supports a finding 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.)

Findings of Fact and Law

- The Agency has submitted no credible evidence that Zen Magnets have caused any injuries.
- Zen Magnets are not intended for use by children, and were not designed, marketed, or manufactured for children under the age of 14.
- Only ingestion can lead to potential injuries.
- Complaint Counsel has not shown how the warnings are defective.
- Zen Magnets are unique and have tremendous utility.
- The NEISS estimates were shown to be unreliable and uncertain, and the injury report narratives were imprecise.

Dr. Edwards was properly admitted as an expert witness in this case.

- Judicial notice of the Federal Rules of Evidence were taken in an order issued on July 30, 2014.
- The plain language of the rule, as well as the case law construing and governing Fed. R. Evid. 702, makes clear that Dr. Edwards was properly admitted as an expert in this case.

- Teacher for 24 years
- Knowledge of SREMs
- Knowledge of physics and applied physics
- Knowledge of using the Subject Products to demonstrate principles of science, nature, and mathematics
- Detailed, scientific understanding of how the Subject Products function
- Professional oversight of teachers
- Use of Subject Products in teaching outside of a formal classroom setting
- Publication of his paper on magnet spheres
- Professional review of class methods and teaching methods as the dean of a university
- Multiple award-winner for teaching at the university level

"Nothing in the Commission's rules or the Federal Rules of Evidence requires an expert to conduct 'independent research' rather than drawing scientifically valid conclusions based on knowledge, experience, and a review of the evidence in the record."

Complaint Counsel's Reply Brief at 7.

Exhibits to which the Commission should pay particular attention:

- R-1 through R-1D, R-192, R-193, CC-5, CC-5(2) (the physical magnet sets and inserts that provide clear warnings about the ingestion hazard)
- R-55 (Zen Magnets insert guide)
- R-155 (Dr. Edwards' expert report, cited in Respondent's Br. at 24, 28, 37, 45, 48, 50, 51, explaining, *inter alia*, that the magnets are both of high utility and are unique: "magnets that comply with [ASTM F963-11] would fail to fill the educational niche occupied by Zen Magnets.")
- R-70A (Dr. Edwards' Report, Appendix E, statements regarding educational utility of the magnets)
- R-70 (cited in Respondent's Br. at 10, 13, 31, a list of 719 YouTube videos showing the documented use of magnet spheres, generally)
- R-155, R-2, R-47, R-49, R-54 (cited in Respondent's Br. at 45, showcasing the science, hobby, and craft uses of the magnets)

Exhibits to which the Commission should pay particular attention:

- R-195, R-196 (cited in Respondent's Br. at 45, examples from the Zen Gallery)
- R-155 Appendix A (a guide to building shapes with Zen Magnets)
- R-197, R-198 (cited in Respondent's Br. at 13, dispensary and Hobby Town sales contracts, respectively, showing how Zen undertook sales and marketing strategies to keep its products away from children)
- R-111 and R-117A (compiled by Shihan Qu, showing the Commission's estimates based on the NEISS were unreliable, as well as the fallacy of the Commission's use of the NEISS data as an epidemiological tool in this particular case)

Sur-Reply

- Zen Magnets was not required to present "expert testimony" to rebut the unreliable, non-probative, and biased testimony of the Commission.
- Commission regulations do not contemplate a finding of defect *solely* on the basis that a product can be dangerous if it is misused. 16 C.F.R. § 1115.4(d): "(d) A power tool is not accompanied by adequate instructions and safety warnings. Reasonably foreseeable consumer use or misuse, based in part on the lack of adequate instructions and safety warnings, could result in injury. Although there are no reports of injury, the product contains a defect *because of* the inadequate warnings and instructions." (Emphasis added.)
- Zen has never said, nor does it maintain now, that the Commission should not fully consider the record in this case. (Reply Br. At 16.)
- Zen did not "attack the integrity" of Mr. Amodeo and roundly rejects Complaint Counsel's assertion of any such attack. (Reply Brief at 16.)

- Dr. Steinberg did not testify that the magnets "are obtained by children": Dr. Steinberg 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).
- Rely Brief at 6 n. 4:

  Dr. Frantz: "And so it's been my experience from that that the public places in which magnets are taken and used tends to be more broad than what my own experience is with balloons."

  Mr. Japha: "Okay. That's not -- my question. . . ."
- Simply because a product can cause an injury does not *a fortiori* mean that the product is defective.
- Complaint Counsel's experts did not test potential warnings and their efficacy, nor even all of Zen's warnings, but rather assumed that no effective warning could be created: 155:22; 368:7-14; 257:15-258:14; 240:2-10; 251:18-255:13.

"Zen continued selling many magnet sets without warnings through at least May 2012. Appeal Br. at 16-18. Zen asserts, however, that products sold after May 2010 contained proper warnings, but cites nothing in support of this contention. R.Br. at 35, 40. Because the record shows that Subject Products were sold without warnings through at least May 2012 and Zen presented no evidence to the contrary, the Commission should find that Zen waived any argument that it should not recall products sold through May 2012." (Reply Br. at 19 n. 15.)

Zen concedes that certain sets of magnets were not sold with physical insert warnings through May 16, 2012. However, as noted by Complaint Counsel, Zen Magnets were sold to consumers online with warnings in 2009. (*See* Second Amended Complaint ¶ 35.) Zen did not sell magnets in stores (*i.e.*, not online) until 2013. (Tr. 1718:1-6.) Before someone purchased magnets from Zen's website, they would see a warning discussing the ingestion hazard. (Tr. 1574:7-1582:18.) Gift sets with the initial warnings were sold in late 2010 (Tr. 2327:22-2328:3), and Zen began including more paper warning inserts in its products after May 2011, following a visit from the CPSC (Tr. 1717:3-19).

Official Notice

"[O]fficial notice [in the APA] allows an administrative agency to take notice of technical or scientific facts that are within the agency's area of expertise." *McLeod v. INS*, 802 F.2d 89, 93 n. 4 (3rd Cir. 1986) (citing *NLRB v. Seven-Up Bottling Co.*, 344 U.S. 344 (1953)).

Federal Rules of Evidence 801(d)(2) defines statements that are not hearsay. Whether a statement is not hearsay it not determinative of whether a statement or piece of evidence is relevant, probative, reliable, or not unduly prejudicial.

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).