UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

Opinion of Acting Chairman Ann Marie Buerkle
Concurring in Part and Dissenting in Part

Under the Consumer Product Safety Act (CPSA), the Commission cannot order a recall solely on the grounds that a product is dangerous. The Commission must also determine, after a hearing on the record, that the product (1) fails to comply with an applicable consumer product safety standard (or similar statutory requirement); or (2) contains a defect that gives rise to the hazard. 15 U.S.C. § 2064(a)(1), (2). In this case, the Commission originally authorized a complaint based on a defect theory (Count I). Later, the complaint was amended to add a count based on a failure to comply with the CPSC's toy standard (Count II).

In the Initial Decision, Administrative Law Judge (ALJ) Dean C. Metry distinguished three groups of the Subject Products: (1) those sold without warnings (before May 2010); (2) those sold with a suggestion that they were appropriate for age 12 and up; and (3) those sold later, with warnings and appropriate age recommendations. Judge Metry found that the Subject Products in the first two groups constitute a substantial product hazard and ordered public notice and a recall. Initial Decision at 16 n.6, 34, 36. As for the third group, he found that Complaint Counsel failed to prove the existence of a defect, either in the design of the product or in the warnings, or any noncompliance with the magnet provisions of the toy standard.

As Zen did not appeal the Initial Decision, Zen is not entitled to relief from the ALJ's recall order with respect to groups (1) and (2) of the Subject Products. I therefore concur in the majority's judgment with respect to those magnets.

With respect to the third group of magnets, I dissent. First, I do not agree with the majority that our defect regulation, 16 C.F.R. § 1115.4, recognizes a design defect that arises solely as a result of product misuse. Second, I agree with the ALJ that Complaint Counsel failed to prove that the warnings accompanying group 3 magnets were defective.

Given its resolution of Count I, the majority found it unnecessary to reach Count II "[a]s a matter of judicial economy." Majority Opinion at 42. In my view, however, the second count of the amended complaint was never properly authorized by the Commission. Therefore, there is no occasion to decide whether the Subject Products constitute a substantial product hazard under section 15(a)(1).

I. CPSC's Defect Regulation Does Not Tacitly Define "Use" to Include Misuse.

The majority excoriates the Administrative Law Judge for "the erroneous assertion that the CPSC cannot protect consumers from hazards resulting from reasonably foreseeable misuse." Majority Opinion at 10. The majority fumes that "[t]his fundamental misunderstanding by the ALJ permeates the entire Initial Decision and Order and is contrary to our regulatory guidance, legislative history, statutory authority, case law, and Commission precedent." *Id.*

As I see it, the majority ascribes to the ALJ a sweeping position he never took. Indeed, the ALJ ordered a partial recall in this case, confirming that the CPSC can protect consumers where appropriate. The majority's straw man only distracts from what is at issue in this case, namely the proper interpretation of our defect rule, 16 C.F.R. § 1115.4(d).

The Text of the Defect Rule. As the majority notes, a threshold legal issue is "whether a design defect that arises out of the 'operation or use' of a consumer product includes reasonably foreseeable misuse." Majority Opinion at 11. The majority points out that the text of the defect rule mentions consumer "misuse" in two places. *Id.* One is in an example of defective instructions or warnings. The other is in a list of factors to be considered in deciding whether a particular risk of injury is the type of risk that gives rise to a defect. In my view, these mentions of misuse elsewhere in the same regulation tend to undercut, rather than strengthen, the majority's position.

The defect rule does not mention or allude to "misuse" in the sentence that relates to "operation or use." That sentence was the basis for Complaint Counsel's second defect theory. *See* Majority Opinion at 5. The regulation states: "A design defect may also be present if the risk of injury occurs *as a result of the operation or use* of the product or the failure of the product to operate as intended." 16 C.F.R. § 1115.4 (emphasis added).

The majority evidently reads the word "use" in this sentence to encompass some types of misuse. In my view, that stretches the plain meaning too far. If the Commission intended to advise the public that a design defect may be present if a risk of injury occurs as a result of reasonably foreseeable misuse, as well as operation and use, it could have, and should have, said so expressly.[1]

The defect rule does refer to misuse elsewhere, but neither of those references interprets the sentence in question. The first mention is in Example (d), which illustrates that a defect can occur as a result of inadequate instructions or warnings. Here, the Commission refers explicitly to "reasonably foreseeable consumer use or misuse." This makes clear that the Commission expects product manufacturers to warn against reasonably foreseeable misuse. That is the essence of most warnings—they don't warn against proper use, of course, but against anticipated misuse.[2]

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[1] The express purpose of the defect rule is to assist subject firms (*i.e.*, manufacturers, retailers and distributors) in understanding the concept of "defect" as used in the Consumer Product Safety Act (CPSA). The rule declares that "a subject firm may be guided by the criteria the Commission and staff use in determining whether a defect exists." 16 C.F.R. § 1115.4.

[2] The power tool example hinges on the fact that injury could result from "[r]easonably foreseeable consumer use or misuse, based *in part* on the lack of adequate instructions and safety warning . . .." 16 C.F.R. § 1115.4 (emphasis

The second reference to misuse is in the last paragraph of the defect rule. This paragraph explains why some products may not be defective even if they present a risk of injury. Specifically, the rule confirms that there is no defect if "the risk of injury is outweighed by the usefulness of the product which is made possible by the same aspect which presents the risk of injury . . .." 16 C.F.R. § 1115.4. In this context, the rule lists a number of factors that the Commission and staff will consider, as appropriate, in determining whether the risk of injury associated with a product is the type of risk which will render the product defective. Among the factors that may be considered is "the role of consumer misuse of the product and the foreseeability of such misuse." *Id.*

This reference makes clear that consumer misuse may be a consideration in balancing the injury risk of a product against its utility. *See* p. 7, infra. But this reference does not address the "use or operation" sentence being interpreted by the majority in this case. As with Example (d), it only underscores the point that the Commission did not hesitate, in promulgating the defect rule, to address consumer misuse explicitly when it might potentially play a role in the analysis. The fact that the rule explicitly refers to "misuse" in these other locations only strengthens the view that it should not be transplanted into the sentence about design defects based on operation or use.[3]

Legislative History. In support of its reading of the defect rule, the majority next turns to the legislative history of the Consumer Product Safety Act. It points out that in the Senate version of the legislation, the term "use" was actually defined to include not only "normal use" but also "reasonably foreseeable misuse." Majority Opinion at 12-13 (citing 92 S. 3419-4A and S. Rep. No. 92-749, at 15). As the majority concedes, however, this version of the legislation was not enacted, and the CPSA as passed does not include any such definition of the word "use." Majority Opinion at 13. In my view, the fact that Congress considered and rejected such a definition tends to cut against the majority's position here, rather than support it.[4]

Other Statutes. Next the majority discusses other statutes administered by the Commission. The majority observes: "These statutes recognize explicitly the important and significant role that reasonably foreseeable consumer misuse of products presents in executing the Commission's mission to protect the public, particularly children, from unreasonable risks of injury, including risks arising from ingesting part or all of a consumer product." Majority Opinion at 13.

I don't dispute that the concept of reasonably foreseeable misuse plays an important role in several of the laws that CPSC administers. Perhaps most significantly, the Federal Hazardous Substances Act (FHSA) defines the term "hazardous substance" to include various types of

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added). Under these circumstances, the rule says, the product "contains a defect because of the inadequate warnings and instructions." Id. Significantly, the rule does not indicate that the product is also defective in design due to the fact that injury could result from reasonably foreseeable misuse of the product.

[3] The reference to misuse as a factor in weighing risk versus utility was added to the defect rule in July 2006. See 71 Fed. Reg. 42028 (July 25, 2006). If that amendment had been intended to alter the meaning of the "use or operation" sentence, one would expect the preamble accompanying the amendment to address the point. In reality, there is no hint of such intent in the preamble. Id.

[4] The majority's argument also proves too much: if the word "use" were understood to encompass "misuse," there would be no need for the latter word to appear in the defect rule where it does.

substances or mixtures if they "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including *reasonably foreseeable ingestion by children*." 15 U.S.C. § 1261(f)(1)(A)(emphasis added). Significantly, the FHSA also has its own recall provision, which was not relied upon here. 15 U.S.C. § 1274.

By contrast, the "operation and use" sentence of the defect rule makes no reference whatsoever to consumer misuse, much less reasonably foreseeable ingestion by children. It makes no sense to argue that explicit references to consumer misuse in other statutes should transform the ordinary meaning of a sentence in the defect rule that does not mention consumer misuse, but only use.

Case law. The majority next points to case law as upholding the CPSC's authority to address reasonably foreseeable consumer misuse of consumer products that present a risk of injury under the CPSA. Majority Opinion at 13-14. Its first citation is to *Southland Mower Co. v. CPSC*, 619 F.2d 499, 513 (5th Cir. 1980). That case involved the Commission's mandatory standard for lawn mowers. One petitioner in that case argued that the Commission lacked authority to adopt a particular requirement of the standard because the risk of injury it was addressing resulted from consumer misuse (removing safety shields). 619 F.2d at 513.

In my view, *Southland Mower* has no application here. In the first place, as noted earlier, the ALJ never claimed that the Consumer Product Safety Act precludes the Commission from addressing injuries that arise in part from consumer misuse. As *Southland Mower* shows, for example, the Commission has clear authority to address such problems through the adoption of consumer product safety standards. Indeed, after the complaint in this case was filed, the Commission promulgated a safety standard to address the risk of ingestion of small, powerful magnets. Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. 59962 (Oct. 3, 2014). That standard was vacated by the U.S. Court of Appeals for the Tenth Circuit after the ALJ had issued the Initial Decision in this matter. *Zen Magnets, LLC v. Consumer Prod. Safety Comm'n*, 841 F.3d 1141 (10th Cir. 2016); *see also* Safety Standard for Magnet Sets; Removal of Final Rule Vacated by Court, 82 Fed. Reg. 12716 (March 7, 2017). But the Tenth Circuit never suggested that the Commission lacks authority to regulate such a risk, only that its factual findings were incomplete and inadequately explained. 841 F.3d at 1144.

The majority also cites two administrative (CPSC) decisions in support of its position. These are *In re Dye*, 1989 WL 435534 [hereinafter cited as "Worm Probes"], and *In the Matter of Francis Alonso, Jr., d/b/a/ Mylar Star Kites*, Initial Decision and Order (June 18, 1976), aff'd in part and set aside in part, Final Decision and Order (Sept. 16, 1977) [hereinafter cited as "Mylar Kites"].

The Administrative Law Judge carefully reviewed each of these decisions and concluded that neither supports Complaint Counsel's position. Initial Decision at 9-11. I agree. Both products involved electrocution hazards that could occur even when the product was being used as expected. The product at issue in *Worm Probes* consisted of two to twelve uninsulated rods, designed to conduct electricity into the ground and so drive earthworms to the surface. The lack of insulation exposed consumers to a risk of death by electrocution, and contact with the energized rods or earth could occur by accident or negligence. Likewise, the product in *Mylar Kites* created a risk of death by electrocution as a result of ordinary use—flying the kite.

As Judge Metry recognized, the possibility of electrocution from an accident, such as slipping and falling on or near the charged electric probes, or getting a kite tangled in an overhead electric wire, does not transform the expected use of the product into a misuse. *Id.* at 9. These are problems that may be difficult or impossible to avoid despite proper use (or warnings). Here, by contrast, proper use of the Subject Products "creates no exposure to danger whatsoever." *Id.* at 10.

In sum, I do not maintain that the Commission is powerless to deal with "reasonably foreseeable misuse" of a consumer product. Rather, I believe that in a rule intended to guide the public, the Commission should say what it means. By the same token, I see no basis for interpreting the words "operation and use" as applying equally to misuse, foreseeable or otherwise. The fact that other portions of the same rule expressly address product misuse only reinforces my conclusion that the "operation and use" sentence was not intended to do so tacitly.

II. Complaint Counsel Failed to Prove that Respondent's Warnings Are Defective.

While the Subject Products pose no risk of injury as a result of operation and use, they pose a serious risk of injury if more than one is swallowed. This is a hazard that consumers should certainly be warned about.

The ALJ ordered a recall of the earliest-sold Subject Products, which were distributed without warnings. The Subject Products sold later, however, were accompanied by warnings. As to this latter group, the ALJ found that Complaint Counsel failed to prove that Zen's warnings were defective. With respect to the warning content, Judge Metry found that the ingestion risk was "roundly, repeatedly and expressly addressed by the Respondent's warnings." Initial Decision at 15. He also rejected Complaint Counsel's argument that the warnings were defective because they did not accompany each individual magnet. *Id.* Finally, the ALJ found that Complaint Counsel "did not present any credible evidence linking any injury to Respondent's product." *Id.* at 16. In the ALJ's view, it was "more than a reasonable inference" that the reason there is so little evidence of injury from the use of Respondent's product (as opposed to other brands of small, powerful magnets) is that "Respondent's warnings sufficiently deter ingestion." *Id.*

The majority claims that the ALJ "completely ignored evidence demonstrating the fact that the risk of injury occurs when magnets are separated from their set, so that even the best warning is unlikely to be seen by the user." Majority Opinion at 31. The majority goes on to say that "*regardless of the warning content*, Respondent's warnings are defective because warnings that are never seen, cannot be read, or are not understood or heeded, cannot mitigate the risk of injury associated with [the magnets]." *Id.* (emphasis added).

I cannot agree that Judge Metry ignored the evidence on this point. He fully understood that the magnets could get separated, but he also recognized that it would be impractical, if not impossible, to inscribe a warning on each individual magnet, given their size (approximately 5 millimeters in diameter). Initial Decision at 15. He also noted that even if someone could manage to make warnings that would travel with each magnet, "no consumer could possibly be informed by such a warning, because it would be simply too small to see . . .." *Id.*

I also take issue with the majority's conclusion that warnings are automatically defective if they don't accompany each individual magnet. With respect to the third group of Subject Products, at least, the original purchaser would have seen appropriate warnings before any magnets could have been separated from the pack. This purchaser was intended and expected to be an adult or older teenager who can read the warnings and is capable of understanding the ingestion risk.

CPSC has many regulations that require warning labels, on the assumption that they will be read and heeded by the purchaser. For example, our regulations generally ban any toy intended for children under 3 years of age if it presents a choking, aspiration or ingestion hazard because of "small parts" as defined. 16 C.F.R. § 1500.18(a)(9); *see also* 16 C.F.R. § 1501.2. If a product containing "small parts" is intended for children ages 3 to 6, on the other hand, it must bear a warning label on the packaging stating that it contains small parts and is not intended for children under 3. 16 C.F.R. § 1500.19(b). Similar warnings are required for small balls, balloons and marbles.

Small parts pose every bit as serious a risk of injury as small magnets. Every year, a substantial number of deaths occur when young children swallow or aspirate small parts. Yet the Commission does not ban all toys or other articles with small parts. It has banned such items only if they are intended for children under 3, whereas it requires warnings if they are intended for children from 3 to 6. No warning at all is required if the product is intended for teenagers or adults.

Nor do the small parts regulations require any warning on individual small items after they are unpackaged. For example, the packaging of a game that is intended for children ages 3 to 8 must display a specific warning label if it contains marbles. 16 C.F.R. § 1500.19(b)(4)(ii). There is no requirement, however, to label individual marbles inside the game, even though it is reasonably foreseeable that a marble might eventually be separated from the game.

These Commission rules count on original purchasers, primarily adults, to pay attention to the warnings and to help protect children from being exposed to the hazard. Unfortunately, they don't always do so, but that doesn't mean that the warnings are inadequate.

In my view, similar considerations should guide our judgment here. We should expect that the Subject Products are accompanied by clear warnings to the purchaser as to the appropriate ages and as to the ingestion risk. We should expect that the purchasers will heed the warnings, just as we expect them to do in the case of small parts.[5]

I also agree with the ALJ that the dearth of evidence linking injuries to the Subject Products suggests that Respondent's warnings were working. The ALJ highlighted some of the problems with other brands' warnings and contrasted them with Respondents'. On this basis, the ALJ found it unsurprising that few of the injury incidents could be traced to Respondent.

[5] I note that Zen Magnets recently petitioned the Commission to establish a mandatory safety standard for high-powered magnet sets that includes both warning and performance requirements. The Commission is seeking public comments on the petition. Petition Requesting Rulemaking on Magnet Sets, 82 Fed. Reg. 46470 (Oct. 6, 2017).

The majority protests that there were "two incidents where we know specifically that the Subject Products were associated with serious injuries." Majority Opinion at 23. In one of these, a mother testified (by stipulation) that her 14-year old daughter obtained six Zen magnets from a friend and accidentally swallowed two. She needed invasive surgery as a result. The ALJ recognized this injury but discounted the traceability of these magnets to Respondent as "little more than hearsay." Initial Decision at 16 n.5.[6]

The other incident involved a 15-month old girl who evidently swallowed a button battery as well as some Zen magnets. As Complaint Counsel recognized, however, the magnets leading to this injury were purchased during the time that Zen distributed its products without any warnings. Appeal Brief at 38. The ALJ determined that the Subject Products in this category should be recalled, and I concur. Nevertheless, this incident sheds no light on the adequacy of the warnings that accompanied the Subject Products in later years.[7]

In sum, I agree with the ALJ that Complaint Counsel failed to prove that Respondent's warnings accompanying the later-sold Subject Products were inadequate.[8]

III. The Utility of Zen Magnets Weighs Against a Defect Finding.

For one of its three defect theories, Complaint Counsel relies on the last paragraph of the Commission's defect rule, which recognizes that some products may not be defective even if they present a risk of injury. The classic example is a sharp knife. Although the knife presents a risk of injury, it is not defective under our law because the same feature that makes it potentially dangerous is the one that makes it useful.

The majority finds that the factors listed in the last paragraph of the defect rule "do not present a separate basis for a defect finding." Majority Opinion at 8, n.6. I agree. The last paragraph of the defect rule was never intended to supply an independent basis for finding a defect. Instead, it serves as a basis for absolving certain products that might otherwise appear to be defective. Apart from that situation, there is no occasion to consider these other factors.

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[6] Complaint Counsel and the majority both overreact to this comment. Judge Metry did not say that the statement was inadmissible as hearsay. Complaint Counsel argues that the statement was, by virtue of the stipulation, "entitled to the same weight as if she presented live testimony," Appeal Brief at 36. Nevertheless, the trier of fact is certainly not obliged to give the same weight to all evidence introduced at trial. Judge Metry obviously didn't find the statement very credible as proof that the injury was caused by Subject Products.

[7] The majority contends that it is often not possible to know which brand of magnets was involved in a particular injury incident because the Subject Products are "functionally identical" to other small, rare earth magnet brands. Majority Opinion at 23. I question this conclusion for two reasons. First, it is my understanding that Neoballs (one of the Subject Products) come in different colors, while Zen magnets (another of the Subject Products) and Buckyballs are all silver in color. This should be a readily observable and memorable difference. Second, it is my understanding that the Zen magnets are much more uniform in size than Neoballs and other popular brands and that this was a selling point. Cf. Majority Opinion at 1 (acknowledging less variation in size for Zen magnets than Neoballs). While these size differences may not be apparent to the naked eye, they might well allow experts to distinguish these brands in many instances.

[8] The majority chides Respondent for the use of "unconventional, tongue-in-cheek, warnings" that were not likely to convey the seriousness of the injuries associated with small rare earth magnets. Majority Opinion at 33. I note, however, that CPSC's own Office of Communications often employs similar unconventional approaches, particularly when it is trying to reach a younger demographic.

In Parts I and II of this opinion, I have concluded that the Subject Products falling into the third group—those accompanied by appropriate age recommendations and warnings against reasonably foreseeable misuse—are not defective. Accordingly, under my analysis, there is no reason to consider whether the factors listed in the last paragraph of the defect rule would weigh against a defect finding. Nevertheless, I touch on a few points of disagreement with the majority.

First, the majority asserts that "[q]uantitative risk analysis—meaning the number of injuries compared to the number of products sold—is not required to prove a defect in a section 15 case." Majority Opinion at 28. I agree that such an analysis is not strictly required, although I believe it would be informative in many cases, including this one. A better assessment of the true injury potential would permit a less subjective balancing of risk and utility than the majority conducts here.

Second, I believe the majority gives undue weight to the factor of "necessity." In this regard, the majority discusses the testimony of respondent's witness, Dr. Edwards, commenting that "for more than 20 years, Dr. Edwards managed to teach physics, and his students managed to learn various concepts, without the use of [small rare earth magnets]." Majority Opinion at 36. By that standard, there are many features of the modern classroom that would not qualify as a "necessity." Twenty years ago, the internet was practically still in its infancy. Physics used to be taught without calculators, too, but few would argue that we should go back to slide rules or counting on our fingers.[9]

Third, I agree with the ALJ that the Subject Products have high utility. The majority admits that there is record evidence showing that academic users who have experience with small rare earth magnets find them useful as teaching devices, but it discounts that finding on the grounds that "the record does not demonstrate widespread use of the Subject Products by academic users or a trend of increased use in academic settings." Majority Opinion at 38. Given that the Commission's 2014 regulation had outlawed magnet sets for the last several years, it is hardly surprising that there is not yet widespread use among academics or any strong trend towards increased usage.

Finally, I note that the majority recognizes two different user groups for purposes of its risk-utility analysis: recreational users and academic users. *Id.* While it acknowledges that the utility may be greater for the academic users, it seems to consider the injury risk as the same for both groups. I doubt that. I do not think there is the same risk of exposure from magnets that are used in a physics lab as there might be in a home with young children. Perhaps a more open-minded analysis might have led the majority to consider the possibility of a more limited recall.

IV. Count Two Was Never Authorized by the Commission.

Having decided that all of the Subject Products present a substantial product hazard under section 15(a)(2), *i.e.*, Count I, the majority found it unnecessary to reach the issue as to whether the same products also present a substantial product hazard under section 15(a)(1), *i.e.*, Count II.

[9] This tendency to undervalue the utility of Respondent's magnets was one of the key factors that caused the Tenth Circuit to vacate the magnet rule.

Majority Opinion at 42. As explained below, Count II was never authorized by the Commission. Therefore, I find it not only unnecessary, but improper, to decide Count II.

Under CPSC rules, "any adjudicative proceedings . . . shall be commenced by the issuance of a complaint *authorized by the Commission* . . .." 16 C.F.R. § 1025.11(a) (emphasis added). The rules prescribe the form and content of such a complaint. Of primary significance here, it must include a "clear and concise *statement of the charges*, sufficient to inform each respondent with reasonable definiteness of the factual basis or bases of the allegations of violation or hazard." *Id*. § 1025.11(b)(3)(emphasis added).

The rules permit the Presiding Officer (*i.e.*, the ALJ) in an adjudicative proceeding to approve an amended complaint, but only if the amendment "do[es] not unduly broaden the issues in the proceedings or cause undue delay." *Id.* § 1025.13. Plainly, this provision was never intended to allow an expansion of the case beyond what the Commission has authorized. Adding a new count, based on a different theory, would fall outside the scope of the original complaint approved by the Commission. For the staff to seek such an amendment without Commission approval would usurp the prerogative of the Commission under § 1025.11(a).

This understanding of the rule was emphasized in the preamble that accompanied it. Commenters on the proposed rule had expressed concern that allowing the Presiding Officer to approve certain amendments could "alter the charges originally authorized by the Commission, thereby usurping the Commission's function . . .." Rules of Practice for Adjudicative Proceedings, 45 Fed. Reg. 29206, 29207 (col. 3) (May 1, 1980). In response, the Commission observed: "[S]ince § 1025.11(a) provides that only a complaint authorized by the Commission may be issued, amendments to the complaint *must come within the scope* of the Commission's authorization." *Id.* at 29208 (col. 1).

In this case, the original complaint, duly authorized by the Commission, was based exclusively on 15 U.S.C. § 2064(a)(2). There was no count alleging noncompliance with the toy standard. On or about September 20, 2012, Complaint Counsel filed a motion seeking leave to file an amended complaint. As explained in the motion, the proposed amendment revised the original complaint by "adding a count alleging that the Subject Product presents a substantial product hazard under Section 15(a)(1) of the CPSA, 15 U.S.C. § 2064(a)(1), because it fails to comply with an applicable consumer product safety rule . . .." Motion for Leave to File an Amended Complaint, at 1. A week later, Complaint Counsel filed a supplemental motion attaching the same amended complaint plus a separate list and summary of documentary evidence.

Although it added a new count with a substantially different theory of the case, this amended complaint was never authorized by the Commission. On the signature page, however, the amended complaint states "ISSUED BY ORDER OF THE COMMISSION." This makes it look like the amendment was authorized by the Commission even though it was not.

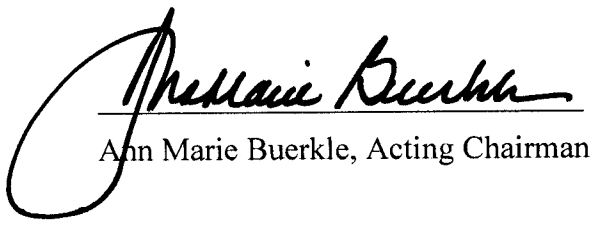
On October 10, 2012, Respondent filed a "Notice of No Objection to Complaint Counsel's Motion for Leave to File Amended Complaint." The notice states that Counsel for Respondent had read the motion and Amended Complaint and "cannot in good faith interpose any legal objection to Complaint Counsel's Motion." Respondent therefore left it up to the

ALJ's discretion whether to grant or deny the motion. Soon thereafter, on October 15, 2012, the ALJ granted the unopposed motion.

If Respondent had understood that the amended complaint was not authorized by the Commission, it would have been entirely appropriate to interpose a legal objection to its filing. Indeed, even though Respondent did not object to its filing, and even though the ALJ allowed the amendment, I believe that the noncompliance count is a nullity, having never been duly authorized by the Commission. Accordingly, I do not reach Count II on appeal, albeit for different reasons than the majority.

CONCLUSION

For the foregoing reasons, I would limit the recall in this case to the first and second groups of Subject Products, as did the ALJ. As for the majority's decision expanding the recall to the later-sold products and its injunction against further sales of the Subject Products, I dissent.



Ann Marie Buerkle, Acting Chairman

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

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

FINAL DECISION AND ORDER

This Final Decision and Order resolves Complaint Counsel's appeal of the Initial Decision and Order of Administrative Law Judge Dean C. Metry (the "ALJ") granting in part, and denying in part, Complaint Counsel's request for relief against Zen Magnets, LLC ("Respondent") under Sections 15(c) and (d) of the Consumer Product Safety Act ("CPSA"), 15 U.S.C. §§ 2064(c) and (d). Complaint Counsel seeks to have Zen Magnets and Neoballs, small rare-earth magnets imported and distributed by Respondent, declared a substantial product hazard and to obtain an order for public notice and a recall.

For the reasons set forth below, the U.S. Consumer Product Safety Commission ("CPSC" or "the Commission") hereby sets aside the Initial Decision and Order because it is based on numerous errors in fact and law. The Commission finds that Complaint Counsel proved by a preponderance of the evidence that the Subject Products present a substantial product hazard and are, therefore, subject to public notification under Section 15(c) of the CPSA, 15 U.S.C. § 2064(c), and recall measures available pursuant to Section 15(d) of the CPSA, 15 U.S.C. § 2064(d).[1]

I. Background

A. The Product

Small rare-earth magnet sets ("SREMs") have been sold in the United States by several distributors under a number of brand names. Respondent began distributing two brands of SREMs, Zen Magnets and Neoballs, in 2009 and 2011, respectively (the "Subject Products"). Compl. Counsel's Post Hr'g Argument [filed Mar. 16, 2013 as Docket Entry ("DE") 139] ("CC Post Hr'g Arg."), Ex. A, ¶¶ 23, 72. The Subject Products are strong magnets that are small, spherical, shiny, reflective, smooth, loose, and separable. *Id.*, Ex. A, ¶¶ 11-17, 60-65, 71; Direct Expert Testimony of Vincent Amodeo ("Ex. CC-1A") at 4-6; Exs. CC-4; CC-4A; CC-5; CC-5(2); CC-5A; CC-7 at 2, 5; Direct Expert Testimony of Dr. Laurence Steinberg ("Ex. CC-19A") at 4; Tr. 343:7-9. Zen Magnets are approximately 5.00 $^{+}$/- 0.01 mm in diameter. CC Post Hr'g Arg., Ex. A, ¶ 14. Neoballs are approximately 4.98 mm to 5.11 mm in diameter. *Id.*, Ex. A, ¶ 63.

[1] The Commission voted (3-1) to issue the Final Decision and Order. Commissioners Adler, Kaye, and Robinson voted to issue the Final Decision and Order. Acting Chairman Buerkle voted to take other action – concurring in part and dissenting in part in accordance with an attached opinion.

Respondent sold the Subject Products as aggregated loose magnets in sets or as individual magnets. *Id.*, Ex. A, ¶¶ 12, 13, 35, 37, 39, 41, 61, 62, 81. Zen Magnets were available in various-sized containers holding 72, 216, or 1,728 magnets, at prices ranging from approximately $12.65 for the 72-piece set, $32.98 to $38.24 for the 216-piece set, and up to $263.85 for the 1,728-piece set. *Id*., Ex. A, ¶¶ 36, 38, 40; Tr. 1468:2-5. Zen Magnets also could be purchased individually for 20 cents per magnet. CC Post Hr'g Arg., Ex. A, ¶ 42. Individual Neoballs could be purchased at prices ranging from 6 cents to 10 cents per magnet. *Id.*, Ex. A, ¶ 85.

The Subject Products, like other SREMs, are strongly magnetic. Magnet strength is measured by "flux index" that is proportional to a magnet's "strength or attraction force" and "can be used to compare relative strengths between magnets." Ex. CC-1A at 3. The Subject Products have a flux index greater than 50kg^2mm^2, which is the maximum strength allowed for accessible magnets in toys, due to the possible hazard if they are stronger and are swallowed. CC Post Hr'g Arg., Ex. A, ¶¶ 15, 64; ASTM International Standard F963-11, *Standard Consumer Safety Specification for Toy Safety*, §§ 3.1.37, 4.38, A8.4.1. This high flux index allows users to create structures that will hold their shapes. Boyd F. Edwards, PhD, *Expert Report: Educational Value of Neodymium Magnet Spheres in the Matter of Zen Magnets, LLC, CPSC Docket No. 12-2* (Aug. 28, 2014) ("Ex. R-155") at 20.

B. The Risk of Injury

The risk of injury from the Subject Products arises when individual magnets are separated from a set and easily swallowed, either accidentally or intentionally, by children. Ex. CC-19A at 4, 7-8, 18.

The intended use and operation of the Subject Products require the magnets to be separated and reattached to create and reshape the magnets into a variety of figures, sculptures, structures, jewelry, and art. *See, e.g.*, Exs. R-55 (product guide with examples of structures that can be created with the Subject Products); R-139 ("Never Let Go of Childhood Wonder" demonstration video); *see also* Direct Testimony of Dr. J. Paul Frantz, Ph.D., C.P.S.M., CPE ("CC-10A") at 13, 15 (discussing Respondent's marketing of the Subject Products as jewelry and refrigerator art). Using the Subject Products for these purposes can result in separated, lost, or shared magnets. *See* Ex. CC-10A at 7, 13-14, 18-19, 22-23, 43, 45; J. Paul Frantz, Ph.D., C.P.S.M., CPE, *Expert Report of: J. Paul Frantz, Ph.D., C.P.S.M., CPE* (July 16, 2014) ("Ex. CC-11") at 48, 51. The very design of the Subject Products as small, loose, separable, high-flux magnets is hazardous to children. Tr. 343:5-344:3; 385:19-386:2; Ex. CC-10A at 6-7, 42-43.

Babies and toddlers may find lost or unaccounted-for SREMs or gain access to SREMs that are stored or unstored in a home or through siblings. Exs. CC-10A at 29-31; CC-11 at 48. Young children -- babies, toddlers, and some preschoolers -- are particularly enticed by SREMs because they are "shiny, reflective, and smooth," look like candies that are sometimes found on cakes and cookies, and "can be manipulated to look like toys and colorful character figures." Ex. CC-19A at 4. Young children who gain access to SREMs may place the magnets in their mouths

to learn more about the objects; once the magnets are in their mouths, children may swallow them, either intentionally or accidentally. *Id*. at 4, 7-8. Such behavior is considered reasonable and age-appropriate for young children. *Id.* at 6-8

Teens and tweens, meaning older children ages 9-16 ("older children"), may obtain SREMs from a friend or a caregiver, or purchase the magnets for themselves. Exs. CC-10A at 29-31; CC-19A at 14-17. These older children may test the magnetic properties of SREMs by sticking the magnets onto their braces, using them to mimic facial piercings, or unconsciously putting the magnets near their mouths while playing with them, and accidentally swallow them. Ex. CC-19A at 13, 16; *see also* Direct Expert Testimony of R. Adam Noel, M.D. ("Ex. CC-27A") at 13. Such behavior is considered developmentally appropriate for children at those ages. Ex. CC-19A at 13-17.

Regardless of how they are obtained or used, if ingested, SREMs that comprise the Subject Products present the same risk of injury to children of all ages. Because of their strong magnetism, ingested SREMs like the Subject Products can attract to each other, or to other metallic objects that are ingested, across loops of bowel or other tissue; once attached, the SREMs become lodged in the digestive system and cannot separate on their own. NASPGHAN Paper, "Protecting Children from Magnet Ingestions" ("Ex. CC-24") at 2; Ex. CC-27A at 7.

Ingested SREMs that press against digestive tissue and that are not removed within approximately 8 hours can cause catastrophic injuries and death through tissue injuries; pressure necrosis ("tissue death"); and fistulas or perforations, *i.e.*, holes of the gastrointestinal tract. Exs. CC-24 at 2; CC-27A at 7-11. If a fistula or perforation occurs, bacteria, partially digested food, or fecal matter could leak from the intestine into the body cavity, resulting in serious infection or sepsis. Ex. CC-27A at 8; Tr. 750:5-752:11. In addition, depending on how they attach in the digestive tract, ingested SREMs can kink portions of the mesentery, cutting off blood supply to that area of the intestinal tract (bowel ischemia) and causing tissue death of part of the digestive tract. Ex. CC-27A at 9; Tr. 752:19-753:11.

SREM ingestions are difficult to diagnose because patients often present with nonspecific symptoms, such as nausea and fever, which parents, caregivers, and medical professionals can mistake for the flu, stomach virus, or gastrointestinal infection. Exs. CC-24 at 2; CC-27A at 10-11. In addition, medical professionals are often not aware of the medical risks that ingested SREMs present, and they assume that magnets will behave similarly to most foreign bodies that are ingested, by just passing through the digestive tract. Ex. CC-27A at 12; Tr. 766:12-767:9. Delays in diagnosis can result in serious injury. Ex. CC-27A at 10, 12.

C. CPSC's Statutory Authority Under Section 15 of the CPSA

Complaint Counsel brought this case against Respondent, on behalf of the Commission, under Sections 15(c) and (d) of the CPSA (15 U.S.C. §§ 2064(c) and (d)), seeking an order that the Subject Products present a substantial product hazard and directing Respondent to take certain remedial actions with respect to the Subject Products.

The Commission may determine that a product presents a substantial product hazard under two different provisions in Section 15 of the CPSA: Sections 15(a)(1) and (a)(2).

Section 15(a)(2) defines "substantial product hazard" as "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2).

Section 15(a)(1) of the CPSA defines "substantial product hazard" as "a failure to comply with an applicable consumer product safety rule under this Act or a similar rule, regulation, standard, or ban under any other Act enforced by the Commission which creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(1).

Sections 15(c) and (d) of the CPSA (15 U.S.C. §§ 2064(c) and (d)) prescribe the remedies that the Commission may order if the Subject Products present a substantial product hazard under either Section 15(a)(1) or (a)(2). Under Section 15(c), the Commission may order public notice after finding that: (1) a product distributed in commerce presents a substantial product hazard; and (2) notification is required in order to adequately protect the public from such substantial product hazard. 15 U.S.C. § 2064(c)(1).[2] Under Section 15(d), the Commission may order repair, replacement, and/or refund of a product after determining that: (1) a product distributed in commerce presents a substantial product hazard; and (2) such action is in the public interest. 15 U.S.C. § 2064(d)(1). Orders under Section 15(d) may also enjoin the manufacture, sale, distribution, or importation of the product. 15 U.S.C. § 2064(d)(2).

D. Procedural History

In 2012, Complaint Counsel filed administrative complaints under Sections 15(c) and (d) of the CPSA against Maxfield and Oberton Holdings, LLC ("Maxfield"), Star Networks USA, LLC ("Star"), and Respondent, seeking orders that SREMs imported and distributed by these firms present a substantial product hazard, and orders directing the firms to take certain remedial actions with respect to the products. *See*, *e.g.*, Second Am. Compl. against Zen Magnets, LLC [filed Feb. 11, 2013 as Ex. B to DE 26] at ¶ 1 ("Second Amended Complaint"). The cases against Maxfield, Star, and Respondent were subsequently consolidated. *See* Order Granting Agency's Mot. to Consolidate CPSC Docket Numbers 12-1/12-2 and 13-2 [filed Jan. 11, 2013 as DE 24]. In May and July 2014, the Commission entered into consent agreements with Maxfield and Star, leaving the action against Respondent the only remaining case.

1. Second Amended Complaint

Count I of the Second Amended Complaint alleged that the Subject Products are a substantial product hazard under Section 15(a)(2) of the CPSA because they contain product defects that create a substantial risk of injury to the public. Second Am. Compl. at 5. Complaint

[2] A hearing in accordance with 5 U.S.C. § 554 is a prerequisite to any order issued under Sections 15(c) and (d). 15 U.S.C. §§ 2064(c)(1), (d)(1), (f)(1). This requirement has been satisfied by the hearing conducted by the ALJ from December 1 through December 18, 2014.

Counsel alleged that the Subject Products contain a defect under three separate theories: (1) the Subject Products contain inadequate instructions, packaging, and warnings; (2) a substantial risk of injury arises as a result of the Subject Products' operation and use and the failure of the Subject Products to operate as intended; and (3) the type of risk of injury renders the Subject Products defective under 16 C.F.R. § 1115.4. *Id.* at 5-19. In addition, Count I alleged that the defect creates a substantial risk of injury to children under the age of 14, who may ingest more than one magnet and suffer acute and long-term health consequences. *Id.* at 19-21.

Count II of the Second Amended Complaint alleged that the Subject Products are a substantial product hazard under Section 15(a)(1) of the CPSA because they fail to comply with ASTM International Standard F963-11, *Standard Consumer Safety Specification for Toy Safety* (the "Toy Standard"), and such failure creates a substantial risk of injury to the public. *Id*. at ¶¶ 128-134. Count II alleged that the Subject Products constitute "toys" under the Toy Standard because the Subject Products are designed, manufactured, and/or marketed as a plaything for children under 14 years of age. *Id.* at ¶¶ 128-129. Count II further alleged that because the Subject Products consist of and contain loose-as-received magnets that are "small objects," as defined under the Toy Standard, with a flux index greater than 50, the Subject Products violate the Toy Standard. *Id.* at ¶ 130-132.

On May 28, 2013, Respondent filed an answer to the Second Amended Complaint, denying the allegations. Respondent Zen Magnet, LLC's Answer to the Second Amended Complaint [DE 43].

2. Initial Decision and Order

From December 1, 2014 to December 18, 2014, the ALJ held an administrative hearing in this matter. On March 25, 2016, the ALJ issued an Initial Decision and Order granting in part, and denying in part, the Commission's request for relief. Initial Decision and Order [DE 141] ("Initial Decision").

The ALJ found in favor of Respondent on all allegations in Count I and ruled that the Subject Products do not contain a defect that creates a substantial risk of injury to the public. Initial Dec. at 12, 16, 29, 36. Significantly, the ALJ found that Complaint Counsel did prove that "*ingesting* SREMs creates a real risk of injury and can result in severe injury or death," however, the ALJ ruled against Complaint Counsel because "[p]roper use of [the Subject Products] creates no exposure to danger whatsoever." *Id*. at 36 (emphasis in original).

Regarding Count II, the ALJ found that Subject Products sold without warnings and/or marketed or labeled for use by children under 14 years of age are toys under the Toy Standard and constitute a substantial product hazard. *Id.* at 16 n.6, 34, 36. However, the ALJ concluded that Subject Products sold with warnings and "appropriate age recommendations" are not toys under the Toy Standard and do not constitute a substantial product hazard. *Id.* at 16 n.6, 33-34, 36.

The ALJ issued an Order requiring Respondent to compile and provide to the Commission lists of consumers who purchased the Subject Products (1) without warnings (before May 2010); and (2) with any information suggesting the appropriate age of use to be 12 years and older. *Id.* at 34-35. Additionally, the Order required Respondent to contact all known customers and retailers identified in the lists, and provide (1) specific warnings about magnet ingestion hazards; (2) the purchaser an opportunity to return the product to Respondent for a full or partial refund, in accordance with specified requirements and time frames; and (3) the Commission with information concerning all responses Respondent receives to the notifications, within specified time frames. *Id.* at 35.

3. Complaint Counsel's Appeal of the Initial Decision and Order

On March 29, 2016, Complaint Counsel filed a Notice of Intent to Appeal [DE 142], which they perfected on May 4, 2016, by filing an Appeal Brief [DE 143] ("Appeal").[3] Because the Appeal was perfected within 40 days of the issuance of the Initial Decision and Order, the ALJ's Initial Decision and Order was not adopted as a Final Decision and Order by the Commission. 16 U.S.C. § 1025.52.

On June 13, 2016, Respondent filed Respondent's Answer Brief [DE 153] ("Answer Br."), and Complaint Counsel filed Complaint Counsel's Reply Brief [DE 154] ("Reply Br.") on June 27, 2017.

On June 7, 2017, the Commission heard oral argument on this matter.[4]

II. Standard of Review and Burden of Proof

A. The Commission's Review Is De Novo

The Administrative Procedure Act ("APA") governs this adjudication (15 U.S.C. § 2064(f)(1)), granting the Commission "all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule." 5 U.S.C. § 557(b). Courts have

[3] Respondent subsequently filed a Motion to Stay Complaint Counsel's Appeal of the Initial Decision Pending Disposition of Respondent's Motion to Disqualify the Commission or Some of its Members [filed May 6, 2016 as DE 145, re-filed on May 16, 2016 as DE 150] ("Motion to Stay") and a Motion to Disqualify the Commission or Some of its Members [filed May 6, 2016 as DE 144, re-filed on May 16, 2016 as DE 149] ("Motion to Disqualify"). Complaint Counsel filed responses opposing these motions [filed May 13, 2016 as DE 146 and May 16, 2016 as DE 151]. On May 25, 2016, the Commission denied the Motion to Stay [DE 152] and, on September 1, 2016, the Commission denied the Motion to Disqualify. Order Denying Respondent's Motion to Stay Complaint Counsel's Appeal of the Initial Decision and Order and Setting a Briefing Schedule, *In the Matter of Zen Magnets, LLC*, CPSC Docket No. 12-2 [DE 152] (May 25, 2016); Opinion and Order Denying Respondent's Motion to Disqualify the Commission or Some of Its Members, *In the Matter of Zen Magnets, LLC*, CPSC Docket No. 12-2 [DE 155] (Sept. 1, 2016). Commissioner Buerkle issued a dissenting opinion in connection with the Motion to Disqualify.

[4] The Commission's regulation at 16 C.F.R. § 1025.55(c) states: "Except as otherwise ordered by the Commission, the Commission shall endeavor to file its Decision within ninety (90) days after the filing of all briefs or after receipt of transcript of the oral argument, whichever is later." On August 3, 2017, the Commission received the final oral argument transcript, which was served on the parties by the Office of the Secretary on the same day.

interpreted this language as granting agencies *de novo* review over an ALJ's decision, unless the agency has limited its standard of review through regulation. *See, e.g.*, *Deere & Co. v. ITC*, 605 F.3d 1350, 1358 (Fed. Cir. 2010); *Vineland Fireworks Co., Inc. v. ATF*, 544 F.3d 509, 514 (3d Cir. 2008); *Vercillo v. CFTC*, 147 F.3d 548, 553 (7th Cir. 1998); *Containerfreight Transp. Co. v. ICC*, 651 F.2d 668, 670 (9th Cir. 1981).

The Commission's applicable regulation does not limit its standard of review and, indeed, states that the Commission "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). This language is nearly identical to Section 557(b) of the APA, 5 U.S.C. § 557(b). The regulation's requirement that the Commission "adopt, modify, or set aside the findings, conclusions, and order contained in the Initial Decision …" (16 C.F.R. § 1025.55(b)) is not a restriction on the Commission's powers to review the Initial Decision. Because the regulation "parallel[s], rather than limit[s]," the APA standard of review, the Commission may conduct a *de novo* review of the Initial Decision. *Vercillo*, 147 F.3d at 553.

De novo review means "an independent determination of the issues," *United States v. First City Nat'l Bank of Houston*, 386 U.S. 361, 368 (1967), and deference to the Initial Decision is not required. *La. Pub. Serv. Comm'n v. FERC*, 522 F.3d 378, 395 (D.C. Cir. 2008).

Respondent is correct that the Initial Decision cannot be "set aside by the Commission *as if the case had never been heard in the first place*." Answer Br. at 6 (emphasis in original). The Commission must consider the Initial Decision, which is part of the record, in its review of the appeal. 5 U.S.C. § 557(c); *see also* 16 C.F.R. § 1025.55(a) ("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 …"). If the Commission departs from the ALJ's findings, the Commission's decision must reflect "attentive consideration" to the Initial Decision. *La. Pub. Serv. Comm'n*, 522 F.3d at 395 (citing *Greater Boston Television Corp. v. FCC*, 444 F.2d 841, 853 (D.C. Cir. 1970)). This consideration "may be found if the agency decision reflects an awareness of the ALJ's findings and gives reasons for reaching a different conclusion with respect to those findings." *Simon v. Simmons Foods, Inc.*, 49 F.3d 386, 390 (8th Cir. 1995); *see also* 16 C.F.R. § 1025.55(b) (requiring the Commission to "include … a statement of the reasons for its action and any concurring or dissenting opinions").

B. Complaint Counsel Have the Burden of Proof to Show Substantial Product Hazard by a Preponderance of the Evidence

Under the APA and the Commission's regulation governing administrative adjudications, Complaint Counsel have the burden of proving that the Subject Products constitute a substantial product hazard under the CPSA. 5 U.S.C. § 556(d) ("the proponent of a rule or order has the burden of proof"); 16 C.F.R. § 1025.43(b)(1) ("Complaint counsel shall have the burden of sustaining the allegations of any complaint."). In addition, the party "who is the proponent of a legal or factual proposition shall have the burden of sustaining that proposition." 16 C.F.R. § 1025.43(b)(2).

The standard of proof that a proponent of a rule or order must meet to prevail in an administrative proceeding under the APA is "preponderance of the evidence." *Steadman v. SEC*, 450 U.S. 91, 102, *reh'g denied*, 451 U.S. 933 (1981). A standard of proof other than "preponderance of the evidence" may apply, but only if the APA is "superseded by an express statutory provision." *Greenwich Collieries v. Director, OWCP*, 990 F.2d 730, 736 (3rd Cir. 1993), *aff'd*, 512 U.S. 267 (1994) (internal footnote omitted).

No such express statutory provision exists here. The CPSA is silent regarding the standard of proof governing Commission adjudications. Therefore, the Commission reaffirms that the preponderance of the evidence standard applies.[5] This simply means that the record must be sufficient to find that a fact is more likely to be true than untrue. *Greenwich Collieries*, 990 F.2d at 736; *see also In re Dye & Dye*, CPSC Docket No. 88-1, 1989 WL 435534 at *4, Opinion and Order (July 17, 1991) ("*In re Dye*") *aff'g* 1989 WL 435526, Initial Decision (March 30 1989) ("*In re Dye* Initial Decision") (citing *Hale v. Dep't of Transp.*, 772 F.2d 882, 885 (Fed. Cir. 1985)).

III. The Subject Products Present a Substantial Product Hazard Under Section 15(a)(2) of the CPSA

Complaint Counsel argue that they have met their burden of proof by a preponderance of the evidence that the Subject Products present a substantial product hazard under Section 15(a)(2) of the CPSA because (1) the Subject Products contain a design defect that creates an ingestion risk to children based on their use and operation, including the reasonably foreseeable misuse of the Subject Products; and (2) the warnings on the Subject Products do not and cannot mitigate the risk of injury.[6] Appeal at 2. Respondent counters that Complaint Counsel failed to meet their burden to prove a defect, and that the Commission should uphold the ALJ's decision that the Subject Products do not present a defect based on their operation and use, because (1) the ingestion hazard arises out of misuse of the Subject Products, not the proper and intended

[5] Respondent contends that the U.S. Supreme Court's holding in *Steadman* does not apply to Commission adjudications. According to Respondent, unlike the securities statute at issue in *Steadman*, which did not specify a standard of proof governing Securities and Exchange Commission violations, the Commission's regulation at 16 C.F.R. § 1025.51(b) requires adjudications to be supported by "substantial evidence." Answer Br. at 4-5. The regulation states: "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) (emphasis added). The Commission disagrees. In *Steadman*, the U.S. Supreme Court interpreted the phrase "reliable, probative, and substantial evidence" to mean by a preponderance of the evidence. 450 U.S. 91, 98-102. Moreover, contrary to Respondent's argument, the substantial evidence standard is a *lower* standard of proof than the preponderance of the evidence standard. Substantial evidence is "more than a scintilla of evidence *but less than a preponderance*; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Rogers v. Comm'r of Soc. Sec.*, 486 F.3d 234, 241 (6th Cir. 2007) (emphasis added) (internal citation omitted); *see also Southland Mower Co. v. CPSC*, 619 F.2d 499, 508 (5th Cir. 1980).

[6] Complaint Counsel also argue that application of the "risk factors" in 16 C.F.R. § 1115.4 (cited in footnote 8 below) proves a defect in the Subject Products. Although we agree that the factors weigh in favor of finding a defect and may be considered as part of a defect analysis, as appropriate, the Commission finds that the factors listed in § 1115.4 do not present a separate basis for a defect finding. Thus, the Commission will consider some of the factors in step 1 of its analysis, as discussed in Sections III.A.1.a and III.A.2, *infra* pp. 9-10, 15-34.

operation and use of the Subject Products; and (2) warnings on the Subject Products are sufficient to mitigate the risk of injury. Answer Br. at 13, 14-15, 31-32.

To find a substantial product hazard under Section 15(a)(2) of the CPSA, the Commission must conclude that:

- the Subject Products contain a defect; and
- such defect, because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public.

15 U.S.C. § 2064(a)(2).

A. The Subject Products Contain a Defect

1. Legal Framework

a. Defect Analysis

Section 1115.4 of the Commission's regulation states, in pertinent part: "[a]t a minimum, defect includes the dictionary or commonly accepted meaning of the word. Thus, a defect is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function."[7] 16 C.F.R. § 1115.4. Section 1115.4 also provides that a product defect may arise in a variety of ways and offers several examples, such as a manufacturing error, use of defective materials, or, as alleged in this case, a design flaw. *Id.* Accordingly, "a product may contain a defect even if the product is manufactured exactly in accordance with its design and specifications, if the design presents a risk of injury to the public." *Id*. Section 1115.4 states that a "design defect may also be present if the risk of injury occurs as a result of the operation or use of the product …." *Id*. Section 1115.4 sets forth the factors the Commission "will consider, as appropriate," in "determining whether the risk of injury associated with a product is the type of risk which will render the product defective." *Id.*

Section 1115.4 provides a great deal of flexibility in interpreting "defect" in Section 15(a)(2) of the CPSA. Because of the breadth of consumer products that fall within the Commission's jurisdiction and the range of product characteristics that could present a defect, the Commission's defect analysis must be very flexible and must take relevant factors into consideration, as appropriately applied to the fact-specific circumstances of each case. *See* Interpretation, Policy, and Procedure for Substantial Product Hazards, 43 *Fed. Reg*. 34,988, 34,991 (Aug. 7, 1978) ("1978 Final Rule") (stating that the Commission conducts defect

[7] Although the primary purpose of the regulation is to provide guidance to manufacturers, importers, distributors, and retailers on when to report substantial product hazards to the Commission, the regulation also provides guidance on how the Commission interprets and enforces the concept of a product defect under Section 15(a) of the CPSA.

determinations on a case-by-case basis and "interprets the term defect as used in Section 15(b) to include the broadest meaning found in Federal and State statutes and judicial pronouncements").

As explained in § 1115.4 and *In re Dye*, 1989 WL 435534 at *9-11, a defect analysis:

1. Begins with an evaluation of the product's characteristics, and whether those product characteristics give rise to a risk of injury.

2. If such characteristics do give rise to a risk of injury, we consider whether the characteristics are necessary for the product to function.

    a. If such characteristics are not necessary for the product to function, then we can dispense with further defect analysis and the Commission may find that the product contains a defect.

    b. If such characteristics are necessary for the product to function, or if the effect of the defect finding will remove the product from the market, then the Commission conducts a balancing test to determine whether the risk of injury outweighs the usefulness of the product to consumers, before the Commission may find that the product contains a defect.[8]

Step 1 of a defect analysis, *i.e.* assessing product characteristics and whether such characteristics create a risk of injury, may include, as appropriate, consideration of some of the same factors identified in § 1115.4 discussed in footnote 8. Thus, in some cases, such as here, the assessment of whether a product's characteristics create a risk of injury, and balancing of the risk of injury with the product's utility, may involve consideration of some of the same factors.

b. Role of Reasonably Foreseeable Misuse in a Defect Determination

Before we consider the characteristics of the Subject Products, we consider the role of consumer misuse of a product when conducting a defect determination. The most fundamental flaw resulting in misapplication of the law in the ALJ's Initial Decision is the erroneous assertion that the CPSC cannot protect consumers from hazards resulting from reasonably foreseeable misuse of a consumer product. This fundamental misunderstanding by the ALJ permeates the entire Initial Decision and Order and is contrary to our regulatory guidance, legislative history, statutory authority, case law, and Commission precedent.

[8] Section 1115.4 lists the following factors CPSC staff considers, as appropriate:

> The utility of the product involved; the nature of the risk of injury which the product presents; the necessity for the product; the population exposed to the product and its risk of injury; the obviousness of such risk; the adequacy of warnings and instructions to mitigate such risk; the role of consumer misuse of the product and the foreseeability of such misuse; the Commission's own experience and expertise; the case law interpreting Federal and State public health and safety statutes; the case law in the area of products liability; and other factors relevant to the determination.

Specifically, the ALJ found that Complaint Counsel did not meet their burden to prove that the Subject Products contain a defect because ingestion is not part of the Subject Products' "use" or "operation," and that the evidence proved that the risk of injury arises only when consumers "misuse" the Subject Products by ingesting SREMs. Initial Dec. at 7-8. The ALJ incorrectly reasoned that because ingestion of SREMs is a misuse of the Subject Products, and is not part of the intended or proper use of the product, a defect does not arise out of the operation or use of the Subject Products. *Id*.

Ingestion of the Subject Products is, of course, not the proper or intended use of the Subject Products. Accordingly, as an initial legal matter, the Commission must determine whether a design defect that arises out of the "operation or use" of a consumer product includes reasonably foreseeable misuse, and whether a defect may arise solely out of reasonably foreseeable misuse of the Subject Products. We conclude that the Commission has the authority to find that a product is defective based solely on reasonably foreseeable misuse of a consumer product.

First, the Commission's regulation recognizes that a defect may be found based on reasonably foreseeable misuse of a product. Section 1115.4 addresses the role of reasonably foreseeable consumer misuse in two places.

Section 1115.4(d) provides an example of a defect that arises out of "reasonably foreseeable consumer use or misuse":

> 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.

The regulation also specifically lists "the role of consumer misuse of the product and the foreseeability of such misuse" as one of the factors to consider in determining whether the product contains a defect. 16 C.F.R. § 1115.4.

Based on the power tool example in § 1115.4(d), Respondent argues that the Commission's regulation only allows for defect findings that are based *in part* on the foreseeable misuse of a product, and that reasonably foreseeable misuse is an insufficient basis, standing alone, on which to base a defect finding. Answer Br. at 14-15 (citing 16 C.F.R. § 1115.4); Transcript of June 7, 2017 Oral Argument ("Oral Arg. Tr.") at 60:1-61:20. Our review of the applicable law cited below demonstrates no conceivable rationale related to product safety that justifies this interpretation. Nothing in the CPSA or accompanying regulation limits the Commission's authority to identify defects to those defects that are based only *in part but not entirely* on reasonably foreseeable misuse.[9]

[9] We also note that the practical effect of such a narrow reading would hobble the Commission's ability to address serious product safety concerns associated with products that children foreseeably misuse, such as children climbing

Second, the concept of "foreseeable misuse" has been an integral part of consumer product safety analysis for more than 40 years, including before the creation of this agency. In 1968, the National Commission on Product Safety ("NCPS") was convened to assess safety threats to consumers. The NCPS reviewed injury reports to determine critical patterns and modes of injury, and to discover predictable product misuses. Final Report of the National Commission on Product Safety (June 30, 1970) ("NCPS Report") at 38. By studying injury reports, the NCPS identified several "unreasonable hazards." *Id*. at 10-36. The NCPS issued a report based on its findings, which included findings of misused consumer products, as well as product hazards improperly characterized as consumer misuse. *Id*. The NCPS Report stated:

> … the manufacturer or seller ought not be absolved merely because the consumer used the product in a manner different from that intended. A manufacturer should be responsible for injury to consumers from use or certain types of misuse which could reasonably have been anticipated. His duty is to design and construct products with these misuses in mind.

Id. at 75.[10] Furthermore, the NCPS Report stated: "[m]anufacturers must take all practical steps systematically to prevent foreseeable misuse of products. In effect, they need to build safety into the design and construction of their products." *Id*. at 62. The NCPS Report recommended creation of a new independent federal agency to regulate consumer product safety. *Id*. at 113. The CPSA was enacted within 2 years of the NCPS Report.

Consistent with the NCPS Report, legislative history associated with the CPSA demonstrates that Congress intended the Commission to regulate products that present a risk of injury to consumers, even if that risk arises out of consumer behavior characterized as misuse of a product. Speaking about the Commission's mandate in Section 2(b)(1) of the CPSA "to protect the public against unreasonable risks of injury associated with consumer products," Senator Frank Moss (D-Utah) stated: "…the word 'associated' was chosen so as to convey the fact that the risk of injury did not have to result from 'normal use' of the consumer product but could also result from such things as 'exposure to or reasonably foreseeable misuse of the consumer product.'" 118 Cong. Rec. 36197, 36198 (daily ed. Oct. 14, 1972).

Notably, the Senate Commerce Committee's version of the CPSA defined the term "use" of a consumer product as: "(A) exposure to, and (B) normal use or reasonably foreseeable misuse." Consumer Safety Act of 1972, S. 3419, 92 Cong. (1972). Commentary on this definition provides additional insight:

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onto furniture and being crushed when it tips over, or children at play being strangled by accessible window covering cords.

[10] For example, the NCPS Report stated that the industry blamed exploding glass bottles on consumer mishandling, but the NCPS concluded that "[t]he industry should anticipate routine stress on bottles, including reported minor impacts when they are checked out at the counter, carried home, or placed in a refrigerator." NCPS Report at 17.

> The definition of "use" includes exposure to and any normal use. In addition, it includes reasonably foreseeable misuse . . . . For example, a child's doll in normal use is cuddled and loved. But it is reasonably foreseeable that such a product can be misused--that a child may tug at the hair ribbon of the doll, thereby exposing a dangerous, sharp pin. In such a case, the Commissioner may determine there is an unreasonable risk of injury associated with the use (including reasonably foreseeable misuse) of the doll which has a hair ribbon attached with a long, sharp pin.

S. Rep. No. 92-749, at 15 (1972). Although the final version of the CPSA does not include a definition of the term "use," this legislative history demonstrates that "use" was intended as an inclusive term that also addresses misuse of a product. The legislative history of the House Commerce Committee version of the CPSA that was ultimately enacted, characterizes "use" in terms of exposure to hazards, which does not preclude misuse, as long as such misuse is reasonably foreseeable. H.R. Rep. No. 92-1153, at 27-28 (1972).

Congressional intent for the Commission to address risks of injury arising from consumers' foreseeable misuse of products appears throughout CPSC-administered statutes. These statutes recognize explicitly the important and significant role that reasonably foreseeable consumer misuse of products presents in executing the Commission's mission to protect the public, particularly children, from unreasonable risks of injury, including risks arising from ingesting part or all of a consumer product.[11] Notably, the Commission's statutory authority to prevent injury to children arising out of reasonably foreseeable misuse of a product is not limited to children's products. Indeed, several CPSC-administered statutes are premised on the concept of addressing reasonably foreseeable misuse of a "general use" product.[12]

Third, the Commission's case law reflects the CPSC's authority to address reasonably foreseeable consumer misuse of consumer products that present a risk of injury under the CPSA.

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[11] *See, e.g.*, Section 108(d) of the Consumer Product Safety Improvement Act of 2008 ("CPSIA") (15 U.S.C. § 2057c(d)(1)) (providing that limits on phthalate content do not apply to inaccessible component parts of children's toys and childcare articles that are "not accessible to a child through normal and reasonably foreseeable use and abuse of such product, as determined by the Commission" and defining "reasonably foreseeable use and abuse" of children's toys and childcare articles to include "swallowing, mouthing, breaking, or other children's activities, and the aging of the product"); Section 2(f)(1)(A) of the Federal Hazardous Substances Act ("FHSA") (15 U.S.C. § 1261(f)(1)(A)) (defining a "hazardous substance" to include injuries "during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children"); Section 2(s) of the FHSA (15 U.S.C. § 1261(s)) (describing a "mechanical hazard" to include properties such as fragmentation, propulsion, self-adhering characteristics, aspiration and ingestion, if such hazard arises "in normal use or when subjected to reasonably foreseeable damage or abuse …").

[12] For example, the Poison Prevention Packaging Act (15 U.S.C. §§ 1471-1477), directs the Commission to issue "special packaging" regulations to address the risk of poisoning to children under five from easily accessing and ingesting toxic or harmful household substances. The Children's Gasoline Burn Prevention Act (Sec. 2, Pub. L. No. 110-278, 122 Stat. 2602 (Jul. 17, 2008)) requires the Commission to regulate child-resistant closures on portable gas can containers to address the risk of burn injury to children. And the Refrigerator Safety Act (15 U.S.C. §§ 1211-1214), requires refrigerators to have doors that can be easily opened from the inside to address the risk of suffocation death to children who climb inside. Each of these authorities is intended to reduce the risk of injury to children from reasonably foreseeable misuse of products that are not specifically intended for use by children.

Southland Mower Co. v. CPSC, 619 F.2d 499, 513 (5th Cir. 1980); *see also In re Dye*, 1989 WL 435534 at *2, *5-7; *In re Dye* Initial Dec., 1989 WL 435526 at *15; *In the Matter of Francis Alonso, Jr. d/b/a/ Mylar Star Kites*, CPSC Docket No. 75-16, Initial Decision and Order (June 18, 1976) ("*Mylar Star Kites*") at 4-5, findings of fact *aff'd*, Initial Decision and Order set aside on jurisdictional grounds, Final Decision and Order (Sept. 16, 1977).

In *Southland Mower*, a manufacturer challenged a Commission regulation addressing a risk of injury arising when consumers remove protective shielding from lawn mowers. 619 F.2d at 503-504, 513. The manufacturer argued that the risk of injury to consumers who remove the shield did not present an unreasonable risk of injury addressable under the CPSA because these consumers chose to assume the risk of injury by removing the shield. *Id*. at 513. Citing legislative history, the U.S. Court of Appeals for the Fifth Circuit found that the Commission's authority extended to reasonably foreseeable consumer misuse. *Id*. The court stated that an understanding of consumer choice to misuse a product was relevant to the Commission's assessment of the reasonableness of the risk of injury. *Id*. The court found "no evidence that consumers accurately appreciate the nature of the risk of blade-contact injuries and that their presumed willingness to defeat protective measures is reasonable." *Id*. This case suggests that when assessing whether product misuse is reasonably foreseeable, the Commission should consider whether and to what extent consumers appreciate the risk of injury presented.

Finally, the ALJ misinterpreted previous Commission precedent as limiting defects to those that arise out of the proper or intended use of the product. Initial Dec. at 8-12. For example, in *In re Dye*, the Commission found a product named "Worm Gett'r" to be defective. 1989 WL 435534 at *7. "Worm Gett'rs" were devices generally known as "worm probes" that came in a set of two, six, or 12 probes intended for insertion into the ground. *Id.* at *1. The probes were then electrically charged to drive worms to the surface to be picked up as fishing bait. *Id.* Worm Gett'rs were manufactured without a "return wire," so that when plugged in, the 120 volts from the electrical outlet were fully available to send an electric current through any conductive path in contact with the probe. *Id.* While no deaths were associated with Worm Gett'rs, worm probes found to be functionally equivalent to Worm Gett'rs were associated with more than two dozen electrocution deaths. *Id*. at *6. The ALJ distinguished Worm Gett'rs from this case, opining that the Commission found Worm Gett'rs defective because the risk of injury arose out of accidents or mistakes while using the product as intended, that is, proper use exposed consumers to the risk of injury. Initial Dec. at 9.

Contrary to the ALJ's interpretation, *In re Dye* does not stand for the proposition that only the proper or intended use of a product can give rise to a defect determination. *In re Dye* involved scenarios that may properly be characterized as reasonably foreseeable use or misuse. In particular, the consumer behavior in *In re Dye* that the ALJ characterized as "mistakes" can also be characterized as "reasonably foreseeable use or misuse" of the product. The facts in *In re Dye* demonstrate that the risk of electrocution arose in a number of ways that could not be adequately prevented by the user, including accidents (slipping, falling, and tripping); mistakes (ignorance of the electrical hazard, not realizing the probes are energized, not realizing a hazardous leakage current in the ground can emanate from the inserted probe, and being distracted); readily foreseeable events (shoes becoming wet and children or other persons coming

into the area where the probes are being used); intended use of the product (picking up worms); and aggravating factors (product instructions to water the ground before use and common use of the product at night). 1989 WL 435534 at *2. Indeed, the Initial Decision and Order in *In re Dye* states that users consistently misused the product. *In re Dye* Initial Dec., 1989 WL 435526 at *15.

The ALJ also attempted to distinguish *Mylar Star Kites* from the instant case because, similar to *In re Dye*, he believed that the aluminized kite in that case presented a risk when properly used by consumers. Initial Dec. at 11. The ALJ reasoned that proper use of the kite in *Mylar Star Kites* could result in injury, through an accident or negligence, by flying the kite into a power line. *Id*. The ALJ misinterpreted the holding in *Mylar Star Kites*. The warnings in *Mylar Star Kites* informed consumers never to fly the kite near power lines or during wet weather, and not to remove kites from power lines if they should fall on or near power lines. *Mylar Star Kites* Initial Dec. at 4. Despite these warnings, consumers were injured because kite flyers disobeyed, did not receive, or did not read the warnings, or there were bystanders (such as children) in the area. *Id*. at 5. In other words, consumers misused the kites. *Mylar Star Kites* found this consumer conduct to be "clearly foreseeable," concluding: "The possibility that incidents similar to those of record herein will occur in the future is clearly foreseeable unless the manufacture of kites containing conductive material is banned." *Id*. at 11.[13]

2. Step 1: The Characteristics of the Subject Products Create a Risk of Injury to Children

Having established that reasonably foreseeable misuse may be the basis for finding a defect, we now turn to whether Complaint Counsel established by a preponderance of the evidence that the Subject Products create a risk of injury based on operation or use of the magnets, including reasonably foreseeable misuse. We conclude that they have.

[13] The ALJ's misinterpretation of *Mylar Star Kites* extended to that case's weighing of risk versus utility. The ALJ found the facts in *Mylar Star Kites* instructive because the aluminized coating that created the injury in that case was not necessary for the performance of the kite. Initial Dec. at 11. The ALJ reasoned that in the instant case, however, the feature that creates the risk, the attractiveness of SREMs to each other, is the "*sine qua non* of their essence." *Id*. The ALJ further stated that for SREMs, "[w]ithout the ability to attract to each other, the product is worthless." *Id*. The ALJ stated that he balanced the risk of harm from SREM use with the necessity of the magnetic pull and, purportedly following the rationale in *Mylar Star Kites*, found that because the magnetic pull is necessary for function, not aesthetics, SREMs do not contain a defect. *Id*. The ALJ stated that "using the approved analysis of Mylar Star, there is no question that Mylar Star would dictate a different result if the magnetic coating improved functionality, not simply aesthetics." *Id*.

Although we agree that magnetic strength is a product characteristic of SREMs like the Subject Products that creates a risk of injury associated with the Subject Products and is also the essence of the product, we disagree that this finding is the deciding factor in a defect query. The ALJ erred by equating the functionality of the magnetic pull with the utility of the product as a whole. The Commission's regulation, which was issued after the *Mylar Star Kites* decision, does not require balancing "the risk of harm with the necessity of the magnetic pull" (Initial Dec. at 11); rather, § 1115.4 states that when a product characteristic that creates a risk of injury is functional to the product (such as magnetism), the utility of the product to consumers must be balanced against the risk of injury. *See also In re Dye*, 1989 WL 435534 at *9-11. Accordingly, even where a product characteristic, such as strong magnetism, provides functionality to a product, a defect determination requires that the utility of the product as a whole be balanced against the risk of injury to consumers, considering, as appropriate, the factors listed in § 1115.4.

a. CPSC's Experience with SREM Ingestions in Children's Toys

Since 2006, before Respondent began selling Zen Magnets in 2009, CPSC conducted more than a dozen recalls of children's toys due to the hazard of small, high-powered magnets not being adequately contained within a product, making them accessible for children to swallow. Exs. CC-10A at 5-6; CC-11 at 32-33. These recalls involved toys that used high-powered magnets to facilitate building structures. During play, the magnets would come loose from a component part; children then played with and ingested the loose magnets. Ex. CC-10A at 5. Magnet ingestion occurred in children younger than 6, as well as in children between the ages of 6 and 11. *Id*. The injuries arising from these ingestions were similar to the injuries associated with swallowing SREMs from magnet sets, *i.e*., aspiration, intestinal injuries, and death. *Id*. The remedy in all of these recalls was to ensure that small, high-powered magnets in each product were inaccessible to prevent children from ingesting them. *Id*.

Based on the Commission's experience with high-powered magnet ingestions, Complaint Counsel's witness, Dr. J. Paul Frantz,[14] opined that the design of the Subject Products as loose, separable magnets is hazardous to children because the magnets are not contained in a way that makes them impossible to ingest, such as in a plastic casing. Tr. 342:14-344:3; 385:19-387:1; Ex. CC-10A at 6-7; 17; 43.

b. Characteristics, Operation, and Use of the Subject Products

As explained in § 1115.4 and *In re Dye*, 1989 WL 435534 at *9-11, we begin with an evaluation of the Subject Products' characteristics and whether those product characteristics create a risk of injury. It is uncontested that the Subject Products are small, spherical, shiny, reflective, smooth, loose, separable, and strongly magnetic. CC Post Hr'g Arg., Ex. A, ¶¶ 11-17, 60-65, 71; Exs. CC-1A at 4-6; CC-4; CC-4A; CC-5; CC-5(2); CC-5A; CC-7 at 2, 5; CC-19A at 4; Tr. 343:7-9. Respondent's witness, Dr. Boyd Edwards, corroborated the salient product characteristics of the Subject Products. Ex. R-155 at 19-20 (confirming, based upon his own measurements, that the Subject Products have a high flux index and fit within the small parts cylinder).

The Subject Products are not encased in plastic to prevent ingestion; rather, they are sold as aggregated, loose magnets in sets or as individual magnets. CC Post Hr'g Arg., Ex. A, ¶¶ 12, 13, 35, 37, 39, 41, 61, 62, 81. Zen Magnets were available in various-sized containers

[14] Dr. Frantz, who has a Ph.D. and holds an M.S.E. in Industrial and Operations Engineering and a B.S.E. in Human Factors Engineering, is Senior Consultant and co-founder of Applied Safety Ergonomics, Inc., and an adjunct faculty member teaching Safety Management in the College of Engineering at the University of Michigan. Ex. 10 at 1; Direct Testimony of Dr. J. Paul Frantz, Ph.D., C.P.S.M., CPE ("Ex. CC-10A") at 1. Dr. Frantz specializes in warnings, safety engineering, and human factors engineering/ergonomics. Ex. CC-10A at 1. For more than 20 years, Dr. Frantz served as a member of the American National Standards Institute ("ANSI") committee that addresses product warnings. *Id.* Complaint Counsel retained Dr. Frantz to evaluate warnings provided with the Subject Products and "to comment on the implications of such warnings from a human factors and product safety perspective." *Id.* at 2.

holding 72, 216, or 1,728 magnets, at prices ranging from approximately $12.65 for the 72-piece set, $32.98 to $38.24 for the 216-piece set, and up to $263.85 for the 1,728-piece set. *Id*., Ex. A, ¶¶ 36, 38, 40; Tr. 1468:2-5. Zen Magnets also could be purchased individually for 20 cents per magnet. CC Post Hr'g Arg., Ex. A, ¶ 42. Individual Neoballs could be purchased at prices ranging from 6 cents to 10 cents per magnet. *Id.*, Ex. A, ¶ 85. Each magnet in the set is a uniform size and shape, and will easily fit into the small-parts cylinder used by the Commission to determine whether something is small enough for a child to swallow. *Id*., Ex. A, ¶¶ 14, 63; Ex. CC-1A at 4-6.

Respondent argues that the natural attractiveness of magnets to each other creates a barrier to loss and is a unique quality of the Subject Products. Respondent Zen Magnets, LLC's Post-Hearing Argument [filed on Mar. 16, 2015 as DE 138] ("R Post Hr'g Arg.") at 13. Respondent maintains that it does not have a containment problem because it recommended that magnets be stored in "Zen Hex" form, which allows users to "easily ensure all magnets are accounted for, while also serving a convenient method of storage." *Id*. at 12-13 (citing Exs. CC-50, CC-51, CC-52, and CC-63); Answer Br. at 10-11 (citing Tr. 1769:20-1770:8). Respondent also relies on the testimony of Dr. Boyd Edwards,[15] who testified that he has more than 18,000 magnets (Ex. R-154A at 3) and has used magnets on hundreds of occasions, but has lost only four magnets. R Post Hr'g Arg. at 13 (citing Tr. 1440: 12-19); Answer Br. at 11. Respondent argues that Dr. Edwards "created a viable and simple containment mechanism" by following three rules: (1) issuing verbal warnings about the ingestion hazard; (2) ensuring that magnets remain on the work table; and (3) ensuring that individual magnets are not separated from one another. R Post Hr'g Arg. at 13; Answer Br. at 11. Respondent states that it expects that users will be able to account for their magnets. R Post Hr'g Arg. at 13 (citing Tr. 2011:14-20); Answer Br. at 11 (citing Tr. 2105:10-15; 2103:16-22).

We do not find Respondent's containment arguments persuasive. Although Respondent has offered various theories of containment, Respondent presented no evidence that these theories actually work, or are generally used by SREM users. Strong magnetic attraction does not prevent children from separating magnets, thus allowing children to place magnets in their mouths and swallow them. Indeed, Dr. Frantz's analysis of 95 incident reports and In-Depth Investigations ("IDIs") regarding magnet ingestion incidents that Complaint Counsel provided (*see* Exs. CC-18.1 - 18.95; CC-30A - CC-32) demonstrate that children gain access to magnets in a variety of ways, including getting them from friends or family members, discovery while stored and un-stored, direct purchase, and finding lost magnets. Exs. CC-10A at 29-31; CC-11 at 34-42.

Moreover, the individual magnets that comprise the Subject Products can easily become separated from the set in a number of ways, creating a risk of ingestion by children. That risk is not obvious for a number of reasons. First, the intended use and operation of the Subject

[15] Dr. Edwards, who has a Ph.D. in applied physics, and holds an M.S. and B.S. in physics, is the Dean, Executive Director, and Physics Professor at Utah State University, Uintah Basin. Direct Testimony Respondent's Expert Witness Boyd F. Edwards, Ph.D. ("Ex. R-154A") at 1-2. Previously, Dr. Edwards taught undergraduate and graduate-level physics at West Virginia University for 24 years. *Id.* at 1. The ALJ accepted Dr. Edwards as an expert regarding the educational utility of the Subject Products. Tr. 1271:6-10; 1285:21-1286:3.

Products as a manipulative "toy" require that the small magnets be separated and reattached to create and reshape them into a variety of figures, sculptures, structures, jewelry, or art. *See*, *e.g.*, Exs. R-55 (product guide with examples of structures that can be created with the Subject Products); R-139 ("Never Let Go of Childhood Wonder" demonstration video); *see also* CC-10A at 13, 15 (discussing Respondent's marketing of the Subject Products as jewelry and refrigerator art). The evidence demonstrates that Respondent marketed the Subject Products for use in ways that lead to separation, loss, or sharing of the Subject Products, such as for use as jewelry and as refrigerator art. *See*, *e.g.*, Exs. CC-10A at 13-16 (discussing Zen's marketing statements, including "wrist worthy chain" and "terrific for refrigerator art," as well as Mr. Shihan Qu's testimony that it is appropriate to use SREMs to create play jewelry); CC-11 at 12-16. Parents and caregivers would not expect a product that can be displayed as refrigerator art to be deadly to children: "refrigerator art frequently consists of children's drawings or magnets for children to play with. Zen's continued marketing of the Subject Products as refrigerator art shows that it expects consumers to leave them out and displayed in areas where children can access them, play with them, and ingest them." Ex. CC-10A at 16.

Separating a few SREMs from a set to give to someone for use as jewelry does not appreciably lower the play value of the original set, but it increases the risk of injury associated with the separated SREMs: "[s]eparating and sharing SREMs creates a risk to anyone who obtains just two magnets (the number necessary for a piercing simulation). It also simultaneously reduces the utility of those shared SREMs to activities that only require a limited number of magnets (such as simulating a piercing)." *Id*. at 14; Tr. 378:9-380:9.

The incident data and expert testimony evince that the risk of injury from SREM ingestion relates to "separated magnets" from a larger set. However, unlike with magnets that fall out of a toy, consumers do not perceive the loose magnets that comprise the Subject Products, which are intended to be separated and played with, to be part of a broken product: "This act of pulling apart Zen SREMs is routine, unremarkable, and necessary for many uses of Zen's SREMs and is not viewed as breaking anything." Ex. CC-10A at 7. Once separated, magnets "become available without information that is related to appropriate or inappropriate uses." *Id*.; *see also* Ex. CC-19A at 15 (Dr. Steinberg testifying that because individual magnets are too small to be labeled, "users would have no way to appreciate the risk of ingestion just by looking at the magnet balls").

Second, Respondent also sold spare SREMs, the availability of which can lead to separation, loss, or sharing of smaller sets of magnets. Respondent sold spare SREMs as part of a sales strategy to assist consumers who lost magnets, either through actual loss or sharing of magnets. Ex. CC-10A at 19; *see also id.* at 23-25 and Tr. 349:16-350:13 (determining, after reviewing Respondent's sales records, that Respondent provided 220,881 spare magnets to consumers). Respondent sold spare SREMs without warnings. Ex. CC-10A at 23, 25. Respondent also did not warn customers about the hazard of separated or lost magnets, the hazard of magnet misuse, or the need to find lost magnets, when Respondent sold spare magnets without such instruction or warning. Ex. CC-10A at 25; Tr. 362:20-363:16.

Finally, SREMs comprising the Subject Products can be lost while being used in the intended way. Dr. Frantz demonstrated that SREMs can be lost when magnets are dropped on a hard surface. Exs. CC-10A at 20; CC-14 (video); Tr. 145:11-21; 147:6-148:2; 173:20-174:7. Magnets that become separated or lost can be propelled into and adhere to the floor, chairs, appliances, furniture, and other places where children are likely to find them. Exs. CC-10A at 20-21; CC-11 at 29-30; *see also* Tr. 1408:17-1409:6. Even experienced users lose magnets. *See, e.g.*, Tr. 1407:9-16 and 1408:22-1409:6 (Dr. Edwards testifying that he found some magnets in a rug two days after use); Joint Notice Regarding Witness Stipulations, Dec. 8, 2014 ("Joint Notice"), Resp't's Ex. T (Pelletier) at 39:8-19 (finding lost magnets on the bottom of classroom desks). Lost SREMs are difficult to find, and many times they are lost without the owner's knowledge. Exs. CC-10A at 20; CC-11 at 30. Dr. Frantz testified that it is unlikely that Zen owners will be able to keep track of all SREMs in a set, which creates an ongoing hazard to children who may enter "contaminated spaces," or areas that contain lost magnets. Ex. CC-10A at 20-21; *see also* Ex. CC-19A at 12 (Dr. Steinberg testifying that "a caregiver acting with reasonable care would not have counted or searched for a small piece of a product that appears to be an innocuous toy like these small magnet balls").

Contrary to Respondent's argument (Answer Br. at 10), Dr. Frantz was not required to conduct an independent study to conclude that magnets can become lost in the environment or can be easily lost or shared, because he based his conclusions on examination of actual incident reports.[16] Respondent's argument that marketing differences between SREM manufacturers insulate his product from a design defect (*id.* at 24-25) similarly fails. The risk of injury in this case results from the characteristics of the Subject Products, specifically, and how consumers use, or foreseeably misuse, the products. Marketing differences do not change the basic characteristics of SREMs. Even products that are designed, manufactured, and marketed as intended by a manufacturer can present a risk of injury to consumers and be found defective. 16 C.F.R. § 1115.4. Moreover, the evidence shows that Respondent marketed the Subject Products in ways that lead to ingestion. Exs. CC-10A at 13-16; CC-11 at 12-16.

[16] Respondent makes various unpersuasive arguments about the reliability of Complaint Counsel's experts, Dr. Frantz and Dr. Steinberg, including that testimony by Dr. Steinberg is insufficient because it was based on "the colloquial, non-comparative, and non-scientific usage of "'likely.'" Answer Br. at 10; R Post Hr'g Arg. at 8. Respondent further faults Dr. Steinberg's testimony because he considered incidents as "illustrative" of the "range of types of incidents," but did not attempt to quantify or qualify the likelihood of children to misuse magnets. Answer Br. at 10; R Post Hr'g Arg. at 8. Respondent argues that Dr. Steinberg's testimony that magnets appeal to children is moot if a child does not have access to magnets in the first place (Answer Br. at 13), and claims that it implemented sales and marketing strategies to keep its products away from children. *Id.* (citing Exs. R-133; R-197; R-198; and Tr. 2525;9-15). Similarly, Respondent argues that Dr. Frantz's testimony that loss of magnets was a "frequent occurrence," and that Respondent accommodates lost magnets by providing spare magnets, was based on a misconception about how Respondent markets its business. *Id.*

Neither Dr. Frantz nor Dr. Steinberg were required to present independent research on how and why children lose magnets or access SREMs and ingest them, particularly when such experts had numerous actual incidents and injuries to evaluate. For example, Dr. Steinberg reviewed the incident data, and drew on his experience as a child psychologist specializing in psychological development during childhood and adolescence, opining on how and why children actually ingest magnets. Moreover, Dr. Steinberg's testimony is consistent with the Commission's experience that young children ingest small, shiny objects.

c. Ingestion of SREMs is a Foreseeable Misuse of the Subject Products by Children who Play with SREMs

Children play with the Subject Products in an age-appropriate and foreseeable manner. Complaint Counsel's expert, Dr. Laurence Steinberg,[17] concluded, to a reasonable degree of scientific certainty, that young children under the age of 5 are "highly likely to play with or use the Subject Products in ways that can lead to ingestion" because the magnets are "shiny, reflective and smooth," qualities that are "particularly enticing to young children." Ex. CC-19A at 3-4; Tr. 418:11-14; 419:4-8. Dr. Steinberg explained that the primary way babies, toddlers, and some preschoolers explore the world is by using their mouths, because a young child "has the most control over his or her own tongue, lips, and mouth." Ex. CC-19A at 4. Accordingly, young children will "put objects they see that they want to learn more about into their mouths." *Id*.; Tr. 420:20-421:2; 423:8-11. A child may swallow the magnet either intentionally or accidentally once the magnets are in the child's mouth. Ex. CC-19A at 4.

Dr. Steinberg testified that how a child gains access to the Subject Products, whether purchased online or in a store, it does not change how a young child would interact with the product. *Id*. at 12. Dr. Steinberg explained that different packaging would not make a difference about how young children interact with the Subject Products because magnets are often "kept outside of the packaging, displayed outside of the packaging, shared without packaging, and lost or misplaced without packaging." *Id*. Moreover, even if a child saw packaging, a young child, under age 5, would be unable to read a warning or recognize from the packaging that the product posed a danger. *Id*. at 4.

Dr. Steinberg testified that he reviewed the 95 magnet ingestion incident reports and IDIs to consider the various ways children interact with the magnets, and opined that all of the children in the 95 reports interacted with the magnets in ways that were reasonable given their ages. *Id*. at 6. For example, it is reasonable and age-appropriate behavior for a 4-year-old to be unable to distinguish between candy and shiny magnetic balls, especially when the magnets are not in their packaging. *Id*.

Regarding older children, Dr. Steinberg explained that some older children may test magnetic properties of the magnets by sticking them to their braces, or they may experiment with behavior, such as facial piercing, which a caregiver may disapprove of, but perceive to be a safe way to experiment with magnets. *Id*. at 13; *see also* Ex. CC-27A at 13 (Dr. Noel testifying that older children unintentionally ingested SREMs when using SREMs as pretend jewelry and to decorate braces). Dr. Steinberg testified that older children may view this behavior as safe

[17] Dr. Steinberg, who has a Ph.D. in Developmental Psychology, is the Distinguished University Professor of Psychology at Temple University, specializing in the study of psychological development during childhood and adolescence. Direct Expert Testimony of Dr. Laurence Steinberg ("Ex. CC-19A") at 1. Complaint Counsel retained Dr. Steinberg to review the Subject Products and "give an expert opinion regarding the psychology of children and their caregivers related to the use, ingestion, and appreciation of any risk of harm posed by the Subject Products." *Id*. at 2.

because of online videos demonstrating adults and children using magnets in this way.[18] Ex. CC-19A at 13. Dr. Steinberg testified that using magnets to mimic tongue piercing is developmentally appropriate for older children. *Id.*

Dr. Steinberg also testified that it was developmentally appropriate for older children to want to share magnets with friends, but not warn friends about the dangers of magnet ingestion:

> As a child gets older and passes through puberty, their brains are developing in such a way that the immediate rewards gained from pleasing or impressing one's peers outweigh risks of hypothetical danger, if that danger is even perceived. Thus, if a child is with a peer group that is using these magnets to imitate piercing, the child is more likely to experiment himself, even if he perceives a risk of accidental ingestion. Further, the more times that a child sees someone else using the magnets as a fake piercing without incident or injury, either online, in the media or with friends, the more likely the child will believe there is no danger and engage in the practice themselves.

Id. at 14.

The injury data are consistent with Dr. Steinberg's testimony. Using the 95 incident reports and IDIs admitted into evidence, Dr. Frantz categorized the magnet ingestion incidents based on how the ingestion occurred. He was able to determine how the ingestion occurred in 55 of the 95 reports, as follows:

- 26 ingestions (47%) involved an older child mimicking a mouth piercing. The average age of children in this group was 11.5 years old, with the age range being 8-15 years old.
- 15 ingestions (27%) involved an older child accidentally swallowing magnets. The average age of children in this group was 10.3 years old, with the age range being 7-16 years old.
- 6 ingestions (11%) involved a young child intentionally swallowing a magnet. The average age of children in this group was 3.5 years old, with the age range being 2-5 years old.
- 3 ingestions (5%) involved an older child sticking magnets to braces. The average age of children in this group was 10 years old, with the age range being 8-12 years old.

[18] Complaint Counsel introduced into evidence two videos (Exs. CC-21 and CC-22) showing older children, including one celebrity, using magnets to mimic tongue piercings. Dr. Steinberg testified that the videos informed his opinion about whether older children will appreciate the risk associated with the Subject Products, concluding that "if older children see other children, especially children who are popular or are celebrities, using magnet balls in this way – that is, to simulate facial piercings – with no apparent serious injury, they are more likely to mimic that behavior themselves, regardless of the brand of the magnet balls." Ex. CC-19A at 13-14.

- 3 ingestions (5%) involved a child dividing or separating the magnets. The average age of children in this group was 9.3 years old, with the age range being 2-14 years old.
- 2 ingestions (4%) involved an older child storing or holding magnets in the mouth. The average age of children in this group was 11.5 years old, with the age range being 9-14 years old.

Ex. CC-10A at 34-36.

Based on his review of the incident reports and IDIs, Dr. Frantz concluded that young children may intentionally swallow magnets as part of their eating behavior, or they may unintentionally swallow magnets as part of mouthing things in their environment. *Id*. at 42.

Dr. Frantz concluded that older children do not intentionally swallow SREMs. *Id*. at 42. Based on his review of the incident reports and IDIs, Dr. Frantz testified that: "[t]weens and teens have reasons to put SREMs in their mouths and are especially likely to do so," and: "Eight- to 14 year olds think they can put the product in or around their mouths without swallowing it." *Id*. at 40; *see also* Ex. CC-19A at 16 (Dr. Steinberg testifying that older children may hold SREMs in their mouths or unconsciously place SREMs near their mouths while playing with the products). Moreover, "[s]wallowing comes as a surprise to tweens and teens and is described as unexpected, accidental, unwanted, and/or undesired." Ex. CC-10A at 40. Finally, "[t]weens and teens do not intend or want to swallow SREMs, nor do they mistake them for food." *Id*. Older children accidentally swallow SREMs "because the magnets moved in unexpected ways." *Id*. at 42.

d. The Nature of the Risk of Injury from SREM Ingestion by Children Is Serious and Can Be Fatal

As explained in Section I.B, *supra* pp. 2-3, SREMs, if swallowed, can cause grievous, life-altering injuries and death. Complaint Counsel's expert, Dr. R. Adam Noel,[19] explained that because of their strong magnetic properties, magnets that are ingested can stick together across loops of bowel or other tissue. Exs. CC-24 at 2; CC-27A at 7.

[19] Dr. Noel, a medical doctor specializing in pediatric gastroenterology, is an Associate Professor of Pediatrics at Baylor College of Medicine, and the Director of Endoscopy at Children's Hospital of San Antonio. Direct Expert Testimony of R. Adam Noel, M.D. ("Ex CC-27A") at 1. In addition to treating, supervising, or being personally involved in approximately 10 magnet-ingestion cases and consulting with treating physicians on at least 25 additional cases, Dr. Noel was the principal investigator for the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition ("NASPGHAN") survey, which was the largest survey at the time of the experiences of pediatric gastroenterologists in diagnosing and treating children who have ingested SREMs. *Id.* at 2, 4; *see also* NASPGHAN Paper, "Protecting Children from Magnet Ingestions" ("Ex. CC-24"). Complaint Counsel retained Dr. Noel "to review available information about the medical risks presented by SREMs," including Zen Magnets, Neoballs, and Buckyballs, and "to give independent expert medical opinions about the nature of the risk SREMs present to children, the injuries associated with ingestion of SREMs, the treatment of such injuries, and the impact of such injuries, including their cost." Ex. CC-27A at 5.

Although the Commission may find a defect even if no incidents may be attributed to the Subject Products, *see* 16 C.F.R. § 1115.4; *In re Dye*, 1989 WL 435534 at *6,[20] Complaint Counsel introduced evidence of dozens of injuries and one death associated with SREM ingestion, including two incidents involving the Subject Products.

When examining the data showing known SREM ingestions, we note that the Subject Products are functionally identical to other brands of magnet sets comprised of SREMs. CPSC mechanical engineer Vincent Amodeo testified that he evaluated Zen Magnets, Neoballs, and Buckyballs using the test method in the Toy Standard. Ex. CC-1A at 3-4; Tr. 73:16-74:2; 79:21-80:8. Mr. Amodeo opined, to a reasonable degree of scientific certainty, that Buckyballs are functionally identical to Zen Magnets and Neoballs in magnetic strength and size. Ex. CC-1A at 8. Each magnet type fits into the small parts cylinder and has a flux measurement greater than 50.[21] *Id*. at 5-7. Mr. Amodeo stated: "[t]he flux index between these magnets are [sic] similar, attraction force versus separation distance is functionally the same, and the attraction of the magnets across 1.5 cm and 2.0 cm is functionally the same." *Id*. at 8; Tr. 113:18-114:11. Mr. Amodeo further testified that beyond color, once out of the original packaging, no apparent visual differences are observable among Zen, Neoballs, and Buckyballs. Ex. CC-1A at 8; *compare* Samples of the Subject Products (Exs. CC-4, CC-4A, CC-5, CC-5(2), CC-5A) with Samples of Buckyballs (Exs. CC-6, CC-6A).

Thus, because SREMs are functionally identical, and brands are indistinguishable, the physical characteristics of SREMs that give rise to a risk of injury are shared by all brands: small, spherical, shiny, reflective, smooth, loose, separable, and strongly magnetic. The fact that SREMs outside of packaging are indistinguishable to consumers means that determining which brand of SREM led to each incident and injury is often not possible or necessary in order for the Commission to act.

The evidence clearly shows that there were two incidents in which we know specifically that the Subject Products were associated with two serious injuries. *See* Joint Notice, Compl. Counsel's Ex. J (Rivas) at ¶¶ 2-4, 11, 13-14[22] (doctors removed 14-year-old girl's colon, appendix, and part of intestines, after child ingested two magnets); Exs. CC-18.35, CC-27A at 11, and CC-30A (doctors resected several portions of 15-month-old's small bowel after toddler ingested magnets and button batteries); *see also* Exs. CC-10A at 28 (identifying two incidents

[20] The Commission considers likelihood of the risk of injury under Section 15(a)(2), regarding whether the defect creates a substantial risk of injury to the public. *See* Section III.B.3, *infra* pp. 41-42; 16 C.F.R. § 1115.12(g)(1)(iii).

[21] A summary of the test data appears in the draft Product Safety Assessments, Exs. CC-7, CC-8, and CC-9.

[22] The ALJ erred in concluding that a statement contained in this stipulated testimony was "little more than hearsay." Initial Dec. at 16, n. 5. During the administrative hearing, and at the request of the ALJ, the parties agreed to submit a Joint Notice Regarding Witness Stipulations, Dec. 8, 2014 ("Joint Notice). Tr. 808:14-18; 870:6-9; 871:22-874:3. The Joint Notice listed 11 witnesses for Complaint Counsel and 10 witnesses for Respondent. Through the Joint Notice, the parties agreed to "admit[] [the witness statements] into the record as if the witness had testified to such statements at the hearing …." Joint Notice at 1. Because neither party reserved, in the Joint Notice, the right to make hearsay objections regarding the stipulated testimony, nor raised hearsay objections with respect to this testimony at the hearing, any statements contained in the stipulated testimony that would otherwise constitute hearsay may be admitted. *Blodgett v. C.I.R.*, 394 F.3d 1030, 1040 (8th Cir. 2005).

associated with the Subject Products); CC-16 at entry 32482 (spreadsheet entry in Respondent's customer list indicating that family friend of 14-year-old girl purchased the Subject Products before the incident); Tr. 2565:3-15 (Mr. Qu testifying that he was aware of two incidents where the Subject Products were ingested).

In addition to evidence of two injuries associated specifically with the Subject Products, evidence consisting of 95 magnet ingestion incident reports and IDIs, as well as a summary of detailed clinical data on 123 ingestions, introduced through Dr. Noel, from the results of a North American Society for Pediatric Gastroenterology, Hepatology and Nutrition ("NASPGHAN") survey (the "NASPGHAN Survey"), demonstrate hundreds of incidents involving SREMs that were physically and functionally equivalent in size and magnetic strength to the Subject Products. *See* Exs. CC-18.1-18.95; CC-24 at 1.[23]

The IDIs contain two cases of particular note that demonstrate just how catastrophic injuries from SREMs can be. In the first, a 19-month-old girl died as a result of ischemic bowel from SREMs located in the small intestine ("Patient A"). Ex. CC-18.15 (autopsy report); Joint Notice, Compl. Counsel's Ex. K (Somerset) at ¶ 11 (conclusion by medical examiner who performed the autopsy on Patient A that "the cause of death was ischemic bowel due to magnet ingestion"). In the second, a 22-month-old boy also suffered ischemic bowel after ingesting at least eight magnets ("Patient B"). Exs. CC-18-27.1; CC-27A at 9. Patient B underwent several surgeries, including one in which surgeons removed most of his small intestine because of a blood clot that had developed, cutting off the blood supply to the small intestine. Exs. CC-18.27.1; CC-27A at 9.

The NASPGHAN Survey, which was published in 2012, was the largest survey at the time of the experiences of pediatric gastroenterologists in diagnosing and treating children who ingested SREMs. Ex. CC-27A at 2-3. The NASPGHAN Survey reviewed 481 reports of magnet ingestions by children spanning 10 years. Exs. CC-24 at 1; CC-27A at 2-3; Tr. 729:6-731:3. NASPGHAN members submitted detailed clinical data on 123 cases. Exs. CC-24 at 1; CC-27A at 6; Tr. 731:5-21. Of these 123 cases, the survey found that for children who had both endoscopy and surgery, 48 percent had intestinal perforation or fistula, 26 percent had deep-pressure lesions, and 5 percent had mucosal erythema (redness and inflammation) or shallow erosion (eating away of the mucosal surface). Ex. CC-27A at 7; Presentation, "NASPGHAN Neodymium Magnet Ball Ingestion Survey Results" ("Ex. CC-28") at 11.

The evidence shows that one of the reasons the injuries from SREM ingestion are so severe is because SREM ingestions are difficult to diagnose. Patients often present with nonspecific symptoms, such as nausea and fever, which parents, caregivers, and medical professionals mistake for the flu, stomach virus, or gastrointestinal infection. *See*, *e.g.*, Exs. CC-27A at 10; CC-18.15 and CC-27A at 12 (physician advised mother that Patient A, who was vomiting and lethargic, likely had a stomach virus); CC-18-27.1 and CC-27A at 9 (parents

[23] Evaluation of such evidence by experts is a sufficient basis for those experts to assess whether a product contains a design defect and to opine on the characteristics of SREMs, how consumers interact with SREMs, why children ingest SREMs, how children are injured by ingested SREMs, and to describe the risk of injury presented by SREMs to children.

believed Patient B had a stomach virus after toddler began vomiting). Young children, in particular, are difficult to diagnose because they cannot verbalize or otherwise explain that they ingested SREMs. Ex. CC-10A at 38-39. For example, in one case, when a 15-month-old girl awoke lethargic and without an appetite, and vomited juice that she drank, her mother believed the toddler had the flu. Exs. CC-18.35; CC-27A at 11. The next day, the toddler went to the hospital, where x-rays were taken, but failed to detect the presence of SREMs. Exs. CC-18.35; CC-27A 11. The medical professionals released the toddler, advising the mother to call the pediatrician the next day if the toddler was not feeling well. Exs. CC-18.35; CC-27A at 11. The next day, the mother took her daughter to the hospital, where another x-ray detected magnets and button batteries inside the toddler's intestines. Exs. CC-18.35; CC-27A at 11.

Furthermore, medical professionals are not generally aware of the medical risks that ingested SREMs present. Ex. CC-27A at 12. According to Dr. Noel, physicians and health care providers assume that magnets will behave similarly to most foreign bodies that are ingested and just pass through the digestive tract. *Id*.; Tr. 766:12-767:9. In one case, an emergency room physician sent a 14-year-old girl home who had ingested SREMs, explaining to the mother that the magnets would eventually pass. Exs. CC-18.48.1; CC-27A at 12. The girl's mother sought a second medical opinion. Exs. CC-18.48.1; CC-27A at 12. Surgeons ultimately removed the girl's appendix and part of her bowel. Exs. CC-18.48.1; CC-27A at 12.

The ALJ pointed to "misdiagnosis and improper medical care" as "significant contributing factors" in Patient A's death. Initial Dec. at 19 (Patient A "was treated after she ingested SREMs and the medical professionals released her from the hospital based on misdiagnosis"). Misdiagnosis, however, is a unique problem associated with SREMs. Tr. 766:22-767:9; Ex. CC-27A at 10-11. Unless a caregiver knows that a child has ingested SREMs, or the child can report that he or she ingested SREMs, physicians do not suspect that a child exhibiting nonspecific symptoms, such as fever and nausea, has ingested SREMs. Ex. CC-27A at 10-11; *see also* Exs. CC-18.35 and CC-27A at 11 (x-rays failed to detect presence of SREMs in 15-month-old girl who appeared lethargic and was vomiting). Additionally, Dr. Frantz testified that, based upon the incident reports he reviewed, young children "generally did not or could not" report they had ingested SREMs. Ex. CC-10A at 38-39. Notably, the ALJ recognized the difficulty in diagnosing a SREM ingestion, stating later in the opinion that magnets "become dangerous when ingested because of their propensity to cause intestinal pinching, something medical professionals, let alone the average consumer, would not realize." Initial Dec. at 24.

The treatment required for SREM ingestion differs from ingestion of other foreign objects. Generally speaking, most foreign bodies that are ingested pass through the digestive system. Tr. 739:7-18; Ex. CC-27A at 7. Magnets, however, are unique because they can cause injury throughout the bowel. Tr. 739:19-21. Because physicians do not know where the magnets will stick together, physicians try to remove the magnets as early as possible. Tr. 739:19-740:3. Consequently, the surgical intervention rate for SREM ingestions greatly exceeds the intervention rate for most other foreign body ingestions. Tr. 656:15-18; 740:5-742:20; Ex. CC-27A at 12. While the surgical intervention rate for other foreign objects ranges between 10

and 20 percent, the intervention rate for SREM ingestions is 79 percent. Tr. 741:6-16; Ex. CC-27A at 6, 12-13.

If a child ingests at least two SREMs, close monitoring, usually by multiple x-rays or body scans, is necessary to determine whether the SREMs have connected to each other through tissue. Ex. CC-27A at 8. If SREMs become lodged in the digestive tract, intervention, usually through endoscopy, colonoscopy, or abdominal surgery, is necessary. *Id.* The NASPGHAN Survey found that of the 123 SREM ingestion cases with detailed clinical data, 52 percent resulted in an endoscopy and 27 percent involved surgery (6 percent involved only surgery and 21 percent involved both endoscopy and surgery). Tr. 705:6-10; Exs. CC-27A at 6; CC-28 at 8.[24] In some cases, intervention was necessary not just to remove the magnets, but to repair or remove damaged or dead tissue. Exs. CC-18-27.1 and CC-27A at 9 (most of Patient B's small intestine removed and ostomy (artificial bowel opening) created to remove stool from body); CC-27A at 11 and CC-31 (9-year-old boy's appendix and portions of small and large intestines removed); CC-27A at 11 and CC-30 (several portions of 15-month-old's small bowel were resected to repair tissue damage); Exs. CC-18.48.1 and CC-27A at 12 (14-year-old girl's appendix and part of bowel removed).

Invasive procedures to remove SREMs present potential complications as well, including infection, postoperative inflammation, and tissue injury. Exs. CC-27A at 8, 13; CC-32 (10-year-old girl suffered respiratory distress after fluid that medical professionals introduced to help pass the magnets from her digestive tract went into her lungs). Although generally considered safe, endoscopy has associated risks, including intestinal bleeding, infection or perforation of the gastrointestinal tract, and risks associated with sedation and/or general anesthesia. Tr. 743:22-744:20; Ex. CC-27A at 8. Multiple x-rays and CAT scans also present risks. Tr. 629:10-17; Ex. CC-27A at 8.

In addition to the acute injuries, some children described in the IDIs will clearly have long-term care requirements and are at risk of future health complications as a result of swallowing SREMs. For example, Patient B will require a colostomy bag to remove stool from his young body until he receives a bowel transplant, which may not be for years. Exs. CC-18.27.1; CC-27A at 9-10. In addition, Patient B is at risk of systemic infection from the intravenous nutrition he receives, and he is at long-term risk of liver damage. Exs. CC-18.27.1; CC-27A at 10. In another case, the 15-month-old girl who swallowed magnets and button batteries is at risk of bowel-related problems and intestinal adhesions. Ex. CC-27A at 11.

Treatment costs associated with SREM ingestions may be "high and even catastrophic." CC-27A at 14. X-rays and multiple CAT images cost several thousand dollars, and an endoscopy costs at least $2,000, excluding the costs of x-ray or CAT imaging. *Id.* If surgery is required, the costs of diagnosis, surgery, and treatment can exceed $75,000. *Id.* Long hospital stays can cost several hundred thousand dollars, and "difficult cases" can cost millions of dollars. *Id.*

[24] Twenty-one percent of the cases involved no invasive medical intervention. Exs. CC-27A at 6; CC-28 at 8.

Finally, the ALJ's conclusion that lack of parental supervision contributes to the risk of injury associated with SREMs (Initial Dec. at 18-19) is both unsupported by the evidence and completely irrelevant to whether children swallowing SREMs constitutes a reasonably foreseeable misuse of the Subject Products.[25]

Dr. Steinberg testified that it was reasonable for parents of children who ingested SREMs not to suspect that the magnets were dangerous. Ex. CC-19A at 9-11, 17 (testifying that the parents had never seen SREMs before, the magnets were not accompanied with any warnings or packaging, and the magnets looked like a toy and could be used to create jewelry). Dr. Steinberg also testified that because "[i]t only takes a few seconds for a child to find and put one of these small magnet balls in their mouths and swallow," "[a] caregiver acting with reasonable care even [sic] may not even see the child put the magnet in his mouth." *Id.* at 8.

Regarding older children, Dr. Steinberg explained that a caregiver acting with reasonable care would not believe that an older child would intentionally ingest SREMs. *Id.* at 17. Dr. Steinberg stated: "[a] reasonable caregiver is unlikely to contemplate that her child will engage in behavior such as mimicking piercing or sticking magnets to braces." *Id.* at 18. Thus, according to Dr. Steinberg, a caregiver would not believe it was necessary to warn older children against engaging in this behavior. *Id.*

Dr. Steinberg concluded:

> [A] caregiver may have no reason to suspect that a child would have access to the magnets. Magnets from the Subject Products are easily separated, easily hidden, and easily shared. In my opinion, no amount of reasonable vigilance from a caregiver is likely to prevent a child from gaining access to the Subject Product and hiding such access from a caregiver.
>
> *Id.*

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[25] The ALJ concluded that the risk of injury from SREM ingestion was "significant" when there was a lack of parental supervision based on unsworn police notes in the case file of Patient A. Initial Dec. at 18-20. Yet, the evidence demonstrates that Patient A died from ingesting SREMs. The medical examiner who performed the autopsy on Patient A concluded: "the only explanation for [Patient A's] death was ischemic bowel due to spherical magnets in the small intestine" and "the manner of death was accidental." Joint Notice, Compl. Counsel's Ex. K (Somerset) at ¶ 11.

Nothing in the record demonstrates that Patient A's parent knew of the risks that SREMs pose to children if ingested. The parent explained that the magnets, which were not in any packaging, did not have any warnings or instructions. Joint Notice, Compl. Counsel's Ex. E (Chaffin) at ¶ 4. In addition, Dr. Steinberg concluded that it was reasonable for Patient A's parent to permit the SREMs to come into the home because the SREMs were not labeled, lacked warnings, appeared harmless, and appeared to be a toy. Ex. CC-19A at 10.

We specifically set aside the ALJ's findings that Patient A's parent was "a more than negligent parent" (Initial Dec. at 19) and that "Patient A's exposure to an insecticide demonstrates a lack of basic custodial supervision, which very likely could have prevented SREM ingestion in the first place" (*id.* at 19) because these conclusions are irrelevant to the Commission's defect determination (*see* Section III.A.1.a, *supra* pp. 9-10) and are not supported by the facts in this case.

Taken together, the 95 incident reports and IDIs, the NASPGHAN Survey, and the testimony of Dr. Noel, demonstrate the catastrophic nature of the risk that swallowing one magnet and a metal object, or two magnets present.[26] Complaint Counsel have met their burden to demonstrate that the characteristics of the Subject Products as loose, small, spherical, high-flux SREMs that can separate from their set creates an ingestion hazard to children, and children can be and have been seriously injured or died from ingesting SREMs.

e. Children Are the Population Exposed to the Product and its Risk of Injury

The Commission's regulation at 16 C.F.R. § 1115.4 states one factor that may be used in a defect analysis is "the population exposed to the product and its risk of injury." The ALJ seems to have interpreted these words as requiring a quantifying analysis of the number of people exposed to the product and possible injury, concluding that the number of individuals exposed to the risk of injury was small in comparison to the number of people exposed to the product. Initial Dec. at 23-24. Once again, the ALJ's erroneous exclusion from consideration of reasonably foreseeable misuse of the Subject Products tainted his analysis and conclusion as to the population exposed. The ALJ stated: "[b]ecause risk of injury can only happen by first inserting SREMs into the consumer's mouth, … the population exposed to the product's risk of injury [is] too amorphous due to extraneous, particularized factors, *i.e.*, age, intelligence, carelessness, and education." *Id*. at 23. The ALJ found that no single individual or group of individuals is "constantly subjected to the product's risk of injury simply because not all individuals, no matter the age, will ingest the product." *Id*. Reviewing the National Electronic Injury Surveillance System ("NEISS") estimates submitted by Complaint Counsel, the ALJ stated: "[t]hese numbers are insignificant to show any specific, identifiable population, particularly given the mass amount of magnets purchased and already on the market." *Id*.

The ALJ's conclusion demonstrates not only his continuing misunderstanding of the role of reasonably foreseeable misuse in finding a product defect, but, also, his fundamental misunderstanding of how the Commission considers the population exposed to the risk of injury when determining whether a product defect exists. Quantitative risk analysis — meaning the number of injuries compared to the number of products sold — is not required to prove a defect in a Section 15 case. Instead of a quantitative analysis of the population exposed, the Commission, in this instance looks at the characteristics of the population exposed to the risk of injury. After reviewing the evidence, we find that children, a vulnerable population, are overwhelmingly the people exposed to the risk of injury presented by the Subject Products. Accordingly, the population exposed to the product's risk of injury is not, as the ALJ would have us believe, "difficult to identify"; nor is it "too amorphous due to extraneous, particularized factors, *i.e.*, age, intelligence, carelessness, and education." Initial Dec. at 23. Nothing in the evidence suggests that the children who swallow magnets are less intelligent, careless, or

[26] The ALJ wrongly believed that an evaluation of the nature of the risk of injury includes not just an analysis of the kind of injury associated with ingestion, but also proper use versus improper use. Initial Dec. at 17. Additionally, the ALJ's consideration of mitigating circumstances, such as misdiagnosis and lack of parental supervision, are not contemplated under the statute or the Commission's regulation, and are not supported by the facts.

uneducated, than other children.[27] In fact, Dr. Steinberg's testimony was that children who swallowed magnets were engaged in age-appropriate behavior. *See* Section III.A.2.c, *supra* pp. 20-21.

Both parties and the ALJ agree that ingested SREMs present a serious risk of injury to children. Initial Dec. at 17; Appeal at 41; Answer Br. at 24. As set forth above, those injuries can be catastrophic. Section III.A.2.d, *supra* pp. 22-26.

The following evidence clearly demonstrates that the population at risk of injury from the Subject Products is children:

(1) A CPSC staff memorandum summarizing magnet set incidents included in NEISS, as well as CPSC's anecdotal data, "Update on NEISS estimates and reported incidents related to ingestion of magnets from high-powered magnet sets," dated June 25, 2014, Ex. CC-39 ("Magnet Incident Memo"),[28] which found that the largest proportion of emergency department-treated, magnet-related ingestions is in the 4 to 12 year-old age group and that 66 of the 84 Consumer Product Safety Risk Management System ("CPSRMS") reports involved children 12 or younger. Ex. CC-39 at 9 (Table 6);

(2) 95 magnet ingestion incident reports and IDIs, which were conducted in response to reports of incidents involving magnet ingestions, as well as expert analysis of these documents. Exhibits CC-18.1-18.95 demonstrate an incident age range of 1 to 16 years old, with a spike in young children (2 – 4 years old) and older children (9 – 13 years old). Ex. CC-10A at 29; and

[27] We note that the NASPGHAN Survey demonstrated that 5 percent of the incidents occurred in patients with a psychiatric disorder, and 12 percent of the incidents involved a patient with a developmental disorder. CC-28 at slide 6. Neither psychiatric disorder nor developmental disorder is correlated in the evidence as a factor influencing intelligence, carelessness, or education level. Intelligence, carelessness, and education appear to be criteria adopted by the ALJ without a tie to the evidence submitted at the hearing.

[28] During the administrative hearing in 2014, the ALJ admitted the Magnet Incident Memo as evidence in this case. Tr. 912:12-913:6. The Associate Executive Director, Directorate for Epidemiology, testified about the information contained in this memorandum during the hearing, stating that a high degree of confidence and certainty exists as to the accuracy in the NEISS projections for magnet incidents. Tr. 913:8-923:4; 961:16-963:8. After conclusion of the administrative hearing in December 2014, Respondent challenged the Commission's Final Rule: Safety Standard for Magnet Sets, 79 *Fed. Reg*. 59,962, 59,964 (Oct. 3, 2014) ("Final Rule for Magnet Sets"). On November 22, 2016, the U.S. Court of Appeals for the Tenth Circuit vacated and remanded the agency's Final Rule for Magnet Sets, stating that the Commission's factual findings supporting the rule, namely certain NEISS data projections, were "incomplete and inadequately explained." *Zen Magnets, LLC v. CPSC*, 841 F.3d 1141, 1144 (10th Cir. 2016) ("Tenth Circuit Decision"). Accordingly, out of an abundance of caution in light of the Tenth Circuit Decision, the Commission will not rely on NEISS data and the Magnet Incident Memo for injury estimates, but will consider the information as instructive regarding the population exposed to the risk of injury from magnet ingestions.

(3) The NASPGHAN Survey conducted by Dr. Noel, which reviewed 481 reports of magnet ingestions by children over a ten year period, and involved detailed clinical data on 123 SREM ingestions, corroborating the risk of injury to two distinct groups of children. Ex. CC-24 at 1. These data demonstrate that children between the ages of 13 months and 6 years old account for just more than 50 percent of the incidents in the Survey and are at the highest risk of ingestion, but that "a significant population of older children and adolescents" also ingest magnets. *Id*. *See also* Ex. CC-28 at slide 4 (demonstrating incident spikes in the 3 to 6 year-old and 9 to 12 year-old age groups).

In addition, as set forth on pages 20-23 of this Final Decision and Order, Dr. Steinberg provided expert testimony concerning the perfectly age-appropriate conduct that puts two distinct age groups (under 5 and between 9 and 13) at risk of injury from the Subject Products. Dr. Frantz, who also reviewed the 95 incident reports and IDIs, testified consistently with Dr. Steinberg that SREM injuries are unique in that a spike in injuries occurs in these two age groups of children. Exs. CC-10A at 29; CC-11 at 36, 47-48; Tr. 373:20-374:11.

f. The Risk of Injury from Ingesting SREMs Is Not Obvious to Children, Caregivers, or Health Professionals

Based on the evidence in the record demonstrating that children, caregivers, and even medical professionals do not appreciate the risk of injury, and Respondent's admission that ingestion is a "hidden risk" associated with magnet sets, the Commission finds that the risk of injury presented by magnet sets is not obvious to consumers. Exs. CC-10A at 4; CC-11 at 7; CC-19A at 4, 11, 13-14, 17; CC-27A at 12; Tr. 766:16-767:9; Answer Br. at 29.

The Commission agrees with the ALJ's finding that ingesting SREMs is dangerous and that "a consumer is not likely to appreciate the full magnitude of the risk associated with SREM ingestion if the product is separated from its packaging and warnings." Initial Dec. at 24. The ALJ stated that magnets "are not mere choking hazards (if at all), but become dangerous when ingested because of their propensity to cause intestinal pinching, something medical professionals, let alone the average consumer, would not realize." *Id*. The ALJ concluded, however, that "warnings adequately address the issue with consumers." *Id.* The ALJ found that without warnings, the obviousness of the risk is low, concluding that this factor weighs in favor of finding a substantial product hazard. *Id*. As discussed below, the record does not support the ALJ's conclusion that warnings mitigate the risk of injury in this case; however, we agree that the hazard is not obvious to consumers and also that this factor weighs in favor of finding the Subject Products defective.

g. Warnings Cannot Mitigate the Risk of Injury Associated with the Subject Products

The ALJ found that *ingestion* of loose or separated magnets is the risk, and that because Respondent warned against ingestion, Respondent's warnings were sufficient. *Id.* at 14-15.

Respondent concedes that the risk of injury is not obvious, but states that "when an otherwise hidden risk is identified and highlighted" by warning statements, it is "only logical" that such risk becomes "better known and apparent." Answer Br. at 28-29. Respondent maintains that the ALJ "correctly found" that the Subject Products' warnings increase the awareness of the risk associated with ingesting SREMs. *Id.* at 28. Respondent also cites "the lack of credible evidence" that the Subject Products have caused injury, and the lack of evidence that SREMs "pose a significant risk of injury given the number of products on the market," as supporting the ALJ's statement that warnings help to mitigate the risk of injury associated with magnets that consumers may not fully appreciate. *Id.* at 29.

We are not persuaded by Respondent's arguments and the ALJ's finding that Respondent's warnings, in particular, sufficiently mitigated the risk of injury presented by the Subject Products. The ALJ completely ignored evidence demonstrating the fact that the risk of injury occurs when magnets are separated from their set, so that even the best warning is unlikely to be seen by the user. The evidence demonstrates that, regardless of the warning content, Respondent's warnings are defective because warnings that are never seen, cannot be read, or that are not understood or heeded, cannot mitigate the risk of injury associated with SREMs.

i. Warning Label Limitations

The evidence demonstrates that no warning could mitigate the risk of injury associated with the Subject Products.

Any warning must be placed on the packaging as the Subject Products are too small to place a warning on each individual magnet. Tr. 382:3-10; Ex. CC-11 at 53. Moreover, even the warnings placed on packaging do not accompany individual magnets that are lost, found, or shared. Product packaging is often discarded, misplaced, or, if kept, is not used to store the Subject Products when not in use.[29] Ex. CC-19A at 4, 10, 12; *see also In re Dye*, 1989 WL

[29] The evidence also demonstrates that even when packaging is retained, traditional warnings, such as "seek immediate medical attention if swallowed," are not effective for the Subject Products due to the following unique medical implications of magnet ingestion:

- Caregivers do not detect an ingestion episode because children do not choke on SREMs and there are no immediate symptoms when a child accidentally or intentionally swallows SREMs that have been separated from the set.
- Toddlers who ingest SREMs cannot tell their caregivers what they ingested, and older children may not tell their caregivers either.
- A child who ingests SREMs requires an abdominal x-ray as soon as possible, yet common medical rules for treating ingestions of foreign bodies do not suggest this medical response.
- Medical specialists have developed a specific treatment regimen for SREM ingestions that hinges on knowledge that SREMs were ingested in the first place.

Ex. CC-10A at 4, 39. Thus, according to Dr. Frantz, the health risks associated with SREM ingestion present practical challenges for warnings because such warnings presume: (1) detection of the swallowing event and (2) the presence of immediate symptoms, neither of which is obvious with respect to an episode of magnet ingestion. *Id*. at 4. In *In re Dye*, this factor was important because the experience of consumers with other, similar products was that those products did not present an electrocution hazard. 1989 WL 435534 at *8.

435534 at *8 (warning label likely discarded). Structures created with SREMs may be placed on display, and not dismantled and returned to packaging. Ex. CC-19A at 4, 12.

The risk of injury to children increases when magnets are separated from their set, such as when magnets are lost, found, or shared. Exs. CC-10A at 42; CC-11 at 48. Injury data show that toddlers through preschool-age children have gained access to SREMs as a result of someone else losing SREMs or because SREMs have separated from their sets. Ex. CC-11 at 48. Older children may receive subsets of magnet sets from their peers. *Id*.; *see also* CC-10A at 40.

Dr. Frantz reviewed the 95 magnet ingestion incident reports and IDIs provided by Complaint Counsel, as described at Section III.A.2.b, *supra* p. 17 (citing CC-10A at 29-31; CC-11 at 34-42). Of the 51 reports that had sufficient data to determine SREM access, 69 percent of the children would not have seen a warning because they obtained SREMs from a friend, found a lost SREM, or found SREMs that had not been stored. Ex. CC-10A at 30-31. Dr. Frantz also provided an age histogram of all 95 incidents, finding that 37 of the incidents involved children 5 and younger, approximately 39 percent of the incidents. Ex. CC-10A at 29-30; Tr. 263:3-19. Moreover, the NASPGHAN Survey data showed that children 13 months to 6 years old accounted for more than 50 percent of the incidents in that Survey. Section III.A.2.e, *supra* p. 30. We note that children this young likely cannot yet read or comprehend a warning, even if present. Ex. CC-10A at 29.

Regarding caregivers, Dr. Steinberg explained that it is reasonable for caregivers of young children, who see warnings regarding SREM ingestion, to discount those warnings. Caregivers may believe that a young child will not be able to access SREMs that are located in a drawer or in another room. Ex. CC-19A at 11. Caregivers of young children also may conclude that any warning pertains to a choking hazard, which they may discount due to the small size of the SREMs. *Id*. Dr. Steinberg stated that caregivers of older children do not heed warnings, believing that their tween or teen is old enough to know not to intentionally swallow SREMs. *Id.* at 17.

Thus, the evidence demonstrates that even if Respondent had the best possible warning label, many consumers do not see, heed, or are unable to read the warning labels.[30] This experience is consistent with the Commission's experience with warning labels. For example, in *In re Dye*, the Commission concluded that even if the respondents improved their instructions to address all of the deficiencies, the substantial product hazard would not be eliminated in the electrified worm probes. 1989 WL 435534 at *19-20. Therefore, the Commission concluded that no warning could cure the substantial product hazard presented by the worm probes. *Id*. at

[30] The NCPS likewise acknowledged these limitations with warnings when it stated:

> A manufacturer's duty does not end with a well drafted warning, especially when he knows it may not prevent injuries. Printed warnings and instructions offer slight protection to young children or those unable to read. If a manufacturer is permitted to avoid liability by providing a warning when he might instead use a less risky design or system of distribution, the warning may become a license for ill practice.

NCPS Report at 75 (internal footnotes omitted).

*20. Similarly, in *Mylar Star Kites*, the ALJ, in rendering the Initial Decision and Order, found that even with adequate instructions, the risk of injury associated with the aluminized kites would not be mitigated, and that the only sure way to cure the defect was to order the removal of the conductive material. *Mylar Star Kites* Initial Dec. at 11 ("There is no guarantee that adequate instructions against flying kites near power lines will invariably be obeyed, even by adults.").

Furthermore, the warnings Respondent included with the Subject Products were unlikely to convey the seriousness of the associated injuries, as Respondent used unconventional, tongue-in-cheek, warnings. Ex. CC-10A at 46. Mr. Qu testified that he drafted the warnings to be "unique," "interesting," and "memorable," to explain his rationale for using unconventional warnings for the Subject Products. Tr. 1979:15-17. Instead of addressing the actual hazard associated with magnets — unintentional swallowing — Respondent pokes fun at the system of age-grading by suggesting that magnets are safe when a child stops eating non-foods, which results in a confusing and contradictory warnings approach. Ex. CC-10A at 35, 46. In *In re Dye*, respondent's warnings also used tongue-in-cheek warnings that presented "inconsistent and confusing messages," were found to "trivialize" and "detract" from the seriousness of the risk, and, most importantly, "impl[ied] that the [respondent] does not believe the warnings are necessary." 1989 WL 435534 at *8.

Respondent argues that even though ingestion of SREMs is a hazard, magnets can be kept away from children. Answer Br. at 10-12; Oral Arg. Tr. 82:17-20. However, the evidence demonstrates that a warning to "keep away from children" is ineffective for the Subject Products, because such a warning cannot be followed by consumers exercising ordinary care. Ex. CC-10A at 9, 44-45. Magnets have unique characteristics — magnets are "so easily separated from their sets" — that make it impossible for owners to follow the basic warning message that would be necessary for the product to be considered safe, *i.e.*, to actually keep magnets away from children, consumers must never lose or share magnets. *Id.* at 9-10; Ex. CC-11 at 49-50. As demonstrated in Dr. Frantz's testimony, including during questioning by the ALJ,[31] consumers exercising ordinary care could not keep magnets away from children or avoid losing or sharing magnets, even if they were warned not to. Ex. CC-10A at 10, 20.

[31] PRESIDING JUDGE: [I]f those caregivers responsible for infants were made aware of the dangers of magnets and also aware that small rare earth magnets can cause the type of damage that you have indicated, would you expect those caregivers to be able to prevent the children from ingesting magnets?

THE WITNESS: No. I think that they can prevent some of the things . . . [t]he difference is that you can provide a warning about knowing where magnets are, keeping track of them and giving them to someone. That's not what I'm talking about. What I'm talking about is having a product where you accept, expect, and accommodate the fact that you will not know where they are. They have separated from the set in a completely unremarkable way, and now they have contaminated a place where small children are or will be, and that becomes an unmanageable risk, even for careful parents.

Tr. 398:12-399:17 (excerpted).

According to Dr. Frantz, this would be true even if the product was sold to adults and not labeled as a toy. Tr. 369:9-22 ("Because of the containment problem associated with the loose magnets and the fact that there's no expectation that people will be able to keep track of each and every magnet in their set as long as they own it.").

Dr. Frantz provided ample testimony indicating that no warning could cure the hazard presented by the defective design of the magnets. *See, e.g.*, Tr. 251:18-252:5; 368:7-369:14; 383:9-384:5; *see also* Ex. CC-10A at 46 (does not know of a warning that addresses "reasonably keeping separated [magnets] away from children"); *see also In re Dye*, 1989 WL 435534 at *8 (holding that improved warnings and instructions could not cure the dangerous design of the worm probes).

Respondent did not offer rebuttal or other expert testimony to demonstrate the efficacy of its warning statements to change consumer behavior. Respondent, instead, relied on the cross-examination of Dr. Frantz over the course of approximately 2 days of the hearing, primarily criticizing Dr. Frantz's testimony regarding the frequency of lost magnets and the availability of spare magnets. Tr. 152:10-205:3; 260:1-331:16.

For these reasons, we find that warnings are inadequate to mitigate the risk of injury associated with the Subject Products.

ii. Injury Data

In finding that Respondent's warnings are not defective, the ALJ started with his flawed analysis of the injury data discussed in Section III.A.2.d, *supra* pp. 23-27, stating that he believed that few or no injuries could be directly attributed to the Subject Products, and concluding that the only explanation could be that Respondent's warnings are effective at adequately warning consumers about the ingestion hazard. Initial Dec. at 16. ("It is a more than reasonable inference that little evidence exists of injury resulting from the use of Respondent's product because Respondent's warnings sufficiently deter ingestion.").[32] The ALJ tried to draw comparisons between Buckyballs' lack of warnings and attributable incidents, and Respondent's affirmative warnings concerning the ingestion hazard and relative absence of incidents. *Id.* at 25. The ALJ inferred a correlation between the use of warnings and their efficacy on preventing ingestion incidents; conversely, the absence of warnings resulted in increased incidents. *Id.* Yet, neither party presented actual evidence concerning what conclusions, if any, could be drawn from these data.

As discussed above, no incidents are necessary in a defect analysis, and here, hundreds of incidents were introduced into evidence, most of which involved SREMs with no known brand name. Furthermore, Respondent did not submit any evidence to support the ALJ's conclusion that Respondent's warnings were effective.

[32] We do not believe this was a reasonable inference because the evidence demonstrates that SREMs cannot be identified by manufacturer after they are removed from packaging. Ex. CC-1A at 8. Thus, we do not know exactly how many incidents are attributable to the Subject Products; however, the evidence demonstrates that at least two of the 95 incidents admitted into evidence are attributable to the Subject Products. *See* Section III.A.2.d, *supra* pp. 23-24.

3. Step 2: The Risk of Injury Outweighs the Utility of the Subject Products

Next, we balance the risk of injury associated with the Subject Products with the utility of the Subject Products.[33]

The ALJ determined, and the Commission agrees, that the feature of the Subject Products that creates the risk, that is, the attractiveness of SREMs to each other, is the "sine qua non of their essence." Initial Dec. at 11. The ALJ further stated: "[w]ithout the ability to attract to each other, the product is worthless." *Id*. In these circumstances, the Commission must "examine the evidence in the record to see if it establishes that the utility to the public of … [the product] outweighs the risk to the public that the product produces."[34] *In re Dye*, 1989 WL 435534 at *9, 11.[35]

a. The Subject Products are Not a Necessity for Consumers

The ALJ failed to consider the issue of the necessity, or lack thereof, for the Subject Products. 16 C.F.R. § 1115.4. The regulation and precedent provide little guidance on what constitutes a "necessity." Meriam-Webster's online dictionary defines a "necessity" as "the quality or state of being necessary."[36] "Necessary" is defined, in relevant part, as "absolutely needed," "required."[37]

Respondent demonstrated that the Subject Products are useful to certain academic users who are acquainted with SREMs. Respondent presented witnesses who testified that the Subject Products can be manipulated into a variety of structures that cannot be built with fixed-angle objects, and that such hands-on manipulation allows students to conceptualize ideas that are difficult to understand through traditional teaching methods, such as in a book or a diagram. Tr. 1333:4-19; 1427:1-1428:1; 1429:9-12; Direct Testimony Respondent's Expert Witness Boyd F. Edwards, Ph.D. ("Ex. R-154A") at 8-9; Ex. R-155 at 16-18; Joint Notice, Resp't's Exs. P (Love); S (Niezgoda); U (Walsh).

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[33] With the exceptions of necessity and utility, we considered other applicable factors from § 1115.4 in Step 1 of our defect analysis; thus, we will not re-analyze those factors at this stage.

[34] We note that even before § 1115.4 was promulgated, the Commission addressed the risk-versus-utility balancing. In 1977, in *Mylar Star Kites*, the Commission balanced the nature and severity of the risk of injury with any offsetting benefit to the public. *Mylar Star Kites* Final Dec. at 3. Because the kite's aluminum surface only added to the beauty of the kite, and did not contribute to the kite's function, the Commission concluded "that because of the nature and severity of the risk without an offsetting benefit sufficient to justify the risk," the kite would present a substantial product hazard if the proceeding occurred under the CPSA. *Id*.

[35] In *In re Dye*, the Commission clarified that when the risk of injury does not arise from a product characteristic that is necessary for the product to function, balancing the risk of injury with the product's utility is not necessary. 1989 WL 435534 at *9. In that instance, the product characteristic can be modified to remove the defect without changing the utility of the product. *Id*.

[36] Dictionary by Merriam-Webster, https://www merriam-webster.com/dictionary/necessity (last visited Oct. 24, 2017).

[37] Dictionary by Merriam-Webster, https://www.merriam-webster.com/dictionary/necessary (last visited Oct. 24, 2017).

However, Dr. Edwards testified that he taught physics for 24 years before learning about the existence of SREMs and admitted that SREMs are not critical for teaching physics or any other subject. Tr. 1258:6-9; 1260:10-15; 1401:14-1402:2. Indeed, for more than 20 years, Dr. Edwards managed to teach physics, and his students managed to learn various concepts, without the use of SREMs. Tr. 1401:14-1402:14. Dr. Edwards also admitted that concepts that have been around for more than 3,000 years, such as platonic solids, were understood and taught before SREMs were available. Tr. 1403:14-18. We also note that Respondent did not present evidence on the number of professors and teachers currently using SREMs in their classrooms. Dr. Edwards stated that he was aware of "two instances" in which SREMs were part of a course plan. Tr. 1422:1-15. He also acknowledged that "in the majority of classes [SREMs] are not used." Tr. 1423:1-5.

After considering all of the evidence, we find that the Subject Products do not constitute a necessity. Although this evidence demonstrates that the Subject Products may have educational value, the evidence does not prove that the Subject Products are a "necessity" under the common usage of the term. *Cf.* Tr. 2210:18-21 (Mr. Qu acknowledging that the Subject Products "are not a necessity in the same sense that water or food or shelter is a necessity").

b. Utility of the Subject Products

Section 1115.4 does not provide a definition of "utility" in the context of a Section 15 case. However, *In re Dye* states that the risk-versus-utility balancing examines "the need of the public for the product," against "the risk the product presents." 1989 WL 435534 at *9; *see also id.* at *12 (staff defining utility as "the ability to supply a consumer want").

The record shows that the Subject Products are modestly priced manipulative toys that are generally available to consumers online, in specialty retail shops, and in head shops and marijuana dispensaries. CC Post Hr'g Arg., Ex. A, ¶¶ 36, 38, 40; Tr. 1543:12-14; 1717:14-1718:6; 1734:15-1735:5. Neither party submitted evidence of market share for recreational, educational, or scientific uses of the Subject Products. Accordingly, beyond price, the Commission must consider the public's need for the product, based solely on the facts presented.

The record demonstrates two groups who use SREMs for different purposes: recreational users involved in play, and academic users involved in teaching and research. Regarding recreational users involved in play, Complaint Counsel demonstrated how the Subject Products were marketed and used by consumers as a manipulative toy for recreation and amusement. *See* Exs. CC-10A at 10-16 and CC-11 at 12-16 (discussing Dr. Frantz's review of Respondent's marketing of the Subject Products as a manipulative toy, jewelry, and refrigerator art). Based on the price and use of the Subject Products for recreation and amusement, the value to consumers is low.

Respondent did not prove that the average consumer has a great need for the Subject Products as a recreational "desk toy." Respondent's witnesses did not testify about the play value of the Subject Products to the average consumer; rather, some witnesses testified that the

general use of SREMs encouraged interest in math and science. Joint Notice, Resp't's Exs. L. (Bayless); Ex. N. (Ibrahim). For example, Ms. Bayless testified that the use of Zen Magnets "fueled [her] four sons' interest in careers in math and science." *Id.*, Ex. L. This anecdotal evidence suggests that the general availability of SREMs to the public has the potential to enhance interest in math and science in those who use them. However, evidence regarding the marketing of the Subject Products to the general public for use as a manipulative toy, jewelry, and refrigerator art, and the availability of the Subject Products in "head shops" and marijuana dispensaries, does not suggest that the average consumer is purchasing the Subject Products for use in math and science.

Respondent presented evidence that SREMs may have a greater utility for academic users who teach, study, and conduct research in the fields of physics, chemistry, metallurgy, engineering, geometry, biology, and mathematics. Ex. R-154A at 5. The testimony presented by Dr. Edwards, and the written stipulated testimony of lay witnesses, demonstrate that those teachers and academics who are acquainted with SREMs find them a superior teaching aid than other products on the market and useful for understanding and researching scientific concepts. Several witnesses, including Dr. Edwards, Dr. Anthony Pelletier, Michele LaForge, Adam Love, and Stephen Niezgoda, concluded that SREMs are superior to other methods of teaching certain concepts because they provide hands-on learning opportunities and are capable of forming structures that other models cannot. Tr. 1333:4-19; 1427:1-1428:1; 1429:9-12; 1431:16-1432:5; Exs. R-154A at 8-9; R-155 at 16-18; Joint Notice, Respt's Exs. O (LaForge); P (Love); S (Niezgoda); T (Pelletier).

Respondent did not, however, present evidence showing that SREMs are routinely used for any of these educational purposes. For example, Dr. Pelletier was not aware of other teachers who used SREMs. Joint Notice, Resp't's Ex. T at 68:16-19. Dr. Edwards testified that he could reasonably foresee a trend to use SREMs in college classes, based on the enthusiasm of his friends; but he admitted that SREMs are not widely used in college classes now. Tr. 1422:1-15 (aware of only "two instances" in which SREMs were part of a course plan); 1426:14-1428:1. Dr. Edwards testified that SREMs would be useful in upper-level undergraduate courses to teach electromagnetism, but he said they would not be useful in advanced graduate-level courses, which are "purely theoretical." Tr. 1423:1-1424:10. Moreover, Dr. Edwards never used SREMs to teach physics in his more than 20 years of teaching. Tr. 1401:14-1402:14. Dr. Edwards also testified that other teaching methods exist, and that students have learned the scientific concepts without using SREMs. Tr. 1402:3-14. For example, platonic solids have been taught and understood for more than 3,000 years without the use of SREMs. Tr. 1403:14-18.

The ALJ agreed with Respondent that "'no other medium can replicate the unique spherical and magnetic properties of [SREMs], and therefore no other alternative can be used to demonstrate the same concepts with the same effectiveness.'" Initial Dec. at 22. Additionally, the ALJ found that "simply because SREMs are not yet in widespread use in academia does not decrease utility, or their viability for use in teaching" because it can take several years to change a course syllabus. *Id*. at 21 n.8 (citing Tr. 1435:5-14).

The ALJ concluded that the Subject Products have "high" utility because the Subject Products are "unique because they can be connected at almost any angle" and are "excellent" tools for teaching various subjects, including physics, geometry, and chemistry. *Id*. at 20-21. However, the record is devoid of information regarding the specific, market breakdown of each user type. Although the evidence shows that academic users *who have experience with SREMs* find them useful, the record does not demonstrate widespread use of the Subject Products by academic users or a trend of increased use in academic settings. Regardless, the Commission generally regulates consumer products to consumers as a whole, and not to specific groups of users.[38]

c. Balancing the Utility of the Subject Products with the Risk of Injury

Balancing the limited value of the product to consumers against the risk of injury, and considering the factors discussed at Sections III.A.2 and 3, we conclude that the risk of injury far outweighs the utility of the Subject Products to recreational users.[39] Furthermore, balancing the value of the Subject Products for use in educational pursuits by a select group of users against the risk of injury, and considering the factors discussed, we conclude that the risk of injury also outweighs the utility of the Subject Products to academic users. All of the factors reviewed above weigh in favor of finding a defect in this case. Accordingly, based on the evidence presented, the Commission finds that the Subject Products contain a design defect, and also finds that the utility of the Subject Products does not outweigh the risk of injury to children.

B. The Subject Products Contain a Defect Which Creates a Substantial Risk of Injury to the Public

Having found that the Subject Products contain a defect, the Commission next considers the second prong of Section 15(a)(2) of the CPSA: whether the product defect is one "which

[38] Respondent argues that because Complaint Counsel failed to rebut Respondent's evidence on the utility of the Subject Products, high utility has been established as a fact. Answer Br. at 22 (citing *Hale v. Dep't of Transp*., 772 F.2d 882, 886 (Fed. Cir. 1985)). We disagree. In *Hale*, the U.S. Court of Appeals for the Federal Circuit affirmed the Merit Systems Protection Board's reversal of an initial decision finding that the Federal Aviation Administration had not met its burden of proof when it relied on time and attendance records to show that employees participated in a strike. 772 F.2d at 885-86. The court affirmed the Board's reasoning that where the signed time and attendance records demonstrated that the employees were absent and no rebuttal evidence was offered, such self-explanatory documentary evidence was sufficient to prove the fact: "the only conclusion that a reasonable mind can make is that the fact of petitioners' absence on the days in question is more likely true than not true." *Id.* at 886. Here, Respondent's witness testimony is not akin to unrebutted documentary evidence of a fact. The Commission is entitled, indeed, required to review the evidence of utility that was presented, weigh the credibility of the witnesses, and then balance that utility against the risk of injury to the public.

[39] A cost-benefit analysis was not admitted in this case, and, as explained in *In re Dye*, such analysis is not required in a Section 15 adjudication. *In re Dye* cautions, and we reaffirm, that the rulemaking requirement, to consider the effect of a rule on "utility, cost, or availability of such products to meet [the need of the public]" is not a requirement in a Section 15 action, and that staff is not required to make such a showing to demonstrate that the risk of injury outweighs the product's utility. 1989 WL 435534 at *10. Rather, § 1115.4 states that when risk/utility balancing is necessary in a Section 15 case, the Commission considers, as appropriate, the factors provided in § 1115.4 to weigh the risk of injury presented by the product with the utility of the product to consumers, before determining whether a product is defective.

(because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2); *see also In re Dye*, 1989 WL 435534 at *13 (reviewing the evidence for each factor). The Commission's regulation explains: "[t]hese factors are set forth in the disjunctive. Therefore, the existence of any one of the factors could create a substantial product hazard." 16 C.F.R. § 1115.12(g)(1).

1. The Pattern of Defect Creates a Substantial Risk of Injury to the Public

A "pattern" of defect may arise from the "design, composition, contents, construction, finish, packaging, warnings, or instructions of the product or from some other cause and [the Commission] will consider the conditions under which the defect manifests itself." 16 C.F.R. § 1115.12(g)(1)(i).

Complaint Counsel argue that the design of the product is defective, based on operation and use of the Subject Products, because loose SREMs are meant to be separated from their set. Appeal at 57. Separation of magnets from their set results in a risk of ingestion and injury. *Id*. (citing Exs. CC-10A at 7, 9-10, 13, 16, 43; CC-27A at 7-10; Tr. 304:21-305:3, 343:5-344:3, 385:19-386:2).

Respondent attempts to refute this argument by criticizing the testimony of Dr. Frantz that separable magnets are "per se defective, as if the product is 'broken'" and the fact that Dr. Frantz did not consider misuse of magnets and how such misuse could result in magnets becoming unaccounted for. Answer Br. at 37 (citing Tr. 252:3-5; 269:18-270:12). Respondent also criticizes Dr. Frantz, stating: "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.'" *Id*. (citing Tr. 272:22-273:5). Respondent also cites Mr. Qu's testimony that a "lost" magnet is not necessarily unaccounted for, it may have been given to another person. *Id*. at 37-38 (citing Tr. 2006:19-2007:7). We find, however, that it does not matter whether SREMs can be lost to the environment or simply shared with other users. In either case, the magnets are now "lost" from the larger set, without warnings, and children can become exposed to such "lost" magnets. Either scenario presents a hazard pattern that is corroborated by the incident data demonstrating that children who access SREMs have ingested the magnets and suffered serious injury. *See* Sections I.B and III.A.2.b-d, *supra* pp. 2-3, 16-28. Therefore, we do not find Respondent's arguments regarding the lack of a "pattern of defect" persuasive.

Complaint Counsel demonstrated that all of the Subject Products are designed to be small, spherical, shiny, loose, separable, and strongly magnetic. Based on the evidence presented, the Commission has already determined that the Subject Products are defective because such separable magnets present an ingestion hazard to children. Accordingly, the Commission also finds that the Subject Products present a substantial product hazard because all of the Subject Products are designed the same, which creates the same substantial risk of injury. *See, e.g., In re Dye*, 1989 WL 435534 at *13 ("With regard to the pattern of defect, all Worm Gett'rs contain the design defect and the inadequate instructions described in detail above. Therefore, the 'pattern of defect' is consistent for all worm probes distributed by respondents.").

2. The Number of Defective Products Distributed in Commerce Creates a Substantial Risk of Injury to the Public

The Commission's regulation states that "[e]ven one defective product can present a substantial risk of injury and provide a basis for a substantial product hazard determination … if the injury which might occur is serious and/or if the injury is likely to occur." 16 C.F.R. § 1115.12(g)(1)(ii). The regulation further states: "[m]ost defects could present a substantial product hazard if the public is exposed to significant numbers of defective products or if the possible injury is serious or is likely to occur." 16 C.F.R. § 1115.4. Thus, to find a substantial product hazard under this prong, the Commission must determine that the evidence supports one of these: (1) the public is exposed to a significant number of defective products; (2) the possible injury is serious; or (3) the possible injury is likely to occur.

The evidence establishes that Respondent sold between 70,000 and 75,000 sets of Zen Magnets and Neoballs totaling more than 10 million individual magnets since the end of 2009. Tr. 1466:11-19; Answer Br. at 39 (acknowledging that Respondent sold "millions" of the Subject Products). Additionally, Respondent distributed approximately 220,000 spare magnets. Tr. 349:16-350:13; Ex. CC-10A at 23-25. The evidence indicates that it takes only one ingested magnet and a metallic object, or two ingested magnets to cause catastrophic injuries to a child. Exs. CC-24 at 2; CC-27A at 7-11. Complaint Counsel demonstrated that the Subject Products are associated with at least two injuries, and are functionally identical to SREMs that have caused many serious injuries and one death. *See* Section III.A.2.d, *supra* pp. 23-24. Based on the sales data and the fact that as few as one SREM and another metallic object, or two SREMs, are sufficient to cause injury, the Commission finds that the public is exposed to a significant number of defective products. The incident data describing the injuries and deaths that can result from ingestion of the Subject Products, as discussed above, show that the possible injury is serious. *See* Sections I.B. and III.A.2.d, *supra* pp. 2-3, 22-28.

Respondent contends that "[w]hile 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." Answer Br. at 39. Respondent contrasts this case, where "the evidence showed that injuries were quite unlikely to occur, especially considering the number of products on the market," with *In re Dye*, "where the evidence established that injuries were *likely* to occur." *Id.* (emphasis in original).

In *In re Dye*, complaint counsel called a Commission economist to testify as an expert regarding the determination of costs and benefits. 1989 WL 435534 at *7. Although useful and instructive in that case, such quantitative cost-benefit evidence is not required to establish a substantial product hazard, meaning a product defect which creates a substantial risk of injury to the public. *See* note 39, *supra* p. 38; *see also, e.g.*, *In re Dye*, 1989 WL 435534 at *10 (cost-benefit analysis not required in Section 15 adjudication); 1978 Final Rule, 43 Fed. Reg. at 34991 ("The Commission does not want to give the impression that the extensive cost/benefit analysis in which it engages before promulgating a standard or ban should be undertaken by subject firms before reporting under Section 15(b)"). Indeed, neither the CPSA, nor the Commission's

regulations, require Complaint Counsel to present a quantitative cost-benefit analysis in a Section 15 adjudication. In this case, Complaint Counsel proved that the Subject Products are functionally identical and look the same to consumers as other SREMs on the market that have caused serious injuries in children. *See* Section III.A.2.d, *supra* pp. 23-24. Because SREMs are indistinguishable once out of the packaging, it is impossible to identify the product brand in every incident. *Id.*

Moreover, likelihood of injury is only one element of this analysis. If the public is exposed to a "significant number of defective products," **or** "if the possible injury is serious," these factors weigh in favor of finding a substantial product hazard. Complaint Counsel established that Respondent distributed more than 10 million individual SREMs. Based on the sheer number of individual SREMs distributed in commerce and the severity of the injury, the Commission finds that this factor weighs in favor of finding a substantial product hazard.

3. The Severity of the Risk Creates a Substantial Risk of Injury to the Public

Under 16 C.F.R. § 1115.12(g)(1)(iii), "[a] risk is severe if the injury which might occur is serious and/or if the injury is likely to occur."

The Commission's regulation defines "serious injury" to include "grievous bodily injury," such as loss of important bodily functions, debilitating internal disorders, and injuries likely to require extended hospitalization, and "[i]njuries necessitating hospitalization which require actual medical or surgical treatment, … injuries to … internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day …" 16 C.F.R. §§ 1115.6(c), 1115.12(d).

The record is replete with evidence demonstrating the severity of the risk of injury, including serious, life-threatening injuries that children suffered after ingesting SREMs and the medical intervention needed to prevent death. *See* Sections I.B and III.A.2.d, *supra* pp. 2-3, 22-28.

Respondent does not contest that ingesting SREMs could result in serious injuries. Answer Br. at 39.

In analyzing the likelihood of any injury, the Commission's regulation instructs the Commission to consider the number of injuries reported to have occurred, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed to the product (*e.g.*, children, elderly, handicapped). 16 C.F.R. § 1115.12(g)(1)(iii).

Regarding the reported number of injuries, Complaint Counsel presented evidence of 95 magnet ingestion incidents, two of which are attributable to Respondent, as well as data from the NASPGHAN Survey conducted by Dr. Noel, which reviewed 481 reports of magnet ingestions by children over a 10-year period, and involved detailed clinical data on 123 SREM ingestions. *See* Section III.A.2.d, *supra* pp. 24-26. Complaint Counsel also submitted evidence that ingestion of SREMs by children is reasonably foreseeable use or misuse of the Subject Products,

and that the population exposed to the risk of injury is children. *See* Sections III.A.2.c and e, *supra* pp. 20-22, 28-30.

Based on the foregoing, the Commission finds that because of the severity of the risk of injury, and the reasonably foreseeable use or misuse of the Subject Products by children, this factor weighs in favor of finding that the Subject Products present a substantial product hazard.

For these reasons, the Commission finds that the Subject Products present a substantial product hazard under Section 15(a)(2) of the CPSA because they contain a defect which creates a substantial risk of injury to the public.

IV. The Commission Need Not Decide Whether the Subject Products Present a Substantial Product Hazard Under Section 15(a)(1) of the CPSA

As a matter of judicial economy, because we found that all of the Subject Products present a substantial product hazard under Section 15(a)(2) of the CPSA, we do not reach the issue of whether the Subject Products present a substantial product hazard under Section 15(a)(1).

The question presented in Count II was whether the Subject Products fail to comply with the Toy Standard (ASTM F-963),[40] and whether such failure to comply creates a substantial risk of injury to the public. The Commission has already determined that the Subject Products present a substantial product hazard under Section 15(a)(2) of the CPSA. The remedy ordered by the Commission in Sections VII.B-D, *infra* pp. 49-53, covers all of the SREMs sold by Respondent. Therefore, finding a substantial product hazard under Count II would have no effect on the scope or nature of the remedy ordered by the Commission. *See, e.g., Groseclose v. Bell*, 130 F.3d 1161, 1171 (6th Cir. 1997) (declining to determine claim on appeal based on tenets of judicial economy where such claim was unnecessary to reach the merits and stating that the court should not resolve issues that cannot alter a final decision); *In the Matter of: *** Applicant for Security Clearance*, ISCR Case No. 08-07803, 2009 WL 1800462, *4 (DOHA June 15, 2009) (extending judicial economy to U.S. Department of Defense hearing, stating that "the principle of judicial economy refers to the practice of a court declining to decide one or more claims in a case on the grounds that it has decided other claims that are sufficient to decide the case and satisfy the parties").

For these reasons, we set aside the ALJ's opinion and order with respect to Count II of the Second Amended Complaint.

[40] Section 106(a) of the CPSIA made the provisions of ASTM F-963 a mandatory consumer product safety standard under Section 9 of the CPSA. Pub. L. No. 110-314.

V. Additional Holdings

A. Holdings on Evidentiary Issues

1. Expert Qualification of Dr. Boyd Edwards

Complaint Counsel maintain that the ALJ erred in qualifying Dr. Edwards as an expert to opine on the educational utility of SREMs and in admitting his expert report. Appeal at 64-69. As a result, according to Complaint Counsel, the Commission should strike the expert testimony and report. *Id.* at 65.

The Commission's regulation governing adjudicative proceedings defines an "expert witness" as:

> … one who, by reason of education, training, experience, or profession, has peculiar knowledge concerning the subject matter to which his/her testimony relates and from which he/she may draw inferences based upon hypothetically stated facts or offer opinions from facts involving scientific or technical knowledge.

16 C.F.R. § 1025.44(a);[41] *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147-49 (1999) (extending the standard announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589-92 (1993) — the trial judge must act as a gatekeeper to ensure that scientific testimony is not only relevant, but reliable — to "technical" and "other specialized" knowledge).

Dr. Edwards holds a Ph.D. in applied physics from Stanford University. Exs. R-154; R-154A at 2. Dr. Edwards taught physics courses at the undergraduate and graduate level for more than 20 years. Tr. 1263:2-8; Ex. R-154A at 1. In connection with his teaching, Dr. Edwards received multiple teaching awards, including one whose criteria included "a commitment to excellence in pedagogical practices." Tr. 1267:15-1268:6; 1269:4-14. After teaching for more than 20 years, Dr. Edwards became a dean at Utah State University, Uintah Basin, charged with

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[41] The Commission's regulation on expert witnesses is similar to Rule 702 of the Federal Rules of Evidence, which provides that:

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

Fed. R. Evid. 702. The Federal Rules of Evidence apply to adjudications under Sections 15(c) and (d) of the CPSA, but the Presiding Officer may relax the rules "if the ends of justice will be better served by so doing." 16 C.F.R. §§ 1025.1, 1025.43(a).

reviewing the performance and teaching methods of the other professors in his department. Tr. 1262:20-1263:1; 1266:19-22; 1267:1-10; 1268:15-22; Ex. R-154A at 1. In addition, Dr. Edwards authored more than 50 peer-reviewed scientific publications, including five on magnetic phenomena. Exs. R-154A at 2; R-155 at 1. Dr. Edwards acquired knowledge of how the Subject Products work, and how they can demonstrate scientific principles, by using the products "hundreds of times" over a period of 2 years. Ex. R-155 at 1-18; Tr. 1440:13-16.

Dr. Edwards is clearly qualified to testify as an expert witness about the educational utility of the Subject Products. *See Am. Tech. Res. v. U.S.*, 893 F.2d 651, 656 (3d Cir. 1990) (holding professor's academic training and practical experience, which included a Ph.D. in finance and teaching courses in speculative markets, corporate finance, investments, and real estate finance, qualified him to testify about the value of a business); *see also* Fed. R. Evid. 702 advisory committee notes (1972): ("… the expert is viewed, not in a narrow sense, but as a person qualified by 'knowledge, skill, experience, training or education.'").

As an expert, Dr. Edwards may draw inferences based upon hypothetically stated facts or offer opinions from facts involving scientific or technical knowledge. 16 C.F.R. § 1025.44(a); *see also* Fed. R. Evid. 702 (requiring that "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"). We find that Dr. Edwards can rely upon the knowledge he acquired during his tenure as a physics professor, and later as a university dean, to offer opinions and answer hypothetical questions about how students learn and grasp difficult scientific principles and the best methods and tools for teaching abstract theories and ideas.

Complaint Counsel's challenges to the qualification of Dr. Edwards as an expert go to the weight, not the admissibility, of his testimony. Complaint Counsel had the opportunity to discredit Dr. Edwards's testimony by thoroughly cross-examining Dr. Edwards and highlighting what it perceived to be deficiencies in Dr. Edwards's testimony and conclusions. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.") (citing *Rock v. Arkansas*, 483 U.S. 44, 61 (1987)). The ALJ properly qualified Dr. Edwards as an expert to opine on the educational utility of the Subject Products.

2. Requests for Official Notice and to Supplement the Record

Both parties request that the Commission take official notice of certain facts. Respondent also requests that the Commission admit additional evidence into the record.

"All relevant and reliable evidence is admissible, but may be excluded by the Presiding Officer if its probative value is substantially outweighed . . . by considerations of undue delay, waste of time, immateriality, or needless presentation of cumulative evidence." 16 C.F.R. § 1025.43(c). The Commission also may take official notice of "facts not appearing on the record and legal conclusions drawn from those facts." 16 C.F.R. § 1025.43(d)(1).

For the reasons set forth below, the Commission denies the parties' requests.

a. Requests for Official Notice

Respondent requests that the Commission take official notice of the Final Rule for Magnet Sets for the proposition that a risk of injury arises when two or more magnets are ingested. Answer Br. at 8-9 & n.5. The Commission denies this request because Complaint Counsel already proved, through the testimony of Dr. Noel, that a risk of injury occurs when two or more magnets, or one magnet and another metallic object, are ingested. *See* Sections I.B and III.A.2.d, *supra* pp. 2-3, 22-28; *see also* 16 C.F.R. § 1025.43(d)(1). Additional evidence on this fact is unnecessary and cumulative. 16 C.F.R. § 1025.43(c).

Complaint Counsel request that the Commission take official notice that Respondent started selling "Compliance Magnets," "advertised as small magnet spheres with less magnetic strength than the Subject Products," in November 2015. Appeal at 40, and Ex. 1. Complaint Counsel argue that the sale of Compliance Magnets demonstrates that (1) the Subject Products do not have utility due to their high magnetic flux; and (2) the ALJ erred in finding that the "spherical and magnetic qualities" of the Subject Products have high utility because they are so "unique." Appeal at 40 (quoting Initial Dec. at 22). The existence of Compliance Magnets is immaterial to the Commission's consideration of utility of the Subject Products. 16 C.F.R. § 1025.43(c). As discussed in Section III.A.3, *supra* pp. 35-38, the Commission found that the utility of the Subject Products for use in teaching scientific concepts to a select group of users does not outweigh the risk of injury to children presented by the Subject Products.

b. Request to Supplement the Record

During oral argument, two Commissioners asked whether additional information should be added to the record. Tr. of Oral Arg. at 34:6-15; 64:6-8; 65:2-5; 76:1-6.

Counsel for Respondent explained that the record should be supplemented with "two peer-reviewed published papers by Dr. Edwards using magnets since the time of the trial in December of '14." *Id.* at 48:6-9. We presume that Respondent seeks to admit these papers to demonstrate the usefulness of SREMs in the classroom.

We recognize that the Subject Products may be useful to certain users in an educational setting, particularly for consumers who teach, study, and conduct research in the fields of physics, chemistry, metallurgy, engineering, geometry, biology, and mathematics. *See* Section III.A.3.b, *supra* p. 37. Product usefulness, or utility, however, must be balanced against the risk of injury, using the multiple factors, as appropriate, listed in 16 C.F.R. § 1115.4. *See* Sections III.A.1.a and III.A.3, *supra* pp. 9-10, 35-38. The addition of two peer-reviewed papers further demonstrating use of the Subject Products for understanding and teaching complex scientific principles is duplicative of the evidence already in the record. Therefore, we deny Respondent's request to supplement the record with the two peer-reviewed papers.

During oral argument, Respondent also stated that the Commission should supplement the record with correspondence between Respondent and Complaint Counsel detailing

Respondent's attempts to draft warnings and age recommendations. Tr. of Oral Arg. at 70:4-14; 71:3-9; 78:2-10. Counsel for Respondent explained that "there were at least three go-rounds with Compliance Counsel before they were candid and said it really doesn't matter what you do, we're not going to accept it." Tr. 70:11-14.

Respondent's good faith efforts to create appropriate warnings and age recommendations do not change the characteristics of the Subject Products that create the risk of injury. As discussed in Section III.A.2.g, *supra* pp. 30-34, no warning can mitigate the risk of injury from the Subject Products. Respondent's request to supplement the record with the correspondence is denied.

VI. Conclusion

We find that Complaint Counsel established by a preponderance of the evidence that the characteristics of the Subject Products create a risk of injury based on their operation and use, which includes reasonably foreseeable misuse. Complaint Counsel submitted credible, unrebutted evidence that the Subject Products are comprised of small, spherical, shiny, reflective, smooth, loose, separable, and strong magnets that are attractive to young children and older children, who mouth the Subject Products for different reasons. Mouthing the Subject Products creates an ingestion risk to all children, regardless of age. The evidence demonstrates that this behavior is reasonably foreseeable and results in the risk of serious injury or death from ingesting the Subject Products.

Balancing the risk of injury with the utility of the Subject Products, the Commission finds that all of the § 1115.4 factors reviewed weigh in favor of finding that the risk of injury outweighs the utility of the Subject Products. Accordingly, the Commission finds that the Subject Products are defective. The Commission also finds that the defect in the Subject Products presents a substantial product hazard, based on the pattern of defect, the number of defective products, and the severity of the risk of injury, which create a substantial risk of injury to the public.

The ALJ's conclusion that the Subject Products do not contain a defect based on the proper or intended use of the Subject Products was an error of law. Additionally, the ALJ's reading of Commission precedent was incorrect. The ALJ's conclusion regarding the lack of a design defect was based on an incomplete defect analysis that failed to consider, among other things, the product characteristics that give rise to the risk of injury and reasonably foreseeable consumer use or misuse of the Subject Products.

VII. Remedy

A. Order in the Initial Decision

The ALJ's Order accompanying the Initial Decision is defective in several ways and is hereby set aside in full.

The ALJ's Order required Respondent to take the following measures:

1. Compile and provide to the Commission within ninety (90) days of the Order lists of known SREM purchasers who purchased Respondent's SREMs (a) without warnings (before May 2010); and (b) with a warning suggesting the appropriate age of use to be twelve years and older (Initial Dec. at 34-35, 37);

2. Within one-hundred fifty (150) days of the Order, contact by electronic mail or U.S. Postal Service First Class Mail all known consumers and retailers identified on the compiled lists and provide: (a) specific warnings about SREM ingestion hazards; and (b) the purchaser an opportunity to return the product to Respondent for a full refund, at the consumer's option, within two-hundred forty (240) days of the Order (*Id*. at 35, 37); and

3. Provide the Commission with information concerning all responses that Respondent receives to the notifications within three-hundred thirty (330) days of the Order (*Id*. at 35, 38).

To obtain a full or partial refund, the ALJ's Order required the consumer to provide to Respondent "a substantially complete set of the purchased product, in substantially the same condition as it was when it was purchased." *Id*. at 35. The ALJ's Order further stated: "[a]ny refund shall be limited by 15 U.S.C.A. § 2064." *Id*.

In addition, the ALJ's Order required the Commission and Respondent to publish this "Order of Recall" on their websites. *Id*. at 37.

The Commission finds that the ALJ's Order does not comply with the statutory requirements in several respects.

Notice of the Defect: First, the ALJ failed to demonstrate how the public notice prescribed by the Initial Decision "adequately protect[s] the public" from the Substantial Product Hazard. 15 U.S.C. § 2064(c)(1). Second, although the ALJ's Order specified the form of the notice, *i.e.*, notice by electronic mail or regular U.S. mail to all known consumers and retailers and posting the ALJ's "Order of Recall" on the Commission and Zen Magnets and Neoballs websites, the order failed to specify the content of the notice, as required under Sections 15(c) and (i)(2) of the CPSA (15 U.S.C. §§ 2064(c), (i)(2)), and the Commission's regulation at 16 C.F.R. § 1115.27. Ordering Respondent to "provide specific warnings about SREM ingestion hazards," without indicating that the notice must contain, among other requirements, descriptions

of the product and the substantial product hazard, failed to comport with the notice requirements under the CPSA and the Commission's regulations. Finally, the ALJ's Order failed to include a provision that any such public notification must be approved by the Commission, as required under 16 C.F.R. § 1115.29(c).

Refunds: In ordering the refund, the ALJ failed to include any meaningful analysis addressing how the refund is in the public interest. The Initial Decision simply stated:

> Without warnings, and when the product suggests appropriate usage by children under the age of 14, SREMs are substantial product hazards and are considered toys under ASTM F963 § 3.1.81, particularly since some of Respondent's product suggested and marketed (in the Question and Answer Section of his website) the appropriate usage age as 12 years and older.

Initial Dec. at 34 (internal footnotes omitted). Arguably, the ALJ's rationale is that magnets sold without warnings or marketed to children 12 years and younger present a risk of injury and a refund to consumers is in the public interest. Because the important connection between the prescribed remedy and the public interest was not clearly stated, however, the ALJ's order is deficient for failing to indicate how the refund is in the public interest.

Additionally, the ALJ's Order did not require Respondent to submit a plan for implementing the refund component for approval by the Commission, as required under Section 15(d)(2) of the CPSA. 15 U.S.C. § 2064(d)(2).

Finally, the ALJ's Order imposed unreasonable burdens on consumers seeking a refund. The ALJ's Order stated:

> In order to avail themselves of a full or partial refund pursuant to 15 U.S.C.A. § 2064, the consumer shall provide a *substantially complete* set of the purchased product, *in substantially the same condition as it was when it was purchased*, to the Respondent for any refund ordered herein.

Initial Dec. at 35 (emphasis added).

Thus, the ALJ's Order actually required two conditions precedent to a consumer seeking a refund. First, the consumer had to locate substantially all of the magnets that came with the set – which, as the evidence demonstrated, would be nearly impossible to do, given the propensity for magnets to be lost or shared. *See* Sections I.B and III.A.2.b, *supra* pp. 2-3, 16-19. Second, the magnets had to be in substantially the same condition as when they were purchased; evidence demonstrated that magnets wear and chip. Tr. 2010:10-14.

The provisions of any recall, including the refund conditions, must be designed to motivate consumers to act on the recall. Requiring a consumer to return 1,700 magnets, in nearly pristine condition, from a 1,728-piece set to receive a refund, is likely to discourage consumers from actually participating in the recall. Furthermore, such a requirement is contrary

to the Commission's mission to protect the public against unreasonable risks of injury associated with consumer products and statutory authority to remove hazardous products from consumers' hands. 15 U.S.C. §§ 2051(b)(1), 2064(d).

B. Prohibition from Manufacturing, Offering for Sale, Distributing, and Importing

Under Section 15(d)(2) of the CPSA (15 U.S.C. § 2064(d)(2)), the Commission may issue an order prohibiting the manufacture for sale, offer for sale, distribution in commerce, or importation into the customs territory of the United States of a product that the Commission has determined presents a substantial product hazard. The Commission may issue an order under Section 15(d)(2), only if the Commission determines that this action is in the public interest. *Id.*

Based upon the evidence in the record, the Commission concludes that an order enjoining Respondent from manufacturing for sale, offering for sale, distributing in commerce, or importing the Subject Products is in the public interest because the Subject Products present a substantial product hazard to children that cannot be mitigated by warnings. 15 U.S.C. § 2064(d)(2).

C. Notice of the Defect

Section 15(c)(1) of the CPSA (15 U.S.C. § 2064(c)(1)) authorizes the Commission to order public notice after determining that: (1) a product distributed in commerce presents a substantial product hazard; and (2) notification is required in order to adequately protect the public (the "Section 15(c) Order"). A Section 15(c) Order may require the manufacturer, importer, distributor, or retailer to take any one or more of the following actions:

1. To cease distribution of the product.
2. To notify all persons that transport, store, distribute, or otherwise handle the product, or to which the product has been transported, sold, distributed, or otherwise handled, to cease immediately distribution of the product.
3. To notify appropriate State and local public health officials.
4. To give public notice of the defect or failure to comply, including posting clear and conspicuous notice on its Internet website, providing notice to any third party Internet website on which such manufacturer, retailer, distributor, or licensor has placed the product for sale, and providing announcements in languages other than English and on radio and television where the Commission determines that a substantial number of consumers to whom the recall is directed may not be reached by other notice.
5. To mail notice to each person who is a manufacturer, distributor, or retailer of such product.

6. To mail notice to every person to whom the person required to give notice knows such product was delivered or sold.

Id.

A Section 15(c) Order shall specify the form and content of the required notice. *Id.*; 16 C.F.R. § 1115.29(a). In addition, recall notices required under a Section 15(c) Order shall include the information specified in Section 15(i) of the CPSA (15 U.S.C. § 2064(i)), and the Commission's corresponding regulations at 16 C.F.R. part 1115, subpart C, unless the Commission determines that one or more of the recall notice requirements is unnecessary or inappropriate. The Commission must review and agree in writing to all aspects of a recall notice required by a Section 15(c) Order before such notice is published, broadcasted, or otherwise disseminated. 16 C.F.R. § 1115.29(c).

Based upon the evidence in the record, the Commission concludes that widespread public notice that the Subject Products present a substantial product hazard is necessary to adequately protect the public. 15 U.S.C. § 2064(c)(1). More than 10 million individual SREMs distributed by Respondent may be in the hands of consumers. Tr. 1466:11-19; Answer Br. at 39 (acknowledging that Respondent sold "millions" of magnets). A child need only ingest one magnet and a metallic object, or two magnets, to suffer catastrophic injuries. *See* Sections I.B and III.A.2.d, *supra* pp. 2-3, 22-26. Furthermore, as set forth in this Final Decision and Order, evidence indicated that caregivers and even medical professionals often do not appreciate the substantial risk of injury presented by SREMs that comprise the Subject Products. *See* Sections III.A.2.d and III.A.2.f, *supra* pp. 25, 27, 30.

The Commission has determined that the following forms of notice must be issued to warn consumers, including caregivers, health care professionals, and other members of the public, about the substantial product hazard posed by the Subject Products:

1. A joint news release from the Commission and Respondent;
2. A video news release;
3. A recall notice to be posted prominently and for an extended period of time on all of Respondent's Internet websites;
4. A recall notice or similar communication to appear prominently and for an extended period of time on every social media platform used by Respondent, including, but not limited to, Google +, YouTube, Twitter, Reddit, Flickr, Facebook, and Internet blogs;
5. Direct notice via first-class mail and electronic mail to each third party Internet website on which Respondent placed the Subjects Products for sale;
6. Direct notice via first-class mail and electronic mail to each manufacturer, distributor, and retailer, including, but not limited to, marijuana dispensaries and head shops, of the Subject Products;

7. Recall poster to be provided with each direct notice sent to retailers with instructions regarding posting;

8. Direct notice via first-class mail and electronic mail to each third party Internet platform on which the Subject Products may be sold by persons other than Respondent, including, but not limited to, eBay; and

9. Direct notice via first-class mail and electronic mail to each person to whom Respondent knows such product was delivered or sold.

Hereinafter, we refer to the above notices collectively as the "Public Notifications."

Except for communications appearing on certain social media platforms maintained by Respondent, each Public Notification shall comply with 15 U.S.C. § 2064(i)(2) and the *Guidelines and Requirements for Mandatory Recall Notices,* as set forth at 16 C.F.R. part 1115, subpart C. Each Public Notification also shall contain the information specified in 15 U.S.C. § 2064(i)(2) and 16 C.F.R. § 1115.27.

In addition, each Public Notification shall specify the name, city, and state of each marijuana dispensary, head shop, hobby store, and toy store that sold the Subject Products. The Commission believes that these retailers constitute "significant retailers" under 16 C.F.R. § 1115.27(i) because such retailers are regionally located and are the only brick-and-mortar locations that sold the Subject Products. In addition, identification of such retailers is in the public interest and will assist consumers in determining whether they purchased the Subject Products, particularly if the notice identifies head shops and marijuana dispensaries, which are not the traditional types of retailers specified in Commission recall notices. *Id*.

Finally, to the extent possible, communications on each social media platform used by Respondent shall include a link to the recall notice posted on Respondent's Internet website, if the recall notice cannot appear on the social media platform because of messaging restrictions.

As ordered below, Complaint Counsel shall submit draft Public Notifications to Respondent within ten (10) days of the service of this Final Decision and Order. Within twenty (20) days of the service of this Final Decision and Order, Respondent shall notify Complaint Counsel of any objections it has to the draft Public Notifications. If Respondent has no objections to the draft Public Notifications, within thirty (30) days of the service of this Final Decision and Order, Complaint Counsel shall submit to the Commission, through the Office of the Secretary, the draft Public Notifications for review and approval by the Commission. If Complaint Counsel and Respondent cannot agree on the draft Public Notifications, within thirty (30) days of the service of this Final Decision and Order, Complaint Counsel and Respondent shall submit, through the Office of the Secretary, a joint statement of the factual and legal issues regarding the draft Public Notifications that are in dispute.

The Commission must review and agree in writing to all aspects of the Public Notifications before each notification may be published, broadcasted, or otherwise disseminated. 16 C.F.R. § 1115.29(c).

D. Refunds

Section 15(d)(1) of the CPSA (15 U.S.C. § 2064(d)(1)) authorizes the Commission to order repair, replacement, and/or refund of a product after determining that: (1) a product distributed in commerce presents a substantial product hazard; and (2) such action is in the public interest (the "Section 15(d) Order"). A Section 15(d) Order may require the manufacturer, importer, distributor, or retailer to provide public notice as specified under Section 15(c) of the CPSA, and to take any one or more of the following actions the Commission determines to be in the public interest:

1. To bring such product into conformity with the requirements of the applicable rule, regulation, standard, or ban or to repair the defect in such product.
2. To replace such product with a like or equivalent product which complies with the applicable rule, regulation, standard, or ban or which does not contain the defect.
3. To refund the purchase price of such product (less a reasonable allowance for use, if such product has been in the possession of a consumer for one year or more (i) at the time of public notice under subsection (c), or (ii) at the time the consumer receives actual notice of the defect or noncompliance, whichever first occurs).

15 U.S.C. § 2064(d)(1).

The Section 15(d) Order shall require the person to whom it applies to submit a plan, for approval by the Commission, for implementing the Commission's order (the "Action Plan"). 15 U.S.C. § 2064(d)(2). If a refund is ordered, the Section 15(d) Order shall specify the persons to whom refunds must be made. 15 U.S.C. § 2064(d)(2). Refunds ordered under Section 15(d) of the CPSA shall also contain provisions for reimbursement for "any reasonable and foreseeable expenses incurred" by consumers who avail themselves of the refund and "[n]o charge shall be made" to any consumers who avail themselves of such remedy. 15 U.S.C. § 2064(e)(1).

In view of the substantial product hazard presented by the Subject Products, as discussed above in Section III, the Commission's interest is in removing as many of the Subject Products as possible from consumers' hands by promoting consumer participation in the recall. Therefore, the Commission concludes that it is in the public interest to order Respondent to refund the purchase price of the Subject Products, less the "reasonable allowance for use" deduction specified at Section 15(d)(1)(C) of the CPSA. 15 U.S.C. § 2064(d)(1)(C).

As ordered below, Respondent shall submit a draft Action Plan that provides for refund of the purchase price of the Subject Products, less a "reasonable allowance for use," in accordance with Sections 15(d) and (e) of the CPSA (15 U.S.C. §§ 2064(d) and (e)) to Complaint Counsel within ten (10) days of the service of this Final Decision and Order. The

terms and conditions for any refund shall take into account the following considerations: (1) the generally accepted useful life of magnets; (2) the original cost paid by consumers; (3) incentives to encourage returns; (4) whether and how many magnets should be returned by consumers to qualify for a refund; (5) the timing and duration of any refund; (6) shipping or other costs associated with returns; and (7) the limits, if any, of the refund.

Within twenty (20) days of the service of this Final Decision and Order, Complaint Counsel shall notify Respondent of any objections they have to the draft Action Plan.

If Complaint Counsel have no objections to the draft Action Plan, within thirty (30) days of the service of this Final Decision and Order, Respondent shall submit to the Commission, through the Office of the Secretary, the draft Action Plan for review and approval by the Commission, as required by Section 15(d)(2) of the CPSA. 15 U.S.C. § 2064(d)(2). If the parties are unable to resolve objections to the draft Action Plan, within thirty (30) days of the service of this Final Decision and Order, Respondent and Complaint Counsel shall submit, through the Office of the Secretary, a joint statement of the factual and legal issues regarding the draft Action Plan that are in dispute to be resolved by the Commission.

ORDER

Having considered the arguments and evidence of record in this proceeding, the Commission (by a 3 - 1 vote, 4 Commissioners voting) finds:

1. That the Subject Products present a "substantial product hazard," as defined in 15 U.S.C. § 2064(a)(2), because they contain a defect which, due to the pattern of the defect, the number of defective products distributed in commerce, and the severity of the risk of injury, creates a substantial risk of injury to children;

2. That because of the substantial risk of injury such magnets pose to children, it is in the public interest that Respondent cease from manufacturing for sale, offering for sale, distributing in commerce, or importing into the customs territory of the United States, the Subject Products;

3. That because Respondent sold millions of individual magnets and caregivers and medical professionals are not generally aware of the substantial risk of injury that the Subject Products present to children, public notification pursuant to 15 U.S.C. § 2064(c)(1) is required to adequately protect children from the substantial product hazard presented by the Subject Products; and

4. That because of the substantial risk of injury that the Subject Products present to children, as many as possible of these hazardous products must be removed from consumers, and, therefore, it is in the public interest that Respondent refund the purchase price of the Subject Products, less the "reasonable allowance for use" deduction, pursuant to 15 U.S.C. § 2064(d)(1)(C).

It is therefore ORDERED:

1. That the ALJ's Initial Decision is set aside in full;

2. That Respondent shall cease from manufacturing for sale, offering for sale, distributing in commerce, or importing into the customs territory of the United States, the Subject Products;

3. That, within ten (10) days of the service of this Final Decision and Order, Complaint Counsel shall submit to Respondent draft Public Notifications, defined above;

4. That each Public Notification shall comply with the requirements in 15 U.S.C. § 2064(i)(2) and the *Guidelines and Requirements for Mandatory Recall Notices,* as set forth at 16 C.F.R. part 1115, subpart C;

5. That each Public Notification shall identify the name, city, and state of all marijuana dispensaries, head shops, hobby stores, toy stores, and other retailers that sold the Subject Products;

6. That every social media platform used by Respondent shall include a link to the recall notice approved by the Commission and posted on Respondent's Internet website prominently and for an extended period of time, to the extent possible, or a hyperlink to this recall notice if the complete recall notice cannot appear on the social media platform because of messaging restrictions;

7. That, within twenty (20) days of the service of this Final Decision and Order, Respondent shall notify Complaint Counsel of any objections it has to the draft Public Notifications;

8. That, if there are no objections to the draft Public Notifications, within thirty (30) days of the service of this Final Decision and Order, Complaint Counsel shall submit to the Commission, through the Office of the Secretary, the draft Public Notifications for review and approval by the Commission, as required by 16 C.F.R. § 1115.29(c);

9. That, if Complaint Counsel and Respondent cannot agree on the draft Public Notifications, within thirty (30) days of service of this Final Decision and Order, Complaint Counsel and Respondent shall submit, through the Office of the Secretary, a joint statement of the factual and legal issues regarding the draft Public Notifications that are in dispute to be resolved by the Commission;

10. That Respondent shall submit a draft Action Plan providing for refund of the purchase price of the Subject Products, less a "reasonable allowance for use," in accordance with 15 U.S.C. §§ 2064(d) and (e), to Complaint Counsel within ten (10) days of the service of this Final Decision and Order, with the terms and conditions of such refund taking into account the following considerations: (a) the generally accepted useful life of magnets; (b) the original cost paid by consumers; (c) incentives to encourage returns; (d) whether and how many magnets should be returned by consumers to qualify for a refund; (e) the timing and duration of any refund; (f) shipping or other costs associated with returns; and (g) the limits, if any, of the refund;

11. That, within twenty (20) days of the service of this Final Decision and Order, Complaint Counsel shall notify Respondent of any objections they have to the draft Action Plan;

12. That, if there are no objections to the draft Action Plan, within thirty (30) days of the service of this Final Decision and Order, Complaint Counsel shall submit to the Commission, through the Office of the Secretary, the draft Action Plan for review and approval by the Commission, as required by 15 U.S.C. § 2064(d)(2);

13. That, if Respondent and Complaint Counsel cannot agree on a draft Action Plan, within thirty (30) days of the service of this Final Decision and Order, Respondent and Complaint Counsel shall submit, through the Office of the Secretary, a joint statement of the factual and legal issues regarding the draft Action Plan that are in dispute to be resolved by the Commission;

14. That Respondent shall file with Complaint Counsel monthly progress reports, in a format specified by Complaint Counsel, documenting the progress of the recall; and

15. That, for a period of five (5) years after the service of this Final Decision and Order, Respondent shall keep records of its actions taken to comply with the Order and supply such records to the Commission for the purpose of monitoring compliance with the Order.

SO ORDERED this 26th day of October, 2017.

BY THE COMMISSION, Acting Chairman Buerkle Concurring in Part and Dissenting in Part

Alberta E. Mills
Acting Secretary
Consumer Product Safety Commission