The Honorable Ann Marie Buerkle, Acting Chairman The Honorable Robert Adler, Commissioner The Honorable Elliot Kaye, Commissioner The Honorable Mariette Robinson, Commissioner c/o Office of the Secretary Consumer Product Safety Commission, Room 820 4330 East West Highway Bethesda, MD 20814

Submitted via <u>www.regulations.gov</u> to Docket No. CPSC-2017-0037

Dear Acting Chairman Buerkle and Commissioners Adler, Kaye, and Robinson:

The undersigned organizations welcome the opportunity to comment on the petition filed by Zen Magnets, LLC (petitioner) requesting that the U.S. Consumer Product Safety Commission (CPSC) initiate rulemaking under the Consumer Product Safety Act (CPSA) to adopt a mandatory safety standard for high-powered magnet sets.¹

Our organizations support a mandatory safety standard for high-powered magnet sets; however, we strongly reject the parameters suggested by the petitioner and instead urge the CPSC to work with patient safety, consumer, and physician organizations to re-issue and consider strengthening the previously promulgated requirements for small, high-powered magnet sets. Sufficient data already exist demonstrating the safety hazard small, high-powered magnet sets pose to children, as documented in the CPSC's previous rule.² Therefore, the CPSC should work in an expeditious manner to finalize a safety standard to address the November 2016 remand order of the Tenth Circuit Court of Appeals pertaining to this rule.³

The petitioner asserts that high-powered magnet sets pose a risk of injury if "misused" in a way that results in ingesting, aspirating, or otherwise inserting more than one magnet into the body. However, injuries from high-powered magnet sets are not only a result of "misuse." It is *expected* that magnets will become separated from their sets and *foreseeable* that a child or toddler will put that magnet(s) in their mouth. As pediatricians and child advocates, we know that this is a part of normal behavior development in children and is a major cause of foreign body ingestion.

¹ https://www.gpo.gov/fdsys/pkg/FR-2017-10-06/pdf/2017-21534.pdf

² 79 Fed. Reg. 59961 (Oct. 3, 2014), removed at 82 Fed. Reg. 12716 (Mar. 7, 2017).

³ Zen Magnets, LLC v. Consumer Product Safety Comm'n, No.14-9610 (10th Cir. Nov. 22, 2016).

The petitioner notes that one potential injury that can result from ingesting high-powered magnets is damage to gastrointestinal tissue. However, the petitioner has grossly understated the severity of injury —including death—that can result. Our organizations have repeatedly highlighted the types of injuries that result from the ingestion of two or more high-powered magnets, and the severity of injuries must not be minimized when establishing a safety standard.

The support and rationale for a strong safety standard for high-powered magnet sets are well-documented by our organizations.⁴ There has been no evidence in the years between the promulgation of the safety standard in 2014 and the 2016 ruling of the Tenth Circuit Court of Appeals which would weaken our position. Rather than weakening the prior standard, we urge the CPSC to continue to study the issue of whether its previous safety standard is adequate to protect against the potential hazards of magnets with a lower magnetic flux⁵ as it indicated it would do in the 2014 final rule.⁶

The petitioner has requested that the CPSC promulgate a mandatory safety standard that includes a number of components. We offer the following comments on the petitioner's specific requests:

Performance standards

The petitioner states that a safety standard should require individual magnets and each magnet in a magnet set that fits entirely within the cylinder described in 16 CFR 1501.4 (small parts cylinder) to have a flux index of 50 kG² mm² or less *if* the product is designed, marketed, or manufactured for children under the age of 14 years.

Regardless of how these magnet sets are marketed, they are attractive to children and have play value. A strong safety standard is necessary for high-powered magnet sets that include individual magnets that fit into the small parts cylinder and have a flux of 50 kG² mm² or greater. The marketing, design, and manufacturing distinction described in this petition is an arbitrary one and has no bearing on the reality that these products are and will be attractive to children.

Put simply: small, high-powered magnet sets pose a substantial risk of injury to children under 14 years of age. Either the magnets must be too large to be swallowed by a child, or weak enough in power so as not to have the ability to reconnect to each other and damage a child's organs once ingested. We therefore disagree with the petitioners and ask the CPSC to reissue its previous requirements that restricts the marketing and sale of magnet sets to those in which each individual magnet has a flux index of 50 kG² mm² or less if it fits completely within the small parts cylinder.

⁴ See note 6.

⁵ For example, it appears that Speks, a new high-powered magnet set from the makers of Buckyballs and Zen Magnets, comes in packaging of 512 separate rare earth magnets that are 2.5 mm in size and are promoted as having a flux index of less than 30 kG² mm². The thickness of the intestinal wall of a child is approximately 1-2 mm. Even with this lower flux index, two Speks could conceivably connect across the bowel wall of a child and cause intestinal perforation or other significant injuries.

⁶ In response to Comment 21 and 22 in the Final Rule (CPSC-2012-0050-2596) CPSC indicated it would continue to study the level of the flux index and the impact of multiple magnets at a lower flux index. https://www.regulations.gov/document? D=CPSC-2012-0050-2596.

As our organizations have previously commented, it is unrealistic that magnet sets will remain in their original packaging, or that simple age grading can keep them away from younger children. For this reason, childproof packaging will not be effective. We are also unconvinced that any type of packaging can clearly indicate to an adult whether all the hundreds of magnets that comprise these magnet sets have been returned to the package after use.

Warning and Instructional Requirements and Age Restrictions

As many of our organizations have previously commented, warning labels do not adequately reduce the injuries associated with high-powered magnet sets.⁷

In 2008, high-powered magnet sets were introduced in the consumer market and generally marketed as adult desk toys. The product was initially labeled for use by children 13 years of age and older but beginning in 2010, high-powered magnet sets were labeled for consumers 14 years of age and older; most included warnings to keep the product away from children. Magnet ingestions and resulting injuries did not decrease with warning labels. In fact, there is evidence that ingestions and injuries *increased* despite warnings and labels.⁸

It should be remembered that the CPSC identified Zen Magnets sets as a "substantial product hazard," which section 15(a)(2) of the CPSA defines 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." For this reason, no level of labeling can sufficiently mitigate the risks of these products or adequately convey potential hazards to children. First, it can be expected that any labels, warnings, or instruction booklets may be discarded after the package is opened. Second, even if magnet sets remain in their individual packaging, warnings would not be understood by most

Kids in Danger comments to the Consumer Product Safety Commission, CPSC-2012-0050; Nov. 19, 2012. https://www.regulations.gov/document?D=CPSC-2012-0050-0467

Consumer Federation of America comments to the Consumer Product Safety Commission, CPSC-2012-0050; Nov. 15, 2012. https://consumerfed.org/testimonial/cfa-comments-cpscs-notice-proposed-rulemaking-safety-standard-magnet-sets/

 $Consumers\ Union\ comments\ to\ the\ Consumer\ Product\ Safety\ Commission,\ CPSC-2012-0050;\ Nov.\ 19,\ 2012.\ \underline{https://www.regulations.gov/document?D=CPSC-2012-0050-1916}$

AAP statement regarding CPSC 2014 final rule: https://www.aap.org/en-us/about-the-aap/aap-press-room/pages/AAP-Commends-U-S-Consumer-Product-Safety-Commission%E2%80%99s-Ruling-to-Protect-Children-from-Dangerous-High-Powered-Magnets.aspx

⁷ North American Society for Pediatric Gastroenterology, Hepatology and Nutrition comments to the Consumer Product Safety Commission, CPSC-2012-0050; Nov. 18, 2012. https://www.naspghan.org//files/documents/pdfs/advocacy/2012/NASPGHAN%20Comment%20Letter%20CPSC-2012-0050.pdf

⁸ North American Society for Pediatric Gastroenterology, Hepatology and Nutrition comments to the Consumer Product Safety Commission, CPSC-2012-0050; Nov. 18, 2012. https://www.naspghan.org//files/documents/pdfs/advocacy/2012/NASPGHAN%20Comment%20Letter%20CPSC-2012-0050.pdf

⁹ Consumer Product Safety Act, section 15(a)(2), Public Law 92-573; 86 Stat. 1207, Oct. 27, 1972.

young children. Thus, warnings may not reduce the risk to younger children or siblings in the home. Third, warning labels are ineffective at preventing ingestions in children with cognitive disorders. Lastly, we are deeply concerned with the hazard pattern identified by the CPSC in older children and teenagers who unintentionally ingest magnets while using them to mimic body art and piercings (of the nose, lip, tongue, and cheek). Parents and other caregivers may purchase these magnet sets for older children without anticipating this non-intuitive risk. We do not believe warning labels can adequately inform older children and teenagers of the dangers associated with accidentally swallowing these magnets.

Our organizations request that the CPSC reject the petitioner's request and instead work with patient safety, consumer, and physician organizations to re-issue and consider strengthening the previously promulgated safety requirements for high-powered magnet sets. Thank you for your consideration of our comments. Should you require additional information, please contact the following representatives:

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Sincerely,

American Academy of Pediatrics
Consumer Federation of America
Consumers Union
Kids in Danger
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Public Citizen
U.S. Public Interest Research Group