NASPGHAN 714 N Bethlehem Pike Suite 300 Ambler, PA 19002 215-641-9800 naspghan@naspghan.org

Vicky Lee Ng, MD, FRCPC Hospital for Sick Children

PRESIDENT

NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY AND NUTRITION

November 19, 2024

Division of Gastroenterology and Nutrition 175 Elizabeth Street, 14th Floor Toronto, ON M5G 2G3 Canada 416-813-7654, ext. 422886 vicky.ng@sickkids.ca PRESIDENT-ELECT

Jeannie S. Huang, MD, MPH

Univ of California San Diego Rady Children's Hospital 3020 Children's Way, MC 5030 San Diego, CA 92123 858-966-4003 jshuang@health.ucsd.edu

PAST PRESIDENT Jenifer R. Lightdale, MD, MPH

Boston Children's Hospital Division of Gastroenterology and Nutrition 300 Longwood Avenue, Fegan, 5th Floor Boston, MA 02115 617-355-6058 jenifer.lightdale@childrens.harvard.edu

 ${\tt SECRETARY-TREASURER}$

Manu Sood, MD

Univ of Illinois College of Medicine 530 NE Glen Oak Avenue Peoria, IL 61637 309-655-4242 mrsood@uic.edu

EXECUTIVE COUNCIL

Alexandra Carey, MD Boston, MA

Conrad Cole, MD Gainesviille, FL

Jorge Chavez Saenz, MD Zapopan, Jalisco, Mexico

Christine Lee, MD Boston, MA

Peter Lu, MD Columbus, OH

Elizabeth Mileti, MD Las Vegas, NV

Veronique Morinville, MD Montreal, PQ

Jennifer Strople, MD Chicago, IL

EXECUTIVE DIRECTOR Margaret K. Stallings mstallings@naspghan.org

NASPGHAN Annual Meeting November 5-8, 2025 Chicago, IL The Honorable Alexander Hoehn-Saric, Chair The Honorable Peter A. Feldman, Commissioner The Honorable Richard Trumka, Commissioner The Honorable Mary T. Boyle, Commissioner The Honorable Douglas Dziak, Commissioner U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, Maryland 20814

Re: Safety Standard for Toys: Requirements for Water Beads; Docket No. CPSC-2024-0027

Dear Chairman Hoehn-Saric and Commissioners Feldman, Trumka, Boyle and Dziak:

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) appreciates the opportunity to comment on the proposed performance and labeling requirements for water bead toys and toys that contain water beads as published on September 8, 2024 in the *Federal Register*.

NASPGHAN represents more than 2,600 pediatric gastroenterologists in the United States, Canada, and Mexico, and is the only organization singularly dedicated to advocating for children with gastrointestinal (GI) disease.

NASPGHAN members are routinely called upon to care for children with a known or suspected water bead ingestion. When water bead ingestions go unwitnessed, there can be delays with diagnosis — days or even months — because these products cannot be easily visualized with a radiograph. The difficulty of assigning a diagnosis is further complicated because symptoms caused by the ingestion can mimic symptoms common with viral infections.

Because of the promotion of water beads as non-toxic, eco-friendly, biodegradable sensory toys, parents and other caregivers may underestimate the risk they pose if they are ingested. Even therapists who use water beads for sensory activities may not appreciate their risk. We commend the Consumer Product Safety Commission (CPSC) for recognizing the requirements currently in ASTM F963–23 for this category of toys are insufficient. The regulations need to address all known water bead hazards and thus necessitate additional performance and labeling requirements. We also appreciate the CPSC has used its authorities to issue recalls of certain water bead products and for making safety resources and educational

materials available to the public. The most effective policy, however, to prevent injury and harm to children caused by water beads is to eliminate their availability. This is why NASPGHAN and more than 40 other organizations¹ endorse legislation that has been introduced in the Senate² that:

- Explicitly establishes a ban on water beads products marketed to children as toys, educational materials, sensory tools, or art materials that expand by 50% or more with hydration or expand to a size of 3 mm or larger;
- Directs CPSC to consider regulations on the colors of other water beads that pose an ingestion hazard to limit their attractiveness to children; and
- Directs CPSC to require warning labels on packages of water beads that are used for other purposes.

Like high-powered magnet sets — a hazardous consumer product that also can result in grave injury and death when two or more are ingested — water beads are often packaged in large quantities. As a result, even when use of the product is under adult supervision, beads can roll or bounce far beyond their initial area of use and can be later discovered by a child. These beads resemble edible items like candy, making them highly attractive to children.

There is a growing body of literature describing the significant hazard associated with ingestion of water beads. A study published in July 2024 in the *Journal of Pediatric Gastroenterology and Nutrition (JPGN)* described the sharp rise of water bead ingestions in children presenting to emergency departments in the United States.³ This retrospective review evaluated the CPSC National Electronic Injury Surveillance System (NEISS) database from 2013 to 2023 and showed a significant increase in the number of water bead injuries over the 10-year period and demonstrates why a voluntary safety standard is insufficient to prevent water bead hazards caused by ingestion.

The study outlined four clear clinical concerns:

- First, children two years of age and younger accounted for 24% of the ingestion encounters. Seventy percent of cases requiring admission were for children 5 years of age or younger.
- Second, 75% of encounters which required escalation of care (e.g., admission or transfer) involved ingestion of multiple water beads.
- Third, the data suggest that children with atypical neurologic status (e.g., case mention of a child with concomitant autism spectrum disorder) are more likely to ingest water beads as compared to more common foreign bodies such as coins.
- Fourth, there was a significant uptrend in water bead injury frequency after 2020.

A retrospective study published in the *American Journal of Emergency Medicine* had similar results.⁴ A review of NEISS data from 2007 to 2022 identified 307 children and adolescents < 20 years of age who were treated for a water beadrelated exposure in an emergency department, which yields an estimated 8,159 emergency department visits nationally during this time period. This study confirmed other study findings that the majority (55%) of water bead ingestions occur in children 5 years of age and younger and that there has been a rapid upward trend in water bead ingestions between 2020 and 2022.

These study findings confirm the need for a stronger and more comprehensive safety standard.

In 2015, a paper on the clinical management of foreign body ingestions in children, developed by a group of pediatric endoscopists, was published in *JPGN*.⁵ The paper addressed a variety of foreign body ingestions, including water beads.

 $^{{}^{1}\;}Esther's\;Law;\;\underline{https://www.baldwin.senate.gov/imo/media/doc/esthers}\;\underline{law_one-pager.pdf}$

 $^{^2 \} Esther's \ Law, \ S. \ 4298 \ https://www.congress.gov/bill/118th-congress/senate-bill/4298?q=\{\text{``search''}: "Esther's+law''} \\ \&s=1 \&r=1 \ https://www.congress/senate-bill/4298?q=\{\text{``search''}: "Esther's+law'' + https://www.congress/senate-bill/4298?q=\{\text{``search''}: "Esther's+law'' + h$

³ Pasman EA, Khan MA, Kolasinski NT, Reeves PT. Water bead injuries by children presenting to emergency departments 2013-2023: An expanding issue. J Pediatr Gastroenterol Nutr. 2024 Sep;79(3):752-757. doi: 10.1002/jpn3.12333. Epub 2024 Jul 24. PMID: 39045753.

⁴ Holden J. Joynes, Sandhya Kistamgari, Marcel J. Casavant, Gary A. Smith; Pediatric water bead-related visits to United States emergency departments, The American Journal of Emergency Medicine, Volume 84, 2024, Pages 81-86, ISSN 0735-6757, https://doi.org/10.1016/j.ajem.2024.07.048.

⁵ Kramer RE, Lerner DG, Lin T, Manfredi M, Shah M, Stephen TC, Gibbons TE, Pall H, Sahn B, McOmber M, Zacur G, Friedlander J, Quiros AJ, Fishman DS, Mamula P; North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Endoscopy Committee. Management of ingested foreign bodies in children: a clinical report of the NASPGHAN Endoscopy Committee. J Pediatr Gastroenterol Nutr. 2015 Apr;60(4):562-74. doi: 10.1097/MPG.000000000000000729. PMID: 25611037.

Health Risks and Medical Management of Water Bead Ingestions

The paper highlights that foreign body ingestions in children create challenging clinical scenarios, the management of which are dependent upon patient size, type of object ingested, location, clinical symptoms, time since ingestion, and other factors. In very young children or children who are unable to verbalize a foreign body ingestion, it can be impossible to ascertain when and if an object was ingested. This especially complicates water bead ingestions because unlike other foreign bodies, water beads change size and may change shape while in the GI tract. Change in size is highly dependent on how long a water bead has been in the GI tract and if that information cannot be obtained, then management is further complicated.

A water bead, when expanded, can obstruct the bowel or gastric outlet. Several articles have documented cases where the ingestion of these super absorbent polymer beads led to obstruction. A series of articles spanning 2012-2024⁶⁻⁹ presented multiple cases of bodily injury and bowel obstruction in children due to these products. The published cases detail/illustrate the medical complications and harm caused by these dangerous water beads and the authors emphasize the necessity of prompt recognition and medical management as well as the need for caregivers to recognize the risks associated with these seemingly benign objects.

Management of water bead ingestions is made more challenging because they do not appear on radiographs without the administration of oral contrast. Newer techniques such as point of care ultrasound testing which was demonstrated in a case by Kim and colleagues has its own limitation such as availability and the location of the beads. Management of water beads and other foreign bodies in patients with no evidence of obstruction requiring surgical intervention has included home observation, hospital admission with observation and, in some cases, endoscopic and laparascopic procedures. A concern is that delaying immediate intervention can lead to worse outcomes as reported by case review studies. A longer lag time from ingestion increases the length of bowel traversed by the water beads, as well as the amount of absorbed water. As radiographic studies prior to removal are unhelpful due to the radiolucent nature of these objects, contrast studies could have utility in identifying areas of obstruction; however, contrast studies could delay plans for endoscopic removal. When ingestion is suspected but not witnessed, the decision to proceed with endoscopy is often made even before the advent of clinical symptoms, depending on the level of suspicion. If upper endoscopic examination fails to identify the object, continued close monitoring is required due to the risk of development of a more distal bowel obstruction.

Scope of Products within the Rule

Proposed performance and labeling requirements would apply to all water beads toys and toys that contain water beads, which are products marketed as a plaything for children under 14 years of age. CPSC notes in the proposed rule that water beads are included in a variety of toy products, including "toy sensory kits." While we appreciate the application of the proposed performance and labeling requirements to include the full range of toy products, we urge CPSC to expand its proposed performance and labeling requirements to include educational materials, sensory tools, or art materials that are not marketed as toys. At a minimum, we strongly recommend the CPSC require that water bead products outside the scope of this proposed rule be regulated in such a manner that minimizes their attractiveness to children, including by requiring that products could not be brightly colored. Alternatively, products that contain brightly colored beads should be included in the scope of products covered by new performance and labeling requirements.

Proposed Performance Requirements for Water Bead Toys

NASPGHAN commends the CPSC for recognizing the hazard water beads pose to children and for its proposed performance requirements. NASPGHAN agrees with CPSC's assessment that the ASTM test method, which uses a 10.0 mm diameter rod to apply force to an expanded water bead to determine whether the water bead can fit through the 20.0 mm test gauge, does not represent compression forces when a water bead is swallowed. Therefore, the ASTM test method

⁶ Kim HB, Kim YB, Ko Y, Choi YJ, Lee J, Kim JH. A case of ingested water beads diagnosed with point-of-care ultrasound. *Clin Exp Emerg Med.* 2020;7(4):330-333. doi:10.15441/ceem.20.041

⁷ Mehmetoğlu F. A Retrospective 10-Year Analysis of Water Absorbent Bead Ingestion in Children. *Emerg Med Int.* 2018;2018:5910527. Published 2018 May 6. doi:10.1155/2018/5910527

⁸ Mehmetoğlu F. A Retrospective 10-Year Analysis of Water Absorbent Bead Ingestion in Children. *Emerg Med Int.* 2018;2018:5910527. Published 2018 May 6. doi:10.1155/2018/5910527

is inadequate to effectively test water beads for an ingestion hazard. Further, we agree with the CPSC proposal that a 20.0 mm test gauge is too large and should be reduced.

Small bowel obstruction warranting laparoscopic intervention has been documented in at least one case involving a 13-month-old child who ingested an absorbed water bead that was 13.2 mm in diameter. This case shows that water beads may pass into the small bowel before reaching maximum size, which demonstrates that a 20.0 mm test gauge — which was based on the assumption that water bead obstructions were most likely to occur at the pyloric sphincter — is insufficient to protect against water bead hazards.

In addition to reviewing incident data to determine the maximum size of fully absorbed water beads that can pass through the GI tract, we also draw to the Commission's attention studies that look at intussusceptions — or obstructions — caused by polyps. 9 Generally intussusceptions are caused by polyps > 15 mm and treatment is mostly surgical. Study results support the approach of enteroscopic surveillance, with removal of small intestinal polyps > 10 - 15 mm to prevent intussusceptions. This and other studies support why the test gauge should not exceed 9.0 mm.

The proposed performance test in the proposed rule would require placing the expanded water bead at the top surface of the 9.0 mm diameter gauge's upper opening in the orientation least likely to pass through, and releasing the bead to allow it to travel down until it reaches the lower opening, then observing if the expanded water bead is able to remain whole and completely pass through the lower opening. CPSC further states in the proposed rule that by testing to observe if the water bead can completely pass through the 9.0 mm diameter funnel test gauge without external force, the test can simulate what occurs in a child's GI tract to determine whether the bead will or will not cause a blockage in a child's GI tract or, specifically, at the child's ileocecal valve.

We believe CSPC should also test multiple absorbed water beads moving through the funnel test gauge in close sequence. Because water beads are small, children often swallow multiple. The study by Pasman et al. ¹⁰ found 12 cases of care escalation reported when multiple water beads were ingested. This finding may indicate an increased severity of injury when multiple absorptive, expanding objects are ingested simultaneously by a child.

We appreciate CPSC is seeking feedback from stakeholders on questions of whether specific water bead products have a tendency to stick together or if there is an environment or scenario that has successfully caused expanded water beads to aggregate with themselves or other substances to cause an obstruction. We have no familiarity with water bead products sticking together; however, there is a likelihood that water beads could aggregate with each other or other substances and cause an obstruction. Whether water beads can aggregate and create an obstruction depends on the motility of the small bowel, which can be 2 to 12 hours and influenced by a variety of factors including food intake, medications, and anatomic issues. Therefore, the CPSC cannot not rule out that obstructions can be caused by "clumping" of multiple water beads.

Our concern with the ingestion of multiple water beads also includes whether the beads can "clog" the intestinal tract. This is why CSPC testing should look at whether multiple water beads, that individually meet the 9.0 mm funnel gauge test, can pass through the GI tract in close sequence.

We also ask CPSC to also clarify in the final rule whether it has considered the possibility of two or more water beads that would otherwise meet the 9.0 mm funnel gauge test getting stuck side-by-side in the intestine, causing an obstruction.

Product Labeling and Marketing

Young children are inherently curious, built to explore their environments, and due to developmentally appropriate exploratory behaviors, ingestion will remain a risk even with improvements in packaging and labeling and why a strong safety standard for water bead products is needed. Children may also be influenced by the attractiveness of water bead products, especially their colors, which can give them a candy-like appearance.

⁹ van Lier MG, Mathus-Vliegen EM, Wagner A, van Leerdam ME, Kuipers EJ. High cumulative risk of intussusception in patients with Peutz-Jeghers syndrome: time to update surveillance guidelines? Am J Gastroenterol. 2011 May;106(5):940-5. doi: 10.1038/ajg.2010.473. Epub 2010 Dec 14. PMID: 21157440.

¹⁰ Pasman EA, Khan MA, Kolasinski NT, Reeves PT. Water bead injuries by children presenting to emergency departments 2013-2023: An expanding issue. J Pediatr Gastroenterol Nutr. 2024 Sep;79(3):752-757. doi: 10.1002/jpn3.12333. Epub 2024 Jul 24. PMID: 39045753.

NASPGHAN supports the Commission's proposal to require the marking, labeling, and instructional literature requirements for all products within scope of the proposed rule. The proposed language for the warning labels for water bead toys and toys that contain water beads describe the hazard and the urgency of seeking medical attention if a water bead ingestion is suspected. NASPGHAN also encourages CPSC to consider whether language should be included in package inserts that states water beads, when ingested, will not appear on an X-ray. This could be valuable information if a water bead ingestion is suspected because health care providers in hospitals or urgent care centers may be unaware that water beads will not appear on an X-ray. As such, a patient with a "negative" X-ray could be sent home, increasing the risk of an adverse medical outcome. Including this additional information in the package insert gives parents and caregivers information that can be conveyed to a health care provider.

Conclusion

NASPGHAN thanks the Commission in advance for its consideration of its concerns and recommendations. While we ask CPSC to act expeditiously in finalizing a new safety standard for water beads, we also encourage the Commission to ensure that in promulgating new requirements it has considered all potential scenarios so that water bead product requirements are comprehensive enough to protect children from medical harm following an ingestion of a water bead(s). We are grateful that CPSC is pursuing regulations to address this hazard, and we thank you for the opportunity to provide input on this critical issue for child health and safety. We look forward to continuing to work with the Commission in protecting the health of all children. Any questions should be directed to Camille Bonta, NASPGHAN policy advisor, at cbonta@summithealthconsulting.com or 202-320-3658.

Sincerely,

Vicky Ng, MD President

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Jenifer Lightdale, MD

Immediate Past President

Aliquidels

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition