No. 22-9578

IN THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

MAGNETSAFETY.ORG; HOBBY MANUFACTURERS ASSOCIATION; NATIONAL RETAIL HOBBY STORES ASSOCIATION, INC.,

Petitioners,

v.

CONSUMER PRODUCT SAFETY COMMISSION,

Respondent.

On Petition for Review from the Consumer Product Safety Commission

BRIEF OF AMERICAN ACADEMY OF PEDIATRICS, NORTH AMERICAN SOCIETY FOR PEDIATRIC GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION, AMERICAN ACADEMY OF OTOLARYNGOLOGY-HEAD AND NECK SURGERY, AMERICAN PEDIATRIC SURGICAL ASSOCIATION, AND AMERICAN COLLEGE OF SURGEONS AS AMICI CURIAE IN SUPPORT OF RESPONDENT

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CORPORATE DISCLOSURE STATEMENTS

The American Academy of Pediatrics is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of AAP.

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of NASPGHAN.

The American Academy of Otolaryngology-Head and Neck Surgery is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of AAO-HNS.

The American Pediatric Surgical Association is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of APSA.

The American College of Surgeons is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of ACS.

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INTEREST OF *AMICI CURIAE*[1]

Amici represent pediatric physicians and surgeons on the front lines of treating children injured by magnet ingestion.

The American Academy of Pediatrics ("AAP") is a national non-profit professional organization dedicated to the health, safety, and well-being of children and adolescents. AAP's membership includes over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists.

The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition ("NASPGHAN" or the "Society") is a national society of more than 3,000 pediatric gastroenterologists and is the only organization singularly dedicated to advocating for children with gastrointestinal disease and injury. NASPGHAN strives to improve the care of infants, children, and adolescents with digestive disorders by promoting advances in clinical care, research, and education.

The American Academy of Otolaryngology-Head and Neck Surgery ("AAO-HNS") serves its 11,000 United States members in many ways to ensure they are able to provide the highest quality care to all patients. Protecting patients and enhancing public safety is a core principle of the AAO-HNS.

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[1] Counsel for all parties have consented to the filing of this brief. *Amici* certifies that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money intended to fund this brief, and no person other than amici, their members, and their counsel contributed money intended to fund this brief.

The American Pediatric Surgical Association ("APSA") represents over 1400-member pediatric surgeons, trainees, and affiliated professionals in pediatric surgery. The mission of APSA is to provide the best surgical care to our patients and families by supporting an inclusive community through education, discovery, and advocacy.

The American College of Surgeons ("ACS") is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient. Many of our more than 84,000 members are actively engaged in the care of pediatric patients.

Members of *amici* work in hospitals across the country, treating children facing serious, and sometimes fatal, injuries that often require life-changing surgery following the ingestion of tiny, high-powered magnets. *Amici* and their members have conducted and published research demonstrating the harms of these high-powered magnets and the significant increase in cases of ingestion following vacatur of the prior Consumer Product Safety Commission (the "Commission") rule, and *amici* have spent more than a decade advocating for a strong federal safety standard for these magnets. Certain *amici* and their members have submitted comments on this and prior Commission rules on high-powered magnets, testified in legislative hearings on these issues, and participated in committees working to implement voluntary standards. As the physicians who treat children for the injuries caused by high-powered magnets, *amici* possess unique expertise and data

that they provided to the Commission to assist its decision-making. *Amici* submit this brief to help the Court understand that data and why it so powerfully supports the critical protections adopted by the Commission.

SUMMARY OF THE ARGUMENT

Amici have witnessed first-hand the grotesque injuries that high-powered magnets have inflicted on children. They have laid children, writhing in pain, on x-ray tables. They have raced against the clock to save children's lives surgically. They have shepherded children and their scared families through difficult—and often lifelong—courses of follow-up treatment. Their medical expertise and experience treating high-powered magnet ingestions, together with their review of the evidence on which the Commission based its decision, lead *amici* to the firm conclusion that the Commission's rule is needed and evidence based.

We file this brief to make three points. First, as Petitioner Magnetsafety.org's Director explained, high-powered magnets are "inherently dangerous product[s]."[2] As *amici* explain, their very nature gives them a unique capacity to maim and kill

[2] Brief for Respondent, Excerpts of Record, at I-ER-148, Magnetsafety.org et al. v. CPSC, No. 22-9578 (10th Cir. Aug. 11, 2023), citing Todd C. Frankel, *Number of Children Swallowing Dangerous Magnets Surges as Industry Largely Polices Itself*, Washington Post (Dec. 25, 2019), https://www.washingtonpost.com/business/economy/number-of-children-swallowing-dangerous-magnets-surges-as-industry-largely-polices-itself/2019/12/25/77327812-2295-11ea-86f3-3b5019d451db_story.html. Citations to the Respondents' Excerpts of Record ("ER") begin with the record volume cited ("I," "II," or "III"), and end with the volume's page number.

children. Second, based on the evidence before it in the administrative record, the Commission's rule is reasonably necessary. Third, Petitioners' arguments rely on distortions of the data that the Commission considered, and that do not change the sufficiency of the evidence supporting the Commission's conclusion.

BACKGROUND

High-powered magnet sets are packages of small, powerful magnets designed to be used for "entertainment, jewelry (including children's jewelry), mental stimulation, [or] stress relief."[3] These sets typically contain dozens of "loose or separable magnets" that are extremely powerful and small.[4] If swallowed, they can cause tremendous harm.

The rule challenged in this case was promulgated following the vacatur and remand of a prior rule on the same subject.[5] On remand, the Commission conducted more research and sought further public input; it also issued recalls of certain magnet sets.

The research in the administrative record—much of which *amici's* members conducted and reviewed—makes clear the lifelong health impacts of magnet

[3] 87 Fed. Reg. 57756, 57756 (Sept. 21, 2022) (III-ER-567).

[4] *Id.*

[5] *Zen Magnets, LLC* v. *Consumer Prod. Safety Comm'n,* 841 F.3d 1141, 1155 (10th Cir. 2016).

ingestion. In one survey of AAP Surgical Section members submitted to the Commission, 73 of 99 children treated by pediatric surgeons for multi-magnet ingestions required abdominal surgery, and more than a third suffered multiple perforations of their gastrointestinal tract.[6] These ingestions can—and have—resulted in children dying.

The epidemiological evidence produced by the 2014 rule and its vacatur made tragically clear why this rule is so necessary: following the original rule's adoption, magnet ingestions dropped sharply, but after the rule's vacatur, ingestions climbed again. In January 2022, the Commission issued a new proposed rule, which, after receiving public comment, the Commission finalized on September 21, 2022 (the "Rule"). This rule establishes requirements for magnets of a certain size (i.e. small, and easier to swallow), requiring that they "have a flux index of less than 50kG^2 mm^2.[7]

[6] AAP and NASPGHAN, Comment Letter on Safety Standard for Magnets Notice of Proposed Rulemaking (Mar. 28, 2022), https://www.regulations.gov/document/CPSC-2021-0037-0718, citing Alicia M. Waters et al., 199 *Surgical Management and Morbidity of Pediatric Magnet Ingestions,* J. of Surgical Rsch. 137 (2015), https://www.journalofsurgicalresearch.com/article/S0022-4804(15)00404-7/fulltext.

[7] 87 Fed Reg. at 57756 (III-ER-567).

ARGUMENT

I. High-powered magnets cause life-threatening injuries to children.

In January 2021, a toddler in Michigan fell ill with vomiting. She wouldn't eat or drink. Because the girl's symptoms "were echoing those of people in her household who had COVID," doctors suggested COVID testing and monitoring.[8] No one knew about the seven tiny, high-powered magnets she'd swallowed until they showed up in the 14-month-old girl's autopsy. The magnets had been an older sibling's Christmas present.[9]

A 2-year-old Florida boy swallowed 16 magnets, which ripped holes from his stomach to his colon. Surgeons saved the boy's life, but at the cost of *three feet* of his intestine. After returning home, the boy continued losing weight, after which doctors diagnosed him with short bowel syndrome and inserted a feeding tube.[10] He may need one for the rest of his life.

These are not isolated examples. The administrative record is replete with physicians recounting gruesome injuries caused by magnet sets. One surgeon told

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[8] Transcript of Public Hearing (Mar. 2, 2022) (II-ER-390).

[9] Amended Staff Briefing Package at 25 (Sept. 13, 2022) (II-ER-450).

[10] Lauren M. Johnson, *A 2-Year-Old from Florida is Hospitalized After Complications from Swallowing 16 Magnetic Balls*, CNN (June 16, 2021), https://www.cnn.com/2021/06/16/us/2-year-old-swallowed-16-magnetic-balls-trnd/index.html.

of a child swallowing 120 magnets, which bulged against the child's stomach lining so tightly that their bright colors were visible through the tissue.[11] Another reported a case involving a three-year-old who required three surgeries in two weeks after magnets pressed so hard against his intestine walls that they fused together. They had come from an adult magnet set. [12] Another surgeon reported a patient with "14 bowel perforations from ingesting several magnets. It was the equivalent of a shotgun blast to the intestine."[13]

A. Magnet ingestion is a pediatric healthcare crisis.

Amici are familiar with difficult medical challenges. Yet the injuries caused by high-powered magnets shake the resolve of even the most experienced pediatric physicians. When a crisis is preventable, it adds a different shade to the experience and makes it even more harrowing. As clinicians, *amici* are well positioned to highlight the serious medical implications of magnet ingestion and the necessity of the degree and nature of the risk of injury sought to be prevented.

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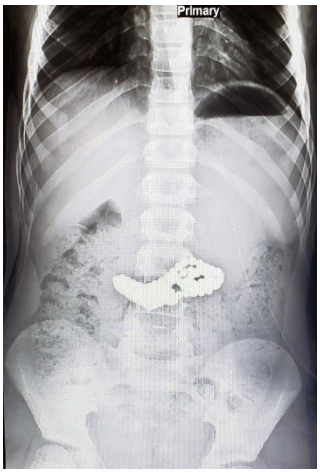
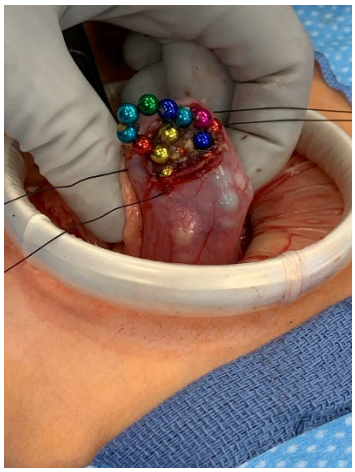
[11] AAP Fellow and Clinician, Comment Letter on Safety Standard for Magnets Proposed Rule (Mar. 15, 2022), https://www.regulations.gov/comment/CPSC-2021-0037-0055.

[12] David Klima, Comment Letter on Safety Standard for Magnets Proposed Rule (Feb. 4, 2022), https://www.regulations.gov/comment/CPSC-2021-0037-0009. The commenter explained that the child developed "multiple fistulae."

[13] Jonathan Kohler, Comment Letter on Safety Standard for Magnets Proposed Rule (Jan. 25, 2022), https://www.regulations.gov/comment/CPSC-2021-0037-0003.





[14]

As shown in these images from the administrative record, these magnets can be colorful and attractive to small children. Small children often swallow or mouth small objects, particularly when they are shiny or colorful, and tiny, spherical, high-powered magnets exactly fit this profile. While most ingestions of foreign objects—magnets and non-magnets—are unintentional,[15] and children pass the non-magnet objects without complication,[16] the ingestion of high-powered

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[14] AAP Fellow and Clinician Comment, *supra* note 11.

[15] In addition, young children often exhibit age-appropriate "mouthing behavior"—the propensity of infants or young children to place objects in their mouths for purposes of sensory development.

[16] "The ingestion of non-food items in children is a relatively common event, often unwitnessed, unknown, and unreported. For those children brought in for medical evaluation, less than 10% require intervention, and only 1% require surgery. This, however, is not the case for magnet ingestion." James R. Bailey et. al, *Unwitnessed Magnet Ingestion in a 5 Year-Old Boy Leading to Bowel Perforation After Magnetic Resonance Imaging: Case Report of a Rare but Potentially Detrimental Complication*, 6 Patient Safety in Surgery (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3468355/.

magnets is "strikingly different."[17] Once in a child's digestive tract, these powerful objects, drawn to each other by strong magnetic force, can tear through the child's insides, ripping through intestines, stomach lining, and anything else between them. Even within the digestive tract, these high-powered magnets will attempt to reconnect with each other, or with any other object with a magnetic force, no matter what is between them.[18]

As this is happening, it is often difficult to diagnose magnet ingestion unless a caregiver witnessed the ingestion. These children often present with stomach pain, vomiting, or a fever, with nothing on the surface suggesting more than a common stomach bug.[19] Many of these patients are too young to be able or willing to tell an adult that they swallowed magnets. Unless a physician has reason to investigate a possible ingestion, the child will likely be sent home for routine care—

[17] AAP and NASPGHAN Comment, *supra* note 6.

[18] As described below, even a single ingested magnet can connect with metal objects like a belt buckle or crib railing. Sunny Z. Hussain et al., *Management of Ingested Magnets in Children*, 55 J. of Pediatric Gastroenterology and Nutrition 239, 240 (2012), https://members.naspghan.org/App_Themes/Members/docs/Management_of_Ingested_Magnets_in_Children%2031.pdf., cited in Staff Briefing Package at 138 (Oct. 6, 2021) (I-ER- 168).

[19] *See* 87 Fed Reg. at 57758 (III-ER-569).

with parents and physicians all unaware that magnets are tearing through the child's insides.[20]

If two magnets (or a single magnet and another magnetic object) reconnect within a child's intestines, the damage is often catastrophic.[21] Magnets can "find" each other "across, or between different segments of the digestive tract, placing children at a remarkably high risk of catastrophic abdominal injury and death. The medical consequences can include gastrointestinal perforations, abdominal abscesses, or fistulas in the bowel."[22]

Death can follow within hours. When high-powered magnets tear intestinal walls, the contents of the intestines—unabsorbed food and feces—pour out. Sepsis, the body's life-threatening emergency battle against infection, often results.[23] In some cases, children suffer a lifetime increased risk of adhesive bowel

[20] *See, e.g.* Lisa Parker and Tom Jones, *Deaths of 2 Children Who Ingested Tiny Magnets Prompt Warning Ahead of Holidays*, NBC Chicago (Nov. 23, 2021), https://www.nbcchicago.com/consumer/2-children-killed-by-tiny-magnets-prompts-warning-ahead-of-holidays/2692301/.

[21] *See* 87 Fed Reg. at 57758 (III-ER-569).

[22] AAP and NASPGHAN Comment, *supra* note 6; *see also* 87 Fed Reg. at 57770 (III-ER-581).

[23] 87 Fed. Reg. 1260, 1276 (Jan. 10, 2022) (II-ER-320).

obstruction. Others are required to use a colostomy bag or feeding tube for the rest of their lives.[24]

These gruesome details are not merely anecdotes. *Amici* have conducted, and the Commission relied on, multiple studies and research surveys demonstrating the severity of high-powered magnet ingestion. A 2022 study emphasized that almost 10% of cases "led to morbidity," and almost 50% "required a procedure for magnet removal, or to address complications from magnet ingestion."[25] In another, "17 percent of the children they had treated were found to have at least one perforation or fistula, and 34 percent of the children had multiple perforations found along their gastrointestinal tract."[26] Yet another study found that the laparoscopic removal of these magnets "increases the lifetime risk of future adhesive bowel obstruction."[27]

Even in cases with positive medical outcomes, children who swallow magnets almost always require screening, monitoring, and emergency services until

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[24] *Id.* at 1277 (II-ER-321).

[25] 87 Fed. Reg. at 57759 (III-ER-570).

[26] AAP and NAPSGHAN Comment, *supra* note 6, at 2, citing Waters et al., *supra* note 6.

[27] AAP and NAPSGHAN Comment, *supra* note 6, at 2, citing Galinos Barmparas et al., *The Incidence and Risk Factors of Post- Laparotomy Adhesive Small Bowel Obstruction*, 14 J. Gastrointestinal Surgery 1619 (2010), https://pubmed.ncbi.nlm.nih.gov/20352368/.

the magnets pass through the body or are surgically or endoscopically removed. *Amicus* NASPGHAN's professional guidelines provide that physicians should consider removing even a single ingested magnet if accessible by endoscopy, though it may be reasonable to instead follow the patient with serial x-rays to ensure the magnet's passage.[28] In cases where ingestion of more than one magnet is confirmed, "pediatric gastroenterologists and surgeons must be engaged to track the movement of magnets through the digestive track."[29] This typically involves multiple x-rays and an endoscopy. One multi-hospital study of children who swallowed magnets found "81.4% of children received more than 1 radiograph, with a median of 5 radiographs" per patient.[30] "If the magnets fail to progress, patients require endoscopy and/or surgery to retrieve the magnets, to prevent complications or to treat resultant injuries."[31]

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[28] Robert E. Kramer et al., *Committee Commentary, Management of Ingested Foreign Bodies in Children, a Clinical Report of the NASPGHAN Endoscopy Committee*, 60 J. of Pediatric Gastroenterology and Nutrition 562, 567 (Figure 3) (2015), https://journals.lww.com/jpgn/pages/articleviewer.aspx?year=2015&issue=04000&article=00028&type=Fulltext, cited in Staff Briefing Package, *supra* note 18, at 33 (I-ER-176).

[29] AAP and NASPGHAN Comment, *supra* note 6.

[30] Leah K. Middelberg et al., *High-Powered Magnet Exposures in Children: A Multi-Center Cohort Study*, 149 Pediatrics 26, 29 (2022), cited in Amended Staff Briefing Package, *supra* note 9, at 34 (II-ER-449).

[31] AAP and NASPGHAN Comment, *supra* note 6, at 2.

The median hospital stay for these children is three days.[32] A three-day hospitalization for a child can be traumatic to children and their families. There are also real economic costs to these families and society. Parents must take time off work; children miss school; hospitals and families must spend significant money caring for children; and caretakers are wracked with guilt, worry, and regret. In the middle of this commotion and tension sits a child—often very young, many no older than two—repeatedly exposed to radiation and/or needles for blood work, and often requiring surgery.[33]

II. The Commission reasonably determined that the mandatory safety standard is necessary.

To issue a rule under the CPSA, the Commission must find that a mandatory safety standard is "reasonably necessary to eliminate or reduce an

[32] Amended Staff Briefing Package, *supra* note 9, at 24 (II-ER-449).

[33] *Id.; see also* National Cancer Institute, *Radiation Risks and Pediatric Computed Tomography (CT): A Guide for Health Care Providers*, NIH (2018) https://www.cancer.gov/about-cancer/causes-prevention/risk/radiation/pediatric-ct-scans ("Children are considerably more sensitive to radiation than adults, as demonstrated in epidemiologic studies of exposed populations"). Notably, these events are not unique to small children. Older children also have swallowed magnets while using them to mimic mouth piercings, only for the magnets to slip into their throats. Darlene Whitlock, Safe Kids Kansas, *Comment Letter on Safety Standard for Magnets Proposed Rule* (Nov. 21, 2012), https://www.regulations.gov/comment/CPSC-2012-0050-0479.

unreasonable risk of injury associated" with the product at issue.[34] *Amici* and their members have led research, education, and advocacy efforts to determine how best to reduce the harms of high-powered magnet ingestion. Based on their extensive experience and review of the record, *amici* can confirm that the Commission's decision to issue this rule is reasonably necessary.

Petitioners' attempt to reinterpret the evidence in the record fails. The Commission's conclusions track the findings of the peer-reviewed studies by Amici's expert members that the Commission considered. Petitioners do not and could not question the methodological rigor of those studies; the only way they can arrive at their preferred outcome is by manipulating selective presentations of the data to support their implausible hypotheses. The statistics and clinical experience described above would be enough to justify the rule. But the Commission had more: it had the benefit of a natural experiment the likes of which is rarely available when evaluating a proposed rule. Research detailed in the administrative record showed "[m]agnet ingestions were higher during the period of 2002 to 2011 prior to the CPSC mandatory magnet safety standard. A 2017 study showed the number of suspected magnet ingestions decreased from an estimated 3,167 cases in 2012

[34] Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (codified as amended at 15 U.S.C. § 2051 *et seq.*) § 2058(f)(3)(A).

(before the CPSC rule) to 1,907 cases in 2015 (after the CPSC rule)."[35] As *amici* explained in their comment, vacating the prior regulation "resulted in a major setback for public health efforts and led to the return of these magnets on the market. This led to a reversal of a prior downward trend when the safety standard was in place, and consequently, we saw a dramatic increase in pediatric ingestions of these dangerous objects."[36]

Amici are not alone in that conclusion. A 2020 study concluded "[r]emoval of [the 2014] rule is associated with increases in ED visits for magnet ingestions."[37] The Commission was correct in determining "during the period when the 2014 magnet sets rule was announced and in effect (2014-2016), magnet injury ingestion estimates are lowest by a significant margin, compared with the earlier and more recent periods."[38]

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[35] AAP and NAPSGHAN Comment, *supra* note 6, at 3.

[36] *Id.*

[37] Michael Flaherty et al., *Pediatric Magnet Ingestions After Federal Rule Changes, 2009-2019*, 324 JAMA 2102, 2103 (2020), https://jamanetwork.com/journals/jama/articlepdf/2773258/jama_flaherty_2020_ld_200102_1610651715.18816.pdf, cited in Staff Briefing Package, *supra* note 18, at 15 (I-ER-142).

[38] 87 Fed. Reg. at 57763 (III-ER-574.; *see also* Todd C. Frankel, *Risk of Children Swallowing Small Magnets Leads to Rare Mandatory Recall*, Washington Post (Aug. 17, 2021) https://www.washingtonpost.com/business/2021/08/17/magnet-safety-recall/ ("Created in 2012, the restrictions were lifted four years later in 2016 following a court challenge. What happened next can be seen in data from poison control centers: cases of accidental swallowing of magnets jumped sixfold").

Evidence from other countries has similarly shown the efficacy of regulations in this context.[39] A Canadian study concluded that in that country, "policy intervention appears to have quickly mitigated the threat of multiple magnet ingestions."[40]

III. Petitioners' arguments do not change the sufficiency of the Commission's findings.

Against the weight of this crisis, Petitioners' arguments do not show the CPSC failed to meet the governing legal standard. Petitioners attempt to obfuscate the issue by cherry-picking information from different sources to construct support for their argument. As organizations representing leading researchers, *amici* feel a responsibility to make clear that this is not a case of two parties using comparable data to support their arguments. The Commission's actions are supported by a large body of peer-reviewed and rigorous research and medical literature, while Petitioners have conducted their own pseudo-analysis of data, lacking any peer review process or adherence to methodological standards. Petitioners' argument suffers from four core defects.

First, Petitioners misconstrue the data in the administrative record.

[39] Staff Briefing Package, *supra* note 18, at 95 (I-ER-221).

[40] AAP and NAPSGHAN Comment, *supra* note 6, at 3.

Second, Petitioners overstate the sufficiency and efficacy of the voluntary standards in effect.

Third, contrary to Petitioners' arguments, the Commission correctly assessed the costs and benefits of the Rule, including how to assess the cost of hospitalization and treatment for those ingestions not requiring invasive surgery. The Commission was also correct to include in its assessment instances of single-magnet ingestion.

And fourth, Petitioners are incorrect that this rule is arbitrary, and should (1) instead focus on button batteries and (2) include within scope kitchen magnets.[41]

Amici address each of these issues in turn.

A. Magnet ingestions have outpaced ingestions of other objects.

Petitioners concede "the data shows that following this Court's *vacatur* of the 2014 Rule, the annual number of magnet ingestions increased as compared to the years when the 2014 rule was in effect."[42] However, Petitioners argue that children's ingestions of other objects has also increased and leap to the conclusion "it is likely that the increase in the ingestion of magnets that occurred between

[41] Petitioners also claim that the Commission itself under-enforced requirements before instituting the mandatory standards, which *amici* do not address here.

[42] Petitioners' Opening Brief at 17, Magnetsafety.org et al. v. CPSC, No. 22-9578 (10th Cir. May 1, 2023).

2018 and 2021 was caused, at least in part, by whatever factor caused the increase in ingestion of other small objects."[43]

What Petitioners decline to acknowledge, though, is that the increase in magnet ingestions dramatically outpaced the rise in overall ingestions. According to the data Petitioners themselves cite,[44] overall ingestions increased from 2006-2021 by about 73 percent (that is, from approximately 2,600 in 2006 to about 4,500 in 2021). However, magnet ingestions increased from approximately 800 in 2006 to about 3,400 in 2021[45]—an increase of *more than 300 percent*.

In other words, the higher rate of magnet ingestions did not merely correspond to the higher rate of overall ingestions; it *far exceeded* the higher rate of overall ingestions. Critically, the graph in Petitioners' brief also shows that while overall ingestions rose between 2014 and 2016—the years in which the prior Commission rule on magnets was in place—magnet ingestions did not.[46] Faced with this significant evidence, Petitioners dismiss NEISS data, arguing it shows "mere correlation."[47] As this Court has held previously, correlation "is nonetheless

[43] *Id.* at 19.

[44] *Id.* at 18.

[45] *Id.*

[46] *Id.*

[47] *Id.*

relevant to identifying causal relationships."[48] And correlation that tracks the promulgation and repeal of the Rule more closely would be difficult to come by. Petitioners' self-serving interpretation is thus inconsistent with the data—and certainly is not a conclusion the Commission and its epidemiologists were obligated to draw.[49]

B. The voluntary standards have not been sufficient.

The CPSA requires "if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that: (1) the voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or that (2) substantial compliance with the voluntary standard is unlikely."[50] The Commission's conclusion here matched *amici*'s own experience: each of the voluntary standards at issue—and all of them collectively[51]—fails to eliminate or adequately reduce these magnets' risks.

Petitioners argue that the Commission should have considered the impact of all four voluntary standards collectively, and its supposed failure to do so means

[48] *Etherton v. Owners Ins. Co.*, 829 F.3d 1209, 1220 (10th Cir. 2016).

[49] *A.L. Pharma, Inc. v. Shalala,* 62 F.3d 1484, 1490 (D.C. Cir. 1995) ("high level of deference" given to "agency's evaluations of scientific data within its area of expertise").

[50] 87 Fed. Reg. at 57757 (III-ER-568).

[51] 87 Fed. Reg. at 57765-57770 (III-ER- 576-581).

the Commission did not meet its burden. -But the Commission *did*: it found "there are subject magnet products, such as magnets sets, or magnet toys, or jewelry kits intended for users 14 years of age and older, and jewelry (both children and adult), that are not within the scope of the existing standards. Accordingly, even industry compliance with *all* the existing voluntary standards, were it achieved, would not adequately address the ingestion hazard."[52] The agency's conclusion is correct. As *amici*'s comments explained, the voluntary standards, considered collectively, "do not adequately protect children from the risk of injury and the severity of injuries that result from the ingestion of high-powered magnets."[53]

These voluntary standards do not sufficiently mitigate the core hazards of the product: namely, the size of the high-powered magnets and strength of the individual magnets that comprise the sets. The voluntary standards address only "marketing, packaging, labeling, and warnings for magnet sets," which are "insufficient to address the severity of the risks these products pose."[54] Indeed, the record demonstrated that, as the Commission explained, most incident reports

[52] 87 Fed Reg at 57769-70 (III-ER-580-81).

[53] AAP and NASPGHAN Comment, *supra* note 6, at 5.

[54] *Id.*

related to magnets involved products with clear labels and warnings to keep the product away from children.[55]

Furthermore, the record showed these warnings are typically on packaging that does not remain with the magnets themselves. An individual magnet is too small to carry a warning, and people often leave the magnets outside of their packaging for display or entertainment. Even if someone thinks they have stowed the magnets in the proper packaging, sets often include so many magnets that some can easily be overlooked and left loose.[56] Consumer Reports indicated that in most cases, "children did not access full magnet sets at the time of ingestion, but rather acquired loose magnets in the home, at daycares, at school, or from friends."[57] Incident data further demonstrate that children and teens "commonly obtain magnets loose in their environments, from friends, or at school, where the product is separated from any packaging or instructions that bear warnings."[58] As the Director of Endoscopy at the Children's Hospital of Philadelphia commented, "[i]t

[55] 87 Fed Reg. at 57765 (III-ER-576).

[56] 87 Fed. Reg. at 57769 (III-ER-580).

[57] Consumer Reports, Comment Letter on Safety Standard for Magnets Proposed Rule (Mar. 28, 2022), https://www.regulations.gov/comment/CPSC-2021-0037-0634.

[58] 87 Fed. Reg. at 57768 (III-ER-579).

is clear that the current warning labels and product inserts are insufficient to protect children."[59]

The Commission was entitled to credit such evidence. Thus, the Commission reasonably and correctly concluded that "warning requirements, alone, are not adequate to address the magnet ingestion hazard because caregivers and children commonly do not heed warnings, and children and teens commonly access magnets that are separated from their packaging where warnings are provided."[60]

In addition, Petitioners argue that voluntary standard ASTM F3458-21 prohibits the sale of certain magnets to consumers under the age of 14 years, and that such a prohibition could be found sufficient.[61] This argument ignores the host of cases in which children swallowed magnets used by older siblings, classmates, or parents.[62] Forbidding two-year-olds from buying magnets solves nothing. Data show that such age-focused prohibitions do not stop children from accessing and ingesting these magnets.[63] None of the tragedies described above (or

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[59] Peter Mamula, Comment Letter on Safety Standard for Magnets Proposed Rule (Mar. 11, 2022), https://www.regulations.gov/comment/CPSC-2021-0037-0024.

[60] 87 Fed. Reg. at 57769 (III-ER-578).

[61] Pet'rs' Br., *supra* note 42, at 19.

[62] Amended Staff Briefing Package, *supra* note 9, at 65 (II-ER-491).

[63] AAP and NASPGHAN Comment, *supra* note 6, at 4.

the many other injuries and near misses detailed in the administrative record and supporting studies) were prevented by the voluntary standards. As one pediatric surgeon explained, restricting "magnets intended for individuals over the age of 14 is imperative. It is not uncommon to see pediatric patients who will get into their parents[']drawers, games …I have had two patients in the last year and a half who were being watched by grandparents that ingested magnets and required surgery."[64]

The Rule is further justified because Petitioners have been resistant to any voluntary standards that incorporate protections that could significantly reduce the number and severity of magnet ingestions. In November 2019, a committee consisting of magnet industry officials, pediatric physicians, and safety advocates worked for almost two years to craft voluntary standards that would make high-powered magnets safer for children. The *amici* and consumer product safety organizations offered two proposals designed to prevent injuries from happening in the first place: weakening the magnets or making them too large to swallow. But the industry opposed both.[65] Without these changes, "I am struggling to see how it will be anything beyond a marginal improvement," *Consumer Reports*' director of product safety told the committee in an e-mail. But the industry resisted

[64] Klima, *supra* note 12.

[65] Frankel, *supra* note 2.

nevertheless, and the voluntary standard was published without the protections that experts believed necessary to reduce the risk.[66]

The next year, the number of magnet ingestions treated in emergency rooms went up more than 20 percent; the year after that, the number went up again by more than 13 percent.[67] It is clear the currently existing voluntary standards are inadequate to "eliminate or adequately reduce the risk of injury."[68]

C. The Commission correctly assessed the costs and benefits of the Rule and correctly scoped the Rule.

Petitioners question the Commission's analysis by arguing "parents will *always* bring a child in [to the Emergency Department] *whenever* the child has swallowed *any* object" and, therefore, that hospital visits do not necessarily equate with danger.[69] They state that, in a 2022 study, "over one-half of magnet ingestion incidents resolved spontaneously . . . suggest[ing] that a large portion of the costs that CPSC has attributed to the dangers of high-powered magnets were actually

[66] *Id.*

[67] 87 Fed. Reg. at 57763 (III-ER-574).

[68] 87 Fed. Reg. at 57757 (III-ER-568).

[69] Pet'rs' Br., *supra* note 42, at 24.

incurred for no reason at all."[70] This is not what the cited study suggested or concluded.

That study, published by AAP, reviewed data on almost 600 cases of magnet exposure by children.[71] Its conclusion could not be clearer: "Despite being intended for use by those >14 years of age, high-powered magnets frequently cause morbidity and lead to high need for invasive intervention and hospitalization in children of all ages."[72] The cases that resolved "spontaneously" in the study were not cases where *no* medical intervention was required;[73] they were simply cases in which *invasive surgery or endoscopy* was not required. Even a case with "spontaneous passage" requires medical attention and monitoring and can include hospitalization, multiple x-rays, laxatives, and IVs. It is impossible to know, without imaging and close monitoring, whether a case will resolve without significant harm or whether it will become a sudden, life-threatening emergency, which is why in most cases, a physician will not send a patient home to allow a magnet to pass; the patient must remain in the hospital for observation.[74]

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[70] *Id.*

[71] Middelberg et al., *supra* note 30, at 26.

[72] *Id.*

[73] Middelberg et al., *supra* note 30, at 30 (Figure 1).

[74] Hussain et al., *supra* note 18, at 240.

One can infer one of two arguments from Petitioners' brief: that Petitioners either believe parents should wait to see if the magnets perforate their child's intestines before seeking medical attention, rather than trying to prevent that damage in the first place; or that ingestions that do not require surgery are somehow harmless and costless. Neither should carry weight, and the Commission was not obligated to base its conclusions on such a dangerous approach.

Next, Petitioners claim that, because some of the data relied on by the Commission included single-magnet ingestions, the Commission overstated the Rule's benefits and understated its costs. Petitioners argue that an ingestion of a single magnet is no more dangerous than ingesting any other object, because a single magnet has no companion magnet to attract,[75] and that the Commission should not have considered data that included single magnet ingestions. This is the wrong conclusion, and the Commission was right to include the harms of single magnet ingestion in its assessments of the Rule's costs and benefits.

For one, single-magnet ingestions are difficult to identify. For example, in one case, a child was mistakenly "thought to have ingested a solitary magnetic toy," which led to "premature discharge from the hospital." [76] The patient returned with

[75] Pet'rs' Br., *supra* note 42, at 21-22.

[76] James Butterworth and Brad Feltis, *Toy Magnet Ingestion in Children: Revising the Algorithm*, 42 J. of Pediatric Surgery e3, e3 (2007), https://sciencedirect.com/science/article/abs/pii/S0022346807006367.

an abdominal perforation "resulting in an emergency laparotomy."[77] Because young children have limited or no verbal skills and cannot adequately communicate when and what they ingested, one cannot reliably know in many cases how many magnets were ingested. Answering that question usually requires multiple x-rays, at a minimum—an experience that brings many of the costs and harms that *amici* have already discussed.[78]

Furthermore, while ingestion of a single magnet may not lead to complications from the magnet attracting to another ingested magnet, it can lead to other concerns. In a forthcoming study from the IMPACT of Magnets Collaborative, 189 *single-magnet* exposures were reviewed. Of those cases, 23 (12.2%) required an endoscopic procedure to remove the item, either because of the child's symptoms, the location of the magnet (e.g., the esophagus), or the failure of the magnet to pass spontaneously. More than 10 percent of these single-magnet ingestions required hospitalization.

Unidentified single-magnet ingestions pose additional risks. High-powered magnets are strong enough to reset or turn off a cardiac pacemaker. And if a child receives an MRI with internalized high-powered magnets, the results are

[77] *Id.*

[78] *Supra* pp. 13 (discussion of radiation, stress, etc.)

catastrophic and possibly fatal, as has been reported in the medical literature.[79] Single magnets ingested with or in close proximity to other metal items—like a belt buckle—can also cause similar effects as multiple-magnet ingestions. For these reasons, *amici*'s professional guidelines state that physicians should consider removing a single ingested magnet if accessible by endoscopy, though it may be reasonable to instead follow the patient with serial x-rays to ensure the magnet's passage.[80]

D. The risks posed by button batteries and kitchen magnets are irrelevant to the sufficiency of the Commission's findings.

Finally, Petitioners attempt to distract from the core issues here by discussing battery ingestion over the same period, and by pointing to different types of magnets (e.g. kitchen magnets) the Commission determined should not be covered by the Rule. But Petitioners' analysis ignores important distinctions about these objects and cherry-picks data to create an inaccurate picture of what the record shows.

First, Petitioners need not explain to physicians the harms of button batteries, which they well know; *amici* support Congressional and regulatory efforts to limit the harm of these small objects as well. Indeed, the Commission

[79] Bailey et. al, *supra* note 16.

[80] Hussain et al., *supra* note 18, at 240 (Figure 3).

promulgated a proposed rule to address button batteries this year.[81] Caselaw has long held that government bodies such as the Commission are able to decide the order in which they address problems.[82] Batteries are not at issue in the present case, and Petitioners' arguments do nothing to rebut the simple fact that the Commission met its burden in demonstrating *this* rule is reasonably necessary to reduce *this* unreasonable risk of injury—to some of our most vulnerable people, no less.

Further, it is important to understand two critical differences between button batteries and high-powered magnets. For one, button batteries are stored *inside* devices—often shielded from ingestion. By contrast, high-powered magnets commonly sit on desks, easily accessible and "separated from the packaging."[83] For another, the Commission is required to consider "the public's need for products subject to the rule."[84] There can be no debate that button batteries, necessary for devices like watches and hearing aids, are of much greater public benefit than magnet sets ostensibly designed for only recreational purposes.

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[81] 88 Fed. Reg. 8692 (Feb. 9, 2023).

[82] See, e.g. *In re Barr Laboratories, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (holding that the FDA was in an "authoritative [ ] position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.").

[83] 87 Fed. Reg. at 57766 (III-ER-577).

[84] 87 Fed. Reg. at 57757 (III-ER-568).

Furthermore, it is important to consider ingestion risk relative to exposure. Button batteries are far more ubiquitous than high-powered magnet sets in American homes, so a comparison that focuses only on the raw number of ingestions is misleading. Petitioners cite data showing the incidence of high-powered magnet ingestion was approximately 0.8 per 100,000 persons, whereas button battery exposures were 1.5 per 100,000 persons between 2017 and 2019.[85] But the domestic button battery market in 2022 was more than 2 billion dollars at an average cost of approximately five dollars a package,[86] suggesting some 400,000,000 units sold per year. The Commission estimated the *highest* estimate of magnet set sales was approximately $35 million, and that an average price was $20—just 1,750,000 units.[87] Using these numbers, there are *228 times* more button batteries in the general populations than magnet sets, but *fewer than twice* as many

[85] Pet'rs' Br., *supra* note 42, at 9; *see also* Elyse Geibel et al., *Impact of the COVID-19 Pandemic on Foreign Body Ingestions in Children: Comparison of the Pre-Pandemic Period to 2020*. 75 *J. of Pediatric Gastroenterology & Nutrition* 299, 301 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9365073/. Further, Petitioners argue that National Poison Data System (NPDS) data provide evidence that there are more ingestions of button batteries than magnets. But NPDS data are *not* representative and cannot be used to argue incidence rates (as opposed to being offered as trend data that supports representative evidence).

[86] *Button Batteries Sales Market Report | Global Forecast From 2023 to 2031*, DataIntelo, https://dataintelo.com/report/global-button-batteries-sales-market/.

[87] 87 Fed. Reg. at 57777 (III-ER-588) (Comment 26).

ingestion cases. The risk of ingesting these magnets is therefore astronomically higher relative to exposure.

Next, Petitioners argue the Commission acted arbitrarily by including high-powered magnet sets, but not kitchen magnets, in the scope of the Rule. Petitioners point to Commission data identifying the number of magnet ingestions, by category, treated by hospital emergency departments.[88] This data says nothing of the severity of such ingestions; when that data is examined, it becomes clear that kitchen magnets "make up a very small portion of incidents that resulted in hospitalization[,] … internal interaction through body tissue, [or] … surgical procedures."[89] It also belies common sense to think that a decorative refrigerator magnet poses as high a risk as a high-powered magnet set. As the Commission stated in the proposed rule, magnets like home/kitchen magnets "are likely to be part of common household products, making them less conspicuous, accessible, and appealing to children and teens, since they are not intended for amusement or jewelry, and making caregivers less likely to give them to, purchase them for, or allow their use by children and teens."[90] The Commission's determination was not arbitrary; it was based on more than a decade of well-founded research.

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[88] 87 Fed. Reg. at 57761 (III-ER-572) (Table 1).

[89] 87 Fed. Reg. at 1291 (II-ER-335).

[90] 87 Fed. Reg. at 1290 (II-ER-334).

CONCLUSION

The Court should deny the petition for review.

RESPECTFULLY SUBMITTED this 18th day of August, 2023.

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CERTIFICATIONS OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6492 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word for Microsoft 365 in Garamond 14-point font, a proportionally spaced typeface.

I further certify that (1) all required privacy redactions have been made; (2) any paper copies of this document submitted to the Court are exact copies of the version filed electronically; and (3) the electronic submission was scanned for viruses and found to be virus-free.

/s/ Madeline Gitomer
Madeline Gitomer

Date: August 18, 2023

CERTIFICATE OF SERVICE

I hereby certify that on August 18, 2023, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Tenth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Madeline Gitomer
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Date: August 18, 2023