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Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

ZEN MAGNETS, LLC,

Petitioner,

v.

CONSUMER PRODUCT SAFETY COMMISSION,

Respondent.

No. 14-9610

Petition for Review of the
Consumer Products Safety Commission
(CPSC No. CPSC 2012 0050)

David C. Japha, Law Offices of David C. Japha, P.C., Denver, Colorado, for Petitioner.

Daniel Tenny (Benjamin C. Mizer, Principal Deputy Assistant Attorney General, Adam C. Jed, and Mark R. Freeman, Attorneys, on the brief) U.S. Department of Justice, Washington, D.C., for Respondent.

Before **GORSUCH**, **EBEL**, and **BACHARACH**, Circuit Judges.

EBEL, Circuit Judge.

Petitioner Zen Magnets, LLC ("Zen") challenges a regulation promulgated by Respondent Consumer Product Safety Commission ("the Commission") restricting the size and strength of the rare earth magnets that Zen sells. See Final Rule: Safety

Standard for Magnet Sets, 79 Fed. Reg. 59,962 (Oct. 3, 2014) (codified at 16 C.F.R. §§ 1240.1-1240.5). We conclude that the Commission's prerequisite factual findings, which are compulsory under the Consumer Product Safety Act, 15 U.S.C. §§ 2051-2089, are incomplete and inadequately explained. Accordingly, we VACATE and REMAND to the Commission.

I. BACKGROUND

This case concerns sets of small, high-powered magnets ("magnet sets") that users can arrange and rearrange in various geometric designs. The component magnets are unusually small (their diameters are approximately five millimeters) and unusually powerful (due to rare earth metal cores, their magnetic flux index[1] ranges from 400 to 500 kG^2mm^2). A set typically comprises on the order of 100 to 200 identical spherical magnets, coated in reflective silver or other bright colors. Magnets of this type were introduced to the United States circa 2009. They have since been marketed and sold to consumers—by Zen and other distributors—as desktop trinkets, stress-relief puzzles, and toys, and apparently also for educational and scientific purposes.

Although the strength of these magnets is part of their appeal, it can also pose a grave danger when the magnets are misused. Specifically, if two or more magnets are ingested—a temptation to which children are especially at risk—they can cause serious damage to intestinal tissue that becomes tightly clamped between them.

[1] Magnetic flux index is one way to estimate the attractive force of a magnet.

Attendant medical consequences can include hospitalization and surgery for such injuries as perforations, infections, gastrointestinal bleeding, and tissue death. The danger is compounded when parents and medical personnel remain unaware of the type of magnets ingested and their heightened risks.

That danger caught the attention of the Consumer Product Safety Commission. The Commission is an independent regulatory agency that administers and enforces the Consumer Product Safety Act ("the Act"), 15 U.S.C. §§ 2051-2089, a primary purpose of which is "to protect the public against unreasonable risks of injury associated with consumer products," id. § 2051(b)(1). In pursuit of that goal, the Commission is authorized to "promulgate consumer product safety standards" establishing performance or warning requirements for consumer products, id. § 2056(a), as well as to ban hazardous products altogether, id. § 2057.

The Commission's regulatory approach towards magnet sets progressed as follows. In 2008, Congress adopted as mandatory safety standards certain requirements developed by the American Society for Testing and Materials ("ASTM") to address hazards associated with children's toys. See generally 15 U.S.C. § 2056b; AR 142. With respect to magnets, those requirements prohibit any product "designed, manufactured, or marketed as a plaything for children under 14 years of age" from containing a loose magnet that (1) has a flux index greater than 50 kG^2mm^2 and (2) is small enough to fit within a standardized "small parts cylinder."[2]

[2] However, small, powerful magnets can be included in "[h]obby, craft, and science kit-type items intended for children over 8 years of age," so long as those

ASTM International Standard F963-11 Consumer Safety Specifications for Toy Safety §§ 3.1.37 (definition of "hazardous magnet"), 3.1.81 (definition of "toy"), 4.38-4.38.1 (prohibition of hazardous magnets in toys), and Fig. 3 (defining the small parts cylinder's dimensions to be a diameter of 31.7 mm with a height that, due to a sloped bottom surface, ranges from 25.4 mm on one side to 57.1 mm on the opposite side).[3] The purpose of those restrictions is to ensure that permissible magnets are either large enough to discourage ingestion or weak enough to avoid tissue strangulation upon ingestion. See ASTM F963-11 4.38; cf. Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. at 59,968.

During 2011, in response to reports of injured children, Commission staff began evaluating whether the magnet sets currently on the market complied with ASTM F963 ("the toy standard"). The Commission found that the individual magnets in those sets tended to be ten times more powerful—or, alternatively, six times smaller—than is permissible to market to children under the toy standard. See ASTM F963-11 §§ 3.1.37, 4.38-4.3.81; Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. at 59,976-77. Accordingly, Commission staff issued Notices of

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items comply with certain safety labeling requirements. ASTM F963-11 4.38.3, 5.17. Because neither party has cited or argued this aspect of the ASTM requirements on appeal, we do not address it further.

[3] This citation refers to the current version of the ASTM standard, which became effective June 2012. See Acceptance of ASTM F963-11 as a Mandatory Consumer Product Safety Standard, 77 Fed. Reg. 10,358, 10,358 (Feb. 22, 2012). The previous version, which was effective from August 2009 to June 2012, imposed the same requirements on children's toy magnets. See id.; ASTM International Standard F963-8 Consumer Safety Specifications for Toy Safety §§ 3.1.33, 3.1.72, 4.38-4.38.1, and Fig. 3. In the interests of brevity and clarity, this opinion cites only to the current version of the ASTM standard.

Noncompliance to companies that labeled or marketed these powerful magnet sets to appeal to children younger than fourteen years old, and warned other firms not to market their sets to children below that age.[4]

Some distributors took steps to comply with the toy standard, including implementing labeling enhancements and marketing restrictions. However, "into spring 2012, staff continued to identify additional firms offering [magnet sets] on the Internet with labeling and marketing violations." Proposed Rule: Safety Standard for Magnet Sets, 77 Fed. Reg. 53,781, 53,782 (proposed Sept. 4, 2012) (to be codified at 16 C.F.R. §§ 1240.1-1240.5). Moreover, reports of child injuries from magnet ingestion continued.

So the Commission stepped up its enforcement efforts. In May 2012, the Commission required the thirteen leading magnet set distributors to report any information of which they were aware reasonably supporting the conclusion that their magnets did not comply with an applicable safety standard, contained a defect, or created an unreasonable risk of serious injury. See 15 U.S.C. § 2064(b) (requiring distributors to report potential noncompliance with safety standards, defects, and risk of serious injury). Based on that information, by July 2012 Commission staff had negotiated agreements with ten of those companies to cease importation and distribution of magnet sets. Commission staff then initiated administrative complaints against the remaining three companies (including Zen), arguing that their

[4] In cooperation with two distributors, the Commission also published a public service announcement regarding magnet sets' dangers.

magnet sets constituted "substantial product hazards" that must be prohibited and recalled because they failed to comply with the toy standard and/or contained a product defect.[5] See 15 U.S.C. § 2064(a) (defining "substantial product hazard" to be a product that either (1) fails to comply with an applicable safety standard or (2) contains a product defect), (c) (authorizing the Commission to order a seller to cease distributing and to recall products that constitute a "substantial product hazard").

Four months after eliminating ten of the leading magnet set distributors, the Commission proposed a new safety standard aimed at regulating the size and strength of all magnet sets. See Proposed Rule: Safety Standard for Magnet Sets, 77 Fed. Reg. 53,781. In effect, the proposed standard extended the size and strength restrictions applicable to children's toys under ASTM F963 to magnets marketed, intended, or used for adult entertainment. After receiving comments and holding a public hearing, the Commission promulgated the proposed rule as a final safety standard on October 3, 2014. See Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. at 59,962, 59,966-72.

The final rule requires that, "Each magnet in a magnet set . . . that fits completely within the cylinder described in 16 CFR 1501.4 must have a flux index of 50 kG^2 mm^2 or less when tested in accordance with the method described in § 1240.4." 16 C.F.R. § 1240.3. The referenced cylinder is the same small parts cylinder as that used in the toy standard. Compare 16 C.F.R. § 1501.4 with ASTM

[5] The other two companies targeted by the Commission subsequently entered into settlement agreements to stop selling and to recall their products.

F963-11 § 3.1.37 and Fig. 3. And the flux index limit of 50 kG^2 mm^2 is the same limit as that used in the toy standard. See 16 C.F.R. § 1240.4 (incorporating the flux index measurement procedure of ASTM F963-11 §§ 8.24.1-8.24.3). As a result, the primary difference between the two standards is their scope of intended consumers. Unlike the toy standard, the final rule is not limited to magnets designed or marketed as toys for children under fourteen years of age, but rather applies to all magnet sets that meet the following definition: "Any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment."[6] 16 C.F.R. § 1240.2(b).

Zen is the only remaining importer and distributor of the magnet sets targeted by the final rule. Over the years, Zen has made efforts to comply with the toy standard by implementing fourteen-and-under age restrictions and placing warnings on its website and packaging, as well as by imposing sales restrictions on its retail distributors. Its magnet sets, however, do not comply with the strength and size restrictions of the final rule set forth at 16 C.F.R. § 1240.3. Accordingly, Zen seeks review of that safety standard pursuant to 15 U.S.C. § 2060(a), which provides that any person adversely affected by a rule promulgated by the Commission "may file a petition with the United States court of appeals . . . for the circuit in which such

[6] The other difference between the two standards that figures into this litigation is the addition of the phrase "commonly used," which enlarges the new rule in comparison with respect to the toy standard. That difference is discussed infra in Section II.C.

person . . . resides or has his principal place of business for judicial review of such rule."

II. DISCUSSION

Exercising jurisdiction pursuant to 15 U.S.C. § 2060(c), we review the magnet set safety standard in accordance with the provisions for judicial review set forth in the Administrative Procedures Act ("APA"), 5 U.S.C. ch. 7. See 15 U.S.C. § 2060(c) ("[T]he court shall have jurisdiction to review the consumer product safety rule in accordance with chapter 7 of title 5, and to grant appropriate relief . . . as provided in such chapter . . . ."). Accordingly, "our review is 'very deferential to the agency.'" Andalex Res., Inc. v. Mine Safety & Health Admin., 792 F.3d 1252, 1257 (10th Cir. 2015) (quoting Ron Peterson Firearms, LLC v. Jones, 760 F.3d 1147, 1161 (10th Cir. 2014)). Notwithstanding that deferential standard, we conclude that the Commission failed to meet the Consumer Product Safety Act's requirements for issuing a safety standard, for the reasons explained below.

I. The Consumer Product Safety Act

Broadly speaking, the Act sets forth a two-step process for promulgating a safety standard. See D. D. Bean & Sons Co. v. Consumer Prod. Safety Comm'n, 574 F.2d 643, 649 (1st Cir. 1978). First, the Commission must "consider" and "make appropriate findings" regarding the social and economic costs and benefits of the rule. See 15 U.S.C. § 2058(f)(1), (2). Specifically, the Commission must make findings identifying (1) the degree and nature of the risk of injury sought to be prevented; (2) the approximate number and type of products subject to the rule; (3)

the public's need for those products, and the probable effect of the rule on the utility, cost, and availability of the products; and (4) any means of reducing the risk of injury while minimizing adverse effects on competition or other commercial practices. Id.

Second, the Commission must balance the costs and benefits identified in its findings to determine whether a safety standard is justified. See 15 U.S.C. § 2058(f)(3). Specifically, the Commission can only promulgate a safety standard if it reaches and articulates four conclusions: (1) "that the rule . . . is reasonably necessary to eliminate or reduce an unreasonable risk of injury"; (2) that the . . . rule is in the public interest"; (3) "that the benefits expected from the rule bear a reasonable relationship to its costs"; and (4) "that the rule imposes the least burdensome requirement which prevents or adequately reduces the risk of injury for which the rule is being promulgated."[7] See 15 U.S.C. § 2058(f)(3)(A), (B), (E), (F).

Overall, then, the determination "involves 'a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation imposes upon manufacturers and consumers.'" Southland Mower Co. v. Consumer Prod. Safety Comm'n, 619 F.2d 499, 508-09 (5th Cir. 1980) (quoting Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831, 839 (5th Cir. 1978)); see also 15 U.S.C. § 2056(a) (requiring that "[a]ny requirement of such a [safety] standard shall be

[7] Additional conclusions (which we need not address, see infra Section II.C) are required for safety bans and rules implicating existing voluntary standards. See 15 U.S.C. § 2058(f)(3)(C), (D).

reasonably necessary to prevent or reduce an unreasonable risk of injury associated with such product").

The Act provides that a court may not uphold a safety standard unless the Commission's statutorily required findings and conclusions are "supported by substantial evidence on the record taken as a whole." 15 U.S.C. § 2060(c). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[8] Fowler v. Bowen, 876 F.2d 1451, 1453 (10th Cir. 1989) (quoting Richardson v. Perales, 402 U.S. 389, 401 (1971) ("The [Supreme] Court has adhered to that definition in varying statutory situations.")); see also Am. Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490, 522-23 (1981) (adhering to that definition when reviewing whether safety standards issued by the Occupational Safety and Health Administration were "reasonably necessary" under 29 U.S.C. § 652(8)). A court may "neither reweigh the evidence nor substitute [its] judgment for that of the agency." Andalex Res., 792 F.3d at 1257 (quoting Branum v. Barnhart, 385 F.3d 1268, 1270 (10th Cir. 2004)). Nonetheless, "[t]he substantiality of evidence must take into

[8] Contrary to Zen's contention, although courts once assumed that the Act's substantial evidence standard of review was more stringent than the APA's arbitrary and capricious standard of review, see, e.g., Aqua Slide, 569 F.2d at 837, that view is no longer viable. Courts now recognize that, "[w]hen the arbitrary or capricious standard is performing th[e] function of assuring factual support, there is no substantive difference between what it requires and what would be required by the substantial evidence test." Olenhouse v. Commodity Credit Corp., 42 F.3d 1560, 1575 (10th Cir. 1994) (quoting Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys., 745 F.2d 677, 683-84 (D.C. Cir. 1984) ("[I]n their application to the requirement of factual support the substantial evidence test and the arbitrary or capricious test are one and the same.")).

account whatever in the record fairly detracts from its weight." Norris v. NLRB, 417 F.3d 1161, 1168 (10th Cir. 2005) (internal quotation marks omitted).

II. The Commission's findings

In this instance, the Commission's rulemaking analysis fails at the first step of the Act's two-step process: the initial cost and benefit findings. Specifically, the Commission's analysis neglected to address critical ambiguities and complexities in the data underpinning the Commission's findings as to (1) the degree of the risk of injury caused by magnet sets, and (2) the public's need for the sets and the rule's effect on their utility and availability, see 15 U.S.C. § 2058(f)(1)(A), (C). As a result of those omissions, the Court is unable to ascertain whether the Commission's findings meet the substantial evidence standard—let alone to proceed to the next step of reviewing the Commission's balancing of the safety standard's costs and benefits.

1. Risk of injury

After analyzing a nationwide sampling of emergency room injury reports, the Commission estimated that the final rule would prevent approximately 900 magnet set-ingestion injuries annually, for a savings of $28.6 million. See Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,978-80; 16 C.F.R. § 1240.5(e)(2), (3). The Commission's benefit analysis, however, gives short shrift to two aspects of the injury data set that cast doubt on the Commission's findings.

The first problem stems from the data set's time frame. In performing its cost-benefit analysis, the Commission chose to rely on data spanning January 2009 through June 2012. See Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,978-80; 16

C.F.R. § 1240.5(e)(2), (3). But that data set does not reflect the subsequent significant market changes triggered by the Commission's compliance activities beginning in May 2012. As of July 2012, ten of the thirteen largest distributors had agreed, "at [Commission] staff's request," to stop selling and start recalling magnet sets; by December 2012, the dominant firm in the market had ceased operating. Id. at 59,964, 59,978. Sales of magnet sets dropped commensurately (in the Commission's words, they dropped "dramatically"). See id. at 59,978 ("[A]s a result of these actions and events, sales of the subject magnet sets currently are dramatically lower than they were at the time of the enforcement actions."); 16 C.F.R. § 1240.5(b) (estimating that magnet set sales, which totaled 2.7 million from 2009 to 2012, dropped to fewer than 25,000 per year after 2012).

As might be expected, injuries associated with ingestion of magnets from magnet sets also declined. According to the Commission's calculations regarding the eighteen months following June 2012, the estimated number of emergency room visits due to magnet sets dropped by about 100 incidents a year.[9] See 16 C.F.R. 1240.5(a). Inasmuch as the Commission estimated the expected useful life of magnet sets to be about one year, the injury rates appeared poised to continue to drop. See Final Rule:

[9] That is, the Commission estimated that an average of 610 emergency room-treated injuries per year occurred during the three and a half years from January 2009 through June 2012. 16 C.F.R. § 1240.5(e)(2). But the Commission estimated that an average of only 580 emergency room-treated injuries per year occurred during the five years from January 2009 through December 2013. 16 C.F.R. § 1240.5(a). In order for the data collected during those last eighteen months to reduce the annual average by that amount, estimated emergency room injuries must have decreased by about 100 injuries per year.

Safety Standard for Magnets, 79 Fed. Reg. at 59,982. Indeed, the number of incidents reported directly to the Commission receded from 52 in 2012, to 13 in 2013, to only 2 in 2014. See id. at 59,962.

The Commission recognized that the decrease in injuries was "[l]ikely due to [Commission] enforcement and regulatory activity beginning in mid-2012." Id. It appears that the Commission's regulatory activity was predicated at least in part on enforcing the preexisting toy standard, see id. at 59,962, 59,978 n.14 (incorporating administrative complaint by reference), which prohibits designing and marketing magnet sets to children, see ASTM F963-11 §§ 3.1.37, 4.38-4.38.1. Most of the pre-enforcement reported and estimated injuries concerned young children. See id. at 59,964 (stating that eighty-seven of the 100 incidents reported directly to the Commission concerned children younger than twelve years old, and 65% of the estimated injuries involved children between four and twelve years old). The Commission's benefits findings, however, do not adequately account for the reduced injury rate (and therefore reduced need for a new standard) resulting from its recent apparent enforcement of the existing safety standard addressed specifically to toys and children.

In general, where there is a known and significant change or trend in the data underlying an agency decision, the agency must either take that change or trend into account, or explain why it relied solely on data pre-dating that change or trend. See, e.g., Cty. of Los Angeles v. Shalala, 192 F.3d 1005, 1020-22 (D.C. Cir. 1999) (remanding a Medicare rate-setting for the agency to explain why it relied on data

collected under its former payment regime, where more recent data collected under its current regime showed a marked downward trend in relevant hospital discharge times); Seattle Audubon Soc. v. Espy, 998 F.2d 699, 703-04 (9th Cir. 1993) (finding that an agency preparing an environmental impact statement erred in failing to address an intervening, independent report indicating that an endangered species' "population [wa]s declining more substantially and more quickly than previously thought").[10]

> Since agencies "have an obligation to deal with newly acquired evidence in some reasonable fashion," Catawba Cnty. v. EPA, 571 F.3d 20, 45 (D.C. Cir. 2009), or to "reexamine" their approaches "if a significant factual predicate" changes, Bechtel v. FCC, 957 F.2d 873, 881 (D.C. Cir. 1992), an agency must have a similar obligation to acknowledge and account for a changed regulatory posture the agency creates—especially when the change impacts a contemporaneous and closely related rulemaking."

Portland Cement Ass'n v. EPA, 665 F.3d 177, 187 (D.C. Cir. 2011) (holding that, before issuing a new rule based on the predicted emissions of certain pollutant sources, an agency should have considered the effect that a parallel pending rulemaking would have on those same emissions). "The refrain that [an agency] must promulgate rules based on the information it currently possesses simply cannot excuse its reliance on that information when its own process [may have] render[ed] it irrelevant." Id.

[10] See generally Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 56-57 (D.C. Cir. 2015) ("[A]n agency cannot ignore new and better data."); Sierra Club v. U.S. EPA, 671 F.3d 955, 968 (9th Cir. 2012) ("[W]e should not silently rubber stamp agency action that is arbitrary and capricious in its reliance on old data without meaningful comment on the significance of more current compiled data.").

Here, the downward trend in injury rates is obvious, and appears to speak directly to the question of whether the new rule is "reasonably necessary." 15 U.S.C. § 2056(a). Yet the Commission offered no explanation or rationale for its apparent assumption that the observed reduction in injury rates would not endure. Rather, in addressing its decision to rely solely on pre-enforcement injury data, the Commission stated only:

> Because [Commission] compliance actions have significantly altered the state of the market, the environment before these actions occurred represents the best approximation of how the market would have operated in the absence of [Commission] intervention and is the appropriate reference baseline for evaluating the impact of the rule.

Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. at 59,978. That conclusory statement is insufficient to fulfill the Commission's duty to explain why the downward trend in post-enforcement injury rates was not relevant to its evaluation of the benefits of the new rule. See Portland Cement, 665 F.3d at 187; Shalala, 192 F.3d at 1020-21.

This Court stands ready and willing to defer to agency expertise and discretion, properly exercised. See Andalex, 792 F.3d at 1257. But "[i]t is not the role of the courts to speculate on reasons that might have supported an agency's decision." Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2127 (2016); see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) ("We may not supply a reasoned basis for the agency's action that the agency itself has not given.'") (quoting SEC v. Chenery Corp., 332 U.S. 194, 196

(1947)). "Whatever potential reasons the [Commission] might have given, the agency in fact gave . . . no reasons at all." Id.

An agency may not simply ignore without analysis important data trends reflected in the record. See Portland Cement, 665 F.3d at 187; Shalala, 192 F.3d at 1020-21. To the extent the Commission's findings rely solely on pre-enforcement injury rates, the Commission must offer a credible record-supported explanation as to why those rates accurately reflect the benefits of the new rule.[11]

The second problem with the Commission's injury findings arises from the imprecision of the injury report narratives. The Commission used a keyword search to identify magnet set-related injuries within a representative sample of emergency room reports. See Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,978. To the resulting injury count, the Commission applied a cost model to extrapolate the overall number of injuries nationwide. See id. at 59,979. We take issue not with the Commission's methodology, but rather with the degree of uncertainty the Commission

[11] The Commission contends Zen forfeited the time frame argument by failing to raise it before the Commission during the notice-and-comment period. Generally, a party challenging an agency regulation must have initially presented its concerns to the agency during the rulemaking process in order for a reviewing court to consider those concerns. See Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1041 n.9 (10th Cir. 2006). There are, however, exceptions to that requirement.

Claims not raised before an agency are not waived if "the problems underlying the claim are 'obvious.'" Forest Guardians v. U.S. Forest Serv., 495 F.3d 1162, 1170 (10th Cir. 2007) (quoting Dep't of Transp. v. Pub. Citizen, 541 U.S. 752, 765 (2004)); see also Sierra Club, Inc. v. Bostick, 787 F.3d 1043, 1048 (10th Cir. 2015) (same). Because the Commission's own calculations show a marked reduction in post-enforcement injury rates, the potential problems with that assumption were obvious. See Forest Guardians, 495 F.3d at 1170. Accordingly, we are not prohibited from reaching Zen's time frame argument.

condoned when implementing it: According to the Commission, ninety percent of the injury reports on which it ultimately relied only "possibly" involved the subject magnets sets.[12] See id. at 59,978, 59,980 ("[A]bout 90 percent of the cases upon which the table [estimating medical costs] was based were described as only possibly involving the magnets of interest . . . ."), 59,985 ("[T]here was an annual average of about 929 medically attended magnet ingestions that were defined as at least 'possibly of interest' during the period from 2009 through June 2012.").[13]

The Act provides that the Commission cannot promulgate a safety standard unless it concludes "that the rule . . . is reasonably necessary to eliminate or reduce an unreasonable risk of injury." 15 U.S.C. § 2058(f)(3)(A). Underlying findings that peg the risk of injury as a mere "possibility" provide the Court no assistance in assessing that conclusion. See Gulf S. Insulation v. Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1148 (5th Cir. 1983) (finding the Commission failed to show an unreasonable risk of injury because the equivocal predictions that the increased cancer risk could be "up to 51 in a million," and that "somewhat less than 20% of the population may

[12] Specifically, of the eighty-six injury reports on which the Commission based its benefits finding, only nine definitively involved the subject magnet sets (as evidenced by brand names mentioned in the injury reports). See Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,978. The remaining seventy-seven injuries "were determined possibly to have involved the magnets of interest" based on a keyword search. Id. (including injury reports with keywords and phrases such as "high-powered," "magnetic ball," "magnetic marble," "BB size magnet," and "magnet beads").

[13] Although a greater percentage of the incidents reported directly to the Commission can be reliably traced to subject magnet sets, 16 C.F.R. § 1240.5(a), the Commission specifically found that those anecdotal incidents could not be used to estimate nationwide injuries, Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,969.

respond" to the given toxicity level, "provides [the court] no basis for review"); Southland Mower, 619 F.2d at 510 ("Without reliable evidence of the likely number of injuries that would be addressed . . . , we are unable to agree that this provision is reasonably necessary to reduce or prevent an unreasonable risk of injury."). Almost anything is "possible." Therefore, the Commission's finding that 90% of the predicate injuries only "possibly" involved magnet sets provides the Court with little guidance as to where, on the spectrum from ninety to 900 annual injuries, the real injury rate lies.

We need not decide here what would be an acceptable degree of uncertainty in a benefits finding; it may vary depending on the inherent factual uncertainties in a given context. However, we are confident that mere possibility falls short of the appropriate standard. See Morall v. Drug Enf't Admin., 412 F.3d 165, 176 (D.C. Cir. 2005) ("Substantial evidence 'means evidence which is substantial, that is, affording a substantial basis of fact from which the fact in issue can be reasonably inferred. Substantial evidence is more than a scintilla, and must do more that create a suspicion of the existence of the fact to be established.'") (quoting NLRB v. Columbian Enameling & Stamping Co., 306 U.S. 292, 299-300 (1939); Greater Yellowstone Coal., Inc. v. Servheen, 665 F.3d 1015, 1028 (9th Cir. 2011) ("It is not enough for the [agency] to simply invoke 'scientific uncertainty' to justify its action.") (citing State Farm, 463 U.S. at 52); Vera-Villegas v. I.N.S., 330 F.3d 1222, 1231 (9th Cir. 2003) ("[C]onjecture is not a substitute for substantial evidence.") (quotation omitted)).

While the Commission is certainly free to rely on the emergency room injury report data set, it may not do so in a way that cloaks its findings in ambiguity and imprecision, and consequently hinders judicial review. We leave it to the Commission to determine whether its methodology and data set can in fact support a higher standard. We find only that the Commission's benefits statistics must instill in the Court a greater degree of confidence in their accuracy than is currently present here.[14] In so holding, we offer no opinion on the number of injuries that would support issuance of a new magnet set safety standard.

2. The public's need for magnet sets

Although the Commission's evaluation of the costs of the rule to magnet distributors was adequate, its evaluation of the costs to consumers was incomplete. Specifically, the Commission failed to address an entire aspect of magnet sets' utility—namely, the public's need for the sets as scientific and mathematics education and research tools—and the rule's probable effect on magnet sets' availability and usefulness for those purposes. See 15 U.S.C. § 2058(f)(1)(C).

[14] The Commission attempted to bolster its injury count by pointing out that (1) some injury reports that did not alert to the keyword search may have in fact involved magnet sets and (2) some medical experts have opined that the available medical research undercounts injuries associated with magnet sets. See Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. at 59,966, 59,980. Those two facts suggest that the true injury count may be higher than the Commission's estimate. The Court, however, takes issue with the uncertainty of the Commission's estimate—not with its magnitude. Inasmuch as those two facts are subject to their own reliability concerns (namely, imprecise report narratives cannot be traced to magnet sets, the experts did not quantify the degree to which they believe injuries are undercounted), they do not assuage the Court's concerns about the accuracy of the Commission's estimate.

Numerous comments received by the Commission indicated that teachers and researchers use magnet sets to model and explain physics, biology, and geometry concepts.[15] The Commission's findings, however, contain no substantive discussion of those uses. The Commission's analysis does not examine how widespread the claimed uses are, or whether substitute products, such as larger magnetic spheres or alternative construction toys, are (or could be made) available to serve those uses. Instead, the Commission's cost finding referred only to "some unknown quantity of lost utility." 16 C.F.R. § 1240.5(e)(6), (h)(2).

Even though the task may be difficult, the Commission is required to advance some explanation that allows a reviewing court to evaluate whether the cost of the lost utility is in fact outweighed by the benefits of the rule. See Aqua Slide, 569 F.2d at 840 ("The Commission does not have to conduct an elaborate cost-benefit analysis. It does, however, have to shoulder the burden of examining the relevant factors and producing substantial evidence to support its conclusion that they weigh in favor of the standard.") (citation omitted). In this instance, the Commission abdicated that responsibility by

[15] See, e.g., AR 911 ("As a physicist, graduate instructor, and Los Alamos National Laboratory employee, I wish to strongly oppose the ban on magnetic toys. These magnet sets are of tremendous educational values [sic], and I have used them in the classroom as well as at scientific community outreach events."); 1410 ("As a practicing physicist, I have used these magnets for experimental and demonstrative purposes, and they are very effective tools."), 1601 ("I am a high school biology teacher and I use magnets such as these as an invaluable teaching tool when discussing proteins structure and function. . . . It would be a great hardship to me and to the education of my students if these tools were no longer available."), 1696 ("I do research into geometric lattice theory with these mini-magnets . . . [now] I can no longer take advantage of a powerful tool."), 3704 (high school math department chair stating, "The Buckyball Science toy [(a certain brand of magnet set)] has been a remarkable teaching and learning tool in our home and in the classroom.").

failing to assess the demand for and usefulness of magnet sets as research and teaching tools. Without that information, the Court cannot accurately gauge the full costs of the safety standard.[16] Cf. id at 839-40 (citing Forester v. Consumer Prod. Safety Comm'n, 559 F.2d 774, 790-91 (D.C. Cir. 1977) (remanding safety requirements for bicycles because the "Commission has evidently not considered the utility of specific items that will be prohibited by the regulations")).

III. Zen's remaining arguments

We find the remainder of Zen's challenges to the rule unpersuasive. To begin, we do not reach Zen's alternative argument that the safety standard is in effect a ban. Because we find the Commission's underlying cost and benefit findings are inadequate, we have no cause to decide whether, in the next stage of cost-benefit balancing, the Commission would be required to meet the arguably higher standard applicable to bans. See 15 U.S.C. § 2058(f)(3)(C) (requiring, in the case of a ban, that the Commission find "that no feasible consumer product safety standard under this

[16] The Commission does not contend that it would not enforce the rule, which applies to magnets "intended, marketed or commonly used . . . for entertainment," 16 C.F.R. § 1240.2(b), against magnets also used for teaching or research. Although the Commission's regulatory analysis does not quantify what amount of use it considers "common," it does make clear that entertainment use by some consumers could trump both a distributor's stated intentions and alternative uses by other consumers. See Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,973 ("Common uses may be indicated by information found in consumer reports to the [Commission], firm reports to the [Commission], injury reports, and consumer comments/reviews posted on product Web sites stating that a product, regardless of whether it is intended or marketed by the manufacturer as such, was, in fact, being used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation or stress relief.") (emphasis added). Accordingly, the Commission should have considered all substantial uses—including research and education—that could be foreclosed by full enforcement of the rule.

chapter would adequately protect the public from the unreasonable risk of injury associated with such product").

Next, we find no merit in Zen's contention that the Commission did not comply with the APA's notice-and-comment procedures. See 5 U.S.C. § 553(b), (c). Zen complains it did not receive adequate notice of the scope of the final rule because it was not given an opportunity to comment on the Commission's insertion of the phrase "or commonly used" into the final definition of subject magnet sets. See 16 C.F.R. § 1240.2(b) ("*Magnet set* means: Any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment . . . .") (emphasis added). However, "[i]t is a well settled and sound rule which permits administrative agencies to make changes in the proposed rule after the comment period without a new round of hearings." Beirne v. Sec'y of Dep't of Agric., 645 F.2d 862, 865 (10th Cir. 1981).

The primary limitation on that principle is that a final rule must be a "logical outgrowth" of the proposed rule. Am. Mining Cong. v. Thomas, 772 F.2d 617, 637 (10th Cir. 1985). "A final rule qualifies as a logical outgrowth if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." CSX Transp., Inc. v. Surface Transp. Bd., 584 F.3d 1076, 1079-80 (D.C. Cir. 2009) (internal quotation marks omitted).

The Commission's notice of proposed rulemaking expressly requested comments regarding the rule's scope. See Proposed Rule: Safety Standard for

Magnets, 77 Fed. Reg. at 53,788, 53,799. Moreover, the notice evinced the Commission's concern that the proposed definition would not address the risks of magnets ostensibly marketed for purposes other than entertainment. See id. at 53,787. As such, it was reasonably foreseeable that the Commission would revise the definition to address that concern.

Moreover, the resulting revision was not "surprisingly distant" from the original definition. CSX Transp., 584 F.3d at 1080. Rather, the addition of the phrase "commonly used" is a logical outgrowth of the Commission's original approach of targeting magnets according to their primary use. See Proposed Rule: Safety Standard for Magnets, 77 Fed. Reg. at 53,800 (original definition applying to magnets "intended or marketed . . . primarily as" manipulative or construction entertainment items). The final rule confirms the purpose of the revision: "[It] seeks to prevent a manufacturer or importer of magnet sets from avoiding the rule by simply stating in marketing and other materials that the magnets are intended for uses other than those specified." Final Rule: Safety Standard for Magnets, 79 Fed. Reg. at 59,973. Because the final definition of magnet sets is a logical outgrowth of the proposed definition, the APA's notice requirement was satisfied.

Finally, we decline to rely on either party's letter purporting to alert the Court to supplemental authority. Neither letter is sanctioned by Federal Rule of Appellate Procedure 28(j), which permits a party to bring new legal authority—not new evidence—to the attention of the court. See Utah v. U.S. Dep't of Interior, 535 F.3d 1184, 1195 n.7 (10th Cir. 2008). Moreover, both letters improperly invite the Court to

review the safety standard on grounds and evidence that was not available to the Commission in promulgating the rule. See Fed. Power Comm'n v. Transcon. Gas Pipe Line Corp., 423 U.S. 326, 331 (1976) ("[W]e have consistently expressed the view that ordinarily review of administrative decisions is to be confined to consideration of the decision of the agency and of the evidence on which it was based. . . . The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.") (internal alteration, quotation marks, and citations omitted); Custer Cnty. Action Ass'n v. Garvey, 256 F.3d 1024, 1027 n.1 (10th Cir. 2001) ("Judicial review of an agency decision is generally limited to review of the administrative record."). Consistent with those conclusions, we do not consider either letter, and we DENY Zen's motion to strike the Commission's supplemental authority as moot.[17]

III. CONCLUSION

For the foregoing reasons, we VACATE and REMAND the Consumer Product Safety Commission's magnet set safety standard, 79 Fed. Reg. 59,962 (codified at 16 C.F.R. §§ 1240.1-1240.5), to the Commission for further proceedings consistent with this opinion.

[17] Of course, on remand, the Commission is free to consider that evidence if it reopens the administrative record to conduct additional fact-finding.

No. 14-9610, *Zen Magnets, LLC v. Consumer Product Safety Commission*
BACHARACH, J., dissenting.

Zen Magnets asserts six challenges to the Consumer Product Safety Commission's final rule establishing safety standards for magnet sets:

1. The Commission lacked substantial evidence in finding that the rule is reasonably necessary to avoid an unreasonable risk of injury.

2. The Commission's cost-benefit analysis was not supported by substantial evidence.

3. The Commission lacked substantial evidence in finding that the rule promotes the public interest.

4. The Commission did not adequately consider the magnets' usefulness in education, research, and art.

5. The rule constitutes a ban, which required additional findings.

6. The final rule impermissibly expanded the definition of the covered products.

I would reject these challenges and deny the petition for review. As a result, I respectfully dissent.

I. Sufficiency of the Evidentiary Support for the Commission's Findings

Zen Magnets challenges the adequacy of the evidentiary support for the Commission's findings on reasonable necessity, an unreasonable risk of injury, balancing of costs and benefits, and consideration of the public interest. For these challenges, we consider only whether the findings were based on substantial evidence. *See* 15 U.S.C. § 2060(c) ("The consumer

product safety rule shall not be affirmed unless the Commission's findings under sections 2058(f)(1) and 2058(f)(3) of this title are supported by substantial evidence on the record taken as a whole."). In my view, such evidence existed.

A. Our Framework for Review

"[O]ur duty is to guarantee that factual determinations are supported by reasonable, substantial and probative evidence considering the record as a whole." *Sidabutar v. Gonzales*, 503 F.3d 1116, 1122 (10th Cir. 2007) (alteration in original) (quoting *Uanreroro v. Gonzales*, 443 F.3d 1197, 1204 (10th Cir. 2006)). The evidence is considered "substantial" if it is relevant and might reasonably lead to a given finding. *TransAm Trucking, Inc. v. Admin. Review Bd.*, 833 F.3d 1206, 1209 (10th Cir. 2016). When applying this test, we follow three steps:

1. "[L]ook to the statute and legislative intent to determine the criteria necessary to establish the required findings."[1]

2 Ascertain "the relevant portions of the record . . . primarily by reference to pages cited by the parties."[2]

3. Evaluate the evidence and reject the agency's finding only if "any reasonable adjudicator would be compelled to conclude to the contrary."[3]

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[1] *Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n*, 569 F.2d 831, 838 (5th Cir. 1978).

[2] *Id.*

[3] *Sidabutar*, 503 F.3d at 1125.

B. Risk of Injury and Reasonable Necessity

The Commission could adopt the rule only by finding that

- the product creates an unreasonable risk of injury and
- the rule is reasonably necessary in light of that risk.

15 U.S.C. § 2058(f)(3)(A). In my view, the record supports the Commission's findings on both the unreasonable risk of injury and reasonable necessity for the rule.

Unreasonable Risk of Injury. A risk of injury is unreasonable when it exceeds "the harm the regulation imposes upon manufacturers and consumers." *Southland Mower Co. v. Consumer Prod. Safety Comm'n*, 619 F.2d 499, 508-09 (5th Cir. 1980) (quoting *Aqua Slide*, 569 F.2d at 839); *see also* Mathew E. Hoffman, *The Consumer Product Safety Commission: In Search of a Regulatory Pattern*, 12 Colum. J.L. & Soc. Probs. 393, 403 (1976) ("Basically, then, the cost of the Commission-imposed standards must be weighed against the cost of their absence.").

The Commission considered the risk posed by the magnet sets in an unregulated market and concluded that the magnet sets pose an unreasonable risk of injury and death. 79 Fed. Reg. at 59,962; 59,978-82. Zen Magnets argues that this finding lacked substantial evidence because the Commission relied on empirical data lacking enough certainty.[4] The

[4] Zen Magnets also contends that the number of ingestions did not increase when the magnets became available in 2009. But the record

majority agrees with Zen Magnets, reasoning that because 90% of the injury data only "possibly" involved the covered magnets, the data was too uncertain and imprecise to constitute substantial evidence for the Commission's findings on the risk of injury. But in addition to the empirical data, the Commission relied on three other sources of information.

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contains contrary evidence. For example, Dr. Oliva-Hemker testified about a clinical case survey conducted by the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Record at 7641-44. She observed that the study had shown an increase in the ingestion of magnets when high-powered magnet sets flooded the market in 2009:

> It was shown that during [a] ten year period. . . there were more than 16,000 emergency department visits for magnet related ingestion's [sic], and such visits in aggregate overall increased more than eight-fold.
>
> Importantly, it shows that magnet ingestion's [sic] began to increase in 2009. This was following a drop in cases from 2007 to 2009. We speculate that the drop in cases from 2007 to 2009 is attributed to the Commission's recall of numerous toy products that contained high powered magnets and adherence to toy safety standards.
>
> The increase in magnet ingestion's [sic] correlates with 2009 being the first year of significant sales of high powered magnet sets. For example, based on data available from one company alone, 1.5 million units of Bucky Balls were sold between 2009 and 2011, and other companies have similar high sales during that time period.

Id. at 7647-48.

The first was a survey of doctors, which showed a sharp increase in injuries caused by ingestion of magnets from 2008 to 2012. Record at 7719-20 (Statement of Dr. Maria Oliva-Hemker).

The second consisted of testimony about the results of a study published in the Journal of Pediatric Gastroenterology and Nutrition. *Id.* at 7644 (Statement of Dr. Maria Oliva-Hemker). This study concluded that incidents had spiked in 2009, when the magnet sets became popular. *Id.* at 7644-48.

The third consisted of comments by medical experts who regarded the statistical data as "a serious under estimation." *Id.* at 7619.

These sources support the Commission's findings that injuries increased when the magnet sets entered the market and that the magnets posed an unreasonable risk of injury.

Zen Magnets responds with two arguments: (1) the risk was reasonable because consumers were aware of the dangers, and (2) the risks were remote. These arguments do not vitiate the evidentiary support for the Commission's findings.

The Commission concluded that many children are unlikely to appreciate the dangers from ingesting the magnet sets. 79 Fed. Reg. at 59,969-71. For this conclusion, the Commission pointed to studies showing that caregivers are unable to constantly monitor children, older children

will "test limits and bend rules," and bitterants would not deter initial ingestions. *Id.*

The Commission also rejected the argument that the risk of injury was remote, noting that "there were an estimated 2,138 injuries treated in U.S. hospital emergency departments from 2009 through June 2012." *Id.* at 59,978; *see also id.* at 59,962 ("We do not agree that this is a low figure for injuries.").

Zen Magnets downplays the risk, citing favorable comparisons to the risk from harmless items like balloons. But these comparisons were far from unanimous. In my view, the record sufficed for the Commission's finding of an unreasonable risk of injury.

Reasonable Necessity in Light of the Risk. Zen Magnets also denies the existence of substantial evidence for Commission's finding that the new rule was reasonably necessary in light of the risk. I regard the evidence as sufficient.

Zen Magnets argues that the rule effectively bans the magnet sets, which is excessive in light of the risk of injury. But as discussed below, the Commission reasonably classified the rule as a safety standard rather than a ban.

Apart from characterizing the rule as a ban, Zen Magnets asserts that the rule is unnecessary in light of its costs. This assertion is neither developed nor persuasive. The Commission quantified the economic loss

from the rule, projecting $6 million in lost surplus. *Id.* at 59,981-82. In addition, the Commission acknowledged that consumers would lose some useful features of the covered magnets. *Id.* But the Commission concluded that the rule was reasonably necessary to curb injuries. *Id.* at 59,988. That conclusion was reasonable based on the record.

C. The Cost-Benefit Analysis

In conducting the cost-benefit analysis, the Commission relied on injury data from 2009 through June 2012. Zen Magnets argues that this data was outdated because the market changed dramatically in mid-2012, when the Commission announced future efforts to regulate magnet sets. The majority concludes that the data's timeframe is potentially problematic.

I would not reach the time-frame argument. During the notice-and-comment period, no one commented on the Commission's choice of a time-period for the cost-benefit analysis. In my view, the absence of public comment on this issue results in waiver of the challenge.

The Necessity of Public Comment. As the majority notes, a party challenging an agency rule must generally present its concerns to the agency during the rulemaking process. Maj. Op. at 16 n.11. "In a review of the decision of an administrative agency, a party waives its right to appeal an issue if it fails to object through comments or documents in the record."

Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1041 n.9 (10th Cir. 2006).

Because no one objected to the Commission's choice of a time-period, the Commission argues that this issue has been waived. Neither Zen Magnets nor the majority suggests otherwise. In fact, Zen Magnets fails to address waiver in either of its appeal briefs.

We ordinarily would go no further, for we generally take the parties' issues as they are presented to us. *Greenlaw v. United States*, 554 U.S. 237, 243 (2008). Instead, the majority concludes that we may address Zen Magnets' time-frame argument because a claim involving obvious defects is not waived even in the absence of a comment during the notice-and-comment process. Maj. Op. at 16 n.11.

So, is the Commission's reliance on data from 2009 through June 2012 an obvious flaw in the Commission's cost-benefit analysis? The majority answers "yes," reasoning that the injury rate substantially declined in 2012. *Id.*

The Commission acknowledged the decline in injuries, attributing the decline to a 2012 announcement of future rulemaking to curtail ingestions of high-powered magnets. Record at 8087. But in the Commission's view, the announcement "significantly altered the state of the market" and the prior environment "represent[ed] the best approximation of how the market would have operated in the absence of [the Commission's] intervention."

Final Rule: Safety Standard for Magnet Sets, 79 Fed. Reg. 59,962, 59,978 (Oct. 3, 2014) (codified at 16 C.F.R. §§ 1240.1-1240.5). Thus, the Commission chose a time-period, 2009 through June 2012, that reflected the injury rate when sellers had been allowed to flood the market with high-powered magnets. *Id.*

I do not think that this rationale is obviously defective. In any event, neither Zen Magnets nor the majority explains what is wrong with the Commission's explanation. I would hesitate to reject the Commission's explanation as "obviously" flawed in the absence of at least some argument by Zen Magnets.

D. The Public Interest

The rule could be adopted only if it promoted the public interest. 15 U.S.C. § 2058(f)(3)(B). The Commission found that this requirement had been met. 79 Fed. Reg. at 59,988 ("The regulations in this part are in the public interest because they would reduce deaths and injuries associated with magnet sets in the future."). Zen Magnets disagrees, contending that this finding was unsupported by substantial evidence and that the Commission ignored the magnet sets' utility as an art medium. I disagree.

Determination of the public interest involves policy-making, which lies within the Commission's expertise. *See* Teresa M. Schwartz, *The Consumer Product Safety Commission,* 51 Geo. Wash. L. Rev. 32, 34 n.5 (1982) ("Such general statutory guidelines delegated to the Consumer

Product Safety Commission . . . wide discretion to balance broad social goals and the competing claims of private interests in selecting products to regulate and in defining the contents of the regulation."). Applying this expertise, the Commission acknowledged the utility of magnet sets but found greater danger through injury and death. *See* p. 6, above. In assessing the public interest this way, the Commission did not err.

II. The Magnets' Usefulness

The majority concludes that the Commission inadequately considered the magnets' usefulness for education, research, and art. I respectfully disagree.

The Commission noted that some commenters had expressed concern that the new rule would eliminate the use of high-powered magnets in education and research. *Id.* at 59,967. Addressing these concerns, the Commission stated that many high-powered magnets would continue to be used in education and research:

> Magnets have long played a role in education. However, the specific products that are covered by the rule have been on the market only since 2008. The rule will cover only "any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." Magnets that are not subject to the restrictions of the rule would continue to be available. For example, less powerful magnets are sometimes included in science kits to demonstrate magnetism. In addition, high-powered magnets that serve industrial and commercial needs would not be covered by the rule.

Id. This explanation was sufficient.

Zen Magnets also argues that the Commission overlooked the magnets' use as an art form. The Commission acknowledged this use and explained that "[m]agnet sets that comply with the rule could serve some purposes of magnet sets that are currently available." *Id.* Zen Magnets does not identify any shortcomings in this explanation.

The majority states that the Commission must provide an explanation that allows meaningful review. Maj. Op. at 20. In my view, the Commission's explanation was sufficient for meaningful review.

III. Classification as a Safety Standard Rather than a Ban

Zen Magnets alternatively argues that the safety standard is functionally a ban. The Consumer Product Safety Act distinguishes between "safety standards" and "bans," but does not define either term. Because the statute is ambiguous and administered by the Commission, we must defer to the Commission's rules if they involve reasonable interpretations of statutory ambiguities. The Commission's classification of its rule as a safety standard, rather than a ban, is reasonable and entitled to deference.

A. The Commission's Administration of the Consumer Product Safety Act

The Commission administers the Consumer Product Safety Act, and Congress expressly instructed the Commission to use the notice-and-

comment process to adopt safety rules. 15 U.S.C. § 2058(d)(2). Therefore, *Chevron* deference applies to the Commission's interpretation of the Consumer Product Safety Act. *See United States v. Mead Corp.*, 533 U.S. 218, 229 (2001) ("[A] very good indicator of delegation meriting *Chevron* treatment [is] express congressional authorizations to engage in the process of rulemaking or adjudication that produces the regulations or rulings for which deference is claimed."); *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984) ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer . . . .").

As a consequence, we undertake the two-step *Chevron*-deference analysis. "When Congress has spoken to the precise question at issue, we must give effect to the express intent of Congress. If the statute is silent or ambiguous, however, we defer to the agency's interpretation, if it is a permissible one." *S. Utah Wilderness All. v. Dabney*, 222 F.3d 819, 1235-36 (10th Cir. 2000) (citing *Chevron*, 467 U.S. at 842-44).

B. Ambiguity of the Statutory Provision

We first consider whether Congress has spoken to the question at issue. Here, Congress failed to specify how to distinguish bans from safety standards. This omission left room for the Commission to exercise its discretion.

The Act contains separate sections for safety standards and bans, but does not give content to those terms. Section 2056(a) authorizes the Commission to adopt consumer product safety standards, which include "[r]equirements expressed in terms of performance requirements." 15 U.S.C. § 2056(a)(1). In contrast, § 2057 allows the Commission to ban a consumer product if "no feasible consumer product safety standard . . . would adequately protect the public from the unreasonable risk of injury associated with such product." 15 U.S.C. § 2057. There is no further discussion of the term "ban."

These provisions are ambiguous because they do not distinguish bans from safety standards. A safety standard that sets performance requirements can always be reframed as a "ban" on nonconforming products. But surely Congress did not mean to treat every safety standard as a ban, for the law states that the Commission can create performance requirements through safety standards. Thus, Congress ruled out the possibility that every prohibition on the sale of nonconforming products would constitute a ban. Instead, Congress allowed the Commission to draw a different line: Some safety standards that create performance requirements must qualify as safety standards rather than bans.

C. The Commission's Distinction Between Bans and Safety Standards

The Commission classified its rule—which prohibits the sale of small magnets with a flux index greater than $50\ kG^2\ mm^2$—as a safety standard. This interpretation of the statute is reasonable and entitled to deference.

Under *Chevron*, we cannot "substitute [our] own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984). Such judicial micromanagement would undermine an important rationale for deferring to administrative agencies: "to 'achieve predictable (and relatively litigation-free) administration of the vast body of complex laws committed to the charge of executive agencies,' by 'assur[ing] that reviewing courts will accept reasonable and authoritative agency interpretation of ambiguous provisions.'" *S. Utah Wilderness Alliance v. Office of Surface Mining Reclamation & Enf't.*, 620 F.3d 1227, 1235-36 (alteration in original) (quoting *Coeur Alaska, Inc. v. Se. Alaska Conservation Council*, 557 U.S. 261, 296 (2009) (Scalia, J., concurring)). Thus, we must defer to the Commission's classification of the rule as a "Safety Standard for Magnet Sets." 79 Fed. Reg. 59,962-01; 16 C.F.R. pt. 1240.

Zen Magnets points out that members of the Commission and public have sometimes referred to the rule as a ban. *E.g.*, Petitioner's Reply Br. at

14. But the Commission definitively expressed its view that the rule is a safety standard, rather than a ban, and we should defer to the Commission's characterization.[5]

IV. Expansion of the Definition of Products

Zen Magnets also contends that the Commission expanded the definition of the regulated products from what had been proposed in the notice of proposed rulemaking. Like the majority, I would reject this contention.

When an administrative agency uses the notice-and-comment process, the final rule must constitute a "logical outgrowth" of the proposed rule. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). This requirement ensures fair notice of what rule the agency might ultimately adopt. *Id.* Thus, a final rule is a logical outgrowth of a proposed rule if the final rule was "reasonably foreseeable" when the rule was proposed. *Id.* at 175.

Zen Magnets argues that the final rule deviated too far from the proposed rule, violating the Administrative Procedure Act, 5 U.S.C. § 553. I agree with the majority's rejection of this argument because the final

[5] In arguing that the safety standard was actually a ban, Zen Magnets maintains that the Commission did not make findings to support a ban. *See* 15 U.S.C. §§ 2057(2), 2058(f)(3)(C). Because the rule was not a ban, I would not address this argument.

definition of regulated products logically grew out of the proposed definition.

Zen Magnets challenges the change to the proposed definition of the magnet sets to be regulated. (The altered text is italicized.)

- **Proposed Rule:** "any aggregation of separable, permanent magnetic objects that is a consumer product *intended or marketed by the manufacturer primarily* as a manipulative or construction desk toy for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." 77 Fed. Reg. 53,783.

- **Final Rule:** "[a]ny aggregation of separable magnetic objects that is a consumer product *intended, marketed, or commonly used* as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." 16 C.F.R. § 1240.2(b).

The final rule reaches further than the proposed rule by adding the phrase "commonly used."

The magnets' common use does not necessarily reflect manufacturers' intentions, for individuals might use magnet sets differently than manufacturers intend. For instance, assume that Zen Magnets advertised only in high school science catalogs and websites, labeled the magnet sets "educational products," and warned that the magnets are not safe for use as toys. With these assumptions, we could infer that Zen Magnets intended purchasers to use the magnet sets as educational products. But if consumers chose to use the magnets as toys, the common use would diverge from Zen Magnets' intended and marketed

uses. Thus, the final rule differs from the proposed rule and we must consider whether the final rule is a "logical outgrowth" of the proposed rule.

This determination generally hinges on the salience of the changed language to a reader of the proposed rule. Salience is a product of

- the prominence of the issue in the proposed rule[6] and
- whether the issue was flagged as something that might be changed in the eventual rule.[7]

Here, both factors indicate that the final rule was a logical outgrowth of the proposed rule, for the Commission unambiguously stated that the definition of "magnet set" was subject to change and invited comments on the definition. *See* Notice of Proposed Rulemaking: Safety Standard for Magnet Sets, 77 Fed. Reg. 53,781, 53,787 (Sept. 4, 2012) ("The Commission seeks comment on the scope of the products proposed to be covered by this proposed rule and, in particular, whether risks are presented by magnets in science kits or craft and hobby kits no matter how they are age graded and labeled.").

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[6] *See, e.g.*, *AFL-CIO v. Donovan*, 757 F.2d 330, 339 (D.C. Cir. 1985) (noting that language that was altered by the final rule "appeared [in the proposed rule] only as part of the entire set of Service Contract Act regulations . . . , which was reprinted in full in some forty pages of the Federal Register").

[7] *See CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009) (explaining that when the notice of proposed rulemaking expressly asked for comments on an issue, changes to the relevant language were a logical outgrowth).

In this manner, the Commission provided notice to interested parties that the definition of "magnet sets" might be broadened or narrowed. Such notice was sufficient. *See CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009) ("We have found that a final rule represents a logical outgrowth where the [notice of proposed rulemaking] expressly asked for comments on a particular issue or otherwise made clear that the agency was contemplating a particular change."); *Alto Dairy v. Veneman*, 336 F.3d 560, 570 (7th Cir. 2003) (holding that notice was sufficient because industry "insiders" would realize that an issue was at stake).

V. Conclusion

Because I would not disturb the Commission's rule, I respectfully dissent.