# UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

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In the Matter of	)	
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ZEN MAGNETS, LLC,	)	CPSC DOCKET NO. 12-2
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RESPONDENT	)	
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		_
	<u>AFFIDAVIT</u>	
The State of Colorado	)	
	) S.S.	
County of Denver	)	

- I, Shihan Qu, Principal Officer of Respondent Zen Magnets, LLC of Denver, Colorado, submit this affidavit pursuant to 5 U.S.C. § 556(b) and hereby SWEAR OR AFFIRM:
  - 1. On September 29, 2014, the Consumer Product Safety Commission ("Commission") concluded a rulemaking concerning the same Subject Products sold by Zen Magnets, LLC. The Rule (16 C.F.R. part 1240) was published on October 3, 2014 and became effective on April 3, 2015. The Subject Products are aggregated masses of high-powered small rare earth magnets ("SREMs") known as Zen Magnets and Neoballs.
  - 2. At the time the Rule was promulgated by the Commission, Zen Magnets was the only remaining major firm selling magnets subject to the Rule.
  - 3. When the Commission promulgated the Rule, it made certain legal and factual findings that necessarily prejudged numerous questions of law and fact that are at issue in the administrative adjudication, CPSC Docket No. 12-2.

4. On September 29, 2014, Commissioner Ann Marie Buerkle issued a statement in which she explained why she was abstaining from voting on the Rule. That statement reads:

I did not vote on the final rule promulgating a mandatory standard for magnet sets because I believe that it would be inappropriate at this time. Currently, the Commission staff is actively pursuing an administrative enforcement case against the only remaining seller of these magnet sets. That case is scheduled for trial before an Administrative Law Judge (ALJ) in early December 2014. After the ALJ issues his initial decision, it may be appealed to the Commission (unless of course the matter is previously settled, as both of the other recent magnet cases have been). As potential future judges in that appeal, the Commissioners are often reminded to keep an open mind on the subject of magnet sets, so that we may decide the enforcement matter impartially. Under these unusual circumstances, I believe it would have been prudent to postpone any decision on whether to adopt a mandatory standard for magnets sets until the adjudication is settled or agency proceedings are concluded.

The preamble accompanying the final rule summarizes the Commission's enforcement efforts involving magnet sets. In May 2012, the agency's Office of Compliance contacted 13 independent importers of magnet sets. In short order, the staff convinced 11 of the 13 firms to stop importation, distribution and sales of the magnet sets voluntarily.

Two firms did not agree to stop selling magnet sets. The Commission therefore approved the initiation of administrative enforcement proceedings against these two in July and August 2012. The first case, involving Buckyballs, was settled earlier this year. That leaves only one case still pending. It involves the firm called Zen Magnets, LLC. [Footnote omitted.] Thus, of all the importers initially approached by the Compliance staff, only one – Zen Magnets – continues to sell magnet sets that would be proscribed by the new mandatory standard, and that same firm is the sole respondent in the last remaining enforcement case. Preamble at 5; see also preamble at 26-27 (of the seven importers that accounted for the great majority of units sold by July 2012—"perhaps more than 98%"—only one, Zen Magnets LLC, continues to market magnet sets that are subject to the rule).

The enforcement case against Zen Magnets is an administrative adjudication subject to special trial-type procedures such as witness testimony and cross examination, which don't apply in ordinary rulemaking. The Administrative Procedure Act (APA) also establishes "separation of functions" safeguards for adjudications. The Commissioners, as possible future decisionmakers, are not allowed to receive or make contacts with either of the parties individually, including our own CPSC staff attorneys who are prosecuting the case. 5 U.S.C. § 557(d). These safeguards help prevent bias and promote fairness.

While such an adjudication is pending, Commissioners are routinely cautioned to avoid making statements, or even asking questions, that may suggest a prejudgment of the matter. To issue a final rule outlawing the very same product that is the subject of the adjudication would seem to be the ultimate prejudgment.

The situation here is particularly unusual in that the only magnet sets that are practically affected by the new standard are those already involved in the adjudication. There is a close identity between the products affected by the rule and those potentially affected by the adjudication. In the usual case, a standard would sweep more broadly, but the agency's prior enforcement efforts have left Zen Magnets as the only firm still selling magnet sets in the United States. [Footnote omitted.]

Some have suggested that finalizing the magnet standard poses no prejudgment problem because the standard will apply only prospectively, *i.e.*, after the effective date, while a decision in the enforcement case – if favorable to the CPSC staff – would operate retroactively (*i.e.*, resulting in a recall of magnet sets already in the market). This view is oversimplified, because if the enforcement case is decided against the respondent, it will also have prospective effect, prohibiting any further distribution of the only magnets sets currently being sold. *See* 15 U.S.C. § 2064(c)(1); Preamble at 4 (in the administrative enforcement case, CPSC staff sought "an order that the firm cease distribution and importation of the products.").

Some have suggested that issuing a final rule would not be prejudicial in this instance because the criteria for promulgating a mandatory standard are different from the criteria necessary to justify a recall. In this case, the differences are more apparent than real. To obtain an involuntary recall, the staff must prove that the magnet sets constitute a "substantial product hazard." 15 U.S.C. § 2064(d). That term is defined in the CPSA to mean a product that creates "a substantial risk of injury to the public," either because of a failure to comply with an applicable standard or because of a defect. 15 U.S.C. § 2064(a). To promulgate a mandatory standard, the Commission must make a number of specific findings, of which one is that the rule "is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product." 15 U.S.C. § 2058(f)(3). While it may be possible to imagine an "unreasonable risk of injury" that is not also a "substantial risk of injury," there is at the least a very substantial degree of overlap between the two. [Footnote Omitted.]

To the best of my knowledge, this Commission has never before promulgated a mandatory standard addressing a hazard that is the subject of a pending adjudication. Indeed, I have not found any judicial decision that addresses any agency promulgating a mandatory standard under these circumstances. Even if such a precedent exists, the situation at hand calls for special treatment, at least to avoid the appearance of prejudgment.

Finally, I wish to address the possibility that postponing a decision on the final rule could lead to more injuries as a result of continuing sales of magnets sets that would be subject to the mandatory standard. Although it is possible that some additional injuries may occur from the small number of ongoing sales, it is far from certain. According to the preamble, there were 52 incidents of magnet ingestions by children reported to CPSC in 2012, but the reports dropped to 13 ingestions in 2013 (including a fatality) and 2 ingestions in 2014. Preamble at 4. Perhaps in view of this sharp decline, the Commission did not set the effective date of the standard for magnet sets as soon as possible, but kept it at 180 days after publication in the Federal Register (as proposed). [Footnote omitted.] If we had postponed decision on the standard, as I recommended, it is entirely possible that the enforcement case would be over by then, and we could decide on the standard without any concern regarding prejudgment.

#### CONCLUSION

I express no view on the merits of the standard for magnet sets because I believe that doing so is inappropriate at this time. We may be called upon to serve as judges of the last remaining enforcement case, which is scheduled for trial shortly. Under these unusual circumstances, I believe we should have postponed the vote on the rule until the administrative enforcement case is settled or agency proceedings are concluded.

CPSC, Ann Marie Buerkle, *Statement on the Final Rule for Magnet Sets*, http://www.cpsc.gov/en/About-CPSC/Commissioners/Ann-Marie-Buerkle/Ann-Marie-Buerkle-Statement-on-the-Final-Rule-for-Magnet-

Sets/?utm\_source=rss&utm\_medium=rss&utm\_campaign=Commissioner+Buerkle+Statements+ (Sept. 29, 2014) (emphasis added).

1. On September 24, 2014, Chairman Kaye read the following statement from Commissioner Buerkle:

I have decided that I will not participate in today's Commission Meeting or vote on the final rule for magnet sets. The mandatory standard being considered would apply to the same magnet sets that are subject of a pending CPSC Administrative Case which is scheduled for trial in December. Since the Commission may be called upon to review the Administrative Law Judge's decision in that case, I do not think it is appropriate for me to vote on a standard addressing the same magnet sets at this time. I appreciate the Chairman's allowing this statement to be read[.]

Statement of Commissioner Buerkle read by Chairman Kaye, Commission Meeting:

Decisional Matter – Safety Standard for Magnet Sets – Final Rule (Sept. 24, 2014).

6. On September 29, 2014, Commissioner Robert Adler issued the following statement:

On September 24, 2014, the Consumer Product Safety Commission, by a 4-0 vote, approved the publication of a consumer product safety standard for certain high-powered magnet sets. I proudly joined this vote and believe that it goes a long way towards protecting young children – among our most innocent and vulnerable citizens – from the extremely serious internal injuries and death that these magnets, if swallowed, can cause.

I regret the absence of the wisdom and good cheer of my colleague, Commissioner Buerkle, from the deliberations on this issue. I particularly regret the reason she offered for not attending these meetings or casting a vote because, while I respect her thoughtful consideration, I do not agree with her decision to abstain.

The general proposition my colleague advances is that the Commission should have postponed its vote on a mandatory standard for high-powered magnets in order to avoid "prejudging" any appeal that might arise in a pending administrative enforcement case brought against several firms that is currently before an Administrative Law Judge. [Footnote omitted.] In that case, the Commission staff seeks to have specific high-powered magnets declared a substantial product hazard under section 15 of the Consumer Product Safety Act (CPSA). Whether the postponement my colleague envisions would be for weeks, months, or years is unclear to me since, as a matter of principle and long-standing practice, I do not know the status of the case.

### **Background: How Enforcement Cases Proceed**

As a starting point, I feel it useful to review how administrative proceedings under section 15 of the CPSA begin and how they are litigated. Under section 15, the Commission is authorized, *inter alia*, to seek the recall of a product that is determined to be a "substantial product hazard." A substantial product hazard arises when a product fails to comply with an applicable CPSC rule that creates a substantial risk of injury to the public or contains a defect that creates a substantial risk of injury to the public. [Footnote omitted.] In order to declare a product a substantial product hazard, the Commission must file an administrative action pursuant to section 554 of the Administrative Procedure Act (APA), which provides for a hearing before an Administrative Law Judge (ALJ) in a trial-type proceeding.

In order to bring such a proceeding, the Commissioners must authorize the filing of a complaint against a respondent or respondents under the provisions of the agency's rules of procedure. [Footnote omitted.] Once a complaint is filed, the case is then tried by CPSC enforcement staff before an ALJ in accordance with the agency's rules and, any appeal from the ALJ's decision will come before the Commission for resolution. [Footnote omitted.]

Here, I note a unique feature of federal administrative law, i.e., the Commission is the body that initiates the adjudication and, if an appeal is taken, the Commission is also the entity that decides the appeal. Although observers occasionally express misgivings about an agency head serving both as initiating and appellate body in an administrative action, [footnote omitted] the Congress has repeatedly enacted this type of administrative structure [footnote omitted] and the courts have consistently upheld this combining of functions. [Footnote omitted.]

# Prejudgment Issues: Distinguishing "Unreasonable Risks" From "Substantial Product Hazards"

As I understand it, the objection in the magnet case is not that the Commission, having initiated an administrative proceeding against respondents, may serve as the appellate body in the case. It is that the Commission should not have voted to promulgate a safety standard during the pendency of the adjudicative proceeding lest we prejudge the results of the enforcement case. Although I understand the concern for due process, I strongly disagree that there has been any interference with it.

I remind interested observers what we have done with our vote to promulgate a safety standard. In accordance with sections 7 and 9 of the CPSA, [footnote omitted] the agency has determined that certain high-powered magnets present an "unreasonable risk of injury" to the public. Having made this determination, the Commission has imposed a set of restrictions on the types of such magnets that may be sold in the United States. [Footnote omitted.] This determination has been made after following the due process requirements of the law, including:

∀ providing notice to the public of the proposed rule,

Vpermitting any member of the public wishing to do so to file comments and objections to the proposed rule,

∀inviting any member of the public wishing to do so to provide oral comments on the proposed rule, and

∀addressing and responding to the comments filed with the agency. [Footnote omitted.]

These due process rights extend to, and safeguard, all interested parties, including any respondent in the enforcement action against high-powered magnets. In my judgment, the Commission and its staff meticulously followed all procedural requirements called for in the Consumer Product Safety Act in drafting the magnet standard. Accordingly, I find it hard to

see any impropriety in the standards setting process. Given this, in accordance with the provisions of the CPSA, the Commission has set an effective date for implementing the standard's requirements. After that date, no one, including any respondent in the ongoing administrative case, will be able to distribute noncomplying magnets in the United States.

At this point, one may ask whether the Commission's determination that high-powered magnets present an "unreasonable risk of injury" somehow means that we have prejudged the issue of whether they also constitute a "substantial product hazard" such that we should be disqualified from hearing an appeal from an ALJ's ruling should one be brought to us. [Footnote omitted.] That is, does a Commissioner's vote to promulgate a mandatory standard automatically mean that the Commissioner has prejudged whether a product presents a "substantial product hazard?" [Footnote omitted.]

I think not. Speaking as one Commissioner, I fully understand the difference between making a determination that a product presents an unreasonable risk of injury and should not be sold in the future versus a determination that a product currently being distributed presents a substantial product hazard and should be recalled from the market. The two determinations involve different facts, different policies and different law. And, in both cases, the full panoply of due process rights applies to anyone affected by Commission action.

I particularly note the sharp differences in the law between the two findings: An "unreasonable risk" determination involves a careful balancing of the risk against the impact of a proposed rule on the product's price, utility, and availability. A "substantial product hazard" determination focuses almost exclusively on the risk of a product and imposes a much higher standard of proof than an "unreasonable risk" finding. This is so because a substantial product hazard determination seeks to remove an otherwise legal product from the marketplace due to its particularly hazardous nature whereas a safety standard never touches products currently in inventory or in distribution. Accordingly, it is entirely possible that a product found to present an <u>unreasonable</u> risk of injury might be completely exonerated as a <u>substantial</u> risk of injury. [Footnote omitted.] And, I am fully confident that every CPSC Commissioner easily understands the distinction and can vote appropriately.

#### An Ominous Precedent

To take the position that assessing the risk of injury of a product in a rulemaking vote would prejudice a Commissioner in assessing the product's risk of injury in a subsequent (but quite different) enforcement proceeding sets an ominous precedent for the Commission's safety efforts. Suppose the

Commission did postpone its vote on a safety standard for an undetermined period of time – perhaps months or years – until all appeals were exhausted in a section 15 enforcement case. Why would there be any less potential prejudice in the Commission's subsequent decision to set a safety standard? [Footnote omitted.]] If the issues are inextricably intertwined such that a decision in one matter irretrievably clouds a Commissioner's mind in another, would there not be significant prejudice either way? In fact, given the higher standard of proof in section 15 cases, one might argue that a Commission decision to uphold an ALJ's determination that a product presents a substantial product hazard would make it virtually impossible for the Commission to decide that the product did not present an unreasonable risk of injury. [Footnote omitted.]

Having searched far and wide, I have found no statutory restriction, administrative agency, or administrative case law (or any other authority) that would bar the Commission from hearing an appeal in an adjudicated case simply because the Commissioners had voted on a safety standard regarding the product in litigation. To the contrary, where Congress has voiced a policy preference regarding agency action against hazards currently in the marketplace and similar hazards in the future, it has blessed concurrent rulemaking and adjudication. [Footnote omitted.]

Moreover, although the pending administrative case involves only one respondent at the moment, one must think of the worrisome precedent of staying action on safety standards more broadly. Assume, for example, enforcement cases involving numerous respondents distributing hundreds of thousands, if not millions, of products in the marketplace during the years of pendency of the cases [footnote omitted] — and I need remind no one that virtually all administrative adjudications, including the current case, typically stretch out for years. To defer a vote on a safety standard while waiting for the resolution of an enforcement case would unnecessarily expose the public to dangerous products for unacceptably long periods of time — to no useful end whatsoever.

#### Conclusion

I find it difficult to believe that Congress would have created the CPSC or any administrative agency with a gaping regulatory hole that bars the agency from providing full protection to the public – in effect, having to choose between protecting consumers now versus those in the future. This would truly be a Hobson's choice of a distressing nature. Accordingly, I stand by the Commission's decision.

CPSC, Robert Adler, Statement on the Final Rule for Magnet Sets, http://www.cpsc.gov/en/About-CPSC/Commissioners/Robert-Adler/Commissioner-Adler-

Statements/Statement-on-the-Final-Rule-for-Magnet-

Sets/?utm\_source=rss&utm\_medium=rss&utm\_campaign=Adler+Statements (Sept. 29, 2014) (emphasis in original).

# 7. On September 29, 2014, Chairman Kaye issue the following statement:

We have no more sacred charge at the U.S. Consumer Product Safety Commission than to protect vulnerable populations, especially children. For this reason, I was proud to join with three of my fellow Commissioners to approve unanimously a new federal safety standard for high-powered magnet sets. Doctors, families of victims and consumers across the country called upon the Commission to vote yes to protecting children and teenagers from the hidden and devastating hazard of magnet ingestion—and we responded.

During the time I have been at the CPSC, the Commission has taken a number of important and uplifting consumer product safety actions. An example that comes to mind is when the Commission approved in 2010 the creation of the SaferProducts.gov database of publicly searchable consumer product safety incidents. For the first time, consumers were given direct access to, and a voice on, reports of harm and potential harm that had been hidden from public view.

Our action on high-powered magnet sets is just as important from a safety perspective. But, for me at least, it is much more solemn.

## CPSC Staff Appropriately and Properly Acted to Protect Children

Before explaining why, it is important to note that I have not seen a better example of the Commission, and particularly the CPSC staff, responding and proceeding in a manner true to our mission and purpose.

The action that culminated in this week's vote began with incident reports. First a few, then more, and finally, enough to become a very alarming and disturbing trend. This was a trend that our staff had experience in detecting and addressing, as many years earlier there was a wave of serious injuries and incidents involving magnets in children's toys. The hazard pattern [footnote omitted] with magnet related incidents is similar—it is hidden, both from caregivers and medical professionals.

In an effort to reverse the trend and address the emerging hazard with aggregated magnet sets, our staff worked through a progression of our authorities starting in 2011. We hoped each step taken would be the last one needed to address the frightening injuries to children – injuries that have been described as gunshot wounds to the gut but without sign of entry or exit.

Unfortunately, the continued prevalence of incidents made pursuing a mandatory rule necessary. And so the staff did, beginning in September 2012, with a Notice of Proposed Rulemaking. This was a bottom-up effort, not the result of any kind of Congressional or Commission-level prompting. As a result, CPSC staff faithfully executed the mission of the agency by recommending to the Commission that federal rulemaking be pursued. I want to express my deep appreciation to all of the CPSC staff who worked so hard on this rule.

### Magnet Sets are Associated with Significant Hurt and Loss

From a consumer product safety perspective, this truly is an important moment. But, as I mentioned, I believe it is also a solemn one. For me, the action CPSC has taken is accompanied by the tremendous amounts of loss and hurt that many have experienced and still will experience.

Many are facing financial loss, whether that be as a result of health care costs piling up from treatment to their children injured by these magnets, or whether that be businesses, and one business in particular, likely to bear the brunt of our regulatory action approved today.

Many hurt emotionally, whether that be from enduring their child suffering from these horrible injuries, or whether that be a business owner grappling to accept an entrepreneurial dream faces possible extinction.

Most heart wrenching of all, one little girl, [AC], was terribly hurt and lost forever.

We all have fears in life. Every single one of us. For me, the biggest without any question, is something tragic happening to one of my boys. Every night, EVERY NIGHT, long after we have put them to bed, I sneak back into their rooms to kiss them one more time. As I do that, I feel tremendous gratitude they are alive and well, and that I am so blessed to have the privilege of hearing in the dark of their rooms the soothing and rhythmic sound of their breathing. I hug them tight,

trying not to wake them, all the while knowing that, as long as I might hang on that particular evening, that moment is rather fleeting. And I also know each night that there is certainly no guarantee I will have even one more night to hold onto them tight.

As a parent and as the Chairman of the CPSC, I hurt so much for [AC's] family. I was so deeply moved that [AC's] mother, brothers, grandmother, aunt, and cousin took the time to drive from Ohio to attend the Commission's vote. I will always think of [AC] when it comes to this rule and the action the Commission has approved, and I am so deeply sorry for [AC's] family's loss.

Also in our thoughts is [BJ] from Louisiana, who had to battle through numerous surgeries as a 2-year old, after his intestines were perforated. [BJ] is not alone, as many children and teenagers have suffered serious injuries after ingesting these hazardous magnets. As many families and the medical community well know.

To the medical community—specifically the gastroenterologists—led by Dr. Athos Bousvaros, the President of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition, we thank you for your contributions to this effort, including your first-person accounts of rushing children into surgery.

# Recognizing Rulemaking Ramifications while Providing a Much Safer Path Forward

There is, of course, another extremely important aspect to our action today. And I alluded to it earlier. I feel the weight of, and am sorry for, the likely loss of one man's dream. While there are some who we do not agree with on how to address the hazards presented by these magnets, they should know I respect their dream to innovate and to create. As many who have worked with me have heard me say, it is important from time to time to "dream big and then even bigger."

Some loss, tragically, is permanent and life-changing. We were witnesses to that with the presence of [AC's] family. But not all loss and hurt need be. At least that is my hope for this process – that the mandatory standard the Commission approved on September 24, 2014, will prevent future loss and hurt by protecting and preserving not only the precious health of children, but will also provide sufficient space for the entrepreneurial dreams of adults.

CPSC, Elliot Kaye, Statement of Chairman Elliot F. Kaye On the Passage of a Federal Safety Standard for High-Powered Magnets, http://www.cpsc.gov/en/About-CPSC/Chairman/Kaye-Biography/Chairman-Kayes-Statements/Statements/Statement-of-Chairman-Elliot-Kaye-on-the-Passage-of-a-Federal-Safety-Standard-For-High-Powered-Magnet-Sets/ (Sept. 29, 2014) (the names of children and other personally identifiable information has been replaced with initials by counsel, pursuant to a protection order signed by Affiant and Affiant's counsel in Docket No. 12-2).

8. On March 23, 2016, the U.S. Department of Justice website published the following statement regarding Zen Magnets, LLC in an ongoing civil case:

"Today's decision puts the rule of law and the safety of children above the profits sought by Zen Magnets," said Chairman Elliot F. Kaye for CPSC. "Far too many children have been rushed into hospital emergency rooms to have multiple, high-powered magnets surgically removed from their stomachs. Young children have suffered infections and one child tragically died from swallowing loose magnets that often look like candy. The ruling is a major victory for the safety of consumers. Our pursuit of this case makes clear we will not tolerate the sale of recalled goods in any form. I am pleased that Judge Arguello ordered Zen to issue refunds to consumers, and I urge anyone who purchased these magnets to immediately seek a refund from Zen."

- U.S. Department of Justice, *Judge Orders Recall of Dangerous Magnets*, https://www.justice.gov/opa/pr/judge-orders-recall-dangerous-magnets (March 23, 2016).
- 9. On September 24, 2014, Commissioner Joseph Mohorovic issued the following statement:

I am proud to support today's rulemaking. Without the requirements set forth in this Rule, small and powerful magnets would continue to present the quintessential latent hazard to young children.

While I am confident that this Rule will achieve its intended purpose, I remain troubled about the prevalence of other small, powerful magnets that may persist in the home environment – be it from jewelry, defective or recalled products. Therefore I anticipate and urge the agency to not view this rulemaking as the final step in mitigating this hazard, but rather one element of an overall risk-

management strategy.

Furthermore, I hope the harrowing recent history with this product category compels the agency and the entire safety community to reevaluate our collective capabilities to quickly identify and respond to emerging hazards. In this regard, the agency should accept the reality of limited resources internally and pursue every viable option to leverage our external stakeholders' data for effective and timely market surveillance.

CPSC, Joseph Mohorovic, Commissioner Joseph P. Mohorovic Statement Safety Standard for

Magnet Sets - Final Rule, http://www.cpsc.gov/en/About-CPSC/Commissioners/Joseph-

Mohorovic/Commissioner-Mohorovic-Statement/Statements/Commissioner-Joseph-P-

Mohorovic-Statement-Safety-Standard-for-Magnet-Sets--Final-Rule/ (Sept. 24, 2014).

10. On May 14, 2014, Commissioner Marietta Robinson issued the following statement:

On May 9, 2014, I voted to approve the settlement In the matter of Maxfield and Oberton Holdings, LLC and Craig Zucker, as an individual and as an officer of Maxfield and Oberton Holdings, LLC. I am delighted the parties came to a resolution that does exactly what was sought both before the Complaint was filed and throughout this litigation: a recall and cessation of all importation and distribution (a "stop sale") of high-powered magnet sets, called Buckyballs and Buckycubes (collectively "Buckyballs"). High-powered magnets are responsible for horrific, long-term, and life threatening injuries in infants and children estimated to be in the thousands

I became a Commissioner of the U.S. Consumer Product Safety Commission ("CPSC" or "Commission") in July 2013 when this lawsuit was already ongoing. Given the peculiar position of a Commissioner in matters such as these where I could become one of the final decision makers in the case, the information I was able to obtain pre-settlement was limited to pre-lawsuit information and what was in the public record.

I learned that CPSC staff estimated there were 1716 injuries from this type of product between 2009 and 2011 based on emergency room data throughout the country. During a hearing held on October 22, 2013, to consider a possible rulemaking on high-powered magnets, five pediatric gastroenterologists testified that they had done a survey of the members of their professional organization and, even with only approximately 25 percent of their members responding, they identified 480 ingestions in ten years with 204 in the 12 months prior to their October 2012 report. The physicians showed that every single state had had at least one person who was injured by these magnets. These numbers are certainly just the tip of the iceberg. Further, these physicians testified that the injuries

from these magnets are insidious, horrific and life-altering often requiring removal of portions of the child's intestines and lifetime care.

The CPSC exists to address just such dangerous products. This lawsuit never asked for anything but a recall and stop sale of, and publicity regarding, this potentially dangerous product. Despite his many hyperbolic assertions to the contrary, this lawsuit has never been about punishing Mr. Zucker.

Prior to becoming a Commissioner, I was a litigator for more than thirty years and participated in many settlement negotiations. I found that when I started settlement discussions, after years of arguing with the other side, it was very important to go back to how I had evaluated the case before discovery began and ask what I would have settled the case for on the day of filing the Complaint.

In this case, I was presented with the recommended settlement by our General Counsel, but without any of the information a client would receive in the private sector, such as the starting positions of the parties, the process of reaching the proposed settlement, the issues raised by the other side and the opposing counsel's views of strengths and weaknesses on both sides. None of this information is available to a Commissioner in making her decision.

So, I went to the Complaint and compared it to the proposed settlement as I would have done in the private sector. The Commission's Complaint requested that the Defendants (1) effectuate a recall of Buckyballs, (2) cease all importation and distribution of Buckyballs, (3) publicize the ability for consumers to receive a refund for the recalled Buckyballs, and (4) publicize the dangers of Buckyballs by posting information regarding incidents and injuries associated with ingestion or aspiration of Buckyballs.

This settlement accomplishes exactly what the Commission set out to do. In short:

- ∀ The Commission has issued a press release announcing a voluntary recall of Buckyballs.
- ∀ Companies and individuals cannot sell, manufacture, distribute, or import Buckyballs in any marketplace, including online services such as eBay or Craigslist.
- ∀ The Buckyballs recall will be publicized appropriately.
- ∀ Consumers will receive refunds as outlined in the settlement for the recalled Buckyballs.
- $\forall$  A website will be set up to further publicize the Buckyballs recall.

The costs of the publicity, refunds and website will be borne by the Defendants. Because the settlement accomplishes what we sought in the Complaint, I accepted the settlement.

I congratulate the parties on reaching this resolution. I hope, as a result, families who own Buckyballs will return the dangerous

product as per the directions in the settlement and all companies and individuals will stop sale of Buckyballs in this country. I also hope that the publicity of this settlement and the accompanying Buckyballs recall and stop sale will lead to a significant decrease in injuries to high-powered magnets.

CPSC, Marietta Robinson, Statement of Commissioner Marietta S. Robinson on the Order in Maxfield and Oberton Holdings, LLC and Craig Zucker, Individually and as an Officer of Maxfield and Oberton Holdings, LLC, http://www.cpsc.gov/en/About-CPSC/Commissioners/Marietta-Robinson/Commissioner-Robinson-Statements/Statement-of-Commissioner-Robinson-on-the-Order-in-Maxfield-and-Oberton-Holdings-LLC-and-Craig-Zucker/?utm\_source=rss&utm\_medium=rss&utm\_campaign=Robinson+Statements (May 14, 2014).

- 11. The magnets sold by Respondent Zen Magnets, LLC are the same magnets as those covered by the Rule, with the exception that the administrative law judge ruling in 12-2 has determined that the packaging marketing and warnings preclude a finding that the magnets, present a hazard to the public when sold as Zen Magnets has done since 2011.
- 12. The Commission has already made factual and legal findings regarding the following: the use of the Subject Products; the risk of injury posed by the Subject Products; the degree and nature of the risk of injury posed by the Subject Products; the need for the SREMs and the probable effect of the rule on the utility, cost, or availability of the SREMs to meet that need; that no feasible safety standard or warning would adequately protect the public from the risk associated with SREMs; that warnings are ineffective; that the danger posed by the Subject Products is not obvious; the number of injuries associated with SREMs; that the benefits of the rule bear a reasonable relationship to its costs; and ultimately that banning the Subject Products is reasonably necessary to reduce the risk of ingestion of injuries associated with

## SREMs.

- 13. In the rulemaking, the Commission examined the same questions raised in the administrative adjudication about the Subject Products' utility in the rulemaking. In the administrative adjudication, Respondent entered into evidence comments from the rulemaking regarding the magnets' high utility. The Commission has already necessarily rejected a finding of high utility by promulgating the Rule and deeming said rule to be necessary to address an unreasonable risk of injury, even considering the magnets' benefits vis-à-vis their costs.
- 14. In the rulemaking, the Commission examined the same questions raised in the administrative adjudication about the degree and nature of the risk of injury posed by the Subject Products. In both the rulemaking and the administrative adjudication, identical incident reports, National Electronic Injury Surveillance System ("NEISS") data, and estimates based on that NEISS data were used to establish both the need for the rule as well the Commission's attempt to prove the existence of a substantial product hazard in the administrative adjudication. Judge Metry, in his Initial Decision, characterized the "nature of the risk of injury" to be low when the Subject Products are properly marketed and labeled, which is the exact opposite of the Commission's finding in 16 C.F.R. § 1240.5(a).
- 15. In the rulemaking, the Commission examined the same questions raised in the administrative adjudication about the number of injuries associated with SREMs and the Subject Products.
- 16. In the rulemaking, the Commission examined the same questions raised in the administrative adjudication about the marketing, manufacture, and design of the Subject products. A critical question of fact and law in the administrative adjudication was whether Zen designed, marketed, or manufactured its products to children under the age of 14. The Commission has already implicitly assumed that Zen's products were intended for and marketed to children

by lumping in Respondent's Subject Products with those from other firms whose magnets were marketed to those under the age of 14, such as Buckyballs. For example, Commissioner Adler stated that the Commission is "faced with a product that's extremely appealing to children." Commission Meeting: Decisional Matter – Safety Standard for Magnet Sets – Final Rule (Sept. 24, 2014). And Dr. Midgett stated, "We have a vulnerable population at risk with an injury mechanism that's very difficult for parents to foresee. The diagnosis is very difficult for the medical community. The severity of the injuries is extremely high and there are acute long-term health effects associated with those injuries." Commission Meeting: Final Rule – Safety Standard for Magnet Sets (Sept. 10, 2014).

17. The Commission has also already decided that no warning or marketing scheme could address the risks posed by the Subject Products, which was a question of fact in the administrative adjudication. For example, Commission Robinson stated, "I would quickly learn that the problem was however that however they were marketed that these were items that were being swallowed by young children and ingested by teenagers and were causing some very, very serious injuries and even deaths." Commissioner Robinson, Commission Meeting: Decisional Matter – Safety Standard for Magnet Sets – Final Rule (Sept. 24, 2014). Commissioner Robinson also said: "So I was really struck with how this hidden hazard was something that as I say however marketed that this was something that needed to be addressed." *Id.* Commissioner Adler stated: "First, it's impossible the put warnings on the magnets themselves. So many adults have never fully appreciated the extremely hazardous nature of high-powered magnets and as we heard sometimes adults never read or have access to the warnings on the boxes." Commissioner Adler, Commission Meeting: Decisional Matter – Safety Standard for Magnet Sets – Final Rule (Sept. 24, 2014).

- 18. In the rulemaking, the Commission examined the same questions raised in the administrative adjudication about whether warnings can adequately product the public from the risks associated with SREMs and whether Respondent's warnings are ineffective. The Commission in both the administrative case and the rulemaking argued that warnings were ineffective because (1) they could not accompany each magnet ball and (2) cannot effectively communicate to consumers the hazard associated with the Subject Products.
- 19. The Commission has already considered the question of lost utility against the risk posed by the Subject Products, which was also a question put before Judge Metry.
- 20. The Commission has already made up its mind regarding the ultimate conclusions of law and fact in this case. For example, Chairman Kaye stated that Zen's products should no longer be available: "Mr. [Qu] this is what I would like to leave you with. I hope your dreaming will continue and that inspiration will strike again and that there is a path forward that secures for you that elusive childhood wonder but in a way that can endure." Chairman Kaye, Commission Meeting: Decisional Matter Safety Standard for Magnet Sets Final Rule (Sept. 24, 2014) (emphasis added). Commissioner Adler was even more to the point: "In short, despite everyone's best effort the conclusion that I reach is that if these magnet sets remain on the market irrespective of how strong the warnings on the boxes in which they're sold or how narrowly they are marketed to adults, children will continue to be at risk of debilitating harm or death from this product." Commissioner Adler, Commission Meeting: Decisional Matter Safety Standard for Magnet Sets Final Rule (Sept. 24, 2014) (emphasis added).
- 21. Chairman Kaye and Commissioners Robinson, Mohorovic, and Robinson have already passed judgment on the factual underpinnings of the administrative case against Plaintiff, and

- have further made statements that objectively show that they are not impartial and would be incapable of being disinterested arbiters.
- 22. In his statements provided above, Chairman Kaye has indicated he is biased against Respondent and/or Respondent's Subject Products, and has clearly prejudged questions of law and fact. Chairman Kaye has either stated or implied: (1) that Subject Products have a hidden danger; (2) that Subject Products are hazardous; (3) that magnets like Subject Products have injured children; (4) that magnets like Subject Products have killed a child; and (5) that removing Subject Products from the market is necessary to protect children, including his own. Chairman Kaye has also made it clear that he cannot separate his emotional feelings about the Subject Products: "I will always think of [AC] when it comes to this rule and the actions the Commission has approved this morning and I'm so deeply sorry for your loss." Chairman Kaye, Commission Meeting: Decisional Matter Safety Standard for Magnet Sets Final Rule (Sept. 24, 2014).
- 23. In his statements provided above, Commissioner Adler has indicated he is biased against Respondent and/or Respondent's Subject Products, and has, in some measure, prejudged questions of law and fact. Commissioner Adler has also stated that he has made up his mind that the products should no longer remain on the market *the* subject of the administrative adjudication: "the conclusion that I reach is that if these magnet sets remain on the market irrespective of how strong the warnings on the boxes in which they're sold or how narrowly they are marketed to adults, children will continue to be at risk of debilitating harm or death from this product." Commissioner Adler, Commission Meeting: Decisional Matter Safety Standard for Magnet Sets Final Rule (Sept. 24, 2014). Commissioner Adler has therefore already decided that the Subject Products are extremely dangerous and present a risk of

- serious internal injuries and death and should be recalled.
- 24. In her statements provided above, Commissioner Robinson has indicated that she is biased against Respondent and/or Respondent's Subject Products, and has, in some measure, prejudged questions of law and fact. Commissioner Robinson also commented that, "if anything I think that with the data that we had even though it made a compelling case for this being an unreasonable risk of injury it was understated so the risk was even higher." Commissioner Robinson, Commission Meeting: Decisional Matter Safety Standard for Magnet Sets Final Rule (Sept. 24, 2014). Commissioner Robinson has, by imputation, made statements regarding: (1) the number of injuries caused by Subject Products; (2) the types of injuries caused by Subject Products; and (3) the desire for the recall of Subject Products.
- 25. In his statements provided above, Commissioner Mohorovic has indicated that he is biased against Respondent and/or Respondent's Subject Products, and has, in some measure, prejudged questions of law and fact. This statements from Commissioner Mohorovic either state or imply: (1) that Subject Products are dangerous; (2) that Subject Products pose a significant, hidden risk to children; and (3) that he is concerned about the continued existence of SREMs, not only in the marketplace (*i.e.*, Respondent's Subject Products), but also magnets, generally.
- 26. Because of the findings made in the rulemaking and the public statements made by members of the Commission, Affiant does not believe that Chairman Kaye and Commissioners Adler, Mohorovic, and Robinson are capable of changing their minds, nor does Affiant believe that they are capable of being neutral fact finders. Rather, Affiant believes that these members of the Commission have already adjudged the facts and law at issue in the administrative

adjudication in advance, precluding any question how they will determine the appeal brought by Complaint Counsel. As such, allowing them to hear the appeal of the Initial Decision and Order would constitute a hearing not attended with complete fairness.

27. It is Affiant's considered view that there is no way Zen Magnets, LLC will be able to prevail on the appeal based on the Rule promulgated by these very same commissioners and the comments they have made to the public outside of consideration of the Rule on these self-same issues.

BY:

Shihan Qu

SUBSCRIBED AND SWORN TO

BEFORE ME, ON THE

16th day of May, 2016

NOTARYPUBLIC

My Commission Expires: Hyper 1 10, 20%

JESSICA ANN HARRIS
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID # 20124023975
MY COMMISSION EXPIRES 04-16-2020

# UNITED STATES OF AMERICA CONSUMER PRODUCT SAFETY COMMISSION

	)	
In the Matter of	)	
	)	
ZEN MAGNETS, LLC,	)	CPSC DOCKET NO. 12-2
	)	
RESPONDENT	)	
	)	
	)	
	)	

# **CERTIFICATE OF GOOD FAITH**

Pursuant to 5 U.S.C. § 556, Counsel hereby certifies that Respondent's Motion to Disqualify the Commission or Some of its Members and the affidavit of Shihan Qu are made in good faith, as are the statements contained therein.

DATED: May 16, 2016

Respectfully Submitted,

LEVIN JACOBSON JAPHA, P.C.

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#### CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on 16th day of May, 2016, I served copies of Shihan Qu's **AFFIDAVIT** and counsel's **CERTIFICATE OF GOOD FAITH** by the service method indicated:

Original and five copies by U.S. Mail, and one copy by electronic mail, to the Secretary of the United States Consumer Product Safety Commission:

Todd A. Stevenson, Secretary U.S. Consumer Product Safety Commission 4330 East West Highway Bethesda, MD 20814 tstevenson@cpsc.gov

U.S. Consumer Product Safety Commission

One copy by electronic mail (by agreement) and one mailed copy to Complaint Counsel:

Mary B. Murphy, Complaint Counsel and Assistant General Counsel

mmurphy@cpsc.gov

and

Daniel Vice, Trial Attorney

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Division of Compliance

David C. Japha

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