

U.S. CONSUMER PRODUCT SAFETY COMMISSION

PUBLIC HEARING ON
SAFETY STANDARD FOR MAGNET SETS

NOTICE OF PROPOSED RULEMAKING

Tuesday, October 22, 2013

Bethesda, Maryland

COMMISSIONERS PRESENT:

INEZ MOORE TENENBAUM, Chairman

ROBERT ADLER, Commissioner

NANCY NORD, Commissioner

MARIETTA ROBINSON, Commissioner

ANN MARIE BUERKLE, Commissioner

A G E N D A

	PAGE
Chairman's Introductions	4
ORAL PRESENTATIONS:	
PANEL 1:	
Rachel Weintraub, Legislative Director and Senior Counsel, Consumer Federation of America	9
Mark Gilger, M.D., FAAP, Pediatrician, Chief at Children's Hospital of San Antonio, Professor and Vice Chair of the Baylor College of Medicine, representing the American Academy of Pediatrics	16
Ami Gadhia, Senior Policy Counsel, Consumers Union	23
PANEL 2:	
Bryan Rudolph, M.D., Assistant Professor of Pediatrics, Division of Pediatric Gastroenterology and Nutrition, Albert Einstein College of Medicine, Children's Hospital, Bronx, New York	57
Maria Oliva-Hemker, M.D., Chief of Pediatric Gastroenterology and Nutrition, Stermer Family Professor of Pediatric Inflammatory Bowel Disease, Johns Hopkins Children's Center, on behalf of North American Society for Pediatric Gastroenterology Hepatology and Nutrition	63
Ian Leibowitz, M.D., Assistant Professor of Pediatrics, Department of Pediatrics, Virginia Commonwealth University, Director, Pediatric Digestive Diseases Center, Inova Fairfax Hospital for Children	73

Marsha Kay, M.D., Chair, Pediatric Gastroenterology,
Director, Pediatric Endoscopy, Cleveland Clinic
Children's Hospital

1 P R O C E E D I N G S [10:00 a.m.]

2 CHAIRMAN'S INTRODUCTIONS

3 CHAIRMAN TENENBAUM: Good morning, everyone, and
4 welcome to the U.S. Consumer Product Safety Commission. We
5 are having a hearing this morning on magnets.

6 Before we get started, I'd like to bring to
7 everybody's attention that today is Commissioner Nord's last
8 public meeting with the CPSC. She has been here many years
9 as a Commissioner, and then she was Acting Chairman for a
10 number of years.

11 Nancy, I just want to say it will be a large void.
12 When I first came here, I remember the first thing you did
13 was bring flowers over to my office, and taught me a lot of
14 things. I want to say that you will be missed, and thank you
15 for your years of service to the CPSC.

16 COMMISSIONER NORD: Madam Chairman, thank you.

17 COMMISSIONER ADLER: If I might say a few words.

18 COMMISSIONER NORD: What is different about this
19 morning than any other morning.

1 (Laughter.)

2 COMMISSIONER ADLER: I think, Nancy, you and I have
3 had what somebody once described to me as an Aongoing mini
4 version of cross fire,@ which I have greatly appreciated. I
5 think you have brought some forceful and eloquent and needed
6 views to the agency and agency discourse. I want you to know
7 how much I have appreciated all of the contributions you have
8 made to the agency over the years.

9 I consider you a friend. One of the things I've
10 discovered about you as a friend that I'm not sure the public
11 knows so much is you have an unbelievably refined sense of
12 style, which I was admiring yesterday in your office.
13 Anybody that doesn't believe me should stop by her office to
14 see just how beautifully decorated it is.

15 The other thing is a delightful sense of humor,
16 which I have always enjoyed and I relish, and I look forward
17 to continuing to appreciate. I just want you to know how
18 much I will miss you and I wish you the best.

19 COMMISSIONER ROBINSON: Don't start on Nancy.

1 CHAIRMAN TENENBAUM: I just want to say that when I
2 was nominated by the President the first time in January
3 2012, Nancy was the first person who was a Commissioner with
4 whom I was able to have some interaction.

5 I was just very, very impressed with her
6 thoughtfulness, her wealth of knowledge about the agency, and
7 we were very much looking forward to working together for a
8 long time, unfortunately, the confirmation process took
9 longer than either of us anticipated. I am very sorry that
10 we didn't have longer together on the Commissioner, Nancy.

11 She is a person with such rich knowledge of the
12 agency and such a sense of history and thoughtfulness and
13 commitment to the agency's mission, and you will be missed.

14 COMMISSIONER BUERKLE: I just want to say from the
15 time I received a call about this appointment, Nancy was
16 available as a resource, help, and a friend. She has proved
17 to be just a wonderful mentor, cares deeply about what the
18 Consumer Product Safety Commission does, and really has, I
19 think, set an example for me and for all the Commissioners

1 for diligence, and her knowledge of the issues is really, I
2 think, what is most remarkable.

3 I know for one, for a lot of reasons, I will miss
4 Nancy and serving with her. I'm sorry we didn't have more
5 time together. Thank you.

6 COMMISSIONER NORD: Thank you so much. I'm really
7 very touched by your comments. I am so sorry our terms of
8 service didn't overlap to a greater extent than it did. I
9 think both of you bring new perspectives and freshness to the
10 agency that is very much needed and appreciated, even though
11 my time working with you both has been short, it has been an
12 absolutely delightful experience.

13 Bob, I think you summed it up well. I have
14 thoroughly enjoyed the intellectual jousting that we have had
15 the opportunity to do. In fact, this agency presents so many
16 rich intellectual issues. It has always been great fun to be
17 able to throw ideas up against the wall and have Bob at least
18 try to catch a few of them, not very many, but every once in
19 a while.

1 Madam Chairman, perhaps more than anyone else on
2 this Commission, I do know the challenges you face in trying
3 to run an organization that has a mission as big as it is,
4 having to deal with such diverse issues with resources that
5 are in the best of times very constrained. You have my
6 admiration in trying to keep all the balls up in the air.

7 This has been just an interesting eight and a half
8 years for me. I have seen the agency morph from one thing to
9 another. Nevertheless, I think we all appreciate and
10 understand the importance of the mission that we were
11 appointed to carry out.

12 All of us believe passionately in it, even though
13 sometimes we approach these issues from different points of
14 view, our interests and our desire to do the right thing for
15 the consumer is always there.

16 Thank you very much, colleagues. To the staff, I
17 will very much miss the wonderfully rich interaction I have
18 had with you also. Thank you.

19 CHAIRMAN TENENBAUM: Thank you. Good morning,

1 everyone, and welcome to the public meeting relating to the
2 Notice of Proposed Rulemaking to create a standard to reduce
3 the risk of injury associated with magnet sets.

4 The Notice of this meeting was published in the
5 Federal Register on Tuesday, September 24. It has been duly
6 noticed.

7 I am pleased this morning that we do have seven
8 panelists who have requested the opportunity to make oral
9 presentations. The Commission also previously received
10 volumes of written comments on this rulemaking. Both the
11 oral and written comments will be part of the rulemaking
12 record.

13 I want to make sure we announce today that the
14 record will be held open for one week, in addition to the
15 full comment period which has now passed.

16 A copy of the agenda includes the rules of conduct
17 for this meeting.

18 I'd like to extend a special welcome to each of our
19 presenters who are here to testify this morning. Our

1 panelists will be heard in the following order:

2 First, Rachel Weintraub, who is the Legislative
3 Director and Senior Counsel, representing the Consumer
4 Federation of America. Second, Dr. Mark Gilger, who is a
5 pediatrician and Chief at Children's Hospital of San Antonio,
6 and Professor and Vice Chair of the Baylor College of
7 Medicine, representing the American Academy of Pediatrics.
8 Ami Gadhia, Senior Policy Counsel, representing Consumers
9 Union.

10 Ms. Weintraub, will you start?

11 PRESENTATION OF MS. RACHEL WEINTRAUB

12 MS. WEINTRAUB: Chairman Tenenbaum, Commissioners
13 Adler, Nord, Robinson, and Buerkle, I appreciate the
14 opportunity to provide comments to you today on CPSC's Notice
15 of Proposed Rulemaking establishing a safety standard for
16 magnet sets.

17 I am Rachel Weintraub, Legislative Director and
18 Senior Counsel with Consumer Federation of America. Consumer
19 Federation or CFA is a non-profit association of

1 approximately 280 pro-consumer groups that was founded in
2 1968 to advance the consumer interests through advocacy and
3 education.

4 CFA is basing our comments today upon our written
5 submission of comments of November 19, 2012 to the CPSC in
6 response to the open comment period regarding the NPR on the
7 safety standard for magnet sets.

8 CFA agrees with CPSC's preliminary determination
9 that there is an unreasonable risk of injury associated with
10 children ingesting high powered magnets that are part of
11 magnet sets.

12 The CPSC and pediatricians and pediatric
13 gastroenterologists from whom we will hear today have
14 documented the serious medical consequences that occur as a
15 result of a child ingesting such high powered magnets. These
16 magnets are appealing to both younger children and older
17 children as well.

18 Unique properties of these magnets cause serious
19 life threatening injuries when a child ingests two or more

1 magnets. These injuries are vastly different from and more
2 serious than those that occur from the ingestion of other
3 small parts.

4 In the Notice of Proposed Rulemaking, the
5 Commission proposes safety standards for magnet sets. The
6 safety standard proposed would prohibit current magnet sets.
7 The proposed rule would require that magnets that fit into
8 the small part cylinder to have a flux density of less than
9 50 or they would be prohibited. We support that proposed
10 standard.

11 CPSC based this proposed rule in part upon ASTM
12 F963's provision addressing magnets in toys. We support that
13 reliance as the ASTM standard appears to have effectively
14 addressed the hazard posed by magnets in toys.

15 CPSC's proposed rule accurately describes the
16 serious injuries caused by the ingestion of magnets from
17 magnet sets, which can be grave and potentially life
18 threatening.

19 CPSC has estimated that 1,700 ingestion's of

1 magnets from magnet sets were treated in emergency
2 rooms/hospitals across the country from 2009 to 2011, and a
3 survey by the North American Society for Pediatric
4 Gastroenterology, Hepatology and Nutrition that we will hear
5 about more from later panelists, released in October of 2012,
6 estimated that in the past ten years, there have been at
7 least 480 cases of high powered magnet ingestion's with 204
8 of those cases occurring in the past 12 months.

9 Thus, serious injuries, many of which required
10 surgical intervention, have been caused by these magnets. We
11 support the CPSC's assessment of the seriousness of these
12 injuries and agree that the data provides evidential support
13 for the promulgation of a proposed rule that effectively
14 addresses this serious hazard.

15 We urge the CPSC to include individual magnets that
16 are sold to be used in conjunction with a magnet set as part
17 of the scope of the proposed rule. Individual magnets bought
18 separately would pose the same hazards as those bought as
19 part of magnet sets. Thus, the same standard should apply to

1 these magnets.

2 We agree with the CPSC's recommendation in the
3 proposed standard that magnets sold as part of magnet sets
4 and magnets intended to be used as part of magnet sets that
5 are smaller than the choke test tube should have a flux
6 density of 50 or less, or else they should be prohibited.

7 First, we applaud the initial test of using the
8 choke test tube to ensure that magnets can be swallowed, the
9 focus of this standard. The incidence data supports that
10 ingestion is the main route of exposure for these severe
11 magnet injuries. The small size of these magnets not only
12 makes them so potentially harmful, but creates similarities
13 between these magnets and candy and jewelry.

14 Regarding the flux density, the CPSC should study
15 whether magnets with a flux density of less than 50 could
16 also potentially cause harm. While the flux density of 50
17 put forth in this proposed standard was based upon the ASTM
18 toy standard and analysis of magnet containing toys on the
19 market, we also suggest that CPSC study other products

1 containing magnets, including magnets used as refrigerator
2 magnets, push pins and jewelry, to evaluate whether a flux
3 density of 50 is in fact the appropriate level.

4 We further urge the CPSC to study whether magnets
5 with a flux density of 50 when aggregated continue to have a
6 flux density of 50 or whether the aggregation of these
7 magnets increases the flux density and could pose more harm.

8 We agree with the CPSC staff that warning labels
9 have never been effective in protecting children from the
10 hazards posed by ingesting magnets from magnet sets.

11 First, warnings are less effective injury
12 prevention methods than changing the product to reduce the
13 hazard. Second, this hazard is hidden. The potential harm
14 is not immediately obvious to purchasers or users of the
15 product, and warning labels are less effective when the harm
16 is not clearly known.

17 Warnings have been included on products and those
18 warnings have not curbed injuries and have not been
19 effective. Since the new label was required in March 2010 on

1 a specific product, reported injuries continued to increase
2 steadily and significantly.

3 Warning labels do not prevent exposure to this
4 product but rather seek to convey information that would
5 alter a consumer's potentially risky interaction with the
6 product.

7 A more effective way to eliminate or reduce
8 ingestion hazards is to prevent exposure to this foreseeably
9 hazardous product.

10 Since the data shows that children six and younger
11 make up the bulk of incidents, a warning label aimed at
12 children who can't read will not be effective.

13 Finally, for those children who could read, they
14 use these products outside of the container, so often the
15 warning label would not be visible to them either.

16 We further urge the CPSC not to rely upon
17 childproof containers but rather upon an effective standard
18 to curb the hazards caused by ingestion of these magnets from
19 magnet sets.

1 Given the nature of the use of these magnet sets,
2 it is likely that magnet sets would not remain in their
3 containers, they would be left out of their containers on a
4 table, dresser or desk, in a geometric shape that the
5 consumer created with the magnets. Given the intended use of
6 the product, the benefit of such a childproof container would
7 be extremely limited.

8 Similarly, CFA would not support bittering agents
9 as a solution to this product. The most effective way to
10 eliminate or reduce ingestion hazards is to prevent exposure
11 to the foreseeably hazardous product.

12 Preventing ingestion by making magnets that are
13 smaller than the choke test tube cylinder, less powerful,
14 less dangerous, is the best way to do this. Bittering agents
15 are not the answer. They have not been shown to change
16 children's behavior in different applications. The agent
17 fades over time and may not be detected in the same way by
18 younger children who have less developed and different taste
19 buds. Also, children put everything in their mouths, and the

1 bad taste will not stop their natural mouthing behavior that
2 leads to these incidents.

3 The CPSC's cost analysis considers the extensive
4 costs of the injuries to children caused by these magnets and
5 magnet sets. The cost must also consider the ongoing health
6 impacts of injuries to children.

7 In conclusion, CFA strongly supports the adoption
8 of the Commission's standard as included in the Notice of
9 Proposed Rulemaking for magnet sets. This standard will
10 effectively limit exposure to the hazard caused by magnet
11 sets currently on the market. Reducing the magnetic force of
12 magnets that can be swallowed is the most robust and
13 successful way to reduce the threat of injury and death to
14 children caused by these magnet sets.

15 Thank you.

16 CHAIRMAN TENENBAUM: Thank you. Dr. Gilger?

17 PRESENTATION OF DR. MARK GILGER

18 DR. GILGER: Good morning. Chairwoman Tenenbaum,
19 Commissioners Nord, Adler, Buerkle and Robinson, I'm a

1 pediatrician, and my job is to keep kids safe. I'm also a
2 pediatric gastroenterologist by training, so I have personal
3 experience with the safety of this very innocuous toy.

4 I appreciate the opportunity to offer comments to
5 the CPSC on behalf of more than 60,000 members of the
6 American Academy of Pediatrics, primary care pediatricians,
7 pediatric medical specialists, like myself, and pediatric
8 surgeons.

9 I intend to summarize the content of the testimony
10 submitted to the Commission. The AAP commends CPSC for
11 taking action to protect children from the serious and
12 growing hazard of neodymium or rare earth magnet ingestion.

13 The Academy supports the Commission's proposed rule
14 on magnet sets and applauds its effort as a significant step
15 toward reducing the incidence of child morbidities and
16 mortalities caused by magnet ingestion.

17 These magnets' unique properties can cause serious
18 and life threatening injuries when a child ingests two or
19 more magnets or a magnet and a ferromagnetic object.

1 As a pediatrician, our job is primarily about
2 prevention, keeping kids safe. Vaccines, counseling for
3 parents, and especially unintended injuries such as with the
4 neodymium magnets. Our job is to prevent disease and injury.

5 Pediatricians have been aware of the rising dangers
6 associated with magnet ingestion for many years. We have
7 seen firsthand significant and life long health impact this
8 can have.

9 Indeed, why am I here? About a year and a half
10 ago, one of my Fellows -- I train pediatricians for a living
11 -- my Fellows presented a case of a young 18 month old infant
12 who had been playing with neodymium magnets left on the floor
13 after they had fallen off the desk of the dad who had used it
14 as a stress relieving desk toy. The magnets were all over
15 the floor and the baby got into them and ate several of them.
16 Kids eat anything.

17 Children are at risk for several reasons. Mouthing
18 behavior - it is a very common and necessary part of early
19 childhood development. In fact, between two months and 36

1 months of age, children spend anywhere from 20 minutes up to
2 2.5 hours per day with mouthing activity. This is a normal
3 part of early childhood development. As kids get older, they
4 stop that behavior.

5 Given this developmentally appropriate behavior, it
6 is very understandable why very young children would readily
7 put things like magnets in their mouths.

8 Second, there is an under estimation of the risks.

9 Toddlers can swallow neodymium magnets because of their
10 appearance. They can be easily mistaken for candy.

11 For example, I brought a prop. In here, I have a
12 cupcake. I hope you can see it. I hope you see the candy on
13 top. I don't know if you remember the old commercial, ALooks
14 like butter but it's not.@ These are not candy. These are
15 neodymium magnets. They look like candy to me and they look
16 like candy to you. They hold together very nicely. I can
17 pick them off this cupcake very easily. That is how strong
18 they are.

19 Once these little magnets get inside the intestine

1 of an infant, bad things can happen. These magnets look a
2 lot like candy that children see on cakes and cookies. It is
3 not just little kids either.

4 Older kids, pre-teens and adolescents, accidentally
5 ingest them or they are using these products to mimic
6 piercings. I've seen a lot of children with piercings now on
7 the tongue, on the lip, on the cheek, on the nose. How do we
8 look like an adult? We demonstrate piercings. These serve
9 that purpose rather well.

10 You can only guess how easily it might be for a
11 child to swallow one of these. Then what happens? The
12 teenager that swallows these is not about to tell mom and dad
13 that I just swallowed a bunch of magnets because I was
14 showing my friends how it looks to have a piercing.

15 From a developmental perspective, both children and
16 adolescents do not possess a full understanding of the risk
17 posed by these products.

18 Also important to know is children cannot always
19 identify or verbalize their injuries delaying diagnosis and

1 treatment. Initial symptoms of ingestion of these high
2 powered magnets are very non-specific. It could include
3 fever, nausea, vomiting, and abdominal pain.

4 Proper diagnosis and treatment can be delayed
5 because of the lack of the specificity of such symptoms.

6 This is particularly the case when very young
7 children who are unable to verbalize have ingested a magnet,
8 and when older kids, as earlier I demonstrated, they are
9 embarrassed to say what they just did, and they don't
10 immediately realize the connection between their symptoms and
11 the ingestion.

12 Delayed diagnosis and treatment can result in
13 additional and in some cases irreparable or life threatening
14 tissue injury.

15 Foreign body ingestion's are common. About 100,000
16 foreign body ingestion's occur annually in the U.S., and 80
17 percent of these occur in kids. By far and away, most pass
18 without symptoms and do not require surgical intervention.

19 However, high powered magnets are an entirely

1 different ball of wax. Magnet ingestion has grown as a child
2 health issue since the mid-2000s when manufacturers
3 introduced to the marketplace children's toys containing
4 these powerful magnets.

5 These injuries are very different and far more
6 serious than ingestion of other small foreign bodies.
7 Neodymium magnets are the strongest type of permanent magnet
8 manufactured.

9 When a child ingests multiple magnets or a magnet
10 along with another ferromagnetic object, they are capable of
11 attracting each other across the bowel wall. That can lead
12 to perforation, ulceration, and ultimately result in sepsis,
13 a life threatening infection.

14 About ten percent of affected children will require
15 long term or repeated interventions. The most common
16 intervention for high powered magnet ingestion is surgical
17 repair of a perforation or fistula. In cases requiring bowel
18 resection, the health implications are long term and serious.

19 In 2012, pediatric gastroenterologists, my

1 colleagues, found that children under age six represented 51
2 percent of all magnet ingestion cases, and 80 percent of
3 reported cases required endoscopic or surgical intervention.

4 These are serious morbidities and significant
5 health interventions that can have life long effects on
6 children. Sadly, most of these injuries are preventable.

7 The AAP commends CPSC for taking action to protect
8 children from the serious and growing hazard of neodymium
9 magnet ingestion, limiting the magnet strength for products
10 meeting the small part size is a common sense solution to
11 reduce the occurrence of these tragic and preventable
12 outcomes.

13 For these reasons, the AAP applauds CPSC for the
14 Notice of Proposed Rulemaking, and urges the Commissioners to
15 move this rule forward into implementation.

16 The safest and most effective regulatory action
17 that CPSC could take to eliminate or reduce the hazard of
18 ingestion is to prevent exposure to this foreseeably
19 hazardous product.

1 As I conclude, I would like to share the following
2 recommendations. Public education. We simply are not aware
3 of the dangers of these simple innocuous magnets. We must
4 remain vigilant. Parents and care givers need to understand
5 the dangers posed by this innocuous toy, and they need to be
6 aware that these products can be purchased today and are in
7 existence.

8 We need to continue to educate our physicians and
9 especially our emergency room physicians, our family
10 practitioners, our pediatricians, and our surgeons. We
11 support the Federal rule.

12 I want to thank you for the opportunity to provide
13 input to the CPSC on this critical child health issue, and I
14 would be happy to entertain any questions. Thank you.

15 CHAIRMAN TENENBAUM: Thank you. Ms. Gadhia?

16 PRESENTATION OF MS. AMI GADHIA

17 MS. GADHIA: Good morning. Chairman Tenenbaum,
18 Commissioners Nord, Adler, Robinson and Buerkle, my name is
19 Ami Gadhia, and I'm Senior Policy Counsel with Consumers

1 Union, the public policy and advocacy arm of Consumer
2 Reports.

3 We very much appreciate the opportunity to provide
4 comments to the CPSC on this proposed rulemaking.

5 CU strongly supports CPSC's proposed rule to
6 address the unreasonable risk of injury associated with
7 children ingesting high powered magnets that are part of
8 magnet sets.

9 This proposed rule would effectively ban very
10 small, highly powerful rare earth magnets, and will help to
11 reduce significantly the horrible incidents of internal
12 injury and life altering medical consequences due to
13 ingestion of these magnets by children and teenagers.

14 As the Commission notes in its Notice of Proposed
15 Rulemaking, in 2008, high powered rare earth magnet sets
16 became available to U.S. consumers.

17 These magnet sets, which often consist of tens or
18 hundreds of tiny, colorful, powerful magnets, are very
19 attractive to children, including infants, as you just heard,

1 and teenagers, and stick together with such force that if
2 they are ingested, they can bore holes in the stomach or
3 intestines, sometimes causing blood poisoning, tissue death,
4 perforations and other injuries that require emergency
5 surgery.

6 The unique and potent hazard posed by these
7 products is especially insidious, because after ingestion, as
8 Dr. Gilger said, children often present with symptoms like
9 vomiting that resemble common illnesses such as the flu,
10 delaying medical attention.

11 While the largest portion of the estimated 1,700
12 incidents treated in emergency departments between 2009 and
13 2011 involved children 4 through 12 years of age, teenagers
14 are at risk as well, as Dr. Gilger well described.

15 A study published this August in the Annals of
16 Emergency Medicine concluded that AMagnet related injuries
17 are an increasing public health problem for young children as
18 well as for older children who may use magnets for play or to
19 imitate piercings. Education and improved magnet safety

1 standards may decrease the risks small magnets pose to
2 children.@"

3 Magnet related injuries can be serious and long
4 term. For example, after swallowing eight magnets in April
5 2012, then 22 month old Braylon Jordan of Kiln, Mississippi,
6 need to have almost all of his small intestine removed,
7 leaving him dependent on intravenous nutrition.

8 In the March issue of the Canadian Medical
9 Association Journal, doctors described their treatment of a
10 three year old boy with laparoscopic surgery after he
11 ingested several small spherical magnets that came together
12 and tore a hole in his small intestine.

13 As the Commission moves forward on this rulemaking,
14 we urge you to consider the long term medical and other costs
15 to the victims of magnet based injuries and to their
16 families.

17 While we commend CPSC for the measures it has
18 already taken, we believe the next appropriate step to
19 address this hazard is the proposed prohibition on products

1 in their current form and a safety standard for magnets.

2 It is clear that CPSC's action is necessary as the
3 potential uses of these rare earth magnets continue to grow,
4 posing new potential hazards. Recently, we heard about a
5 crowd funding appeal for a pen and stylus product that is
6 composed of small, cylindrical neodymium magnets.

7 What happens if the small, cylindrical pieces are
8 swallowed by a child? Is the same devastating injury
9 possible as with the magnet sets?

10 The agency's action on magnet sets is necessary to
11 stay abreast of potential hazards with rare earth magnets.

12 Also, as the Commission moves forward with the
13 rulemaking and looks into examining magnet flux strength and
14 the possibility of developing tests to measure it, the agency
15 should ensure that such a standard adequately identifies and
16 eliminates hazardous magnets, including whether magnets of a
17 flux density less than 50 could also potentially cause harm.

18 The Commission should study other products
19 containing magnets including jewelry to evaluate if and

1 whether a flux density of 50 is the appropriate level.

2 The CPSC's proposed rule rightly builds upon work
3 already done by industry, consumer groups, and the Commission
4 to address high powered magnets in toys.

5 In the mid-2000s, construction toys for children
6 featuring small powerful magnets were introduced. CPSC
7 received reports of injuries after the magnets inside these
8 toys came loose and children swallowed them in multiples.
9 CPSC also received reports of incidents in which children had
10 swallowed intact magnet components that were small parts.

11 These incidents revealed the hazard posed by high
12 powered magnets. The Commission appropriately recalled those
13 magnetic construction toys.

14 To better address this hazard and prevent injuries
15 before they occur, consumer advocates worked with the
16 Commission and with industry members of the ASTM F963
17 Subcommittee to create in 2011 a strong consensus based
18 standard which eventually became a mandatory Federal
19 standard, and upon which the CPSC now bases the proposal

1 under consideration today.

2 ASTM F963-11 defines a hazardous magnet and a
3 hazardous magnetic component as one that has a flux index
4 greater than 50, and that is a small object.

5 F963 applies to toys intended for children under 14
6 years of age. The ASTM Working Group established a flux
7 index of 50 as a cutoff for what it considered to be a safe
8 magnet based on measurements of toys on the market.

9 CPSC is right to build upon the work of the ASTM
10 F963 Subcommittee and to take a consensus based standard to
11 address the hazard posed by rare earth magnet sets.

12 The NPR also discusses possible alternatives to the
13 proposed rule. CU does not think that alternatives such as
14 packaging changes or warning labels are sufficient. We agree
15 with CPSC that child resistant packaging would not deter
16 teenagers from accessing the magnets, and would only be
17 effective if an adult resembled the child resistant packaging
18 after each use, which seems unlikely.

19 Nor do we think warning labels to be sufficient.

1 CU believes that the best solution to such a hazard is to
2 design out the hazard by applying a safety standard such as
3 that proposed in the NPR.

4 A warning cannot sufficiently apprise care givers
5 of the serious medical consequences associated with ingestion
6 of these magnets. In addition, parents and care givers may
7 not appreciate the unique harm posed by the high strength of
8 these magnets as opposed to the hazards posed by ingestion of
9 other small parts, nor will many consumers, especially young
10 children who access the product, whether from parents or
11 older siblings, be able to appreciate the message
12 communicated in the warning label.

13 In conclusion, CU strongly supports adoption of
14 CPSC's proposed rule to address the serious and unreasonable
15 risks posed by high powered magnet sets. CPSC's previous
16 actions, including improving warnings, publishing public
17 service announcements, and recalling the existing products
18 were necessary and appropriate, but it is clear that
19 additional steps are needed to protect public safety.

1 Alternative proposals will not adequately address
2 the medical consequences of ingestion of these products,
3 which some have likened to gunshot like injuries, to
4 children and teenagers.

5 CPSC's proposed mandatory safety standard for these
6 magnet sets will help reduce incidences of injury to some of
7 the most vulnerable consumers.

8 CHAIRMAN TENENBAUM: Thank you. Now we will have
9 questions from our Commissioners. I have a question about
10 the flux rate. You all said you would support a flux density
11 of 50 or less.

12 Dr. Gilger, what happens if a child swallows a
13 magnet, say we did the flux rate at 50, if he swallowed
14 several magnets that had a flux rate of 50?

15 DR. GILGER: Excellent question. I think it needs
16 further study to know exactly what lowering the flux, the
17 strength of the magnets, would actually do.

18 I think what we know is these high powered magnets
19 really do not separate. I think as that flux decreases,

1 there is probably a level at which they will separate easily.

2 An example would be the most common foreign body

3 ingested by a young child is a penny found on the floor.

4 They eat these every day. Very common. Passes right on

5 through, really of no consequence whatsoever.

6 A metallic object that doesn't have enough strength

7 to maintain its magnetic flux most likely would pass through

8 without consequence.

9 CHAIRMAN TENENBAUM: We don't know if 50, if we

10 dropped it to 50 as a threshold, would allow the object to

11 pass through?

12 DR. GILGER: I don't think we know that for a fact.

13 I think there is reasonable suspicion that would be correct,

14 but I think those types of things need further evaluation.

15 CHAIRMAN TENENBAUM: Ms. Weintraub, you mentioned

16 in your presentation that you urged the CPSC to promulgate a

17 mandatory standard for these magnet sets under Sections 7 and

18 9 of the Consumer Product Safety Act rather than a ban under

19 Section 8, that APromulgating a rule under Sections 7 and 9

1 provides an effective framework for manufacturers who may
2 want to enter this product market.@

3 Do you want to elaborate on that a little bit?

4 MS. WEINTRAUB: Sure. Our analysis was based on
5 the fact that if there was a rule that clarified what the
6 parameters were for manufacturers who may want to enter the
7 market, that would be even more effective than a straight out
8 ban. The consequence would be the same in terms of the
9 magnet sets that we are seeing on the market would not be
10 permitted to be sold, and it would also provide a framework
11 in which future products could be developed.

12 CHAIRMAN TENENBAUM: We have banned very few
13 products over the course of decades. Lawn darts was one. If
14 you were looking and comparing the neodymium magnets to lawn
15 darts -- I'm to ask you all -- do you think lawn darts are
16 more dangerous or the neodymium magnets?

17 MS. WEINTRAUB: I think one thing that is certainly
18 clear is the hazard of lawn darts is not hidden. I think it
19 is much more clear what the consequences would be to the

1 user, to the purchaser of a product like that.

2 I think for these magnet sets, it is very much
3 hidden, and I think it is not at all as clear what the
4 consequences are. I also think it is much more likely
5 because these products are so small in the way in which they
6 are used that what happened to the patient that Dr. Gilger
7 described, that these things could be on the floor with a
8 parent not knowing, is very likely.

9 The hidden nature of this hazard is extreme and
10 problematic.

11 CHAIRMAN TENENBAUM: Dr. Gilger?

12 DR. GILGER: Chairman Tenenbaum, I remember playing
13 with lawn darts myself. It is a toy. It almost looks like a
14 weapon. It is pretty obvious to convey there might be
15 dangers involved. When I played with them, I threw them as
16 high as I possibly could throw them to come down with as much
17 force as they possibly could.

18 The difference with neodymium magnets is they are
19 innocuous. I think we showed you, I think they look like

1 candy. When you get a young child and show them something
2 that looks like candy, that is what they think it is.

3 Even more than that, kids experiment, and they take
4 these neodymium magnets and they mimic piercings, it is a
5 whole different ball game. I think it is the innocuous
6 nature and the fact that you get creative children playing,
7 and they will come up with creative things to do with these.

8 CHAIRMAN TENENBAUM: Ms. Gadhia?

9 MS. GADHIA: My answer is going to echo the other
10 panelists. As the parent of an 18 month old, you all know
11 very well you are intrinsically wired to keep them away from
12 sharp objects, but I think very few consumers know exactly
13 the kinds of injuries that can occur when these magnets are
14 swallowed in multiples, so the agency's approach is
15 appropriate.

16 CHAIRMAN TENENBAUM: Thank you. Commissioner Nord?

17 COMMISSIONER NORD: Thank you so much. I'm a bit
18 concerned about the scope of the definition of Amagnet sets@
19 that we find in the NPR. In any of your views, would the

1 definition that we have in the proposed rule cover the pen
2 example that was given early on? Do you think this
3 definition covers that?

4 MS. GADHIA: I think the agency rightfully took a
5 look at the products that were on the market, these kinds of
6 magnets. The pen example that I brought up, I actually just
7 became aware of it fairly recently as I was preparing my oral
8 testimony, it is clear this is something that has a lot of
9 potential to take off in a bunch of different directions.

10 I think it is very appropriate that the agency is
11 approaching the products that it has a lot of information
12 about.

13 COMMISSIONER NORD: I guess in my view something
14 that is intended for a pen is not something that is a
15 manipulative or construction desk toy, it seems on its face,
16 it wouldn't be covered by the definition that we have.
17 Hence, I'm wondering whether the scope of the definition in
18 the rule is appropriate.

19 I'm also curious about whether this definition

1 picks up magnets that are intended for scientific purposes or
2 for crafting. I recently read an article in a national
3 magazine that is intended for potters in the ceramics
4 industry where it was suggested that these magnets have a use
5 in a pottery studio, just to give you an example of something
6 that perhaps our staff wouldn't have anticipated but is a
7 very useful use for these magnets.

8 Do you see it as appropriate to exclude magnets
9 that a crafter might use or somebody using it in a science
10 kit for scientific experiments or for doing art projects and
11 that kind of thing?

12 MS. GADHIA: I think the agency staff is working
13 very hard to build the body of knowledge in the database
14 information and the previous steps taken on these particular
15 magnet sets to build to the definition that is in the current
16 NPR.

17 It is clear from the link I just found very
18 recently that these uses are something that are changing and
19 morphing every day. We would urge the Commission to continue

1 to study those new and emerging uses the way they have
2 studied so well the hazards presented by these magnets.

3 COMMISSIONER NORD: Okay. I take it you don't
4 think the data supports an expansion of the definition beyond
5 what is there?

6 MR. GADHIA: I think what is in the NPR is very
7 appropriate and what is clear is the hazard is ever changing,
8 and we know the agency likes to stay on top of emerging
9 hazards.

10 COMMISSIONER NORD: The definition in the NPR is
11 really keyed on the intent of the manufacturer. With respect
12 to individual magnets, if a manufacturer makes them and sells
13 them to all comers, then I presume that manufacturer probably
14 wouldn't fit in this definition because it is not marketed
15 primarily as a manipulative or construction desk set.

16 I guess CFA argues we should keep in the individual
17 magnets' provisions of the NPR, but it just seems to me it
18 may be a provision that is so easily avoided, I'm just
19 wondering whether it really serves its purpose.

1 MS. WEINTRAUB: We would argue, as you stated our
2 position accurately, that individual magnets that can be used
3 in magnet sets should be subject to the same rules, because
4 they can be used in the same way.

5 COMMISSIONER NORD: Isn't it the manufacturer's
6 intent that is the key here in the definition?

7 MS. WEINTRAUB: I think that is important.

8 COMMISSIONER NORD: It says it on its face.

9 MS. WEINTRAUB: Yes, I think it does. I think CPSC
10 needs to look broader and look at how these things would be
11 used.

12 COMMISSIONER NORD: You think we should expand the
13 scope a little bit?

14 MS. WEINTRAUB: I do.

15 COMMISSIONER NORD: Okay. Thank you. I'm tempted
16 to get into a discussion of how this rule would interact with
17 our 1110 rule and what kind of certificate would be needed,
18 given this conversation about a ban and a rule, and it really
19 is a ban except its being cast in terms of a rule.

1 I think I'm going to forego that. Dr. Gilger, in
2 your testimony, you indicated there are additional things the
3 agency should be doing, including public education. I'm just
4 wondering what an effective public education campaign would
5 look like.

6 In your view if the agency were to do a one shot
7 public service announcement, would that be sufficient, or
8 does it need to be an ongoing effort?

9 DR. GILGER: Excellent question, of course. I
10 would say with physicians, we have what is called continuing
11 medical education, meaning I know myself I have to have
12 something repeated at least seven times until I remember it.

13 I think the essence is yes, we have to always be
14 constantly reminded of the dangers. These types of neodymium
15 magnets remind me of a product that simply has unintended
16 consequences.

17 I don't think for a minute that the manufacturers
18 when they came out with this toy just a matter of a few years
19 ago had any idea of the consequences of the magnets. I think

1 now they do.

2 COMMISSIONER NORD: How do you educate the medical
3 community and the public? Again, I assume a one shot PSA is
4 not probably going to do it in your view, putting words in
5 your mouth. Does it have to be continuing?

6 DR. GILGER: I think it has to be continuing.
7 There are some very good materials out now by CPSC which are
8 very to the point and very effective. I don't think that it
9 is widely known.

10 COMMISSIONER NORD: Have you seen a growing
11 awareness in the medical community about this and then as a
12 corollary, within those doctors' patients' community, about
13 this danger?

14 DR. GILGER: There is definitely a growing
15 awareness. I can just reflect back to even a year and a half
16 ago where when I realized what was happening with these
17 magnets, just in Texas, I went down to our emergency room and
18 I asked the first emergency room physician I came to, tell me
19 about these things and what kind of problem you are having.

1 They looked at me with blank eyes, had no idea.

2 This is only a year and a half ago. We have a lot of work to
3 do.

4 COMMISSIONER NORD: Do you think if you went and
5 asked the same question today, there would be still blank
6 eyes?

7 DR. GILGER: We are still going to find people that
8 don't know.

9 COMMISSIONER NORD: You're going to have to keep
10 pushing the information out there. When you push the
11 information out there, do they understand the hazard? Do
12 they get it?

13 DR. GILGER: Yes. I think it's very easy to point
14 out what happens once they are ingested, and I think we are
15 going to learn a little bit more about this later this
16 morning. I think you can get very constructive, clear,
17 concise education that gets the point across very well.

18 COMMISSIONER NORD: Okay. You think if we were to
19 construct some sort of effort, working constructively with

1 the medical community, to try to reach mom's and parents,
2 that is something that needs to be done?

3 DR. GILGER: Absolutely.

4 COMMISSIONER NORD: Okay. Thank you so much.

5 CHAIRMAN TENENBAUM: Commissioner Adler?

6 COMMISSIONER ADLER: Thank you very much, Madam
7 Chairman. I would point out to my colleague that the
8 definition is not just using the word Aintending,@ it is also
9 using the word Amarketed,@ which is to anybody who knows the
10 law, you always get two elements, you often get two elements.

11 One is what was the intent and the other is what
12 was the effect. I'm not sure I would agree with her that
13 Aintent@ subsumes the entire concern that the Commission had.
14 I just note that in passing.

15 I did also want to make a quick observation about
16 lawn darts. One of the things that I've always found
17 fascinating about lawn darts is when I came to the Commission
18 there had been decades of concern about lawn darts which had
19 led first to very strong warnings about not using them around

1 children, then had led to actual changes in marketing, such
2 that lawn darts were not sold in toy stores. They were only
3 sold in sporting goods stores or in the sporting goods area
4 of department stores.

5 Nevertheless, experience over decades demonstrated
6 that kids still got seriously injured by lawn darts, which
7 eventually led to a ban of lawn darts.

8 I'm not claiming that is an exact precedent, but it
9 is something that gives me pause.

10 What I'd like to do is ask Ms. Gadhia and Ms.
11 Weintraub a question about something you both raised, which
12 is intriguing, and I must admit it wasn't something I had
13 thought about, but I'm going to read from Ms. Gadhia's
14 testimony.

15 It says AWe further urge CPSC to study magnets with
16 a flux density of 50 when aggregated continue to have a flux
17 density of 50.@ That is intriguing.

18 Is this something you have any expert input on or
19 is this something you are raising as a concern that the staff

1 ought to be focusing on?

2 MS. WEINTRAUB: It's an issue we were discussing as
3 we were preparing our comments actually a year ago in
4 November, and it is something we think there needs to be
5 further study on, when these magnets are aggregated, even if
6 they have a flux density of 50, what is their flux density
7 when they are altogether. Does the nature of the aggregation
8 actually increase the flux density or does it not.

9 COMMISSIONER ADLER: I think it is a great
10 question. I am planning to call the engineering staff right
11 after the hearing and asking if they have any information on
12 that. I appreciate you raising the issue.

13 Did you want to --

14 MS. GADHIA: No, I think Rachel covered what I was
15 going to say.

16 COMMISSIONER ADLER: Dr. Gilger, I'm intrigued by
17 the notion of the difficulty of making a diagnosis, because
18 this goes to whether or not we have under reporting. I can
19 certainly understand how you would have the potential for a

1 delay in diagnosis.

2 When it gets very serious, do you think that even
3 then some of these hazards are missed, that maybe a child
4 dies because nobody ever thought to look to see what the
5 issue was, or is this the sort of thing that we may not catch
6 it right away but ultimately we are very likely to catch it,
7 or you may not have any idea one way or the other? I'm
8 intrigued by that.

9 DR. GILGER: Interesting question. The symptoms
10 are very non-specific early. As the injury progresses, they
11 become more obvious, as the abdominal pain becomes
12 remarkable, vomiting and other things.

13 I think when the child is known to have ingested
14 them and is being observed, the correct diagnosis will be
15 made.

16 I think the issue is parents may have even have
17 seen the child eat them and not think anything of it. That
18 is where the concern is and I think it will remain there.

19 COMMISSIONER ADLER: I guess the question is

1 suppose the parents don't realize the child has ingested it
2 and they have come in, taken them to an emergency room. Is
3 it at some point quite likely that a physician, when it gets
4 to extreme symptoms, would be able to catch this, or is it
5 still the case that maybe no one really catches the hazard?

6 DR. GILGER: I think it can be missed. The example
7 earlier by Ami about little Braylon, a family I know, that
8 child was very delayed in presentation. As a matter of fact,
9 when the child got to the initial emergency room, they were
10 sent home. It was only quite honestly an adept nurse who had
11 watched the web and said wait a minute, I heard about these
12 things.

13 I think there is an intense education that still
14 needs to be out there, both public, mom and dad, and
15 physicians alike.

16 MS. WEINTRAUB: One point that I wanted to make
17 addressing something you said as well, something Commissioner
18 Nord said, about a year ago when my nine year old son was
19 eight, it was in August when there is a lot of attention

1 about these products, we were reading about it in the paper
2 in the morning as we often do, and my eight year old said all
3 of my friends have these things. He's prone to exaggeration,
4 I don't think it is all his friends, but many of his friends,
5 his eight year old friends, have these products in their
6 homes.

7 It just points to the need for extensive consumer
8 education. These parents don't want to place their children
9 at risk but they don't know. They see these products. They
10 think they are interesting. When we were talking about it,
11 my son said yeah, I'd like that product, why don't I have it,
12 it's not fair.

13 I think it just goes to the point about education,
14 that it is something that because of how hidden the hazard
15 is, how parents don't perceive the severity of the potential
16 consequence, that education is very important, in conjunction
17 with a strong rule that would design out this hazard.

18 COMMISSIONER ADLER: Thank you very much. Dr.
19 Gilger, I'm delighted to hear the vote of confidence for

1 nurses.

2 CHAIRMAN TENENBAUM: Commissioner Robinson?

3 COMMISSIONER ROBINSON: I think I'd like to start
4 with Dr. Gilger, and thank you, all three, for your
5 thoughtful comments today.

6 Dr. Gilger, in your testimony you referred to the
7 under estimation of risk and spoke about the 400,000
8 ingestion's and the different ways in which children of all
9 ages take these products in.

10 Commissioner Adler was talking about the under
11 reporting, but I would like to focus on another area, and
12 that is the numbers that we actually have where there have
13 been problems.

14 In looking at the written testimony of all the
15 people who will be talking today and the information we have,
16 the numbers of actual incidents seem to be based exclusively
17 on estimates from the NEISS data, and from the survey -- I'm
18 sure there is a way to pronounce this but I would blow it --
19 NASPGHAN.

1 You listed in your oral testimony other areas of
2 medical specialty that deal with this problem where we may
3 not actually have the numbers even where doctors know this is
4 what happened but there is any forum in which they have
5 talked about the numbers.

6 I would just like your comments, if you would, on
7 whether the numbers that we do are anywhere close to
8 accurate.

9 DR. GILGER: I would venture to guess the data in
10 the NEISS database is the tip of the iceberg. We can report
11 it. CPSC certainly has abilities to report it. Obviously,
12 it can make the NEISS database, but that is a serious under
13 estimation.

14 Also, NASPGHAN, North American Society for
15 Pediatric Gastroenterology, Hepatology and Nutrition.

16 COMMISSIONER ROBINSON: Thank you. I would like to
17 go back for a moment to the issue that Commissioner Nord
18 raised. I guess I would focus on Ms. Weintraub and Ms.
19 Gadhia just because you brought it up, but Dr. Gilger, if you

1 would like to comment as well, you are certainly welcome to.

2 This definition that we have, Ms. Weintraub, I know
3 you talked about the individual magnets. Certainly, Ms.
4 Gadhia, you talked about the pen and the fact that it
5 wouldn't be addressed in our definition of Amagnet sets@ in
6 this proposed standard, and we are supposed to stay on
7 emerging hazards.

8 Have any of you given thought, setting aside the
9 size and flux index, just the definition of Amagnet sets?@
10 Obviously, this is a limited definition. We all know what it
11 is aimed at through this definition. We are seeing other
12 things.

13 Have you given thought to the wording of that
14 definition of Amagnet sets@ that might help us out if we were
15 to adopt such a standard?

16 MS. WEINTRAUB: I think the definition is a very
17 good start. I think in the review of this rule, the
18 Commission should look at whether there are emerging hazards
19 that should be further included. I think the definition is a

1 very important standard by which to move forward, because I
2 think it really reflects what we are seeing in the
3 marketplace when it was drafted, but I think what is also
4 very telling is just how important the promulgation and the
5 speedy promulgation of the standard is because the market is
6 developing and the standard needs to be in place to protect
7 children from this hazard.

8 COMMISSIONER ROBINSON: Even though you mentioned
9 the individual magnets, at this point you wouldn't advocate
10 expanding the definition?

11 MS. WEINTRAUB: I think individual magnets should
12 be included, but I think this is a good start and I think the
13 Commission staff should consider whether adding individual
14 magnets and looking at the marketplace, how it has evolved
15 over time, whether it should be expanded. I think it is a
16 good base from which to do a further review.

17 MS. GADHIA: I concur. We wouldn't want to delay
18 what the agency is trying to do here, but I think if I'm
19 understanding correctly what Rachel and I were trying to get

1 at in our respective testimony was that with regard to the
2 individual magnets, it not essentially become a work around
3 to making sets available to consumers through a big bin full
4 of individual magnets.

5 Yes, there are other uses out there like jewelry,
6 like this pen, which I think is the subject of a kick
7 starter, so it may not even exist yet. Clearly, it's moving
8 in other directions and it's going to need the same kind of
9 study and consideration by agency staff.

10 MS. WEINTRAUB: The concern with individual magnets
11 could be it could end up being a loophole around this
12 important standard, and it's also important for compliance
13 staff and enforcement staff to ensure that there is
14 widespread compliance with the standard when it is
15 promulgated.

16 Our point was we don't want there to be a loophole
17 that is inadvertently created by not covering individual
18 magnets.

19 COMMISSIONER ROBINSON: Dr. Gilger?

1 DR. GILGER: I would just add that I think it is
2 the appropriate starting place for this common sense
3 approach, but human ingenuity is remarkable, and we are going
4 to see another 100 plus uses of these in a variety of
5 different forms that I can't imagine right now.

6 I just learned about the pen in the past month.
7 It's remarkable. Technically, it can cause exactly the same
8 problems once it breaks apart.

9 How we define it? I think we need to really look
10 closely at that, but I think this is the appropriate starting
11 place to address the current issue.

12 COMMISSIONER ROBINSON: Thank you all.

13 CHAIRMAN TENENBAUM: Commissioner Buerkle?

14 COMMISSIONER BUERKLE: Thank you, Madam Chair. Let
15 me begin by thanking all the members of the first panel for
16 your compelling testimony, for being here today, and for your
17 concern and interest about safety, especially among children.

18 I wanted to just kind of pick up where some of my
19 colleagues have talked about education, because I think

1 education is where this should start. Dr. Gilger, you talked
2 about prevention. I think the way we prevent this is through
3 education.

4 I'd like to ask each one of you, can you tell me
5 and the rest of the Commissioners, what have your
6 organizations been doing to educate the public about this
7 potential risk? Rachel, if we could start with you.

8 MS. WEINTRAUB: Sure. Like I said, I think
9 consumer education is very important but I think it is not
10 the sole solution, that a strong standard is very important
11 to design out the hazard.

12 Actually, our work has involved something
13 unprecedented, not only can I now perhaps appropriately
14 pronounced ANASPGHAN@ but I first found out about NASPGHAN
15 and started to work with them about this issue, and Consumers
16 Union, NASPGHAN and AAP have been working together for well
17 over a year now.

18 Working together, we have had periodic meetings at
19 different times, really organizing each other, having

1 educational sort of seminars that we have had for members and
2 colleagues to truly educate, educate our members about the
3 hazard.

4 I think this is actually rather unprecedented in
5 terms of the meetings that we have had and participated in to
6 get the word out. We have also issued a number of press
7 releases and have coordinated, had different panels at
8 conferences, where it has been a concerted effort to get the
9 word out.

10 COMMISSIONER BUERKLE: Have any of those meetings
11 and collaborations, which sound extremely important, resulted
12 in a public service campaign, other than a press release?

13 I think we have seen with SIDS and balloons, very,
14 very effective educational programs, where we have reduced
15 injuries from balloons and ingestion of them by 50 percent.

16 We were always taught to put our kids on their
17 stomachs when we laid them down, and now, my kids will say to
18 me, no, mom, no, no, they have to be on their back. That is
19 the result and effectiveness of public education.

1 My concern is how can we educate when someone goes
2 into the emergency room, Dr. Gilger, this would probably be
3 best directed to you, when a child is brought into the
4 emergency room, how do we get physicians to immediately think
5 this could be -- they think in terms of appendix -- how can
6 we educate them and what has the American Academy of
7 Pediatrics doing about educating physicians?

8 Is there a blanket education program? Is there
9 something included in medical school curriculum? How is this
10 being disseminated among our physicians?

11 DR. GILGER: A project in progress. The AAP in
12 concert with NASPGHAN has produced a series of webcasts,
13 websites, physician education seminars. There have been a
14 series of education seminars in medical schools across the
15 country, specifically pediatric departments, grand rounds,
16 that sort of thing.

17 I was actually encouraged recently, our Chief of ER
18 at Children's Hospital in San Antonio is actually an
19 authority on this topic.

1 I think we are getting to people. I think we have
2 a lot of work to do.

3 In terms of medical school curricula, that is a
4 really interesting question and I will investigate that
5 personally at Baylor. I don't think so. I don't think it's
6 in the curricula.

7 I do know that when we train our residents, our
8 next generation of physicians, this is in there, when we
9 discuss foreign body ingestion by children, I have included it
10 because it is part of what I do, but it is across the banner.

11 I think also with American Academy of Family
12 Practitioners and with our surgical colleagues, pediatric
13 surgical scenario's, they are now exquisitely aware of the
14 consequences of these magnets, but there is no question there
15 is more work to do.

16 COMMISSIONER BUERKLE: Thank you.

17 MS. GADHIA: Consumer Reports has written about
18 this going back over a year. We conducted interviews of some
19 of the victims and their families and we did a video on

1 Consumer Reports on line to show to our subscribers and
2 people who come to the website, and the content is not just
3 available to subscribers but all consumers, of exactly what
4 is involved. The visual is always very helpful. We have put
5 video as well as text on our website to walk through the
6 hazard and nature of the concern.

7 We have written about it several times since the
8 issue first started to crop up last year. We continue to
9 write about it. One of our writers participated recently in
10 a webinar with NASPGHAN doc's to inform, as I understand it,
11 State Department of Public Health and Poison Control folks
12 about the hazard, to begin to bring them up to speed.

13 We continue to get the word out and we will
14 continue to push on those fronts.

15 COMMISSIONER BUERKLE: Thank you. Dr. Gilger, to
16 your point about reaching beyond the pediatric community
17 especially when you are talking about adolescents and making
18 sure family practice physicians and internists are aware of
19 this as well, I would really suggest that it is incumbent

1 upon all of us to collaboratively work with along with the
2 industry to raise public education.

3 This is such a public health threat, we should all
4 be working collaboratively with this messaging and this
5 ongoing education. I think it is going to be critical.

6 Rachel, I just have one question, if you wouldn't
7 mind clarifying. You mentioned using Section 7 and Section 9
8 for rulemaking was more effective than using Section 8, if
9 you could just clarify that for me.

10 MS. WEINTRAUB: Sure. Our analysis was based on
11 the fact that first of all the end result would be the same,
12 that the product would essentially not be permitted to remain
13 on the market, so the consequence would be the same, but that
14 using Section 7 or 9 would be more instructive for future
15 market entrants, and that in moving forward, a rule that
16 would contain information such as the parameters of the choke
17 test tubes and the flux density would be more instructive,
18 and would potentially prevent other similar products from
19 coming onto the market, and the rule would be broader and

1 more instructive in that regard.

2 COMMISSIONER BUERKLE: Thank you. Thank you all
3 very much. I yield back, Madam Chair.

4 CHAIRMAN TENENBAUM: Thank you. We thank all of
5 our panelists this morning and we will go on and move into
6 the second panel. Thank you very much.

7 For our second panel, we have Dr. Bryan Rudolph,
8 who is the Assistant Professor of Pediatrics, Division of
9 Pediatric Gastroenterology and Nutrition, Albert Einstein
10 College of Medicine, Children's Hospital in the Bronx, New
11 York.

12 Dr. Maria Oliva-Hemker, Chief of Pediatric
13 Gastroenterology and Nutrition and Stermer Family Professor
14 of Pediatric Inflammatory Bowel Disease at Johns Hopkins
15 Children's Center in Baltimore, Maryland, and on behalf of
16 the North American Society for Pediatric Gastroenterology,
17 Hepatology and Nutrition.

18 We have Dr. Ian Leibowitz, Assistant Professor of
19 Pediatrics, Department of Pediatrics, Virginia Commonwealth

1 University, and Director, Pediatric Digestive Diseases Center
2 at Inova Fairfax Hospital for Children in Fairfax, Virginia.

3 We have Dr. Marsha Kay, Chair, Pediatric
4 Gastroenterology, Director of Pediatric Endoscopy, Cleveland
5 Clinic Children's Hospital in Cleveland, Ohio.

6 I am so impressed with all of your accomplishments
7 and titles, that I hope I did them all justice.

8 Typically, we are allowing our panelists to have
9 ten minutes, and if you look over here to Todd Stevenson, he
10 will give you the sign when it is five minutes remaining and
11 two minutes remaining, and then we will ask questions from
12 all the Commissioners.

13 Dr. Rudolph?

14 PRESENTATION OF DR. BRYAN RUDOLPH

15 DR. RUDOLPH: Thank you very much. I appreciate
16 the opportunity to be here today. Good morning to you all.

17 My name is Dr. Bryan Rudolph. I am Assistant
18 Professor of Pediatrics at Children's Hospital in Montefiore,
19 and a practicing pediatric gastroenterologist and member of

1 NASPGHAN, North American Society for Pediatric
2 Gastroenterology, Hepatology and Nutrition.

3 The focus of my comments today is on the
4 demographics of magnet ingestion's. I'd like to start by
5 echoing the statements of the previous panelists and the
6 panelists up here by offering my own strong support for the
7 Commission's proposed safety standard for high powered magnet
8 sets.

9 I firmly believe that these products are
10 fundamentally unsafe and pose an unnecessary risk to
11 children.

12 For the past several years, pediatric
13 gastroenterologists have been on the front lines of this
14 national epidemic. Increasingly, there is a growing body of
15 medical literature documenting what we have known
16 anecdotally, that is high powered magnets ingestion's are
17 common, they are dangerous, and they occur across all
18 pediatric age groups, including frequently in older children
19 and in adolescents.

1 Much of this literature followed a NASPGHAN member
2 survey conducted from July to October 2012. This survey
3 included responses from 201 pediatric gastroenterologists
4 from 44 states. NASPGHAN researchers identified 481 cases of
5 documented magnet ingestion's in children over a ten year
6 period with 320 occurring over the previous three years.

7 The high frequency of magnet ingestion's in the
8 latter time period corresponds to the introduction of rare
9 earth magnet sets to the market.

10 It's likely that this NASPGHAN survey under
11 estimates magnet ingestion's because pediatric
12 gastroenterologists were the only group surveyed. A variety
13 of other specialists treat these ingestion's, including
14 pediatric surgeons, general pediatricians, family
15 practitioners, and emergency room physicians.

16 NASPGHAN researchers were able to obtain detailed
17 clinical data on 123 of these cases. Similar to other
18 foreign bodies, children between the ages of 13 months and
19 six years appear to be at the highest risk for ingestion.

1 This age range accounted for slightly greater than
2 50 percent of ingestion's, but what is perhaps most striking
3 is the number of ingestion's occurring to those least
4 amenable to adult supervision, that is older children and
5 adolescents.

6 Magnet ingestion's were identified in 15 children
7 between the ages of six and nine years; 24 children between
8 the ages of nine and 12; 15 children between the ages of 12
9 and 15; four adolescents between the ages of 15 and 18.

10 Most of the older children who ingested high
11 powered magnets did so accidentally while mimicking facial
12 piercings; 12 percent of the ingestion's occurred in
13 developmentally delayed children, and five percent had a
14 diagnosed psychiatric condition.

15 Within the past year alone, there have been at
16 least seven additional published reports on high powered
17 magnet ingestion's affecting children in the United States.
18 An article published three months ago and drawn from the
19 National Electronic Injury Surveillance System data estimates

1 that 16,386 children visited an emergency department in the
2 United States over the past ten years, that is from 2002 to
3 2011, for possible magnet ingestion's. Of those, 45.3
4 percent occurred in children over the age of five.

5 The other six studies were all case series of
6 varying sizes in pediatric centers throughout the country,
7 Boston, Atlanta, Honolulu, Southern California, Buffalo, and
8 Seattle, all detailed ingestion's by adolescents and older
9 children.

10 Ingestion's involving toddlers are somewhat easier
11 to understand, as Dr. Gilger pointed out previously. These
12 toys are small, usually brightly colored, and often comes
13 with hundreds of individual magnets to a pack. It is easy
14 for a care giver to lose individual magnets and even easier
15 to see why a child might be attracted to them.

16 The consequences of accidental magnet ingestion's,
17 however, are serious and potentially fatal. Approximately
18 six months ago, an 19 month girl who swallowed six of these
19 magnets required a colonoscopy at my institution.

1 The mother was well educated, loving, and by all
2 measures, a good parent. The toddler found and swallowed the
3 toy magnets after they were accidentally dropped by an older
4 sibling. Our patient was lucky and we were able to remove
5 the magnets endoscopically, and she was discharged home the
6 following day.

7 One toddler in Mississippi, who you already heard
8 about, Braylon Jordan, was not as fortunate. His parents
9 accidentally dropped several magnets on a carpeted floor
10 prior to putting the magnet set away.

11 After finding the magnets and ingesting them,
12 Braylon required multiple abdominal surgeries, and has lost
13 the majority of his small intestine. He currently requires
14 an essential I.V. catheter for nutritional support, and will
15 need an intestinal transplant most likely in the coming
16 years.

17 This is not an issue of poor parenting. These
18 magnets are accidents involving an irreparably unsafe
19 product. There is no amount of warning or parental diligence

1 sufficient to completely prevent accidental injuries in
2 children.

3 We have seen a dramatic increase in high powered
4 magnet ingestion's despite multiple product warnings,
5 widespread press and exhausted advocacy efforts, and
6 remember, ingestion's occur in older children as well as
7 toddlers.

8 Ultimately, removing high powered magnets from the
9 market constitutes the only course of action to adequately
10 reduce ingestion's and their associated injuries.

11 Unfortunately, high powered neodymium magnets are
12 no longer just found in desk toys and a variety of new
13 novelties are quickly appearing on the market, as you heard
14 about earlier.

15 A quick Internet search, for example, shows small,
16 individual neodymium magnets in a variety of shapes, sizes
17 and colors.

18 I guess it is two weeks ago now that I also came
19 across the Polar Pen on Kickstarter, which is a ball point

1 pen comprised entirely of small interchangeable neodymium
2 magnets. In fact, the magnet components are similar in size
3 to the very product the proposed safety standard intends to
4 address.

5 The Polar Pen is being manufactured and will soon
6 be shipped all over the world including to consumers in the
7 United States.

8 I urge the Commission to quickly finalize its
9 proposed safety standards for high powered magnet sets and
10 ensure that the proposed definition of Amagnet sets@ captures
11 new high powered magnet novelties such as the Polar Pen.

12 A consequence of small rare earth magnet
13 ingestion's in children can be catastrophic and are
14 completely preventable.

15 The longer these products remain commercially
16 available, the longer our children are needlessly exposed to
17 danger.

18 Thank you.

19 CHAIRMAN TENENBAUM: Thank you. Dr. Oliva-Hemker?

1 PRESENTATION OF DR. MARIA OLIVA-HEMKER

2 DR. OLIVA-HEMKER: Good morning, Chairman Tenenbaum
3 and Commissioners Buerkle, Nord, Adler and Robinson.

4 My name is Dr. Maria Oliva-Hemker. I am the Chief
5 of Pediatric Gastroenterology and Nutrition and Stermer
6 Family Professor of Inflammatory Bowel Disease at the
7 Children's Center at Johns Hopkins and the John Hopkins
8 University School of Medicine in Baltimore, Maryland.

9 Thank you for the opportunity to present testimony
10 regarding the Commission's proposed standard to reduce the
11 risk of injury associated with magnet ingestion's in
12 children.

13 Specifically, I am here to offer comments on behalf
14 of the North American Society for Pediatric Gastroenterology,
15 Hepatology and Nutrition, which we now know goes by the name
16 of NASPGHAN. My comments are to demonstrate the correlation
17 between the emergence of high powered magnet sets in the
18 commercial market and the rise in the incidents of high
19 powered magnet ingestion's.

1 Information from the medical literature tells us,
2 as you have heard, that about 80 percent of foreign body
3 ingestion's occur in children. As experts in foreign body
4 ingestion, pediatric gastroenterologists expect most
5 gastrointestinal foreign bodies to pass spontaneously without
6 symptoms.

7 Only about 10 to 20 percent require endoscopic
8 removal, and less than one percent require surgical
9 intervention. Surprisingly, even sharp objects like needles
10 and pins usually pass without incident.

11 High powered magnets, however, as we have heard
12 today, are different from other ingested foreign bodies.
13 These types of magnets are being increasingly ingested and
14 can seriously injure the GI tract, as you have heard.
15 Unfortunately, because the ingestion of high powered magnets
16 may initially cause no symptoms, there can be a marked delay
17 in diagnosis and treatment. At times, the ingestion is not
18 discovered until the child presents with signs and symptoms
19 of intestinal obstruction or perforations.

1 NASPGHAN became aware of an apparent rise in high
2 powered magnet ingestion's in the Spring of 2012, when it was
3 noticed that more and more pediatric gastroenterologists were
4 discussing these types of cases on gastroenterology message
5 forums.

6 NASPGHAN leaders determined that a survey study was
7 needed to document any changes in the frequency of cases and
8 complications associated with these ingestion's.

9 A study survey was performed between July 26, 2012
10 and October 10, 2012. It was divided into two parts. The
11 first part of the survey was to determine the changes in
12 frequency of physicians encountering magnet ingestion's over
13 the past ten years.

14 The second part of the survey was directed at
15 providing clinical case information on patients who had
16 ingested these neodymium magnet balls.

17 This clinical case survey concentrated on the
18 period from 2008 to 2012, and the researchers chose 2008 as
19 the start of the clinical case review because this was the

1 first year in which high powered or these neodymium magnet
2 ball sets were marketed and sold in the United States.

3 The first part of the survey was completed by 355
4 physicians who represented a total of 481 magnet cases over
5 the ten year period.

6 Respondents were 201 physicians from 44 states.
7 All the regions of the country, including Alaska and Hawaii,
8 had at least one physician who had been involved in a magnet
9 ingestion.

10 My figure here is not as visually appealing to
11 children as Dr. Gilger's cupcake, but it provides important
12 data nonetheless.

13 The number of cases per year increased during each
14 time period of the study. What I am showing you here is
15 using 2012 as the beginning year of the study and moving
16 backward to the number of magnet cases that had been seen and
17 presented by the individuals, so we will show the first
18 figure, please.

19 As you can see, within a year of the study, there

1 were 200 cases that had been reported by these physicians.

2 In blue, you see the number of cases for time period and then

3 in red is the average number of cases per year.

4 When you go back six to ten years, certainly the

5 number of cases that were reported were less.

6 So 320 of the 481 cases occurred during the past

7 three years.

8 Turning to Figure 2, all cases reported in the

9 second part of the survey, which provided more detailed

10 information about the patients, came specifically from

11 physicians practicing in the United States. Of these 123

12 clinical cases, 102 occurred in 2011 and 2012. As you can

13 see, there was a sharp increase in the number of cases from

14 2010 to 2011 and then extending into 2012.

15 The data obtained from this survey is very

16 important in providing us with patient related information

17 and outcomes. However, these are individual case reports and

18 to get a sense as to whether there was a trend, an increased

19 trend in ingestion's, we needed additional information.

1 Using the National Electronic Injury Surveillance
2 System, NEISS, database, Dr. Mazen Abass and colleagues
3 conducted a study of foreign body ingestion's in children,
4 and obtained epidemiologic data on magnet ingestion's from
5 2002 to 2011. This report is the first published study to
6 provide national estimates of emergency department visits for
7 magnet foreign body ingestion's in children, and it was
8 recently published in the Journal of Pediatric
9 Gastroenterology and Nutrition.

10 Since the NEISS database did not include an
11 officially designated category of magnets, in the study, each
12 case narrative was manually reviewed for the term Amagnet,@
13 and to further determine whether there was documentation for
14 the magnets as being round or spherical or small in size, as
15 well as how many magnets were involved in the ingestion.

16 Additional data collected included date of
17 emergency department visit, age, gender, type of products
18 ingested and the emergency department disposition.

19 All children less than 18 years of age during the

1 study period were included.

2 During the ten year study period, there was an
3 estimated 16,386 magnet ingestion related emergency
4 department visits among children. These estimates were
5 derived from the 678 reported emergency department visits for
6 magnet ingestion's that were reported by these cohorts of
7 emergency departments across the country.

8 As I mentioned earlier, there were no magnet
9 categories in the database, so most of the ingestion's were
10 actually reported under the categories of Akitchen magnets@
11 or Atoys.@ These had to be manually reviewed to extract
12 those emergency department visits that described small and/or
13 round magnets.

14 With more than 16,000 magnet ingestion's, there was
15 enough information to estimate that 7,159 emergency
16 department visits for ingestion of magnets were described as
17 the magnets ingested were small and/or round.

18 Interestingly, the patients ingesting these small
19 and/or round magnets when compared to those ingesting another

1 type of magnet were more likely to be older than five years
2 of age, and this goes against the general trend for foreign
3 body ingestion's in children where typically it is the
4 younger children, as you have heard, who typically are at
5 highest risk for these types of ingestion's.

6 Further analysis of the cases with reported small
7 and/or round magnet ingestion's revealed that children older
8 than five years of age were more likely to ingest multiple
9 magnets compared to a single magnet. Those ingesting
10 multiple small and/or round magnets had a statistically
11 higher chance of being admitted, observed or transferred to
12 another hospital compared to those who had ingested only one
13 magnet.

14 As you will see in our Figure 3, which shows you
15 both estimated total number of emergency department visits as
16 well as the estimated number of visits per 100,000 children,
17 what you see are three lines. In blue, the 5 to 13 years of
18 age, that is in the middle. Red, on the top, 0 to 4 years of
19 age. Purple, 14 to 17 years of age.

1 All of the age groups had statistically significant
2 trend increases of magnet ingestion's over the ten year study
3 period.

4 The group of 14 to 17 years had almost no
5 documented magnet ingestion related emergency department
6 visits as you can see here until 2009, after which a
7 statistically significant rise is noted from a rate of 0.1
8 per 100,000 to 1.15 per 100,000.

9 The age group of 5 to 13 years had the largest
10 increase in those suspected to have multiple small and/or
11 round magnet ingestion's, and this is shown in the next
12 figure. The rate there increased from .02 per 100,000 in
13 2007 to 1.22 per 100,000 in 2011. This represents a 61 fold
14 increase.

15 To summarize, the ten year review of the NEISS
16 database that was independently conducted by Dr. Abass and
17 colleagues provides important information on the trend of
18 magnet ingestion's in children in the United States.

19 It was shown that during this ten year period,

1 there were more than 16,000 emergency department visits for
2 magnet related ingestion's, and such visits in aggregate
3 overall increased more than eight-fold.

4 Importantly, it shows that magnet ingestion's began
5 to increase in 2009. This was following a drop in cases from
6 2007 to 2009. We speculate that the drop in cases from 2007
7 to 2009 is attributed to the Commission's recall of numerous
8 toy products that contained high powered magnets and
9 adherence to toy safety standards.

10 The increase in magnet ingestion's correlates with
11 2009 being the first year of significant sales of high
12 powered magnet sets. For example, based on data available
13 from one company alone, 1.5 million units of Bucky Balls were
14 sold between 2009 and 2011, and other companies have similar
15 high sales during that time period.

16 Critics of the Commission's proposed high powered
17 magnet safety standard have suggested that the Commission's
18 estimate of ingestion's of magnets from magnet sets is
19 overstated. We disagree.

1 In fact, it is highly possible that some number of
2 the estimated 16,380 magnet ingested related emergency
3 department visits not classified as high powered magnets
4 could be attributable to those high powered magnet sets,
5 however, it is just that many of the NEISS reports did not
6 include sufficient detail to place them in that category.

7 Therefore, our numbers most likely underestimate
8 the prevalence of these ingestion's.

9 On behalf of NASPGHAN, I urge the Commission to
10 finalize this year its proposed safety standard for high
11 powered magnet sets. The sales of these sets by multiple
12 manufacturers indicate there are billions of high powered
13 magnet balls now in our environment.

14 Consequently, the risk of ingestion of magnets by
15 children will remain high for a period of time, despite
16 efforts by NASPGHAN as well as the American Academy of
17 Pediatrics and other physician and consumer groups from whom
18 you have heard today to educate the public about these
19 dangers.

1 Thank you very much for your time.

2 CHAIRMAN TENENBAUM: Thank you. Dr. Leibowitz?

3 PRESENTATION OF DR. IAN LEIBOWITZ

4 DR. LEIBOWITZ: Chairman Tenenbaum, thank you for
5 inviting me to come and speak here today. My name is Dr. Ian
6 Leibowitz and I am Director of the Pediatric Digestive
7 Disease Center at Inova Fairfax Hospital for Children right
8 here in Fairfax, Virginia.

9 I have for 25 years been a practicing pediatric
10 gastroenterologist, a member of NASPGHAN, which I won't
11 repeat the entire name, and Chair of the Clinical Care and
12 Quality Committee for that same organization nationally.

13 The focus of my comments today is in the management
14 and interventions required for these types of high powered
15 magnet ingestion's, and I will make every effort not to
16 repeat things you have already heard.

17 In June of 2012, I and several of my pediatric
18 gastroenterology colleagues had the opportunity to meet with
19 the Commission staff to alert them to the growing incidence

1 of high powered magnet ingestion's, which I believe they were
2 already aware of.

3 I would like to start my presentation by thanking
4 the Commission for its swift and appropriate response to the
5 growing problem of magnet ingestion's. I strongly support
6 the Commission's proposed safety standard for high powered
7 magnet sets, and would encourage the Commission to finalize
8 its magnet safety standard as proposed.

9 One of my first encounters as a clinical
10 gastroenterologist with these magnet ingestion's was this x-
11 ray, called to me by the emergency room in our local
12 hospital, where a child had been actually transferred from a
13 smaller hospital where they don't have pediatric emergency
14 room physicians, and in response to some of the questions
15 asked before, I'd like to point out the difficulty in
16 alerting all physicians to this.

17 Many, many hospitals don't have pediatric
18 gastroenterologists, pediatric surgeons, and educating that
19 part of the population is critical, but probably will never

1 be complete and elimination of these risk products is
2 probably the only way we will get everyone protected.

3 This was a three year old child who had presented
4 with a string of magnets in her mid-abdomen on x-ray, which
5 she presented with relatively vague complaints of abdominal
6 pain. She was transferred to our hospital when this x-ray
7 was obtained and an endoscopic examination under anesthesia
8 was performed, but only one magnet remained in the stomach,
9 even though it looks like many of them were, and only one
10 magnet could be removed.

11 The next day again under anesthesia she was taken
12 by our surgeons to the operating room where initially a
13 laparotomy was obtained, which is simply to make an incision
14 and look inside.

15 What they found was multiple loops of bowel that
16 were adherent to each other and they had to open up both her
17 stomach, her small intestine and her large intestine,
18 including several areas of her small intestine, as these
19 magnets had attracted each other through the wall of the

1 bowel and created multiple fistulas.

2 She spent nine days in the hospital recovering from
3 her surgery and is still followed by us, and is at risk for
4 all kinds of complications.

5 All patients with foreign body ingestion's are
6 generally referred to emergency rooms for evaluation of the
7 type and location of the foreign body. As pointed out by
8 multiple people before me, most of these foreign bodies,
9 which are extremely frequent, pass by themselves, even ones
10 that would seem dangerous.

11 Unfortunately, with magnets, these ingestion's are
12 frequently not recognized immediately, and it may take time
13 for their symptoms as opposed to things like coins which
14 frequently if they are going to cause problems get lodged in
15 the esophagus and children are immediately gagging and
16 choking and sometimes even vomiting.

17 When they present with immediate symptoms, those
18 patients are almost always brought in for medical care, the
19 symptoms are relatively clear.

1 In this patient, they were witnessed actually by an
2 older brother who watched her swallow these magnets, didn't
3 tell his parents, approximately two to three weeks before she
4 was actually brought in with her abdominal pain.

5 The vast majority of these magnet ingestion's
6 require some type of medical intervention. In the 2012
7 survey that you have already heard about, 80 percent
8 underwent either endoscopy, surgery, or both, a dramatically
9 different number than we would find from patients with other
10 types of ingestion's.

11 Twenty-five percent of the patients required both
12 procedures with the concomitant risk of multiple
13 anesthesia's, and as few as two magnets, even though I showed
14 you multiple on this patient, create this entire risk. In
15 fact, if you looked at the data, most of the association did
16 not have to do with more magnet ingestion's, as many as two
17 cause problems.

18 Endoscopy is generally minor, although if they have
19 been in for several hours, ulceration and inflammation has

1 been noted in as many as a third of the cases. Those
2 patients that require surgery have a much greater risk of
3 morbidity, with almost half having perforations and fistulas
4 which are significant medical life time risks.

5 We have also documented cases that have led to
6 extensive loss of intestine and potential complications, as
7 you have heard.

8 All of these patients who have surgery are at risk
9 for strictures or narrowing of the intestines as well as
10 adhesions which are the most common cause of bowel
11 obstructions in patients.

12 These interventions are markedly different from the
13 management of most foreign body ingestion's in children. As
14 pointed out, the large number of ingestion's requires simply
15 checking and observation and frequently no other
16 intervention.

17 Coins are by far the most common object ingested
18 but it also includes things like nails, pins, safety pins,
19 even pencils. Despite this, only ten percent or so will

1 require endoscopic removal and less than one percent actually
2 require surgery.

3 Compare those rates to intervention for ingestion
4 of high powered magnets, where 80 percent need intervention
5 and 20 percent may need surgery.

6 Since our initial case at my institution, we have
7 had to develop a plan for management of magnets because we
8 have had several others, and this is one of the ways
9 institutions can handle it, so that the emergency room
10 physicians know as a referral center, if the child gets
11 magnets, they are not to be sent home until x-rays are
12 obtained and appropriate consultation is done.

13 As medical providers, we have had to single out
14 these products for special attention. Unfortunately, they
15 are attractive to little children and easy to ingest, which
16 increases the risk of complications as they can swallow more
17 than one.

18 New products seem to appear continuously using
19 different types of these high powered magnets, all of which

1 put our children at risk.

2 I in my career have taken out hundreds of different
3 foreign body objects but few seem to pose the morbidity risk
4 of these magnets.

5 I urge the Commission in summary to finalize its
6 proposed safety standards for high powered magnet sets, and
7 to ensure that the Amagnet set@ definition captures other
8 types of high powered magnets such as jewelry and some of the
9 other products you have been hearing about.

10 The risk to our children of these ingestion's is
11 significant, and more importantly, as a pediatrician, the
12 risks are entirely preventable. Designing these magnet sets
13 out of the product lines is probably the only effective way
14 to reach all of our children.

15 As a pediatrician, nothing is worse than a child
16 suffering a preventable injury. As long as these sets are
17 available, these injuries will inevitably occur.

18 Thank you for your time.

19 CHAIRMAN TENENBAUM: Thank you, Dr. Leibowitz. Dr.

1 Kay?

2 PRESENTATION OF DR. MARSHA KAY

3 DR. KAY: I'm Dr. Marsha Kay, Chair of the
4 Pediatric Gastroenterology and Nutrition and Director of
5 Pediatric Endoscopy at Cleveland Clinic Children's Hospital
6 in Cleveland, Ohio. I am also a member of NASPGHAN.

7 I would like to thank the Commissioners, Chairman
8 Tenenbaum, Commissioners Buerkle, Nord, Adler, and Robinson,
9 and the Consumer Product Safety Commission for holding
10 today's hearing and providing me the opportunity to talk
11 about the dangers that high powered or neodymium magnets pose
12 to children.

13 In the interest of time, I will focus my remarks on
14 the types and severity of injuries that result from ingestion
15 of high powered magnets and why there is a high likelihood of
16 injury upon ingestion.

17 As a physician who is an expert in the removal of
18 ingested foreign bodies, I want to emphasize that high
19 powered magnet ingestion is different than other ingested

1 foreign bodies.

2 Because of their small size and smooth surface,
3 ingestion of magnets may cause no immediate symptoms,
4 consequently, there can be a marked delay in diagnosis and
5 treatment.

6 Unless the ingestion is witnessed by an adult, as
7 you have heard, which is typically not the case, early
8 diagnosis is often complicated by the inability of a toddler,
9 a young child, or a child or adolescent with developmental
10 disabilities to verbalize that an ingestion has occurred.

11 Injury from magnet ingestion occurs almost
12 immediately but initial symptoms are not unique to magnet
13 ingestion, making diagnosis difficult.

14 First symptoms, such as abdominal pain from bowel
15 trapped between magnets, may take 8 to 24 hours or longer to
16 occur. Later symptoms, such as fever and vomiting, are non-
17 specific and resemble more common ailments such as an acute
18 infection, such as acute gastroenteritis.

19 Magnet ingestion's are serious and life

1 threatening. If more than two of these high powered magnets
2 are swallowed, their attractive force allows the magnets to
3 find each other in the body. This can occur between
4 different segments of the bowel. For example, connections
5 can occur between the stomach and the small intestine,
6 between the small intestine and the colon, or sometimes cross
7 loops of bowel, as shown in the Figure.

8 Although the tissue of the intestinal tract is
9 tough, it is no match for these magnets. Once magnetically
10 attached across the bowel, they do not break apart or
11 separate, which can cause severe injury.

12 Ulceration can occur within eight hours or less
13 following ingestion. If left untreated, this can lead to
14 bowel wall perforation, which represents a serious and
15 immediate risk to the patient. The leakage of intestinal
16 contents into the abdominal cavity rapidly results in
17 infection and peritonitis, which is inflammation of the
18 tissues that cover the intestines and internal organs.

19 To answer the question that was asked of the first

1 panel, this can be devastating and present with a child in a
2 serious condition.

3 Fistulization, which can be between the stomach and
4 the small intestine, between small intestinal loops or
5 between the stomach and the colon, are development of
6 connections between two bowel segments not normally connected
7 caused by high powered magnet ingestion has been reported
8 frequently. In rare cases, magnets may attract across
9 several loops of bowel, causing the bowel to twist, which is
10 also known as volvulized, the twisted loop of bowel obstructs
11 the blood flow of intestinal contents, and the blood flow
12 leading to a lack of oxygen to the bowel wall and results in
13 ischemia or bowel wall death. This is a surgical emergency
14 requiring immediate operation.

15 Delay in treatment can lead to the need for
16 resecting necrotic or dead bowel. If too much bowel is
17 removed, a condition known as short bowel syndrome may be the
18 result, requiring life long intravenous nutrition, also known
19 as total parenteral nutrition or TPN, and potentially even a

1 small bowel transplant, with both its morbidity and
2 associated costs.

3 In my institution, due to delay between time of
4 ingestion and the family recognizing the need to seek medical
5 attention, most patients who have suffered a magnet ingestion
6 have required surgery as a result of subsequent
7 complications, including bowel obstruction and fistulization
8 between loops of bowel.

9 There is a spectrum of diagnostic issues, symptoms,
10 treatment requirements and injuries following ingestion. If
11 ingestion is recognized, it may be acted upon in a timely
12 way, including through endoscopic removal, which I and my
13 colleagues do, and/or surgical intervention.

14 However, even with a known ingestion, there may be
15 delay in recognition of the seriousness of the ingestion by
16 either the family or the health care provider, which you have
17 heard testimony about today.

18 Other cases may be unrecognized until significant
19 consequences occur, and in the best case, this may yield a

1 stable patient for whom surgery is required which may include
2 bowel resection, and in the worse case, this may include an
3 unstable patient secondary to intestinal perforation who may
4 be septic, require admission or transfer to a pediatric
5 intensive care unit, and one or more bowel resections.

6 If the patient survives the episode, significant
7 consequences are possible, including the need for additional
8 surgery. If the bowel is necrotic and needs to be removed,
9 the patient may develop short gut syndrome.

10 Over the long term, the patient may require
11 multiple hospitalizations due to complications, and in
12 addition, following peritonitis, there may be long term
13 fertility issues, especially in females analogous to what
14 happens following perforated appendicitis.

15 These magnet issues, ingestion issues,
16 unfortunately continue to occur, and patients that are cared
17 for at our hospital and medical institutions throughout the
18 country, despite educational efforts by both NASPGHAN, the
19 American Academy of Pediatrics, patient and consumer

1 organizations, and the media, there remains a lack of
2 awareness by the lay public, primary care providers, and
3 emergency room personnel as to the potential consequences of
4 these types of ingestion's and the correct management
5 algorithms to be followed for management of magnet
6 ingestion's.

7 Additionally, because patients may be initially
8 asymptomatic, the need for urgent evaluation as well as
9 urgent therapy may not be appreciated, resulting in
10 potentially devastating consequences for the patient as
11 outlined above.

12 For these reasons, I strongly support and ask the
13 Commission to finalize its proposed magnet safety standards.

14 Thank you.

15 CHAIRMAN TENENBAUM: Thank you, Dr. Kay. Thank all
16 of you for the excellent presentations and for the amount of
17 effort that you put into your presentations to let us know
18 how serious you think this issue is.

19 Dr. Kay, I was thinking about this as you were

1 speaking because the cases I have read demonstrate that there
2 is a lack of knowledge about diagnosing this early. I have
3 read cases where the parents either brought the child to the
4 hospital, demonstrating flu like symptoms.

5 You said it correctly, despite the educational
6 efforts of both NASPGHAN, the American Academy of Pediatrics,
7 patient and consumer organizations and the media, there
8 remains a lack of awareness by the lay public, primary care
9 providers and emergency personnel about these hazards.

10 I am from a state, South Carolina, that has many
11 rural areas. You will go into the emergency room and you
12 will see a family practitioner.

13 I think it is beyond what we are able to do in
14 terms of educating all the physicians in America and
15 emergency personnel, but how could such an effort be
16 designed? We could work with FDA, HHS and other agencies,
17 but that is a very large problem, to link the time children
18 go misdiagnosed.

19 If you will elaborate on that, how can we get the

1 word out to just family practitioners in all the states?

2 DR. KAY: I think a two part effort is required.

3 The first part, which you can be tremendously impactful on,
4 is in terms of preventing these ingestion's by reducing the
5 availability of these products, and that is a huge impact on
6 it.

7 We as physician organizations and consumer
8 organizations and the Consumer Product Safety Commission
9 really do have a role in public service announcements.

10 It is interesting, I was at a family dinner on
11 Sunday and I was speaking with my family members about it.
12 My mom said is this like the mattresses. When we walked in
13 and I saw on the screen information that the Consumer Product
14 Safety Commission has done in terms of mattress safety, this
15 is the same thing.

16 This is an important area that we need to act
17 legislatively on in terms of preventing these ingestion's,
18 and then we as physician organizations and consumer
19 organizations need to get the word out to both patients, ER

1 physicians, family physicians, about really the risk of these
2 objects that are perceived to be innocuous and harmless, and
3 how serious these ingestion's are.

4 CHAIRMAN TENENBAUM: Every state had a Medical
5 Board of Examiners that licenses physicians. They would have
6 the address of every physician, and also there is a Board of
7 Nursing Examiners. When we think about how we could best get
8 the word out, it is very difficult when no matter how many
9 PSAs you do -- we have done over 20 campaigns here at the
10 Commission -- it is very hard to saturate it in such a way as
11 to inform everyone.

12 DR. KAY: I think the one thing that is interesting
13 about these magnet ingestion's is if you get a plain x-ray,
14 you can see how obvious these are. What we need is that
15 physicians in an emergency room think about getting an
16 abdominal x-ray in cases where this is a possibility.

17 More than 90 percent of foreign bodies that are
18 ingested by children are radiopaque, which means they are
19 readily seen on x-ray.

1 As pediatric gastroenterologists, we take care of a
2 tremendous number of foreign body ingestion's and we are
3 asked to remove those. Sometimes even for other reasons,
4 coins or things like that, the child may present with
5 respiratory symptoms. There is no history they have
6 swallowed something.

7 Even getting the message out if there is a concern,
8 if a patient is presenting with unknown abdominal pain, these
9 products in the house, just get a plain x-ray. Those are
10 very obvious immediately, and then the right algorithms for
11 management can occur.

12 CHAIRMAN TENENBAUM: Thank you. Dr. Rudolph, you
13 called these magnet injuries Aa national epidemic.@ The
14 panel know how the injury rate and severities compare with
15 other similar childhood injuries? Is there any kind of
16 comparative study?

17 DR. RUDOLPH: Not to my knowledge. I don't think
18 this has been compared at least directly to other such
19 ingestion's, unless anyone else on the panel can correct me

1 on that.

2 DR. OLIVA-HEMKER: We actually do not have that
3 information although there have been a lot of studies in
4 ingestion's of batteries and other foreign objects. Based on
5 our experience being physicians that deal with foreign
6 bodies, the fact that we are seeing 20 percent of these
7 children are actually needing to go to surgery is a
8 significantly high increase compared to the one percent or
9 less that typically are associated with other foreign body
10 ingestion's.

11 Although we do not have head to head comparisons or
12 studies to be able to apply certain numbers, based on the
13 data that we have, I think we would all agree these again are
14 different types of foreign bodies than what we have become
15 used to.

16 CHAIRMAN TENENBAUM: Dr. Leibowitz, do you want to
17 add anything?

18 DR. LEIBOWITZ: I would just make a couple of
19 comments. Mr. Adler asked earlier today about the

1 underestimation. I think we are all vulnerable to not
2 knowing the accurate details.

3 Being a veteran of many NASPGHAN surveys in the
4 past, I can speak to the fact that most NASPGHAN surveys way
5 underestimate all of the issues that we do because
6 unfortunately, like many physicians, we are busy. We don't
7 get the kind of responses that we would like. Even looking
8 at the data, we probably got responses from about somewhere
9 between a third and a quarter of our membership, which either
10 suggests the others haven't dealt with this, which I think is
11 unlikely considering the frequency we have all dealt with it,
12 or they simply didn't take the time to respond.

13 The frequency has clearly gone up. I don't think
14 any of us would debate that. I think there is an uncertainty
15 to these kinds of numbers.

16 What has impressed the NASPGHAN membership is
17 obviously the severity of the types of injury that occur with
18 these, more than the numbers themselves.

19 CHAIRMAN TENENBAUM: Certainly severe outcomes for

1 swallowing these magnets. That is all I have. I know
2 Commissioner Nord has questions.

3 COMMISSIONER NORD: Thank you so much, Madam
4 Chairman. Thank you to the panel. I think you have
5 certainly made the point that the medical community is very,
6 very concerned about the hazards this product presents.

7 I guess I would just request that regardless of
8 what this body decides to do with respect to the rulemaking,
9 I would hope all my colleagues would agree that we need to
10 come together with the medical community to educate both
11 practitioners and patients about the potential hazard here.

12 I just have one small question for you, Dr. Oliva-
13 Hemker. You said in your testimony that kids older than five
14 years are more likely to ingest multiple magnets. I am
15 wondering if you can tell us why. That seems very
16 counterintuitive. I was just surprised to hear you say that.

17 DR. OLIVA-HEMKER: As I said, about five, and the
18 teenage years. It is surprising as well. What we are
19 assuming is what we are seeing is these children are using

1 the magnets as jewelry and piercings. This has already been
2 said.

3 Within that age range, it just so happens when you
4 swallow multiple magnets, they are in your mouth or you are
5 playing with them, these are the children that seem to be
6 swallowing them all at once at greater numbers.

7 COMMISSIONER NORD: At what age is a child able to
8 understand danger and hazard? I'm a mom. I've raised
9 children. I know there are lots of things they wanted to get
10 into but when told no or explained about the danger, they
11 were able to process that and understand it.

12 At what age does that happen?

13 DR. OLIVA-HEMKER: Some might say there is no age
14 limit to that. There are very interesting studies coming up
15 actually in young adults showing that the mind is still not
16 fully formed to the point of identifying danger.

17 Here is the real issue. If a child touches a hot
18 stove or something that is sharp and cuts themselves, they
19 have an immediate reaction and response, realizing that is

1 danger.

2 What we are dealing with here is these are objects
3 that are smooth, shiny and round, and nothing about them says
4 danger, whether you are two, three, or four, or 14, 15, 16.
5 It is a bit complex to think about the process that happens
6 and what the danger is that happens in your GI tract.

7 What I would say is the issue here is you have a
8 product where the danger is not attached to the visual or
9 anything about the product. Irregardless of when children
10 understand true danger, like fire or not crossing the street,
11 not putting their hands on the stove, that wouldn't
12 necessarily hold with a product like this.

13 COMMISSIONER NORD: I guess we see trends where
14 kids do things they think are pretty cool but are really
15 quite dangerous. We have this state of injuries with aerosol
16 cans a while back. When I was a kid, it was glue sniffing.

17 That fits into the same category that you just
18 described. Again, regardless of what this agency decides to
19 do with this particular rulemaking, it seems to me we ought

1 to be thinking a lot more aggressively and creatively about
2 how we can address this issue.

3 I hope we can count on the medical community to
4 help us do that.

5 DR. OLIVA-HEMKER: Thank you, Commissioner Nord.
6 Your point is very well taken. There is another group that
7 we haven't mentioned here in aggregate, and that is the
8 school system, and all our educators. In the last three
9 months, it was a sixth grade girl who ingested a whole series
10 of magnets. She was playing with them at school and she
11 swallowed them, and she didn't want to tell anybody, but one
12 of her classmates realized it and said well, I think there is
13 something about this that's not right, and then went to the
14 teacher.

15 The teacher was unsure but she had enough sense to
16 actually call the parent, call the nurse, and say the child
17 has to be taken to our emergency department, where we handled
18 things appropriately and we actually were able to remove the
19 magnets.

1 These are now in our school systems, as stated
2 before, and that is an entire other group of individuals, our
3 teachers, our educators, that also need to be given this
4 information.

5 DR. LEIBOWITZ: If I might add one thing, there is
6 in medicine a well known time frame of diffusion of
7 information, and it is way longer than any of us would like
8 to admit. I think we all recognize that.

9 Diffusion of information here from
10 gastroenterologists to emergency room, pediatric emergency
11 room doctors to adult emergency room doctors at hospitals, in
12 South Carolina, it will inevitably be a process that will
13 take more time than any of us would want to admit.

14 I just think we all need to take that into
15 consideration as we talk about what we are going to do.

16 CHAIRMAN TENENBAUM: Commissioner Adler?

17 COMMISSIONER ADLER: Thank you very much, Madam
18 Chairman. I just wanted to pose a question to the panel at
19 large, but I'm going to start with Dr. Rudolph.

1 I have over the last year or so received probably
2 on the order of 3,000 very, very angry e-mails from folks who
3 oppose any regulatory action with respect to magnets by
4 making the argument that most of these incidents would not
5 occur if parents were more conscientious, in other words, bad
6 parents.

7 I was struck, Dr. Rudolph, by your comment and the
8 specific example of the case that seemed so dramatic was
9 someone you characterized as a good parent, and you said this
10 is not just an issue of poor parenting.

11 I am just curious, how many of you have had much
12 experience in meeting the parents of kids who have had these
13 problems, and have you drawn any conclusions one way or the
14 other about the degree of care or carelessness of the parents
15 involved in these incidents?

16 DR. RUDOLPH: I think the panel has much more
17 experience than me and they have seen a lot of patients that
18 have had foreign body ingestion's. I think one thing that is
19 not going to change is kids are going to swallow things. I'm

1 sure you have dealt with this repeatedly and we deal with it
2 on a day by day basis as well.

3 This really can happen pretty much in any family.
4 These are accidents, they happen. I've met one or two
5 families. Again, as I said in my testimony, by all intents
6 and purposes, they have been great parents, very concerned.
7 This particular mother didn't leave the bedside the entire
8 time, was hysterical and in tears. I really felt for her.

9 This is something that I think truly can happen.
10 These products are there, it is going to happen. They are
11 unsafe.

12 COMMISSIONER ADLER: Thank you. I'd be curious to
13 hear if any of the other panelists have drawn any conclusions
14 or made any observations.

15 DR. OLIVA-HEMKER: What I would just say is this is
16 not an issue of bad parenting. This is an issue of
17 availability of devices that unfortunately cause way more
18 harm than initially thought. They thought they were
19 innocuous. Many of these children are having access to these

1 magnets outside of the home, in the school system, in a
2 friend's house, in other places, where the parent is not even
3 around.

4 I think we would be pointing in the wrong direction
5 to say this is something that would be fixed by a good
6 parent. These are all very caring and good parents. I think
7 that line of argument is incorrect. I would think my other
8 colleagues probably feel the same way.

9 DR. LEIBOWITZ: Far and away the most common
10 foreign body swallowed is coins. I've taken coins out of
11 famous people's children and important people's children and
12 physician colleagues' children, and physician colleagues'
13 children who are embarrassed to admit it in medical staff
14 meetings. I can't speak to what they do at home, but they
15 all seem to be extraordinarily responsible people who care
16 intensely about their children to the point of being
17 helicopter type of parents, and that doesn't seem to prevent
18 it.

19 I think magnets are no different. In fact, they

1 cause no discomfort going down, so they may be more
2 attractive in some ways to doing multiple ingestion's rather
3 than coins which are uncomfortable to go down.

4 Like the others, I would say the issue of parenting
5 is probably not the core issue here.

6 DR. KAY: I would concur with the previous
7 comments. This really isn't a parenting issue. It is an
8 object issue and a risk issue. In kids, sometimes the
9 ingestion occurs because one sibling feeds the object to
10 another sibling. There are a variety of reasons for it.

11 Parenting is not the cause of this, and better
12 parenting would not prevent this in any way.

13 COMMISSIONER ADLER: Dr. Kay, you commented about
14 the importance of education, as did all of you, but you also
15 seemed to feel that education by itself would not solve the
16 problem. I'm curious, if I've stated your position
17 correctly, and if any of you have additional thoughts about
18 that?

19 DR. KAY: As Mark alluded to in the earlier

1 testimony, this is a product that had unanticipated
2 consequences, it was thought to be an innocuous product.
3 Some of the prior magnet sets were actually used for kids
4 with developmental disabilities because they were smooth,
5 they were thought not to be sharp.

6 We can educate but we are behind the game when we
7 are educating on this. Although that is a component of it,
8 we really need to try to prevent these ingestion's, and that
9 is why we are seeking your assistance in that, to try to
10 offer appropriate regulations to prevent the vast majority of
11 these ingestion's.

12 COMMISSIONER ADLER: Dr. Leibowitz, anything to
13 add?

14 DR. LEIBOWITZ: No.

15 COMMISSIONER ADLER: Okay. Thank you all very
16 much.

17 CHAIRMAN TENENBAUM: Commissioner Robinson?

18 COMMISSIONER ROBINSON: Thank you, Madam Chair. I
19 would like to preliminarily say that CPSC has the task of

1 identifying and addressing emerging hazards, but I really
2 view doctors, hospitals, and medical organizations as being
3 critical partners of ours in helping us do our jobs.

4 I would first of all like to thank all of you for
5 coming here and taking the time to answer our questions today
6 and to testify, but I would also very much like to applaud
7 NASPGHAN and Dr. Abass for the effort that went into getting
8 us good information that we could not have otherwise
9 obtained, and acting so promptly and proactively.

10 In another venue, I am just reminded of this, 30
11 years ago, anesthesiologists took it upon themselves as a
12 group to figure out why the morbidities and mortalities under
13 general anesthesia were so high, and found wonderful ways of
14 addressing that.

15 I know it is different, but the proactivity is
16 there, and I just want to thank you and your organization
17 very much for that, in helping us do our jobs better.

18 When I asked Dr. Gilger in panel one about the
19 numbers, and I know, Dr. Oliva-Hemker and Dr. Leibowitz, you

1 have talked about the tip of the iceberg, as Dr. Gilger said,
2 but I noticed, Dr. Rudolph, for example, you were shaking
3 your head pretty hard when I asked the question.

4 If you or Dr. Kay would like to comment on that, I
5 would very much like to hear your thoughts.

6 DR. RUDOLPH: Sure. I think if you look at just
7 the case series, and I mentioned several in my testimony,
8 there were six others from across the country, there is one
9 in Boston that had 112 kids, I think. Another center listed
10 two, another listed one, one had listed eight. There is a
11 wide range.

12 Many of them were not from pediatric
13 gastroenterologists. A lot of them were from surgeons. A
14 lot of them were ingestion's elsewhere, outside the GI tract.

15 The data we have I don't think really does justice
16 to the magnitude of this issue.

17 DR. KAY: I'll just give you an anecdotal story.
18 Ten days ago we had our national meeting. At our meeting, I
19 was one of the faculty in an endoscopy course. I met a young

1 Fellow who was training in New York, a young lady who was 14
2 months into her fellowship. She had already encountered
3 these neodymium magnets five times in those 14 months, and
4 she's not on call every day.

5 The incidence of this is escalating, it is despite
6 actions to withdraw some of these products from the market.
7 We really don't know the total numbers. What happens with
8 case reports is as something that has been published a number
9 of times, as editors of journals, we say it is already
10 published, it is already known, we are not going to
11 necessarily accept that.

12 The case reports don't keep up with really the true
13 frequency of these ingestion's but they are happening
14 throughout the country. I'm sure they are happening
15 throughout the world. Like I said, this really just
16 represents the tip of the iceberg of what's going on.

17 COMMISSIONER ROBINSON: All of you today at some
18 level have addressed the fact that these kinds of injuries
19 that occur with the magnets require long term care. I

1 wondered and I know all of you are qualified to answer this
2 question, so I don't really care who decides to respond, but
3 I would very much like a little bit of amplification -- I
4 understand the long term care, for example, of fistulas would
5 be very different than a bowel resection.

6 I just wondered if one of you could just address
7 what we are talking about, if a young child, for example, has
8 a bowel resection, in terms of long term care.

9 DR. KAY: If a child loses a substantial part of
10 their bowel, and we will say 50 percent of their small
11 intestine, as was alluded to, they typically require
12 placement of a catheter, for which the family will need to
13 administer nutrition every single day and night, because they
14 can't absorb nutrients adequately through the GI tract.

15 Those catheters are associated with a high risk of
16 infection, even in the best parenting situations. The child
17 may be admitted repetitively to the hospital for septic
18 episodes associated with that catheter. Typically, the
19 catheters need to be replaced, so they need to undergo

1 repetitive surgical procedures.

2 Despite advances in nutrition, a lot of times long
3 term intravenous nutrition, and we know this from babies who
4 have a condition of colitis, who ultimately develop liver
5 disease as a consequence and stage liver disease, so patients
6 may need a liver transplant, they may need a small bowel
7 transplant. Those procedures cost hundreds of thousands of
8 dollars on an individual basis, up to \$1 million, and are not
9 always successful. Even if you get a liver transplant or a
10 small bowel transplant, you may not survive that for more
11 than five years.

12 The cost to an individual patient or the health
13 care system may be \$1 million or more for a child who suffers
14 and needs a bowel resection from one of these ingestion's.

15 Just from a financial aspect, these are really
16 devastating to the family in terms of the child's life
17 expectancy, the quality of life, and finances for the family
18 and the health care system.

19 COMMISSIONER ROBINSON: Thank you. I would also

1 like to know if any of you have any thoughts with respect to
2 this definition of Amagnet sets,@ given what you are
3 encountering, and whether you think it is broad enough.

4 DR. LEIBOWITZ: I think we would all agree that
5 this is the beginning of a process and we would be obviously
6 in favor of moving forward with as far as we have gone.

7 It is always difficult to predict the future, but
8 having seen the evolution of the use of these kinds of
9 magnets over the last couple of years, in a million different
10 ways, I think we all expect them to continue to expand and
11 continue to be new ways found.

12 How many of them will be something we can address
13 or that require addressing, I think is uncertain, but I think
14 we are all very, very concerned that even with the absence of
15 these, that you all will be dealing with this issue again in
16 the future unless the rules are significant enough to predict
17 for the future, which I think is very hard.

18 COMMISSIONER ROBINSON: Thank you all very much. I
19 would only like to say in concluding that if you think of any

1 ways in which your organizations can give us information, we
2 are a data drive organization, and we are looking for the
3 best information we can find, and we really appreciate this
4 very much. Thank you.

5 CHAIRMAN TENENBAUM: Commissioner Buerkle?

6 COMMISSIONER BUERKLE: Thank you, Madam Chair. I
7 want to concur with my colleagues, thank you all very much
8 for being here, for being on the front lines, for bringing
9 this critical information to us.

10 You all present, as I mentioned to the first panel,
11 very compelling information to us.

12 I just want to continue on with this education
13 suggestion because as you were talking, you mentioned it and
14 preempted my question, what about schools? We have anti-
15 bullying campaigns. We have massive educational efforts to
16 educate our kids about dangers.

17 Is there anything that is being done right now?
18 Certainly, that would address the problem of rural areas or
19 at least help to, and should be considered a component of

1 this collaboration of education efforts?

2 DR. OLIVA-HEMKER: You are certainly right. We as
3 physicians, while we have started the processes of
4 collaborating with other multiple physician groups, as you
5 have heard, as well as on our own and with other groups
6 trying to educate the public directly, and school teachers
7 are part of the public, but certainly additional campaigns
8 are going to be required to that effect.

9 Again, I guess I would stress that clearly we need
10 education because as I mentioned, even if these magnets
11 stopped existing now, there are so many in the environment,
12 billions in the environment, that still education is going to
13 be needed, but we stress the fact that ultimately education
14 is not going to solve the problem, that more likely removal
15 of these products in some shape or form is getting to the
16 root cause of the problem and will be more beneficial to the
17 children in the long run.

18 COMMISSIONER BUERKLE: Thank you. I should have
19 said this first time around but I want to thank the Chair for

1 extending the comment period for a week. I think that has
2 given the confusion about this morning's hearing. I think
3 that is the appropriate thing to do. I want to thank you for
4 doing that.

5 Again, thank you to all our experts here this
6 morning and the testimony you have given. It is all very
7 compelling and I thank you for being here.

8 CHAIRMAN TENENBAUM: Thank you all very much again.

9 We look forward to being partners with you. Perhaps we can
10 design and work together on education campaigns. We
11 appreciate you spending the time you have with us this
12 morning. Thank you.

13 (Whereupon, at 12:15 p.m., the hearing was
14 concluded.)

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