

November 12, 2013

**VIA E-MAIL**

Office of the Secretary  
U.S. Consumer Product Safety Commission  
Washington, D.C. 20207  
Attn: Information Quality Guidelines

**Re: Petition for Disclosure and Correction**

Dear Sir/Madam:

This is a Petition for Disclosure and Correction in accordance with the Information Quality Act (IQA);<sup>1</sup> the information quality guidelines issued by the Office of Management and Budget, (the “OMB Guidelines”);<sup>2</sup> and, IQA Guidelines issued by the U.S. Consumer Product Safety Commission (CPSC or the “Commission”).<sup>3</sup> This Petition seeks: (a) disclosure of the data and methods needed to determine whether influential information disseminated by the CPSC regarding (1) magnets sold under the trade names Buckyballs® and Buckycubes® and (2) a defunct company called Maxfield and Oberton Holdings, LLC (“M&O”) meet IQA requirements, and (b) correction of disseminated influential information that does not appear to meet statutory and OMB information quality requirements.

**I. REQUESTOR’S IDENTITY**

The requestor is Craig Zucker, through his counsel, Cause of Action, Inc., a 501(c)(3) government accountability organization.

The CPSC has illegally named Mr. Zucker, M&O’s former CEO, as an individual respondent in the matter titled: *In the matter of MAXFIELD AND OBERTON HOLDINGS LLC, et*

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<sup>1</sup> Pub. L. No. 106-554, § 515, 114 Stat. 2763A-154 (App. C), 44 U.S.C. § 3516 Note.

<sup>2</sup> 67 Fed. Reg. 8452-60 (Feb. 22, 2002).

<sup>3</sup> *Information Quality Guidelines*, U.S. CONSUMER PROD. SAFETY COMM’N, <http://www.cpsc.gov/Research--Statistics/Information-Quality-Guidelines/> (last visited Nov. 6, 2013) [hereinafter IQA Guidelines]. OMB Guidelines set the minimum information quality standards that CPSC must meet in this case. Pursuant to 44 U.S.C. § 3516 Note, Congress allowed agencies to create administrative review and correction mechanisms with OMB approval, but mandated agency compliance with quality standards contained in the OMB Guidelines). To the extent that CPSC’s own guidelines are less stringent, they do not apply.

*al.*<sup>4</sup> Mr. Zucker has suffered significant economic and reputational injury due to CPSC's violation of the IQA, the OMB Guidelines, and its own IQA guidelines, and as a consequence of CPSC's wrongful dissemination of the information that is the subject of this Petition. CPSC's information quality violations and wrongful dissemination drove M&O, Mr. Zucker's former employer, out of business. Therefore, Mr. Zucker is an "affected person" entitled to seek and obtain IQA correction.

## II. SPECIFIC DESCRIPTION OF THE INFORMATION THAT IS THE SUBJECT OF THIS PETITION.

A. The influential information that is the subject of this Petition includes the following statements disseminated in an April 12, 2013 recall announcement:

1. These products contain defects in the design, warnings and instructions, which pose a substantial risk of injury and death to children and teenagers.
2. These retailers have agreed to participate because Maxfield & Oberton has refused to participate in the recall of all Buckyballs® and Buckycubes®.
3. In July 2012, CPSC staff filed an administrative complaint against Maxfield & Oberton Holdings LLC, of New York, N.Y., after discussions with the company and its representatives failed to result in a voluntary recall plan that CPSC staff considered to be adequate to address the very serious hazard posed by these products.
4. CPSC has received 54 reports of children and teens ingesting this product, with 53 of these requiring medical interventions.<sup>5</sup>

B. The influential disseminated information that is the subject of this Petition also includes the following statement contained in a CPSC news release: "CPSC Sues Maxfield & Oberton Over Hazardous Buckyballs® and Buckycube™ Desk Toys Action prompted by ongoing harm to children from ingested magnets."<sup>6</sup>

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<sup>4</sup> U.S. Consumer Prod. Safety Comm'n Docket 12-1 (consolidated).

<sup>5</sup> Recall Announcement, U.S. Consumer Prod. Safety Comm'n, Six Retailers Announce Recall of Buckyballs and Buckycubes High-Powered Magnet Sets Due to Ingestion Hazard (Apr. 12, 2013) [hereinafter Recall Announcement], *available at* <http://www.cpsc.gov/en/Recalls/2013/Six-Retailers-Announce-Recall-of-Buckyballs-and-Buckycubes-High-Powered-Magnet-Sets/>.

<sup>6</sup> News Release, U.S. Consumer Prod. Safety Comm'n, CPSC Sues Maxfield & Oberton Over Hazardous Buckyballs® and Buckycube™ Desk Toys Action prompted by ongoing harm to children from ingested magnets (July 25, 2012) [hereinafter News Release], *available at* <http://www.cpsc.gov/en/Newsroom/News-Releases/2012/CPSC-Sues-Maxfield--Oberton-Over-Hazardous-Buckyballs-and-Buckycube-Desk-Toys-Action-prompted-by-ongoing-harm-to-children-from-ingested-magnets-/>.

### III. GROUNDS FOR DISCLOSURE AND CORRECTION.

#### Background

The IQA provides, in relevant part, that OMB “shall . . . provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies,” and that agencies must “establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply.”<sup>7</sup>

The law requires that CPSC disseminate only accurate and objective information that is supported by scientifically-sound data. It also requires the Commission to ensure that Mr. Zucker and others have meaningful access to the data and methodological information needed to test and reproduce CPSC’s claims and assertions.<sup>8</sup>

Information quality is a direct function of objectivity and reproducibility.<sup>9</sup> As the OMB Guidelines make clear, the public’s capacity to test objectivity and reproducibility depends entirely upon the full and accurate disclosure of data and research methods.<sup>10</sup> According to CPSC:

Under the OMB information guidelines three aspects of quality must be considered: utility, objectivity, and integrity. In addition, for influential data, higher standards of transparency and reproducibility must be met. CPSC’s guidelines use the definitions of the key statutory terms such as ‘information,’ ‘disseminate,’ ‘utility,’ ‘objectivity,’ ‘integrity,’ ‘influential,’ ‘transparency,’ and ‘reproducibility’ as defined in the OMB guidelines.<sup>11</sup>

The IQA bars CPSC and other federal agencies from disseminating inaccurate, imprecise, unsupported, or misleading information, as it has done here. Correction is the congressionally-mandated remedy. For the reasons set forth below, Mr. Zucker is entitled to such relief.

#### The Disseminated Influential Information of Concern

##### A. Influential information disseminated in the April 12, 2013 recall announcement:<sup>12</sup>

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<sup>7</sup> 44 U.S.C. § 3516 Note.

<sup>8</sup> OMB Guidelines §§ III(2), (3), V(3), 67 Fed. Reg. 8459-60.

<sup>9</sup> *Id.* at § V(3), 67 Fed. Reg. 8459-60.

<sup>10</sup> *Id.* at § V(3)(a), 67 Fed. Reg. at 8455-58 (agency must identify sources of disseminated information so public can assess for itself the objectivity of that information and have access to full, accurate, transparent documentation and error sources affecting data quality).

<sup>11</sup> IQA Guidelines, *supra* note 3.

<sup>12</sup> *See generally* Recall Announcement, *supra* note 5.

1. *“These products contain defects in the design, warnings and instructions, which pose a substantial risk of injury and death to children and teenagers.”*

Grounds for Disclosure/Correction: The claim that “defects in the design, warnings and instructions . . . pose a substantial risk of injury and death” in the recall announcement, and on the CPSC website, is the “dissemination” of “influential” scientific or statistical information because it (a) concerns health and safety risks and (b) was designed to influence important private sector decisions regarding the purchase and/or use of the subject products.<sup>13</sup>

CPSC has wrongfully failed to define precisely the alleged “defects,” or to disclose the performance standards needed for the design, warnings, and instructions to avoid being termed such. Indeed, CPSC has an on-going administrative proceeding in which the very question of whether these products contains a “product defect” is being adjudicated.<sup>14</sup> Until that adjudication is complete, the question of whether these products contain any kind of “defect” has not been decided, and the unqualified statement to the contrary in CPSC’s recall announcement is inaccurate. Therefore, the “defect” claim fails the IQA’s utility test because, without objective performance metrics against which the relevant design, warnings, and instructions may be tested, it is impossible for the public to evaluate whether this information is useful or not.<sup>15</sup>

Furthermore, the absence of such metrics means that CPSC fails the IQA’s presentation objectivity test because it is impossible to determine whether its statement is accurate, clear, complete, and unbiased, as the law commands.<sup>16</sup>

CPSC’s “substantial risk” claim is also a particularly egregious IQA “substance” objectivity violation. The OMB Guidelines state:

‘Objectivity’ includes whether disseminated information is being presented in an accurate, clear, complete, and unbiased manner. This involves whether the information is presented within a proper context. Sometimes...other information must also be disseminated in order to ensure an accurate, clear, complete, and unbiased presentation. Also, the agency needs to identify the sources of the disseminated information...and, in a scientific, financial, or statistical context, the supporting data and models, so that the public can assess for itself whether there may be some reason to question the objectivity of the sources. Where appropriate, data should have full, accurate, transparent documentation, and error sources affecting data quality should be identified and disclosed to users.<sup>17</sup>

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<sup>13</sup> OMB Guidelines § V(8),(9), 67 Fed. Reg. 8460.

<sup>14</sup> See *In the Matter of Maxfield and Oberton Holdings, LLC*, U.S. Consumer Prod. Safety Comm’n Docket No. 12-1 (consolidated case).

<sup>15</sup> *Id.* § V(2), 67 Fed. Reg. 8459.

<sup>16</sup> *Id.* at § V(3)(a), 67 Fed. Reg. 8459.

<sup>17</sup> *Id.*

CPSC had a duty to provide “a high degree of transparency” about the data and methods that it used to determine substantiality.<sup>18</sup> Yet, without some context, such as relative risk ratios, and disclosure of its supporting data and models, CPSC’s substantial risk claim cannot be evaluated for accuracy or bias. Based on CPSC’s own statistics, nursery equipment, toys, household cleaning chemicals, single-load laundry packets, and trampolines are statistically far more dangerous to children than Buckyballs® and Buckycubes®.<sup>19</sup> Even blankets cause a higher rate of hospitalization and death.<sup>20</sup>

Because CPSC fails to put the alleged risk posed by Buckyballs® and Buckycubes® in context, and offers no metrics for measuring substantiality, it wrongfully denies Zucker and other members of the public their right to test and reproduce the CPSC’s findings and violates the IQA’s utility and objectivity tests.<sup>21</sup>

Furthermore, because CPSC claimed the products in question posed “a substantial risk of injury or death,” it was required to apply the test contained in the Safe Drinking Water Act Amendments.<sup>22</sup> This required CPSC to specify (a) each population addressed by any estimate of risk; (b) the central estimate of risk for the specific populations affected; (c) each appropriate upper-bound or lower-bound estimate of risk; (d) each significant uncertainty identified in the process of risk assessment effects and the studies that would assist in resolving the uncertainty; and (e) peer-reviewed studies known that support, are directly relevant to, or fail to support any estimate of risk

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<sup>18</sup> *Id.* at § V(3)(b)(ii), 67 Fed. Reg. 8460.

<sup>19</sup> *See, e.g., infra* note 20.

<sup>20</sup> According to CPSC, “nursery equipment” causes injuries requiring emergency room treatment at the rate of 31.0 per 100,000 individuals in the population, and hospitalization or death at the rate of 1.7 per 100,000. U.S. CONSUMER PROD. SAFETY COMM’N, NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS) DATA HIGHLIGHTS - 2012 at 1, *available at* [http://www.cpsc.gov/Global/Neiss\\_prod/2012NeissDataHighlights.pdf](http://www.cpsc.gov/Global/Neiss_prod/2012NeissDataHighlights.pdf) (last visited Nov. 10, 2013) (the “NEISS Data Highlights”). “Toys” cause 78.5 injuries requiring emergency room visits per 100,000, and hospitalization or death at the rate of 2.2 per population of 100,000. *Id.* CPSC has never claimed that the injury rate for Buckyballs® and Buckycubes® even begins to approximate these numbers, much less the numbers for “Sound recording equipment” (emergency room treatment at the rate of 12.4 per 100,000 population, and hospitalization or death at the rate of 1.1 per 100,000 population), “blankets” (emergency room treatment at the rate of 4.4 children per 100,000 population, and hospitalization and/or death at a rate of 0.4 children per 100,000 population), or “Glass bottles and jars” (emergency room treatment at the rate of 12.4 children per 100,000 population, and hospitalization and/or death at a rate of 0.3 children per 100,000 population). *Id.* at 2-4.

<sup>21</sup> OMB Guidelines §§ V(2),(3), 67 Fed. Reg. 8459.

<sup>22</sup> 42 U.S.C. § 300g-1(b)(3)(A)-(B); OMB Guidelines § V(3)(b)(ii)(C), 67 Fed. Reg. 8460.

and the methodology used to reconcile inconsistencies in the scientific data.<sup>23</sup> CPSC, however, wrongly failed to do any of these things and violated the IQA's utility and objectivity tests.<sup>24</sup>

Requested CPSC Action: Mr. Zucker requests that CPSC disclose the statistical and scientific metrics used to determine that there were "defects" in the product design, warnings, and instructions, and to determine substantiality with respect to the alleged risk.

Mr. Zucker also requests that CPSC clarify and disclose all of its statistical and scientific bases that supposedly support its determination of, and provide context for, the claims of risk, injury, and/or hazard "substantiality" it made relative to Buckyballs® and Buckycubes®.

Mr. Zucker also requests that CPSC replace the phrase "These products contain defects in the design, warnings and instructions, which pose a substantial risk of injury and death to children and teenagers" on CPSC website with the phrase, "CPSC believes that the misuse of these products by unsupervised children could, under certain circumstances, result in potential injury".

2. *"These retailers have agreed to participate because Maxfield & Oberton has refused to participate in the recall of all Buckyballs® and Buckycubes®."*

Grounds for Disclosure/Correction: The claim that "These retailers have agreed to participate because Maxfield & Oberton has refused to participate in the recall of all Buckyballs® and Buckycubes®" in the recall announcement and on the CPSC website is the "dissemination" of IQA information.<sup>25</sup> It fails the IQA's quality test because it is inaccurate.<sup>26</sup> Maxfield & Oberton did not "refuse to participate" but no longer exists and, therefore, cannot participate in any recall.

Requested CPSC Action: Mr. Zucker requests that the current statement, "These retailers have agreed to participate because Maxfield & Oberton has refused to participate in the recall of all Buckyballs® and Buckycubes®," be replaced by the statement, "These retailers have agreed to participate because Maxfield & Oberton no longer exists and therefore cannot participate in a recall of all Buckyballs® and Buckycubes®."

3. *"In July 2012, CPSC staff filed an administrative complaint against Maxfield & Oberton Holdings LLC, of New York, N.Y., after discussions with the company and its representatives failed to result in a voluntary recall plan that CPSC staff considered to be adequate to address the very serious hazard posed by these products."*

Grounds for Disclosure/Correction: The claim that the subject products pose a "very serious hazard" in the recall announcement and on the CPSC website is the "dissemination" of "influential"

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<sup>23</sup> 67 Fed. Reg. 6458.

<sup>24</sup> OMB Guidelines §§ V(2),(3), 67 Fed. Reg. 8459-60.

<sup>25</sup> *Id.* at § V(5), 67 Fed. Reg. 8460.

<sup>26</sup> *Id.* at § V(3)(a) (stating that "disseminated information" must be presented "in an accurate, clear, complete, and unbiased manner").

scientific or statistical information, for it concerns health and safety risks and was designed to influence important private sector decisions regarding the purchase and/or use of the subject products.<sup>27</sup>

However, CPSC has failed to define precisely what a “very serious hazard” is or provide metrics so that Mr. Zucker and other members of the public may distinguish between a “very serious hazard,” a “serious hazard,” a “moderate hazard,” and no hazard at all. Therefore, CPSC’s the “very serious hazard” claim fails the IQA’s utility test, because without objective performance metrics, it is impossible for the public to evaluate whether this information is useful or not.<sup>28</sup> Similarly, CPSC’s failure to define the term “very serious hazard” in its own right and in a relative sense violated its IQA “substance” objectivity obligations.<sup>29</sup>

Furthermore, CPSC had a duty to provide “a high degree of transparency” about the data and methods that it used to determine why the products here were determined to be a “very serious” hazard.<sup>30</sup> Yet, without some context (such as relative risk ratios) and disclosure of its supporting data and models, CPSC’s “very serious hazard” claim cannot possibly be evaluated for accuracy or bias and the claim fails the IQA’s “presentation” objectivity test. As noted in § A(1) above, based on CPSC’s own statistics, there have been no deaths due to the misuse or ingestion of Buckyballs® and Buckycubes®, and as noted in the NEISS Data Highlights *supra*, skateboarding, household cleaning chemicals, single load laundry packets and trampolines (among other products) are statistically far more dangerous. Without some appropriate context and definitional clarity, it is impossible to determine whether CPSC’s statement is accurate, clear, complete, and unbiased as the law commands.<sup>31</sup>

Furthermore, because CPSC claimed the products in question posed “a very serious hazard,” it was required to apply the test contained in the Safe Drinking Water Act Amendments.<sup>32</sup> This required CPSC to specify (a) each population addressed by any estimate of risk; (b) the central estimate of risk for the specific populations affected; (c) each appropriate upper-bound or lower-bound estimate of risk; (d) each significant uncertainty identified in the process of risk assessment effects and the studies that would assist in resolving the uncertainty; and (e) peer-reviewed studies known that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.<sup>33</sup> CPSC, however, wrongly failed to do any of these things and violated the IQA’s utility and objectivity tests.<sup>34</sup>

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<sup>27</sup> *Id.* at § V(8), (9), 67 Fed. Reg. 8460.

<sup>28</sup> *Id.* at § V(2), 67 Fed. Reg. 8459.

<sup>29</sup> *Id.* at § V(3)(a), 67 Fed. Reg. 8459.

<sup>30</sup> *Id.* at § V(3)(b)(ii), 67 Fed. Reg. 8460.

<sup>31</sup> *Id.* at § V(3)(a), 67 Fed. Reg. 8459.

<sup>32</sup> 42 U.S.C. § 300g–1(b)(3)(A) & (B); OMB Guidelines § V(3)(b)(ii)(C), 67 Fed. Reg. 8460.

<sup>33</sup> 67 Fed. Reg. 6458.

<sup>34</sup> OMB Guidelines §§ V(2),(3), 67 Fed. Reg. 8459-60.

Requested CPSC Action: Mr. Zucker requests that CPSC disclose the statistical and scientific metrics used to determine that the subject products posed a “very serious hazard,” rather than a “serious hazard,” a “moderate hazard,” a “hazard,” or no hazard at all. CPSC had a duty to provide the “high degree of transparency” needed to allow Mr. Zucker and other members of the public to reproduce CPSC’s findings, to determine whether its claims were accurate and unbiased, and/or to assess CPSC’s compliance with its IQA duties. It also had a duty to comply with IQA’s health risk assessment transparency and utility obligations. Without full disclosure, Mr. Zucker’s ability to assess its IQA compliance is frustrated.

Mr. Zucker also requests that the phrase “In July 2012, CPSC staff filed an administrative complaint against Maxfield & Oberton Holdings LLC, of New York, N.Y., after discussions with the company and its representatives failed to result in a voluntary recall plan that CPSC staff considered to be adequate to address the very serious hazard posed by these products” be taken down from the CPSC website and replaced with the following: “In July 2012, CPSC staff filed an administrative complaint against Maxfield & Oberton Holdings LLC, of New York, N.Y., after discussions with the company and its representatives failed to result in a voluntary recall plan that CPSC staff considered to be adequate.”

4. *“CPSC has received 54 reports of children and teens ingesting this product, with 53 of these requiring medical interventions.”*

Grounds for Disclosure/Correction: The claim that “CPSC has received 54 reports of children and teens ingesting this product, with 53 of these requiring medical interventions” in the recall announcement and on the CPSC website is the “dissemination” of influential information.<sup>35</sup> This claim fails the IQA’s quality test because it is inaccurate.<sup>36</sup> Review of the website Saferproducts.gov suggests that there are at least two ingestions that did not require medical interventions.<sup>37</sup>

Requested CPSC Action: Mr. Zucker requests that the current statement “CPSC has received 54 reports of children and teens ingesting this product, with 53 of these requiring medical interventions” be corrected to accurately report the data in CPSC’s possession

B. Influential information disseminated in the July 25, 2012 news release, “CPSC Sues Maxfield & Oberton Over Hazardous Buckyballs® and Buckycubes™ Desk Toys Action prompted by ongoing harm to children from ingested magnets.”<sup>38</sup>

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<sup>35</sup> *Id.* at § V(8), (9), 67 Fed. Reg. 8460.

<sup>36</sup> *Id.* at § V(3)(a) (stating that “disseminated information” must be presented “in an accurate, clear, complete, and unbiased manner”).

<sup>37</sup> <http://saferproducts.gov/ViewIncident/1243200> (last visited Nov. 11, 2013);

<http://saferproducts.gov/ViewIncident/1187028> (last visited Nov. 11, 2013).

<sup>38</sup> News Release, *supra* note 6.



*“CPSC Sues Maxfield & Oberton Over Hazardous Buckyballs® and Buckycube™ Desk Toys Action prompted by ongoing harm to children from ingested magnets.”*

Grounds for Disclosure/Correction: The claims that the subject products are “hazardous” and cause “ongoing harm to children” in the recall announcement and on the CPSC website are the “dissemination” of “influential” scientific or statistical information, for they concern health and safety risks and were designed to influence important private sector decisions regarding the purchase and/or use of the subject products.<sup>39</sup>

CPSC has failed to define precisely what a “hazard” is or to provide metrics to evaluate the bases for this designation. Therefore, the “hazard” claim fails the IQA’s utility test because it is currently impossible for the public to evaluate whether this information is useful or not.<sup>40</sup> Additionally, the lack of metrics means that the statement also fails the IQA’s “presentation” objectivity test, because it is now impossible to determine whether the claim is accurate, clear, complete, and unbiased as the law commands.<sup>41</sup> Again, as noted *supra*, skateboarding, household cleaning chemicals, single load laundry packets and trampolines are statistically far more dangerous. Without the benefit of this contextual information with respect to risk and “hazard,” CPSC’s claim is biased and violates the IQA.

The “Hazard” claim also violates CPSC’s IQA “substance” objectivity obligations.<sup>42</sup> CPSC had a duty to provide “a high degree of transparency” about the data and methods that it used to determine why the products here were determined to be a “very serious” hazard.<sup>43</sup> Yet, without some context (such as relative risk ratios) and disclosure of its supporting data and models, CPSC’s “hazard” claim cannot possibly be evaluated for accuracy or bias.

Furthermore, because CPSC claimed the products in question pose a “hazard,” it was required to apply the test contained in the Safe Drinking Water Act Amendments.<sup>44</sup> This required CPSC to specify (a) each population addressed by any estimate of risk; (b) the central estimate of risk for the specific populations affected; (c) each appropriate upper-bound or lower-bound estimate of risk; (d) each significant uncertainty identified in the process of risk assessment effects and the studies that would assist in resolving the uncertainty; and (e) peer-reviewed studies known that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to

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<sup>39</sup> *Id.* at § V(8),(9), 67 Fed. Reg. 8460.

<sup>40</sup> *Id.* at § V(2), 67 Fed. Reg. 8459.

<sup>41</sup> *Id.* at § V(3)(a), 67 Fed. Reg. 8459.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* at § V(3)(b)(ii), 67 Fed. Reg. 8460.

<sup>44</sup> 42 U.S.C. § 300g–1(b)(3)(A) & (B); OMB Guidelines § V(3)(b)(ii)(C), 67 Fed. Reg. 8460.

reconcile inconsistencies in the scientific data.<sup>45</sup> CPSC, however, wrongly failed to do any of these things and violated the IQA's utility and objectivity tests.<sup>46</sup>

CPSC's "ongoing harm to children" claim fails the IQA's presentation quality test because it is inaccurate.<sup>47</sup> There is no evidence of "ongoing harm to children" from the subject products. Absent ingestion, which happens only in statistically insignificant circumstances, there is no harm to children, much less "ongoing harm," resulting from Buckyballs®, Buckycubes® or any other magnets. Also, without some definition of what an "ongoing harm to children" is, or how the CPSC defines "ongoing harm" in a given case, it is impossible to determine the utility, objectivity, and reproducibility of this claim. Therefore, it fails the IQA's requirements.<sup>48</sup>

The "ongoing harm to children" claim also violates CPSC's IQA "substance" objectivity obligations.<sup>49</sup> CPSC had a duty to provide "a high degree of transparency" about the data and methods that it used to determine that the products here pose such an "ongoing harm."<sup>50</sup> Yet, none is provided, and absent full disclosure of its supporting data and models, CPSC's claim cannot possibly be evaluated for accuracy or bias.

Furthermore, because CPSC claimed the products in question pose an "ongoing harm to children," it was required to apply the test contained in the Safe Drinking Water Act Amendments.<sup>51</sup> This required CPSC to specify (a) each population addressed by any estimate of risk; (b) the central estimate of risk for the specific populations affected; (c) each appropriate upper-bound or lower-bound estimate of risk; (d) each significant uncertainty identified in the process of risk assessment effects and the studies that would assist in resolving the uncertainty; and (e) peer-reviewed studies known that support, are directly relevant to, or fail to support any estimate of risk and the methodology used to reconcile inconsistencies in the scientific data.<sup>52</sup> CPSC, however, wrongly failed to do any of these things and violated the IQA's utility and objectivity tests.<sup>53</sup>

Requested CPSC Action: Mr. Zucker requests that CPSC disclose the statistical and scientific metrics used to determine that Buckyballs® and Buckycubes® pose an "ongoing harm to children" and explain how CPSC determines what an "ongoing harm" is in any given case.

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<sup>45</sup> 67 Fed. Reg. 6458.

<sup>46</sup> OMB Guidelines §§ V(2),(3), 67 Fed. Reg. 8459-60.

<sup>47</sup> *Id.* at § V(3)(a) (stating that "disseminated information" must be presented "in an accurate, clear, complete, and unbiased manner").

<sup>48</sup> *Id.* at §§ V(2),(3), 67 Fed. Reg. 8459.

<sup>49</sup> *Id.* at § V(3)(a), 67 Fed. Reg. 8459.

<sup>50</sup> *Id.* at § V(3)(b)(ii), 67 Fed. Reg. 8460.

<sup>51</sup> 42 U.S.C. § 300g-1(b)(3)(A) & (B); OMB Guidelines § V(3)(b)(ii)(C), 67 Fed. Reg. 8460.

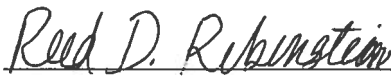
<sup>52</sup> 67 Fed. Reg. 6458.

<sup>53</sup> OMB Guidelines §§ V(2),(3), 67 Fed. Reg. 8459-60.

Mr. Zucker also requests that the phrase, "CPSC Sues Maxfield & Oberton Over Hazardous Buckyballs® and Buckycube™ Desk Toys Action prompted by ongoing harm to children from ingested magnets," be taken down from the CPSC website and replaced with the following: "CPSC Sues Maxfield & Oberton Over Buckyballs® and Buckycubes® Desk Toys."

If you have any questions about this request, please contact me by email at [reed.rubinstein@causeofaction.org](mailto:reed.rubinstein@causeofaction.org), or by telephone at (202) 499-4232. Thank you for your attention to this matter.

Sincerely,



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REED D. RUBINSTEIN  
SENIOR VICE PRESIDENT, LITIGATION