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Commentary: Getting the Government in Bed: How to Regulate the Sex-Toy Industry

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I. THE PROBLEMS WITH SEX TOYS

Simply by walking into almost any sex shop in the United States, one can browse an astounding selection of sex toys, from dildos that range from realistic to rainbow colored to cock rings with vibrating tongue-like attachments. Although few people speak about them, sex toys are incredibly common in the United States. Recent studies show that in the United States nearly half of all men[1] and over half of heterosexual women have previously used a vibrator.[2] Sex-toy use is especially prevalent in the LGB community, with 78.5 percent of

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1. Michael Reece et al., *Prevalence and Characteristics of Vibrator Use by Men in the United States*, 6 J. SEXUAL MED. 1867, 1869 (2009).
2. Debra Herbenick et al., *Women's Vibrator Use in Sexual Partnerships: Results from a Nationally Representative Survey in the United States*, 36 J. SEX & MARITAL THERAPY 49, 55 (2010).

gay or bisexual men reporting having used some kind of sex toy[3] and 70.6 percent of lesbian women and 79.7 percent of bisexual women reporting vibrator usage.[4] Although there is no formal tracking of the amount consumers spend on sex toys per year, sources estimate that North Americans spend between $500 million and $15 billion per year.[5] Despite the commonness of sex toys in Americans' homes and beds, the industry has been almost wholly unregulated at both the state and federal level,[6] aside from some recently repealed statewide bans on selling and advertising sex toys.[7]

While administrative agencies such as the Food and Drug Administration (FDA), the Consumer Product Safety Commission (CPSC), and the Federal Trade Commission (FTC) regulate thousands of other consumer products for dangers such as toxic chemicals, harmful design flaws, and inaccurate or misleading packaging, sex-toy manufacturers remain free to engage in all three practices. Although the FDA classifies vibrators as obstetrical and gynecological therapeutic medical devices for treating sexual dysfunction and improving pelvic-floor muscle tone,[8] most consumers use vibrators and other sex toys purely for pleasure. In order to try to avoid adhering to the FDA regulations imposed on medical devices,[9] manufacturers frequently label vibrators and other sex toys "for novelty use only."[10] Even though courts have held that

3. Joshua Rosenberger et al., *Sex Toy Use by Gay and Bisexual Men in the United States*, 41 ARCHIVES SEXUAL BEHAV. 449, 452 (2012).
4. Herbenick et al., *supra* note 2, at 55.
5. Regina Nuzzo, *Good Vibrations: U.S. Consumer Web Site Aims to Enhance Sex Toy Safety*, SCI. AM. (May 24, 2011), http://www.scientificamerican.com/article.cfm?id=good-vibrations-us-consumer-web-site-aims-to-enhance-sex-toy-safety. One manufacturer claims that Americans spend $15 billion a year on sex toys. Margaret Johnson, *Sex Toy Sales Per Capita Highest in These States, According to Manufacturer*, HUFFINGTON POST (Aug. 16, 2012), http://www.huffingtonpost.com/2012/08/16/sex-toy-sales-per-capita-_n_1790014.html.
6. Zach Biesanz, *Dildos, Artificial Vaginas, and Phthalates: How Toxic Sex Toys Illustrate A Broader Problem for Consumer Protection*, 25 LAW & INEQ. 203, 205-06 (2007).
7. Kan. Stat. Ann. § 21-4301 (repealed 2011); Ala. Code § 13A-12-200.2; Williams v. Attorney Gen. of Ala., 378 F.3d 1232 (11th Cir. 2004) (declining to recognize a fundamental interest in obtaining sex toys); Ga. Code Ann. § 16-12-80 (preempted 2002); Miss. Code. Ann. § 97-29-105; Tex. Penal Code Ann. § 43.23(a) (2003). While these bans on sex toys were an extreme form of regulation, the bans were not motivated by the desire to protect consumers. Rather, bans on sex toys were motivated by the desire to enforce conservative norms about morality and sexuality. The moral motivation behind these state laws is apparent, because they are referred to as "obscenity" laws. *See also* William Charles Hayes, *"Rabbit" Hunting in the Supreme Court: The Constitutionality of State Prohibitions of Sex Toy Sales Following* Lawrence v. Texas, 44 GA. L. REV. 245, 252-54 (2009).
8. *See* 21 C.F.R. § 884.5960 (2013). The pelvic-floor muscles surround and support the vagina and bladder. When they become weak, this can cause problems such as reduced sexual sensation and incontinence. *What Are Pelvic Floor Exercises?*, NAT'L HEALTH SERVICE, http://www.nhs.uk/chq/Pages/1063.aspx?CategoryID=52&SubCategoryID=146#close (last updated Dec. 7, 2011).
9. *See, e.g.*, 21 C.F.R. § 801 (requiring labeling instructions on medical devices); § 802 (requiring reporting instructions for medical devices); § 807 (establishing registration and device listing for manufacturers and importers).
10. Biesanz, *supra* note 6, at 215-16; *Sex Toys as Adult Novelties: Why Are Sex Toys Sold as Novelties?*, HOLISTIC WISDOM, http://www.holisticwisdom.com/sex-toy-novelty-

manufacturers cannot escape legal action through such labeling,[11] sex-toy manufacturers continue to use the disclaimer to dissuade consumers from holding them liable for faulty products.[12] The resultant absence of regulation and liability for manufacturers means that many sex toys lack features or warnings that would help consumers use them safely.

This Comment proposes that regulating the sex-toy industry through the CPSC's petition process would benefit consumers by reducing the possibility of injury. Part I.A details the harms that can and do occur from sex toys that are poorly designed, toxic, or improperly used. Part I.B details the problems caused by phthalates, a group of chemicals found in the plastic from which many sex toys are constructed. Part II illustrates how the federal government regulates the dangers outlined in Part I in other products and contexts, such as children's toys and environmental exposure to phthalates. Part III explores the feasibility of federally regulating sex toys. Part III.A argues that sex toys should be classified as consumer goods under the jurisdiction of the CPSC. Part III.B analyzes whether the two methods of initiating regulation by the CPSC, internal investigation and the petition process, would be successful. Part III.C examines the types of rules that could result from regulation. Finally, Part IV concludes that, despite some hurdles, regulation is possible and could protect consumers from the perils posed by these commonly used but infrequently acknowledged products.

A. Consumer Injuries and Flawed Toy Designs

Although the current lack of regulation may seem to suggest that consumers use sex toys safely, a number of potential dangers exist. Despite the dearth of research into Americans' sex-toy usage, one recent study found that 6,799 individuals over age twenty sought emergency room care in the United States for injuries caused by sex toys between 1995 and 2006.[13] Injuries were caused most often from "[v]ibrating devices (including personal massagers) . . . (73.5%), followed by dildos (12.9%), other/unspecified devices (11.7%), and

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definition.htm (last visited Dec. 1, 2012); Debbie Pacheco, *Novelty Use Only? Know Your Dildo*, BLOGTO (Nov. 28, 2009), http://www.blogto.com/tno/2009/11/novelty_use_only_know_your_dildo/; Garnet Joyce, *Sex Toys to Avoid: For Novelty Use Only*, MY SEX PROFESSOR (Sept. 27, 2010), http://www.mysexprofessor.com/warnings/sex-toys-to-avoid-for-novelty-use-only/comment-page-1/.

11. *See* State v. Curtis, 356 S.C. 622, 627 (2004) (finding that a product intended to create false negatives that was labeled "for novelty use only" had an intent to defraud drug tests); State v. Brenan, 772 So.2d 64, 76 (2000) (finding vibrators labeled "[s]old as a Novelty Only. This Product is not Intended as a Medical Device" still satisfied the statute's definition as an obscene device); Original Cosmetics Products, Inc. v. Strachan, 459 F. Supp. 496, 502 (S.D.N.Y. 1978), *aff'd*, 603 F.2d 214 (2d Cir. 1979) (affirming a fraud conviction for selling aphrodisiac products marked "to be used as a novelty only").
12. *See* discussion *supra* note 10.
13. Russell Griffin & Gerald McGwin Jr., *Sexual Stimulation Device-Related Injuries*, 35 J. SEX & MARITAL THERAPY 253, 255 (2009).

rings (1.9%)."[14] The authors concluded that injuries from sex toys increased sharply after 1999, possibly because more Americans began using them.[15] The authors warned that the actual number of injuries was greater than reported in the study, because embarrassment about sexual injuries likely prevents many people from seeking treatment.[16] Shame about sexual injuries also lengthened the average time that it took for patients to seek treatment, which could "result in the use of more invasive procedures to remove the foreign body . . . and [could] even lead to death due to complications."[17]

While the study did not investigate how exactly the harms occurred, many sex toys contain design or labeling flaws that can lead to injuries. For example, in order to be safe for anal penetration, sex toys must have a flared end that is sufficiently wide enough so that the toy does not get sucked into the body and lost, potentially causing serious injury.[18] With 78.1 percent of injuries occurring in the anorectal region, the study suggested that this is the most common kind of sex toy-related injury.[19] Similarly, toys with sharp edges can cause cuts and tears.[20] Vibrators or other toys with electrical elements can expose the user to unsafe wiring and shocks.[21] Vibrations themselves can cause chronic numbness and pain over time.[22] Furthermore, Americans' discomfort discussing sex[23] means that many consumers likely feel uncomfortable asking a sex-toy store employee or a health provider about proper usage.[24] Thus, unless toys come with

14. *Id.* at 257.
15. *Id.* Although no research has confirmed that sex-toy use is becoming more common, the advent of the Internet—making sex toys widely available for anonymous purchase online—as well as increasing awareness of sex toys, such as the rabbit vibrator popularized by *Sex and the City*, makes increased usage of sex toys a likely reason for increased sex-toy injuries. *See Rabbit Vibrator Toys*, ADAM & EVE, http://www.adameve.com/t-what-are-rabbit-vibrators.aspx (last visited Dec. 1, 2012).
16. Griffin & McGwin, *supra* note 13, at 259.
17. *Id.*
18. TRISTAN TAORMINO, THE ANAL SEX POSITION GUIDE: THE BEST POSITIONS FOR EASY, EXCITING, MIND-BLOWING PLEASURE 104 (2009); *see* Nuzzo, *supra* note 5.
19. Griffin & McGwin, *supra* note 13, at 255.
20. Jennifer Parks, *Sex Toy Safety*, EDMONTON J. (Mar. 21, 2008) http://www2.canada.com/edmontonjournal/news/ed/story.html?id=f3155009-ae6e-41cb-b1d6-e3aee4a0671e.
21. *See, e.g.*, *Incident Report Details, Report No. 20120517-65AF0-2147467529*, SAFERPRODUCTS.GOV (June 15, 2012), http://www.saferproducts.gov/ViewIncident/1248612.
22. *See* Nuzzo, *supra* note 5 ("A 2009 Indiana University study published in the Journal of Sexual Medicine found that 53 percent of all women have used a vibrator, and 18 percent of those have had numbness, pain and other side effects. Known in the occupational-safety world as 'vibratory strain injury,' these problems may at first merely frustrate but can develop into chronic conditions.").
23. *Id*.
24. *See* Pamela Madsen, *Dangerous Sex Toys: What You Need to Know About Phthalates*, PSYCHOL. TODAY (Aug. 7, 2011), http://www.psychologytoday.com/blog/shameless-woman/201108/dangerous-sex-toys-what-you-need-know-now-about-phthalates ("Because people are still filled with shame around buying and using sex toys we have found ourselves in a lovely Catch 22. Because of our shame and embarrassment over using and buying sex toys, the sex-toy industry often gets away with using materials that are dangerous."); *see also*

safe design features and warnings, consumers may be altogether unaware of the risks of improper use.[25]

B. Chemicals Found in Sex Toys

In addition to design flaws and lack of proper warnings, many sex toys contain chemicals that can damage consumers' health. Many vibrators and other sex toys made of so-called "jelly"-type plastic[26] contain phthalates, a group of chemicals used to increase flexibility in plastic products.[27] Phthalates can enter the body orally, through food or water, through inhalation, or through absorption by the skin including the mucous membranes where sex toys generally contact the skin.[28] Sources disagree about the extent of harm that different phthalates pose. While the CPSC found minimal risks present from Diisononyl Phthalate (DINP),[29] it concluded that Diisodecyl Phthalate (DIDP) is a "probable toxicant" when ingested orally.[30] The CPSC further labeled Di(2-ethylhexyl) Phthalate (DEHP) as "toxic" within the meaning of the Federal Hazardous Substances Act, based on testing showing both short and long-term toxic effects on the liver, kidneys, testes, uterus, ovaries, thyroid, and to fetuses.[31]

Congress also has banned six phthalates, including DEHP and DINP, present in concentrations of 0.1 percent in children's toys and several other child-related products.[32] Similarly, in 1999 the European Parliament banned

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Susan Quilliam, *Everything You Ever Wanted to Know About Sex Toys But Were Too Afraid to Ask*, 33 J. FAM. PLAN. REPROD. HEALTH CARE 129, 130 (2007).

25. See Biesanz, *supra* note 6, at 220, for further discussion of how shame influences the regulation of sex toys.
26. "Jelly is a very pliable material that has on overall smooth, soft and even supple feel to it." *What Are Vibrators Made of?*, ADAM & EVE, http://www.adameve.com/t-vibrator-material.aspx (last visited Dec. 1, 2012); *see also Savage Love Episode 292*, at 22:50-23:30 (May 22, 2012), *available at* http://www.thestranger.com/SavageLovePodcast/archives/2012/05/22/savage-love-episode-292.
27. *Phthalates*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/info/toysafety/phthalates.html (last visited Dec. 1, 2012); Biesanz, *supra* note 6, at 206 ("Sex toys made of Jelly plastic, which allegedly has a natural feel, enjoy massive popularity in sex shops. However, Jelly plastic is composed of a substantial amount of toxic chemicals. These chemicals include 'enormous amounts' of phthalates which leach out of the PVC, pass through the skin, and collect in the body.").
28. THE NAT'L ACADS., PHTHALATES AND CUMULATIVE RISK ASSESSMENT: THE TASKS AHEAD 2 (2008).
29. Memorandum from Michael A. Babich, Chemist, Div. of Health Sci., and Cheryl A. Osterhout, Pharmacologist, Div. of Health Sci., to Mary Ann Danello, Assoc. Exec. Dir. for Health Sci., U.S. Consumer Prod. Safety Comm'n, Toxicity Review of Diisonyonyl Phthalate (DINP) (Apr. 7, 2010).
30. *Id*.
31. Memorandum from Kent. R. Carlson, Toxicologist, Directorate of Health Servs., to Michael A. Babich, Project Manager, Phthalates, U.S. Consumer Prod. Safety Comm'n, Toxicity Review of Di(2-ethylhexyl) Phthalate (DEHP) (Apr. 1, 2010).
32. 15 U.S.C. § 2057c(a)-(b) (2011). DEHP, dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP) are effectively permanently banned in children's toys and products, while DINP, DIDP, and di-n-octyl phthalate (DnOP) are banned on an interim basis until the CPSC issues a mandatory rule governing their use in children's products, *id*. at § 2057c(a), (b)(i),.

DINP in products that children might chew or suck on.[33] However, the Danish study on sex toys concluded that there was no risk in using toys containing DEHP for fifteen minutes to an hour per day unless breastfeeding or pregnant, in which case a danger of minor developmental effects existed.[34]

However, the cumulative effects of phthalates and other hormone disrupters have not been studied thoroughly.[35] Of the other sex toys the study examined, several presented minor risks from other potentially hazardous chemicals including trimethyltin chloride, phenol, and cadmium.[36] While the exact risks and impacts of phthalates are beyond the scope of this Comment and have been extensively covered elsewhere,[37] phthalates are toxic to humans and can enter the body through sex-toy use.

Many sex-toy manufacturers use phthalates to inexpensively produce softer, more flexible plastic.[38] A study done by Greenpeace Netherlands determined that of eight sex toys tested, seven contained phthalates, including DEHP, DINP, and DIDP.[39] The concentrations of phthalates in the toys studied were very high, ranging from 24 percent to 49 percent of the product's total weight.[40] Similarly, a Danish study of the contents of sex toys found that ten of the fifteen tested contained large quantities of phthalates, including DEHP and DINP.[41] In particular, eight of the products contained high levels of DEHP, in

33. *Six Chemicals in Soft Plastic Toys Banned Across Europe*, ENV'T NEWS SERV. (July 6, 2012), http://www.ens-newswire.com/ens/jul2005/2005-07-06-05.asp.

34. NILS H. NILSSON ET AL., ENVTL. PROT. AGENCY, DANISH MINISTRY OF THE ENV'T, SURVEY AND HEALTH ASSESSMENT OF CHEMICALS SUBSTANCES IN SEX TOYS (2006), *available at* http://www2.mst.dk/udgiv/publications/2006/87-7052-227-8/pdf/87-7052-228-6.pdf.

35. The CPSIA attempted to fill the gap in this research by ordering a study into the cumulative effects of phthalates. *See* 15 USC § 2057c(b)(2)(B)(iv). A study done on rats and rabbits showed that cumulative exposure to phthalates caused reproductive abnormalities. Kembra Howdeshell et al., *Cumulative Effects of Dibutyl Phthalate and Diethylhexyl Phthalate on Male Rate Reproductive Tract Development: Altered Fetal Steroid Hormones and Genes*, 99 TOXICOL. SCI. 190 (2007).

36. *See id.* (detailing the risks of trimethyltin chloride, phenol, and cadmium).

37. *See, e.g.*, Shanna H. Swan, *Environmental Phthalate Exposure in Relation to Reproductive Outcomes and Other Health Endpoints in Humans*, 180 ENVTL. RES. 177 (2008); Stephanie Engel et al., *Prenatal Phthalate Exposure Is Associated with Childhood Behavior and Executive Functioning*, 118 ENVTL. HEALTH PERSP. 565 (2010); Robin Whyatt et al., *Maternal Prenatal Urinary Phthalate Metabolite Concentrations and Child Mental, Psychomotor, and Behavioral Development at 3 Years of Age*, 120 ENVTL. HEALTH PERSP. 290 (2012).

38. Brian Alexander, *When Sex Toys Turn Green—For Health That is*, NBC NEWS (June 21, 2007), http://www.msnbc.msn.com/id/19333870/ns/health-sexual_health/t/when-sex-toys-turn-green-health/#.UPhwd-gk9kc.

39. GREENPEACE NETH., DETERMINATION OF PHTHALATES IN SEX TOYS, TNO BUILT ENVIRONMENT AND GEOSCIENCES 3 (2006), *available at* http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/7938.pdf. Three of the toys contained high concentrations of DEHP, two contained high concentrations of DINP, and two contained high levels of DIDP.

40. *Id.*

41. NILSSON, *supra* note 34.

concentrations ranging up to 70 percent.[42] In comparison, the level of several common phthalates, including DEHP, permitted in children's toys in the United States is 0.1 percent.[43] The European Parliament takes an even stricter approach to phthalates and bans six types, including DEHP, DINP, and DIDP, in toys and childcare products.[44]

II. REGULATORY DOUBLE STANDARDS FOR SEX TOYS

The United States government turns a blind eye toward the hazards posed by sex toys discussed in Part I. When the same types of risks arise in other products or contexts, the government regulates them. Consumers' inability to effectively advocate for protection because of the taboo nature of publically discussing sex toy is a major reason for this regulatory double standard.

The government currently protects people from many of the dangers posed by sex toys when they exist in other products. In the United States, DEHP is regulated in environmental uses and exposure,[45] children's toys,[46] and baby products.[47] The CPSC regulates consumer product design hazards that tend to cause injury.[48] Accurate labeling and advertising is controlled by the FDA for pharmaceuticals,[49] the Department of Agriculture (USDA) in foods,[50] and the Federal Trade Commission (FTC) for a variety of other consumer products and services.[51] Despite the protections from these dangers in other contexts, such as food, drugs, the environment, and children's toys, sex toys are not subject to any protective regulations to ensure consumers' safety. For a product that roughly half of the American population will use during their lives and that can cause serious injury or even death if used incorrectly, this situation presents a dangerous deficiency in the regulatory scheme. The regulatory gap that sex toys

42. *Id.*
43. 15 U.S.C. § 2057c(a).
44. *See Permanent Ban of Phthalates: Commission Hails Long-Term Safety for Children's Toys*, EUROPA (July 5, 2005), http://europa.eu/rapid/press-release_IP-05-838_en.htm. Several European countries, including France and Denmark, have also moved to ban phthalates in other products as well. Michelle Yoemans, *Denmark Bans Four Phthalates, Despite EU Decision*, CAMPAIGN FOR SAFER COSMETICS (Aug. 29, 2012), http://safecosmetics.org/article.php?id=1062; *France's Important Move Toward Phasing Out Phthalates in Medical Devices*, HEALTH CARE WITHOUT HARM (Dec. 13, 2012), http://www.noharm.org/europe/news_hcwh/2012/dec/hcwh2012-12-13.php.
45. *See, e.g.*, 27 C.C.R. § 25805 (regulation of DEHP in drinking water); 40 C.F.R. Pt. 63, Subpt. XXXX, Tbl. 16 (regulation as a hazardous air pollutant); 40 C.F.R. Pt. 132, Tbl. 6 (regulation as a bioaccumulative chemical of concern in the Great Lakes); 49 C.F.R. § 172.101, App. A (regulation in transportation usage).
46. 15 U.S.C. § 2057c(a), (b) (2011).
47. § 2057c.
48. § 2051.
49. 21 C.F.R. § 201.
50. *Labeling & Consumer Protection*, U.S. DEP'T OF AGRIC., http://www.fsis.usda.gov/about/labeling_&_consumer_protection/index.asp (last modified Aug. 5, 2011).
51. 2 Fed. Trade Comm'n. § 22:1 (2012).

currently inhabit merits further inquiry into why these products have evaded regulation and how regulation might be initiated to better protect the public.

In many cases the impetus to regulate dangerous products stems from consumer advocacy or industry groups that hold a stake in having uniform standards and protecting customers.[52] For example, the CPSC's initial petitioning process for setting standards on consumer goods was designed to be extremely responsive to petitions from the public and industry groups.[53] Section 10 of the Consumer Product Safety Act (CPSA) originally allowed more rights to petitioners seeking promulgation, amendment, or revocation of product standards than were afforded under the Administrative Procedure Act.[54] The CPSC received a large number of petitions under the CPSA during its early years, which greatly influenced the Commission's priorities on standard setting.[55] More recently, in 2008, Congress passed the Consumer Product Safety Improvement Act (CPSIA),[56] granting increased powers and resources to the CPSC[57] after "significant high-profile product recalls in 2007, including numerous recalls involving lead paint in children's toys, powerful magnets falling out of toys, and dangerous cribs, [leading] to the moniker 'Year of the Recall.'"[58] Plainly, consumer outcry affects the priorities of consumer protection agencies and, in many cases, leads to new regulation designed to address these problems.

Unlike the users of many other products, consumers of sex toys are unlikely to have the information, political will, and organizational capacity to effectively advocate for regulatory protection. Few studies investigate sex toy-related injuries, and none explicitly address whether the injury occurred due to a design flaw or improper use. Historically, consumers have also lacked information about sex toys' safety, although this is beginning to change with more knowledge readily available on the Internet. Without the ability to know if

52. *See* Richard A. Merrill, *CPSC Regulation of Cancer Risks in Consumer Products: 1972-1981*, 67 VA. L. REV. 1261, 1274, 1363 (1981) (discussing how petitions for regulation of carcinogen-containing products shaped the CPSC's regulatory agenda).

53. *See* Teresa M. Schwartz, *The Consumer Product Safety Commission: A Flawed Product of the Consumer Decade*, 51 GEO. WASH. L. REV. 32, 45-48, 54 (1982).

54. The CPSC's original provisions allowed for public hearings, investigations into product hazards in response to petitions, a 120-day deadline for the CPSC to grant or deny petitions, prompt action after the grant of a petition, and a CPSC publication detailing the reasons behind denial of petitions in the Federal Register. Petitioners were also permitted to bring a suit in federal district court to compel action if the Commission did not act within the 120-day period. *Id.* at 45-46.

55. *Id.* at 48; Merrill, *supra* note 52, at 1274, 1305.

56. Consumer Product Safety Improvement Act of 2008, Pub. L. No. 110-314, 122 Stat. 3016 (2008).

57. U.S. CONSUMER PROD. SAFETY COMM'N, STRATEGIC PLAN 2011-2016 1 [hereinafter STRATEGIC PLAN].

58. Leslie Cornell, Note, *Product Liability and Internet Prevention: The CPSC Online Consumer Database*, 24 LOY. CONSUMER L. REV. 254, 260 (2011); *see also* Eileen Flaherty, Note, *Safety First: The Consumer Product Safety Improvement Act of 2008*, 21 LOY. CONSUMER L. REV. 372, 381-83 (2009).

their sex toys contain toxic chemicals or if they are using them safely, consumers cannot demand change. Furthermore, discomfort with frank talk about sex lowers the chances of consumers discussing problems with sex toys and seeking out information. However, these issues should not prevent Americans from having access to safe, non-toxic sex toys that contain proper warnings and informational labeling. The regulatory system contains possibilities for regulating sex toys and holding manufacturers accountable for ill-designed and toxic products.

III. POSSIBILITIES FOR REGULATING SEX TOYS

The hazards posed by sex toys suggest that regulating sex toys could protect consumers. Many agencies shield the public from a plethora of harms that arise from various goods and services. The CPSC is the most logical choice of agency to regulate sex toys, because its job is to regulate consumer goods, which most sex toys should be regarded as. The CPSC's jurisdiction would allow initiation of regulation either by investigation or by petition from interested parties. If successful, a rulemaking could result in mandatory or voluntary rules for the industry.

A. Classifying Sex Toys as a Consumer Good Under the Consumer Product Safety Commission's Jurisdiction

The CPSC is the independent federal regulatory agency responsible for the safety of consumer products in the United States[59] and would be the most logical choice for regulating sex toys. The agency's mission is "to protect the public 'against unreasonable risks of injury or death from consumer products.'"[60] It does this through issuing mandatory regulations, creating voluntary guidelines, barring products from the market altogether if no safety standard feasibly protects the public, and conducting research on consumer hazards.[61] The CPSA defines "consumer products" as:

> [A]ny article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.[62]

Except for a number of exceptions handled by other agencies,[63] the CPSC has

59. *Frequently Asked Questions*, U.S. CONSUMER PRODUCT SAFETY COMM'N, http://www.cpsc.gov/en/About-CPSC/Frequently-Asked-Questions/ (last visited Nov. 24, 2012).
60. *Id.*
61. STRATEGIC PLAN, *supra* note 57, at 3.
62. 15 U.S.C. § 2052(5).
63. § 2052(5)(B)-(I). These exceptions to the CPSC's jurisdiction include tobacco products,

jurisdiction over the thousands of consumer goods on the market.[64] Currently, the FDA is the only agency to have any regulatory control over sex toys, which it classifies as medical devices.[65] The FDA defines medical devices as instruments "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or . . . intended to affect the structure or any function of the body of man or other animals."[66] However, this classification does not protect most consumers of sex toys, which meet most of the CPSC's definition of a consumer good. Classification of sex toys as consumer goods under the CPSC's jurisdiction would allow the CPSC to set standards for the industry without products going through approval as medical devices, as the FDA currently requires of the three FDA-approved sex toys on the market.[67]

Courts determining whether a product meets the CPSC's definition of a consumer good and falls into its jurisdiction have looked at the plain meaning of the Act first.[68] Initially, the court decides if the good is something used around the house for the personal enjoyment or use of the consumer.[69] Consumers typically use sex toys in the privacy of their home. Contrary to the FDA's definition of a vibrator as a device for treating sexual dysfunction or other health problems, most sex toys are used for personal enjoyment and pleasure instead.

Next, courts determine whether the product falls into one of the exceptions to the CPSC's jurisdiction,[70] which includes "any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer."[71] Sex toys do not fit into any of the exceptions, including the broad exception for any article not distributed to or used by consumers. The legislative history of CPSA indicates that this broad exception was intended "to exclude industrial products, on the theory that industrial purchasers are better able to protect themselves and are subject to the separate

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motor vehicles and motor vehicle equipment, pesticides, aircraft and their various appliances and mechanical parts, boats, drugs, medical devices, cosmetics, food, and "any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer." § 2052(5)(A).

64. *Regulated Product*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/businfo/reg1.html (last visited Jan. 16, 2013).
65. 21 C.F.R. § 884.5960(a).
66. 21 U.S.C. § 321(h)(2)-(3).
67. 21 C.F.R. § 884.5960(a). FDA-approved vibrators are classified as Class II medical device by the FDA; however, sex-toy manufacturers attempt to escape regulation by labeling their products as novelty use only. *See supra* Part I. For information on the three FDA-approved sex toys, see *supra* notes 80-82.
68. *See, e.g.*, Kaiser Aluminum & Chem. Corp. v. U. S. Consumer Prod. Safety Comm'n, 574 F.2d 178, 180 (3d Cir. 1978); United States v. Anaconda Co., 445 F. Supp. 486, 491-92 (D.D.C. 1977).
69. *Kaiser Aluminum & Chem. Corp.*, 574 F.2d at 180.
70. *Id.* at 180-81.
71. 15 U.S.C. § 2052(a)(5)(A). The exceptions to the CPSC's jurisdiction are tobacco and tobacco products, motor vehicles, pesticides, firearms, aircraft, boats, drugs, cosmetics, and food, all of which are covered by other regulatory statutes. *Id.* at § 2052(a)(5)(B)-(I).

regulatory scheme enacted by the Occupational Safety and Health Act of 1970."[72] Courts have also looked to whether a product is distributed directly to consumers in judging if it is industrial.[73] Sex toys are marketed and distributed directly to consumers via brick-and-mortar stores,[74] the Internet,[75] and sex-toy parties.[76] While courts have also taken legislative history into account in this determination,[77] unsurprisingly no legislative history exists regarding sex toys.

Finally, courts have considered whether exempting a product from classification as a consumer good would "create a loophole that might work to the injury of public protection through a technical construction" and whether classification would effectuate the policies behind the CPSA.[78] In this case, classifying sex toys as medical devices under the FDA, the only agency to currently impose any standards on sex toys, would not protect the general public from harm for two reasons.

First, the FDA's classification only covers therapeutic vibrators,[79] leaving out the myriad of other sex toys used by the general public, such as anal beads, cock rings, and butt plugs. The FDA has only approved a few sex vibrators, including Viberect, which treats penile erectile dysfunction and enables ejaculation for those with spinal cord injuries, requires a doctor's prescription, and currently costs $300.[80] Another vibrator approved by the FDA is the $850, prescription-only Ferticare, which assists procreation for those with spinal cord injuries and also treats "sexual dysfunction, incontinence, and depression related to sexual dysfunction."[81] The FDA has also approved the $179, prescription-only Eros, a handheld suction device for sexual dysfunction that operates by "stimulating blood flow" to the clitoris and increasing vaginal lubrication.[82]

Second, most sex-toy manufacturers' products do not go through the FDA's regulatory approval process for medical devices. This system leaves the general public, who do not need FDA devices tailored and approved for treating sexual dysfunction,[83] in a regulatory void where manufacturers and retailers have complete control.

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72. *Kaiser Aluminum & Chem. Corp.*, 574 F.2d at 180-81.
73. *Id.* at 181; *Anaconda Co.*, 445 F. Supp. at 492-93.
74. *See, e.g.*, *Good Vibrations*, GOOD VIBRATIONS, http://www.goodvibes.com/main.jhtml (last visited Dec. 2, 2012).
75. *See, e.g.*, *Adam & Eve*, ADAM & EVE, http://www.adameve.com/ (last visited Dec. 2, 2012).
76. *See, e.g.*, Martha McCaughey & Christina French, *Women's Sex-Toy Parties: Technology, Orgasm, and Commodification*, 5 SEXUALITY & CULTURE 77 (2001).
77. *Kaiser Aluminum & Chem. Corp*, 574 F.2d at 181; *Anaconda Co*., 445 F. Supp. at 94.
78. *Anaconda Co.*, 445 F. Supp. at 494.
79. 21 C.F.R. § 884.5960.
80. *Viberect*, REFLEXONIC, http://reflexonic.com/viberect.html (last visited Dec. 2, 2012).
81. *Ferticare Personal*, FERTILITY HEALTHCARE & SUPPLIES, INC., http://www.medicalvibrator.com/id69.html (last visited Apr. 27, 2013); *Ferticare Personal*, FERTILITY HEALTHCARE & SUPPLIES, INC., http://medicalvibrator.com/ferticare-personal (last visited Apr. 27, 2013).
82. *Eros Therapy*, NUGYN, http://www.eros-therapy.com/index.cfm?optionid=522 (last visited Dec. 2, 2012).
83. *See supra* Part I.

Because the FDA's regulatory regime for medical devices only serves the needs of those consumers with diagnosed sexual dysfunction, assigning the CPSC jurisdiction of all other sex toys would vindicate the policies behind the CPSA—namely, protecting the public.[84] The few devices that are FDA-approved are available only with a doctor's prescription and are expensive.[85] For many if not most consumers, this would be prohibitively expensive for a sex toy.[86] FDA-approved sex toys are intended specifically for individuals with medical issues, and the FDA's premarket approval guidance document demonstrates how the product must be tailored to a particular medical problem. Manufacturers must point to "the specific intended use(s), including the specific therapeutic and/or diagnostic indications" which "must be consistent with the descriptions of intended medical uses contained within the CFR section that is applicable to the device and must identify the specific medical conditions for which the device is indicated."[87] While the FDA's approval process is designed specifically to ensure effective treatment for the condition indicated, most consumers use sex toys only for personal satisfaction, not a medical need. While the FDA's process vindicates important consumer interests in prescription medical devices and should be retained for those devices that address particular medical needs, the innumerable sex toys left unregulated by the FDA's process should not exist in a regulatory loophole. Forcing these products to go through the FDA approval process would not serve most consumers' needs and would be prohibitively costly and burdensome for manufacturers. Therefore, most sex toys should be considered consumer goods within the CPSC's jurisdiction, not the FDA's, and regulated as such.

B. Initiating Regulation by the CPSC

There are two ways to initiate regulation by the CPSC that could set standards for materials, design, and warning labels of sex toys: (1) at the initiation of the agency, often as a result of the agency's investigation,[88] and (2) by petitioning the agency, which can be done by anyone.[89]

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84. United States v. Anaconda Co., 445 F. Supp. 486, 493 (D.D.C. 1977).
85. *See supra* notes 80-82.
86. Although some non-medical vibrators and other toys are quite expensive, most are under $100. For example, a survey of the "Rabbit Style" vibrators available on the Good Vibrations website reveals that only five of the twenty-one vibrators listed cost over $100. *Rabbit Style Vibrators*, GOOD VIBRATIONS, http://www.goodvibes.com/display_category.jhtml?id=catalog70002_cat33929&show=ALL PRODUCTS (last visited Dec. 2, 2012).
87. FDA, GUIDANCE DOCUMENT FOR THE PREPARATION OF PREMARKET NOTIFICATION [150(K)] APPLICATIONS FOR THERAPEUTIC MASSAGERS AND VIBRATORS 4 (1997) (emphasis omitted) ("It is not necessary to notify FDA of an intent to market a device if it will not be labeled or promoted for medical uses.").
88. *See, e.g.*, Fire Pots and Gel Fuel, 76 Fed. Reg. 80,832 (proposed Dec. 27, 2011) (discussing how the CPSC investigation and analysis led to the advanced notice of proposed rulemaking).
89. 16 C.F.R. § 1051.2(a).

1. Regulation Initiated Internally by the CPSC

It is unlikely that the CPSC would act of its own accord to regulate sex toys, although the number of sex-toy-related injuries is sufficient to merit the CPSC's designation of sex toys as products that have an unreasonable risk of injury. The CPSC collects data "on product hazards from hospitals, medical examiners', coroners' reports, and review of [the agency's] news clips."[90] When the CPSC judges the danger to be severe or widespread enough, this information can serve as the basis for an investigation that culminates in a rulemaking.[91] Judging from past CPSC rulemakings, the emergency room statistics on sex-toy injuries, as discussed in Part I.A of this Commentary, are sufficiently numerous—6,799 over an eleven year period or an average of 618 injuries per year[92]—to merit concern about the safety of these products and justify a CPSC rulemaking.

Past Advanced Notices of Proposed Rulemakings (ANPRMs), both recent and in the more distant past, show that the CPSC has undertaken rulemakings where the rate of injury was approximately the same as those caused by sex toys or lower. For example, the 2012 ANPRM for a Safety Standard for Magnet Sets, which applied to small, extra-strength magnets that children frequently swallow, noted 1,700 injuries over a three-year period or an average of 567 injuries per year.[93] Another 2012 ANPRM, for Safety Standards for Bassinets and Cradles, noted 335 incidents over a four-year period or an average of eighty-nine per year.[94] A 2001 ANPRM for Household Products Containing Hydrocarbons reported a rate of 1,200 potential aspiration injuries over a two-year period or 600 injuries per year.[95] In a 1996 ANPRM for Plastic Buckets, the CPSC considered incidents in which children had fallen headfirst into buckets and drowned or were injured.[96] The agency characterized "more than 250 instances" over ten years, or 25 per year, to be an "unreasonable risk of injury."[97] Another 1996 ANPRM for Amendments to Requirements for Full-Size and Non-Full-Size Baby Cribs noted twelve injuries and deaths in an eleven-year period, or roughly one per year, and judged this level to be an unreasonable risk of injury and death.[98] Although some of the Commission's ANPRMs discuss the severity

90. STRATEGIC PLAN, *supra* note 57, at ii, 70-77.
91. *See, e.g.*, Merrill *supra* note 52, at 1354-60 (discussing the CPSC's initiation of formaldehyde regulation).
92. Griffin & McGwin, *supra* note 13, at 255.
93. Safety Standard for Magnet Sets, 77 Fed. Reg. 53,781 (proposed Sept. 4, 2012) (to be codified at C.F.R. pt. 1240).
94. Safety Standard for Bassinets and Cradles, 77 Fed. Reg. 64,055 (proposed Oct. 18, 2012) (to be codified at C.F.R. pts. 1112, 1218).
95. Household Products Containing Hydrocarbons, 66 Fed. Reg. 18,738 (proposed Apr. 11, 2001) (to be codified at 16 C.F.R. pt. 1700).
96. Plastic Buckets, 59 Fed. Reg. 35,058 (proposed July 8, 1994) (to be codified at 16 C.F.R. pt. 1307).
97. *Id*.
98. Amendments to Requirements for Full-Size and Non-Full-Size Baby Cribs, 61 Fed. Reg.

and types of injuries in detail,[99] other ANPRMs treat them in a more conclusory manner.[100] The data available on sex-toy-related injuries in the National Electronic Injury Surveillance System (NEISS), which reports injuries treated in hospital emergency rooms, does not address the severity of the harm,[101] although presumably the harm was grave enough to convince the victim to seek emergency room services despite the embarrassment caused by such an injury. While more research into the causal factors behind sex-toy-related injuries would be helpful to making a careful evaluation, the frequency of such injuries suggests that sex toys are at least worthy of investigation by the CPSC.

Another potential internal way of bringing sex toys to the attention of the CPSC is its new product complaint database. As part of the passage of the Consumer Product Safety Improvement Act (CPSIA) in 2008, the CPSC launched SaferProducts.gov, a website containing a searchable database of reviews of consumer goods alongside an online method for reporting unsafe products.[102] While a search of SaferProducts.gov reveals only one consumer complaint about vibrators,[103] a query of CPSC's NEISS, revealed forty-one injuries from sex toys classified as "massage devices or vibrators" during 2011.[104] The injuries were mostly caused by vibrators or dildos becoming lodged inside the rectum or vagina, although there were also reports of vaginal bleeding, parts of vibrators breaking off inside of people during usage, pelvic pain, and vaginal candidiasis[105] attributed to sex toys.[106] If SaferProducts.gov becomes more widely used, consumers reporting the same type of sex-toy-related injuries

65996-97 (proposed Dec. 16, 1996) (to be codified at 16 C.F.R. pts. 1508, 1509).

99. *See, e.g.*, Safety Standard for Bassinets and Cradles, 77 Fed. Reg. at 64,056-58 (discussing fatalities, injuries, and the causal factors of the harm); Safety Standard for Magnet Sets, 77 Fed. Reg. at 53,783 (discussing the nature of the injuries and including specific incidents reported).

100. *See, e.g.*, Plastic Buckets, 59 Fed. Reg. 35,060 (*see* Part E. Risks of Injury and Death, discussing the age, socioeconomic status, and race of the victims in more depth than the nature and severity of the injuries).

101. NEISS hospitals collect data related to each injury that correlates to date, product, sex, age, diagnosis, number of persons admitted, locale, and body part. *National Electronic Injury Surveillance System (NEISS) On-line*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/library/neiss.html (last visited January 16, 2013).

102. *SaferProducts.gov*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.saferproducts.gov/ (last visited Nov. 24, 2012).

103. *Incident Report Details, Report No. 20120517-65AF0-2147467529*, SAFERPRODUCTS.GOV (June 15, 2012), http://www.saferproducts.gov/ViewIncident/1248612.

104. The author ran a search for injuries caused by products coded 1610 (massage device or vibrator) during 2011. *See* U.S. CONSUMER PROD. SAFETY COMM'N, NEISS CODING MANUAL 83 (2012), *available at* www.cpsc.gov/neiss/completemanual.pdf. Injuries clearly not caused by sex toys were not counted toward the results, leaving forty-one injury reports that were explicitly caused by sex toys. A search can be run at *NEISS Estimates Query Builder*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, https://www.cpsc.gov/cgibin/NEISSQuery/home.aspx (last visited Dec. 12, 2012).

105. Vaginal candidiasis is "an infection of the vagina involving overgrowth of a yeast, or fungus, known as Candida." *Vaginal Candidiasis*, BETTER MED. (May 2, 2011), http://www.localhealth.com/article/vaginal-candidiasis.

106. The resultant report from the author's NEISS search is on file with the author.

that appear in the NEISS database could alert the CPSC to some of the dangers of sex toys[107] and instigate rulemaking. One way to increase reports of sex-toy injuries to Saferproducts.gov would be encouragement through websites related to sexual health, sex shops, and similar groups. Although the CPSC has not explicitly indicated its intent to use SaferProducts.gov as a source for prompting rulemaking,[108] the Federal Trade Commission uses a similar consumer complaint database, Consumer Sentinel, as a way of monitoring risks that may result in agency action.[109] Of course, for this to be a viable way of engaging the CPSC, consumers would have to overcome the embarrassment that Americans tend to carry regarding sex-toy usage.[110] Theoretically, if enough consumers reported sex-toy injuries, SaferProducts.gov could function as an initiator for the CPSC's investigations and rulemaking.

Despite the relative frequency of sex-toy-related injuries, an investigation initiated by the CPSC that leads to rulemaking seems very unlikely. Although the passage of the CPSIA in 2008 increased the agency's funding and legislative mandate,[111] the CPSC still focuses heavily on regulations aimed at protecting children and the elderly.[112] As a small agency,[113] it is doubtful that the CPSC would want to expend political capital or the necessary resources to initiate regulation of the sex-toy industry. Such a move would probably be contentious and unpopular due to the conservative movement toward restricting sexual liberty and prescribing morality,[114] which has persisted even though Americans

107. Because NEISS only reports injuries from emergency room visits and the effects of phthalate exposure are cumulative and not acute, it is unlikely that rulemaking stemming from SaferProducts.gov complaints would address the chemical composition of sex toys. For more information on how phthalates injure the body, see generally Rachael Rawlins, *Teething on Toxins: In Search of Regulatory Solutions for Toys and Cosmetics*, 20 FORDHAM ENVTL. L. REV. 1 (2009); James Bothwell, *Toy Story: Timeout for Phthalates*, 39 MCGEORGE L. REV. 551, 556-62 (2008).

108. The CPSC does characterize SaferProducts.gov as part of the agency's method of identifying hazards to inform agency priorities. *See* U.S. CONSUMER PROD. SAFETY COMM'N, 2011 PERFORMANCE AND ACCOUNTABILITY REPORT 69 (2011).

109. The FTC may investigate and ultimately prosecute offenders based off of reports from their consumer complaint database Consumer Sentinel. *See Before You Submit a Complaint*, FED. TRADE COMM'N, https://www.ftccomplaintassistant.gov/ (last visited Dec. 9, 2012).

110. *See supra* note 24.

111. STRATEGIC PLAN, *supra* note 57, at 5.

112. *See* 16 C.F.R. § 1009.8(c)(6) (explaining that the CPSC considers in setting priorities the vulnerability of the population at risk, such as children, the elderly, and the disabled).

113. The Department of Justice lists the CPSC as a small agency, defined as having between 100 and 999 employees. U.S. DEP'T OF JUSTICE, CIVIL RIGHTS DIV., SECTION 508 OF THE REHABILITATION ACT: ACCESSIBILITY FOR PEOPLE WITH DISABILITIES IN THE INFORMATION AGE (RESULTS OF 2001 SURVEY), I.X. AGENCIES LISTED BY SIZE CATEGORIES (2004), *available at* http://www.justice.gov/crt/508/report2/agencies.php.

114. *See* Diane di Mauro & Carole Joffee, *The Religious Right and the Reshaping of Sexual Policy: An Examination of Reproductive Rights and Sexuality Education*, 4 SEXUALITY RES. & SOC. POL'Y 67 (2007); Steven Epstein, *The New Attack on Sexuality Research: Morality and the Politics of Knowledge Production*, 3 SEXUALITY RES. & SOC. POL'Y 1 (2006); *see also* Tracy Clark-Flory, *The GOP's Bizarre War on Sex*, SALON (Jan. 7, 2012), http://www.salon.com/2012/01/07/its_the_sex_stupid/.

appear to be gravitating toward a more liberal attitude to sexuality.[115] Although very recently consumer awareness of the risks of sex toys has improved,[116] this sentiment has not become mainstream enough to put pressure on the CPSC to take action. Instead, regulations initiated by petition from consumer groups or individuals have a greater chance of spurring agency action.

2. Regulations Initiated by Petition

Parties may petition the CPSC to initiate rulemaking activities that could set standards for the sex-toy industry.[117] Petitions may be brought by "[a]ny person," including groups.[118] Either industry stakeholders or consumer protection watchdog groups typically bring petitions for regulation of consumer goods. Unlike some industries where manufacturers or other stakeholders desire regulation,[119] the sex-toy industry has very little reason to bring a petition. Individual consumers would be unlikely to bring a petition for a number of reasons. For example, many consumers are unaware that sex toys can be dangerous,[120] and the industry does not have any coalition or official body with which to interface, making lobbying efforts difficult.[121] Using cheap plastics containing chemicals like DEHP and other phthalates also allows manufacturers to make a large profit off of sex toys, which they likely would be loath to change.[122] Therefore, a more probable candidate for bringing such a petition would be an organization or group, rather than the sex-toy industry itself or individual consumers.

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115. For example, public opinion in support of same-sex marriage has increased dramatically in the past ten years, and the BDSM erotica trilogy *Fifty Shades of Grey* spent forty-four weeks (at the time this commentary was written) on the New York Times' Bestseller list. *Changing Attitudes on Gay Marriage*, PEW F. ON RELIGION & PUB. LIFE (Nov. 2012), *available at* http://features.pewforum.org/same-sex-marriage-attitudes/; *Best Sellers*, N.Y. TIMES (Jan. 13, 2013), http://www.nytimes.com/best-sellers-books/2013-01-13/overview.html; *see also* Christie Nicholson, *Attitudes Towards Sex are Changing: Scientific American Podcast*, SCI. AM. (Aug. 19, 2012), http://www.scientificamerican.com/podcast/episode.cfm?id=attitudes-towards-sex-are-changing-12-08-19.

116. *See, e.g.*, *Safe Sexual Products Campaign*, NAT'L ASSOC. FOR ADVANCEMENT SCI. & ART SEXUALITY, http://naasas.com/safe-sexual-products.htm (last visited Dec. 2, 2012); Madsen, *supra* note 24; Andrea Neblett, *Are Sex Toys Dangerous?*, QUALITY HEALTH (Aug. 11, 2009), http://www.qualityhealth.com/sexual-health-articles/sex-toys-dangerous; Tristan Taormino, *Dangerous Dildos, Part 1*, VILLAGE VOICE (Jan. 30, 2007), http://www.villagevoice.com/2007-01-30/columns/dangerous-dildos-part-1/; Violet Blue, *Unsafe Sex Products and Toys—Consumer Beware*, TINY NIBBLES, http://www.tinynibbles.com/unsafe (last visited Dec. 9, 2012).

117. 16 C.F.R. § 1051.2(a).

118. *Id.*

119. For example, industries where consumers have ready access to information about the products would desire regulation to encourage all industry players to be forced to adhere to the same standards, so that they would be forced to carry the same costs for protecting consumers.

120. *See* Madsen, *supra* note 24.

121. Biesanz, *supra* note 6, at 222.

122. *Id.* at 232.

Several groups already in existence make logical candidates for petitioning the CPSC. One obvious choice is the Coalition Against Toxic Toys (CATT), a network of adult shops, educators, manufacturers, and other organizations whose mission is to "demystify the adult sex-toy industry and positively transform socially irresponsible, environmentally and personally hazardous sex-toy manufacturing and sex-toy sales practices."[123] Another similar group that is well-positioned to petition the CPSC is the National Association for the Advancement of Science & Art in Sexuality (NAASAS). NAASAS is an "academic organization and coalition that serves professionals in the field of sexuality and adult industry" by providing classes, workshops, webinars, resources, and consulting, including "work[ing] with professionals in promoting nontoxic sexual products from personal lubricants to sex toys."[124] LGBQ organizations could also be a source of potential petitioners, because LGBQ community members use sex toys more than the general public.[125] However, many in the LGBQ community would probably be unwilling to do this because of significant efforts by mainstream LGBQ groups over the past few decades to "normalize" their image.[126] Campaigning for regulation of sex toys could potentially reinforce the image of the LGBQ community as "sexual deviants." Thus, it is unlikely that many mainstream LGBQ groups would choose to petition. In addition to groups like CATT and NAASAS, individual consumers could also petition the CPSC, although it would be much more difficult for an individual to marshal the necessary data for a successful petition.

A petition must identify the "facts which establish the claim that the issuance, amendment, or revocation of the rule is necessary,"[127] as well as an "explicit request to initiate Commission rulemaking and . . . a brief description of the substance of the proposed rule or amendment or revocation thereof which it is claimed should be issued by the Commission."[128] Any relevant data and evaluation on the severity and nature of the risks should be included.[129]

In considering whether to grant petitions, the Commission considers three factors: (1) whether the product poses "an unreasonable risk of injury"; (2)

123. *About CATT*, COALITION AGAINST TOXIC TOYS, (Aug. 20, 2012), http://badvibes.org/category/about-catt/.

124. *About Us*, NAT'L ASSOC. FOR ADVANCEMENT SCI. & ART SEXUALITY, http://naasas.com/about-us.htm (last visited Dec. 12, 2012).

125. Herbenick et al., *supra* note 2, at 55; Reece et al., *supra* note **Error! Bookmark not defined.**, at 1869.

126. *See* Gust Yep et al., *Assimilationist and Radical Ideologies Underlying Same-Sex Marriage in LGBT Communities in the United States*, 45 J. HOMOSEXUALITY 45, 51 (2003). Normalization of the LGBQ community is best illustrated by some LGBQ groups' desire for equal marriage rights, which some view as undesirable assimilation into the heteronormative mainstream culture. *Id.* ("One of the central themes of the assimilationist position is that sexual behavior has to be moderated, because unstructured sexual license leads to considerable social destabilization, which among other things, is destructive to the process of raising children").

127. 16 C.F.R. § 1051.5(a)(4) (2013).

128. § 1051.5(a)(5).

129. § 1051.5(b).

whether the "rule is reasonably necessary to eliminate or reduce the risk of injury"; and (3) if failure to take the rulemaking action would unreasonably expose consumers to injury or risk.[130] The Commission considers those factors in light of the CPSC's overall priorities and resources, which vary from year to year.[131] For 2011-2016, the CPSC's goals are "to provide outreach and technical assistance to domestic and foreign stakeholders; facilitate the development of voluntary standards and undertake mandatory rulemaking where consistent with statutory authority; issue recalls; and impose civil penalties."[132]

As discussed in Part II.D.1, sex-toy-related injuries fulfill the first factor by posing an "unreasonable risk of injury,"[133] although more research is needed to fully understand the prevalence, severity, and causes of these injuries. It would not be unreasonable to find that products made with phthalates pose a risk, because the Commission already regulates phthalates in children's toys and baby products. While children tend to carry a higher metabolic rate of phthalates than adults, adults are still affected.[134] In particular, children may carry increased phthalate loads because of their frequent contact with phthalate-containing products that are in direct contact with their skin, such as toys that are chewed or sucked on.[135] Therefore, phthalate-containing sex toys that come into direct contact with adults' skin should similarly trigger concern. Under the CPSIA passed in 2008, six phthalates are now essentially eliminated from children's toys.[136] The CPSIA also created a Chronic Hazard Advisory Panel on Phthalates "to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles."[137] The data the Phthalate Panel collects might bring to light some dangers that phthalates pose in adult populations, which could assist the Commission in finding that phthalates create an unreasonable risk of harm. In addition, the Environmental Protection Agency (EPA) and the FDA also regulate phthalates and thus presumably have evidence showing harm from phthalate exposure.[138] The CPSC labels DEHP as a

130. § 1051.9(a)(1)-(3). When contemplating completely banning a hazardous material, the Commission considers a fourth prong. § 1051.9(a)(4).

131. § 1051.9(b).

132. STRATEGIC PLAN, *supra* note 57, at 4.

133. 16 C.F.R. § 1051.9(a)(2).

134. *See* Sheela Sathyanarayana et al., *Baby Care Products: Possible Sources of Infant Phthalate Exposure*, 121 PEDIATRICS 260, 261 (2008) ("Phthalate metabolic concentrations tend to be higher in young children as compared to other age groups . . . . [o]f particular concern for children is sucking and playing with plastic toys and child care products that are used directly on the skin.").

135. *Id.*

136. 15 U.S.C. § 2057c.

137. § 2057c(2)(A); *see also Chronic Hazard Advisory Panel (CHAP) on Phthalates*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/about/cpsia/chapmain.html#otherDocs (last visited Dec. 10, 2012).

138. *See, e.g.*, 21 C.F.R. § 177.1200(c) (FDA regulating the phthalate content of cellophane for food use); 40 C.F.R. § 302.4 (EPA listing of various phthalates as hazardous substances); 40 C.F.R. § 372.65 (various phthalates listed by the EPA as a toxic chemical for purposes of Toxic Chemical Reporting).

hazardous substance for purposes of the Federal Hazardous Substances Act, meaning that it considers DEHP to be toxic to humans.[139] In the past, the CPSC has relied on evidence from outside sources such as other agencies, like the EPA, and industry stakeholders to initiate rulemaking.[140] Thus, a petition addressing phthalates in sex toys would be more likely to result in deeming them unreasonable risk than one addressing design flaws or labeling.

The second factor asks "whether a rule is reasonably necessary to eliminate or reduce the risk of injury."[141] In this step, the Commission considers alternative methods of reducing harm, whether the rule will drive consumers to other equally dangerous products, and the level of the burden upon users of the product.[142] Specifically, "costs to consumers . . . are to be considered: increases in price, decreased availability of a product, and also reductions in product usefulness."[143] Several potential rules could reduce risks to consumers from sex toys. One might set maximum levels of phthalates such as DEHP and DINP in the plastics used in sex toys, which could reduce long-term toxic exposure. Another example might mandate flared bases for toys intended for anal use or warnings on toys not intended for anal use to alert consumers to the dangers of incorrect use of these toys.

The Commission also considers whether "consumers [are] unaware of either the severity, frequency, or ways of avoiding the risk. If consumers have accurate information, and still choose to incur the risk, then their judgment may well be reasonable."[144] Some sex-toy injuries likely occur because people do not know how to properly use them and are too embarrassed to ask a salesperson or educate themselves.[145] Furthermore, the taboo surrounding sex toys makes it difficult for consumers to learn about and compare products. Warnings and

139. Memorandum from Kent. R. Carlson, Toxicologist, Directorate for Health Sciences, U.S. Consumer Prod. Safety Comm'n, to Michael A. Babich, Project Manager, Phthalates, Section 108 of CPSIA (Apr. 1, 2010).

140. *See* Merrill, *supra* note 52, at 1319-20 (discussing the CPSC drawing on the conclusions of the Federal Interagency Task Force on Inadvertent Modification of the Stratosphere and the National Academy of Science to find that chlorofluorocarbon propellants posed a hazard and should carry warning labels); *id.* at 1340 (discussing the CPSC relying partly on information from OSHA and the EPA's recent listing of benzene as a pollutant as evidence for rulemaking).

141. 16 C.F.R. § 1051.9(a)(2).

142. *See* Response to Petition from Dr. Michael Fox, U.S. CONSUMER PROD. SAFETY COMM'N (Apr. 11, 2006) at 2; Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831, 839 (5th Cir. 1978) ("The necessity for the standard depends upon the nature of the risk, and the reasonableness of the risk is a function of the burden a standard would impose on a user of the product.").

143. *Id.*

144. *Id.*

145. Biesanz, *supra* note 6, at 220 ("Sex toys are becoming less taboo and more mainstream, so for many consumers, sex toys are an entirely new line of products about which they know very little. It is unlikely that many consumers can even pronounce 'phthalate,' much less recognize it as a dangerous toxin, but even those few who understand the risk involved with such chemicals cannot use that knowledge if they do not know the composition of the products. If consumers do not know about the risks involved in the products they purchase, they cannot factor those risks into the decision whether to buy a product.").

product labeling could help alleviate this information gap and educate consumers on proper usage to lessen the chance of injury. Additionally, because rules could mandate a standard across the entire industry for certain kinds of toys (such as requiring all vibrators to be DEHP-free), consumers would not be able to simply switch to another product that carried a greater risk.

The economic burden of these changes on consumers would be slight, and product utility would not suffer. When looking at the economic implications, the Commission "does not have to conduct an elaborate cost-benefit analysis."[146] Mandating materials made without phthalates may increase the cost of sex toys marginally, as would labeling and design changes. However, many moderately priced sex toys on the market already feature safe materials and would require only minimal packaging changes to accommodate warnings and other instructions.[147] Accordingly, the utility of sex toys would not suffer, as products already exist on the market with the same functionality.[148] While further research on sex-toy usage and injuries is necessary to determine how best to reduce or eliminate sex-toy hazards,[149] many standards could potentially satisfy the Commission's requirement that a rule eliminate or reduce the risk of injury.

The third factor asks whether failure to take rulemaking action would "unreasonably expose the petitioner or other consumers to the risk of injury."[150] This largely depends on the previous two factors, because "the meaning of 'unreasonable risk' . . . is interrelated with the 'reasonably necessary' requirement."[151] Because some sex toys likely pose an unreasonable danger that could be reduced or eliminated by setting industry standards, the Commission's failure to engage in rulemaking would unreasonably subject consumers to toxic and ill-designed toys. The current lack of regulation in the industry should weigh even more heavily on the Commission's decision, because the average consumer has no assurance when they buy a sex toy that it will be safe and will include instructions on its proper use. Therefore, this prong should not be an obstacle to a petition seeking regulation of sex toys.

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146. *Aqua Slide 'N' Dive Corp*., 569 F.2d at 840; *see also* D. D. Bean & Sons Co. v. Consumer Prod. Safety Comm'n, 574 F.2d 643, 648 (1st Cir. 1978).

147. The Smitten Kitten is one example of a sex-toy shop that offers non-toxic and well-designed sex toys while seeking to educate consumers about possible dangers. *See, e.g.*, *As Heard on Savage Love*, SMITTEN KITTEN, https://www.smittenkittenonline.com/savage-love.html (last visited Dec. 10, 2012).

148. The Commission's analysis must weigh the utility of the product against the proposed design changes. *See, e.g.*, *Aqua Slide 'N' Dive Corp*., 569 F.2d at 839-40 ("a sharp knife might pose a reasonable risk of injury, because dulling the blade to make it safe would also make it useless. A sharp knife in a child's silverware set, however, might be unreasonable. In the Forester case, the D.C. Circuit found the Commission failed to show the risk of protrusions on a bicycle frame was unreasonable because it had not considered the extent to which a regulation which banned the protrusions would impair the bicycle's utility.").

149. Courts reviewing petition decisions demand actual "substantial" evidence that warnings or other standards would decrease the risk posed by a product. *Id.* at 841-42.

150. 16 C.F.R. § 1051.9(a)(3).

151. *Aqua Slide 'N' Dive Corp*., 569 F.2d at 839; *see also* Response to Petition from Dr. Michael Fox, *supra* note 142, at 2.

Examining the petition process indicates that sex toys fulfill the criteria the Commission considers in granting petitions for rulemaking.[152] Petitions initiated by consumers or other agency outsiders have led to rulemakings in the past and can be an important method of agency priority-setting and regulation on critical issues.[153] However, whether the Commission would actually grant such a petition also depends on intangible factors such as the political leanings of Commissioners,[154] agency resources, and whether the Commission would have the political willpower to address an uncomfortable topic.[155] If a petition to regulate sex toys did initiate rulemaking, it could result in the promulgation of either voluntary rules negotiated with the industry or mandatory rules enforced by the CPSC.

C. Voluntary Versus Mandatory Rules

The CPSC can promulgate either voluntary or mandatory rules if the agency chooses to take action after an investigation or petition. Mandatory standards are set when the CPSC "determines that compliance with a voluntary standard would not eliminate or adequately reduce a risk of injury or finds that it is unlikely that there will be substantial compliance with a voluntary standard."[156] Mandatory regulations for consumer products may include performance or design standards or warning labels that products must carry.[157] However, promulgating mandatory regulations is a lengthy process[158] that, in the CPSC's case, caters to industry demands and often leads to a voluntary agreement instead of a mandatory rule because of the unique rulemaking

152. "The Commission may choose to hold a public hearing" or begin an investigation to elicit more information before ruling on a petition. 16 C.F.R. § 1051.8(a). After this, the Commission must make a determination by voting to grant or deny the petition within a "reasonable time." § 1051.10(a).

153. Schwartz, *supra* note 53, at 47-52. See Eric Biber & Berry Brosi, *Officious Intermeddlers or Citizen Experts? Petitions and Public Production of Information in Environmental Law*, 58 UCLA L. Rev. 321 (2010), for an in-depth discussion of the value of outside petitions and how agencies can best utilize these kinds of petitions in the context of environmental agencies.

154. *See* Neal Devins & Davis Lewis, *Not So Independent Agencies: Party Polarization and the Limits of Institutional Design*, 88 B.U. L. REV. 459 (2008).

155. Not all governments are so loath to address sex toys: ten parliament members of Germany's Green Party urged that action be taken on sex toys containing phthalates and other chemicals. However, the central government's response was indifferent. Anna Reiman, *Safer Sex: Greens Warn Against Dangerous Dildos*, SPEIGEL ONLINE (July 1, 2011), http://www.spiegel.de/international/germany/safer-sex-greens-warn-against-dangerous-dildos-a-771863.html.

156. U.S. CONSUMER PROD. SAFETY COMM'N, 2011 PERFORMANCE AND ACCOUNTABILITY REPORT, 5 (2011).

157. *Id.*

158. *See* Cornell, *supra* note 58, at 265 (explaining that the CPSC must first decide that a mandatory rule is necessary, then issue an Advance Notice of Proposed Rulemaking, then within a year issue a publish a Notice of Proposed Rulemaking, and within sixty days either publish the final rule or withdraw the Notice of Proposed Rulemaking).

procedures the CPSC must follow.[159]

Unlike many other agencies, the CPSC's procedure contains extra steps that allow the industry a significant degree of control over the final outcome. For example, the CPSC must halt rulemaking if the industry submits a voluntary standard during the process that is likely to resolve the risk of injury and garner compliance.[160] Before publishing the final rule, the CPSC must consider and make findings on any other potential ways of achieving the goal that minimize "adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety."[161] The CPSC also may not promulgate a final rule where compliance with a voluntary standard eliminates or adequately reduces the risk of injury and there is substantial industry compliance, or if there is a less burdensome regulation which sufficiently reduces the risk of injury.[162] These requirements effectively give the industry the power to intervene and preempt rulemakings. Doing so deters the CPSC from mandatory rulemakings and favors industry at the expense of consumer interests.[163]

Voluntary guidelines that arise when an industry intervenes to stop a mandatory rulemaking can fail to protect consumers. Before the CPSIA essentially banned DEHP and six other phthalates from children's toys in 2008, the CPSC had negotiated a voluntary agreement with the children's toy industry and major retailers.[164] Beginning in 1983, the CPSC studied the effects of phthalates in polyvinyl chloride (PVC), a plastic used to manufacture children's toys, baby bottles, pacifiers, and similar items.[165] DEHP was among these chemicals that the CPSC determined "might result in a substantial exposure of children to a substance that causes cancer in animals."[166] Voluntarily, the industry agreed to stop the use of DEHP in certain children's toys and baby products.[167] In the late 90's the CPSC again negotiated a voluntary agreement with toy manufacturers and retailers to remove DINP and another phthalate, dioctyl phthalate, from certain children's items.[168] Despite this, phthalates, including DEHP and dibutyl phthalate (DBP), were still found in children's toys—yet phthalates were never banned or subject to mandatory regulation through the CPSC's rulemaking process.[169] Only congressional action finally

159. *See, e.g.*, U.S. CONSUMER PROD. SAFETY COMM'N, VOLUNTARY STANDARDS ACTIVITIES 10/1/11-3/31/12 (2012).
160. 15 U.S.C. § 2058(b)(2).
161. *Id.* at § 2058(f)(1)(D).
162. *Id.* at § 2058(f)(3)(D), (F).
163. *See* Cornell, *supra* note 58, at 265-66.
164. Marilyn Wind, *Phthalates in Plastic Toys*, 8 CONSUMER PROD. SAFETY REV. 1, 4 (Summer 2003).
165. *Id.*
166. *Id.*
167. *Id.*
168. *Id.*
169. THE RIGHT START: THE NEED TO ELIMINATE TOXIC CHEMICALS FROM BABY PRODUCTS, U.S. PIRG EDUCATION FUND 18 (2005).

eliminated the use of three phthalates (DINP, DIDP and DnOP2) in an amount more than 0.1 percent and allowed less than 0.1 percent of three other phthalates (DEHP, DBP or benzyl butyl phthalate (BBP)) on an interim basis.[170] The CPSIA also mandated the Phthalate Panel to conduct testing of the health effects of phthalates commonly found in children's toys and products.[171] The CPSC's previous inability to protect consumers from phthalates in the more centralized and scrutinized children's toy industry suggests that voluntary guidelines for the sex-toy industry would suffer similar problems. It fact, the sex-toy industry would be more likely to get away with breaking voluntary guidelines because consumers are so ill-informed about sex toys.

The CPSC can promulgate mandatory rules if it determines that consumers would not be protected by voluntary industry agreement, but it is difficult for the Commission to demonstrate that a voluntary agreement would not sufficiently protect consumers. Judicial review of the Commission's rulemaking decisions is not the normal arbitrary and capricious standard but a higher level of review where the Commission's actions must be "supported by substantial evidence on the record taken as a whole."[172] While the sex-toy industry appears very decentralized,[173] it seems likely that the industry would respond to the prospect of regulatory action by creating voluntary guidelines to stave off mandatory rules. It would also be difficult for the Commission to preemptively show that manufacturers and retailers would not honor the voluntary agreements. Thus, the most likely outcome of a rulemaking action on sex toys would be voluntary industry agreement.

Although voluntary guidelines are not as strong as a mandatory rule, they would be more effective in protecting consumers than the current total lack of regulation for sex toys. With a little more research and the right group bringing a petition, a voluntary agreement with industry manufacturers and retailers could help protect and educate consumers. Such a potential rule could take the form of limits on chemical content, design standards, or packaging and labeling requirements.[174]

IV. CONCLUSION

Statistically, a sex toy will be part of most Americans' sex lives at some point.[175] Whether one plays with a simple vibrator, a double dildo, or anal beads, the last thing anyone wants from their experience is to end up in the emergency

170. *FAQs: Ban on Pthalates in Children's Toys*, U.S. CONSUMER PRODUCT SAFETY COMMISSION, http://www.cpsc.gov/Regulations-Laws—Standards/CPSIA/Phthalates/FAQs-Bans-on-Phthalates-in-Childrens-Toys/ (last visited Dec. 12, 2012).

171. 15 U.S.C. § 2057c.

172. Aqua Slide 'N' Dive Corp. v. Consumer Prod. Safety Comm'n, 569 F.2d 831, 835 (5th Cir. 1978).

173. Biesanz, *supra* note 6, at 205-206, 222.

174. The specifics of a model rule are beyond the scope of this Comment.

175. Reece, *supra* note 1; Herbenick, *supra* note 2.

room. The fact that sex toys can cause serious injury or introduce toxins into users' bodies should and increasingly does concern consumers.[176] The federal regulatory system has not addressed these hazards yet, although it protects consumers from phthalates and dangerous design defects in other products. The lack of regulation may stem from consumers' lack of information about sex toys, a lack of will to expend political capital on an unpopular topic, or discomfort with sex. However, regulation from the CPSC that could result in voluntary or mandatory standards is possible through the petition process. Consumer groups such as CATT or NAASAS should take advantage of public participation in setting the CPSC's regulatory agenda by petitioning for safer sex toys. Although generally the bedroom is not a place most people desire the government's presence,[177] where sex toys are concerned, the government has the power to protect consumers and the public should demand that this power be exercised.

176. *See* discussion *supra* note 116.

177. For example, the LGBTQ community spent years trying to decriminalize sodomy and get the government "out of the bedroom." *See* Lawrence v. Texas, 539 U.S. 558 (2003) (overturning Bowers v. Hardwick, 478 U.S. 186 (1986) (upholding criminal punishment for sodomy)).