# Penetrating FDA Regulation: Justifications for FDA Oversight of Sex "Toys" as Medical Devices

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*Sex devices, commonly referred to as "toys,"** have grown in popularity over the past decade and somehow evaded regulations from consumer protection agencies. The Consumer Product Safety Commission (CPSC) has no specific regulatory standards for sex devices, regulating them as "novelty toys." And the Food and Drug Administration (FDA) unnecessarily limits its oversight by only regulating "therapeutic" sex devices. These shortcomings create significant regulatory gaps, exposing consumers to harm, leading to thousands of emergency room visits annually. This Comment argues that FDA jurisdiction over sex devices as "medical devices" is appropriate and necessary to protect consumer health, especially for women and LGBTQ+ communities who are more likely to experience harm from sex devices.*

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** The word "toys" is in quotations because manufacturers' use of the word toy is one way they avoid regulation.

## INTRODUCTION

The common perception of products regulated by the Food and Drug Administration (FDA) typically does not include dildos, butt plugs, nipple clamps, or vibrators. Yet, as the FDA is the oldest consumer protection organization in the country, this Comment invites the FDA into the bedroom to protect the pleasure of the people. Many sex instruments or devices are currently regulated

as novelty toys and 'gag gifts,' which require fewer quality controls and warnings for consumers, allowing harm to sex toy[1] users that can be traumatizing and taboo to discuss.[2] This Comment argues that the FDA is the favorable agency to regulate sex devices.

Part I introduces the current regulatory regime, or lack thereof, for sex devices as well as the harms these devices present to consumers. Part II argues that it is permissible for the FDA to regulate adult sex devices because they fit the literal definition of medical devices under the Food, Drug, and Cosmetics Act (FDCA). Part III establishes how the FDA could extend jurisdiction over sex devices by utilizing the intended use of the products through a review of sex toy promotional materials. Part IV explores additional policy arguments in favor of designating the FDA as the appropriate agency to regulate sex devices, including legislative intent, the agency's role in protecting vulnerable consumers, and providing a consistent regulatory regime. Part V concludes by showcasing the efficiencies of FDA regulation that support this solution and providing guiding principles that would address concerns of overbreadth regulation by the agency.

## I. THE ISSUES WITH SEX TOYS

### A. THE FDA AND THE (LACKING) REGULATORY REGIME OF SEX TOYS

The FDA is the oldest comprehensive consumer protection agency in the United States[3] with a mission to protect and promote public health.[4] In 1976, Congress passed the Medical Device Amendments to give the FDA oversight of medical devices.[5] As of October 2024, the FDA regulates the safety of over $3.9 trillion worth of food, tobacco, and medical products produced in the

1. This Comment uses the terms sex toys and sex devices interchangeably. "Sex devices" is conceptually more in line with this Comment's argument, but "sex toys" is the colloquial use. For the purposes of this Comment, both terms should be read to mean the same thing.

2. *See* Joana Marie Sipe et al., *Bringing Sex Toys Out of the Dark: Exploring Unmitigated Risks*, 3 MICROPLASTICS AND NANOPLASTICS 1, 10–1 (2023).

3. *See FDA History*, U.S. FOOD & DRUG ADMIN. (June 12, 2018) (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/about-fda/fda-history.

4. *See About FDA*, U.S. FOOD & DRUG ADMIN. (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/about-fda (last visited Apr. 26, 2025).

5. *See* Medical Device Amendments of 1976, 21 U.S.C § 360c.

United States and abroad.[6] That total includes over 7,000 medical device products, more than half of which are imports.[7] Some of those medical devices currently include speculums,[8] examination gowns,[9] non-powdered examination gloves,[10] non-powered breast pumps,[11] enema kits,[12] acupuncture needles,[13] daily activity assist devices,[14] breast implants,[15] tampons,[16] patient lubricant,[17] condoms,[18] and menstrual cups.[19] Regarding sex devices, the FDA currently regulates penis pumps[20] and vibrators for therapeutic use[21] but does not regulate non-therapeutic penis pumps, dildos that do not use batteries, or sex devices that are promoted as "toys." Their exclusion permits regulatory loopholes and safety implications.[22]

Currently, the FDA only regulates certain sex devices as medical devices when they are marketed for therapeutic[23] purposes.[24] For instance, the FDA currently regulates therapeutic

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6. *See FDA at a Glance*, U.S. FOOD & DRUG ADMIN., (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/about-fda/economics-staff/fda-glance (Oct. 16, 2024).
7. *See id.*
8. *See* 21 C.F.R. § 878.1800 (2025).
9. *See* 21 C.F.R. § 880.6265 (2025).
10. *See* 21 C.F.R. § 880.6250 (2025).
11. *See* 21 C.F.R. § 884.5150 (2025).
12. *See* 21 C.F.R. § 876.5210 (2025).
13. *See* 21 C.F.R. § 880.5580 (2025).
14. *See* 21 C.F.R. § 890.5050 (2025).
15. *See* 21 C.F.R. § 878.3530 (2025); 21 C.F.R. § 878.3540 (2025).
16. *See* 21 C.F.R. § 884.5460 (2025); 21 C.F.R. § 884.5470 (2025).
17. *See* 21 C.F.R. § 880.6375 (2025).
18. *See* 21 C.F.R. § 884.5300 (2025); 21 C.F.R. § 884.5310 (2025).
19. *See* 21 C.F.R. § 884.5400 (2025).
20. *See* 21 C.F.R. § 876.5020 (2025).
21. *See* 21 C.F.R. § 884.5960 (2025).
22. For more on regulatory loopholes, see *infra* Part III; *see also* Shawna Seed, *What Is a Penis Pump?*, WEBMD (June 6, 2024), https://www.webmd.com/sex/what-is-a-penis-pump [https://perma.cc/STH7-2ST5]; Rebecca Strong, *Do Penis Pumps Work? What to Know About Vacuum Erection Devices, According to Experts.*, MEN'S HEALTH (Aug. 20, 2024), https://www.menshealth.com/sex-women/a44042618/do-penis-pumps-work/ [https://perma.cc/B6U5-WRGT]; *How to Find the Safest Penis Pump for Male Enhancement*, FACE MED STORE, https://facemedstore.com/blogs/blog/safest-penis-pump-for-male-enhancement-how-to-find [https://perma.cc/HW3C-48V7].
23. FDA regulations do not specifically define "therapeutic," but an *intended* therapeutic action or effect is defined as "any effect or action . . . intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body." 21 C.F.R. § 3.2 (2025).
24. *See* Emily Stabile, *Getting the Government in Bed: How to Regulate the Sex-Toy Industry*, 28 BERKELEY J. GENDER L. & JUST. 161, 170 (2013).

genital vibrators,[25] clitoral engorgement devices,[26] external penile rigidity devices such as penis pumps and penis constriction rings,[27] and vibrators for climax control of premature ejaculation.[28] The FDA regulates some sex devices as medical devices when they are advertised for therapeutic purposes, such as correcting sexual dysfunction.[29] However, similar sex devices that pose indistinguishable risks to consumers and are not explicitly marketed as "therapeutic" remain unregulated by the FDA.[30]

Sex devices not explicitly regulated by the FDA typically adhere to less scrutinous safety standards set by the Consumer Product Safety Commission (CPSC).[31] CPSC is an independent federal agency with a mission to protect the public from unreasonable risks of injury or death from consumer products.[32] CPSC has no specific standards for sex devices; thus, sex device importers and manufacturers follow voluntary safety standards and only report to the CPSC if their product poses a substantial risk of injury to the public.[33] This lack of oversight leads to sex devices being regulated by the same safety standards used for "massage devices,"[34] such as back scratchers and acupressure balls. The CPSC also does not publicly release any reports on sex device safety.[35]

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25. *See* 21 C.F.R. § 884.5960 (2025).
26. *See* 21 C.F.R. § 884.5970 (2025).
27. *See* 21 C.F.R. § 876.5020 (2025).
28. *See* 21 C.F.R. § 876.5025 (2025).
29. *See* 21 C.F.R. § 876.5020 (2023); 21 C.F.R. § 884.5960 (2025); 21 C.F.R. § 884.5970 (2025).
30. *See* Seed, *supra* note 22.
31. *See* Chuiyan Mo, *Sex Toy Safety Standards & Regulations in the United States: An Overview*, COMPLIANCE GATE (Apr. 12, 2022), https://www.compliancegate.com/sex-toys-regulations-united-states/ [https://perma.cc/L2GA-LQ8X].
32. *See About Us*, CONSUMER PROD. SAFETY COMM'N, (on file with the *Columbia Journal of Law & Social Problems*), https://www.cpsc.gov/About-CPSC (last visited Apr. 5, 2025).
33. *See* Mo, *supra* note 31. An example of general controls would be that importers and manufacturers are required to report to the CPSC if their product could create a substantial risk of injury to the public, for example, because of a manufacturing defect or a design issue. For more on the CSPC and possible ways sex toys could be regulated under their agency, see Stabile, *supra* note 24, at 169–84. It is worth noting, however, that this article is over a decade old and the CPSC has still decided not to provide specific regulations for sex toys.
34. Regina Nuzzo, *Good Vibrations: U.S. Consumer Web Site Aims to Enhance Sex Toy Safety*, SCI. AM. (May 24, 2011), https://www.scientificamerican.com/article/good-vibrations-us-consumer-web-site-aims-to-enhance-sex-toy-safety/ [https://perma.cc/EN69-DXMM].
35. *Id.*

In light of marketing sex devices as "novelty toys," the federal government does not require the more rigorous review of materials, labeling, or safety instructions mandated by the FDA.[36] By simply calling these devices "toys," companies can avoid regulations that would impose more stringent requirements for materials used, warnings included, and other consumer protections.[37] For example, sex devices receive less stringent regulations than children's toys regarding the level of toxic phthalates in the devices because children's toys have specified standards beyond general controls.[38] Though these sex devices may be "toys" in some capacity, this labeling can contribute to the thousands of injuries we see each year from these devices.

Sex devices are made from a variety of materials, some of which are considered safer than others. Sex toys are deemed safer when made from materials such as silicone, glass, or stainless steel.[39] Materials that are not considered safe can lead to increased risks of health complications.[40] Some public health experts note that sex devices have virtually no safety standards regulating which chemicals can be used to manufacture sex toys, leading to the use of potentially carcinogenic materials.[41] Phthalates, "a family of synthetic chemical compounds that increase the flexibility of plastics," can present chemical hazards, including short and long-term health effects.[42] A study testing the abrasion of four popular sex devices found that they all contained phthalates at rates banned in the United States and European Union for children's toys but legal for sex products.[43] However, many of the products in the study claim to be "body safe" or made of "body safe materials."[44] These studies emphasize the importance of safer

36. Sipe et al., *supra* note 2, at 10; *see also* Gray Babbs, *Rules of Play*, PUB. HEALTH POST (Nov. 30, 2020), https://www.publichealthpost.org/viewpoints/rules-of-play/ [https://perma.cc/CCT3-HABE].

37. *See* Stabile, *supra* note 24, at 162.

38. *See* Sipe et al., *supra* note 2, at 5; *see also* 16 C.F.R. § 1199.1 (2025).

39. *See* Jordan E. Rullo et al., *Genital Vibration for Sexual Function and Enhancement: Best Practice Recommendations for Choosing and Safely Using a Vibrator*, 33 SEXUAL & RELATIONSHIP THERAPY, 275, 277 (2018).

40. *See* L. Svobodova et al. *Safety Testing of Adult Novelties Using In Vitro Methods*, 117 REGUL. TOXICOLOGY & PHARMACOLOGY, 1, 7–8 (2020).

41. *Id*. at 2.

42. Sipe et al., *supra* note 2, at 2.

43. *See id.* at 5.

44. *Id.* at 9 tbl.2.

regulations because sex toy materials might be used in direct contact with sensitive body tissues and parts.[45]

Sex toys are used in a variety of ways due to the broad spectrum of products with differing shapes, sizes, and functions. This Comment emphasizes the regulation of the most common sex devices: dildos, butt plugs, anal beads, penis constriction rings, sleeves, and nipple clamps.[46] These devices are used in many various ways, but at a high level, they are intended to be inserted into the body or to constrict certain parts of the body.[47] Despite their diverse uses and forms, one commonality among all of these devices is that they come into contact with the body.[48]

## B. SEX TOY CONSUMERISM, HARMS, AND HISTORY

Sex toys can be taboo,[49] which can lead to gaps in research, regulation, and general discussion among users.[50] Because society has historically deemed sex toys unmentionable, discussing or purchasing them can lead to embarrassment and cause individuals to keep their sex toy usage a secret to avoid harmful attention.[51] It is true that sex toys are currently more acceptable on a societal level than in the past due to normative forces such as sexualization and the promotion of sex toys for sexual health.[52] Yet, on an individual level, people may still feel resistant to deconstructing the taboo due to embarrassment or a desire to maintain social status.[53]

Even though sex devices remain taboo on some levels, that has not stopped people from purchasing them at high rates.[54] It is estimated that anywhere from 46–78% of adults own a sex toy of

45. *See id.* at 9.

46. *See Sex Toys*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/sex-pleasure-and-sexual-dysfunction/sex-and-pleasure/sex-toys [https://perma.cc/NZC7-JW5V].

47. *See id.*

48. *See* Sipe et al., *supra* note 2, at 2.

49. *See* Samuel Piha et al., *From Filthy to Healthy and Beyond: Finding the Boundaries of Taboo Destruction in Sex Toy Buying*, 34 J. MKTG. MGMT. 1078, 1080 (2018) (defining taboo as "a behavioral or verbal act that provokes emotional ambivalence and is prohibited by societal norms or is generally considered to be publicly unmentionable").

50. *See* Sipe et al., *supra* note 2, at 11.

51. *See* Piha et al., *supra* note 49, at 1080 (finding that while some avoid the taboo, others find violating taboos exciting and may be part of the thrill of purchasing sex toys).

52. *See id.* at 1094 ("Sexualisation is used to describe the extraordinary proliferation of discourses about sexuality in the consumer culture.").

53. *See id.*

54. *See id.* at 1079, 1096.

some kind.[55] In the United States alone, the sex toy industry was worth $15.6 billion in 2023 and is projected to continue growing over the next decade.[56] While the popularity and growth of sex toys have helped people achieve sexual pleasure, they have also led to thousands of injuries over the last two decades.[57] From 2000 to 2019, there were an estimated 18,547 vibrator injuries and 6,468 dildo injuries reported.[58] This data only includes injuries that resulted in emergency room visits, averaging about 1,250 sex toy injuries per year.[59] Additionally, this study only includes emergency room visits found using the search terms "vibrat" or "dildo," so it is likely that the actual number of total injuries is higher.[60] Even putting aside the likely underreporting, the volume of sex toy injuries has increased every year, with a few thousand injuries reported annually and at least 35% necessitating hospitalization.[61] The most common injuries involve devices being lodged in the rectum or stuck in the vagina.[62] The increase in popularity and purchases of sex toys by adults in the United States, alongside the increase in reported injuries, highlights the dangers of sex toy use, underscoring the importance of improving the current regulatory scheme.

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55. *See* Justin Lehmiller, *How Many People Have Used Sex Toys During the Pandemic?*, SEX & PSYCH. (Aug. 26, 2020), https://www.sexandpsychology.com/blog/2020/8/26/how-many-people-have-used-sex-toys-during-the-pandemic/ [https://perma.cc/UHQ9-LQSX] (reporting the results of a survey conducted between March and April 2020 where 46% of respondents said they had "played with a vibrator or sex toy alone since the [COVID-19] pandemic began"); *see also* Bedbible Rsch. Ctr., *The State of Sex Toys*, BEDBIBLE.COM (Nov. 30, 2023), https://bedbible.com/state-of-sex-toys-industry-statistics/ [https://perma.cc/CGY8-HNFV] ("78% of Americans own a sex toy as of 2023, which has increased from 65% in 2017.").

56. *See* Bedbible Rsch. Ctr., *supra* note 55; *Adult Toys Market Size, Share, Growth, and Industry Analysis, By Type (Vibrators, Runner Penis and Others), By Application (Women Use and Men Use), Regional Insights, and Forecast From 2025 to 2033*, BUS. RSCH. INSIGHTS, https://www.businessresearchinsights.com/market-reports/adult-toys-market-101902 [ https://perma.cc/2CMU-V75P] (reporting that the global adult toys market size is projected to continue growing at a compound annual rate of 8.2% from 2025 to 2033).

57. *See generally* Mathias B. Forrester, *Vibrator and Dildo Injuries Treated at Emergency Departments*, 47 J. SEX & MARITAL THERAPY 687 (2021).

58. *See id*. at 689.

59. *See* Sipe et al., *supra* note 2, at 2; *see also* Forrester, *supra* note 57, at 689 (2021) (reporting that the rate of injury from sex toys has increased over time, going from "a few hundred [injuries] per year in 2000 to a few thousand per year by 2019").

60. *See* Forrester, *supra* note 57 at 694 (stating that one of the limitations of the study is the limited search terminology and lack of consistent terminology, likely leading to an under-reporting in the number of actual injuries studied).

61. *See id*. at 692.

62. *See id*.

Furthermore, marginalized populations may be more likely to experience harm from sex devices. Women, non-binary, asexual, and LGBTQ+ individuals use sex toys at higher rates than others.[63] It is estimated that LGBTQ+ individuals spend 13.4% more on sex toys per year than their heterosexual counterparts.[64] Additionally, LGBTQ+ people face challenges when seeking healthcare due to a lack of financial resources or social support, as well as possible stigma from healthcare providers.[65] Even when LGBTQ+ people have access to healthcare, complications can arise due to a lack of training among healthcare professionals, personal biases, and stereotypes about LGBTQ+ individuals impacting treatment.[66] Because LGBTQ+ people utilize sex devices more often and have more barriers to entry in their healthcare, the regulation of sex devices is not only important for general public health, but also to protect marginalized populations.

Sex devices also have an interesting history, as vibrators were initially developed and used as medical devices to treat hysteria.[67] Hysteria was a sweeping diagnosis given to women who exhibited a broad range of symptoms, from headaches to using profanities to heart disease.[68] The treatment for hysteria included clitoral stimulation, which was not considered sexual since it was non-penetrative, and female orgasm to reduce symptoms.[69] After the Industrial Revolution, vibrating massagers were among the first electronic home devices invented after sewing machines.[70] Thus, vibrators became standard medical devices used to treat hysteria

63. *See* Bedbible Research Center, *supra* note 55.

64. *See id.*

65. *See GLAAD Media Reference Guide—In Focus: LGBTQ Health and Healthcare*, https://glaad.org/reference/health/ [https://perma.cc/JDE8-62AB].

66. *See id.*

67. *See* Rainey Horwitz, *Medical Vibrators for Treatment of Female Hysteria*, EMBRYO PROJECT ENCYC. (Feb. 29, 2020), https://embryo.asu.edu/pages/medical-vibrators-treatment-female-hysteria [https://perma.cc/5LRB-T666].

68. *See id.* ("Symptoms included headache, forgetfulness, irritability, insomnia, writing cramps, hot flashes, excessive vaginal bleeding, heaviness in the limbs, usage of coarse language, severe cramping, difficulty breathing, desire for clitoral stimulation, hyper-promiscuity, mood swings, nausea, anxiety, drowsiness, loss of appetite, aging, back pain, swollen feet, cancer, organ failure, endometriosis, heart disease, epileptic fits, and what are now known as symptoms of depression, schizophrenia and other psychological disorders.").

69. *See id.* ("If the female patient became flushed and relieved during the pelvic massage treatment for hysteria, physicians explained that she was experiencing a hysterical paroxysm, which is now known as an orgasm. That signified that the treatment was successful and the physician would believe the patient to be relieved of her negative symptoms attributed to hysteria.").

70. *See id.*

alongside constipation, arthritis, and muscle fatigue.[71] Vibrators continued to be used for medical purposes until depicted in pornographic stag films in the 1920s, where featuring medical vibrators in a sexual context made them socially unacceptable.[72] In 1952, hysteria was removed from the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.[73]

Today, we no longer use the term "hysteria," and sex devices exist within a very different societal context. However, at one point, vibrators were considered medical devices that could have led to comprehensive FDA regulation. Although times have changed, this Comment argues that the FDA should still regulate sex devices for four main reasons. First, the FDA can bring sex toys under its jurisdiction because they fit the literal definition of medical devices in the Food, Drug, and Cosmetic Act. Second, the intended use of sex toys—seen in their labeling, product descriptions, and supplemental context—supports imposing FDA regulation on the grounds that these devices are intended to alter the structure and function of the human body and possibly for "the treatment, prevention, and mitigation of disease."[74] Third, policy reasons fortify the argument that the FDA should regulate sex toys because it is within the FDA's mission to protect public health, especially among vulnerable or unknowing consumer populations, and to provide consistent and transparent regulations. Finally, FDA regulation serves as an efficient solution to close regulatory loopholes, with limiting principles to combat concerns of a slippery slope expansion of FDA oversight.

## II. THE FDA CAN REGULATE SEX DEVICES BECAUSE THEY TEXTUALLY FIT THE DEFINITION OF MEDICAL DEVICES

Arguing that the FDA should regulate sex devices as medical devices begins with establishing that the FDA has the authority to do so. Part II.A explores how the literal definition of the term "medical device" in the FDCA opens the door for FDA regulation of sex devices. Part II.B documents that the FDA has utilized this literal interpretation of the term medical device to establish

71. *See id.*
72. *See id.*
73. *See id.*
74. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(h)(1)(B) (2018).

jurisdiction over products in the past. Part II.C shows that courts have also upheld this literal reading of the statute by the FDA to establish jurisdiction.

## A. THE DEFINITION OF MEDICAL DEVICES IN SUBPART (C) OF THE FOOD, DRUG, AND COSMETICS ACT PERMITS SEX DEVICES TO BE REGULATED

First, the FDCA establishes FDA oversight of medical devices, which are defined as:

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . .
>
> (B) 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
>
> (C) *intended to affect the structure or any function of the body of man* or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[75]

Subsection (B) targets devices that are therapeutic, while subsection (C) targets devices intended to affect the structure or function of the body. By using the word "or" at the end of subsection (B), the statute permits the FDA to regulate medical devices when they make therapeutic claims or when the device alters the structure or function of the body. The statute does not require both definitions to apply, which it could have done by using the word "and" at the end of subsection (B). Additionally, subsection (C) is the final definition of medical devices and employs broad language, expanding the scope of devices permissible for regulation beyond therapeutic uses.

The drafting and language of the text support the notion that a literal reading, which requires only one aspect of the statute to be implicated, is a permissible interpretation for establishing FDA

75. 21 U.S.C. § 321(h)(1)(B)–(C) (emphasis added).

regulation. At a baseline, the statute is drafted broadly with a clear intention for the FDA to regulate devices, leading to the longstanding practice of FDA regulation in a manner consistent with what this Comment argues.[76] Although the FDA is unlikely to extend jurisdiction over every possible device that could be implicated by subsection (C) of the definition for medical devices, subsection (C) opens the door for further textual and policy arguments proposed by this Comment regarding why FDA regulation is appropriate.

## B. THE FDA HAS BROADENED THE AGENCY'S JURISDICTION OVER NEW DEVICES THROUGH A LITERAL READING OF THE FDCA BEFORE

The FDA itself has argued that a literal interpretation of the statute can establish regulation of products under its jurisdiction. In *FDA v. Brown & Wages & White Lion Investments, L.L.C.*, the FDA extended jurisdiction to e-cigarette devices as tobacco products because there is clear regulatory jurisdiction for it to do so.[77] E-cigarettes are a more recent phenomenon, but the broad grants of authority that expanded FDA oversight through the Pure Food and Drug Act of 1906, the Federal Food, Drug, and Cosmetic Act (FDCA), and the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) culminated in Congress empowering the FDA to regulate e-cigarettes.[78] Each of these grants of authority from Congress to the FDA was broad and unambiguously permitted the FDA to regulate new types of products, allowing the agency to adapt its regulation of food, drugs, tobacco, and devices as times changed.[79] This case reaffirms that when Congress clearly delegates authority to the FDA to regulate certain products, which include medical devices, broad statutory language permits the FDA to extend jurisdiction over new products not explicitly named in the statute but that fall within the text.[80]

Justice Breyer's dissent in *Brown & Williamson Tobacco Corp.* provides further arguments supporting FDA regulation of sex

76. *See* Loper Bright Enters. v. Raimondo, 603 U.S. 369, 386 (2024) (holding that the federal courts reserve the final say in interpreting *ambiguous* statues but respect the longstanding executive practices of executive action to carry out statutes).

77. 145 S. Ct. 898, 910 (2025).

78. *See id.* at 907–08.

79. *See id.* at 908–10.

80. *See id.*

devices under the FDCA's text. First, Justice Breyer emphasizes that the FDCA "is to be given a liberal construction consistent with [its] overriding purpose to protect the public health."[81] Justice Breyer documents that legislative history recognizes the drafters' intention to use broad language so that jurisdiction could be had over "*all* devices intended to affect the structure or any function of the body."[82] Concededly, Congress originally drafted the definition of devices this broadly to address the issue of products with slenderizing effects such as "antifat remedies."[83] However, Justice Breyer notes that Congress did not use language that precluded devices beyond antifat remedies, in this case sex toys, from coming under FDA jurisdiction.[84] Justice Breyer's dissent highlights that Congress drafted the definition of medical device in broad terms so that the FDA could have discretion in choosing what to regulate under the literal text of the statute.

Further evidence that the FDA understands the definition of medical devices literally is seen through its ongoing regulation of other devices that do not have therapeutic functions and only alter the structure of the body. Breast implants are currently regulated by the FDA at the most stringent level of medical device regulation, designated as class III devices.[85] The purpose of breast implants is described as "augment[ing] or reconstruct[ing] the female breast."[86] This practical description does not include any therapeutic use relating to the cure, treatment, mitigation, or prevention of disease and only concerns altering the structure or function of the body. The FDA's regulation of breast implants is intended to "help ensure that patients considering breast implants are provided with adequate risk information so that they can make fully informed decisions."[87] Thus, the FDA's regulation of breast implants supports that even when products only affect the

81. Brown & Williamson Tobacco Corp., 529 U.S. at 162 (Breyer, J., dissenting) (citing United States v. Bacto-Unidisk, 394 U.S. 784 (1969)).

82. *Id.* at 164–65 (Breyer, J., dissenting) (citing *Hearings on S.1944 before the Subcomm. of the Sen. Comm. on Com.*, 73d Cong., 15–16 (1933), reprinted in 1 FDA, Legislative History of the Federal Food, Drug, and Cosmetic Act and Its Amendments 107–108 (1979)).

83. *Id.* (Breyer, J., dissenting).

84. *See id.* (Breyer, J., dissenting).

85. *See* 21 C.F.R. § 878.3530 (2023).

86. *Id.*

87. *Breast Implants*, U.S. FOOD & DRUG ADMIN. (Dec. 15, 2023) (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants.

structure of the body, that is sufficient to bring them under FDA regulation.[88]

Similar to breast implants, sex devices alter the structure of the body, and regulating these devices would provide consumers with the information needed to make informed decisions about what they put into or on their bodies. Although breast implants are inserted into the body for longer periods of time, which may pose different harms, sex devices still alter the structure of the body and pose risks. Dildos or other insertable objects can tear delicate skin at the entrance of the vagina or anus, sex devices can get lost in vaginal or anal cavities, or may constrict body parts, trapping blood and potentially lead to partial amputation.[89] Consumers should be informed of these potentially severe harms when purchasing and using these devices.[90] Because sex devices come into contact with and alter the structure of the body in similar ways to other already regulated medical devices that have no therapeutic justifications, the FDA should also be permitted to regulate sex devices.

Based on the text of the FDCA and the FDA's own interpretation of devices, a literal application of the definition of medical devices in the FDCA can encompass sex toys. Furthermore, FDA jurisdiction currently includes devices that only affect the structure of the body without therapeutic claims. These already regulated devices bolster the assertion that sex toys do not need to meet the therapeutic definition of medical devices for FDA regulation to apply. Individual inquiries may be necessary for sex toys that do not make contact with the body or are distinguishable from previous cases. However, from a cursory understanding of how the most popular sex devices are used, they meet the baseline requirement of influencing the structure of the body.

## C. COURTS SUPPORT THIS LITERAL INTERPRETATION OF MEDICAL DEVICES BY THE FDA

Case law affirms that the FDCA permits the FDA to regulate a device when it affects the structure of the body without requiring

88. *See* 21 C.F.R. § 878 (2023).
89. *See* Nuzzo, *supra* note 34.
90. *See id.*

additional therapeutic claims to treat or mitigate disease.[91] Courts construing the "structure or . . . function" definition of "device" have applied the definition to articles that purport literally to change the structure or function of the body.[92] Courts have gone so far as to allow FDA regulation when a product affects only the structure or only the function of the body, affirming that using the word "or" does not require multiple sections of the statute to be implicated for regulation to be appropriate.[93] Consequently, courts have not allowed the FDA to regulate devices that in no way come into contact with the body, such as in vitro home pregnancy tests.[94]

Courts do not require that devices have a significant impact on the structure of the body to permit FDA regulation. Products with impacts as incidental as smoothing wrinkles have been ruled to change the structure of the body under the literal definition of the FDCA.[95] Courts have used strong language, saying that products intended to "smooth, firm and tighten skin" would "obviously" have an objective to affect the structure of the body.[96] Courts have also affirmed that it does not matter if the changes to the structure of the body are temporary, as the statute provides no exceptions for temporary structural changes.[97]

Additionally, the FDA can regulate a product that claims to change the structure of the body through only superficial contact.[98] For example, a lotion with only temporary effects that did not

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91. *See* Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455, 459 (4th Cir. 1960); United States v. Article . . . Consisting of 216 Cartoned Bottles, More or Less, Sudden Change, 409 F.2d 734, 741 (2d Cir. 1969) [hereinafter *Sudden Change*]; United States v. Article Consisting of 36 Boxes, More or Less, Labeled "Line Away, Temporary Wrinkle Smoother, Coty," 284 F. Supp. 107 (D. Del. 1968), *aff'd*, 415 F.2d 369 (3d Cir. 1969) [hereinafter *Line Away*].

92. E.R. Squibb & Sons v. Bowen, 870 F.2d 678, 682–83 (D.C. Cir. 1989) (stating that items like surgical nails inserted into broken bones or lotions that tighten skin literally change the structure of the body, but items that in no way come into contact with the body do not change the structure).

93. See *id.* (citing Orthopedic Equipment Co., 276 F.2d at 459; *Sudden Change*, 409 F.2d at 741; *Line Away*, 284 F. Supp. at 107; United States v. 23, More or Less, Articles, 192 F.2d 308, 309 (2d Cir. 1951); United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959); United States v. Article Consisting of 46 Devices, "Dynatone," 315 F. Supp. 588, 589 (D. Minn. 1970)).

94. *Cf.* United States v. Article of Drug, 414 F. Supp. 660, 666 (D.N.J. 1975).

95. *See Line Away*, 284 F. Supp. at 109–110 ("[The] claimant argues that Congress had no desire that cosmetics which were intended to have an 'incidental' or 'insignificant' effect on the bodily structure should be included within the drug definition. These limitations are suggested by claimant, not by Congress.").

96. *Id.*

97. *Id.* at 110–11.

98. *See Sudden Change*, 409 F.2d 734, 734 (2d Cir. 1969).

absorb into the skin and made no changes to skin tissue was ruled to alter the structure of the body.[99] The lotion worked by drying on top of the skin, creating a clear film that mechanically smoothed and firmed the skin by tightening the surface.[100] Even though the lotion created a temporary mask that could be washed off, the court ruled that because the lotion was promoted to literally affect the structure of the skin through smoothing wrinkles, FDA regulation was permissible.[101] Thus, the FDA can regulate products even characterized by courts as having minor and temporary effects if the products alter the structure of the body, thus fitting within the literal definition of the FDCA.[102]

The regulation of lotions by the FDA under the literal meaning of affecting the structure of the body supports the argument that the FDA should regulate sex toys. Sex toys are typically inserted into body cavities, penetrating mucous membranes or constricting body parts.[103] If lotions that claim to tighten skin affect the structure of the body, then sex toys that are used in contact with body parts, sometimes near permeable membranes and sensitive areas, would also alter the structure of the body.[104] The fact that sex toys are only used temporarily on the body does not undermine the position that the FDA should have regulatory power over these devices. As determined by the Third Circuit, products used temporarily are not exempt from statutory regulation.[105] Similar to finding that the FDA can regulate lotions which create clear, impermanent masks to smooth imperfections, it is likely that the courts would uphold FDA regulation of sex devices used to temporarily stretch, penetrate, or constrict parts of the body.

Courts have interpreted the FDCA to cover products with minor and temporary impacts because they are concerned with protecting vulnerable consumers who may be exploited.[106] The Supreme

99. *See id.* at 736.
100. *See id.*
101. *See id.* at 742.
102. *See id.*; *see also Line Away*, 284 F. Supp. 107, 110–11 (D. Del. 1968).
103. *See* Planned Parenthood, *supra* note 46.
104. *See* Sipe et al., *supra* note 2, at 9–10.
105. *See Line Away*, 284 F. Supp. at 110–11.
106. *See Sudden Change*, 409 F.2d 734, 741 (2d Cir. 1969) (citing Florence Mfg. Co. v. J. C. Dowd & Co., 178 F. 73, 75 (2d Cir. 1910); United States v. 62 Packages Marmola Prescription Tablets, 48 F. Supp. 878, 887 (W.D. Wis. 1943), *aff'd*, 142 F.2d 107 (7th Cir. 1944); Raladam Co. v. United States, 323 U.S. 731 (1944)); *see also* United States v. 250 Jars 'Cal's Tupelo Blossom U.S. Fancy Pure Honey', 344 F.2d 288, 289 (6th Cir. 1965) (holding that "the [FDCA] was passed to protect unwary customers in vital matters of health and, consequently, must be given a liberal construction to effectuate this high purpose, and

Court interprets the FDCA broadly because it touches on the lives and health of individuals who are largely beyond self-protection.[107] Consequently, the standard courts use to determine whether a consumer would believe a product affects the structure or function of the body is from the perspective of the "ignorant, unthinking or credulous" consumer.[108] The FDCA was not intended to protect health experts, but those who may be preyed upon by loopholes that exploit their "weakness, gullibility, and superstitio[us] human nature."[109] The idea is that these consumers make choices based on appearances and general impressions and do not pause to analyze products when purchasing.[110] Thus, courts interpret the FDCA's language to protect a gullible person who may be taken advantage of by products that claim to affect the structure or function of the body.

The standard for protecting vulnerable consumers who may be taken advantage of by misleading products or claims is significant in the case of sex devices. Many devices are marketed as "body safe" to consumers, even though these products do not undergo review to substantiate that they are made of body-safe materials[111] or designed to function safely.[112] Thus, people purchasing sex devices may take the promotional materials at face value because they are unaware of the toxic chemicals in their devices,[113] porous material that could lead to bacteria,[114] or unsafe designs that can lead to devices being lodged in the body.[115] Sex device companies are utilizing the very loopholes that the courts were concerned about, exposing gullible or exploitable consumers to risks that could be mitigated through FDA oversight.[116]

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[this court should] not open a loophole through which those who prey upon the weakness, gullibility, and superstition of human nature can escape the consequences of their actions").

107. *See* United States v. Dotterweich, 320 U.S. 277, 280 (1943).

108. *Sudden Change*, 409 F.2d at 741. This standard utilizes harsh and slightly problematic word choice so it is important to highlight that the primary concern is to protect vulnerable consumers who may be taken advantage of, not just "reasonable" consumers or experts.

109. *Id.* at 740–41.

110. *See* Florence Mfg. Co. v. J.C. Dowd & Co., 178 F. 73, 75 (2d Cir. 1910).

111. *See* Sipe et al., *supra* note 2, at 10.

112. *See* Nuzzo, *supra* note 34.

113. *See* Sipe et al., *supra* note 2, at 2.

114. *See* Kelsey Borresen, *What's the Difference Between a Cheap Vibrator and an Expensive One?*, HUFFPOST (Mar. 16, 2022, 8:23 PM), https://www.huffpost.com/entry/difference-cheap-sex-toy-expensive_l_6231017ce4b05e14cc3aa7e6 [https://perma.cc/ZPF9-XX8G].

115. *See* Nuzzo, *supra* note 34.

116. *See Sudden Change*, 409 F.2d 734, 740–41 (2d Cir. 1969).

The regulation of sex devices under the literal definition of medical devices in the FDCA is supported by the language in the statute, historical FDA interpretation, and courts upholding a literal reading. Due to the broad language of the statute, it is within the FDA's discretion to decide how to best protect public health regarding medical devices that alter the structure of the body.[117] The FDA has also previously argued for a literal reading of the statute to establish its jurisdiction over products that change the structure of the body, and courts have upheld this literal reading.[118] Because sex devices come into contact with the body either through penetrating mucous membranes or constricting body parts,[119] they surpass the requirements set out by the lotion cases of altering the structure of the body, even if temporarily.[120] Finally, in the event that the FDA is challenged over regulating sex devices as medical devices, the broad delegation of authority from Congress to the FDA through the FDCA and the FDA's longstanding interpretation of medical devices would be given great respect supporting FDA regulation.[121]

## III. THE INTENDED USE OF SEX DEVICES SUPPORTS THAT THEY ARE MEDICAL DEVICES AS DEFINED IN THE FDCA

In addition to sex toys fitting the literal definition of medical devices, the intended use of sex devices supports their regulation under the FDA as medical devices. It is well established that the FDA can decide to regulate products as drugs, devices, and foods depending on the labeling, promotion, and contextual understanding of their intended use.[122] Courts have held that deciding the intended use of products by the FDA is not limited to affirmative representations made about products on labels or

117. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 321; *see also* Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 162 (2000) (Breyer, J., dissenting).

118. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 120; *Sudden Change*, 409 F.2d at 734; *Line Away*, 284 F. Supp. 107, 110–11 (D. Del. 1968).

119. *See* Nuzzo, *supra* note 34.

120. *See Sudden Change*, 409 F.2d at 736; *Line Away*, 284 F. Supp. at 110–11.

121. *See* Loper Bright Enters. v. Raimondo, 603 U.S. 369, 385–86 (2024).

122. *See, e.g.*, Kordel v. United States, 335 U.S. 345 (1948); V. E. Irons, Inc. v. United States, 244 F.2d 34 (1st Cir. 1957); *Sudden Change*, 409 F.2d 734 (2d Cir. 1969); Nat'l Nutritional Foods Ass'n v. Matthews, 557 F.2d 325, 334 (2d Cir. 1977); United States v. Storage Spaces Designated Nos. 8 & 49, 777 F.2d 1363, 1366 n.5 (9th Cir. 1985); United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001); United States v. Undetermined Quantities of an Article of Drug Labeled as "Exachol," 716 F. Supp. 787, 791 (S.D.N.Y. 1989).

promotions, but can include "*any other relevant source*."[123] This can consist of consumer intent in using products to demonstrate a seller's intended use.[124] Thus, the FDA can determine a device's intended use through claims made in the description of the product, promotion of the product, statements made by decision makers of the product, consumer intent in using the product, or any other relevant source, making regulation by the FDA appropriate.[125]

In *Kordel v. United States,* the Supreme Court established that when the FDA reviews product labeling to decipher a product's intended use for regulation, labeling includes supplemental materials that explain the benefits or uses of the product.[126] In *Kordel*, the plaintiff sold health food products made of various vitamins, minerals, and herbs while also separately distributing informational pamphlets about the products' efficacy.[127] The Court held that the food products were misbranded drugs due to how the products were promoted through the pamphlets.[128]

When considering intended use, the Court stated the FDA is not limited to reviewing only declarations included directly on a product's label, in the packaging, or shipped with the product.[129] Literature or other promotional materials separate from the product, meant to inform consumers and promote sales, can be considered labeling, since they can create a textual relationship between the promotion to consumers and the product.[130] To decide if a textual relationship exists, the Court may look to promotional materials and products having a common origin and a common destination to reinforce that a textual relationship exists.[131] The Court communicated in *Kordel* that labeling is interpreted broadly so that the FDA can close loopholes that products might try to exploit, such as separating their promotional materials from the

123. *Travia*, 180 F. Supp. 2d at 119.
124. *See id*.
125. *See id*.
126. *See* 335 U.S. at 346.
127. *See id*. at 346–47.
128. *See* Kordel v. United States, 335 U.S. 345, 346–47 (1948).
129. *See id*. at 348–49.
130. *See id*. at 350. This textual relationship is not related to the textual analysis in Part II. The Court in *Kordel* understands a textual relationship to be how promotional materials create a link between the product and the promotional material to identify a product's intended use.
131. *See id*. at 348.

product label, to avoid higher FDA regulatory standards.[132] *Kordel* thus established that if supplemental materials can be understood as promotions or explanations for products, they can be used as evidence for the intended use of a product by the FDA and inform the level of regulation required.

Additionally, when product labeling or promotion is nonexistent, evidence such as surrounding context, consumer intent, and other external circumstances may be used to determine the intended use of products. For example, in *United States. v. Trivia* the FDA was part of a joint investigation involving the illegal distribution of nitrous oxide, commonly referred to as laughing gas.[133] The nitrous oxide was being distributed without promotional materials via unlabeled balloons in the parking lot outside of a rock concert venue.[134] The distributor of the laughing gas balloons argued that since there were no labels or promotions on the product, this instance fell outside of the scope of the FDCA.[135] The court denounced the argument and stated that the surrounding environment of selling unlabeled balloons at a rock concert provided all the necessary information between buyer and seller to infer intended use.[136] Thus, producers cannot circumvent FDA regulation by avoiding labeling or promoting products. Rather than allow for regulatory loopholes, the court held that the FDA can look at a product's distribution or the intended use of the product by the consumer to infer a distributor's intent and bring a product under FDA jurisdiction.[137]

Similar to *Kordel*, the promotion of sex toys—including supplemental materials that instruct how to use them—reflects an intention to affect the structure or function of the body. Distributors selling sex toys commonly tout the benefits of these devices to boost sales.[138] Websites that sell sex toys also provide information on how to use these devices, creating the same relationship found in *Kordel* between the food product and pamphlets.[139] When distributors post descriptions of sex toys, promotional blog posts, and supplemental materials explaining

132. *See id*.
133. *See* 180 F. Supp. 2d 115, 116 (D.D.C. 2001).
134. *See id*. at 119.
135. *See id*.
136. *See id*.
137. *See id*.
138. *See infra* notes 140–143 and text accompanying.
139. *See* Kordel v. United States, 335 U.S. 345, 346–47 (1948).

how to use sex devices on the same websites selling to consumers, they create a link between the product and its supposed benefits.

To illustrate how supplemental materials create a link permitting FDA regulation of sex toys as medical devices, this Comment provides a case study on a company whose messaging exemplifies sex toy promotions. Holistic Wisdom promotes and sells sex toys online. The product descriptions of Holistic Wisdom's devices use phrases such as "designed for g-spot stimulation" and that their products can be used for "vaginal or anal penetration."[140] Additionally, product descriptions on Holistic Wisdom's site regularly use the terms "penetration,"[141] "sensation,"[142] or "stimulation"[143] to describe the function of their products. These types of descriptions are meant to inform consumers of the use and benefits of various products and show that the seller's intended use for sex devices is to affect the structure or function of the body.

The definitions of these commonly used words in promotional materials support that the devices are meant to come into contact with the body and affect its structure or functions. Penetrate means "to pass into or through,"[144] implicating the FDCA's medical devices definition of altering the structure of the body. The top definition of sensation under Webster's Dictionary includes four subparts, all of which include some form of impact on the structure or function of the body.[145] Similarly, stimulation is understood as "the stimulating action of various agents on muscles, nerves, or a sensory end organ by which activity is evoked."[146] The agent in this definition would be sex toys having an action on muscles, nerves, and sensory end organs, which supports that they are

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140. *Alyssum Spinning Glass Dildo*, HOLISTIC WISDOM SEX TOYS, https://www.holisticwisdom.com/products/alyssum-glass-dildo [https://perma.cc/C2NB-NADB].

141. *Njoy Fun Wand*, BABELAND, https://www.babeland.com/p/BL2731/BLSKU0252100/njoy-fun-wand [https://perma.cc/A3Y2-55XN].

142. *Id*.

143. *Silicone Anal Exerciser Kit*, BABELAND, https://www.babeland.com/p/BLD474581/1322572/silicone-anal-exerciser-kit [https://perma.cc/N477-9Y47].

144. *Penetrate*, MERRIAM-WEBSTER.COM: DICTIONARY (2023), https://www.merriam-webster.com/dictionary/penetrate [https://perma.cc/WL8C-GP9N].

145. *See Sensation*, MERRIAM-WEBSTER.COM: DICTIONARY (2023), https://www.merriam-webster.com/dictionary/sensation [https://perma.cc/Z23S-UADH]. The four subparts of "sensation" include: "an impact on mental processes . . . from stimulation of a sense organ," "awareness . . . due to stimulation of a sense organ," a "state of consciousness due to internal bodily changes," and an "indefinite bodily feeling." *Id.*

146. *Stimulation*, MERRIAM-WEBSTER.COM: DICTIONARY (2023), https://www.merriam-webster.com/medical/stimulation [https://perma.cc/VMN6-DLWU].

intended to alter the structure or function of the body. These descriptions, which are common across how sex toys are promoted, show that the intended use of these products is to affect the structure or function of the body. This relationship between promotional materials and the sale of the devices implicates the definition of medical devices and makes FDA regulation appropriate.

Furthermore, sex toy promotional materials may go beyond merely claiming to affect the structure and functions of the body; they also make therapeutic claims that sex toys can mitigate, treat, or prevent disease, implicating subsection (B) of the FDCA's medical device definition. First, many sex toys are promoted as supporting "sexual health" in their online advertisements. For example, Holistic Wisdom claims that it produces "body safe sexual products" and states they are "focused on sexual health."[147] The term "sexual health" is defined by the World Health Organization as not only the mere absence of disease, dysfunction, or infirmity, but also "a state of physical, emotional, mental and social well-being in relation to sexuality."[148] This type of language found in the promotion of sex toys suggests to "unthinking, ignorant or credulous"[149] consumers that these toys provide sexual benefits in preventing diseases or pain, as well as implying a state of sexual well-being. This language in the description of sex toys goes beyond use for pleasure or fun because these promotions make claims about their products maintaining the sexual health of their consumers. Thus, if the FDA wanted to claim it regulates sex toys because of therapeutic claims in addition to their impacts on the structure or function of the body, the agency could utilize these supplemental materials to support that these products should be regulated as medical devices.

Moreover, the FDA could argue that the broader context of sex device promotion supports that the FDA should regulate these devices because doctors promote them. *Travia* makes clear that the FDA can look to broader contexts that supply information to consumers to determine the intended use of products.[150] Similarly,

147. *Alyssum Spinning Glass Dildo*, *supra* note 140.

148. *Sexual Health: Definitions*, WHO, https://www.who.int/health-topics/sexual-health#tab=tab_2 [https://perma.cc/S539-AM3S].

149. *Sudden Change*, 409 F.2d 734, 741 (2d Cir. 1969).

150. *See* United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (using the context of a rock concert to find that products being sold as unlabeled balloons filled with laughing gas were misbranded drugs).

in the case of sex toys, the FDA can look at the surrounding context of the information supplied to consumers. Much of the information about the use of sex toys comes from mental health professionals. For example, the CEO of Holistic Wisdom is Dr. Lisa Lawless, who has a Ph.D. in psychology.[151] Another popular website that promotes sex toys and provides information on their use is The Sex and Psychology blog, founded by Dr. Justin Lehmiller, a psychologist and research fellow at the Kinsey Institute.[152] Both individuals leverage their credentials as mental health professionals to run websites that sell sex devices and include supplemental information on sex products.[153] Due to their doctor titles, it is possible that gullible or uninformed consumers could understand the claims about sex devices to be therapeutic in nature.

Lawless and Lehmiller are not rare examples of professionals promoting the therapeutic use of sex toys. Others have also claimed that sex toys can offer benefits that may cross the line into therapeutic messaging.[154] These claims include that sex toys can aid in sexual well-being, provide a greater chance for orgasm, and even treat pelvic floor disorders.[155] It is possible for the FDA to argue that these claimed benefits from using sex devices made by medical professionals lean towards health messaging, thus making their regulation permissible.

In addition to supplemental messaging, the Court's concerns in *Kordel* and *Travia* about manufacturers exploiting promotional loopholes to avoid FDA regulation are present in the sex device context. In *Kordel*, the Court was concerned with companies manipulating their promotions to allow them to evade FDA regulations.[156] In line with this principle, many sex device companies market their products as 'novelty toys,' exploiting promotional loopholes to avoid FDA oversight.[157] In *United States v. Travia*, the court expressed concern with misbranded products that allow distributors to circumvent regulation and expose

151. *See Our Story*, HOLISTIC WISDOM, https://www.holisticwisdom.com/pages/about-holistic-wisdom [https://perma.cc/MB9P-39XC].

152. *See About Dr. Lehmiller*, SEX & PSYCH., https://www.sexandpsychology.com/about-dr/ [https://perma.cc/53JK-MH84].

153. *See supra* notes 151–152.

154. *See* Andrea Rapkin & Wendy Satmary, *A Deep Dive into Devices for Sexual Health*, 69 CONTEMP. OB/GYN J., 14, 17–18 (2024).

155. *See id*.

156. *See* Kordel v. United States, 335 U.S. 345, 348–49 (1948).

157. *See* Sipe et al., *supra* note 2, at 10.

consumers to risky products. Similarly, sex 'toy' manufacturers label their products as gag gifts with no functional use.[158] Yet, on the same box, these manufacturers claim that the product is "body safe."[159] Even when sex 'toys' are mislabeled by companies as a "novelty gag gift not intended for safe use" to avoid regulation, consumers' intent reveals that these products are being used as devices to alter the structure or function of their bodies.[160] Beyond FDA jurisdiction being appropriate over sex toys because of their intended use, it is in line with previous court concerns to close regulatory loopholes.

The primary intended use of sex toys, as seen through their product descriptions, supplementary blogs, relevant authorities, and broader context, supports that FDA regulation is appropriate. Labeling and product promotions suggest that these devices are used to affect the structure or function of the body and may even have therapeutic uses, fitting the definition of medical devices under the FDCA. Additionally, doctors frequently promote the use of sex devices, which could give vulnerable consumers the impression they have therapeutic uses. Finally, there are concerns about promotional loopholes that allow companies to avoid FDA oversight, exposing consumers to risk. Thus, the intended use analysis supports the conclusion that sex devices should be regulated as medical devices.

## IV. THE FDA HAS STRONG POLICY INTERESTS IN REGULATING SEX TOYS

In addition to textual arguments and intended use analysis, policy arguments favor FDA regulation of sex devices. First, the history and mission of the FDA support that the regulation of sex devices is in line with the FDA's duty to protect consumers, especially those who may be less critical in their consumption practices. Second, FDA regulation would fill in the gaps of the current regulatory regime for sex devices, providing transparency for consumers and producers.

158. *See id.*
159. *Id.*
160. *See id.*

## A. THE FDA SHOULD REGULATE ADULT SEX DEVICES TO ADVANCE ITS MISSION OF PROTECTING CONSUMERS

The FDA should regulate sex toys because it is able to protect the general consumers and vulnerable populations likely to experience harm. The FDA, the oldest consumer protection agency in the United States, seeks to promote public health.[161] The FDA's mission is to protect consumers from dangerous products as enacted through the FDCA.[162] The purpose of the FDCA is to protect the "lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection."[163] The standard the FDA uses when protecting consumers is to ensure that the "ignorant, unthinking or credulous" consumers have access to health products that are safe and effective.[164] The FDA's mission thus sets the regulatory baseline to ensure that the health of the most vulnerable consumers is protected.

The Center for Devices and Radiological Health (CDRH) specifically oversees the regulation of medical devices within the FDA. CDRH aims to provide consumers with information about the products it oversees and industries with predictable, consistent, transparent, and efficient regulatory pathways to assure consumer confidence in medical devices.[165] Additionally, the CDRH includes the Health for Women Program, which seeks to protect and promote the health of all women by providing access to high-quality, safe, and effective medical devices on the market.[166] The broader missions of the FDA and the CDRH support regulating sex devices because they would protect general consumers and marginalized populations who are more likely to experience harm from using these products at higher rates.

To protect consumers, the FDA provides important clarity on the safety measures that are in place. The FDA protects

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161. *See FDA History*, *supra* note 3.

162. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 331.

163. *Sudden Change*, 409 F.2d 734, 740 (2d Cir. 1969).

164. Florence Mfg. Co. v. J.C. Dowd & Co., 178 F. 73, 75 (2d Cir. 1910).

165. *See CDRH Mission, Vision and Shared Values*, U.S. FOOD & DRUG ADMIN. (Jan. 25, 2023) (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-mission-vision-and-shared-values.

166. *See Portfolio of Women-Specific Medical Devices*, U.S. FOOD & DRUG ADMIN. (Aug. 12, 2021) (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/science-research/fda-stem-outreach-education-and-engagement/portfolio-women-specific-medical-devices .

consumers by requiring specific labeling and product warnings,[167] designating medical devices into three classes to provide appropriate protection levels,[168] upholding quality control regulations,[169] and supplying reporting mechanisms.[170] Some of the quality control regulations for medical devices include specific regulations and warnings for materials such as natural rubber, which includes latex,[171] a material used for inflatable dildos and other sex devices.[172]

FDA regulation of sex devices falls squarely within the agency's role to protect consumers. The most important role of the FDA is to protect consumers, particularly vulnerable individuals who may not approach purchases critically. With the expansion of the sex toy industry and the increasing popularity of sex devices, there has been a rise in emergency room visits due to harms caused by these devices.[173] Further, studies focusing on the possible negative impacts of microplastics and phthalates on the body support that the sex toy industry is in need of regulation so that consumers are not purchasing products which may be misbranded as "body safe" and should have material requirements enforced.[174]

The regulatory framework the FDA provides would enhance the amount of consumer protections currently provided to sex toys, which are regulated as 'novelty toys' or massagers under the CPSC. For example, a regulation requiring a specific warning label for products that contain latex would improve the safety warnings provided to consumers when purchasing latex inflatable dildos. Additionally, sex devices that contain phthalates or other harmful materials would be required to be disclosed to consumers, creating pressure for producers to use safer materials. Further, the FDA's reporting mechanisms give consumers post-market data on possible harms that can occur and allow manufacturers of adult sex devices to better understand risks that can occur through using their products. Through the general provisions that are required of medical devices and possible special controls, sex devices would

167. *See* 21 C.F.R. § 801 (2025).
168. *See* 21 C.F.R. § 860 (2023).
169. *See* 21 C.F.R. § 820.1 (2023).
170. *See* 21 C.F.R. § 803 (2023).
171. *See* 21 C.F.R. § 801.437 (2023).
172. *See* Rachel Sommer, *11 Best Inflatable Dildos, Reviewed by a Sex Educator*, MY SEX TOY GUIDE (Nov. 18, 2022), https://www.mysextoyguide.com/best-inflatable-dildo/ [https://perma.cc/Z8WE-JY4U].
173. *See* Sipe et al., *supra* note 2, at 2; Forrester, *supra* note 57.
174. *See* Sipe et al., *supra* note 2, at 9–10.

become safer for consumers, effectuating the consumer protection purpose of the FDA.

The FDA also has enforcement mechanisms to incentivize sex device manufacturers to comply with standards that protect consumer health. These mechanisms include monetary penalties, seizure, injunctions, and possible criminal actions.[175] These enforcement mechanisms are important when regulating sex devices due to the potential harms that can arise from their use. Sex toys are intended to stretch cavities that can tear skin,[176] restrict blood circulation leading to partial amputation,[177] or contain phthalates that can cause long-term health problems.[178] These enforcement mechanisms can incentivize manufacturers to comply with regulatory standards set by the FDA to protect consumers and avoid penalties.

Some may argue that FDA regulation intrudes on the liberty interests of Americans regarding privacy and access. However, neither Congress nor the Court has ever spoken to a direct liberty interest in using sex toys. Further, the FDA currently regulates sex devices with therapeutic purposes, which are still available over the counter and do not impose burdensome accessibility restrictions such as a prescription.[179] It is true that FDA regulation would likely lead to an increase in the cost of some sex devices, but this is not an unintended consequence. If companies are using cheap materials that are unsafe for the body, it is reasonable for prices to rise so that companies can use higher-quality materials.[180] This cost is purposeful and would mitigate the alternative harm and cost of consumers being sent to the emergency room or experiencing long-term health problems. Additionally, since a majority of sex devices are currently not regulated by the FDA, competition is not set on a level playing field to drive down the cost amongst competitors because the industry

175. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 332–34.
176. *See* Nuzzo, *supra* note 34.
177. *See id.*
178. *See* Babbs, *supra* note 36.
179. *See* U.S. FOOD & DRUG ADMIN., EXTERNAL PENILE RIGIDITY DEVICES—CLASS II SPECIAL CONTROLS GUIDANCE DOCUMENT FOR INDUSTRY AND FDA STAFF n.4 (2018), https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/external-penile-rigidity-devices-class-ii-special-controls-guidance-document-industry-and-fda-staff [https://perma.cc/7XFK-R6DQ].
180. *See* Régis Chenavaz, *Better Product Quality May Lead to Lower Product Price*, 17 B.E. J. THEORETICAL ECON. 1, 3 (2016).

is only held to voluntary safety standards.[181] If the FDA extended oversight over a majority of sex devices, even with the increase in cost due to materials and FDA review, competitors would have to lower prices in order to compete for the consumer base.[182] In light of the economic size of the sex toy industry,[183] the thousands of sex toy-related emergency room visits, and likely many other unreported injuries,[184] the benefits of permitting FDA oversight have the potential to outweigh the costs.

Additionally, FDA regulation can further support and legitimize a person's access and use of safe sex devices rather than inhibit it. Through providing transparent regulation by one of the oldest agencies protecting public health, FDA oversight helps legitimize the use of sex devices to combat stigma and promote transparency. By regulating the materials in sex devices and reporting risks, the FDA can work to protect and promote the pleasure of the people. Through mitigating traumatic and stigmatized harm, the FDA can support people in expressing their sexuality in ways that are safer and more effective. Rather than allowing sex devices to continue being marketed as "gag gifts" with "no intended use," agency regulation can help destigmatize the use of sex devices by providing official regulatory foundations.

More regulation does not necessarily mean fewer rights. If the FDA were to take the regulation of sex devices more seriously, instead of allowing them to remain unregulated via legal loopholes, consumers would be better protected. FDA regulation of sex toys aligns with its duty to protect consumers, especially those who may be vulnerable. By regulating sex devices, the FDA can provide consumers with safer and more effective products to enhance sexual health.

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181. *See* Mo, *supra* note 31.

182. *See Impact of Regulatory Compliance on Quality and Profits*, METRICSTREAM, (on file with the *Columbia Journal of Law & Social Problems*) https://www.metricstream.com/insights/impactRegulatoryComp.htm (last visited April 21, 2025) (stating that initial regulatory oversight may seem expensive but can lead to greater product differentiation, consumer safety, and financial results for the company).

183. *See* Bedbible Rsch. Ctr., *supra* note 55.

184. *See* Forrester, *supra* note 57.

## B. THE FDA SHOULD REGULATE SEX TOYS TO PROVIDE A CONSISTENT REGULATORY REGIME

The FDA should also regulate sex devices because it already has regulatory standards and expertise overseeing similar, if not identical, products.[185] FDA policy is to consistently regulate devices with therapeutic uses as medical devices, even if these devices do not make medical claims.[186] For example, existing regulatory loopholes allow consumers to buy penis pumps with or without FDA regulation simply because of the therapeutic claims that one makes over the other.[187] This creates an arbitrary designation between devices, both of which arguably meet the definition of medical device under the FDCA, especially when many have similar, if not identical, functions and risks. Consumer safety is thus left up to marketers who know how to skirt responsibility by using language that promotes these devices as toys even when their function is the same. This is not only true for penis pumps, but also for vibrators, dildos, cock rings, and other devices that are only regulated as novelty toys by the CPSC and are not subject to FDA safety regulations.

Manufacturers also benefit from clear safety regulations because a consistent regulatory regime provides guidelines that lead to greater efficiency. Holistic Wisdom, the company mentioned in Part III, admits on its website that calling a sex toy "safe" is debatable due to the lack of legal guidance.[188] This concession reveals manufacturers' underlying interest in understanding what would be considered safe so that they can effectively market to consumers. A standardized regulatory regime benefits consumers and manufacturers by eliminating the guesswork surrounding regulations, allowing manufacturers to invest in developing safe products, accurately market those products, and build trust with consumers.

Overall, FDA regulation is not only textually permissible but also has numerous policy justifications. By extending FDA jurisdiction to regulate sex devices, the multitude of consumers

185. *See supra* notes 25–28 and text accompanying.

186. *See* E.R. Squibb & Sons, Inc. v. Bowen, 870 F.2d 678, 683 (D.C. Cir. 1989) (citing Immunology and Microbiology Devices; General Provisions and Classification of 162 Devices, 47 Fed. Reg. 50814, 50815 (1982)).

187. *See* Seed, *supra* note 22.

188. Lawless, *supra* note 40.

who purchase sex toys every year would be better protected. Additionally, FDA regulation would allow for more transparent standards and oversight for consumers to understand risks and manufacturers to set expectations. Finally, FDA regulation provides for a regulatory regime that both manufacturers and consumers can rely on. An FDA regulatory regime can close the current loopholes, hold manufacturers to a consistent standard, and allow consumers to utilize their devices as they please.

## V. IT IS EFFICIENT FOR THE FDA TO REGULATE SEX TOYS AS MEDICAL DEVICES AND WOULD NOT OVER BROADEN FDA REGULATORY AUTHORITY

Having established the authority and justification for FDA regulation of sex devices in multiple ways, this Comment concludes with the efficiencies of FDA regulation. First, the FDA has procedures available that allow sex device companies to demonstrate the comparable safety and efficiency of their devices to other already-regulated devices. Second, the FDA has guidance on "general wellness" devices, which helps construct a limiting principle to ensure FDA regulation is not overbroad.

### A. FDA INFRASTRUCTURE CAN SUPPORT AND ACCOMMODATE THE REGULATION OF SEX TOYS

The FDA should regulate sex toys because there is a low procedural barrier to entry to expand its jurisdiction to include sex toys as medical devices. The Medical Device Amendments of 1976 established three regulatory classes for medical devices to provide flexible controls based on the degree necessary to ensure that the devices are safe and effective.[189] The classification procedures for those devices can be found in 21 C.F.R. § 860. This process includes a streamlined application where manufacturers can petition for their devices to be regulated as class I or class II,[190] as

189. *See* U.S. FOOD & DRUG ADMIN., PMA APPROVALS (on file with the *Columbia Journal of Law & Social Problems*), https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals (May 29, 2024).

190. Class I devices receive the lowest level of regulation under general controls. Class II devices receive special controls because general controls themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Class III devices receive the highest level of regulation by the FDA and require premarket approvals. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c.

long as they demonstrate substantial safety and effectiveness equivalent to other regulated devices.[191] Many of the medical sex devices already regulated by the FDA are regulated as class II devices, such as genital vibrators for therapeutic use,[192] condoms,[193] and external penile rigidity devices.[194] So if the FDA regulates other sex toys, there are clear blueprints for devices that function in identical or very similar ways to submit applications for consistent regulation. The ease provided by the FDA's current process makes for an efficient structure for standardized regulation.

## B. THE FDA'S RECOMMENDATION ON "GENERAL WELLNESS" DEVICES CAN BE USED TO CREATE A LIMITING PRINCIPLE FOR FDA AUTHORITY

The FDA has published guidance on devices that should be considered "general wellness" devices and, thus, exempt from FDA regulation. The FDA recommendation illustrates its understanding of what constitutes a low-risk device, as well as different ways devices can create risk that warrant FDA oversight. Though the guidance is a non-binding recommendation, it sheds light on how the FDA perceives general wellness products and why the sex devices emphasized in this paper should not be considered "general wellness" devices. Understanding the FDA's conceptions of regulatory limits in the guidance document illuminates a possible limiting principle for FDA regulation.

The title of the recommendation is "General Wellness: Policy for Low Risk Devices," establishing from the outset that these non-binding recommendations only cover low-risk devices. General wellness products are defined as products that meet the following two factors: (1) they are intended only for general wellness use, and (2) present a low risk to the safety of users and other persons.[195] The FDA further defines general wellness products as products with one of the following intended uses:

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191. *See id.*
192. *See* 21 C.F.R. § 884.5960 (2025).
193. *See* 21 C.F.R. § 884.5300 (2025).
194. *See* 21 C.F.R. § 876.5020 (2025).
195. *See* U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2019) [hereinafter GENERAL WELLNESS].

> (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
>
> (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.[196]

The first intended use category includes products that do not make any claims regarding disease or conditions, including devices that aid in physical fitness, mental acuity, self-esteem, and sexual functions.[197] For example, general wellness uses are found in products that claim to promote relaxation or manage stress, or increase and improve muscle size or body tone.[198] The only example for sexual activity claims that would be designated as general wellness uses is for products that claim to improve sexual performance.[199] Unfortunately, the guidelines do not designate where devices such as dildos, butt plugs, anal beads, or nipple clamps would fall.

However, based on the general wellness recommendations, it is likely that most sex toys would not be considered general wellness devices exempt from FDA regulation. First, the general wellness guidelines focus on sex devices that "improve sexual performance."[200] As seen in Part III of this Comment, sex device companies do not limit themselves to claiming that these products are intended to improve sexual performance. Instead, they explicitly state that sex toys can be used to alter the structure of the body through penetration or constriction.[201] Thus, the sex devices emphasized in this Comment go beyond improving performance and would not be exempt.

Further, the general wellness device guidelines state that products similar to those already regulated by the FDA should not be considered low risk and should not receive general wellness device exemptions.[202] The guidelines specifically mention the FDA's regulation of external penile rigidity devices as an example

196. *Id.* at 3.
197. *See id.* at 3–4.
198. *See id.*
199. *See id.*
200. *Id.*
201. *See supra* Part III.
202. *See* GENERAL WELLNESS, *supra* note 195, at 5–6.

of products that are not exempt from FDA regulation because of their risks.[203] Since the FDA is concerned about the risks posed by already regulated products, such as penile constriction rings, vibrators, and other sex devices, it's possible to argue that non-regulated sex devices pose similar risks. For example, penile rigidity devices pose risks of tissue injury, trauma, and infection,[204] all of which are also risks presented by dildos, butt plugs, anal beads, nipple clamps, and other popular sex devices.[205] Thus, sex devices would not likely be considered general wellness devices because sex devices introduce similar risks to external penile rigidity devices.[206] Moreover, the FDA makes clear that risk is one of its primary concerns.[207] Infection and the introduction of toxic chemicals into the body is an especially worrisome risk due to the lack of regulation of the materials sex devices are made of, because they are classified as "novelty toys."[208]

Finally, the recommendations provide that products should not be considered low risk when they are invasive, implanted, or involve an intervention or technology that may pose a risk to the safety of users and other persons if specific regulatory controls are not applied.[209] The guidelines define invasive to mean devices that penetrate or pierce the skin or mucous membranes of the body.[210] Sex toys are typically used near sensitive body tissues. They are inserted into the body with the potential to pierce skin or mucous membranes, providing another reason they would not be exempt from FDA regulation as general wellness devices.[211]

The general wellness guidelines and FDA recommendations on assessing the risk of devices establish a limiting principle to ensure that FDA regulation applies only to appropriate products. The sex devices discussed in this Comment[212] present similar risks to already regulated devices. Sex devices that are not invasive or do not constrict body parts—essentially, sex devices that do not come

203. *See id.* at 5.
204. *See id.* at 6.
205. *See* Nuzzo, *supra* note 34.
206. *See* GENERAL WELLNESS, *supra* note 195, at 6.
207. *See id.* at 5–6.
208. Sipe et al., *supra* note 2, at 2.
209. *See* GENERAL WELLNESS, *supra* note 195, at 5.
210. *See id.*
211. *See* Babbs, *supra* note 36.
212. *See supra* Part I ("This Comment emphasizes regulation for the most common sex devices: dildos, butt plugs, anal beads, penis constriction rings, sleeves, and nipple clamps.").

into contact with the body—could be considered low-risk general wellness devices. For example, a sex stimulator that uses puffs of air for arousal would be exempt from FDA regulation as a general wellness device.

This limiting principle aligns with FDA conceptions because it is another form of designating the primary intended use. This principle differentiates the regulation of products based on whether their primary intended use is invasive or constrictive, in addition to the corresponding risks they present. Additionally, this principle is in line with FDA interpretation as seen in the "general wellness" device recommendations and Part III of this Comment. Since the FDA considers intended use as one way to bring instruments, apparatuses, machines, contrivances, and other products under its jurisdiction, it makes logical sense that intended use can also serve as a limiting principle. This process allows for less arbitrary regulation over similar, if not identical, sex devices and individual inquiries for outliers or fringe cases. This individualized inquiry of primary usage allows the FDA to regulate similar devices because they present similar risks or are used in identical ways. Thus, penis pumps or cock constriction rings could be regulated consistently even when distributors try to exploit labeling loopholes through avoiding therapeutic claims. This approach protects vulnerable consumers and provides for a consistent regulatory regime through investigation of a device's primary intended use and risk assessment. This allows the FDA to assert appropriate jurisdiction over medical devices while allowing other devices to be regulated by other agencies when they function differently or present less risk.

## CONCLUSION

Though dildos, butt plugs, and nipple clamps are likely not the first things that come to mind when contemplating FDA regulation, perhaps they should be. After all, statutory drafting, the FDA's own understanding, and case law all support that the FDCA can establish FDA jurisdiction over sex devices that affect the structure or function of the body. The intended use of sex toys, derived from their labeling, promotional materials, and surrounding context, can also establish FDA oversight of these products as medical devices. Moreover, the history and mission of the FDA to protect consumers in their health decisions and supply

transparent regulatory standards favor FDA regulation of sex toys. Finally, FDA regulation of sex toys is an efficient solution because of the agency's application procedures and regulatory regime that falls within the scope of limiting principles. For all these reasons, the FDA is the appropriate agency to regulate sex toys as medical devices to protect the pleasure of the people.