UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

WOMEN'S HEALTH SPECIALISTS, PLLC., Plaintiff, v. CYNOSURE, LLC, Defendant.	Case No. _____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, WOMEN'S HEALTH SPECIALISTS, PLLC ("Plaintiff" or "Plaintiff Women's Health Specialists") by its attorneys, for its Complaint against the Defendant, CYNOSURE, LLC, ("Cynosure" or "Defendant"), respectfully alleges upon information and belief as follows:

PARTIES

1. Plaintiff Women's Health Specialists, PLLC is a citizen of the State of Tennessee, it is incorporated in the State of Tennessee, and its offices are located in Germantown, Shelby County, Tennessee.

2. Defendant, Cynosure, LLC, (formerly Cynosure, Inc.) is a Delaware corporation with its headquarters in Westford, Massachusetts, and is a division of Hologic, Inc., which is a Delaware corporation that has headquarters in Marlborough, Massachusetts.

JURISDICTION AND VENUE

3. This Court has diversity jurisdiction over this case under 28 U.S.C. § 1332 because Plaintiff is a citizen of a State other than that of the citizenship of the Defendant. The

amount in controversy is alleged to be over the minimum requirement of $75,000.

4. Venue is proper in this Court because Plaintiff resides in this District.

5. This Court has personal jurisdiction over Defendant as Defendant conducts business in Tennessee and committed the acts herein in Tennessee, as described further in this Complaint.

FACTUAL BACKGROUND

6. This action concerns Plaintiff's financing and purchase of a medical device sold by Defendant called the MonaLisa Touch.

7. Plaintiff learned of the MonaLisa Touch on or about March of 2015 through direct marketing efforts by Cynosure, including emails sent by Cynosure directly to Dr. Val Vogt, a member of Women's Health Specialists practice at that time.

8. Cynosure representative, Christopher Binion ("Binion") was a representative of Defendant, and at all times discussed herein acted as Defendant's agent.

9. Binion stated that several million dollars would be spent on multimedia advertising for the MonaLisa Touch to ensure an "excellent and high profile 'branding'" for the device, and that Women's Health Specialists would be provided web and marketing support.

10. Binion also specifically promoted the MonaLisa Touch as a device to treat the symptoms of vulvovaginal atrophy. [See Christopher Binion email of March 17, 2015 attached hereto as Exhibit A and incorporated herein by reference.]

11. As a result of this promotion and representations, Plaintiff justifiably believed that the MonaLisa Touch had been approved by the United States Food and Drug Administration ("FDA") specifically for the treatment of the symptoms of vulvovaginal atrophy (VVA) as it would have been unlawful for Cynosure to market the device for these treatments unless the FDA

specifically approved such marketing.

12. At no time did Binion or any other representative for Defendant advise Plaintiff that using the MonaLisa Touch to treat symptoms of VVA was an "off-label" use.

13. Binion also represented that Plaintiff would realize well more than the lease payments from using the MonaLisa Touch.

14. Based upon Binion's representations, Plaintiff purchased the MonaLisa Touch on or about March 20, 2015, for $156,780.00.

15. The MonaLisa Touch was delivered to Plaintiff by the end March of 2015.

16. Given the considerable cost of the MonaLisa Touch, Plaintiff financed the purchase through Oneplace Capital, a finance company arranged by Defendant.

17. Plaintiff entered into an agreement with Oneplace on or about March 20, 2015, requiring Plaintiff to pay 6 monthly payments at $99 each followed by 60 monthly repayments at $3,344.51, with the last payment due in October 2020. These payments totaled $201,264.60.

18. Binion made the representations described in the paragraphs above to Dr. Val Vogt who was acting on behalf of Plaintiff in order to induce Plaintiff to finance and purchase the MonaLisa Touch.

19. On July 30, 2018, the FDA issued a warning ("July 30, 2018 FDA Warning") to "patients considering any . . . procedure or procedures intended to treat vaginal conditions and symptoms related to menopause . . ." and to "health care providers who perform vaginal procedures using energy-based devices" "to alert patients and health care providers that the use of energy-based lasers to perform . . . non-surgical vaginal procedures to treat symptoms related to menopause . . . may be associated with serious adverse events [and that] [t]he safety and effectiveness of energy-based devices for treatment of these conditions has not been established.

(Emphasis added.).

20. The FDA went on to state that "[t] o date, we have not cleared or approved for marketing any energy-based devices to treat these symptoms or conditions, or any symptoms related to menopause . . ." (emphasis added) but was "aware that certain device manufacturers may be marketing their energy-based medical devices for vaginal 'rejuvenation'" (which it defined to include the typical vaginal symptoms of menopause).

21. As succinctly explained by FDA Commissioner Dr. Scott Gottlieb, the FDA:

> recently become aware of a growing number of manufacturers marketing "vaginal rejuvenation" devices to women and claiming these procedures will treat conditions and symptoms related to menopause, urinary incontinence or sexual function. The procedures use lasers and other energy-based devices to destroy or reshape vaginal tissue. These products have serious risks and don't have adequate evidence to support their use for these purposes. We are deeply concerned women are being harmed.

Statement from FDA Commissioner Scott Gottlieb, M.D., on efforts to safeguard women's health from deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation", dated July 30, 2018, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm615130.htm; *see also* FDA Warns Against Use of Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures: FDA Safety Communication, dated July 30, 2018, available at https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm615013.htm (text of warning).

22. As Commissioner Gottlieb further explained, while the FDA had cleared various laser and other energy-based devices to treat such conditions as abnormal or pre-cancerous cervical or vaginal tissue or genital warts, "the safety and effectiveness of these devices hasn't been evaluated or confirmed by the FDA for 'vaginal rejuvenation.'" *Id.* Nonetheless, companies who produce and sell these devices make "deceptive health claims" and engage in "deceptive marketing

of a dangerous procedure with no proven benefit," which he stated was, in a word, "egregious." *Id.* As the July 30, 2018 FDA Warning itself stated, using such devices for vaginal rejuvenation "may lead to serious adverse events," including vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain.

23. Cynosure was one of the companies the FDA was referring to in its July 30, 2018 FDA Warning with regard to its marketing of its energy-based laser – the MonaLisa Touch.

24. In a letter dated July 24, 2018 to Defendant, the FDA raised a number of examples of Defendant's improper marketing of its MonaLisa Touch to treat the vaginal symptoms of menopause which the FDA could hardly have been clearer – are purposes for which it was not approved by the FDA and for which its safety and effectiveness had not been established.

25. The FDA stated that the MonaLisa Touch had only been cleared "for incision, excision, ablation, vaporization and coagulation of body soft tissues in medical specialties including aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics, general and thorasic surgery (including open and endoscopic), dental and oral surgery and genitourinary surgery." July 24, 2018 Letter from Cesar A. Perez, PhD, Chief of the Surveillance and Enforcement Brach, Division of Premarket and Labeling Compliance, Office of Compliance, Center for Devices and Radiological Health to Connie Hoy, Official Correspondent, Cynosure, Inc.

26. On or about November, 2019, Plaintiff became aware of the July 30, 2018 FDA Warning, which revealed to them for the first time that the MonaLisa Touch was not FDA approved for the purposes for which Defendant sold the MonaLisa Touch to Plaintiff and the treatments for which Defendant's Sales Representative represented to Plaintiff, specifically the treatment of the symptoms of VVA.

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