Alex R. Straus, SBN 321366
Astraus@Milberg.com
**MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN PLLC**
16748 McCormick Street
Los Angeles, CA 91436
Telephone: (917) 471-1894
Facsimile: (310) 496-3176

*Counsel for Plaintiff and Proposed Classes*

*Additional attorneys on signature page*

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**
**SAN FRANCISCO DIVISION**

PHORNPHAN CHUBCHAI, [redacted], JAVIER VALENCIA, PAULA BROOKS, individually and on behalf of all others similarly situated persons,

Plaintiff,

v.

ABBVIE, INC. f/k/a ALLERGAN, INC., f/k/a ALLERGAN plc, and f/k/a ZELTIQ AESTHETICS, INC,

Defendants.

Case No.: 3:21-cv-4099

**CLASS ACTION COMPLAINT**

**DEMAND FOR JURY TRIAL**

## CLASS ACTION COMPLAINT

Plaintiffs on behalf of themselves and all other similarly situated class members, file this class action Complaint against Defendant AbbVie, Inc., formally known as Allergan plc, also formally known as Allergan Inc., also formally known as Zeltiq Aesthetics, Inc. ("Defendant"), and allege as follows:

## NATURE OF THE PROCEEDINGS

1. This class action lawsuit arises from a popular non-invasive fat reducing medical device called the CoolSculpting System, which has the ability to cause permanent deformities to a person's body.

2. Defendant advertised and continues to advertise CoolSculpting as a "nonsurgical" procedure intended to reduce stubborn fat bulges "in the areas that bother you most." CoolSculpting promises "up to 20-25% reduction in fat layer thickness after a single session."[1]

3. Defendant knew since at least 2011 that the CoolSculpting device can cause consumers to develop a condition called Paradoxical Adipose Hyperplasia (PAH) a/k/a Paradoxical Hyperplasia (PH), which results in the *opposite effect* of the medical device's advertised purpose. The CoolSculpting device can *permanently* damage the tissue in the area it targets to reduce, creating a deformity on the patient's body much *larger* in size than the original "stubborn fat bulge." The condition does not resolve on its own, and unlike regular fat tissue, tissue affected by PH does *not* respond to weight loss. Thus, the only method of removing PH is through invasive surgery. The condition is solely attributed to the CoolSculpting device.

4. Since the device went on the market, Defendant has received thousands of reports of CoolSculpting consumers that have developed Paradoxical Hyperplasia (PH) after undergoing the CoolSculpting procedure.

5. Defendant created an environment that deprived consumers of being properly informed about the risk of PH. Defendant withheld critical information about PH from CoolSculpting providers, entangled itself in the providers' CoolSculpting business, and gave assurance to providers that if a patient developed PH, Defendant would cover the claim with its "liposuction program." This created an atmosphere wherein providers did not understand the

[1] https://www.coolsculpting.com/coolsculpting/

gravity of the adverse effect and were not motivated to disclose the risk thereof to their patients. As the result of Defendant's conduct, the Plaintiffs' CoolSculpting provider did not advise the Plaintiffs about the risk of developing PH after CoolSculpting.

6. Consequently, all Plaintiffs unknowingly subjected themselves to the risk of the CoolSculpting procedure.

7. Defendant's conduct was systemic across the nation and resulted in thousands of consumers being affected in the same manner.

**PARTIES**

8. Plaintiff, **Phornphan "Lisa" Chubchai**, is an individual and a resident of California. In December 2018, April 2019, and June 2019, she underwent the CoolSculpting procedure in Fresno, California.

9. Plaintiff, [redacted], is an individual and a resident of California. From March 2018 through October 2018, she underwent multiple CoolSculpting procedures in [redacted] California.

10. Plaintiff, **Javier Valencia**, is an individual and a resident of New York. In July 2018, he underwent the CoolSculpting procedure in Stony Brook, New York.

11. Plaintiff, **Paula Brooks**, is an individual and a resident of Massachusetts. In May 2019, she underwent the CoolSculpting procedure in Hyannis, Massachusetts, and in August 2019, she underwent another CoolSculpting procedure in Mt. Pleasant, South Carolina.

12. Defendant, **AbbVie, Inc.** is a corporation formed under the laws of Delaware with a principal place of business at 1 North Waukegan Road, North Chicago, IL 60064. On May 8, 2020, AbbVie Inc. acquired Allergan plc., Allergan, Inc., and Zeltiq Aesthetics, Inc. and is the current owner of the CoolSculpting medical device.

13. At all times material, Defendant's CoolSculpting business was based in Pleasanton, California. The CoolSculpting headquarters is currently located at 4410 Rosewood Drive,

Pleasanton, CA. Prior to operating from that address, the CoolSculpting business operated from 4698 Willow Rd., Pleasanton, CA. Defendant has designated both Pleasanton addresses as its official CoolSculpting business office. Defendant also operated manufacturing and assembly facilities for the CoolSculpting device in Dublin, California and Livermore, California.

14. Defendant made corporate decisions related to selling, promoting, advertising, and labeling the CoolSculpting medical device from the State of California.

**JURISDICTION AND VENUE**

15. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d)(2) because this is a class action lawsuit in which the matter in controversy exceeds the value of $5,000,000, exclusive of interest and costs, and is a class action in which the majority of the class members are citizens of a different state than the Defendant.

16. This Court has personal jurisdiction over Defendant because the acts giving rise to sustained to the Plaintiffs' claims occurred in this District from Defendant's sale of the CoolSculpting device and cycles in this District which were used on the Plaintiffs, in the jurisdiction of this Court, such that maintenance of this action is consistent with traditional notions of fair play and substantial justice.

17. Venue is proper in this district pursuant to 28 U.S.C. §§1391(b)(2) and 1391(c)(2) because a substantial part of the events or omissions giving rise to the claims occurred in this judicial district, and the Defendant is subject to this Court's personal jurisdiction.

**INTRADISTRICT ASSIGNMENT**

18. Pursuant to Civil Local Rule 3-2(c-d), a substantial part of the events giving rise to the claims herein arose in Alameda County, California and this action should be assigned to the San Francisco Division.

## FACTUAL ALLEGATIONS

19. Zeltiq Aesthetics, Inc., either directly or through its agents, servants, and employees, created, designed, manufactured, labeled, marketed, advertised, distributed, and sold its CoolSculpting System medical device to be used on individuals to induce lipolysis (the breaking down of fat cells) in the body.

20. On April 28, 2017, Allergan plc and Allergan Inc. acquired Zeltiq Aesthetics, Inc. for the purchase price of $2.48 billion. Since Allergan's acquisition of Zeltiq, Allergan held itself out to the world as the owner of the CoolSculpting System and had apparent dominion and control over all aspects of the CoolSculpting business including the manufacturing, labeling, advertising, distribution, and sale of the medical device and its consumables.

21. On May 8, 2020, AbbVie, Inc. acquired Allergan plc, Allergan, Inc., and Zeltiq Aesthetics, Inc. for the purchase price of $63 billion and took control over all of the companies' assets and liabilities, it is now the owner of the CoolSculpting System medical device and is financially responsible for the claims set forth in this lawsuit.

22. At all times material, the Defendant's CoolSculpting headquarters and manufacturing facilities operated out of California.

### ABOUT COOLSCULTPING

23. CoolSculpting is a body contouring procedure that is supposed to work by using a process called Cryolipolysis®, which freezes fat cells and programs them to die over the course of several months.

24. The Cryolipolysis® process was developed and patented by Drs. Richard Rox Anderson and Dieter Manstein at Harvard University and Massachusetts General Hospital in the early 2000's.[2]

[2] *Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al.*, Case No.: 2:15-cv-00186 ¶10.

25. In 2005, Defendant made a deal with Massachusetts General Hospital for an exclusive license to manufacture a medical device based on this patented process.[3]

26. Defendant developed a medical device called CoolSculpting System to administer the Cryolipolysis procedure on patients seeking to reduce stubborn fat without surgery.

27. The CoolSculpting System device consists of several parts, including the main control unit (the body of the device), the applicators (arms extending from the body), gel pads for the applicators, massage function, consumable cards, liners, pretreatment skin wipes, and securement systems.

28. The concept of Cryolipolysis® is based on a theory that fat tissue is more vulnerable to cold temperatures than the skin; therefore, if cold is applied to a person's unwanted fat bulge, the cold temperature will kill the fat cells and leave the skin intact. The fat cells are not killed immediately but are rather "programmed" to die over time. Persons undergoing the procedure are expected to see "results" 1-3 months after the procedure, as the fat cells wither away in the treatment area.

29. CoolSculpting's premise is based on the fact that the human body has a certain number of fat cells that does not change during the course of a person's life. The CoolSculpting device can reduce fat by reducing the number of fat cells through this cold-assisted lipolysis process.

30. Although the CoolSculpting device has other possible indications for use, such as cooling or heating with the device to minimize temporary pain and provide temporary relief from muscle aches, improve circulation, and temporarily reduce the appearance of cellulite with an optional massage function, the CoolSculpting device's primary purpose is for Cryolipolysis® treatments or "cold-assisted lipolysis (breakdown of fat)."[4]

---

[3] *Id.* at ¶¶7, 10.

[4] Zeltiq Aesthetics, Inc. (2015). *Annual 10-K Report.* Page 19/153. Retrieved from https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm.

31. The U.S. Food and Drug Administration ("FDA") cleared Defendant's Cryolipolysis® CoolSculpting device for the performance of Cryolipolysis® services to the following areas: upper arm, bra fat, back fat, banana roll (underneath the buttocks), thighs, abdomen, and flank ("love handles"), submental, and submandibular areas.[5]

32. The CoolSculpting device is the only medical device in the United States with FDA clearance to offer body contouring services via Cryolipolysis®.

33. The CoolSculpting device is a Class II prescription medical device that should only be sold to physicians.

34. In order to facilitate Cryolipolysis®, the CoolSculpting device's suction applicators are applied to a person's body and cool the treatment area for 30 to 60 minutes. Each application of the applicator is called a "cycle." A person may undergo multiple cycles in one CoolSculpting session, depending on the size of the area they desire to treat with Cryolipolysis®.

35. CoolSculpting is a relatively expensive procedure. An average session of CoolSculpting costs $2,000-$4,000, at an average price per cycle (one application of the device) of $650-$800.

**COOLSCULPTING ADVERTISING**

36. Defendant has extensively marketed and promoted its CoolSculpting system directly to the public and continues to do so today.[6]

37. At all times material, Defendant used the same or similar language and messaging throughout its advertisement materials.

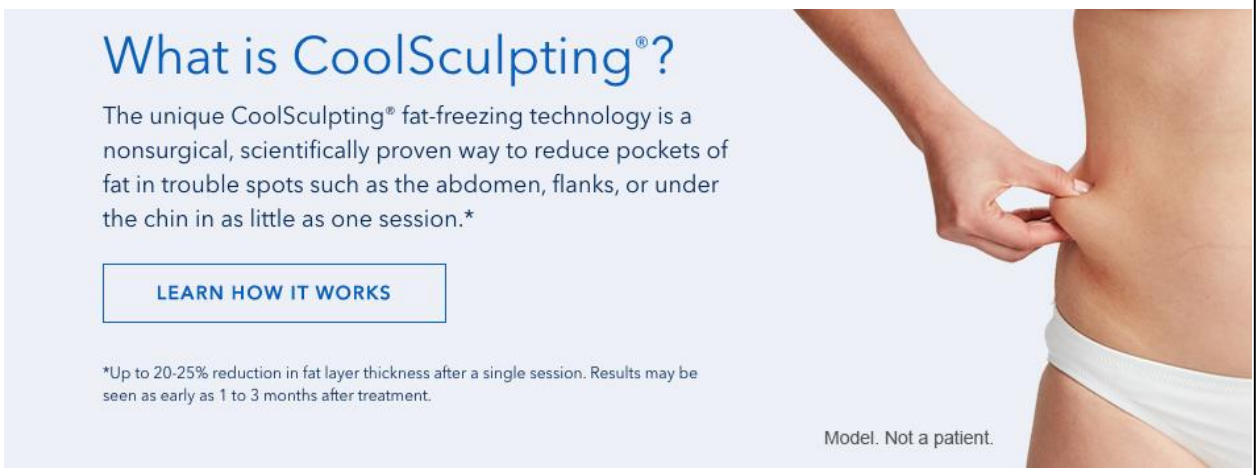
---

[5] Department of Health and Human Services, Food and Drug Administration. Dermal Cooling Pack/Vacuum/Massager, 510(k), K193544*:* ZELTIQ Coolsculpting System. Indication for Use. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193566.pdf.

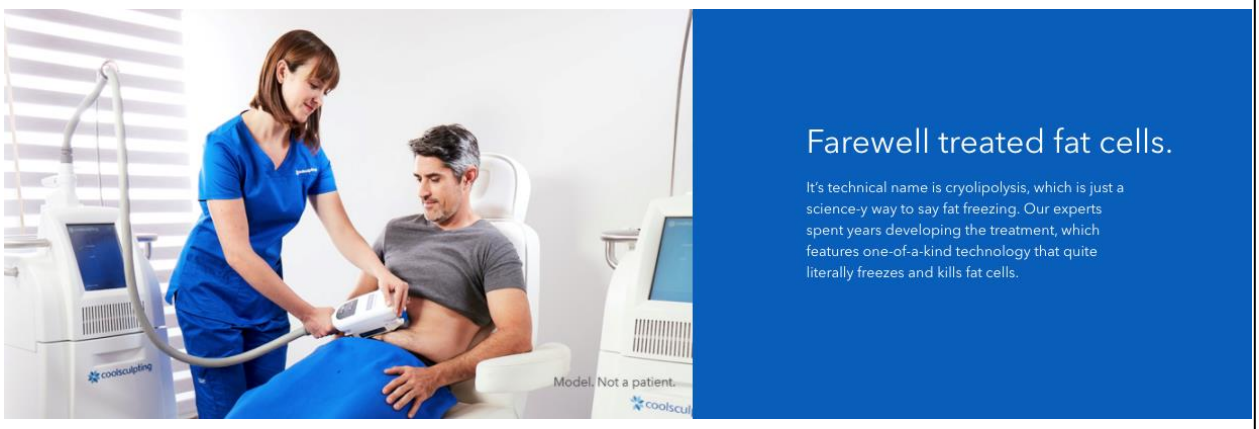
[6] Zeltiq Aesthetics, Inc. (2015). *Annual 10-K Report.* Page 6/153. Retrieved from https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm

38. CoolSculpting is advertised and marketed as a *non-invasive* and *surgery-free* procedure that is an alternative to liposuction and other fat reducing surgeries.


39. CoolSculpting promises to reduce fat up to 20-25% after only one session.




40. CoolSculpting claims that the fat reduction after the procedure is "long lasting" and that the device permanently kills the fat cells. It boasts, "Our experts spent years developing the treatment, which features one-of-a-kind technology that quite literally freezes and kills fat cells."[7]




7 https://www.coolsculpting.com/what-is-coolsculpting/

41. The CoolSculpting System has received substantial press coverage in the national media since its clearance by the FDA for non-invasive, cosmetic, body-contouring, including features on television shows such as The Today Show, Good Morning America, The CBS Early Show, The Rachel Ray Show, The Dr. Oz Show, Extra, Nightline, The Doctors, and E! News, and in magazines such as O, Elle, Marie Claire, Allure, Men's Fitness, Town & Country, Elevate, W, and Vie.[8]

42. Defendant operated and still operates a website www.coolsculpting.com where it also advertises CoolSculpting directly to the public and refers prospective patients to CoolSculpting providers in their geographical area.

43. In addition to intensely marketing the CoolSculpting device to the general public, Defendant aggressively pursued doctor's offices, medical spas, laser hair removal clinics, and other cosmetic procedure establishments to sell its CoolSculpting System device and induce them to add CoolSculpting to their list of medical procedures provided to their cosmetic patients.[9]

44. Defendant also spent millions of dollars partnering with individual CoolSculpting providers, paying for local ads that promote the CoolSculpting services at the providers' clinics.

**DEFENDANT'S CONTROL OVER THE COOLSCULPTING PROVIDERS**

45. Defendant's relationship with CoolSculpting providers differs from traditional relationships between medical device manufacturers and device users.

46. Defendant has masterminded a system where it injects itself into the provider's CoolSculpting practice and becomes entangled in the patient's medical treatment with the device. The system is strategically designed to financially benefit both the owner of the device and the Defendant, so long as consumers continue to undergo the CoolSculpting procedure.

---

[8] *Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al.*, Case. No.: 2:15-cv-00186. ¶15.

[9] Zeltiq Aesthetics, Inc. (2015). *Annual 10-K Report.* Page 6/153. Retrieved from https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm.

47. Defendant controlled and continues to control all aspects of the CoolSculpting providers' CoolSculpting business.

48. The CoolSculpting medical device is specifically programmed to only function with the use of consumable cards, called "cycles," which CoolSculpting providers *must* buy from Defendant to operate the medical device.[10] "A cycle is an authorization to perform one procedure to one specific area on the body; [providers] can only perform a treatment if they have purchased a cycle."[11]

49. The Defendant actually makes more money on selling the consumable cards to CoolSculpting providers than on selling the CoolSculpting devices. In 2018, it made $235.3 million on selling consumable cards and $126.3 million on selling the CoolSculpting devices and applicators.[12]

50. Incentivized by these profits from each CoolSculpting cycle, Defendant also closely controlled and continues to control the CoolSculpting providers' sales methods of the medical procedure. During training on the device, Defendant devotes a substantial part of the training time to boasting about the device's potential to substantially increase the providers' revenues and how to increase CoolSculpting sales by using various sales tactics. Defendant's training materials include sample scripts to use on prospective CoolSculpting patients and describe upselling methods such as having the patients return for a "follow-up appointment" where the provider has an opportunity to sell additional cycles or by pre-selling CoolSculpting packages

[10] Zeltiq Aesthetics, Inc. (2015). *Annual 10-K Report.* Page 6/153. Retrieved from https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm.

[11] *Id.*

[12] Allergan Reports Fourth Quarter and Full-Year 2018 Financial Results. Retrieved from https://allergan.gcs-web.com/news-releases/news-release-details/allergan-reports-fourth-quarter-and-full-year-2018-financial

where the patient pays for multiple cycles in advance for future uses.[13]

51. Defendant collects data from its medical devices, completely bypassing the CoolSculpting providers. To help with promoting sales of the procedure, Defendant installed a cellular device inside each CoolSculpting machine that automatically reports information about each cycle administered by the CoolSculpting providers *directly* to the Defendant.

52. This platform, which is called CoolConnect, is used by the Defendant to obtain data from the CoolSculpting devices and use it to pressure CoolSculpting providers to sell more procedures. According to Keith Sullivan, the Zeltiq Aesthetics, Inc.'s former CEO (2012 - April 2017), in an interview he gave to PRIME Journal, "In this way, we know what we are doing, and we can show [the CoolSculpting providers] how they are doing such as if you're only treating flanks, why aren't you looking at their belly, and so on. The PDM[14] has the data to bring back to those accounts on a monthly or quarterly basis and follow their progress."[15]

53. Likewise, at all times material, Defendant controlled how the CoolSculpting providers advertised their CoolSculpting services. Defendant established a minimum advertised price policy, restricting providers from independently setting and advertising prices for the CoolSculpting procedure and penalized providers that advertised a lower price for their CoolSculpting services.[16]

54. Defendant also gave money or other valuable consideration to CoolSculpting providers for marketing CoolSculpting services on billboards, print ads, local TV, radio, and other

---

[13] Guidelines for CoolSculpting Success. Retrieved from https://docplayer.net/docview/26/9289425/#file=/storage/26/9289425/9289425.pdf.

[14] Practice Development Manager, also known as CoolSculpting's sales Representative.

[15] Lewis, Wendy. "Fat Chance Building a Better Body the Cool Way." *Prime Journal.* May/June 2016: 16-20. Retrieved from https://www.prime-journal.com/fat-chance-building-a-better-body-the-cool-way/

[16] Lewis, Wendy. "Fat Chance Building a Better Body the Cool Way." *Prime Journal.* May/June 2016: 16-20. Retrieved from https://www.prime-journal.com/fat-chance-building-a-better-body-the-cool-way/

media outlets.

55. The CoolSculpting website lists local providers, links directly to their websites, and gives prospective patients an option to request a CoolSculpting appointment directly with the providers.

56. Defendant also furnished CoolSculpting providers with advertisement materials directed at CoolSculpting patients, which describe the benefits of the procedure, such as brochures and posters.

57. Defendant also provided documents and forms to CoolSculpting providers to use in their practice when administering the CoolSculpting procedure to patients. This incentivized providers to use forms drafted by Defendant in their CoolSculpting practice, including consent forms that contain vague language about PH.

58. The documents, brochures, posters, and forms provided by Defendant to CoolSculpting providers depict the CoolSculpting logo and clearly promote the Defendant's medical device.

59. Defendant promised CoolSculpting providers to cover liability claims for PH if a patient develops the adverse effect. Defendant offered to refund patients or pay them for one liposuction procedure to correct the effect of PH in exchange for a release of liability benefiting the Defendant and the provider. This "liposuction program" mislead providers to believe that the condition can be successfully corrected with a single liposuction procedure, *if* required, and assuaged the providers in their worry about liability to CoolSculpting patients that could develop the adverse effect.

60. The CoolSculpting medical device is unique in that it is not only a medical device, but it is also a brand name that consumers seek out due to Defendant's direct advertising. CoolSculpting providers do not use independent judgment to prescribe the medical device based on the patient's needs but rather provide the CoolSculpting service at their request.

61. Therefore, after a consumer sees a CoolSculpting advertisement, he or she is directed to visit www.coolsculpting.com, which refers the consumer to a local CoolSculpting provider. When a consumer arrives at a CoolSculpting provider's office, he or she sees CoolSculpting posters and brochures which describe the benefits of the CoolSculpting procedure. The provider sells the procedure to the consumer using specific sales techniques according to the training that the Defendant provided. The provider uses special forms depicting the CoolSculpting trademark logo in administering the procedure. And the provider pays Defendant a portion of the cycle price charged to the consumer for the CoolSculpting procedure. Defendant also protected CoolSculpting providers from liability in regard to PH through its "liposuction program."

62. Ultimately, through a uniquely designed system which Defendant controlled, the Defendant used CoolSculpting providers to sell CoolSculpting procedure on its behalf and effectively took away the CoolSculpting providers' independence in treating patients with the CoolSculpting medical device.

**THE PROBLEM WITH COOLSCULPTING**

63. Although the idea of eliminating fat cells by using cooling technology makes sense in theory, in practice, it is nothing more than an illusion.

64. The CoolSculpting device can only *attempt* to kill fat cells by traumatizing them with the application of cold temperature in the hopes of a later death.

65. The problem with the CoolSculpting device is twofold. First, the CoolSculpting device cannot ensure that *any* of the fat cells it targets will actually die. Second, even if *some* fat cells die, the effect is minimal and temporary.

66. On September 23, 2016, the National Advertising Division of the Better Business Bureau found that the typical fat layer reduction from CoolSculpting is *one millimeter* (1mm) and

cautioned the manufacturer to "avoid making fat elimination claims.[17]

67. Moreover, even when the CoolSculpting device does actually kill some targeted fat cells, the unwanted fat bulges easily return because the device does not eliminate all fat cells in the targeted area. The void is quickly filled by the expansion of surviving fat cells, resulting in a reversal of the effect.

68. Therefore, although a CoolSculpting patient may initially see a reduction of fat in the treated area, the stubborn fat bulge will inevitably return if the patient does not adhere to a very strict diet.

69. But in some cases, the *intended injury* of the CoolSculpting device triggers the body's wound healing process in response to the *cryo-assault* and the injured tissue goes into cellular adaptation mode.

70. Cellular adaptation is a process in which injured cells try to adapt to an adverse environment by acting abnormally. Cellular adaptation can present itself in various ways including, *hyperplasia* – a process in which a cell multiplies, thereby increasing the size of the affected tissue, and *hypertroph*y – a process in which a cell enlarges caused by an increase in organelles, and structural proteins, also resulting in an increase in the size of the affected tissue.

71. Hyperplasia and hypertrophy is the first step of the wound healing process which eventually results in *fibrosis* or *fibroplasia*,[18] an irreversible disease of the tissue. Fibrosis is the end result of the body's wound healing process in response to an injury.

72. Paradoxical Hyperplasia (PH) sometimes described as Paradoxical Adipose Hypertrophy, an adverse effect of CoolSculpting, is an example of the body's response to an injury.

---

[17] *Zeltiq Aesthetics, Inc. - CoolSculpting® Cryolipolysis® Body Contouring System.* National Advertising Division. NAD Case Report No. September 23, 2016. Back Refence: ¶3020.

[18] The terms *fibrosis* and *fibroplasia* refer to the same process and effect.

**PARADOXICAL HYPERPLASIA "PH" A/K/A**
**PARADOXICAL ADIPOSE HYPERPLASIA "PAH"**

73. At some point in 2011, Defendant became aware that its CoolSculpting System device had the ability to cause patients to develop a condition that results in the *opposite effect* of the device's advertised purpose – a *permanent increase in the size of the treated fat bulges.*

74. Paradoxical Adipose Hyperplasia, also known as "PAH" and referred to as Paradoxical Hyperplasia or "PH" by the Defendant is a permanent condition that is developed *only* as of the result of undergoing Cryolipolysis® via the CoolSculpting device.

75. Other than a single report in 2019 of a patient developing a similar condition from a different fat reducing device (or a combination of two devices), PH has solely been associated with the CoolSculpting device.

76. PH, as seen in CoolSculpting patients, is not known to occur naturally.

77. Thus, with the invention of the CoolSculpting System device and the process of Cryolipolysis®, a new adverse medical condition was created called Paradoxical Hyperplasia.

78. PH causes *permanent* pathological change to the microstructure of the tissue in the CoolSculpting treatment area, affecting various types of cells, including adipocytes, vascular cells, blood cells, macrophages, endothelial cells, stem cells, and interstitial cells.[19] The tissue affected by PH becomes fibrous and different from regular, untreated tissue resulting in enlarged and sometimes hardened tissue masses that are disfiguring to the body.

79. Defendant's internal investigation of the condition revealed that PH tissue is consistent with *fibroplasia*, which is fibrosis of the treated tissue.

[19] Seaman, SA; Tannan, SC; Cao, Y; Peirce, SM; Gampper, TJ. Paradoxical Adipose Hyperplasia and Cellular Effects After Cryolipolysis: A Case Report. *Aesthetic Surgery Journal.* 2015 Nov; Vol. 36(1): NP6-NP13. DOI:10.1093/asj/sjv105; and Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018; Vol 38(4): 411-417, 415. DOI: 10.1093/asj/sjx159.

80. Fibroplasia is scarring (fibrosis) of the affected tissue resulting from the body's wound healing process after an injury. It is an irreversible process. To manage the fibroplasia the tissue must be surgically excised.

81. Defendant has known that PH tissue can *recur* after surgery and in some cases cannot be fully removed.

82. PH is not a simply an enlargement of fat in the treatment area, it is a disease of the tissue that results in a *deformation* of the body.

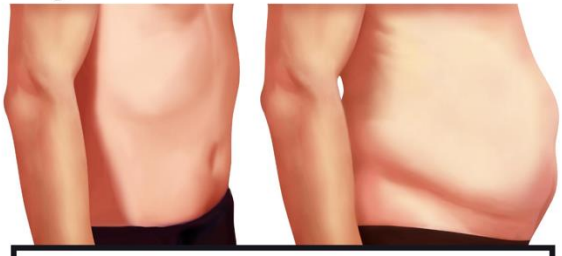
83. Unlike regular fat tissue, PH does not resolve on its own. Once a person develops PH after CoolSculpting, the affected tissue does not react the same as regular fat to weight loss. No matter how much weight a person loses after developing PH, the area affected by PH will never get smaller. The deforming effect of PH remains *permanently* and can only be removed surgically.

84. The visual effect of PH varies from person to person, and may present differently in a single person, depending on the area of the body affected.

85. PH has a wide range of effects on a person's body. In more fulminant cases, it can present itself as an obvious hardened protruding mass (Figure A), a soft enlargement of tissue (Figure D), sagging folds (Figure B), or as a bulge of tissue in the shape of the CoolSculpting applicator (Figure C).

86. The following illustrations show examples of PH, that are more visually apparent:

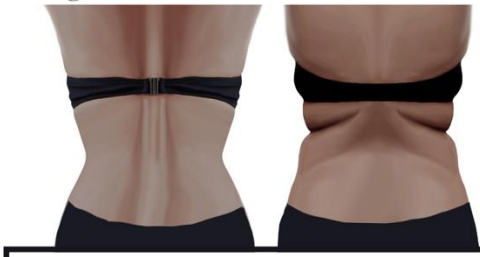
**Figure A**



**BEFORE:** abdominal area before CoolSculpting procedure

**AFTER:** abdominal area affected by PAH after CoolSculpting procedure

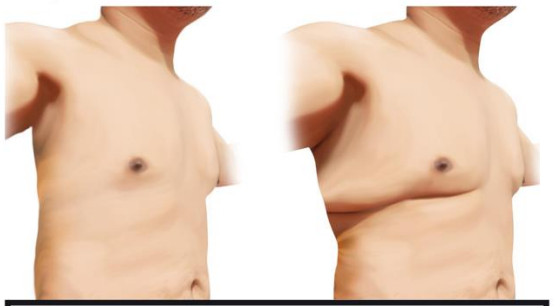
**Figure B**



**BEFORE:** upper (bra area) and lower flanks before CoolSculpting procedure

**AFTER:** upper (bra area) and lower flanks affected by PAH after CoolSculpting procedure

**Figure C**



**BEFORE:** upper flanks (under arm area) before CoolSculpting procedure

**AFTER:** upper flanks (under arm area) affected by PAH after CoolSculpting procedure

**Figure D**

**BEFORE:** lower flanks, lower abdomen and inner thighs before CoolSculpting procedure

**AFTER:** lower flanks, lower abdomen and inner thighs affected by PAH after CoolSculpting procedure

87. In addition to the obvious, well demarcated cases, PH can also present itself as unchanged or worsening of "girth" following CoolSculpting, characterized as a mild to moderate effect of PH, wherein the tissue damage is more difficult to identify visually.

88. The most accurate method of diagnosing PH is through a wedge biopsy of the affected tissue because only a microscopic evaluation can definitively determine whether the tissue sustained damage from CoolSculpting. Although fulminant cases of PH can be diagnosed by palpitation and visual comparison of pre-treatment photographs, milder cases of PH where the masses are not as obvious cannot be identified without more invasive diagnostics.

89. A single person undergoing CoolSculpting in several places on their body may, and *usually does* develop PH in *each treatment area*. (See Figure D).

90. In some cases of PH, the subcutaneous tissue is also affected, causing the skin to lose firmness, resulting in laxity or sagging of the skin in the area of treatment. (See Figure B).

91. Correcting PH requires various surgeries. The specific type and number of surgeries depend on multiple factors such as: the extent of tissue damage, the particular area of the body affected, and the outcome of the initial surgery to remove affected tissue.

92. The types of reconstructive surgeries and procedures necessary to remove PH include, but are not limited to: power assisted liposuction, liposculpture, excision, abdominoplasty, laser treatment to remove surgery scars.

93. Because PH changes the character of the subcutaneous tissue, removing the fat tissue with liposuction is a difficult process. The affected tissue becomes lumpy, fibrous, and scar-like, which requires the surgeon to use more invasive and aggressive methods of removing the PH tissue, resulting in longer recovery time and unpredictable results.

94. Even with surgeries, a full reconstruction of the affected area is not guaranteed, and the long-term consequences of developing PH are still unknown.

95. A person with PH is at risk for future health problems, including the return of the deformity years after surgery.

96. A person suffering from PH either has to live with it forever or try to remove it through plastic surgery. Surgical interventions to alleviate the condition require general anesthesia and involve aesthetic and health risks, including death.

97. Males are at a higher risk of developing PH.

98. PH is spontaneous and unpredictable, occurring unexpectedly without any specific triggering event. At this time, the only known prevention of Paradoxical Hyperplasia is abstinence from CoolSculpting.

99. Because PH arises from CoolSculpting and is a new medical condition related to that specific medical device, the medical community is not independently familiar with the condition.

**DEFENDANT'S SUPERIOR KNOWLEDGE ABOUT PH**

100. Soon after the CoolSculpting device went on the market, Defendant received multiple reports of patients developing "firm bulges" and fat tissue "increases" in the treatment area after undergoing Cryolipolysis® with the CoolSculpting device.

101. In 2012, Defendant investigated the never before observed phenomenon and realized that the CoolSculpting device caused irreversible tissue damage that resulted in fibrous and scar-like masses to grow on patients' bodies as a biological response to the trauma caused by the device.

102. Defendant knew that the disfiguring "bulges" were not healthy fat tissue and required physical removal through surgery to manage.

103. Through its investigation, Defendant knew that the CoolSculpting device caused a pathological change to the tissue resulting in fibrosis of the treatment area, which is disfiguring to the body.

104. The Defendant named the condition "Paradoxical Hyperplasia" a/k/a "PH" and still uses this term to describe the condition. Internally, Defendant has also referred to the condition as Paradoxical *Tissue* Hyperplasia.

105. In 2012, Defendant created its own diagnosis criteria for the condition, which it required CoolSculpting providers to use to diagnose PH.

106. Defendant also knew in 2012 that people can develop PH in every CoolSculpting treatment area, suffering from multiple fibrous masses that will require surgical removal.

107. By 2013, Defendant knew that various types of surgeries had been required to remove PH masses which were not limited to liposuction and included abdominoplasty, excision, and panniculectomy.

108. By 2013, Defendant calculated that the incidence rate was 1 in 3,500 patients, but that the number of people developing the condition was increasing exponentially.

109. Since 2011, Defendant frequently and consistently received reports of consumers developing PH after CoolSculpting.

110. Defendant knew that out of all adverse events associated with the CoolSculpting device, PH was the *most serious* and the *most frequently* reported.

111. Defendant implemented a confirmation system to re-evaluate reports of PH remotely through its internal "Medical Safety Team" and rejected many reports of PH, despite medical providers' diagnoses.

112. This practice is exemplified in a letter that Defendant sent to a CoolSculpting provider:

> Hello Amber,
>
> Thank you for your patience and assistance with this case.
>
> **I have received feedback from the medical safety team that this case was deemed consistent with PH to the Flanks.**
>
> The Claim has been denied to the patients lower abdomen. Upon the medical teams review of the before and after photos they stated there is no clear enlargment or demarcation notible to the lower abdomen. They did state there was Skin Laxity, which I have noted to the case.
>
> I have submitted this case to claims for the Flanks.

***Defendant's Control Over PH Diagnosis and Claims Process***

113. Defendant took an active role in helping CoolSculpting providers diagnose PH and mitigated the provider's liability exposure by offering the patients money in exchange for a release of liability.

114. Because PH is a condition that was not generally known by the medical community, CoolSculpting providers relied on Defendant for information about the condition.

115. Defendant guided providers in determining whether the patient should be diagnosed with PH through its Medical Safety Team or a similar department. Defendant's employees reviewed the patients' medical information and photographs and suggested to the CoolSculpting providers whether a patient should be diagnosed with PH.

116. Defendant had a system in place which automatically turned the adverse event reporting process into a claims process. Defendant instructed providers to submit Clinical Event Forms and other documents, including a copy of the consent signed by the patient with the language describing PH.

117. The Clinical Event Form requested personal information such as the patient's full name, phone number, email address, and home address. Defendant used the information provided through the adverse event report to contact the patients directly and solicit settlement in exchange for a release of liability.

118. Defendant designed a "program" for persons that had developed PH. The Defendant offered to cover the cost of *sing*le liposuction surgery or pay a refund in exchange for a release of liability for any future damages associated with PH. Defendant included the CoolSculpting providers as parties who were released from liability in the settlement agreements.

119. Through the adverse event reports and its "liposuction program," Defendant was a centralized hub of information about PH.

120. Through this program, Defendant had direct communications with CoolSculpting providers and CoolSculpting patients that developed PH, which allowed Defendant to collect information not available to anyone else.

121. Through this program, Defendant knew that the CoolSculpting providers used CoolSculpting consent forms that were either identical or mirrored the language drafted by the Defendant in regard to PH which did accurately represent the condition to the patients.

122. Through this program, Defendant provided assurance to CoolSculpting providers that if their patient developed PH after CoolSculpting, the manufacturer would cover the cost to fix the condition.

123. Through this program, CoolSculpting providers believed that a single liposuction surgery will successfully resolve the condition.

124. If a CoolSculpting patient reported PH directly to the Defendant, Defendant required that CoolSculpting the patient to return to their CoolSculpting provider and request an evaluation of their condition.

125. Defendant instructed CoolSculpting providers to follow a very narrow protocol for diagnosing patients with PH, which resulted in many patients not being diagnosed with PH despite suffering tissue damage from CoolSculpting. Defendant's diagnosis protocol only recognized fulminant cases with well demarcated masses as PH and relied on the physicians' hand palpation of the affected tissue and a visual review of photographs taken of the patient before the procedure.

126. Many CoolSculpting providers did not agree to cooperate in diagnosing a patient with PH for the fear of liability.

127. If the CoolSculpting providers did not agree to cooperate with the CoolSculpting patients in diagnosing PH, the patients were left on their own. In many cases, patients sought out an evaluation from providers that did not have any experience with the CoolSculpting device and did not have any knowledge about PH and therefore could not be effective in diagnosing and treating the condition.

128. CoolSculpting providers benefited directly from Defendant's "liposuction program" because they were released from liability for future damages if the patient took the offer.

129. Moreover, if the CoolSculpting provider was a plastic surgeon, the provider would benefit directly from the patient's development of PH because Defendant would offer to pay the provider to correct the condition through plastic surgery.

130. However, the liposuction program was insufficient to cover the true losses suffered by CoolSculpting patients. Defendant did not cover the cost of travel for surgery, any other surgeries required to remove PH, lost wages during recovery, or any other damages directly resulting from the injury caused by the CoolSculpting device.

131. Likewise, Defendant performed its own studies on PH to determine the cause of the condition. Defendant never release the findings of its studies to CoolSculpting providers.

***Defendant's Knowledge About PH***

132. Defendant knew that people with PH must undergo multiple invasive surgeries to remove it, which were *not* limited to one liposuction.

133. Defendant also knew that persons afflicted with PH were emotionally distraught to find out that the only way to remove PH is through invasive surgeries because the draw of the CoolSculpting procedure was to *avoid* invasive surgery.

134. Defendant knew that the surgeries required to remove PH involved long recoveries, pain, health risks, and financial expenditures. Defendant also knew that some people may not want to undergo invasive surgeries after developing PH because they are not willing to subject themselves to the risks, pain, inconvenience of recovery, or financial burdens of undergoing the reconstructive procedures, leaving them with the deformity for life.

135. Defendant kept a record of the reported incidents of PH which included important data such as place of treatment, date of treatment, area(s) of the body affected, date PH was diagnosed, etc. The data gave Defendant information regarding the incidence rate of the condition.

136. Though its own investigation of PH, the adverse event reports, and it's "liposuction program" Defendant had superior knowledge about the extent, severity, and frequency of the condition, better than any other person in the world.

## DEFENDANT'S STRATEGIC CONTROL OVER PUBLIC INFORMATION ABOUT PH

***The Secret "White Paper"***

137. In 2012, soon after Defendant discovered that its device has the ability to seriously harm users by causing them to develop PH after CoolSculpting, the manufacturer commissioned the inventor of the Cryolipolysis® process, Dr. R. Rox Anderson and his colleague at Massachusetts General Hospital, Dr. Mathew Avram, to author a document about the serious and permanent adverse effect, to which Defendant referred to as "the White Paper."

138. The White Paper described the condition as follows: "Recently, the manufacturer received eleven separately confirmed reports of patients who developed growth of soft tissue in the treated site(s) over several months following treatment. The soft tissue growth is painless, firm, and visibly enlarged within the treated areas. The enlargement typically started two to three months post treatment, often after the expected reduction in fat, becoming visibly evident at four to five months post treatments. Because the soft tissue enlargement is a rare, unexpected growth of subcutaneous fat tissue, this phenomenon is being termed "paradoxical hyperplasia."[20]

139. The White Paper also described very strict criteria for diagnosing PH, admitted that the side effect is "significant," but also emphasized the rarity of the condition.

140. The White Paper also warned, "Patients who are considering undergoing this procedure should be counseled on the possibility of its occurrence, as well as the surgical options available should it occur."[21]

141. The Defendant kept the White Paper a *secret* from CoolSculpting providers and *did not* disclose the document unless a provider insisted on obtaining additional information about PH, and only *after* the provider had a patient develop the condition.

---

20 https://skinrenu.com.au/wp-content/uploads/2017/03/13.PH-white-paper-FINAL.pdf

21 *Id at* p. 4.

142. In some cases, Defendant even required the CoolSculpting providers to sign a *confidentiality agreement* before it disclosed the White Paper to them.

143. When Defendant did share the White Paper with a select few providers, under specific circumstances, it always used the November 30, 2012 version of the document, which was never updated with the most current information about PH and which acknowledged only *eleven* known cases of PH.

144. The White Paper, although more informative than the device's User Manual and Defendant's training presentations, was still inadequate. It was outdated and did not present the true danger of the CoolSculpting device.

***Defendant's use of consultant's scholarly articles about PH***

145. Although Defendant knew that PH was a significant and serious adverse effect of its CoolSculpting device since at least 2011 and had Drs. Anderson and Avram draft the *secret* White Paper detailing the newly discovered condition in 2012, it was not until March 2014 that the medical community received any information about the serious and permanent adverse effect.

146. In March 2014, Dr. Anderson, his colleague Dr. Avram, and several other persons associated with the Defendant published a scholarly article called "Paradoxical Adipose Hyperplasia After Cryolipolysis" in JAMA Dermatology, announcing that "[v]ery rarely, a delayed increase in adipose tissue at the treatment site can occur, which to our knowledge has not yet been reported in the medical literature. We suggest the term "paradoxical adipose hyperplasia" (PAH) for this phenomenon."[22]

[22] Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C. MD; Anderson, R. Rox MD. Paradoxical Adipose Hyperplasia After Cryolipolysis®. *JAMA Dermatology*. 2014 Mar; Vol. 150(3): 317-319. DOI: 10.1001/jamadermatol.2013.8071.

147. The majority of the authors, including the inventor of the Cryolipolysis process, Dr. Anderson, who was serving on Zeltiq's Medical Advisory Board, reported a financial conflict of interest connected to the manufacturer of CoolSculpting.

148. The authors suggested to name the never-before-reported adverse effect of Cryolipolysis "Paradoxical Adipose Hyperplasia" (PAH).[23]

149. Defendant knew that the term suggested by its consultants in the JAMA article was a misnomer for the condition and erroneously suggested a less serious condition.

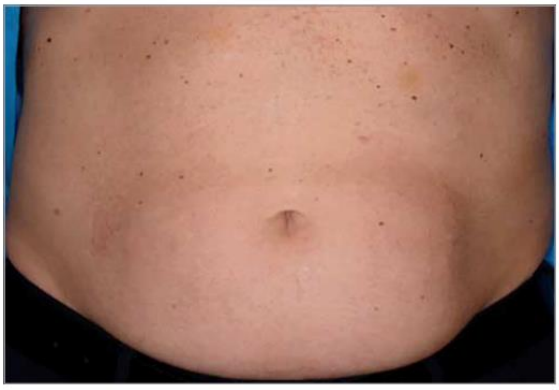
150. Since the term "Paradoxical Adipose Hyperplasia" (PAH) was first announced in the 2014 JAMA article, the condition is still referred to as "Paradoxical Adipose Hyperplasia" or "PAH," by the medical community, even though Defendant did not and does not use the word *adipose* in naming the adverse effect.

151. The JAMA article described one case of a man in his 40s who underwent the Cryolipolysis® procedure with the CoolSculpting medical device and initially noticed a reduction in fat tissue, but three months after CoolSculpting, his fat grew into a noticeable mass even though he did not gain any weight. He elected not to undergo invasive surgery to remove the deformity.

152. The following photograph was provided:

[23] The term "Paradoxical Adipose Hyperplasia" (PAH) differs slightly from how the same authors called the condition in the secret White Paper in 2012 and how the Defendant continues to call the condition today – "Paradoxical Hyperplasia" (PH).

Figure 1. Paradoxical Adipose Hyperplasia Approximately 5 Months Following Cryolipolysis



There is a sharply demarcated, rectangular enlargement around the umbilicus corresponding to the treatment zone. This soft-tissue protrusion was soft, mobile, and slightly tender to palpation. The overlying skin was unremarkable.

153. The photograph chosen for the article depicted just one possible presentation of PH on a person's body, out of a wide range of deformities the condition can cause, misleading the reader into believing that tissue affected by PH is always so patently obvious.

154. The article also mentioned a woman in her 50s that had developed PH nine months after CoolSculpting and needed abdominoplasty to remove the deformity.[24] A photograph of her PH affected area was not provided in the article.

155. Throughout the three-page article, the word "rare" was mentioned seven times; three times in the abstract.

156. The article focused on Cryolipolysis and did not mention the device's name "CoolSculpting," vaguely referring to Zelitq Aesthetics, Inc. as the device used to administer the procedure.

24 Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C. MD; Anderson, R. Rox MD. Paradoxical Adipose Hyperplasia After Cryolipolysis®. *JAMA Dermatology*. 2014 Mar; Vol. 150(3): 317-319. DOI: 10.1001/jamadermatol.2013.8071.

157. The article "estimated" that the incidence of PH is about "0.0051%, or about 1 in 20,000 treated patients." It noted that "[t]o date, 33 confirmed cases of paradoxical hyperplasia have been reported to the device manufacturer as part of post marketing surveillance data."[25]

158. By the time the article was published, Defendant was aware of *over 100* cases of PH.

159. Defendant knew that the number of PH patients and the incidence rate cited by the authors were incorrect and grossly underestimated the risk, but it did not take any action to clarify this information to the medical community.

160. In fact, Defendant cited the 2014 JAMA article in its training slide presentations and in 2016 (and later) versions of the User Manual.

161. Defendant, itself, never directly notified CoolSculpting providers about its post-market discovery of PH or what it knew about the deforming condition through the adverse event reports that it had received since 2011.

162. Instead, Defendant strategically used the 2014 JAMA article in its training materials and referred to the article when CoolSculpting providers asked questions about PH, even though the Defendant knew that the information in the article was misleading in regard to the number of PH reports that it has received, the incidence rate of PH, the range of presentation of PH on the human body, the extent of tissue damage, etc.

163. Likewise, since the 2014 JAMA article, Defendant continued to receive a multitude of reports of people suffering from PH after CoolSculpting. The Defendant's previously estimated incidence rate grew exponentially every year.

---

[25] Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C. MD; Anderson, R. Rox MD. Paradoxical Adipose Hyperplasia After Cryolipolysis®. *JAMA Dermatology*. 2014 Mar; Vol. 150(3): 317-319. DOI: 10.1001/jamadermatol.2013.8071.

164. Defendant, despite knowing that it had seriously underestimated the frequency of PH, *still* did not notify the CoolSculpting providers about the substantial increase in the incidence rate.

165. When CoolSculpting providers individually asked the manufacturer about the current incidence rate of PH, Defendant gave inaccurate statistics, directed the providers to Dr. Anderson's outdated 2014 JAMA article, or simply pointed to the User Manual for information about the device's adverse effects.

166. From 2012 until the present, Defendant *never* updated the CoolSculpting System User Manual to reflect updated information about PH.

167. Defendant manipulating the calculation of the incidence rate and stated inaccurate incidence rate statistics to CoolSculpting providers.

168. Defendant also instructed its employees to use the words "rare" when referring to PH in their communications with CoolSculpting providers, the public, and the FDA.

169. To support the statements that the likelihood of developing PH was "rare" Defendant used paid consultants to disseminate *inaccurate* information regarding the incidence rate of PH under the guise of scientific publications. The articles emphasized the rarity of the condition and presented false data to support this claim. The paid consultants' articles cited to other publications written by Defendant's paid consultants. Defendant would then cite to these articles when answering questions about PH to CoolSculpting providers and in its training materials to support its statements that PH was rare and unlikely to occur.

170. For example, in the March 2014 JAMA publication authored by the inventor of Cryolipolysis and a number of his colleagues with financial conflicts of interest they stated, "We

estimate that the incidence rate of PH is about 0.0051%, or about 1 in 20 000 treated patients."[26]

171. Contrary to this statistic, an unbiased author reported the incidence rate of PH for the same time period was 0.010%, twice higher than the statistic reported by Defendant's consultants."[27]

172. A manufacturer-sponsored article published in 2015 in the Aesthetic Surgery Journal, stated that no serious adverse effects were observed at 16-weeks post treatment, and did not even mention the possibility of PH when boasting about the wonders of CoolSculpting. The study was paid for by the manufacturer, who also provided ultrasound and photography support, both of which were used to prove the effectiveness of the medical device.[28]

173. Then, in March 2016 a group of unbiased authors addressed the incidence rate of PH as reported in the March 2014 article written by Defendant's consultants, stating, "Our reported incidence is 0.78 percent [1 in 129], more than 100 times higher than the device manufacturer reported incidence of 0.0051 percent. Ours is not a unique experience, as a dermatology practice in Houston, Texas, recently reported a paradoxical adipose hyperplasia incidence of 0.47 percent [1 in 213]. Although our treatment numbers are low when considering the popularity of the procedure, *we believe that paradoxical adipose hyperplasia is underreported*."[29] (emphases added).

---

[26] Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C. MD; Anderson, R. Rox MD. Paradoxical Adipose Hyperplasia After Cryolipolysis®. *JAMA Dermatology*. 2014 Mar; Vol. 150(3): 317-319. DOI: 10.1001/jamadermatol.2013.8071.

[27] Stefani, William A. MD, FACS. Adipose Hypertrophy Following Cryolipolysis®. *Aesthetic Surgery Journal*. 2015, Vol. 35(7): NP218-NP220, at NP219. DOI: 10.1093/asj/sjv069.

[28] Stevens, W. Grant; Bachelor, Eric P. Cryolipolysis Conformable-Surface Applicator for Nonsurgical Fat Reduction in Lateral Thighs. *Aethetic Surgery Journal*. 2015 Jan; Vol 35: 66-71. DOI: 10.1093/asj/sju024.

[29] Kelly, Emma B.A.; Rodriguez-Feliz, Jose M.D.; Kelly, Michael E. Paradoxical Adipose Hyperplasia after Cryolipolysis®: A Report on Incidence and Common Factors Identified in 510 Patients. *Plastic and Reconstructive Surgery*. 2016 Mar; Vol. 137: 639e-640e. DOI: 10.1097/01.prs.0000480023.35573.b7.

174. To which, a paid consultant for Defendant wrote a response stating that, "The manufacturer reports that since the first quarter of 2014, the paradoxical adipose hyperplasia incidence rate has fluctuated between 0.021 and 0.026 percent, or approximately one in 4000 treatment cycles."[30]

175. While an independent study published on November 14, 2017, found that although the manufacturer has reported 33 cases of PH worldwide, estimating the incidence rate of 0.021%, the rate is "probably underestimated." The authors of the study, who were not associated with the manufacturer, found that the incidence rate of PH in their series was 1% (4 out of 398 patients developed PH). They noted that "many of the more than 2 million patients treated with cryolipolysis worldwide are affected by PH." [31]

176. In response to this independent study, a solo practitioner plastic surgeon wrote that he too has seen two "fulminant PH" cases out of 150 patients, and "10 other patients had what we considered unchanged or even worsened "girth," which in retrospect may represent a new classification of PH considered to be mild to moderate."[32]

177. Although the Defendant never disclosed the information it possessed about PH to CoolSculpting providers, it used the scholarly articles written by its paid consultants, which contained inaccurate information about PH and were skewed in favor of the Defendant, to refer CoolSculpting providers for "additional" information regarding PH.

---

[30] Sasaki, Gordon H. Reply: Cryolipolysis for Fat Reduction and Body Contouring: Safety and Efficacy of Current Treatment Paradigms. *Plastic and Reconstructive Surgery.* 2016 Mar; Vol. 137: 640e-641e. DOI: 10.1097/PRS.0000479983.49996.c0.

[31] Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018; Vol 38(4): 411-417, 414. DOI: 10.1093/asj/sjx159.

[32] Vogel, James E MD. Comments on 'Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018; Vol 38(9): NP135-NP137. DOI: 10.1093/asj/sjy129.

178. As recently as October 5, 2020, one of Defendant's "consultant" and "research collaborator" published an article in the Aesthetic Surgery Journal about PH declaring that "the most recent data included …. 291 patients" with PH.

179. By October 5, 2020, Defendant had received *thousands* of reports of PH, and confirmed over 3,300 people with PH after CoolSculpting.

**DEFENDANT DOWNPLAYED THE SERIOUSNESS OF PH TO THE FDA**

180. Defendant also downplayed the seriousness, permanency, and frequency of PH to the FDA.

181. For example, on March 14, 2016, Defendant submitted a 510(k) Summary of Safety and Effectiveness report to the FDA, citing to "literature review" for evidence of adverse events caused by CoolSculpting and reporting that there have been only "6 cases" of "serious adverse events" which include Paradoxical Hyperplasia. By 2016, Defendant was aware of *thousands* of PH reports.

182. Likewise, Defendant failed to report all known incidents of PH to the FDA, despite the FDA's repeated requests to do so.

183. PH is a reportable adverse event under 21 CFR 803 due to the permanency and severity of the condition, and because surgical intervention is the only means of resolving the permanently disfiguring condition.

184. Since the CoolSculpting device went on the market, Defendant has received *thousands* of reports of PH through September 2019. Defendant reported *less than* 70 to the FDA's public databased MAUDE (Manufacturer and User Facility Device Experience).

185. This allows Defendant to control the information about the number of patients suffering from PH after CoolSculpting, since providers and the public cannot independently obtain the most current numbers via the FDA's public database.

## INADEQUATE "WARNINGS" ABOUT PH

***Labeling***

186. Although Defendant provided *some* information regarding PH to CoolSculpting providers, it was misleading and written in such a way as to give the providers the impression that the condition causes a less serious effect and is not likely to occur.

187. Defendant creatively chose words that were ambiguous and did not provide enough specificity on the details that were necessary for a CoolSculpting provider to understand the condition.

188. Defendant used the following language to describe the disfiguring condition of PH in the User Manuals for the CoolSculpting device, dedicating only two lines to inform the provider about the permanent condition, stating:

> **Rare Side Effects**
>
> - Paradoxical hyperplasia: Visibly enlarged tissue volume within the treatment area, which may develop two to five months after treatment. Surgical intervention may be required.

189. Defendant used similarly vague language to describe PH to CoolSculpting providers in its slide-show presentations which it used during its online and live training on how to operate the device.

190. Defendant's "warnings" about PH to CoolSculpting providers were *inaccurate* in content and *ambiguous* in the manner of expression. The language used by Defendant did not relay the seriousness, permanency, and frequency of the condition.

191. Defendant's inadequate disclosure about PH *failed* to inform the CoolSculpting providers:

a. That PH is the opposite effect of CoolSculpting's advertised purpose;

b. That PH is a disease of the tissue;

c. That the CoolSculpting device damages the tissue;

d. That PH results in a physical deformity;

e. That a single patient can suffer multiple deformities on the body from PH;

f. That the deformity will never resolve on its own because it is permanent;

g. That PH changes the microstructure of the tissue;

h. That invasive surgeries are required to remedy the affected tissue;

i. That surgery may not resolve PH affected tissue;

j. That the CoolSculpting device can cause cutaneous tissue laxity requiring surgery to cut, lift, and sew the skin;

k. That PH has a wide range of physical effects on the body;

l. That the frequency of occurrence of PH is not rare and that thousands of people have suffered from the condition after undergoing CoolSculpting;

m. That the future impact on a person's health after developing PH is unknown, and there is a possibility that future medical treatment will be required to treat the condition.

n. That PH was the most commonly reported adverse effect of CoolSculpting.

192. Defendant also made false statements to CoolSculpting providers that the device's smaller sized applicators used to administer the cycles eliminated or significantly reduced the occurrence of PH.

193. Defendant's labeling materials were uniform for all CoolSculpting providers and the information contained therein did not differ materially from one CoolSculpting provider to another.

***Training by Defendant's Representative***

194. Defendant used non-medical salespeople called Practice Development Managers ("PDMs") to provide training to Plaintiffs' CoolSculpting provider and to inform the providers about PH.

195. Defendant's PDMs were the primary points of contact for CoolSculpting providers to obtain and relay any information regarding the CoolSculpting device. The PDMs provided training on operating the CoolSculpting device, provided information about the device's side effects, gave marketing advice, relayed information from providers to Defendant, and sold consumable cards to the CoolSculpting providers.

196. The PDMs' primary role was to sell Defendant's products to the providers. After the providers purchased the CoolSculpting device, the PDMs' role was to ensure that the providers continued to purchase the consumable cards which are required to operate the CoolSculpting device.

197. Thus, the same persons that were tasked with providing adverse effect information to CoolSculpting providers were also tasked with selling Defendant's products to them.

198. The training provided by Defendant to CoolSculpting providers on the CoolSculpting device consisted mainly of training on sales tactics and emphasized the device's ability to increase revenues for the providers' medical offices.

199. The presentation slide that described PH used the term "Paradoxical Adipose Hyperplasia" even though the Defendant knew that PH was not an increase in healthy fat cells. The slide also described PH as an "increase in subcutaneous adipose tissue" which was a misrepresentation of the condition which Defendant knew was *fibroplasia* or *fibrosis* of the subcutaneous tissue. The slide also used a photograph from the 2014 JAMA article (*see supra* ¶*147*), which did not represent the majority of PH deformities whose masses were not in the shape of the applicator. Furthermore, the slide also inaccurately stated that "surgical intervention *may* be required" although Defendant knew that surgery *is* required.

200. Defendant did not allow the PDMs to discuss PH in detail if providers had specific questions. PDMs were instructed by Defendant to present only the information contained in a single presentation slide that misrepresented information about PH.

201. Through its training slide presentation, Defendant assured providers that the CoolSculpting device precisely targets the fat (adipose) cells and does not damage any surrounding tissue or structures.

202. During training, Defendant's PDMs made verbal statements to CoolSculpting providers that the likelihood of CoolSculpting patients developing PH is very low and that the provider will probably not see a case of PH in their practice.

203. The PDMs gave false statistics about the incidence rate of PH to the CoolSculpting providers.

204. Defendant's PDMs did not inform CoolSculpting providers on the true incidence rate of PH and made statements that minimized the risk of developing the condition.

205. Defendant's PDMs downplayed the seriousness and permanency of the condition to the CoolSculpting providers in order to incentivize the providers to purchase the CoolSculpting devices and sell more cycles to their patients.

206. Defendant's training methods and materials were uniform for all CoolSculpting providers and the information provided in training did not differ materially from one CoolSculpting provider to another.

**DEFENDANT'S MISREPRESENTATIONS ABOUT PH TO COOLSCULPTING PROVIDERS**

207. Defendant knew that CoolSculpting providers were not independently familiar with PH and that they relied on Defendant for information about the condition solely associated with the CoolSculpting device.

208. Despite Defendant's extensive knowledge about PH, the information the manufacturer released to CoolSculpting providers was *de minimis* and *deceptive*.

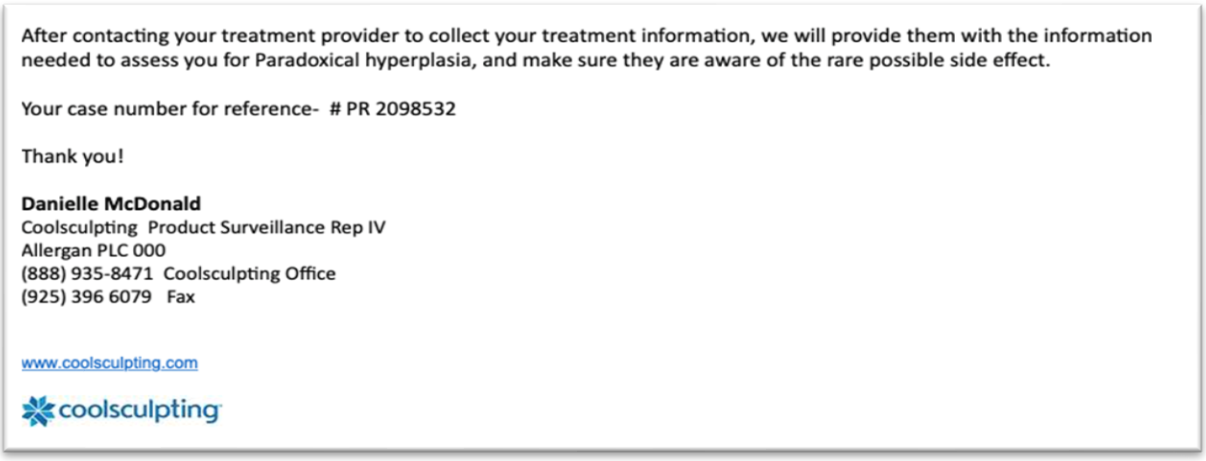
209. Defendant did not provide information regarding PH to CoolSculpting providers *prior* to the purchase of the medical device.

210. After the devices were purchased from Defendant, Defendant downplayed the severity, permanency, and frequency of PH to CoolSculpting providers.

211. Defendant withheld important information about PH from CoolSculpting providers and did not inform the providers about the details of the condition or how to diagnose PH until *after* a patient developed PH.

212. Defendant's policy in regard to PH was to provide very little information about PH and wait until a patient develops the condition. Once a CoolSculpting provider notified the Defendant about a potential PH case, Defendant would release additional information to the CoolSculpting providers about the condition and how to diagnose it.

213. This practice is exemplified in a letter that Defendant sent to a CoolSculpting patient:



After contacting your treatment provider to collect your treatment information, we will provide them with the information needed to assess you for Paradoxical hyperplasia, and make sure they are aware of the rare possible side effect.

Your case number for reference- # PR 2098532

Thank you!

**Danielle McDonald**
Coolsculpting Product Surveillance Rep IV
Allergan PLC 000
(888) 935-8471 Coolsculpting Office
(925) 396 6079 Fax

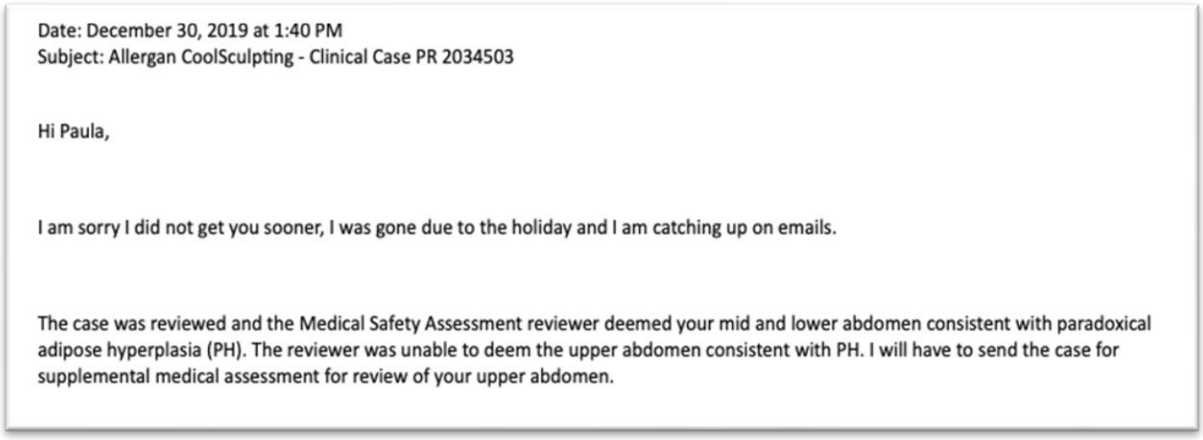
www.coolsculpting.com

coolsculpting

214. Defendant also advised CoolSculpting providers not to mention "Paradoxical Hyperplasia" or "PH" to patients who requested an evaluation for the condition until the Defendant's claims department had an opportunity to review the patients' medical records and diagnosis of the CoolSculpting providers and "confirm" the diagnosis.

215. Defendant implemented a practice of rejecting CoolSculpting patients' diagnoses of PH and refused to confirm cases of PH to all parts of the body affected. For example, in one

CoolSculpting patient's case, although she was diagnosed with PH to her entire abdomen by multiple physicians, Defendant refused to confirm PH to her upper abdomen.



Date: December 30, 2019 at 1:40 PM
Subject: Allergan CoolSculpting - Clinical Case PR 2034503

Hi Paula,

I am sorry I did not get you sooner, I was gone due to the holiday and I am catching up on emails.

The case was reviewed and the Medical Safety Assessment reviewer deemed your mid and lower abdomen consistent with paradoxical adipose hyperplasia (PH). The reviewer was unable to deem the upper abdomen consistent with PH. I will have to send the case for supplemental medical assessment for review of your upper abdomen.

216. Likewise, in another patient's case, although her provider diagnosed her with PH on each of her flanks and on her abdomen, Defendant "confirmed" PH only on her flanks, rejecting the diagnosis of her abdomen.[33]

217. Defendant's custom of selectively "confirming" cases of PH without ever seeing the patient and rejecting medical providers' diagnoses was a systemic company-wide practice designed to minimize the number of PH incidents reported to the manufacturer and to avoid liability.

218. By rejecting cases of PH, Defendant lowered the incidence rate of its device's adverse effect.

219. Defendant's practice of involving itself in every aspect of a CoolSculpting consumer's treatment, from consent to diagnosis to treatment took away the CoolSculpting providers' objectivity and independence related to this particular condition and assuaged them that Defendant would take care of everything.

[33] *See supra* ¶107.

**EFFECT OF DEFENDANT'S REPRESENTATIONS ON COOLSCULPTING PROVIDERS**

220. Defendant controlled the information that was available about PH by using vague and inadequate language in the labeling materials, incentivizing PDMs to make false verbal statements about PH to providers, paying consultants to write favorable scholarly publications, by concealing crucial information about PH from CoolSculpting providers, and by downplaying the seriousness and frequency of the adverse event to the FDA.

221. Even if a CoolSculpting provider wanted to find out additional information regarding PH, they would most likely find a manufacturer-friendly scholarly article on the subject or be pacified by the low number of PH incidents reported on the FDA's public database MAUDE (Manufacturer and User Facility Device Experience.)

222. Although Defendant received thousands of reports of people developing permanent deformities from PH after undergoing CoolSculpting, it never disclosed the number of people injured by its device to the CoolSculpting providers. Yet, Defendant repeatedly used terms such as "rare" and "a small number of people" when referring to PH and cited to its consultant's articles, to pacify the providers and mislead them into believing that PH was not a likely risk of using the CoolSculpting device.

223. As the result of Defendant's misrepresentations, CoolSculpting providers did not understand the severity, permanency, and frequency of PH.

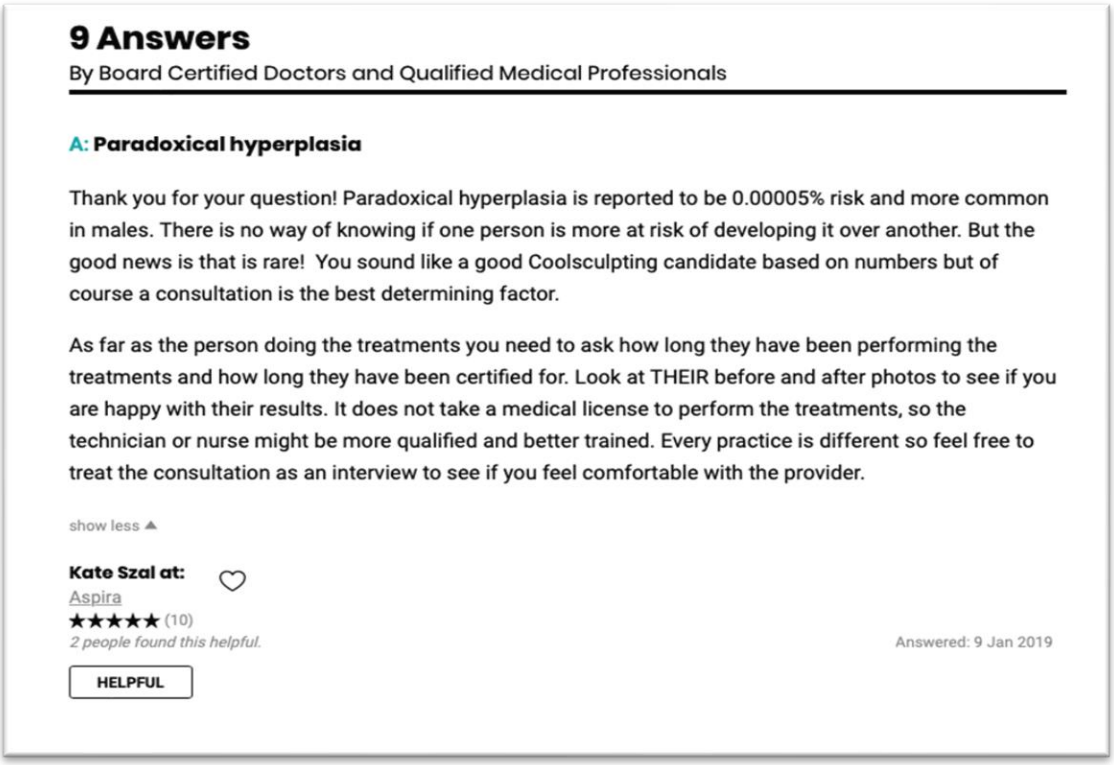
224. CoolSculpting providers believed that the adverse effect is extremely rare and were under the impression that it was highly unlikely to ever see a CoolSculpting patient develop PH.

225. Believing that PH was not a real risk to CoolSculpting patients, CoolSculpting providers did not inform CoolSculpting patients about the possibility of suffering the opposite effect of the procedure's advertised purpose.

226. Due to Defendant's failure to adequately warn CoolSculpting providers about PH, the providers did not have an accurate understanding of the condition and could not properly inform their patients about it.

227. Moreover, Defendant was aware that CoolSculpting providers did not understand PH and were not properly informing their patients about the possibility of developing this serious condition after CoolSculpting because Defendant had numerous communications directly with persons who developed PH and because of a multitude of public personal accounts online about how CoolSculpting patients were not being told about this serious adverse effect.

228. For example, even as late as January 2019, actual CoolSculpting providers cited a range of incorrect incidence rate statistics in their responses to prospective CoolSculpting patients on the popular review website www.RealSelf.com:



**9 Answers**

By Board Certified Doctors and Qualified Medical Professionals

A: **Paradoxical hyperplasia**

Thank you for your question! Paradoxical hyperplasia is reported to be 0.00005% risk and more common in males. There is no way of knowing if one person is more at risk of developing it over another. But the good news is that is rare! You sound like a good Coolsculpting candidate based on numbers but of course a consultation is the best determining factor.

As far as the person doing the treatments you need to ask how long they have been performing the treatments and how long they have been certified for. Look at THEIR before and after photos to see if you are happy with their results. It does not take a medical license to perform the treatments, so the technician or nurse might be more qualified and better trained. Every practice is different so feel free to treat the consultation as an interview to see if you feel comfortable with the provider.

show less ▲

**Kate Szal at:**
Aspira
★★★★★ (10)
*2 people found this helpful.*
Answered: 9 Jan 2019

HELPFUL

**A: CoolSculpting**

Dear cosmeticcurls,

Great question! The statistic for PAH is 0.0036%. PAH is less common with newer applicators.

- Dr. Edward Tangchitnob

**A: Pah after CoolSculpting**

PAH is a condition in which the fat cells become thicker and expand instead of being eliminated. The incidence of this is extremely rare. Most recent quotes on this condition are about .0051% of all the millions of CoolSculpting treatments performed worldwide. There really isn't a way to know if you in particular would be at risk or not.

**Laura A. Katz, MD**

★★★★★ 9 reviews

laurakatzmdpc.com

(734) 548-9424

**VISIT WEBSITE ▸**

**GET A FREE CONSULTATION**

**CALL DOCTOR**

Answered: 22 Jan 2019

229. On March 19, 2019, a plastic surgeon described his experience of trying to obtain information about the incidence rate of PH from his CoolSculpting representative after he personally saw three PH patients within a period of six months:

> I imagine that the incidence of this complication, paradoxical adipose hyperplasia, is exceedingly rare. When I asked one of the representatives from the company about its incidence, he reassured me that this condition occurs in one out of 70,000 cycles. As I have seen three patients in the past six months with this condition, I wonder if this is underreported or if the technology is that exceedingly popular. In any case, I believe it is in the best interest of my patients to understand what paradoxical adipose hyperplasia (PAH) is, what it means, and how it can be treated.

[34]

[34] https://zelkeninstitute.com/2019/03/19/paradoxical-adipose-hyperplasia/

230. Contrary to the statistics believed by CoolSculpting providers, a recent study suggested that the incidence rate is closer to 1 in 100 or 1%.[35]

231. Adverse events with an incidence rate of 1% or higher are considered "common," not rare by the World Health Organization.[36]

232. The actual incidence rate of PH after CoolSculpting may be closer to 10% when considering the number of CoolSculpting patients that developed mild to moderate tissue increases, which did not present as well-demarcated masses and remain undiagnosed.

**CLASS REPRESENTATIVES**

233. Plaintiff, **Javier Valencia,** was advised about a non-invasive procedure to reduce stubborn fat on his upper flanks during one of his laser acne treatments on his shoulder at his dermatologist office.

234. Mr. Valencia read the CoolSculpting advertisements provided by the RN on the dermatologist office and became interested in the CoolSculpting procedure.

235. On July 24, 2018, Mr. Valencia visited Rafal Center for Dermatology & Cosmetic Surgery, a CoolSculpting provider, located at 2500 Nesconset Highway, Building 22A, Stony Brook, NY 11790 and underwent two (2) cycles of the CoolSculpting procedure, one on each of his upper flanks.

---

[35] Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018; Vol 38(4): 411-417, 412. DOI: 10.1093/asj/sjx159; and

Vogel, James E. MD, FACS. Comments on "Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis." *Aesthetic Surgery Journal.* 2018; Vol 38(9): NP135-NP137, 135. DOI: 10.1093/asj/sjy129.

[36] Wang, Erica MD; Kaur, Ramanjot MD; Jagdeo, Jared MD. Commentary on: Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018, Vol 38(4): 418-420, 419. DOI: 10.1093/asj/sjx167.

236. At no point in time did anyone at Rafal Center for Dermatology & Cosmetic Surgery tell Mr. Valencia, and he did not know that the CoolSculpting device can cause damage to tissue, causing PAH and skin laxity.

237. Several months after the CoolSculpting procedure, Mr. Valencia began noticing that the treatment area started growing in size, even though Mr. Valencia kept losing weight.

238. Mr. Valencia developed protruding masses on his upper flanks where he had undergone CoolSculpting.

239. On January 11, 2019, he returned to his CoolSculpting provider and met with the supervising physician. The physician examined Mr. Valencia but did not know that he had developed an adverse effect of the CoolSculpting device. The physician was *not able* to diagnose him and offered to perform thermal treatments on the affected area, not understanding that PAH can only be removed with surgery.

240. After the thermal treatments did not work, the physician referred Mr. Valencia to a plastic surgeon. The plastic surgeon did not know about PAH and could not state a diagnosis.

241. Mr. Valencia began researching online for a plastic surgeon that had experience with adverse effects of CoolSculpting, and on December 9, 2019, he was finally diagnosed with PAH on his *right* and *left* upper flank by a plastic surgeon that had experience treating patients with PAH.

242. Mr. Valencia was advised that he would need an excision surgery on both of his flanks to cut out the affected tissue. He was told that although he would no longer have protruding masses, he would be left with large scars on both sides.

243. As the result of Defendant's systemic failure to adequately warn CoolSculpting providers about the danger of the CoolSculpting medical device, Mr. Valencia's CoolSculpting provider was not adequately informed about the extent of the serious and permanent adverse effect

of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical Hyperplasia (PH) which requires surgical intervention to resolve.

244. As the direct and proximate cause of Defendant's conduct, Mr. Valencia was not properly informed about PAH prior to undergoing CoolSculpting.

245. Had Mr. Valencia known that there was a chance that he could develop a condition that results in the opposite effect of the device's advertised purpose, he would not have undergone the procedure.

246. Mr. Valencia's damages include past and future medical expenses, past and future pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.

247. Plaintiff, **Paula Brooks**, was interested in a non-invasive procedure to reduce fat in her abdomen.

248. She had seen CoolSculpting advertisements in the past, and when her former employer purchased the CoolSculpting device, she was eager to undergo the procedure to address the stubborn fat.

249. On May 24, 2019, Ms. Brooks underwent the CoolSculpting procedure at Cape Cod Aesthetics and MediSpa located at 11 Potter Ave, Hyannis, MA 02601, where she had received three (3) cycles on her abdominal region.

250. Prior to undergoing to CoolSculpting procedure, Ms. Brooks was never advised by her CoolSculpting provider and did not know that the CoolSculpting device can cause damage to tissue, causing PAH and skin laxity.

251. Ms. Brooks was told by her CoolSculpting provider that she may need additional cycles of CoolSculpting to achieve optimum results.

252. Ms. Brooks did not see any results from the CoolSculpting procedures and on August 8, 2019, Ms. Brooks visited Rhett Women's Center/Aesthetics located at 1300 Hospital

Drive, Suite 130, Mt. Pleasant, SC 29464 for an additional two (2) cycles of the CoolSculpting procedure on her upper and lower abdomen.

253. At no point prior to undergoing the CoolSculpting procedures at Rhett Women's Center/Aesthetics was Ms. Brooks advised that the CoolSculpting device can cause damage to tissue, causing PAH and skin laxity.

254. In the months following the procedures, Ms. Brooks began noticing that her abdomen started growing in size and developing a large mass.

255. On October 28, 2019, she was diagnosed with PAH at the location of each of the CoolSculpting cycles, covering *her entire abdomen*.

256. Ms. Brooks sought out the evaluation and opinion of multiple plastic surgeons who agreed that the best course of action in reconstructing the affected area is through multiple surgeries, including abdominoplasty and liposuction.

257. On May 13, 2020, Ms. Brooks underwent abdominoplasty to try to correct the affected area. Due to the extent of tissue damage from CoolSculpting, her plastic surgeon had to make a long cut extending from her right to her left hip. She now has a scar traversing her lower abdomen. The surgery did not completely correct the affected area, and she will need additional reconstructive surgeries.

258. As the result of Defendant's systemic failure to adequately warn CoolSculpting providers about the danger of the CoolSculpting medical device, Ms. Brooks's CoolSculpting providers were not adequately informed about the extent of the serious and permanent adverse effect of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical Hyperplasia (PH) which requires surgical intervention to resolve.

259. As the direct and proximate cause of Defendant's conduct, Ms. Brooks was not properly informed about PAH prior to undergoing CoolSculpting.

260. Had Ms. Brooks known that there was a chance that she could develop a condition that results in the opposite effect of the device's advertised purpose, she would not have undergone the procedure.

261. Ms. Brooks' damages include past and future medical expenses, past and future pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.

262. Plaintiff, **Phornphan "Lisa" Chubchai**, was interested in a non-invasive procedure to reduce fat in her abdomen.

263. Ms. Chubchai saw advertisements for CoolSculpting, which promised to reduce fat without surgery and became interested in the CoolSculpting procedure.

264. On December 19, 2018, Ms. Chubchai visited Valley Legs Beauty & Diagnostics located at 1805 E Fir Ave, Suite 101, Fresno, CA 93720, and underwent two (2) cycles of the CoolSculpting procedure on abdomen area.

265. On April 17, 2019, Ms. Chubchai returned for an additional two (2) cycles on abdomen area.

266. On June 11, 2019, Ms. Chubchai completed her last two (2) cycles on abdomen area.

267. At some point, Ms. Chubchai also underwent cycles of CoolSculpting on both of her flanks at the same provider.

268. Prior to undergoing to CoolSculpting procedure, Ms. Chubchai was never advised by her CoolSculpting provider, and she did not know that the CoolSculpting device can cause damage to tissue, causing PAH and skin laxity.

269. Several months after the CoolSculpting procedure, Ms. Chubchai began noticing that the fat tissue in her abdomen and flanks began growing and getting larger.

270. Ms. Chubchai complained to her CoolSculpting provider about her growing abdomen, but the supervising physician at Valley Legs Beauty & Diagnostics did not know about PAH or how to diagnose it. The provider was unable to diagnose her.

271. Ms. Chubchai was left to seek out another physician who could explain to her what she was experiencing and give her a diagnosis. She eventually found a knowledgeable plastic surgeon, and on January 29, 2020, she was diagnosed with PAH on her *abdomen* and *each flank*. Her plastic surgeon advised her that she will need abdominoplasty and liposuction to try to remove the disfigurement caused by PAH.

272. As the result of Defendant's systemic failure to adequately warn CoolSculpting providers about the danger of the CoolSculpting medical device, Ms. Chubchai's CoolSculpting provider was not adequately informed about the extent of the serious and permanent adverse effect of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical Hyperplasia (PH) which requires surgical intervention to resolve.

273. As the direct and proximate cause of Defendant's conduct, Ms. Chubchai was not properly informed about PAH prior to undergoing CoolSculpting.

274. Had Ms. Chubchai known that there was a chance that she could develop a condition that results in the opposite effect of the device's advertised purpose, she would not have undergone the procedure.

275. Ms. Chubchai's damages include past and future medical expenses, past and future pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.

276. Plaintiff, [redacted] was interested in a non-invasive procedure that could reduce stubborn fat in various parts of her body.

277. [redacted] saw advertisements for CoolSculpting, which promised to reduce fat without surgery and became interested in the CoolSculpting procedure.

278. On March 29, 2018, [redacted] visited Healthy for Life Weight Loss & Nutrition Center, a CoolSculpting provider, located at 950 S. Arroyo Parkway, 3rd Floor, Pasadena, CA 91105.

279. Healthy for Life Weight Loss & Nutrition Center sold [redacted] a package of multiple cycles of CoolSculpting for use in the future.

280. Over the course of six months, [redacted] underwent multiple cycles of CoolSculpting during six appointments: March 29, 2018, April 9, 2018, May 28, 2018, August 28, 2018, September 6, 2018, and October 22, 2018. The following areas of her body were treated: Left anterior thigh, left posterior thigh, right anterior thigh, right posterior thigh, right flank, left flank, left lower abdomen, and right lower abdomen.

281. Prior to undergoing to CoolSculpting procedure, [redacted] was never advised by her CoolSculpting provider, and she did not know that the CoolSculpting device can cause damage to tissue, causing PAH and skin laxity.

282. Several months after the CoolSculpting procedures, [redacted] started noticing that the areas of CoolSculpting treatment were beginning to increase, despite her vigilant diet.

283. [redacted] complained to her CoolSculpting provider about her symptoms, but the physician at Healthy for Life Weight Loss & Nutrition Center did not understand that she was exhibiting signs of PAH after CoolSculpting. The CoolSculpting provider was unable to diagnose her, and she was left on her own.

284. The treated areas of her body continued to grow. Her inner thighs got so big that when she walks, they rub together and develop sores that turn into painful open wounds. She can no longer wear dresses and must only wear thick jeans, which develop holes and must be thrown out. Her flanks and abdomen have also got substantially larger, despite her weight loss.

285. For many months [redacted] could not find a doctor that could diagnose her because most physicians were not familiar with PAH. After much searching, she was finally able to find a plastic surgeon that had experience with PAH and was able to diagnose her.

286. [redacted] was diagnosed with PAH to all of the treatment areas. She must undergo multiple invasive procedures to try to remove the affected tissue and reconstruct her body.

287. As the result of Defendant's systemic failure to adequately warn CoolSculpting providers about the danger of the CoolSculpting medical device, [redacted] CoolSculpting provider was not adequately informed about the extent of the serious and permanent adverse effect of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical Hyperplasia (PH) which requires surgical intervention to resolve.

288. As the direct and proximate cause of Defendant's conduct, [redacted] was not informed about PAH prior to undergoing CoolSculpting.

289. Had [redacted] known that there was a chance that she could develop a condition that results in the opposite effect of the device's advertised purpose, she would not have undergone the procedure.

290. [redacted] damages include past and future medical expenses, past and future pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.

## CLASS ACTION ALLEGATIONS

291. **Class Action Provisions:** Plaintiffs bring this action individually on behalf of themselves and all those similarly situated persons, pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and 23(c)(4).

292. **Definition of Class:**

a. **Nationwide Class:** All individuals who purchased cycle(s) of the CoolSculpting procedure in the United States.

b. **Nationwide Subclass:** All individuals who underwent the CoolSculpting procedure and suffered tissue damage in the form of Paradoxical Adipose Hyperplasia (PAH), also known as Paradoxical Hyperplasia (PH).

c. **Excluded Persons:** Excluded from the putative class are: (i) Defendant, any entity in which Defendant has a controlling interest, and Defendant's legal Representative, predecessors, successors, and assigns; (ii) governmental entities; (iii) Defendant's employees, officers, directors, agents and Representative, and their family members; and (iv) the Judge and staff to whom this case is assigned, and any member of the Judge's immediate family. Plaintiffs reserve the right to amend the class definition as appropriate after class discovery is completed.

293. **Numerosity:** The number of members of the Class is so numerous that individual joinder is impracticable. Tens of thousands of people purchased CoolSculpting cycle(s) in the United States. Thousands of people suffered PH after undergoing the CoolSculpting procedure, Defendant has received at least 3,300 reports of persons that developed PH from CoolSculpting through July 2020. The members of the Class can be identified through Defendant's records.

294. **Commonality and Predominance:** The Plaintiffs' and the Class members' claims involve important common questions of fact and law that predominate over any individual issues. The injuries sustained by Plaintiffs and Class member stem from the same nucleus of operative facts surrounding the Defendant's conduct in selling, promoting, advertising, and labeling the CoolSculpting medical device. The claimants' injuries arose from the same policy and practice implemented by the Defendant. The conduct described herein did not differ materially from one CoolSculpting provider to another and was uniform across the nation. The following questions are central to Plaintiffs and Class member's individual claims and resolving these common contentions in one class action will be an efficient and productive method of achieving a classwide resolution for thousands of similarly situated claimants.

295. **Common Questions of Fact and Law:** The following questions are common to the class:

i. Whether the CoolSculpting System was defective?

ii. What did Defendant know about PH?

iii. Whether Defendant had a duty to adequately warn CoolSculpting providers about the device's ability to cause harm?

iv. Whether Defendant failed to adequately warn CoolSculpting providers about the device's ability to cause harm?

v. Whether Defendant intentionally misrepresented material facts about PH to CoolSculpting providers?

vi. Whether Defendant intentionally concealed material facts about PH from CoolSculpting providers?

vii. Whether Defendant negligently misrepresented material facts about PH to CoolSculpting providers?

viii. Whether Defendant negligently concealed material facts about PH from CoolSculpting providers?

ix. Whether Defendant's conduct was unfair and deceptive under California's consumer protection laws?

x. Whether Defendant failed to use reasonable care in warning CoolSculpting providers about PH?

xi. Whether Defendant's deceptive practices in regard to PH were illegal?

xii. Whether Defendant's reliance on the CoolSculpting providers to warn consumers about PH was reasonable under the specific circumstances created by the Defendant?

xiii. Whether Defendant's system of entangling itself in consumers' CoolSculpting medical treatment gave rise to a duty to warn the consumers directly about the PH?

296. **Typicality**: Plaintiffs' claim is typical of the claims of all members of the Class against the Defendant. The Plaintiffs' claim is based on the same or similar set of facts and legal theories against the Defendant that affect a much larger class of people who also purchased cycles of CoolSculpting and underwent the procedure. Plaintiffs and Class members were the victim of Defendant's defective medical device, the Defendant's deceptive practices, and the Defendant's failure to adequately inform the CoolSculpting providers about the medical device's ability to cause serious and permanent harm to the Plaintiffs and the Class members. Consequently, the Plaintiffs and the Class members all suffered similar damages as the result of the Defendant's illegal conduct.

297. **Superiority.** A class action is a superior method of resolving the controversy between thousands of people that suffered similar injuries and economic damages after purchasing cycles of the CoolSculpting procedure and undergoing CoolSculpting due to the Defendant's illegal course of conduct which affected the Class members in the same way. Each claim is based on the same evidence and requires the same expert witnesses to prove the claims against the Defendant. A resolution of common questions of fact and law in one action based on the same evidence against the same Defendant will be economical for the claimants and the judicial system. A single class action on thousands of the same claims will avoid repetitive motion practice, inconsistent discovery rulings, multiple depositions of the same witnesses, cumulative expenses to obtain the same evidence, and delays in obtaining justice. Moreover, the Defendant will benefit from a single centralized action that will totally resolve the question of liability to thousands of claimants alleging the same claims.

298. **Injunctive Relief – Rule 23(b)(2)**. In addition to monetary damages, this action seeks injunctive relief against the Defendant which affects the Class as a whole. This class action seeks an order from the Court requiring Defendant to change the CoolSculpting device's labeling in regard to PH and establish medical monitoring for persons that underwent the CoolSculpting procedure.

299. **Adequacy of Representation:** The Class Representative will fairly and adequately represent the members of the Class. No material conflicts of interest exist between the Class Representative and the members of the Class. The Class Representative' interests are aligned with the interests of the members of the Class and the Representative' claims against the Defendant are common to the claims of the members of the Class. The Class Representative will actively participate in the litigation and intend to be involved in important decision making on behalf of the Class throughout the course of this litigation. Likewise, the undersigned class counsel selected by the Class Representative to file this class action is competent to litigate the issues in this case, has in-depth knowledge about the issues in this case.

**COUNT I**
**STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN**

300. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

301. Defendant is, and at all times mentioned in this Complaint was, engaged in the business of designing, manufacturing, assembling, and selling a medical device product known as CoolSculpting System with the purpose of gaining profits from the distribution thereof.

302. Defendant intended that the subject product be used in the way in which it was used on the Plaintiffs.

303. Defendant's design of the CoolSculpting System medical device was unreasonably dangerous, unsafe, and/or defective for use on Plaintiffs at the time it left the Defendant's control as well as when it was used on Plaintiffs.

304. Defendant knew that its CoolSculpting System device was unreasonably dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiffs. Specifically, Defendant knew that its medical device can cause tissue damage and permanent deformity to the user's body in the form of Paradoxical Hyperplasia (PH).

305. Defendant advertised CoolSculpting as a non-invasive procedure, designed to reduce fat. None of Defendant's advertising, marketing, or informational materials to the Plaintiffs, mentioned that CoolSculpting had the ability to cause a condition that results in a permanent disfigurement to the body that can only be resolved through invasive surgeries resulting in the *opposite effect* of the device's advertised purpose.

306. Plaintiffs relied on the skill and judgment of the Defendant and Defendant's representations that the device was adequately tested and rendered safe to use for its intended purpose.

307. Plaintiffs became interested in and underwent the CoolSculpting procedure based on the Defendant's representation about the procedure.

308. Because of the innate defective nature of the CoolSculpting System device, Plaintiffs and the individuals performing the CoolSculpting procedure on Plaintiffs, through the use of reasonable care could not have discovered the defective nature of the CoolSculpting System device or its perceived dangers.

309. As the direct and proximate result of Defendant's conduct, Plaintiffs sustained damages that were directly caused by the defective, unsafe, and unreasonably dangerous CoolSculpting System device that could not safely be used for the purpose for which it was marketed, advertised, promoted and intended.

310. Defendant is strictly liable for Plaintiffs' and the Class members' damages.

311. As the direct and proximate result of Defendant's wrongful conduct, Plaintiffs and the members of the Class suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

**COUNT II**
**STRICT PRODUCT LIABILITY – FAILURE TO WARN**

312. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

313. Defendant is, and at all times mentioned in this Complaint was, engaged in the business of designing, manufacturing, assembling, and selling a medical device product known as CoolSculpting System with the purpose of gaining profits from the distribution thereof.

314. Defendant directly or through its agents, apparent agents, servants, or employees designed, manufactured, tested, marketed, and commercially distributed the CoolSculpting System device that was used on Plaintiffs.

315. Defendant knew that its CoolSculpting System device was unreasonably dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiffs. Specifically, Defendant knew that its medical device can cause the opposite effect of the device's advertised purpose in the form of Paradoxical Hyperplasia (PH).

316. Defendant knew that PH is not preventable and is unavoidable if undergoing the CoolSculpting procedure. Defendant also knew that there was a possibility that Plaintiffs could develop PH after undergoing the CoolSculpting procedure.

317. Defendant had superior knowledge about PH because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendant was a centralized hub of information about the device's

adverse effects, including PH. It had received thousands of reports of users developing the condition, had access to those person's medical records and information regarding diagnosis, treatment, and occurrence rate of PH, which it did not disclose to the medical community.

318. Defendant had a duty to provide adequate warnings about PH, a dangerous adverse effect of its CoolSculpting medical device, to Plaintiffs' CoolSculpting provider.

319. Defendant failed to provide adequate warnings to Plaintiffs' CoolSculpting provider because the language used by Defendant to describe PH in its training materials:

a. was inaccurate in content and ambiguous in manner of expression;

b. did not adequately inform the providers about a condition which is: 1) unfamiliar to the medical community, 2) is only associated with the CoolSculpting device, and 3) about which Defendant had superior knowledge;

c. creatively used insufficient and vague language that did not provide enough specificity about the condition, which was necessary for the CoolSculpting providers to know about the risks of using the device;

d. misrepresented facts about the adverse effect;

e. did not use concrete terms like "deformity" and "disfigurement" to describe PH;

f. did not definitively state that PH is a disease of the tissue called fibroplasia or fibrosis;

g. did not definitively state that PH can only be removed with invasive surgery;

h. did not warn that it is likely that multiple surgeries may be necessary to remove PH;

i. did not disclose that a single patient can develop the condition in multiple areas;

j. did not disclose that PH causes permanent cutaneous and subcutaneous tissue damage;

k. did not disclose that long term effects of PH affected tissue are unknown;

l. did not disclose that even with surgery, patients affected by PH may still be left with deformities on their body;

m. did not disclose that PH tissue may recur after surgery; and

n. used words such as "rare side effect" to imply that PH is unlikely to occur, while knowing that the adverse event is not rare.

320. Defendant is strictly liable for Plaintiffs' and the Class members' damages because its product was defective due to its failure to adequately warn CoolSculpting providers about the danger of the CoolSculpting devise.

321. As the direct and proximate result of Defendant's wrongful conduct, Plaintiffs and the members of the Class suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

**COUNT III**
**NEGLIGENCE**

322. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

323. Defendant had superior knowledge about PH because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendant was a centralized hub of information about the device's adverse effects, including PH. It had received thousands of reports of users developing the condition, performed its own research on PH, had access to PH patients' medical records and information regarding diagnosis, treatment, and occurrence rate of PH, which it did not disclose to the medical community. Likewise, Defendant controlled PH diagnosis rate by instructing CoolSculpting providers not to mention PH to patients until the Defendant's claims department

"confirmed" the providers' diagnosis and by systemically rejecting or refusing to confirm all of the providers' diagnoses.

324. The CoolSculpting providers acted as the Defendant's agents in selling the CoolSculpting cycles, because Defendant, among other things, conducted itself in the following ways: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2) shared profits with the providers on each cycle administered to patients, 3) provided forms and documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting patients, 4) referred CoolSculpting patients to the CoolSculpting providers via its website, 5) controlled the advertised price of CoolSculpting, 6) controlled how patients were diagnosed with PH resulting from CoolSculpting, and so on.

325. Defendant owed a duty to protect Plaintiffs from unreasonable risk of its CoolSculpting medical device which it knew had the ability to cause permanent injury resulting in the opposite effect of the device's advertised purpose.

326. **Duty to take Corrective and Preventive Actions.** Defendant had a duty to take corrective and preventive actions when it found out that its medical device causes permanent deformities to patient's bodies.

327. Defendant failed to exercise ordinary care when it: 1) failed to acknowledge that PH is a *serious side effect* of the CoolSculpting device, and 2) failed to take corrective and preventive actions such as drafting proper labeling for the product that accurately and adequately describes PH, updating its labeling for the product when if found out more information about the serious and permanent side effect associated with its medical device, or taking the device off the market to prevent harm to thousands of people.

328. **Duty to Inform Providers.** Defendant had a duty to adequately inform Plaintiffs' CoolSculpting provider that PH, an adverse effect associated with Cryolipolysis and the CoolSculpting medical device: 1) causes cutaneous and subcutaneous tissue damage, 2) is a

permanent deformity, 3) which will never resolve on its own, 4) which may affect a single patient in multiple treatment areas, 5) PH requires multiple plastic surgeries, per affected area, to remove, 6) the effect of PH is the opposite of the intended result of CoolSculpting, 7) that males are more likely to develop PH, 8) the long term effect of the tissue damage from PH is unknown, 9) that additional treatment in future may be required, 10) in some cases, plastic surgery will not resolve PH.

329. Defendant failed to exercise ordinary care when it used misleading language in describing PH to the CoolSculpting providers that did not adequately inform them about the seriousness of the condition and when Defendant concealed material facts about the condition from CoolSculpting providers. Defendant made ambiguous and inaccurate statements about the effect PH has on the body, its permanency, treatment options, and rate of risk in the written materials it furnished to Plaintiffs' CoolSculpting provider.

330. Due to Defendant's failure to use ordinary care, Plaintiffs' CoolSculpting provider did not and could not adequately inform Plaintiffs and other CoolSculpting patients about the real risk of developing serious and permanent condition. Consequently, Plaintiffs and Class members were induced to purchase CoolSculpting cycles and undergo the CoolSculpting procedure and suffered economic damages and/or personal injuries as a result.

331. **Duty to be Honest in Advertising CoolSculpting.** Defendant also had a duty to be honest in its advertisement materials directed at Plaintiffs and Class members, such as commercials, website content, and the brochures and posters that it furnished to the CoolSculpting providers to use in the office. Specifically, Defendant had a duty:

o. Not to claim that the CoolSculpting procedure is a "non-invasive" and "non-surgical" alternative to liposuction;

p. Not to claim that the CoolSculpting procedure produced "long lasting results";

q. Not to claim that the CoolSculpting procedure "kills" fat cells;

r. Not to claim that the CoolSculpting procedure results in "up to 20%-25% reduction of fat in a treated area";

s. To disclose that the CoolSculpting procedure may cause the opposite effect of what it claims to achieve;

t. To disclose that even after an initial reduction in fat, a person may develop the *opposite effect* (via PH);

332. Defendant failed to exercise ordinary care when it made deceptive claims in its advertisement materials, which were directed at the Plaintiffs and the Class members, about the CoolSculpting device's effectiveness of reducing fat *without surgery* and omitted any information about the CoolSculpting's device's ability to cause the opposite effect.

333. Due to Defendant's failure to use ordinary care, Plaintiffs and Class members were not aware that by purchasing CoolSculpting cycles and undergoing the CoolSculpting procedure they were subjecting themselves to a risk of developing permanent deformities in the form of substantially increased and damaged fat tissue and skin laxity which requires multiple invasive surgeries to remove.

334. Consequently, Plaintiffs and Class members were induced to purchase and undergo the expensive CoolSculpting procedure and suffered economic damages and personal injuries.

335. **Duty to Warn CoolSculpting Consumers.** Defendant created a system wherein CoolSculpting providers relied on it to support their CoolSculpting business. Defendant involved itself in every step of the CoolSculpting treatment, from attracting consumers through advertisement, furnishing CoolSculpting providers with patient-facing documents (including consent forms) that informed consumers about the procedure, profit-sharing on each cycle sold to the consumers, diagnosing the consumer with PH, and offering to settle PH claims which protected the CoolSculpting providers from liability to the consumers. Defendant's participation in the consumers' medical treatment gave rise to a duty to warn the consumers directly about the danger

of its medical device, because it was not reasonable for the Defendant to rely on CoolSculpting providers to properly inform their patients about the risk of PH under the circumstances created by Defendant.

336. Defendant failed to exercise ordinary care when it unreasonably relied on CoolSculpting providers to inform the CoolSculpting patients about the risk of PH, knowing that: 1) the consent language used by providers did not accurately and adequately explain PH to consumers, 2) PH was the most serious adverse effect of CoolSculpting, 3) PH was the most frequently reported adverse effect of CoolSculpting, 4) PH was the opposite effect of CoolSculpting, and 5) CoolSculpting providers would not be incentivized to disclose the truth to their patients about PH because they would lose sales.

337. Due to Defendant's failure to use ordinary care, Plaintiffs and Class members were not aware that by purchasing CoolSculpting cycles and undergoing the CoolSculpting procedure they were subjecting themselves to a risk of developing permanent deformities in the form of substantially increased and damaged fat tissue and skin laxity which requires multiple invasive surgeries to remove.

338. Consequently, Plaintiffs and Class members were induced to purchase and undergo the expensive CoolSculpting procedure and suffered economic damages and personal injuries.

339. As the direct and proximate result of Defendant's wrongful conduct, Plaintiffs and Class members suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

**COUNT IV**
**MEDICAL MONITORING**

340. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

341. As the result of the Plaintiffs' and Class members' development of a serious and permanent condition, Paradoxical Hyperplasia, after undergoing the CoolSculpting procedure, the need for future monitoring is reasonably certain because the condition results in cellular damage, the long-term effect of which is currently unknown.

342. Even in those persons, whose affected tissue has been substantially removed via surgery, it is not certain that PH will not return to the affected area in the future.

343. It is also unknown whether the development of PH is correlated to other health issues that may develop or present themselves over time.

344. Therefore, medical monitoring is reasonable and necessary to preserve the health and wellness of those affected by Paradoxical Hyperplasia resulting from CoolSculpting.

345. Plaintiffs and the Class members are entitled to a medical monitoring program which will cover the future costs and related expenses of monitoring their health subsequent to developing PH, and the Defendant is obligated to pay for such a program.

**COUNT V**
**NEGLIGENT MISREPRESENTATION AND CONCEALMENT**

346. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

347. Defendant had superior knowledge about PH because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendant was a centralized hub of information about the device's adverse effects, including PH. It had received thousands of reports of users developing the condition, performed its own research on PH, had access to PH patients' medical records and information regarding diagnosis, treatment, and occurrence rate of PH, which it did not disclose to the medical community.

348. The CoolSculpting providers acted as the Defendant's agents in selling the CoolSculpting cycles, because Defendant, among other things, conducted itself in the following ways: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2) shared profits with the providers on each cycle administered to patients, 3) provided forms and documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting patients, 4) referred CoolSculpting patients to the CoolSculpting providers via its website, 5) controlled the advertised price of CoolSculpting, 6) controlled how patients were diagnosed with PH resulting from CoolSculpting, and so on.

349. Defendant made these statements and concealed material facts about PH without regard for the truth of the statements it was making.

350. **Severity.** Defendant knew that PH is a disfigurement and a deformity to the body that is completely different from a normal "enlargement of fat" because PH permanently damages the tissue it affects. Defendant also knew that many PH patients also suffered cutaneous tissue damage resulting in skin laxity, which requires additional surgeries to reconstruct. Defendant misrepresented the consequences of PH to CoolSculpting providers by creatively using insufficient and ambiguous language to describe the condition and intentionally avoided using concrete terms that would fairly and accurately describe the adverse event.

351. **Permanency.** Defendant knew that PH will *never* resolve on its own and that the *only* means of removing it is through invasive plastic surgery but instead, it used false language in describing PH to CoolSculpting providers, downplaying the permanency of the condition and stating, "surgical intervention *may* be required."

352. **Frequency.** Based on the number of PH reports Defendant received, it knew that the likelihood of developing PH after CoolSculpting was *not* rare. Defendant concealed its knowledge of the unreasonably dangerous risks of its CoolSculpting device from the CoolSculpting providers, while simultaneously relying on words "rare" and "small number" to

induce CoolSculpting providers to believe that it is *unlikely* that a patient will develop the condition. Defendant concealed the fact that PH was the most frequently reported adverse effect of CoolSculpting.

353. Defendant's intent in making material misrepresentations about PH and concealing material information was motivated by profits. Because the majority of the Defendant's CoolSculpting profits are gained from the *use* of the device on consumers rather than sales of the device to the providers, Defendant's conduct was highly driven by consumers' purchase of the CoolSculpting cycles.

354. Defendant knew that the CoolSculpting providers' lack of knowledge and understanding about PH will result in consumers being uninformed about the serious and permanent adverse effect. On the other hand, Defendant knew that if consumers knew that there was a risk of developing the opposite effect of CoolSculpting's advertised purpose, consumers would not likely undergo the elective procedure.

355. As the result of Defendant's superior knowledge about PH, CoolSculpting providers justifiably relied on Defendant's representations about the adverse effect solely associated with Defendant's medical device. Believing that the adverse effect is unlikely to occur and is not as serious and permanent, CoolSculpting providers did not properly inform CoolSculpting patients about the risk of PH. Information regarding PH was material and necessary for the Plaintiffs and the Class to make an informed decision about undergoing this elective procedure. Had the Plaintiffs and the Class known that there was a risk that they could suffer the *opposite effect* of the CoolSculpting device's advertised purpose, they would not have purchased cycles of CoolSculpting.

356. As the proximate result of Defendant's fraudulent conduct, Plaintiffs and the Class suffered damages that include economic and non-economic losses.

**COUNT VI**
**FRAUDULENT MISREPRESENTATION AND CONCEALMENT**

357. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

358. Defendant had superior knowledge about PH because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendant was a centralized hub of information about the device's adverse effects, including PH. It had received thousands of reports of users developing the condition, performed its own research on PH, had access to PH patients' medical records and information regarding diagnosis, treatment, and occurrence rate of PH, which it did not disclose to the medical community.

359. The CoolSculpting providers acted as the Defendant's agents in selling the CoolSculpting cycles, because Defendant, among other things, conducted itself in the following ways: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2) shared profits with the providers on each cycle administered to patients, 3) provided forms and documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting patients, 4) referred CoolSculpting patients to the CoolSculpting providers via its website, 5) controlled the advertised price of CoolSculpting, 6) controlled how patients were diagnosed with PH resulting from CoolSculpting, and so on.

360. Defendant intentionally concealed and misrepresented important facts about the severity, permanency, and frequency of PH in the device's labeling.

361. **Severity.** Defendant knew that PH is a disfigurement and a deformity to the body that is completely different from a normal "enlargement of fat" because PH permanently damages the tissue it affects. Defendant also knew that many PH patients also suffered cutaneous tissue damage resulting in skin laxity, which requires additional surgeries to reconstruct. Defendant

misrepresented the consequences of PH to CoolSculpting providers by creatively using insufficient and ambiguous language to describe the condition and intentionally avoided using concrete terms that would fairly and accurately describe the adverse event.

362. **Permanency.** Defendant knew that PH will *never* resolve on its own and that the *only* means of removing it is through invasive plastic surgery but instead, it used false language in describing PH to CoolSculpting providers, downplaying the permanency of the condition and stating, "surgical intervention *may* be required."

363. **Frequency.** Based on the number of PH reports Defendant received, it knew that the likelihood of developing PH after CoolSculpting was *not* rare. Defendant concealed its knowledge of the unreasonably dangerous risks of its CoolSculpting device from the CoolSculpting providers and the public, while simultaneously relying on words "rare" and "small number" to induce CoolSculpting providers to believe that it is *unlikely* that a patient will develop the condition. Defendant concealed the fact that PH was the most frequently reported adverse effect of CoolSculpting.

364. Defendant's intent in making material misrepresentations about PH and concealing material information was motivated by profits. Because the majority of the Defendant's CoolSculpting profits are gained from the *use* of the device on consumers rather than sales of the device to the providers, Defendant's conduct was highly driven by consumers' purchase of the CoolSculpting cycles.

365. Defendant knew that the CoolSculpting providers' lack of knowledge and understanding about PH will result in consumers being uninformed about the serious and permanent adverse effect. On the other hand, Defendant knew that if consumers knew that there was a risk of developing the opposite effect of CoolSculpting's advertised purpose, consumers would not likely undergo the elective procedure.

366. As the result of Defendant's superior knowledge about PH, CoolSculpting providers justifiably relied on Defendant's representations about the adverse effect solely associated with Defendant's medical device. Believing that the adverse effect is unlikely to occur and is not as serious and permanent, CoolSculpting providers did not properly inform CoolSculpting patients about the risk of PH. Information regarding PH was material and necessary for the Plaintiffs and the Class to make an informed decision about undergoing this elective procedure. Had the Plaintiffs and the Class known that there was a risk that they could suffer the *opposite effect* of the CoolSculpting device's advertised purpose, they would not have purchased cycles of CoolSculpting.

367. As the proximate result of Defendant's fraudulent conduct, Plaintiffs and the Class suffered damages that include economic and non-economic losses.

**COUNT VII**
**CALIFORNIA FALSE ADVERTISING LAW ("FAL")**
**California Business and Professions Code §§ 17500, *et seq.***

368. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

369. California Business and Professions Code § 17500 prohibits deceptive or misleading practices in connection with advertising or representations made for the purpose of inducing, or which are likely to induce, consumers to purchase products or services.

370. Defendant directly or through its agents, apparent agents, servants, or employees designed, manufactured, tested, marketed, and commercially distributed the CoolSculpting System device that was used on Plaintiffs.

371. Defendant, directly or through its agents, apparent agents, servants, or employees, misrepresented the consequences of PH to CoolSculpting providers by creatively using insufficient and ambiguous language to describe the condition and intentionally avoided using concrete terms that would fairly and accurately describe the adverse event.

372. Defendant used false language in describing PH to CoolSculpting providers, downplaying the permanency of the condition and stating, "surgical intervention *may* be required" despite its knowledge that PH will *never* resolve on its own and that the *only* means of removing it is through invasive plastic surgery.

373. Defendant used the words "rare" and "small number" to induce CoolSculpting providers to believe that it is *unlikely* that a patient will develop the condition despite its knowledge of the unreasonably dangerous risks of its CoolSculpting device.

374. At the time of its misrepresentations, Defendant was either aware of the dangers alleged herein, or was aware that it lacked the information and/or knowledge required to make such a representation truthfully. Defendant concealed and omitted and failed to disclose this information to Plaintiffs.

375. Defendant's descriptions of its CoolSculpting System were false, misleading, and likely to deceive Plaintiff and other reasonable consumers.

376. Defendant's conduct therefore constitutes deceptive or misleading advertising.

377. Plaintiff has standing to pursue claims under the FAL as they reviewed and relied on Defendant's advertising, representations, and marketing materials regarding CoolSculpting, when purchasing and undergoing the CoolSculpting procedure.

378. In reliance on the statements made in Defendant's advertising and marketing materials and Defendant's omissions and concealment of material facts regarding the CoolSculpting System, Plaintiff purchased and underwent the CoolSculpting procedure.

379. Had Defendant disclosed the true defective and dangerous nature of CoolSculpting, Plaintiff and California Class Members would not have purchased or undergone the CoolSculpting procedure or would have paid substantially less for it.

380. As a direct and proximate result of Defendant's actions, as set forth herein, Defendant has received ill-gotten gains and/or profits, including but not limited to money from Plaintiffs who paid for CoolSculpting.

381. Plaintiff and California Class Members seek injunctive relief, restitution, and disgorgement of any monies wrongfully acquired or retained by Defendant and by means of its deceptive or misleading representations, including monies already obtained from Plaintiffs as provided for by the California Business and Professions Code § 17500.

**COUNT VIII**
**VIOLATION OF THE CALIFORNIA CONSUMER LEGAL REMEDIES ACT ("CLRA"), Civil Code §§ 1750, *et seq.***

382. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

383. The conduct described herein took place in the State of California and constitutes unfair methods of competition or deceptive acts or practices in violation of the Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750, *et seq.*

384. The CLRA applies to all claims of all Class Members because the conduct which constitutes violations of the CLRA by Defendant occurred within the State of California.

385. Plaintiff and California Class Members are "consumers" as defined by Civil Code § 1761(d).

386. Defendant is a "person" as defined by Civil Code § 1761(c).

387. The CoolSculpting device qualifies as a "Product" as defined by Civil Code § 1761(a).

388. The CoolSculpting procedure qualifies as "services" as defined by Civil Code § 1761(b).

389. Plaintiff and the California Class Members' purchases of CoolSculpting are "transactions" as defined by Civil Code 25 § 1761(e).

390. As set forth below, the CLRA deems the following unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which does result in the sale or lease of goods or services to any consumer as unlawful.

a. "Representing that goods or services … have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have." Civil Code § 1770(a)(5); and

b. "Representing that goods or services … are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another." Civil Code § 1770(a)(7).

391. Defendant engaged in unfair competition or unfair or deceptive acts or practices in violation of Civil Code §§ 1770(a)(5) and (a)(7) when it represented, through its advertising and other express representations, that CoolSculpting had benefits or characteristics that it did not actually have.

392. As detailed in the body of this Complaint, Defendant has repeatedly engaged in conduct deemed a violation of the CLRA, and has made representations regarding CoolSculpting benefits or characteristics that it did not in fact have, and represented CoolSculpting to be of a quality that was not true. Indeed, Defendant concealed this information from Plaintiff and California Class Members.

393. CoolSculpting was not and is not reliable, in that CoolSculpting is not safe and is of inferior quality and trustworthiness compared to other products in the industry. As detailed above, Defendant further violated the CLRA when it falsely represented that CoolSculpting meets a certain standard or quality.

394. As detailed above, Defendant violated the CLRA when it advertised CoolSculpting with the intent not to sell the service as advertised and knew that CoolSculpting was not as represented.

395. Defendant's deceptive practices were specifically designed to induce Plaintiffs to purchase and undergo CoolSculpting.

396. Defendant engaged in uniform marketing efforts to reach Plaintiffs, their agents, and/or third parties upon whom they relied, to persuade them to purchase and undergo CoolSculpting designed, tested, marketed, and commercially distributed by Defendant, directly or through its agents, apparent agents, servants, or employees, containing numerous false and misleading statements regarding the quality, safety, and reliability of CoolSculpting. These include, *inter alia*, the following misrepresentations:

- "surgical intervention may be required" despite Defendant's knowledge that PH will never resolve on its own and that the only means of removing it is through invasive plastic surgery;
- a "small number" may develop PH despite Defendant's knowledge of the unreasonably dangerous risks and high incident rate of PH; and
- instructed its employees to use the words "rare" when referring to PH in their communications with CoolSculpting providers, the public, and the FDA.

397. Despite these representations, Defendant also omitted and concealed information and material facts from Plaintiffs.

398. In their purchase of CoolSculpting, Plaintiffs relied on Defendant's representations and omissions of material facts.

399. These business practices are misleading and/or likely to mislead consumers and should be enjoined.

400. On May 28, 2021, Plaintiffs sent written notice to Defendant via USPS Certified Mail demanding corrective actions pursuant to the Consumers Legal Remedies Act ("CLRA"), California Civil Code § 1770, *et seq*. Plaintiffs will amend her complaint to add claims for monetary damages if Defendant fails to take the corrective actions.

401. Plaintiffs' counsel's declaration stating facts showing that venue in this District is proper pursuant to Cal. Civ. Code § 1780(c) is attached hereto as **Exhibit A**.

402. In accordance with Civil Code § 1780(a), Plaintiffs seek injunctive and equitable relief for Defendant's violations of the CLRA, including an injunction to enjoin Defendant from continuing its deceptive advertising and sales practices.

403. Pursuant to California Civil Code § 1780(a)(1)-(5) and § 1780(e), Plaintiff seeks an order enjoining Defendant from the unlawful practices described above, a declaration that Defendant's conduct violates the Consumers Legal Remedies Act, reasonable attorneys' fees and litigation costs, and any other relief the Court deems proper under the CLRA.

**COUNT IX**
**VIOLATIONS OF THE CALIFORNIA UNFAIR COMPETITION LAW ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.***

404. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

405. Defendant is a "person" as defined by Cal. Bus. & Prof. Code § 17201.

406. Plaintiff and California Class Members who purchased CoolSculpting suffered an injury by virtue of buying products and services in which Defendant misrepresented and/or omitted CoolSculpting's true quality, reliability, and safety.

407. Had Plaintiff and California Class Members known that Defendant materially misrepresented CoolSculpting and/or omitted material information regarding its defective CoolSculpting product and services and its safety they would not have purchased or undergone CoolSculpting.

408. Defendant's conduct, as alleged herein, violates the laws and public policies of California and the federal government, as set out in the preceding paragraphs of this complaint.

409. There is no benefit to consumers or competition by allowing Defendant to deceptively label, market, and advertise CoolSculpting.

410. Plaintiffs who purchased CoolSculpting had no way of reasonably knowing that CoolSculpting was deceptively marketed and advertised, was defective, not safe, and unsuitable for its intended use. Thus, Plaintiffs could not have reasonably avoided the harm they suffered.

411. The gravity of the harm suffered by Plaintiff and California Class Members who purchased and underwent CoolSculpting outweighs any legitimate justification, motive or reason for marketing, advertising, and selling the dangerous CoolSculpting in a deceptive and misleading manner. Accordingly, Defendant's actions are immoral, unethical, unscrupulous and offend the established public policies as set out in federal regulations and are substantially injurious to Plaintiffs.

412. The above acts of Defendant in disseminating said misleading and deceptive statements to consumers were and are likely to deceive reasonable consumers by obfuscating the true defective nature of CoolSculpting, and thus were violations of Cal. Bus. & Prof. Code §§ 17500, *et seq*.

413. As a result of Defendant's above unlawful, unfair and fraudulent acts and practices, Plaintiff, on behalf of herself and all others similarly situated, and as appropriate, on behalf of the general public, seeks injunctive relief prohibiting Defendant from continuing these wrongful practices, and such other equitable relief, including full restitution of all improper revenues and ill-gotten profits derived from Defendant's wrongful conduct to the fullest extent permitted by law.

414. Dangerous CoolSculpting cannot legally be advertised or sold. Thus, CoolSculpting has no economic value and are worthless as a matter of law, and purchasers of CoolSculpting are entitled to a restitution refund of the purchase price.

**COUNT X**
**VIOLATION OF NEW YORK GBL §§ 349, et seq.**

415. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this Complaint as if fully set forth herein.

416. New York General Business Law § 349 ("NY GBL § 349") prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in furnishing of any service in this state. . . ." NY GBL § 349(a).

417. Defendants' foregoing acts and practices, including their omissions, were directed at consumers.

418. Defendants' foregoing deceptive acts and practices, including their omissions, were material, in part, because they concerned a material aspect of the CoolSculpting product and service provided, including the intended use and safety.

419. Defendants omitted material facts regarding the safety of the CoolSculpting by failing to disclose that they posed a serious health risk to consumers. Rather than disclose this information, Defendants marketed CoolSculpting as safe for their intended purpose.

420. CoolSculpting poses an unreasonable safety risk to consumers.

421. Defendants did not disclose this information to consumers or otherwise cause this information to be disclosed to consumers

422. Defendants' foregoing deceptive and unfair acts and practices, including their omissions, were and are deceptive acts or practices in violation of the New York's General Business Law § 349, Deceptive Acts and Practices, N.Y. Gen. Bus. Law 349, et seq., by:

a. Misrepresenting that CoolSculpting were safe for its intended purpose; and

b. Omitting and failing to disclose their knowledge that CoolSculpting posed a serious health risk to consumers.

425. Defendants' business practices, in manufacturing, warranting, advertising, marketing and selling CoolSculpting products and services while concealing, failing to disclose, suppressing or omitting material information, including the existence of serious health risk to consumers and Defendants' knowledge of it, all while continuing to misrepresent CoolSculpting

as safe for their ordinary and intended use and free of defects, constitutes the use of fraud, misrepresentation, and deceptive practices.

426. These practices deceived Plaintiffs, causing them to lose money by purchasing and undergoing CoolSculpting products and services or paying more than they otherwise would, as herein alleged, and deceived and are likely to deceive the consuming public.

427. Accordingly, Defendants' business acts and practices, as alleged herein, have caused injury to Plaintiffs.

428. Plaintiffs suffered damages when they purchased CoolSculpting services. Defendants' unconscionable, deceptive and/or unfair practices caused actual damages to Plaintiffs who were unaware that CoolSculpting posed a serious health risk. Defendants' foregoing deceptive acts and practices, including their omissions, were likely to deceive, and did deceive, consumers acting reasonably under the circumstances.

429. Consumers, including Plaintiffs either would not have purchased the Products had they known about the serious health risk they posed to consumers, or would have paid less for them.

430. As a direct and proximate result of Defendants' deceptive acts and practices, including their omissions, Plaintiffs have been damaged as alleged herein, and are entitled to recover actual damages to the extent permitted by law, including class action rules, in an amount to be proven at trial.

431. In addition, Plaintiffs seek equitable and injunctive relief against Defendants on terms that the Court considers reasonable, and reasonable attorneys' fees and costs.

**COUNT XI**
**VIOLATION OF NEW YORK GBL §§ 350, et seq.**

432. Plaintiffs repeat and re-alleges all previous paragraphs, as if fully included herein.

433. New York General Business Law § 350 ("NY GBL § 350") prohibits "[f]alse advertising in the conduct of any business, trade or commerce . . . ." NY GBL § 350.

434. Defendants' foregoing acts and practices, including their advertising, were directed at consumers. 121. Through the acts and conduct alleged herein, Defendants committed unfair or deceptive acts and practices, by falsely advertising and misleadingly representing that CoolSculpting was safe for its intended purpose.

435. Defendants also committed unfair or deceptive acts and practices by omitting material information from their advertising and representations, including their failure to disclose that CoolSculpting poses serious, continuous safety risks to consumers, which is material because it concerns safety.

436. CoolSculpting poses an unreasonable risk to the health and safety of Plaintiffs and Class members.

437. Defendants did not disclose this information to consumers in their advertising or representations.

438. Defendants' foregoing, consumer-oriented, unfair or deceptive acts and practices, including their advertising, representations, and omissions, constitutes false and misleading advertising in a material way in violation of the New York's General Business Law § 350.

439. Defendants' false, misleading, and deceptive advertising and representations include:

a. Misrepresenting and misleadingly advertising that CoolSculpting was fit for its intended purpose; and

b. Omitting and failing to disclose their knowledge that CoolSculpting is not safe for its intended purpose.

440. Defendants' false, misleading, and deceptive advertising and representations of fact were and are directed at consumers.

441. Defendants' false, misleading, and deceptive advertising and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

442. Defendants' false, misleading, and deceptive advertising and representations of fact have resulted in consumer injury or harm to the public interest.

443. Plaintiff and other Class Members were injured because (a) they would not have purchased CoolSculpting on the same terms if the true facts concerning the safety risk posed by CoolSculpting had been known; (b) they would have paid less for CoolSculpting if the true facts concerning the safety risk posed by CoolSculpting had been known; and (c) CoolSculpting did not and cannot be perform as promised due to the inherent safety risk.

444. On behalf of themselves and Class members, Plaintiffs seeks to enjoin the unlawful acts and practices described herein, to recover actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

445. Defendants' business practices, in manufacturing, warranting, advertising, marketing and selling CoolSculpting while concealing, failing to disclose, suppressing or omitting material information, including the existence of a serious safety risk and Defendants' knowledge of it, all while continuing to misrepresent CoolSculpting as safe for its ordinary and intended use and free of defects, constitutes the use of fraud, misrepresentation, and deceptive practices. These practices deceived Plaintiff and Class members, causing them to lose money by purchasing the CoolSculpting or paying more than they otherwise would, as herein alleged, and deceived and are likely to deceive the consuming public. Accordingly, Defendants' business acts and practices, as alleged herein, have caused injury to Plaintiff and Class members.

446. Plaintiff and Class members suffered damages when they purchased CoolSculpting. Defendant's unconscionable, deceptive and/or unfair practices caused actual damages to Plaintiff and Class members who were unaware that CoolSculpting posed a serious health risk. Defendant's

foregoing deceptive acts and practices, including omissions, were likely to deceive, and did deceive, consumers acting reasonably under the circumstances.

447. Consumers, including Plaintiff and Class members either would not have purchased the CoolSculpting had they known about the safety risk, or would have paid less for it.

448. As a direct and proximate result of Defendant's deceptive acts and practices, including their omissions, Plaintiff and Class members have been damaged as alleged herein, and are entitled to recover actual damages to the extent permitted by law, including class action rules, in an amount to be proven at trial.

449. In addition, Plaintiff and Class members seek equitable and injunctive relief against Defendants on terms that the Court considers reasonable, and reasonable attorneys' fees and costs.

**COUNT XII**
**MASSACHUSETTS CONSUMER PROTECTION LAW**
**(Mass. Gen. Laws ch. 93A *et seq.*)**

450. Plaintiff incorporates by reference and re-alleges the preceding paragraphs as if fully set forth herein.

451. Plaintiff asserts a claim under the Massachusetts Consumer Protection Law ("MCPL") ("Chapter 93A"), which makes it unlawful to engage in any "[u]nfair methods of competition or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 92A, § 2(a).

452. Defendant developed, manufactured, marketed and sold the CoolSculpting containing the dangerous safety defect as alleged herein. Defendant developed, manufactured, marketed and sold CoolSculpting despite knowledge of the defect and that CoolSculpting posed a serious safety risk to consumers like Plaintiffs and Class Members.

453. Defendant's sale of CoolSculpting as safe for its intended purpose despite knowing that CoolSculpting posed a serious safety risk to consumers, failing to disclose the safety risks known to Defendant but hidden from the consumer, and Defendant's knowing concealment of

CoolSculpting's unreasonable safety risks, constitute misrepresentations, omissions and concealments of material fact that constitute unfair and/or deceptive trade practices in violation of MCPL.

454. Defendant's unfair and deceptive practices alleged herein constitute unfair and deceptive acts or practices in or affecting commerce pursuant to 940 C.M.R. § 6.04(1)-(2).

455. Defendant's practices are illegal, unfair or deceptive acts or practices in the conduct of trade or commerce and are inherently deceptive.

456. Defendant's practices alleged herein offend public policy and are immoral, unethical, oppressive, and unscrupulous.

457. Defendant violated MCPL not only when it sold CoolSculpting as safe to be used by consumers, but when it failed to disclose to Plaintiff and Class Members that CoolSculpting had a defect that posed a serious safety risk to consumers and the public despite the knowledge that CoolSculpting posed such a risk to Plaintiff and Class Members.

458. Defendant engaged in deceptive trade practices, in violation of MCPL, including selling a product and services that was unsafe, holding out to the public that CoolSculptingwas safe, and failing to warn consumers that CoolSculpting contained a defect that posed a serious safety risk to consumers and the public.

459. Defendant deceptive trade practices were designed to induce Plaintiffs and Class Members to purchase CoolSculpting.

460. Defendant's violations of MCPL were designed to conceal, and Defendant failed to disclose, material facts about CoolSculpting and its unreasonable safety in order to induce Plaintiff and Class Members to purchase CoolSculpting.

461. By engaging in the unfair and deceptive conduct described herein ad more fully above, Defendant actively concealed and failed to disclose material facts about the CoolSculpting.

462. The omissions set forth above regarding CoolSculpting are material facts that a reasonable person would have considered important in deciding whether or not to CoolSculpting. Indeed, no reasonable consumer would have knowingly bought CoolSculpting if that consumer had known that the product has a serious safety risk.

463. Defendant's acts were intended to be deceptive and/or fraudulent, namely, to market, distribute and sell CoolSculpting.

464. Plaintiff and Class Members suffered injury in-fact as a direct result of Defendant's violations of MCPL in that they have paid for CoolSculpting that poses an immediate safety risk and have not received the benefit of the bargain they made when purchasing CoolSculpting.

465. Had Defendant disclosed the true quality, nature and defects of CoolSculpting, Plaintiff and Class Members would not have purchased CoolSculpting.

466. To this day, Defendant continues to violate MCPL by concealing the defective nature of CoolSculpting in failing to notify customers, and in collecting the profits from consumers.

467. Plaintiff and Class Members have been damaged by these violations of MCPL. The damages should be trebled and Plaintiff and Class Members should be allowed to recover attorneys' fees pursuant to Mass. Gen. Laws ch. 93A § 9.

**PUNITIVE/EXEMPLARY DAMAGES**

468. Plaintiffs incorporate the substantive allegations contained in this Complaint as if fully set forth herein.

469. Defendant's conduct in deceiving CoolSculpting providers and the public, including the Plaintiffs and the Class, about the seriousness, permanency, and frequency of Paradoxical Hyperplasia, concealing material information regarding the serious adverse effect of the CoolSculpting device, and creating a system by which consumers did not have fair access to

important information about PH, was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.

470. Defendant, as a corporation, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to Paradoxical Hyperplasia and its CoolSculpting System device.

471. Defendant's malicious and fraudulent conduct must be punished to deter future harm to others. Therefore, exemplary damages are appropriate under that the circumstances.

472. The Defendant's significant relationship with the State of California in regard to the conduct giving rise to punitive damages requires of law applicable to this particular issue.

473. The malicious conduct described herein occurred and arose from the CoolSculpting headquarters in Pleasanton, California from where the Defendant made corporate decisions related to selling, promoting, advertising, and labeling the CoolSculpting medical device. Therefore, Cal. Civ. Code § 3294 applies to the punitive damages' aspect of this case.

## REQUEST FOR RELIEF

**WHEREFORE**, Plaintiffs, respectfully requests this Court enter a judgment:

1. Certifying the Classes described herein pursuant to Rule 23 of the Federal Rules of Civil Procedure;

2. Ordering the Defendant to pay compensatory damages to Plaintiffs and the Class for past and future economic and non-economic damages, including but not limited to pain and suffering, permanent disfigurement, economic loss, future medical expenses, mental anguish, and loss of enjoyment of life;

3. Ordering the Defendant to pay restitution of Defendant's profits earned from its wrongful conduct;

4. Ordering the Defendant to establish a medical monitoring program for persons that underwent the CoolSculpting procedure and exposed themselves to risk of developing PH;

5. Ordering the Defendant to change labeling for the CoolSculpting medical device to reflect accurate information about Paradoxical Hyperplasia associated with the CoolSculpting device;

6. Ordering the Defendant to pay punitive/exemplary/treble damages for the wanton, willful, fraudulent and reckless conduct against Plaintiffs and the Class;

7. Ordering the Defendant to pay reasonable attorney's fees;

8. Ordering the Defendant to pay court costs; and

9. Granting any and all other relief the Court may deem just and proper.

**DEMAND FOR A JURY TRIAL**

Plaintiffs hereby demand a trial by jury on all issues raised in this Class Action Complaint.

**DATED:** May 28, 2021

Respectfully Submitted,

**MILBERG COLEMAN BRYSON PHILLIPS GROSSMAN PLLC**

*/s/ Alex R. Straus*
Alex R. Straus, Esq. (SBN 321366)
alex@gregcolemanlaw.com
16748 McCormick Street
Los Angeles, CA 91436
T: (917) 471-1894

Louiza Tarassova, Esq.*
LOU LAW
2180 N. Park Avenue., Suite 208
Winter Park, FL 32789
Telephone: (407) 622-1885
Fax: (407) 536-5041
E-Mail: louiza@mylawadvocate.com
Secondary E-Mail: service@mylawadvocate.com

***Attorneys for Plaintiff***

**to be admitted pro hac vice*