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

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

5 2. Defendant advertised and continues to advertise CoolSculpting as a "nonsurgical"  
6 procedure intended to reduce stubborn fat bulges "in the areas that bother you most."  
7 CoolSculpting promises "up to 20-25% reduction in fat layer thickness after a single session."<sup>1</sup>  
8

9 3. Defendant knew since at least 2011 that the CoolSculpting device can cause  
10 consumers to develop a condition called Paradoxical Adipose Hyperplasia (PAH) a/k/a  
11 Paradoxical Hyperplasia (PH), which results in the *opposite effect* of the medical device's  
12 advertised purpose. The CoolSculpting device can *permanently* damage the tissue in the area it  
13 targets to reduce, creating a deformity on the patient's body much *larger* in size than the original  
14 "stubborn fat bulge." The condition does not resolve on its own, and unlike regular fat tissue, tissue  
15 affected by PH does *not* respond to weight loss. Thus, the only method of removing PH is through  
16 invasive surgery. The condition is solely attributed to the CoolSculpting device.  
17

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

21 5. Defendant created an environment that deprived consumers of being properly  
22 informed about the risk of PH. Defendant withheld critical information about PH from  
23 CoolSculpting providers, entangled itself in the providers' CoolSculpting business, and gave  
24 assurance to providers that if a patient developed PH, Defendant would cover the claim with its  
25 "liposuction program." This created an atmosphere wherein providers did not understand the  
26

27  
28 <sup>1</sup> <https://www.coolsculpting.com/coolsculpting/>

1 gravity of the adverse effect and were not motivated to disclose the risk thereof to their patients.

2 As the result of Defendant's conduct, the Plaintiffs' CoolSculpting provider did not advise the  
3 Plaintiffs about the risk of developing PH after CoolSculpting.

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

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

8  
9 **PARTIES**

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

13 9. Plaintiff, **Emily Michelle McGoldrick**, is an individual and a resident of  
14 California. From March 2018 through October 2018, she underwent multiple CoolSculpting  
15 procedures in Pasadena, California.

16 10. Plaintiff, **Javier Valencia**, is an individual and a resident of New York. In July  
17 2018, he underwent the CoolSculpting procedure in Stony Brook, New York.

18 11. Plaintiff, **Paula Brooks**, is an individual and a resident of Massachusetts. In May  
19 2019, she underwent the CoolSculpting procedure in Hyannis, Massachusetts, and in August 2019,  
20 she underwent another CoolSculpting procedure in Mt. Pleasant, South Carolina.

21 22 12. Defendant, **AbbVie, Inc.** is a corporation formed under the laws of Delaware with  
23 a principal place of business at 1 North Waukegan Road, North Chicago, IL 60064. On May 8,  
24 2020, AbbVie Inc. acquired Allergan plc., Allergan, Inc., and Zeltiq Aesthetics, Inc. and is the  
25 current owner of the CoolSculpting medical device.

26 27 13. At all times material, Defendant's CoolSculpting business was based in Pleasanton,  
28 California. The CoolSculpting headquarters is currently located at 4410 Rosewood Drive,

1 Pleasanton, CA. Prior to operating from that address, the CoolSculpting business operated from  
2 4698 Willow Rd., Pleasanton, CA. Defendant has designated both Pleasanton addresses as its  
3 official CoolSculpting business office. Defendant also operated manufacturing and assembly  
4 facilities for the CoolSculpting device in Dublin, California and Livermore, California.

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

7 **JURISDICTION AND VENUE**

8  
9 15. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28  
10 U.S.C. § 1332(d)(2) because this is a class action lawsuit in which the matter in controversy  
11 exceeds the value of \$5,000,000, exclusive of interest and costs, and is a class action in which the  
12 majority of the class members are citizens of a different state than the Defendant.

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

18  
19 17. Venue is proper in this district pursuant to 28 U.S.C. §§1391(b)(2) and 1391(c)(2)  
20 because a substantial part of the events or omissions giving rise to the claims occurred in this  
21 judicial district, and the Defendant is subject to this Court's personal jurisdiction.

22 **INTRADISTRICT ASSIGNMENT**

23 18. Pursuant to Civil Local Rule 3-2(c-d), a substantial part of the events giving rise to  
24 the claims herein arose in Alameda County, California and this action should be assigned to the  
25 San Francisco Division.  
26

**FACTUAL ALLEGATIONS**

1  
2 19. Zeltiq Aesthetics, Inc., either directly or through its agents, servants, and employees,  
3 created, designed, manufactured, labeled, marketed, advertised, distributed, and sold its  
4 CoolSculpting System medical device to be used on individuals to induce lipolysis (the breaking  
5 down of fat cells) in the body.

6 20. On April 28, 2017, Allergan plc and Allergan Inc. acquired Zeltiq Aesthetics, Inc. for  
7 the purchase price of \$2.48 billion. Since Allergan’s acquisition of Zeltiq, Allergan held itself out  
8 to the world as the owner of the CoolSculpting System and had apparent dominion and control  
9 over all aspects of the CoolSculpting business including the manufacturing, labeling, advertising,  
10 distribution, and sale of the medical device and its consumables.  
11

12 21. On May 8, 2020, AbbVie, Inc. acquired Allergan plc, Allergan, Inc., and Zeltiq  
13 Aesthetics, Inc. for the purchase price of \$63 billion and took control over all of the companies’  
14 assets and liabilities, it is now the owner of the CoolSculpting System medical device and is  
15 financially responsible for the claims set forth in this lawsuit.  
16

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

**ABOUT COOLSCULPTING**

19  
20 23. CoolSculpting is a body contouring procedure that is supposed to work by using a  
21 process called Cryolipolysis®, which freezes fat cells and programs them to die over the course of  
22 several months.  
23

24 24. The Cryolipolysis® process was developed and patented by Drs. Richard Rox  
25 Anderson and Dieter Manstein at Harvard University and Massachusetts General Hospital in the  
26 early 2000’s.<sup>2</sup>  
27

28 <sup>2</sup> *Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al.*, Case No.: 2:15-cv-00186 ¶10.

1 25. In 2005, Defendant made a deal with Massachusetts General Hospital for an exclusive  
2 license to manufacture a medical device based on this patented process.<sup>3</sup>

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

5 27. The CoolSculpting System device consists of several parts, including the main control  
6 unit (the body of the device), the applicators (arms extending from the body), gel pads for the  
7 applicators, massage function, consumable cards, liners, pretreatment skin wipes, and securement  
8 systems.  
9

10 28. The concept of Cryolipolysis® is based on a theory that fat tissue is more vulnerable  
11 to cold temperatures than the skin; therefore, if cold is applied to a person's unwanted fat bulge,  
12 the cold temperature will kill the fat cells and leave the skin intact. The fat cells are not killed  
13 immediately but are rather "programmed" to die over time. Persons undergoing the procedure are  
14 expected to see "results" 1-3 months after the procedure, as the fat cells wither away in the  
15 treatment area.  
16

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

20 30. Although the CoolSculpting device has other possible indications for use, such as  
21 cooling or heating with the device to minimize temporary pain and provide temporary relief from  
22 muscle aches, improve circulation, and temporarily reduce the appearance of cellulite with an  
23 optional massage function, the CoolSculpting device's primary purpose is for Cryolipolysis®  
24 treatments or "cold-assisted lipolysis (breakdown of fat)."<sup>4</sup>  
25

26 \_\_\_\_\_  
27 <sup>3</sup> *Id.* at ¶¶7, 10.

28 <sup>4</sup> 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>.

1 31. The U.S. Food and Drug Administration (“FDA”) cleared Defendant’s Cryolipolysis®  
2 CoolSculpting device for the performance of Cryolipolysis® services to the following areas: upper  
3 arm, bra fat, back fat, banana roll (underneath the buttocks), thighs, abdomen, and flank ("love  
4 handles"), submental, and submandibular areas.<sup>5</sup>

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

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

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

13 35. CoolSculpting is a relatively expensive procedure. An average session of  
14 CoolSculpting costs \$2,000-\$4,000, at an average price per cycle (one application of the device)  
15 of \$650-\$800.  
16

#### 17 **COOLSCULPTING ADVERTISING**

18 36. Defendant has extensively marketed and promoted its CoolSculpting system  
19 directly to the public and continues to do so today.<sup>6</sup>  
20

21 37. At all times material, Defendant used the same or similar language and messaging  
22 throughout its advertisement materials.  
23

24  
25 <sup>5</sup> Department of Health and Human Services, Food and Drug Administration. Dermal Cooling  
26 Pack/Vacuum/Massager, 510(k), K193544: ZELTIQ Coolsculpting System. Indication for Use.  
Retrieved from  
[https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K193566.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193566.pdf).

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



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

3  
4 CoolSculpting® is not a weight-loss treatment—it's the #1 nonsurgical fat  
5 reduction treatment used by doctors.  
6

7 \* CoolSculpting is the treatment doctors use most for nonsurgical fat reduction.

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

9 **What is CoolSculpting®?**

10 The unique CoolSculpting® fat-freezing technology is a  
11 nonsurgical, scientifically proven way to reduce pockets of  
12 fat in trouble spots such as the abdomen, flanks, or under  
the chin in as little as one session.\*

13 [LEARN HOW IT WORKS](#)

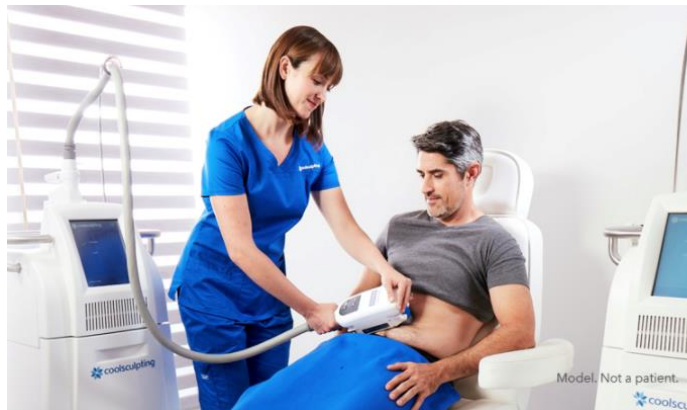
14 \*Up to 20-25% reduction in fat layer thickness after a single session. Results may be  
15 seen as early as 1 to 3 months after treatment.

16 Model. Not a patient.

17 40. CoolSculpting claims that the fat reduction after the procedure is “long lasting” and  
18 that the device permanently kills the fat cells. It boasts, “Our experts spent years developing the  
19 treatment, which features one-of-a-kind technology that quite literally freezes and kills fat cells.”<sup>7</sup>

20  
21 **Farewell treated fat cells.**

22 It's technical name is cryolipolysis, which is just a  
23 science-y way to say fat freezing. Our experts  
24 spent years developing the treatment, which  
25 features one-of-a-kind technology that quite  
26 literally freezes and kills fat cells.



<sup>7</sup> <https://www.coolsculpting.com/what-is-coolsculpting/>



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

7  
8 42. Defendant operated and still operates a website [www.coolsculpting.com](http://www.coolsculpting.com) where it  
9 also advertises CoolSculpting directly to the public and refers prospective patients to  
10 CoolSculpting providers in their geographical area.

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

15  
16 44. Defendant also spent millions of dollars partnering with individual CoolSculpting  
17 providers, paying for local ads that promote the CoolSculpting services at the providers' clinics.

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

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

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

25  
26 \_\_\_\_\_  
27 <sup>8</sup> *Zeltiq Aesthetics, Inc. v. Daron Scherr, M.D. et. al.*, Case. No.: 2:15-cv-00186. ¶15.

28 <sup>9</sup> 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>.

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

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

8  
9 49. The Defendant actually makes more money on selling the consumable cards to  
10 CoolSculpting providers than on selling the CoolSculpting devices. In 2018, it made \$235.3  
11 million on selling consumable cards and \$126.3 million on selling the CoolSculpting devices and  
12 applicators.<sup>12</sup>

13  
14 50. Incentivized by these profits from each CoolSculpting cycle, Defendant also  
15 closely controlled and continues to control the CoolSculpting providers' sales methods of the  
16 medical procedure. During training on the device, Defendant devotes a substantial part of the  
17 training time to boasting about the device's potential to substantially increase the providers'  
18 revenues and how to increase CoolSculpting sales by using various sales tactics. Defendant's  
19 training materials include sample scripts to use on prospective CoolSculpting patients and describe  
20 upselling methods such as having the patients return for a "follow-up appointment" where the  
21 provider has an opportunity to sell additional cycles or by pre-selling CoolSculpting packages  
22  
23  
24

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

27 <sup>11</sup> *Id.*

28 <sup>12</sup> 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](https://allergan.gcs-web.com/news-releases/news-release-details/allergan-reports-fourth-quarter-and-full-year-2018-financial)

1 where the patient pays for multiple cycles in advance for future uses.<sup>13</sup>

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

6 52. This platform, which is called CoolConnect, is used by the Defendant to obtain data  
7 from the CoolSculpting devices and use it to pressure CoolSculpting providers to sell more  
8 procedures. According to Keith Sullivan, the Zeltiq Aesthetics, Inc.'s former CEO (2012 - April  
9 2017), in an interview he gave to PRIME Journal, "In this way, we know what we are doing, and  
10 we can show [the CoolSculpting providers] how they are doing such as if you're only treating  
11 flanks, why aren't you looking at their belly, and so on. The PDM<sup>14</sup> has the data to bring back to  
12 those accounts on a monthly or quarterly basis and follow their progress."<sup>15</sup>

13 53. Likewise, at all times material, Defendant controlled how the CoolSculpting  
14 providers advertised their CoolSculpting services. Defendant established a minimum advertised  
15 price policy, restricting providers from independently setting and advertising prices for the  
16 CoolSculpting procedure and penalized providers that advertised a lower price for their  
17 CoolSculpting services.<sup>16</sup>

18 54. Defendant also gave money or other valuable consideration to CoolSculpting  
19 providers for marketing CoolSculpting services on billboards, print ads, local TV, radio, and other  
20  
21  
22

23 <sup>13</sup> Guidelines for CoolSculpting Success. Retrieved from

24 <https://docplayer.net/docview/26/9289425/#file=/storage/26/9289425/9289425.pdf>.

25 <sup>14</sup> Practice Development Manager, also known as CoolSculpting's sales Representative.

26 <sup>15</sup> Lewis, Wendy. "Fat Chance Building a Better Body the Cool Way." *Prime Journal*. May/June  
2016: 16-20. Retrieved from

27 <https://www.prime-journal.com/fat-chance-building-a-better-body-the-cool-way/>

28 <sup>16</sup> 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/>

1 media outlets.

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

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

8 57. Defendant also provided documents and forms to CoolSculpting providers to use  
9 in their practice when administering the CoolSculpting procedure to patients. This incentivized  
10 providers to use forms drafted by Defendant in their CoolSculpting practice, including consent  
11 forms that contain vague language about PH.  
12

13 58. The documents, brochures, posters, and forms provided by Defendant to  
14 CoolSculpting providers depict the CoolSculpting logo and clearly promote the Defendant's  
15 medical device.  
16

17 59. Defendant promised CoolSculpting providers to cover liability claims for PH if a  
18 patient develops the adverse effect. Defendant offered to refund patients or pay them for one  
19 liposuction procedure to correct the effect of PH in exchange for a release of liability benefiting  
20 the Defendant and the provider. This "liposuction program" mislead providers to believe that the  
21 condition can be successfully corrected with a single liposuction procedure, *if* required, and  
22 assuaged the providers in their worry about liability to CoolSculpting patients that could develop  
23 the adverse effect.  
24

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



1 cautioned the manufacturer to “avoid making fat elimination claims.”<sup>17</sup>

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

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

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

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

17 71. Hyperplasia and hypertrophy is the first step of the wound healing process which  
18 eventually results in *fibrosis* or *fibroplasia*,<sup>18</sup> an irreversible disease of the tissue. Fibrosis is the  
19 end result of the body’s wound healing process in response to an injury.

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

22  
23  
24  
25  
26  
27 <sup>17</sup> Zeltiq Aesthetics, Inc. - CoolSculpting® Cryolipolysis® Body Contouring System. National  
28 Advertising Division. NAD Case Report No. September 23, 2016. Back Refence: ¶3020.

<sup>18</sup> The terms *fibrosis* and *fibroplasia* refer to the same process and effect.

**PARADOXICAL HYPERPLASIA “PH” A/K/A  
PARADOXICAL ADIPOSE HYPERPLASIA “PAH”**

1  
2 73. At some point in 2011, Defendant became aware that its CoolSculpting System  
3 device had the ability to cause patients to develop a condition that results in the *opposite effect* of  
4 the device’s advertised purpose – a *permanent increase in the size of the treated fat bulges*.

5  
6 74. Paradoxical Adipose Hyperplasia, also known as “PAH” and referred to as  
7 Paradoxical Hyperplasia or “PH” by the Defendant is a permanent condition that is developed *only*  
8 as of the result of undergoing Cryolipolysis® via the CoolSculpting device.

9  
10 75. Other than a single report in 2019 of a patient developing a similar condition from  
11 a different fat reducing device (or a combination of two devices), PH has solely been associated  
12 with the CoolSculpting device.

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

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

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

21  
22 79. Defendant’s internal investigation of the condition revealed that PH tissue is  
23 consistent with *fibroplasia*, which is fibrosis of the treated tissue.

24  
25  
26 <sup>19</sup> Seaman, SA; Tannan, SC; Cao, Y; Peirce, SM; Gampper, TJ. Paradoxical Adipose Hyperplasia  
27 and Cellular Effects After Cryolipolysis: A Case Report. *Aesthetic Surgery Journal*. 2015 Nov;  
28 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.



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

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

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

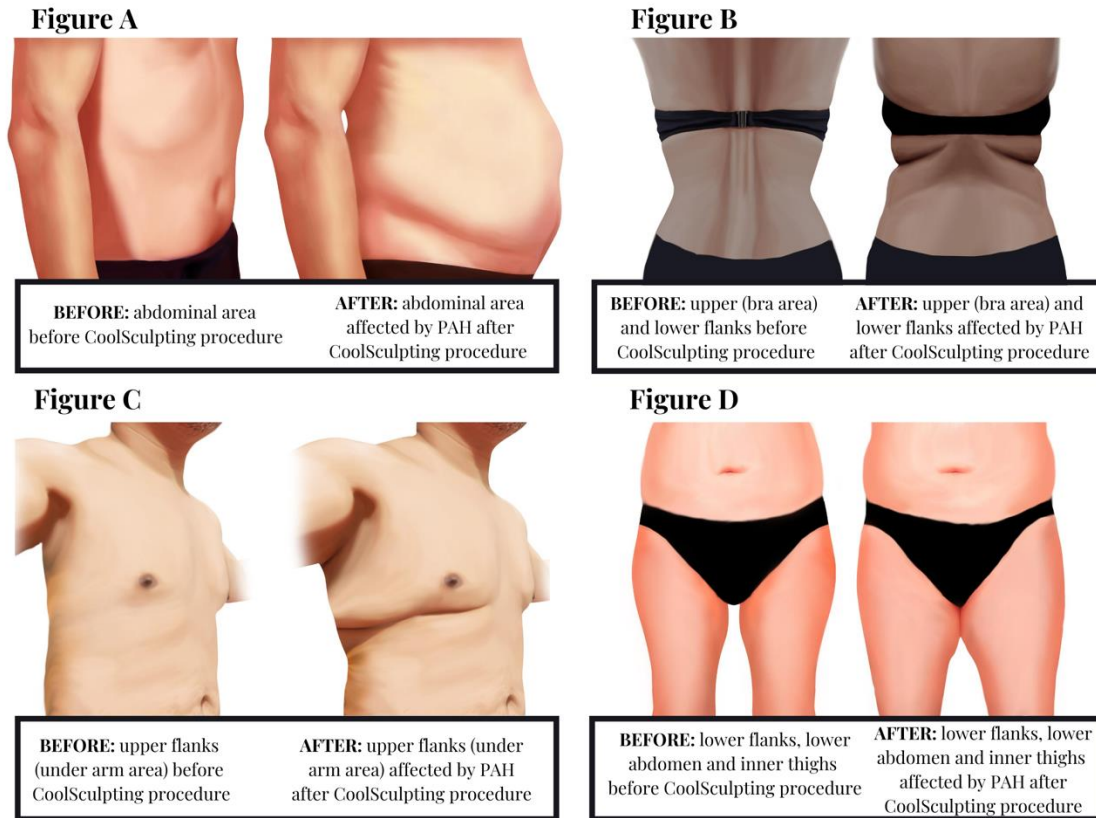
8 83. Unlike regular fat tissue, PH does not resolve on its own. Once a person develops  
9 PH after CoolSculpting, the affected tissue does not react the same as regular fat to weight loss.  
10 No matter how much weight a person loses after developing PH, the area affected by PH will never  
11 get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

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

14 85. PH has a wide range of effects on a person's body. In more fulminant cases, it can  
15 present itself as an obvious hardened protruding mass (Figure A), a soft enlargement of tissue  
16 (Figure D), sagging folds (Figure B), or as a bulge of tissue in the shape of the CoolSculpting  
17 applicator (Figure C).  
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20 86. The following illustrations show examples of PH, that are more visually apparent:  
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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).

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

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

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

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

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

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

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

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

22 99. Because PH arises from CoolSculpting and is a new medical condition related to  
23 that specific medical device, the medical community is not independently familiar with the  
24 condition.  
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28

**DEFENDANT’S SUPERIOR KNOWLEDGE ABOUT PH**

1  
2 100. Soon after the CoolSculpting device went on the market, Defendant received  
3 multiple reports of patients developing “firm bulges” and fat tissue “increases” in the treatment  
4 area after undergoing Cryolipolysis® with the CoolSculpting device.

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

9  
10 102. Defendant knew that the disfiguring “bulges” were not healthy fat tissue and  
11 required physical removal through surgery to manage.

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

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

18  
19 105. In 2012, Defendant created its own diagnosis criteria for the condition, which it  
20 required CoolSculpting providers to use to diagnose PH.

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

23  
24 107. By 2013, Defendant knew that various types of surgeries had been required to  
25 remove PH masses which were not limited to liposuction and included abdominoplasty, excision,  
26 and panniculectomy.

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

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

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

5 111. Defendant implemented a confirmation system to re-evaluate reports of PH  
6 remotely through its internal “Medical Safety Team” and rejected many reports of PH, despite  
7 medical providers’ diagnoses.

8 112. This practice is exemplified in a letter that Defendant sent to a CoolSculpting  
9 provider:  
10

11 Hello Amber,

12 Thank you for your patience and assistance with this case.

13 **I have received feedback from the medical safety team that this case was deemed consistent with PH to the  
14 Flanks.**

15  
16 The Claim has been denied to the patients lower abdomen. Upon the medical teams review of the before and after  
17 photos they stated there is no clear enlargement or demarcation notable to the lower abdomen. They did state there  
18 was Skin Laxity, which I have noted to the case.

19 I have submitted this case to claims for the Flanks.

20  
21 ***Defendant’s Control Over PH Diagnosis and Claims Process***

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

25 114. Because PH is a condition that was not generally known by the medical community,  
26 CoolSculpting providers relied on Defendant for information about the condition.  
27  
28

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

5 116. Defendant had a system in place which automatically turned the adverse event  
6 reporting process into a claims process. Defendant instructed providers to submit Clinical Event  
7 Forms and other documents, including a copy of the consent signed by the patient with the  
8 language describing PH.  
9

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

14 118. Defendant designed a "program" for persons that had developed PH. The  
15 Defendant offered to cover the cost of *single* liposuction surgery or pay a refund in exchange for  
16 a release of liability for any future damages associated with PH. Defendant included the  
17 CoolSculpting providers as parties who were released from liability in the settlement agreements.  
18

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

21 120. Through this program, Defendant had direct communications with CoolSculpting  
22 providers and CoolSculpting patients that developed PH, which allowed Defendant to collect  
23 information not available to anyone else.  
24

25 121. Through this program, Defendant knew that the CoolSculpting providers used  
26 CoolSculpting consent forms that were either identical or mirrored the language drafted by the  
27 Defendant in regard to PH which did accurately represent the condition to the patients.  
28

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

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

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

9 125. Defendant instructed CoolSculpting providers to follow a very narrow protocol for  
10 diagnosing patients with PH, which resulted in many patients not being diagnosed with PH despite  
11 suffering tissue damage from CoolSculpting. Defendant's diagnosis protocol only recognized  
12 fulminant cases with well demarcated masses as PH and relied on the physicians' hand palpation  
13 of the affected tissue and a visual review of photographs taken of the patient before the procedure.  
14

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

17 127. If the CoolSculpting providers did not agree to cooperate with the CoolSculpting  
18 patients in diagnosing PH, the patients were left on their own. In many cases, patients sought out  
19 an evaluation from providers that did not have any experience with the CoolSculpting device and  
20 did not have any knowledge about PH and therefore could not be effective in diagnosing and  
21 treating the condition.  
22

23 128. CoolSculpting providers benefited directly from Defendant's "liposuction  
24 program" because they were released from liability for future damages if the patient took the offer.  
25

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



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

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

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

8  
9 132. Defendant knew that people with PH must undergo multiple invasive surgeries to  
10 remove it, which were *not* limited to one liposuction.

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

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

19  
20 135. Defendant kept a record of the reported incidents of PH which included important  
21 data such as place of treatment, date of treatment, area(s) of the body affected, date PH was  
22 diagnosed, etc. The data gave Defendant information regarding the incidence rate of the condition.

23  
24 136. Though its own investigation of PH, the adverse event reports, and it's "liposuction  
25 program" Defendant had superior knowledge about the extent, severity, and frequency of the  
26 condition, better than any other person in the world.

**DEFENDANT’S STRATEGIC CONTROL OVER PUBLIC INFORMATION ABOUT PH**

***The Secret “White Paper”***

1  
2  
3 137. In 2012, soon after Defendant discovered that its device has the ability to seriously  
4 harm users by causing them to develop PH after CoolSculpting, the manufacturer commissioned  
5 the inventor of the Cryolipolysis® process, Dr. R. Rox Anderson and his colleague at  
6 Massachusetts General Hospital, Dr. Mathew Avram, to author a document about the serious and  
7 permanent adverse effect, to which Defendant referred to as “the White Paper.”  
8

9 138. The White Paper described the condition as follows: “Recently, the manufacturer  
10 received eleven separately confirmed reports of patients who developed growth of soft tissue in  
11 the treated site(s) over several months following treatment. The soft tissue growth is painless, firm,  
12 and visibly enlarged within the treated areas. The enlargement typically started two to three months  
13 post treatment, often after the expected reduction in fat, becoming visibly evident at four to five  
14 months post treatments. Because the soft tissue enlargement is a rare, unexpected growth of  
15 subcutaneous fat tissue, this phenomenon is being termed “paradoxical hyperplasia.”<sup>20</sup>  
16

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

19 140. The White Paper also warned, “Patients who are considering undergoing this  
20 procedure should be counseled on the possibility of its occurrence, as well as the surgical options  
21 available should it occur.”<sup>21</sup>  
22

23 141. The Defendant kept the White Paper a *secret* from CoolSculpting providers and *did*  
24 *not* disclose the document unless a provider insisted on obtaining additional information about PH,  
25 and only *after* the provider had a patient develop the condition.  
26

27  
28 <sup>20</sup> <https://skinrenu.com.au/wp-content/uploads/2017/03/13.PH-white-paper-FINAL.pdf>

<sup>21</sup> *Id* at p. 4.

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

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

7 144. The White Paper, although more informative than the device's User Manual and  
8 Defendant's training presentations, was still inadequate. It was outdated and did not present the  
9 true danger of the CoolSculpting device.  
10

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

12 145. Although Defendant knew that PH was a significant and serious adverse effect of  
13 its CoolSculpting device since at least 2011 and had Drs. Anderson and Avram draft the *secret*  
14 White Paper detailing the newly discovered condition in 2012, it was not until March 2014 that  
15 the medical community received any information about the serious and permanent adverse effect.  
16

17 146. In March 2014, Dr. Anderson, his colleague Dr. Avram, and several other persons  
18 associated with the Defendant published a scholarly article called "Paradoxical Adipose  
19 Hyperplasia After Cryolipolysis" in JAMA Dermatology, announcing that "[v]ery rarely, a  
20 delayed increase in adipose tissue at the treatment site can occur, which to our knowledge has not  
21 yet been reported in the medical literature. We suggest the term "paradoxical adipose hyperplasia"  
22 (PAH) for this phenomenon."<sup>22</sup>  
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27 <sup>22</sup> Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C.  
28 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.

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

4 148. The authors suggested to name the never-before-reported adverse effect of  
5 Cryolipolysis “Paradoxical Adipose Hyperplasia” (PAH).<sup>23</sup>

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

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

12 151. The JAMA article described one case of a man in his 40s who underwent the  
13 Cryolipolysis® procedure with the CoolSculpting medical device and initially noticed a reduction  
14 in fat tissue, but three months after CoolSculpting, his fat grew into a noticeable mass even though  
15 he did not gain any weight. He elected not to undergo invasive surgery to remove the deformity.  
16

17 152. The following photograph was provided:  
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27 <sup>23</sup> The term “Paradoxical Adipose Hyperplasia” (PAH) differs slightly from how the same authors  
28 called the condition in the secret White Paper in 2012 and how the Defendant continues to call  
the condition today – “Paradoxical Hyperplasia” (PH).

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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.<sup>24</sup> 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.

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<sup>24</sup> 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.

1 157. The article “estimated” that the incidence of PH is about “0.0051%, or about 1 in  
2 20,000 treated patients.” It noted that “[t]o date, 33 confirmed cases of paradoxical hyperplasia  
3 have been reported to the device manufacturer as part of post marketing surveillance data.”<sup>25</sup>

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

6 159. Defendant knew that the number of PH patients and the incidence rate cited by the  
7 authors were incorrect and grossly underestimated the risk, but it did not take any action to clarify  
8 this information to the medical community.  
9

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

12 161. Defendant, itself, never directly notified CoolSculpting providers about its post-  
13 market discovery of PH or what it knew about the deforming condition through the adverse event  
14 reports that it had received since 2011.  
15

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

21 163. Likewise, since the 2014 JAMA article, Defendant continued to receive a multitude  
22 of reports of people suffering from PH after CoolSculpting. The Defendant’s previously estimated  
23 incidence rate grew exponentially every year.  
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27 <sup>25</sup> Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C.  
28 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.

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

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

8 166. From 2012 until the present, Defendant *never* updated the CoolSculpting System  
9 User Manual to reflect updated information about PH.  
10

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

13 168. Defendant also instructed its employees to use the words "rare" when referring to  
14 PH in their communications with CoolSculpting providers, the public, and the FDA.  
15

16 169. To support the statements that the likelihood of developing PH was "rare"  
17 Defendant used paid consultants to disseminate *inaccurate* information regarding the incidence  
18 rate of PH under the guise of scientific publications. The articles emphasized the rarity of the  
19 condition and presented false data to support this claim. The paid consultants' articles cited to  
20 other publications written by Defendant's paid consultants. Defendant would then cite to these  
21 articles when answering questions about PH to CoolSculpting providers and in its training  
22 materials to support its statements that PH was rare and unlikely to occur.  
23

24 170. For example, in the March 2014 JAMA publication authored by the inventor of  
25 Cryolipolysis and a number of his colleagues with financial conflicts of interest they stated, "We  
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1 estimate that the incidence rate of PH is about 0.0051%, or about 1 in 20 000 treated patients.”<sup>26</sup>

2 171. Contrary to this statistic, an unbiased author reported the incidence rate of PH for  
3 the same time period was 0.010%, twice higher than the statistic reported by Defendant’s  
4 consultants.”<sup>27</sup>

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

10 173. Then, in March 2016 a group of unbiased authors addressed the incidence rate of  
11 PH as reported in the March 2014 article written by Defendant’s consultants, stating, “Our reported  
12 incidence is 0.78 percent [1 in 129], more than 100 times higher than the device manufacturer  
13 reported incidence of 0.0051 percent. Ours is not a unique experience, as a dermatology practice  
14 in Houston, Texas, recently reported a paradoxical adipose hyperplasia incidence of 0.47 percent  
15 [1 in 213]. Although our treatment numbers are low when considering the popularity of the  
16 procedure, *we believe that paradoxical adipose hyperplasia is underreported.*”<sup>29</sup> (emphases  
17 added).  
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22 <sup>26</sup> Jalian, H. Ray MD; Avram, Mathew M. MD, JD; Garibyan, Lilit MD, PhD; Mihm, Martin C.  
23 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.

24 <sup>27</sup> 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.

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

27 <sup>29</sup> Kelly, Emma B.A.; Rodriguez-Feliz, Jose M.D.; Kelly, Michael E. Paradoxical Adipose  
28 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.

1 174. To which, a paid consultant for Defendant wrote a response stating that, “The  
2 manufacturer reports that since the first quarter of 2014, the paradoxical adipose hyperplasia  
3 incidence rate has fluctuated between 0.021 and 0.026 percent, or approximately one in 4000  
4 treatment cycles.”<sup>30</sup>

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

12 176. In response to this independent study, a solo practitioner plastic surgeon wrote that  
13 he too has seen two “fulminant PH” cases out of 150 patients, and “10 other patients had what we  
14 considered unchanged or even worsened “girth,” which in retrospect may represent a new  
15 classification of PH considered to be mild to moderate.”<sup>32</sup>

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

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

25 <sup>31</sup> Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD;  
26 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.

27 <sup>32</sup> Vogel, James E MD. Comments on ‘Paradoxical Adipose Hypertrophy (PAH) After  
28 Cryolipolysis. *Aesthetic Surgery Journal*. 2018; Vol 38(9): NP135-NP137. DOI:  
10.1093/asj/sjy129.

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

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

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

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

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

15 182. Likewise, Defendant failed to report all known incidents of PH to the FDA, despite  
16 the FDA’s repeated requests to do so.  
17

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

21 184. Since the CoolSculpting device went on the market, Defendant has received  
22 *thousands* of reports of PH through September 2019. Defendant reported *less than 70* to the FDA’s  
23 public databased MAUDE (Manufacturer and User Facility Device Experience).  
24

25 185. This allows Defendant to control the information about the number of patients  
26 suffering from PH after CoolSculpting, since providers and the public cannot independently obtain  
27 the most current numbers via the FDA’s public database.  
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**INADEQUATE “WARNINGS” ABOUT PH**

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***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.

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

6 196. The PDMs' primary role was to sell Defendant's products to the providers. After  
7 the providers purchased the CoolSculpting device, the PDMs' role was to ensure that the providers  
8 continued to purchase the consumable cards which are required to operate the CoolSculpting  
9 device.  
10

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

13 198. The training provided by Defendant to CoolSculpting providers on the  
14 CoolSculpting device consisted mainly of training on sales tactics and emphasized the device's  
15 ability to increase revenues for the providers' medical offices.  
16

17 199. The presentation slide that described PH used the term "Paradoxical Adipose  
18 Hyperplasia" even though the Defendant knew that PH was not an increase in healthy fat cells.  
19 The slide also described PH as an "increase in subcutaneous adipose tissue" which was a  
20 misrepresentation of the condition which Defendant knew was *fibroplasia* or *fibrosis* of the  
21 subcutaneous tissue. The slide also used a photograph from the 2014 JAMA article (*see supra*  
22 ¶147), which did not represent the majority of PH deformities whose masses were not in the shape  
23 of the applicator. Furthermore, the slide also inaccurately stated that "surgical intervention *may* be  
24 required" although Defendant knew that surgery *is* required.  
25

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

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

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

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

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

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

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

17  
18  
19 **DEFENDANT'S MISREPRESENTATIONS ABOUT PH TO COOLSCULPTING PROVIDERS**

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

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

25 209. Defendant did not provide information regarding PH to CoolSculpting providers  
26 *prior* to the purchase of the medical device.  
27  
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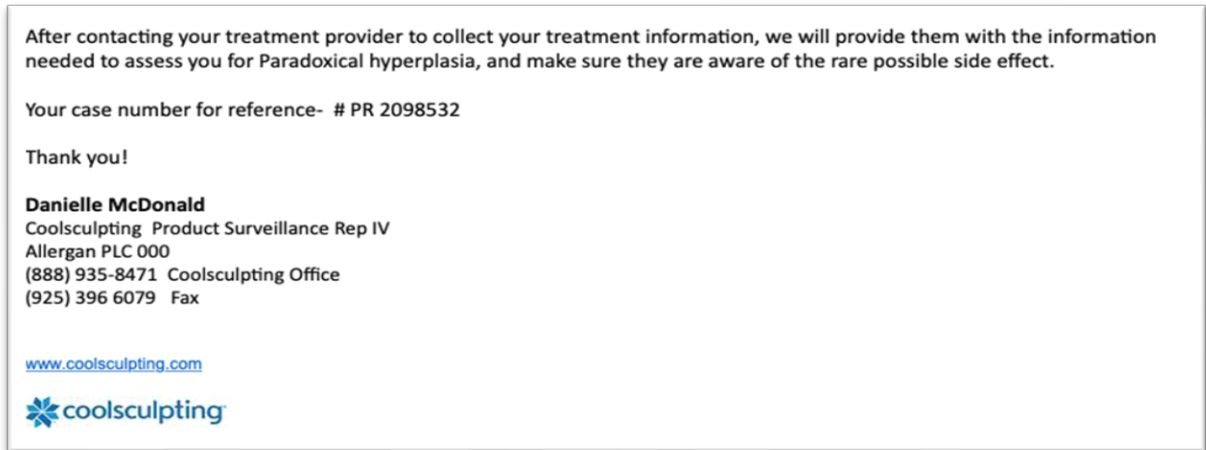


1           210. After the devices were purchased from Defendant, Defendant downplayed the  
2 severity, permanency, and frequency of PH to CoolSculpting providers.

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

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

10           213. This practice is exemplified in a letter that Defendant sent to a CoolSculpting  
11 patient:  
12



21           214. Defendant also advised CoolSculpting providers not to mention “Paradoxical  
22 Hyperplasia” or “PH” to patients who requested an evaluation for the condition until the  
23 Defendant’s claims department had an opportunity to review the patients’ medical records and  
24 diagnosis of the CoolSculpting providers and “confirm” the diagnosis.

25           215. Defendant implemented a practice of rejecting CoolSculpting patients’ diagnoses  
26 of PH and refused to confirm cases of PH to all parts of the body affected. For example, in one  
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1 CoolSculpting patient’s case, although she was diagnosed with PH to her entire abdomen by  
2 multiple physicians, Defendant refused to confirm PH to her upper abdomen.

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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.

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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.<sup>33</sup>

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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.

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

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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.

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<sup>33</sup> See *supra* ¶107.

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

1  
2 220. Defendant controlled the information that was available about PH by using vague  
3 and inadequate language in the labeling materials, incentivizing PDMs to make false verbal  
4 statements about PH to providers, paying consultants to write favorable scholarly publications, by  
5 concealing crucial information about PH from CoolSculpting providers, and by downplaying the  
6 seriousness and frequency of the adverse event to the FDA.

7  
8 221. Even if a CoolSculpting provider wanted to find out additional information  
9 regarding PH, they would most likely find a manufacturer-friendly scholarly article on the subject  
10 or be pacified by the low number of PH incidents reported on the FDA’s public database MAUDE  
11 (Manufacturer and User Facility Device Experience.)

12 222. Although Defendant received thousands of reports of people developing permanent  
13 deformities from PH after undergoing CoolSculpting, it never disclosed the number of people  
14 injured by its device to the CoolSculpting providers. Yet, Defendant repeatedly used terms such  
15 as “rare” and “a small number of people” when referring to PH and cited to its consultant’s articles,  
16 to pacify the providers and mislead them into believing that PH was not a likely risk of using the  
17 CoolSculpting device.  
18

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

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

23 225. Believing that PH was not a real risk to CoolSculpting patients, CoolSculpting  
24 providers did not inform CoolSculpting patients about the possibility of suffering the opposite  
25 effect of the procedure’s advertised purpose.  
26  
27  
28

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

4 227. Moreover, Defendant was aware that CoolSculpting providers did not understand  
5 PH and were not properly informing their patients about the possibility of developing this serious  
6 condition after CoolSculpting because Defendant had numerous communications directly with  
7 persons who developed PH and because of a multitude of public personal accounts online about  
8 how CoolSculpting patients were not being told about this serious adverse effect.  
9

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

13

14 **9 Answers**  
By Board Certified Doctors and Qualified Medical Professionals


---

15 **A: Paradoxical hyperplasia**

16 Thank you for your question! Paradoxical hyperplasia is reported to be 0.00005% risk and more common  
17 in males. There is no way of knowing if one person is more at risk of developing it over another. But the  
18 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.

19 As far as the person doing the treatments you need to ask how long they have been performing the  
20 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  
21 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.

22 show less ▲

23 **Kate Szal at:**   
Aspira  
★★★★★ (10)  
2 people found this helpful.

24 HELPFUL

25 Answered: 9 Jan 2019

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**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](http://laurakatzmdpc.com)

(734) 548-9424

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**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

<sup>34</sup> <https://zelkeninstitute.com/2019/03/19/paradoxical-adipose-hyperplasia/>

1 230. Contrary to the statistics believed by CoolSculpting providers, a recent study  
2 suggested that the incidence rate is closer to 1 in 100 or 1%.<sup>35</sup>

3 231. Adverse events with an incidence rate of 1% or higher are considered “common,”  
4 not rare by the World Health Organization.<sup>36</sup>

5 232. The actual incidence rate of PH after CoolSculpting may be closer to 10% when  
6 considering the number of CoolSculpting patients that developed mild to moderate tissue  
7 increases, which did not present as well-demarcated masses and remain undiagnosed.  
8

9 **CLASS REPRESENTATIVES**

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

13 234. Mr. Valencia read the CoolSculpting advertisements provided by the RN on the  
14 dermatologist office and became interested in the CoolSculpting procedure.  
15

16 235. On July 24, 2018, Mr. Valencia visited Rafal Center for Dermatology & Cosmetic  
17 Surgery, a CoolSculpting provider, located at 2500 Nesconset Highway, Building 22A, Stony  
18 Brook, NY 11790 and underwent two (2) cycles of the CoolSculpting procedure, one on each of  
19 his upper flanks.  
20  
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22

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23 <sup>35</sup> Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD;  
24 Nail Barthlemy, Raphael MD; Atlan, Michael MD. Paradoxical Adipose Hypertrophy (PAH)  
25 After Cryolipolysis. *Aesthetic Surgery Journal*. 2018; Vol 38(4): 411-417, 412. DOI:  
26 10.1093/asj/sjx159; and  
27 Vogel, James E. MD, FACS. Comments on “Paradoxical Adipose Hypertrophy (PAH) After  
28 Cryolipolysis.” *Aesthetic Surgery Journal*. 2018; Vol 38(9): NP135-NP137, 135. DOI:  
10.1093/asj/sjy129.

<sup>36</sup> 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.

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

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

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

8 239. On January 11, 2019, he returned to his CoolSculpting provider and met with the  
9 supervising physician. The physician examined Mr. Valencia but did not know that he had  
10 developed an adverse effect of the CoolSculpting device. The physician was *not able* to diagnose  
11 him and offered to perform thermal treatments on the affected area, not understanding that PAH  
12 can only be removed with surgery.  
13

14 240. After the thermal treatments did not work, the physician referred Mr. Valencia to a  
15 plastic surgeon. The plastic surgeon did not know about PAH and could not state a diagnosis.  
16

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

21 242. Mr. Valencia was advised that he would need an excision surgery on both of his  
22 flanks to cut out the affected tissue. He was told that although he would no longer have protruding  
23 masses, he would be left with large scars on both sides.  
24

25 243. As the result of Defendant's systemic failure to adequately warn CoolSculpting  
26 providers about the danger of the CoolSculpting medical device, Mr. Valencia's CoolSculpting  
27 provider was not adequately informed about the extent of the serious and permanent adverse effect  
28

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

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

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

8 246. Mr. Valencia's damages include past and future medical expenses, past and future  
9 pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.  
10

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

13 248. She had seen CoolSculpting advertisements in the past, and when her former  
14 employer purchased the CoolSculpting device, she was eager to undergo the procedure to address  
15 the stubborn fat.  
16

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

20 250. Prior to undergoing to CoolSculpting procedure, Ms. Brooks was never advised by  
21 her CoolSculpting provider and did not know that the CoolSculpting device can cause damage to  
22 tissue, causing PAH and skin laxity.  
23

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

26 252. Ms. Brooks did not see any results from the CoolSculpting procedures and on  
27 August 8, 2019, Ms. Brooks visited Rhett Women's Center/Aesthetics located at 1300 Hospital  
28



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

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

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

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

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

13 257. On May 13, 2020, Ms. Brooks underwent abdominoplasty to try to correct the  
14 affected area. Due to the extent of tissue damage from CoolSculpting, her plastic surgeon had to  
15 make a long cut extending from her right to her left hip. She now has a scar traversing her lower  
16 abdomen. The surgery did not completely correct the affected area, and she will need additional  
17 reconstructive surgeries.  
18

19 258. As the result of Defendant's systemic failure to adequately warn CoolSculpting  
20 providers about the danger of the CoolSculpting medical device, Ms. Brooks's CoolSculpting  
21 providers were not adequately informed about the extent of the serious and permanent adverse  
22 effect of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical  
23 Hyperplasia (PH) which requires surgical intervention to resolve.  
24

25 259. As the direct and proximate cause of Defendant's conduct, Ms. Brooks was not  
26 properly informed about PAH prior to undergoing CoolSculpting.  
27  
28

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

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

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

8           263. Ms. Chubchai saw advertisements for CoolSculpting, which promised to reduce fat  
9 without surgery and became interested in the CoolSculpting procedure.  
10

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

14           265. On April 17, 2019, Ms. Chubchai returned for an additional two (2) cycles on  
15 abdomen area.  
16

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

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

21           268. Prior to undergoing to CoolSculpting procedure, Ms. Chubchai was never advised  
22 by her CoolSculpting provider, and she did not know that the CoolSculpting device can cause  
23 damage to tissue, causing PAH and skin laxity.  
24

25           269. Several months after the CoolSculpting procedure, Ms. Chubchai began noticing  
26 that the fat tissue in her abdomen and flanks began growing and getting larger.  
27  
28

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

4 271. Ms. Chubchai was left to seek out another physician who could explain to her what  
5 she was experiencing and give her a diagnosis. She eventually found a knowledgeable plastic  
6 surgeon, and on January 29, 2020, she was diagnosed with PAH on her *abdomen* and *each flank*.  
7 Her plastic surgeon advised her that she will need abdominoplasty and liposuction to try to remove  
8 the disfigurement caused by PAH.  
9

10 272. As the result of Defendant's systemic failure to adequately warn CoolSculpting  
11 providers about the danger of the CoolSculpting medical device, Ms. Chubchai's CoolSculpting  
12 provider was not adequately informed about the extent of the serious and permanent adverse effect  
13 of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical  
14 Hyperplasia (PH) which requires surgical intervention to resolve.  
15

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

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

21 275. Ms. Chubchai's damages include past and future medical expenses, past and future  
22 pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.  
23

24 276. Plaintiff, **Emily Michelle McGoldrick**, was interested in a non-invasive procedure  
25 that could reduce stubborn fat in various parts of her body.

26 277. Ms. McGoldrick saw advertisements for CoolSculpting, which promised to reduce  
27 fat without surgery and became interested in the CoolSculpting procedure.  
28

1 278. On March 29, 2018, Ms. McGoldrick visited Healthy for Life Weight Loss &  
2 Nutrition Center, a CoolSculpting provider, located at 950 S. Arroyo Parkway, 3<sup>rd</sup> Floor, Pasadena,  
3 CA 91105.

4 279. Healthy for Life Weight Loss & Nutrition Center sold Ms. McGoldrick a package  
5 of multiple cycles of CoolSculpting for use in the future.

6 280. Over the course of six months, Ms. McGoldrick underwent multiple cycles of  
7 CoolSculpting during six appointments: March 29, 2018, April 9, 2018, May 28, 2018, August 28,  
8 2018, September 6, 2018, and October 22, 2018. The following areas of her body were treated:  
9 Left anterior thigh, left posterior thigh, right anterior thigh, right posterior thigh, right flank, left  
10 flank, left lower abdomen, and right lower abdomen.

11 281. Prior to undergoing to CoolSculpting procedure, Ms. McGoldrick was never  
12 advised by her CoolSculpting provider, and she did not know that the CoolSculpting device can  
13 cause damage to tissue, causing PAH and skin laxity.  
14

15 282. Several months after the CoolSculpting procedures, Ms. McGoldrick started  
16 noticing that the areas of CoolSculpting treatment were beginning to increase, despite her vigilant  
17 diet.  
18

19 283. Ms. McGoldrick complained to her CoolSculpting provider about her symptoms,  
20 but the physician at Healthy for Life Weight Loss & Nutrition Center did not understand that she  
21 was exhibiting signs of PAH after CoolSculpting. The CoolSculpting provider was unable to  
22 diagnose her, and she was left on her own.  
23

24 284. The treated areas of her body continued to grow. Her inner thighs got so big that  
25 when she walks, they rub together and develop sores that turn into painful open wounds. She can  
26 no longer wear dresses and must only wear thick jeans, which develop holes and must be thrown  
27 out. Her flanks and abdomen have also got substantially larger, despite her weight loss.  
28

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

4 286. Ms. McGoldrick was diagnosed with PAH to all of the treatment areas. She must  
5 undergo multiple invasive procedures to try to remove the affected tissue and reconstruct her body.

6 287. As the result of Defendant's systemic failure to adequately warn CoolSculpting  
7 providers about the danger of the CoolSculpting medical device, Ms. McGoldrick's CoolSculpting  
8 provider was not adequately informed about the extent of the serious and permanent adverse effect  
9 of CoolSculpting procedure called Paradoxical Adipose Hyperplasia (PAH) or Paradoxical  
10 Hyperplasia (PH) which requires surgical intervention to resolve.  
11

12 288. As the direct and proximate cause of Defendant's conduct, Ms. McGoldrick was  
13 not informed about PAH prior to undergoing CoolSculpting.

14 289. Had Ms. McGoldrick known that there was a chance that she could develop a  
15 condition that results in the opposite effect of the device's advertised purpose, she would not have  
16 undergone the procedure.  
17

18 290. Ms. McGoldrick's damages include past and future medical expenses, past and  
19 future pain and suffering, mental anguish, emotional distress, scarring, and bodily disfigurement.  
20

21 **CLASS ACTION ALLEGATIONS**

22 291. **Class Action Provisions:** Plaintiffs bring this action individually on behalf of  
23 themselves and all those similarly situated persons, pursuant to Federal Rules of Civil Procedure  
24 23(a), 23(b)(2), 23(b)(3), and 23(c)(4).

25 292. **Definition of Class:**

- 26 a. **Nationwide Class:** All individuals who purchased cycle(s) of the CoolSculpting  
27 procedure in the United States.  
28

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

4           c. **Excluded Persons:** Excluded from the putative class are: (i) Defendant, any entity  
5           in which Defendant has a controlling interest, and Defendant's legal  
6           Representative, predecessors, successors, and assigns; (ii) governmental entities;  
7           (iii) Defendant's employees, officers, directors, agents and Representative, and  
8           their family members; and (iv) the Judge and staff to whom this case is assigned,  
9           and any member of the Judge's immediate family. Plaintiffs reserve the right to  
10          amend the class definition as appropriate after class discovery is completed.  
11

12          293. **Numerosity:** The number of members of the Class is so numerous that individual  
13          joinder is impracticable. Tens of thousands of people purchased CoolSculpting cycle(s) in the  
14          United States. Thousands of people suffered PH after undergoing the CoolSculpting procedure,  
15          Defendant has received at least 3,300 reports of persons that developed PH from CoolSculpting  
16          through July 2020. The members of the Class can be identified through Defendant's records.  
17

18          294. **Commonality and Predominance:** The Plaintiffs' and the Class members' claims  
19          involve important common questions of fact and law that predominate over any individual issues.  
20          The injuries sustained by Plaintiffs and Class member stem from the same nucleus of operative  
21          facts surrounding the Defendant's conduct in selling, promoting, advertising, and labeling the  
22          CoolSculpting medical device. The claimants' injuries arose from the same policy and practice  
23          implemented by the Defendant. The conduct described herein did not differ materially from one  
24          CoolSculpting provider to another and was uniform across the nation. The following questions are  
25          central to Plaintiffs and Class member's individual claims and resolving these common  
26          contentions in one class action will be an efficient and productive method of achieving a classwide  
27          resolution for thousands of similarly situated claimants.  
28

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

- 3                   i. Whether the CoolSculpting System was defective?
- 4                   ii. What did Defendant know about PH?
- 5                   iii. Whether Defendant had a duty to adequately warn CoolSculpting providers  
6                   about the device’s ability to cause harm?
- 7                   iv. Whether Defendant failed to adequately warn CoolSculpting providers  
8                   about the device’s ability to cause harm?
- 9                   v. Whether Defendant intentionally misrepresented material facts about PH to  
10                   CoolSculpting providers?
- 11                   vi. Whether Defendant intentionally concealed material facts about PH from  
12                   CoolSculpting providers?
- 13                   vii. Whether Defendant negligently misrepresented material facts about PH to  
14                   CoolSculpting providers?
- 15                   viii. Whether Defendant negligently concealed material facts about PH from  
16                   CoolSculpting providers?
- 17                   ix. Whether Defendant’s conduct was unfair and deceptive under California’s  
18                   consumer protection laws?
- 19                   x. Whether Defendant failed to use reasonable care in warning CoolSculpting  
20                   providers about PH?
- 21                   xi. Whether Defendant’s deceptive practices in regard to PH were illegal?
- 22                   xii. Whether Defendant’s reliance on the CoolSculpting providers to warn  
23                   consumers about PH was reasonable under the specific circumstances  
24                   created by the Defendant?
- 25
- 26
- 27
- 28

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

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

13  
14          297. **Superiority.** A class action is a superior method of resolving the controversy  
15          between thousands of people that suffered similar injuries and economic damages after purchasing  
16          cycles of the CoolSculpting procedure and undergoing CoolSculpting due to the Defendant's  
17          illegal course of conduct which affected the Class members in the same way. Each claim is based  
18          on the same evidence and requires the same expert witnesses to prove the claims against the  
19          Defendant. A resolution of common questions of fact and law in one action based on the same  
20          evidence against the same Defendant will be economical for the claimants and the judicial system.  
21          A single class action on thousands of the same claims will avoid repetitive motion practice,  
22          inconsistent discovery rulings, multiple depositions of the same witnesses, cumulative expenses to  
23          obtain the same evidence, and delays in obtaining justice. Moreover, the Defendant will benefit  
24          from a single centralized action that will totally resolve the question of liability to thousands of  
25          claimants alleging the same claims.  
26  
27  
28



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

6           299.    **Adequacy of Representation:** The Class Representative will fairly and adequately  
 7 represent the members of the Class. No material conflicts of interest exist between the Class  
 8 Representative and the members of the Class. The Class Representative’ interests are aligned with  
 9 the interests of the members of the Class and the Representative’ claims against the Defendant are  
 10 common to the claims of the members of the Class. The Class Representative will actively  
 11 participate in the litigation and intend to be involved in important decision making on behalf of  
 12 the Class throughout the course of this litigation. Likewise, the undersigned class counsel selected  
 13 by the Class Representative to file this class action is competent to litigate the issues in this case,  
 14 has in-depth knowledge about the issues in this case.  
 15

16  
 17                                   **COUNT I**  
 18                                   **STRICT PRODUCT LIABILITY – DEFECTIVE DESIGN**

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

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

24           302.    Defendant intended that the subject product be used in the way in which it was used  
 25 on the Plaintiffs.  
 26  
 27  
 28

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

4 304. Defendant knew that its CoolSculpting System device was unreasonably  
5 dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiffs.  
6 Specifically, Defendant knew that its medical device can cause tissue damage and permanent  
7 deformity to the user's body in the form of Paradoxical Hyperplasia (PH).  
8

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

14 306. Plaintiffs relied on the skill and judgment of the Defendant and Defendant's  
15 representations that the device was adequately tested and rendered safe to use for its intended  
16 purpose.  
17

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

20 308. Because of the innate defective nature of the CoolSculpting System device,  
21 Plaintiffs and the individuals performing the CoolSculpting procedure on Plaintiffs, through the  
22 use of reasonable care could not have discovered the defective nature of the CoolSculpting System  
23 device or its perceived dangers.  
24

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

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

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

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

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

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

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

16 315. Defendant knew that its CoolSculpting System device was unreasonably  
17 dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiffs.  
18 Specifically, Defendant knew that its medical device can cause the opposite effect of the device's  
19 advertised purpose in the form of Paradoxical Hyperplasia (PH).  
20

21 316. Defendant knew that PH is not preventable and is unavoidable if undergoing the  
22 CoolSculpting procedure. Defendant also knew that there was a possibility that Plaintiffs could  
23 develop PH after undergoing the CoolSculpting procedure.  
24

25 317. Defendant had superior knowledge about PH because it was in possession and had  
26 access to facts and information about the condition that was not available to anyone else. As the  
27 manufacturer of the device, Defendant was a centralized hub of information about the device's  
28

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

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

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

- 8 a. was inaccurate in content and ambiguous in manner of expression;
- 9 b. did not adequately inform the providers about a condition which is: 1) unfamiliar  
10 to the medical community, 2) is only associated with the CoolSculpting device, and  
11 3) about which Defendant had superior knowledge;
- 12 c. creatively used insufficient and vague language that did not provide enough  
13 specificity about the condition, which was necessary for the CoolSculpting  
14 providers to know about the risks of using the device;
- 15 d. misrepresented facts about the adverse effect;
- 16 e. did not use concrete terms like "deformity" and "disfigurement" to describe PH;
- 17 f. did not definitively state that PH is a disease of the tissue called fibroplasia or  
18 fibrosis;
- 19 g. did not definitively state that PH can only be removed with invasive surgery;
- 20 h. did not warn that it is likely that multiple surgeries may be necessary to remove  
21 PH;
- 22 i. did not disclose that a single patient can develop the condition in multiple areas;
- 23 j. did not disclose that PH causes permanent cutaneous and subcutaneous tissue  
24 damage;
- 25 k. did not disclose that long term effects of PH affected tissue are unknown;
- 26
- 27
- 28



1 “confirmed” the providers’ diagnosis and by systemically rejecting or refusing to confirm all of  
2 the providers’ diagnoses.

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

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

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

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

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

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

7  
8 329. Defendant failed to exercise ordinary care when it used misleading language in  
9 describing PH to the CoolSculpting providers that did not adequately inform them about the  
10 seriousness of the condition and when Defendant concealed material facts about the condition from  
11 CoolSculpting providers. Defendant made ambiguous and inaccurate statements about the effect  
12 PH has on the body, its permanency, treatment options, and rate of risk in the written materials it  
13 furnished to Plaintiffs' CoolSculpting provider.

14  
15 330. Due to Defendant's failure to use ordinary care, Plaintiffs' CoolSculpting provider  
16 did not and could not adequately inform Plaintiffs and other CoolSculpting patients about the real  
17 risk of developing serious and permanent condition. Consequently, Plaintiffs and Class members  
18 were induced to purchase CoolSculpting cycles and undergo the CoolSculpting procedure and  
19 suffered economic damages and/or personal injuries as a result.

20 331. **Duty to be Honest in Advertising CoolSculpting.** Defendant also had a duty to  
21 be honest in its advertisement materials directed at Plaintiffs and Class members, such as  
22 commercials, website content, and the brochures and posters that it furnished to the CoolSculpting  
23 providers to use in the office. Specifically, Defendant had a duty:  
24

- 25 o. Not to claim that the CoolSculpting procedure is a "non-invasive" and "non-  
26 surgical" alternative to liposuction;
- 27 p. Not to claim that the CoolSculpting procedure produced "long lasting results";
- 28 q. Not to claim that the CoolSculpting procedure "kills" fat cells;

- 1 r. Not to claim that the CoolSculpting procedure results in “up to 20%-25% reduction
- 2 of fat in a treated area”;
- 3 s. To disclose that the CoolSculpting procedure may cause the opposite effect of what
- 4 it claims to achieve;
- 5 t. To disclose that even after an initial reduction in fat, a person may develop the
- 6 *opposite effect* (via PH);

7  
8 332. Defendant failed to exercise ordinary care when it made deceptive claims in its  
9 advertisement materials, which were directed at the Plaintiffs and the Class members, about the  
10 CoolSculpting device’s effectiveness of reducing fat *without surgery* and omitted any information  
11 about the CoolSculpting’s device’s ability to cause the opposite effect.

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

17  
18 334. Consequently, Plaintiffs and Class members were induced to purchase and undergo  
19 the expensive CoolSculpting procedure and suffered economic damages and personal injuries.

20 335. **Duty to Warn CoolSculpting Consumers.** Defendant created a system wherein  
21 CoolSculpting providers relied on it to support their CoolSculpting business. Defendant involved  
22 itself in every step of the CoolSculpting treatment, from attracting consumers through  
23 advertisement, furnishing CoolSculpting providers with patient-facing documents (including  
24 consent forms) that informed consumers about the procedure, profit-sharing on each cycle sold to  
25 the consumers, diagnosing the consumer with PH, and offering to settle PH claims which protected  
26 the CoolSculpting providers from liability to the consumers. Defendant’s participation in the  
27 consumers’ medical treatment gave rise to a duty to warn the consumers directly about the danger  
28



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

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

11  
12 337. Due to Defendant's failure to use ordinary care, Plaintiffs and Class members were  
13 not aware that by purchasing CoolSculpting cycles and undergoing the CoolSculpting procedure  
14 they were subjecting themselves to a risk of developing permanent deformities in the form of  
15 substantially increased and damaged fat tissue and skin laxity which requires multiple invasive  
16 surgeries to remove.

17  
18 338. Consequently, Plaintiffs and Class members were induced to purchase and undergo  
19 the expensive CoolSculpting procedure and suffered economic damages and personal injuries.

20 339. As the direct and proximate result of Defendant's wrongful conduct, Plaintiffs and  
21 Class members suffered and continue to suffer economic losses, emotional distress, permanent  
22 disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical  
23 expenses.  
24

25 **COUNT IV**  
26 **MEDICAL MONITORING**

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

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

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

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

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

11 345. Plaintiffs and the Class members are entitled to a medical monitoring program  
12 which will cover the future costs and related expenses of monitoring their health subsequent to  
13 developing PH, and the Defendant is obligated to pay for such a program.  
14

15  
16 **COUNT V**  
**NEGLIGENT MISREPRESENTATION AND CONCEALMENT**

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

19 347. Defendant had superior knowledge about PH because it was in possession and had  
20 access to facts and information about the condition that was not available to anyone else. As the  
21 manufacturer of the device, Defendant was a centralized hub of information about the device's  
22 adverse effects, including PH. It had received thousands of reports of users developing the  
23 condition, performed its own research on PH, had access to PH patients' medical records and  
24 information regarding diagnosis, treatment, and occurrence rate of PH, which it did not disclose to  
25 the medical community.  
26  
27  
28

1 348. The CoolSculpting providers acted as the Defendant's agents in selling the  
2 CoolSculpting cycles, because Defendant, among other things, conducted itself in the following  
3 ways: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2)  
4 shared profits with the providers on each cycle administered to patients, 3) provided forms and  
5 documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting  
6 patients, 4) referred CoolSculpting patients to the CoolSculpting providers via its website, 5)  
7 controlled the advertised price of CoolSculpting, 6) controlled how patients were diagnosed with  
8 PH resulting from CoolSculpting, and so on.  
9

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

12 350. **Severity.** Defendant knew that PH is a disfigurement and a deformity to the body  
13 that is completely different from a normal "enlargement of fat" because PH permanently damages  
14 the tissue it affects. Defendant also knew that many PH patients also suffered cutaneous tissue  
15 damage resulting in skin laxity, which requires additional surgeries to reconstruct. Defendant  
16 misrepresented the consequences of PH to CoolSculpting providers by creatively using insufficient  
17 and ambiguous language to describe the condition and intentionally avoided using concrete terms  
18 that would fairly and accurately describe the adverse event.  
19

20 351. **Permanency.** Defendant knew that PH will *never* resolve on its own and that the  
21 *only* means of removing it is through invasive plastic surgery but instead, it used false language in  
22 describing PH to CoolSculpting providers, downplaying the permanency of the condition and  
23 stating, "surgical intervention *may* be required."  
24

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

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

4 353. Defendant's intent in making material misrepresentations about PH and concealing  
5 material information was motivated by profits. Because the majority of the Defendant's  
6 CoolSculpting profits are gained from the *use* of the device on consumers rather than sales of the  
7 device to the providers, Defendant's conduct was highly driven by consumers' purchase of the  
8 CoolSculpting cycles.  
9

10 354. Defendant knew that the CoolSculpting providers' lack of knowledge and  
11 understanding about PH will result in consumers being uninformed about the serious and  
12 permanent adverse effect. On the other hand, Defendant knew that if consumers knew that there  
13 was a risk of developing the opposite effect of CoolSculpting's advertised purpose, consumers  
14 would not likely undergo the elective procedure.  
15

16 355. As the result of Defendant's superior knowledge about PH, CoolSculpting  
17 providers justifiably relied on Defendant's representations about the adverse effect solely  
18 associated with Defendant's medical device. Believing that the adverse effect is unlikely to occur  
19 and is not as serious and permanent, CoolSculpting providers did not properly inform  
20 CoolSculpting patients about the risk of PH. Information regarding PH was material and necessary  
21 for the Plaintiffs and the Class to make an informed decision about undergoing this elective  
22 procedure. Had the Plaintiffs and the Class known that there was a risk that they could suffer the  
23 *opposite effect* of the CoolSculpting device's advertised purpose, they would not have purchased  
24 cycles of CoolSculpting.  
25

26 356. As the proximate result of Defendant's fraudulent conduct, Plaintiffs and the Class  
27 suffered damages that include economic and non-economic losses.  
28

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

1  
2 357. Plaintiffs incorporate the substantive allegations of all previous Paragraphs of this  
3  
4 Complaint as if fully set forth herein.

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

12 359. The CoolSculpting providers acted as the Defendant's agents in selling the  
13 CoolSculpting cycles, because Defendant, among other things, conducted itself in the following  
14 ways: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2)  
15 shared profits with the providers on each cycle administered to patients, 3) provided forms and  
16 documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting  
17 patients, 4) referred CoolSculpting patients to the CoolSculpting providers via its website, 5)  
18 controlled the advertised price of CoolSculpting, 6) controlled how patients were diagnosed with  
19 PH resulting from CoolSculpting, and so on.  
20  
21

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

24 361. **Severity.** Defendant knew that PH is a disfigurement and a deformity to the body  
25 that is completely different from a normal "enlargement of fat" because PH permanently damages  
26 the tissue it affects. Defendant also knew that many PH patients also suffered cutaneous tissue  
27 damage resulting in skin laxity, which requires additional surgeries to reconstruct. Defendant  
28

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

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

8  
9       363. **Frequency.** Based on the number of PH reports Defendant received, it knew that  
10 the likelihood of developing PH after CoolSculpting was *not* rare. Defendant concealed its  
11 knowledge of the unreasonably dangerous risks of its CoolSculpting device from the  
12 CoolSculpting providers and the public, while simultaneously relying on words “rare” and “small  
13 number” to induce CoolSculpting providers to believe that it is *unlikely* that a patient will develop  
14 the condition. Defendant concealed the fact that PH was the most frequently reported adverse  
15 effect of CoolSculpting.

16  
17       364. Defendant’s intent in making material misrepresentations about PH and concealing  
18 material information was motivated by profits. Because the majority of the Defendant’s  
19 CoolSculpting profits are gained from the *use* of the device on consumers rather than sales of the  
20 device to the providers, Defendant’s conduct was highly driven by consumers’ purchase of the  
21 CoolSculpting cycles.

22       365. Defendant knew that the CoolSculpting providers’ lack of knowledge and  
23 understanding about PH will result in consumers being uninformed about the serious and  
24 permanent adverse effect. On the other hand, Defendant knew that if consumers knew that there  
25 was a risk of developing the opposite effect of CoolSculpting’s advertised purpose, consumers  
26 would not likely undergo the elective procedure.  
27  
28

1 366. As the result of Defendant’s superior knowledge about PH, CoolSculpting  
2 providers justifiably relied on Defendant’s representations about the adverse effect solely  
3 associated with Defendant’s medical device. Believing that the adverse effect is unlikely to occur  
4 and is not as serious and permanent, CoolSculpting providers did not properly inform  
5 CoolSculpting patients about the risk of PH. Information regarding PH was material and necessary  
6 for the Plaintiffs and the Class to make an informed decision about undergoing this elective  
7 procedure. Had the Plaintiffs and the Class known that there was a risk that they could suffer the  
8 *opposite effect* of the CoolSculpting device’s advertised purpose, they would not have purchased  
9 cycles of CoolSculpting.  
10

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

13 **COUNT VII**  
14 **CALIFORNIA FALSE ADVERTISING LAW (“FAL”)**  
15 **California Business and Professions Code §§ 17500, *et seq.***

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

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

21 370. Defendant directly or through its agents, apparent agents, servants, or employees  
22 designed, manufactured, tested, marketed, and commercially distributed the CoolSculpting System  
23 device that was used on Plaintiffs.  
24

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

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

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

8 374. At the time of its misrepresentations, Defendant was either aware of the dangers  
9 alleged herein, or was aware that it lacked the information and/or knowledge required to make  
10 such a representation truthfully. Defendant concealed and omitted and failed to disclose this  
11 information to Plaintiffs.  
12

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

15 376. Defendant’s conduct therefore constitutes deceptive or misleading advertising.

16 377. Plaintiff has standing to pursue claims under the FAL as they reviewed and relied  
17 on Defendant’s advertising, representations, and marketing materials regarding CoolSculpting,  
18 when purchasing and undergoing the CoolSculpting procedure.  
19

20 378. In reliance on the statements made in Defendant’s advertising and marketing  
21 materials and Defendant’s omissions and concealment of material facts regarding the  
22 CoolSculpting System, Plaintiff purchased and underwent the CoolSculpting procedure.  
23

24 379. Had Defendant disclosed the true defective and dangerous nature of CoolSculpting,  
25 Plaintiff and California Class Members would not have purchased or undergone the CoolSculpting  
26 procedure or would have paid substantially less for it.  
27  
28



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

4 381. Plaintiff and California Class Members seek injunctive relief, restitution, and  
5 disgorgement of any monies wrongfully acquired or retained by Defendant and by means of its  
6 deceptive or misleading representations, including monies already obtained from Plaintiffs as  
7 provided for by the California Business and Professions Code § 17500.  
8

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

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

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

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

19 385. Plaintiff and California Class Members are "consumers" as defined by Civil Code  
20 § 1761(d).

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

22 387. The CoolSculpting device qualifies as a "Product" as defined by Civil Code §  
23 1761(a).

24 388. The CoolSculpting procedure qualifies as "services" as defined by Civil Code §  
25 1761(b).

26 389. Plaintiff and the California Class Members' purchases of CoolSculpting are  
27 "transactions" as defined by Civil Code 25 § 1761(e).  
28

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

- 4 a. “Representing that goods or services ... have sponsorship, approval,  
5 characteristics, ingredients, uses, benefits, or quantities which they do  
6 not have.” Civil Code § 1770(a)(5); and  
7 b. “Representing that goods or services ... are of a particular standard,  
8 quality, or grade, or that goods are of a particular style or model, if they  
9 are of another.” Civil Code § 1770(a)(7).

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

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

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

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

26 395. Defendant’s deceptive practices were specifically designed to induce Plaintiffs to  
27 purchase and undergo CoolSculpting.  
28

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

- 7
- 8 • “surgical intervention may be required” despite Defendant’s knowledge that PH  
9 will never resolve on its own and that the only means of removing it is through  
10 invasive plastic surgery;
- 11 • a “small number” may develop PH despite Defendant’s knowledge of the  
12 unreasonably dangerous risks and high incident rate of PH; and
- 13 • instructed its employees to use the words “rare” when referring to PH in their  
14 communications with CoolSculpting providers, the public, and the FDA.

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

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

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

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

25 401. Plaintiffs’ counsel’s declaration stating facts showing that venue in this District is  
26 proper pursuant to Cal. Civ. Code § 1780(c) is attached hereto as **Exhibit A**.  
27  
28

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

4 403. Pursuant to California Civil Code § 1780(a)(1)-(5) and § 1780(e), Plaintiff seeks an  
5 order enjoining Defendant from the unlawful practices described above, a declaration that  
6 Defendant’s conduct violates the Consumers Legal Remedies Act, reasonable attorneys’ fees and  
7 litigation costs, and any other relief the Court deems proper under the CLRA.  
8

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

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

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

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

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

22 408. Defendant’s conduct, as alleged herein, violates the laws and public policies of  
23 California and the federal government, as set out in the preceding paragraphs of this complaint.  
24

25 409. There is no benefit to consumers or competition by allowing Defendant to  
26 deceptively label, market, and advertise CoolSculpting.  
27  
28

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

4 411. The gravity of the harm suffered by Plaintiff and California Class Members who  
5 purchased and underwent CoolSculpting outweighs any legitimate justification, motive or reason  
6 for marketing, advertising, and selling the dangerous CoolSculpting in a deceptive and misleading  
7 manner. Accordingly, Defendant's actions are immoral, unethical, unscrupulous and offend the  
8 established public policies as set out in federal regulations and are substantially injurious to  
9 Plaintiffs.  
10

11 412. The above acts of Defendant in disseminating said misleading and deceptive  
12 statements to consumers were and are likely to deceive reasonable consumers by obfuscating the  
13 true defective nature of CoolSculpting, and thus were violations of Cal. Bus. & Prof. Code §§  
14 17500, *et seq.*

15 413. As a result of Defendant's above unlawful, unfair and fraudulent acts and practices,  
16 Plaintiff, on behalf of herself and all others similarly situated, and as appropriate, on behalf of the  
17 general public, seeks injunctive relief prohibiting Defendant from continuing these wrongful  
18 practices, and such other equitable relief, including full restitution of all improper revenues and  
19 ill-gotten profits derived from Defendant's wrongful conduct to the fullest extent permitted by law.  
20

21 414. Dangerous CoolSculpting cannot legally be advertised or sold. Thus,  
22 CoolSculpting has no economic value and are worthless as a matter of law, and purchasers of  
23 CoolSculpting are entitled to a restitution refund of the purchase price.  
24

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

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

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

4 417. Defendants’ foregoing acts and practices, including their omissions, were directed  
5 at consumers.

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

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

12 420. CoolSculpting poses an unreasonable safety risk to consumers.

13 421. Defendants did not disclose this information to consumers or otherwise cause this  
14 information to be disclosed to consumers  
15

16 422. Defendants’ foregoing deceptive and unfair acts and practices, including their  
17 omissions, were and are deceptive acts or practices in violation of the New York’s General  
18 Business Law § 349, Deceptive Acts and Practices, N.Y. Gen. Bus. Law 349, et seq., by:  
19

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

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

23 425. Defendants’ business practices, in manufacturing, warranting, advertising,  
24 marketing and selling CoolSculpting products and services while concealing, failing to disclose,  
25 suppressing or omitting material information, including the existence of serious health risk to  
26 consumers and Defendants’ knowledge of it, all while continuing to misrepresent CoolSculpting  
27  
28

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

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

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

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

13 429. Consumers, including Plaintiffs either would not have purchased the Products had  
14 they known about the serious health risk they posed to consumers, or would have paid less for  
15 them.  
16

17 430. As a direct and proximate result of Defendants' deceptive acts and practices,  
18 including their omissions, Plaintiffs have been damaged as alleged herein, and are entitled to  
19 recover actual damages to the extent permitted by law, including class action rules, in an amount  
20 to be proven at trial.  
21

22 431. In addition, Plaintiffs seek equitable and injunctive relief against Defendants on  
23 terms that the Court considers reasonable, and reasonable attorneys' fees and costs.  
24

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

27 432. Plaintiffs repeat and re-alleges all previous paragraphs, as if fully included herein.  
28

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

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

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

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

13 437. Defendants did not disclose this information to consumers in their advertising or  
14 representations.  
15

16 438. Defendants’ foregoing, consumer-oriented, unfair or deceptive acts and practices,  
17 including their advertising, representations, and omissions, constitutes false and misleading  
18 advertising in a material way in violation of the New York’s General Business Law § 350.  
19

20 439. Defendants’ false, misleading, and deceptive advertising and representations  
21 include:

- 22 a. Misrepresenting and misleadingly advertising that CoolSculpting was fit for its  
23 intended purpose; and  
24 b. Omitting and failing to disclose their knowledge that CoolSculpting is not safe for  
25 its intended purpose.

26 440. Defendants’ false, misleading, and deceptive advertising and representations of fact  
27 were and are directed at consumers.  
28



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

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

5 443. Plaintiff and other Class Members were injured because (a) they would not have  
6 purchased CoolSculpting on the same terms if the true facts concerning the safety risk posed by  
7 CoolSculpting had been known; (b) they would have paid less for CoolSculpting if the true facts  
8 concerning the safety risk posed by CoolSculpting had been known; and (c) CoolSculpting did not  
9 and cannot be perform as promised due to the inherent safety risk.  
10

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

14 445. Defendants' business practices, in manufacturing, warranting, advertising,  
15 marketing and selling CoolSculpting while concealing, failing to disclose, suppressing or omitting  
16 material information, including the existence of a serious safety risk and Defendants' knowledge  
17 of it, all while continuing to misrepresent CoolSculpting as safe for its ordinary and intended use  
18 and free of defects, constitutes the use of fraud, misrepresentation, and deceptive practices. These  
19 practices deceived Plaintiff and Class members, causing them to lose money by purchasing the  
20 CoolSculpting or paying more than they otherwise would, as herein alleged, and deceived and are  
21 likely to deceive the consuming public. Accordingly, Defendants' business acts and practices, as  
22 alleged herein, have caused injury to Plaintiff and Class members.  
23  
24

25 446. Plaintiff and Class members suffered damages when they purchased CoolSculpting.  
26 Defendant's unconscionable, deceptive and/or unfair practices caused actual damages to Plaintiff  
27 and Class members who were unaware that CoolSculpting posed a serious health risk. Defendant's  
28

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

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

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

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

11  
12 **COUNT XII**  
13 **MASSACHUSETTS CONSUMER PROTECTION LAW**  
14 **(Mass. Gen. Laws ch. 93A *et seq.*)**

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

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

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

25 453. Defendant's sale of CoolSculpting as safe for its intended purpose despite knowing  
26 that CoolSculpting posed a serious safety risk to consumers, failing to disclose the safety risks  
27 known to Defendant but hidden from the consumer, and Defendant's knowing concealment of  
28

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

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

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

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

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

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

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

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

23 461. By engaging in the unfair and deceptive conduct described herein and more fully  
24 above, Defendant actively concealed and failed to disclose material facts about the CoolSculpting.  
25

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

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

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

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

13 466. To this day, Defendant continues to violate MCPL by concealing the defective  
14 nature of CoolSculpting in failing to notify customers, and in collecting the profits from  
15 consumers.  
16

17 467. Plaintiff and Class Members have been damaged by these violations of MCPL.  
18 The damages should be trebled and Plaintiff and Class Members should be allowed to recover  
19 attorneys' fees pursuant to Mass. Gen. Laws ch. 93A § 9.  
20

21 **PUNITIVE/EXEMPLARY DAMAGES**

22 468. Plaintiffs incorporate the substantive allegations contained in this Complaint as if  
23 fully set forth herein.  
24

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

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

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

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

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

10 473. The malicious conduct described herein occurred and arose from the CoolSculpting  
11 headquarters in Pleasanton, California from where the Defendant made corporate decisions related  
12 to selling, promoting, advertising, and labeling the CoolSculpting medical device. Therefore, Cal.  
13 Civ. Code § 3294 applies to the punitive damages' aspect of this case.  
14

15 **REQUEST FOR RELIEF**

16 **WHEREFORE**, Plaintiffs, respectfully requests this Court enter a judgment:  
17

- 18 1. Certifying the Classes described herein pursuant to Rule 23 of the Federal Rules of Civil  
19 Procedure;
- 20 2. Ordering the Defendant to pay compensatory damages to Plaintiffs and the Class for past  
21 and future economic and non-economic damages, including but not limited to pain and  
22 suffering, permanent disfigurement, economic loss, future medical expenses, mental  
23 anguish, and loss of enjoyment of life;
- 24 3. Ordering the Defendant to pay restitution of Defendant's profits earned from its wrongful  
25 conduct;
- 26 4. Ordering the Defendant to establish a medical monitoring program for persons that  
27 underwent the CoolSculpting procedure and exposed themselves to risk of developing PH;
- 28 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**

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