BACH MILI LLP
Rami Bachour, State Bar No. 324844
rbachour@bachmili.com
1800 Vine St, Ste. 100
Los Angeles, CA 90028
Telephone: (323) 438-8400

HADERLEIN & KOUYOUMDJIAN LLP
Jonathan Haderlein, State Bar No. 336644
jhaderlein@handklaw.com
Krikor Kouyoumdjian, State Bar No. 336148
kkouyoumdjian@handklaw.com
700 Flower St., Ste. 1000
Los Angeles, CA 90017
Telephone: (818) 304-3435

Attorneys for Plaintiffs Salma Dwabe and Kefah Dwabe

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

SALMA DWABE, an individual; KEFAH DWABE, an individual,

as Plaintiff,

v.

ABBVIE, INC. a Delaware Corporation; ALLERGAN USA INC., a Delaware Corporation; ZELTIQ AESTHETICS, INC., formerly a Delaware Corporation; LA BELLA LASER & SLIMMING, a business entity form unknown; and DOES 1-20, inclusive;

as Defendants.

Case No.: 24NNCV04761

COMPLAINT FOR:

1. **STRICT PRODUCT LIABILITY (MANUFACTURE, DESIGN, AND WARNING DEFECT)**
2. **NEGLIGENCE (MANUFACTURE, DESIGN, MISBRANDED)**
3. **BREACH OF EXPRESS WARRANTY**
4. **BREACH OF IMPLIED WARRANTY**
5. **STRICT LIABILITY (FAILURE TO WARN)**
6. **NEGLIGENT ACTS/OMISSIONS OF AGENTS**
7. **NEGLIGENT MISREPRESENTATION AND CONCEALMENT**
8. **FRAUDULENT MISREPRESENTATION AND CONCEALMENT**
9. **LOSS OF CONSORTIUM**

DEMAND FOR JURY TRIAL

Plaintiffs Salma Dwabe and Kefah Dwabe (respectively, "Mrs. Dwabe" and "Mr. Dwabe"), based upon personal knowledge as to all acts or events that they have undertaken or witnessed, and upon information and belief as to all others, brings this action against Defendants AbbVie, Inc., Allergan USA Inc., and Zeltiq Aesthetics, Inc., and La Bella Laser & Slimming (collectively, "Defendants"), allege and affirmatively state as follows:

PARTIES

1. Plaintiff **Salma Dwabe** is an individual residing in the City of Buena Park, County of Orange, and the State of California.

2. Plaintiff **Kefah Dwabe** is an individual residing in the City of Buena Park, County of Orange, and the State of California.

3. Defendant, **AbbVie, Inc**. ("AbbVie") is and, at all times relevant herein was, a corporation formed under the laws of the State of Delaware with a principal place of business and headquarters located at 1 North Waukegan Road, North Chicago, IL 60064.

4. Defendant, **Zeltiq Aesthetics, Inc**. ("Zeltiq") is and, at all times relevant herein was, a corporation formed under the laws of the State of Delaware with a principal place of business located at 1 North Waukegan Road, North Chicago, IL 60064.

5. Defendant, **Allergan, Inc**. ("Allergan") is and, at all times relevant herein was, a corporation formed under the laws of the State of Delaware with a principal place of business located at 1 North Waukegan Road, North Chicago, IL 60064.

6. Defendant **Bella Laser & Slimming** ("La Bella" or "CoolSculpting Provider") is and, at all times relevant herein was, a business organization, form unknown, authorized to do business in the State of California and was doing business in the State of California.

7. Defendants DOES 1 through 20, inclusive, are sued herein under fictitious names. Their true names and capacities are unknown to Plaintiffs. When their true names and capacities are ascertained, Plaintiffs will amend this Complaint by inserting their true names and capacities. Plaintiffs are informed and believe and thereon alleges that each of the fictitiously named Defendants is responsible in some manner for the occurrence herein alleged, and that Plaintiffs' damages were proximately and legally caused by those Defendants. Each reference in this complaint to

"Defendant," "Defendants," or specifically named Defendants refers to all named Defendants and those sued under fictitious names.

8. Plaintiffs are informed and believe that each of the Defendants is responsible in some manner, either by act or omission, strict liability, fraud, negligence, breach of contract, breach of express/implied warranty, negligence per se, res ipsa loquitur, respondeat superior, employment, agency, breach of statute, joint tortfeasor, or otherwise, for the occurrences alleged herein, and that Plaintiffs' damages were proximately and legally caused by the conduct of the Defendants.

9. Plaintiffs are informed and believe and thereon alleges that, at all times herein mentioned, each of these Defendants, including Defendants sued under fictitious names, was the agent, employee, alias and/or alter ego of each of the remaining Defendants, and in doing the things herein alleged, was acting within the course and scope of such agency, alias, alter ego and/or employment, and with the knowledge, consent, and approval of the co-defendants. Each Defendant's conduct was ratified by each co-defendant.

10. Each reference in this Complaint to defendants, any defendant and or specifically named defendants includes a reference to all defendants sued by their fictitious names.

VENUE

11. Venue is proper in this jurisdiction in that all of the acts giving rise to this lawsuit, which are described more fully below, occurred within the County of Los Angeles, and the damages incurred by Plaintiffs exceed the jurisdictional minimum of this Court.

JURISDICTION

12. On April 28, 2017, Allergan acquired Zeltiq. Since this acquisition, Allergan has held itself out as the owner of the CoolSculpting medical device and had/has apparent dominion and control over all aspects of the CoolSculpting business including the manufacturing, labeling, advertising, distribution, and sale of the medical device and its consumables.

13. On May 8, 2020, AbbVie acquired Allergan (and consequently, Zeltiq), took control of the companies' assets and liabilities, and is now the owner of the CoolSculpting medical device business.

14. At all times relevant herein, Defendants entered into contracts, obtained revenue, and conducted business in the State of California to sell, promote, and advertise the CoolSculpting medical device.

15. At all times relevant herein, Defendants were in the business of creating, designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling, and distributing their CoolSculpting device into the stream of commerce for use by the public, including Mrs. Dwabe.

16. At all times relevant herein, Defendants conducted and continue to conduct substantial business within the State of California.

17. Defendants expected or should have expected their acts to have consequences within the State of California, as they derive substantial revenue from interstate commerce within the United States of America, including in the State of California.

18. Defendants, at all relevant times, were in the business of creating, designing, testing, manufacturing, labeling, advertising, marketing, promotion, selling, and distributing CoolSculpting through providers and jointly placed CoolSculpting into the stream of commerce for use by the public, including Mrs. Dwabe.

19. At times relevant and material hereto, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, developing, designing, formulating, licensing, manufacturing, testing, producing, processing, assembling, packaging, inspecting, distributing, selling, labeling, monitoring, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the State of California, either directly or indirectly, through third-parties, subsidiaries and/or related entities, Coolsculpting, used in patients throughout the United States, including Plaintiffs.

20. At all times alleged herein, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale or selling the Coolsculpting.

21. At all times alleged herein, Defendants were authorized to conduct or engage in business within the state of California and supplied Coolsculpting within the state of California.

Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing Coolsculpting within the state of California.

22. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiffs. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiffs for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

23. Defendants Zeltiq, Allergan, and AbbVie are alter egos of each other and should be treated as such for purposes of liability in this case. The corporate structure and actions of these Defendants demonstrate that they are not independent entities but are so intertwined in their business operations, finances, management, and oversight that they operate as one entity.

Common Stock Ownership

24. AbbVie owns all outstanding shares of Allergan, which in turn owns and controls Zeltiq. On May 8, 2020, AbbVie completed its acquisition of Allergan in a cash and stock transaction, issuing 286 million shares of AbbVie common stock to Allergan shareholders in connection with the acquisition.[1] Previously, Allergan acquired all outstanding equity interests in Zeltiq on April 28, 2017, for $2.4 billion, thereby absorbing Zeltiq into its corporate structure.[2]

Common Directors or Officers

25. Zeltiq and Allergan do not have their own independent officers or directors. Rather, Zeltiq's and Allergan's corporate boards are composed exclusively of AbbVie's own directors and officers.

26. According to the Statement of Information filed with the California Secretary of State, Zeltiq and Allergan list only AbbVie executives as their officers and directors, with no individuals

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[1] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2020) https://www.sec.gov/Archives/edgar/data/1551152/000155115221000008/abbv-20201231.htm (last visited Aug. 19, 2024).

[2] U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

serving independently of AbbVie, demonstrating that AbbVie exercises complete control over the governance of both subsidiaries and further evidencing the lack of separateness between these entities and the parent corporation.

27. After Allergan's acquisition of Zeltiq, Zeltiq executive officers and directors were integrated into the Allergan leadership structure, with their compensation and equity awards converted into Allergan equity, highlighting how Zeltiq was fully absorbed into Allergan's operational framework.

28. This integration not only blurred the lines between the two entities but also reflected a consolidation of authority under AbbVie, particularly after AbbVie's subsequent acquisition of Allergan. The absorption of Zeltiq's leadership into the Allergan system, and ultimately under AbbVie's control, further underscores the subsidiaries' lack of independence and highlights that their actions are directed by AbbVie.

Common Business Departments

29. Allergan's acquisition of Zeltiq marked the beginning of a significant integration process aimed at merging Zeltiq's operations with Allergan's broader business structure.

30. Allergan's 2017 10-K underscored that "prior to each acquisition, the acquired business operated independently, with its own business, corporate culture, locations, employees, and systems." However, following the acquisition, Allergan set out to merge these distinct aspects of the businesses, bringing Zeltiq's operations into alignment with its own. [3]

31. The goal of this integration was to "achieve synergies" across departments and optimize operational efficiency, which included incorporating Zeltiq's management, employees, and systems into a unified structure.[4]

[3] U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

[4] U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

32. The company emphasized the importance of fully integrating acquired businesses such as Zeltiq into its overall business operations, stating that it needed to "successfully integrate the operations of recently and pending acquired businesses, including LifeCell and Zeltiq, with our business operations."[5]

33. Allergan detailed that such integration is a "complex, costly, and time-consuming process, which requires significant management attention and resources," highlighting the extensive overlap and coordination required between the business departments of AbbVie, Allergan, and Zeltiq post-acquisition.

34. This integration posed challenges, as Allergan acknowledged that difficulties could arise from "distracting management from day-to-day operations" and "incompatibility of corporate cultures." Nevertheless, the company was committed to incorporating Zeltiq's operations into its own, because the failure to fully integrate these operations, according to Allergan, could result in "substantial difficulties, costs, and delays," potentially leading to adverse effects on their business performance.[6]

35. This integration continued as Allergan itself was later acquired by AbbVie. Following its acquisition, AbbVie and Allergan integrated their business operations across multiple departments, including research and development, manufacturing, sales, and administration. AbbVie boasted about this integration plan in its public filings, stating: "AbbVie implemented an integration plan designed to reduce costs, integrate, and optimize the combined organization."[7]

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5 U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

6 U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

7 U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2022) https://www.sec.gov/Archives/edgar/data/1551152/000155115223000011/abbv-20221231.htm (last visited Aug. 19, 2024).

36. AbbVie projected this plan would realize "$2.5 billion of annual cost synergies in 2022," further absorbing Allergan's departments, and by extension, Zeltiq's operations, into its broader corporate structure.[8]

37. The operations of Zeltiq and Allergan are now fully integrated into AbbVie's broader corporate structure, with neither subsidiary maintaining its own independent employees. Instead, AbbVie employees are responsible for conducting the business affairs of both Zeltiq and Allergan, and the same personnel carry out the day-to-day operations of all three entities. None of the employees who work on matters related to Zeltiq or Allergan are dedicated exclusively to those subsidiaries; rather, they work under the umbrella of AbbVie, reflecting the pervasive overlap in staffing across the corporations.

38. Upon AbbVie's acquisition of Allergan, and previously, Allergan's acquisition of Zeltiq, the subsidiaries' workforces were absorbed into AbbVie's broader operational framework, leaving Zeltiq and Allergan without distinct employees or independent workforces. Employees who handle business matters for Zeltiq and Allergan do so as part of their roles within AbbVie, rather than as dedicated personnel exclusive to the subsidiaries.

39. This extensive overlap in employees demonstrates that Zeltiq and Allergan do not function as independent entities. Instead, they rely entirely on AbbVie's employees to effectuate their business. AbbVie has centralized control over staffing, directing employees across its various departments—such as sales, marketing, R&D, and administration—to work on Zeltiq and Allergan business matters, as needed. This staffing arrangement eliminates any operational distinction between the companies, as the same individuals who execute AbbVie's business operations are also responsible for managing the affairs of Zeltiq and Allergan.

40. By relying solely on AbbVie's employees, Zeltiq and Allergan have no capacity to operate independently, further evidencing that the business departments of the three entities are fully

[8] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2022) https://www.sec.gov/Archives/edgar/data/1551152/000155115223000011/abbv-20221231.htm (last visited Aug. 19, 2024).

intertwined. This pervasive overlap in employees underscores the lack of corporate separateness, as Zeltiq and Allergan are wholly dependent on AbbVie's workforce for their continued operations.

41. As such, this staffing arrangement highlights the common business departments between the entities, demonstrating that Zeltiq and Allergan have been subsumed into AbbVie's corporate infrastructure, with no independent workforce of their own.

Consolidated Financial Statements and Tax Returns

42. Allergan's financial statements (before AbbVie acquired it) consolidated Zeltiq's financial performance post-acquisition. See U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024) ("The following consolidated financial statements of the registrants and their subsidiaries are required to be included.").

43. Similarly, AbbVie files a consolidated financial statement that reflect the results of its subsidiaries, including Allergan and Zeltiq. AbbVie's consolidated financial statements include the results of operations for Allergan and its subsidiaries post-acquisition, demonstrating financial integration.

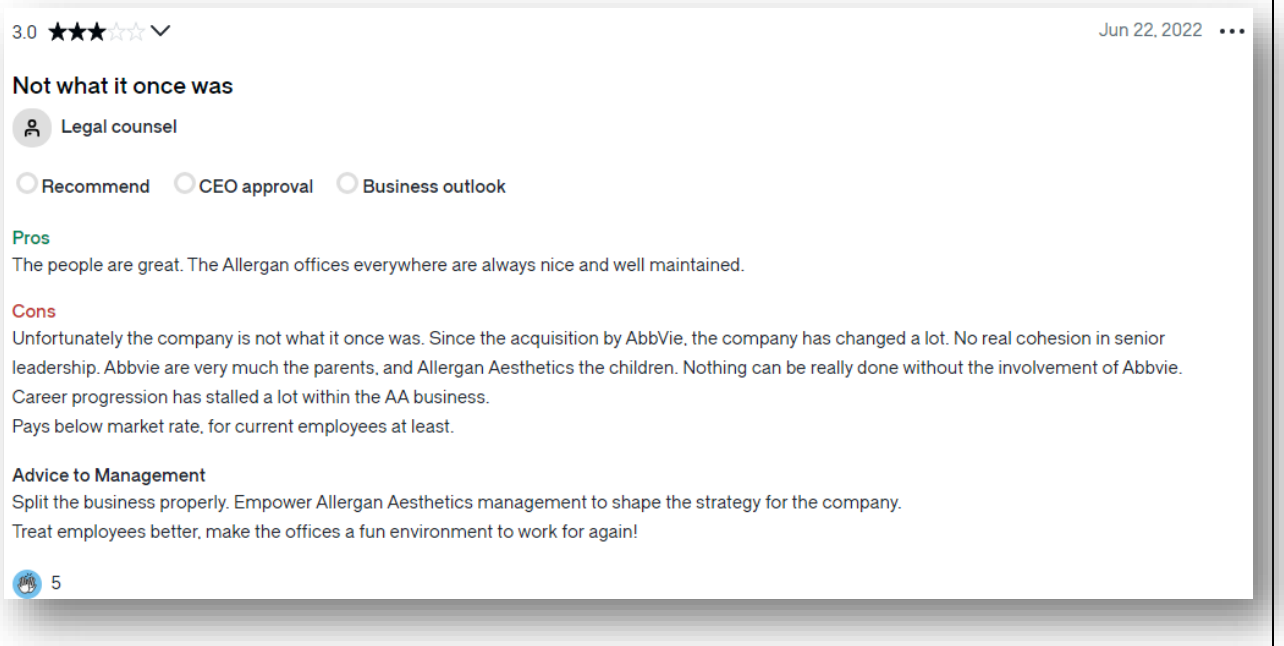
Parent Finances the Subsidiary

44. Allergan's public filings also highlight various acquisition-related costs and integration costs, including severance and other post-acquisition expenses. For example, Allergan incurred substantial costs for its integration of Zeltiq, showing that Allergan took on Zeltiq's operational costs, including severance payments and other financial liabilities. This cost financing was so high that Allergan specifically noted it in its public disclosures as a fact that a reasonably prudent investors would find material in determining whether to maintain their investment in Allergan: "the increase in selling and marketing expenses relates to the addition of Zeltiq, which contributed spending of $39.0 million."[9]

[9] U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2017) https://www.sec.gov/Archives/edgar/data/1578845/000156459018002345/agn-10k_20171231.htm (last visited Aug. 19, 2024).

45. Similarly, as part of acquiring Allergan, AbbVie financed the acquisition of Allergan through the issuance of $30 billion in unsecured senior notes and $3 billion in term loans, which included the assumption of Allergan's and Zeltiq's liabilities.[10] Specifically, AbbVie's 2024 10-K reveals that the parent company made strategic decisions to reduce sales and marketing investment in CoolSculpting, demonstrating direct financial control over Zeltiq's operations.

46. AbbVie recorded "a pre-tax impairment charge of $1.4 billion to costs of products sold" related to its definite-lived intangible assets, which includes CoolSculpting, underscoring that Zeltiq's financial health is tied to AbbVie's decisions.[11] Indeed, this commingling is not a secret. According to Allergan employee reviews on Glassdoor, "[n]othing can be really done without the involvement of Abbvie." See:



47. AbbVie has also assumed responsibility for managing Allergan's product liability claims, including lawsuits pending against Allergan and its former officers, which demonstrates that Allergan's liabilities are not separate from AbbVie's financial obligations.

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[10] U.S. Securities and Exchange Commission, Form 10-K AbbVie, Inc. (2020) https://www.sec.gov/Archives/edgar/data/1551152/000155115221000008/abbv-20201231.htm (last visited Aug. 19, 2024).

[11] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

48. For instance, AbbVie's public filings explicitly state that product liability claims against Allergan 'may have a material adverse effect on AbbVie's business, results of operations and reputation,' indicating that AbbVie has financially and operationally integrated Allergan into its corporate structure, and any liabilities arising from Allergan's products are borne by AbbVie as if they were its own. Such an assumption of liability supports the contention that AbbVie finances its subsidiary Allergan and fails to observe corporate separateness between the entities.

Parent Caused the Incorporation of the Subsidiary

49. While AbbVie did not directly cause the incorporation of Allergan, AbbVie's acquisition led to the privatization of Allergan, a once publicly traded company.[12] Similarly, Allergan caused the privatization of Zeltiq upon acquiring it.

Subsidiary Operates with Grossly Inadequate Capital

50. Allergan and Zeltiq operate with grossly inadequate capital due to their complete reliance on AbbVie for financing. AbbVie assumed control over Allergan's and Zeltiq's financial obligations, including their debt and equity compensation, and directed all financing activities for these subsidiaries.[13]

51. For example, according to AbbVie's 2024 10-K, the company made a strategic decision in the fourth quarter of 2023 to "reduce current sales and marketing investment related to both CoolSculpting, a body contouring technology for aesthetic nonsurgical fat reduction."[14] This reduction in investment contributed to "significant decreases in the estimated future cash flows" for CoolSculpting, resulting in a partial impairment of both the gross and net carrying amounts of the

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[12] See AbbVie, Inc. News Center, ABBVIE COMPLETES TRANSFORMATIVE ACQUISITION OF ALLERGAN https://news.abbvie.com/2020-05-08-AbbVie-Completes-Transformative-Acquisition-of-Allergan (last visited Aug. 19, 2024) ("Allergan common stock ceased trading on the New York Stock Exchange as of the close of trading today.").

[13] See, e.g., U.S. Securities and Exchange Commission, Form 10-K AbbVie, Inc. (2021) https://www.sec.gov/Archives/edgar/data/1551152/000155115219000008/abbv-20181231x10k.htm (last visited Aug. 19, 2024).

[14] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

CoolSculpting assets. AbbVie recorded a "pre-tax impairment charge of $1.4 billion" related to CoolSculpting, which was reported in its consolidated statement of earnings.[15]

52. This evinces that Zeltiq was unable to maintain adequate capital on its own and relied heavily on AbbVie's financial decisions and assessments. AbbVie's determination to reduce investment directly impacted Zeltiq's financial standing, further demonstrating that Zeltiq operates with inadequate capital and is dependent on AbbVie for financial stability.

Parent Pays the Salaries and Other Expenses of the Subsidiary

53. AbbVie and Allergan incurred substantial costs related to the integration of their subsidiaries, including severance, stock-based compensation, and other employee-related expenses. According to public filings, AbbVie incurred total cumulative charges of $2.3 billion through 2022.[16] "These costs consisted of severance and employee benefit costs (cash severance, non-cash severance, including accelerated equity award compensation expense, retention and other termination benefits) and other integration expenses."[17]

54. AbbVie also routinely pays the legal fees and expenses of Allergan. For example, in 2022, AbbVie agreed to pay up to $2.37 billion to resolve legal claims against Allergan for improperly promoting and selling prescription opioid products.[18]

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[15] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

[16] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

[17] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

[18] See Tonya Alanez, *AbbVie Agrees to Pay Up to $2.37 Billion to Resolve Allergan Opioid Lawsuits*, Wash. Post (July 29, 2022), https://www.washingtonpost.com/business/economy/abbvie-agrees-to-pay-up-to-237-billion-to-resolve-allergan-opioid-lawsuits/2022/07/29/6abbc304-0f2d-11ed-bf3a-cdf532019c52_story.html.

55. Similarly, AbbVie absorbed the legal costs and settlement payment of a patent infringement lawsuit filed by BTL Industries solely against Allergan and Zeltiq, alleging that the CoolTone and CoolSculpting devices infringe its patents.[19]

Subsidiary Receives No Business Except from Parent

56. The business operations of Zeltiq, after its acquisition by Allergan, and Allergan, after its acquisition by AbbVie, were exclusively directed by their parent corporations. Zeltiq's body contouring business was fully integrated into Allergan's medical aesthetics division, while Allergan's revenues were fully consolidated into AbbVie's broader pharmaceutical and medical aesthetics businesses.

57. Any association between the CoolSculpting procedure and Zeltiq has been deliberately erased and rebranded as a product of Allergan and AbbVie. On Allergan's website, the CoolSculpting procedure is advertised as its own product, with CoolSculpting listed under the "Our Brands" tab alongside Botox and Juvederm, which are heritage Allergan products. This marketing approach further blurs the lines, making CoolSculpting appear as though it has always been an Allergan product, thus erasing any independent identity Zeltiq once had.

58. Even the CoolSculpting website urges users of the device to join the "Allē" program, stating "As a member of the Allē loyalty program, not only will you learn about the latest news and deals on CoolSculpting but you'll also earn points and rewards to use on the Allergan Aesthetics products and treatments you love."[20]

59. Additionally, Allergan's website organizes its services under a **"**Treatment Area" tab, which is broken down into two major categories: Facial Aesthetics and Body Contouring. The CoolSculpting procedure is nestled under the Body Contouring category, alongside other Allergan products. This demonstrates that Allergan has fully integrated CoolSculpting into its broader body

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[19] See Matthew Perlman, AbbVie Settles Patent Dispute Over Muscle Stimulation Tech, Law360 (Sept. 9, 2021), https://www.law360.com/articles/1419349/abbvie-settles-patent-dispute-over-muscle-stimulation-tech ("AbbVie has agreed to pay BTL Industries an undisclosed sum to settle patent litigation over muscle stimulation technology used for aesthetic purposes, the latter company said Tuesday.")

[20] *Discover Our Story*, CoolSculpting, https://www.coolsculpting.com/discover-our-story/ (last visited Aug. 25, 2024).

contouring business and does not intend to allow CoolSculpting to operate in a silo as an independent brand. Instead, it is treated as a core part of Allergan's overall business strategy in aesthetics.

60. Moreover, in an interview on "The Technology of Beauty" podcast, Carrie Strom (Senior Vice President at AbbVie and President of Global Allergan Aesthetics) confirmed Allergan's broader vision for integrating CoolSculpting into its business model. Strom stated, "Our vision for body contouring is to make it the third strategic pillar. We have toxins. We have fillers. And we want body contouring to be that third leg of the stool as they say."[21]

61. She further emphasized Allergan's commitment to body contouring as a critical business strategy by stating, "[w]hen you think about all the unmet needs that consumers have in aesthetics, forget about the solutions that Allergan has."[22] This reinforces that CoolSculpting has become an integral part of Allergan's business strategy and is no longer treated as an independent product under Zeltiq.

62. The integration of CoolSculpting into Allergan's broader business and the deliberate rebranding away from Zeltiq demonstrates that Zeltiq receives no business except that directed by Allergan and AbbVie. Any previous autonomy that Zeltiq held before the acquisition has been systematically dismantled and absorbed into the parent companies' strategic objectives.

63. Similarly, AbbVie's decision to reduce investment in CoolSculpting shows that Zeltiq receives no business except that directed by AbbVie. "The company made a decision to reduce current sales and marketing investment related to CoolSculpting," thereby demonstrating control over Zeltiq's business operations.[23]

64. Allergan's 2019 10-K also reported that "The increase in selling and marketing expenses relates to the addition of Zeltiq, which contributed spending of $39.0 million, as well as

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[21] *Leveraging Technology to Create the Optimal Patient Experience*, Influx Mktg., https://www.influxmarketing.com/technology-of-beauty/leveraging-technology-to-create-the-optimal-patient-experience/ (last visited Aug. 25, 2024).

[22] *Leveraging Technology to Create the Optimal Patient Experience*, Influx Mktg., https://www.influxmarketing.com/technology-of-beauty/leveraging-technology-to-create-the-optimal-patient-experience/ (last visited Aug. 25, 2024).

[23] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2024) https://www.sec.gov/Archives/edgar/data/1551152/000155115224000011/abbv-20231231.htm (last visited Aug. 19, 2024).

increased promotional spending associated with Ozurdex, Botox Cosmetics, and the Juvederm Collection and recent product launches."[24] This reinforces that Zeltiq's financial activities are not independently driven but are entirely dependent on the strategic decisions made by the parent company.

65. Similarly, the business operations and revenue generation of Allergan are entirely dependent on AbbVie's control and ownership of the proprietary technology, developed product rights, and intellectual property (IP) that were once owned by Allergan. Upon AbbVie's acquisition of Allergan, all of the valuable IP that underpinned Allergan's business—including, but not limited to, the rights to products such as Botox, Juvederm, and other developed product rights—transferred to AbbVie. This transfer of IP rights renders AbbVie the true owner of the assets that drive Allergan's revenue generation.

66. AbbVie's ownership of these rights is significant because it illustrates that Allergan no longer operates independently but rather as a conduit for exploiting AbbVie's assets. Allergan's ability to continue its legacy business, including generating revenue from its existing product lines, is contingent entirely on AbbVie's control and decision-making. Simply put, Allergan cannot operate or generate income without AbbVie's authorization, as AbbVie now holds the ultimate rights to Allergan's core products and technologies.

67. In AbbVie's own public filings, the company acknowledges that "in connection with the acquisition of Allergan, AbbVie's balances of intangible assets, including developed product rights and goodwill acquired, have increased significantly."[25] This confirms that AbbVie now controls Allergan's developed product rights, and any "impairment charges" related to these assets will adversely affect AbbVie's financial condition—not Allergan's—further demonstrating that Allergan's business and success are now intertwined with AbbVie's control.

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[24] U.S. Securities and Exchange Commission, Form 10-K Allergan plc (2019) https://www.sec.gov/Archives/edgar/data/1578845/000156459020005038/agn-10k_20191231.htm (last visited Aug. 19, 2024).

[25] U.S. Securities and Exchange Commission, Form 10-K AbbVie, Inc. (2021) https://www.sec.gov/Archives/edgar/data/1551152/000155115219000008/abbv-20181231x10k.htm (last visited Aug. 19, 2024).

68. Allergan's revenues are thus derived from business activities made possible only by AbbVie's ownership and control over its formerly proprietary technology. As a result, Allergan's business activities and financial outcomes are dictated and directed entirely by AbbVie, showing that Allergan receives no business or revenue that is not provided or permitted by its parent company. This level of dependency further demonstrates that Allergan functions as a mere instrumentality of AbbVie, operating under the parent's control and not as an independent entity.

Parent Uses the Subsidiary's Property as Its Own

69. AbbVie's acquisition of Allergan resulted in AbbVie assuming ownership and control over Allergan's most valuable assets, including intellectual property, developed product rights, and goodwill. These critical assets now belong to AbbVie and are used for its own benefit, fully integrating them into AbbVie's operations.

70. AbbVie's filings confirm that "in connection with the acquisition of Allergan, AbbVie's balances of intangible assets, including developed product rights and goodwill, have increased significantly."[26] This demonstrates that AbbVie now owns the proprietary technology and products that once belonged to Allergan, including Botox, Juvederm, and other key products.

71. As a result, AbbVie directly controls and benefits from these assets, integrating them into its business and financial reporting. Any revenue generated from Allergan's legacy products now flows to AbbVie, further proving that AbbVie treats these assets as its own.

72. Similarly, Allergan treats Zeltiq's property as its own following its acquisition. Allergan advertises and markets the CoolSculpting procedure and related IP without mentioning Zeltiq, instead promoting these assets as part of Allergan's broader medical aesthetics portfolio. This lack of distinction between the original owner (Zeltiq) and Allergan shows that Allergan fully absorbed and utilizes Zeltiq's assets, treating them as its own property.

73. This pattern demonstrates that neither AbbVie nor Allergan respects the separate ownership of these valuable assets. Allergan no longer controls its key assets independently, and

[26] U.S. Securities and Exchange Commission, Form 10-K AbbVie Inc. (2020) https://www.sec.gov/Archives/edgar/data/1551152/000155115221000008/abbv-20201231.htm (last visited Aug. 19, 2024).

Zeltiq's property is fully exploited by Allergan without attribution to its original source. Both subsidiaries' intellectual property is used by the parent companies for their own financial benefit, without recognition of corporate separateness.

74. By controlling and utilizing these assets as if they were their own, AbbVie and Allergan show a disregard for the separateness of the subsidiaries, using their property for their own operational and financial advantage. This underscores that Allergan and Zeltiq do not operate as independent entities, but as extensions of AbbVie's larger corporate structure.

Daily Operations of the Two Corporations Are Not Kept Separate

75. The daily operations of Zeltiq, Allergan, and AbbVie are intertwined, with no meaningful separation between them. According to public filings, "AbbVie remains committed to driving continued expansion of operating margins and expects to achieve this objective through continued realization of expense synergies from the Allergan acquisition, leverage from revenue growth, productivity initiatives in supply chain and ongoing efficiency programs to optimize manufacturing, commercial infrastructure, administrative costs and general corporate expenses."[27] This statement confirms that AbbVie has not kept Allergan's operations independent but has instead fully integrated Allergan into its own operations, merging manufacturing, administrative, and corporate expenses.

76. Allergan, in turn, similarly integrated Zeltiq's operations into its own, as reflected by the "transaction and integration costs" incurred following the Zeltiq acquisition. This demonstrates that Zeltiq's daily business activities were folded into Allergan's broader operations. Zeltiq is no longer run as an independent entity, but as part of Allergan's medical aesthetics division.

77. Furthermore, AbbVie, Allergan, and Zeltiq all share the same principal address at 1 N. Waukegan Rd., North Chicago, IL 60064, reinforcing the lack of separation between their operations. Sharing a headquarters further illustrates the blending of corporate activities, including shared resources, decision-making, and infrastructure.

[27] U.S. Securities and Exchange Commission, Form 10-K AbbVie, Inc. (2021) https://www.sec.gov/Archives/edgar/data/1551152/000155115219000008/abbv-20181231x10k.htm (last visited Aug. 19, 2024).

78. The shared principal address also signifies more than just a common mailing location. It evidences shared leadership, staff, and administrative functions, which are housed under the same roof. This setup suggests that key operational decisions and business functions are handled centrally at AbbVie's headquarters, rather than independently at the subsidiary level.

79. The absence of separate offices or facilities demonstrates that the subsidiaries are not functioning autonomously and are instead fully integrated into AbbVie's daily operational framework. By centralizing operations, AbbVie eliminates any meaningful distinction between itself and its subsidiaries, further eroding the concept of corporate separateness.

Subsidiary Does Not Observe Basic Corporate Formalities

80. Plaintiff is informed and believes, and thereon alleges, that Defendants Allergan and AbbVie have failed to observe basic corporate formalities in their management of Zeltiq. This includes, but is not limited to, a failure to maintain separate board meetings, tax filings, financial accounts, corporate records, and shareholder meetings for the distinct corporate entities.

81. Upon the acquisition of Zeltiq by Allergan and later by AbbVie, the corporate structure of Zeltiq was largely dismantled. Zeltiq no longer maintained independent board meetings; instead, all major decisions regarding the operations of the CoolSculpting brand were made under the supervision of Allergan's and AbbVie's executives. The conversion of Zeltiq's leadership structure into the Allergan framework further demonstrates the consolidation of authority. Any prior corporate formalities Zeltiq observed were effectively nullified, with Allergan, and subsequently AbbVie, absorbing and centralizing control over what used to be separate corporate governance.

82. The failure to maintain separate financial accounts also supports this point. Zeltiq's financial operations, including budgeting, revenue, and liabilities, were fully integrated into Allergan's financial statements, which were later consolidated under AbbVie. Separate financial statements for Zeltiq were no longer kept, and any independent financial identity that Zeltiq once had was erased through the consolidation of its revenue and liabilities into AbbVie's larger financial framework.

83. Furthermore, Allergan and AbbVie disregarded corporate formalities by using Zeltiq's intellectual property and marketing as their own without separate acknowledgment of

Zeltiq's existence as a distinct corporate entity. The CoolSculpting brand is now advertised as an Allergan product, with no mention of Zeltiq in Allergan's branding or public statements. This lack of corporate distinction further evidences the disregard for corporate separateness that should otherwise be maintained under basic corporate formalities.

FACTS

A. Plaintiffs' Injuries.

84. This lawsuit arises from a popular non-invasive medical device called CoolSculpting. Defendants, directly or through their agents and employees, created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold CoolSculpting to be used on individuals, including Mrs. Dwabe, to induce lipolysis, the metabolic process through which fat stored in the human body is broken down via hydrolysis into its constituent molecules.

85. Mrs. Dwabe learned about the CoolSculpting System from Defendants' direct-to-consumer advertisements, Defendants' promotional materials, and socially among her family and friends. Defendants advertised CoolSculpting as "the only non-invasive treatment FDA-cleared to freeze fat away. CoolSculpting targets unwanted fat so your body can eliminate it naturally – without surgery or downtime."

86. Mrs. Dwabe, like many CoolSculpting users, developed Paradoxical Adipose Hyperplasia ("PAH") following her treatment. PAH is a permanent condition that is developed only as of the result of undergoing cryolipolysis via CoolSculpting wherein CoolSculpting causes permanent pathological change to the microstructure of the tissue in the treatment area, affecting various types of cells, including adipocytes, vascular cells, blood cells, macrophages, endothelial cells, stem cells, and interstitial cells. The tissue affected by PAH becomes fibrous, resulting in enlarged and sometimes hardened tissue masses that cause disfigurement. This fibrous tissue is dead tissue, not an overgrowth of healthy tissue, which must be surgically removed from surrounding healthy tissue.

87. PAH-affected tissue does not react the same to weight loss as regular fat. No matter how much weight a person loses after developing PAH, the affected area will never get smaller. The deforming effect of PAH remains permanently and can only be removed surgically.

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

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

90. Even with surgeries, a full reconstruction of the affected area is not guaranteed, and the long-term consequences of developing PAH are still unknown. A person with PAH is at risk for future health and aesthetic problems, including the return of the deformity years after surgery.

91. At this time, the only known prevention of PAH is abstaining from CoolSculpting.

92. Neither the significant risk of PAH, nor its severity, was communicated in Defendants' advertisements, promotional materials, communications with treatment providers, or public statements. Instead, consumers were enticed to try a technique that left them open to a far-greater risk of requiring invasive, corrective surgery, or live with permanent, disfiguring growths.

93. Mrs. Dwabe chose Defendants' CoolSculpting system and elected to undergo CoolSculpting treatment based on Defendants' representations that CoolSculpting was a safe and effective, non-invasive alternative to liposuction surgery for contouring small areas of the body, and Mrs. Dwabe underwent CoolSculpting treatment for that purpose.

94. Unaware of the health risks and serious adverse effects associated with use of the CoolSculpting System, including, but not limited to, the true incidence and occurrence of PAH following treatment, Mrs. Dwabe underwent CoolSculpting treatment on her abdomen at the medical offices of La Bella in Arcadia, California.

95. Mrs. Dwabe was in good physical shape, mental well-being, and superior self-esteem prior to using Defendants' CoolSculpting system.

96. Mrs. Dwabe pursued CoolSculpting treatment in the hopes of contouring small areas of her body as Defendants represented and promised in their direct-to-consumer advertising and marketing and promotional materials detailed herein.

97. Beginning in May 2023, Mrs. Dwabe underwent several treatments using Defendants' CoolSculpting system for the intended purpose of breaking down fat cells in her upper and lower abdomen.

98. La Bella used the CoolSculpting system on Mrs. Dwabe in a reasonable and foreseeable manner and pursuant to the instructions for use accompanying the CoolSculpting system.

99. Following the final round of CoolSculpting treatments, Mrs. Dwabe noticed that the areas treated with the CoolSculpting System were getting larger not smaller.

100. Mrs. Dwabe was unaware that PAH was an adverse effect associated with use of the CoolSculpting system that will give the complete opposite effect of what she desired to achieve, that PAH was alarmingly common amongst CoolSculpting patients, and that to treat the effects of PAH, surgical intervention is necessarily required—not may be required.

101. Within a few months, Mrs. Dwabe developed hard, bulging, painful masses under her skin in those areas of her body treated with Defendants' CoolSculpting system.

102. In or around November 2023, Mrs. Dwabe was diagnosed with PAH by her physician.

103. In or around November 2023, Mrs. Dwabe was diagnosed with PAH by Defendants.

104. As a result of the PAH, Mrs. Dwabe's abdomen developed significant and abnormal growth in both the upper and lower sections, creating a pronounced and disfigured appearance. The PAH has caused these areas to expand rapidly, effectively splitting Mrs. Dwabe's abdomen into two distinct bulges.

105. This abnormal tissue growth and the resulting disfigurement have left Mrs. Dwabe with a misshapen and uneven midsection, drastically different from the intended smooth and contoured outcome.

106. The tissue overgrowth has also created folds and creases, exacerbating the disfigurement and contributing to an uncomfortable and unsightly appearance. These folds not only affect the aesthetic symmetry of Mrs. Dwabe's abdomen but have also led to chronic skin irritation and fungal infections, necessitating ongoing medical attention.

107. The unnatural bulging and splitting of her midsection has made everyday activities more challenging, further diminishing her quality of life.

108. Mrs. Dwabe's PAH also caused her tissue to become fibrinous and her skin to loosen, stretch, and sag, all sequela that several plastic surgeons have noted will require both liposuction and an abdominoplasty to resolve due to the seriousness of the injury.

109. The physical deformity caused by PAH has left Mrs. Dwabe self-conscious and distressed, impacting her mental and emotional well-being and leading to social withdrawal and a loss of self-esteem.

110. Mrs. Dwabe has also had to discontinue her employment because the physical and emotional toll of her condition has made it impossible for her to perform her job duties. The chronic pain, frequent medical appointments, and psychological distress have rendered her unable to maintain regular work attendance or productivity, leading to a loss of income and earning capacity.

111. Additionally, Mrs. Dwabe has been unable to fit into her clothes due to the abnormal growth and deformity of her abdomen, forcing her to frequently purchase new clothing and further contributing to her financial burden. The inability to wear her usual attire has deepened her feelings of frustration and humiliation, as she is constantly reminded of her condition.

112. The impact of PAH on Mrs. Dwabe's physical appearance and emotional state has severely affected her marital life. The disfigurement and associated mental health struggles have created a barrier between her and her spouse, leading to a significant decrease in intimacy and emotional connection.

Mr. Kefah Dwabe has also experienced a profound loss of companionship, affection, and support due to his wife's condition. The strain on their relationship has resulted in marital discord, adding another layer of distress to Mrs. Dwabe's already challenging situation.

113. Had Defendants properly disclosed and adequately warned physicians and consumers, including Mrs. Dwabe, of the known health risks and serious adverse effects associated with use of the CoolSculpting system, including the true incidence and occurrence rate of PAH following a completed set of CoolSculpting treatments, Mrs. Dwabe would not have pursued, chosen, or undergone CoolSculpting treatment.

B. Defendants' CoolSculpting System.

114. Defendants created, designed, developed, manufactured, distributed, labeled, advertised, marketed, promoted, and/or sold CoolSculpting as a "no surgery, no anesthesia, no downtime" alternative to liposuction surgery.

115. CoolSculpting is an elective, cosmetic treatment that purports to remove fat from the body, targeting those areas of the body where it is difficult to lose stubborn fat (i.e., abdomen, flanks, back and bra area, inner thighs, and the chin) through "cryolipolysis" or "fat-freezing."

116. Defendants' CoolSculpting works by pulling the flesh of the treated area between two paddles and cooling it to below freezing temperatures for a period of thirty minutes or more. When effective, the freezing technique causes the reduction of fat cells in the treated area.

117. Cryolipolysis is based on the theory that fat tissue is more vulnerable to cold temperatures than the skin; therefore, if cold is applied to a person's unwanted fat bulge, the cold temperature will kill the fat cells. Persons undergoing the procedure are expected to see "results" one to three months after the procedure, as the fat cells begin to wither away.

118. According to Defendants, the frozen, dead fat cells are absorbed by the body and excreted in the four-to-six-month period following the CoolSculpting procedure, leading to a promised "more contoured appearance" in the treated area.

C. CoolSculpting Is an Elective Cosmetic Treatment and Does Not Require a Medical Doctor to Prescribe or Administer.

119. According to Defendants, "the CoolSculpting procedure is not technique dependent, does not require significant training or skill and is largely automated."[28]

120. CoolSculpting does not require a medical doctor to administer. Indeed, it is offered and performed by dermatologists and estheticians – non-medical professionals who typically perform facials, hair removal, and other beauty and skin treatments – alike.

[28] U.S. Securities and Exchange Commission, Form 10-K Zeltiq Aesthetics, Inc. (2015) https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm (last visited Mar. 19, 2024).

121. A CoolSculpting provider must buy the CoolSculpting device and the consumable cards or cycles in advance from Defendants to operate the CoolSculpting System. The cards are essentially akin to a game token that must be inserted for the CoolSculpting device to work.

122. This structure creates a "pay to play" scheme where Defendants and CoolSculpting providers are financially invested partners in this multi-million-dollar industry.

123. Defendants utilize a "Practice Development Manager" to ensure that physicians meet sales quotas by initiating direct to consumer advertising as well as providing CoolSculpting providers with a clinic marketing package detailing specific practice protocols.

124. The protocols include branding and digital marketing tactics, sales pitches for physicians and/or providers to use, and recommends that these physicians and/or providers recommend additional CoolSculpting sessions to patients.

D. Paradoxical Adipose Hyperplasia

125. In 2007, Zeltiq became aware that CoolSculpting was causing some patients to develop a condition that results in the opposite effect of the device's advertised purpose—a permanent increase in the size of the treated fat bulges.

126. Paradoxical Adipose Hyperplasia ("PAH") is a permanent condition that is developed only as of the result of undergoing cryolipolysis via CoolSculpting.

127. PAH causes permanent pathological change to the microstructure of the tissue in the treatment area, affecting various types of cells, including adipocytes, vascular cells, blood cells, macrophages, endothelial cells, stem cells, and interstitial cells.

128. The tissue affected by PAH becomes fibrous, resulting in enlarged and sometimes hardened tissue masses that cause disfigurement. This fibrous tissue is dead tissue, not an overgrowth of healthy tissue, which must be surgically removed from surrounding healthy tissue.

129. PAH-affected tissue does not react the same to weight loss as regular fat. No matter how much weight a person loses after developing PAH, the affected area will never get smaller. The deforming effect of PAH remains permanently and can only be removed surgically.

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

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

132. Even with surgeries, a full reconstruction of the affected area is not guaranteed, and the long-term consequences of developing PAH are still unknown. A person with PAH is at risk for future health and aesthetic problems, including the return of the deformity years after surgery.

133. At this time, the only known prevention of PAH is abstaining from CoolSculpting.

E. Defendants Misrepresented the Risk of PAH, Repressed PAH Diagnosis, and Withheld Material Information on PAH Risk from Treatment Providers and Consumers

a. Defendants Failed to Communicate the Actual Incident Rate of PAH

134. Defendants market, promote, advertise, and sell the CoolSculpting System directly to consumers, through television commercials, radio commercials, magazine advertisements, social media, and Defendants' websites, as a non-invasive alternative to liposuction with "no surgery" and "no down time."

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

136. CoolSculpting claims that the fat reduction after the procedure is "long lasting", and that the device permanently kills targeted fat cells. It boasts, "Our experts spent years developing the treatment, which features one-of-a-kind technology that quite literally freezes and kills fat cells."[29]

137. Defendants, however, failed to adequately warn consumers and physicians of the risks the incidence and occurrence of PAH, a known and serious adverse effect where the targeted fat cells increase in number and size and grow larger after CoolSculpting treatment, forming hard, bulging masses under the skin. At the same time, Defendants withheld critical information about PAH from

[29] The Science of Fat Freezing, CoolSculpting, https://www.coolsculpting.com/what-iscoolsculpting/ (last visited Mar. 19, 2024).

CoolSculpting providers and financially entangled itself in the providers' CoolSculpting business by controlling the practice of medicine.

138. Since 2011, Defendants frequently and consistently received reports of consumers developing PAH after undergoing CoolSculpting procedures.

139. Defendants knew that out of all adverse events associated with the CoolSculpting device, PAH was the **most serious** and the **most frequently reported**.

140. PAH is the very opposite of the fat loss results that Defendants represent, promise, and warrant with their CoolSculpting System.

141. PAH requires invasive, corrective liposuction surgery to remove the masses that form as a result of CoolSculpting treatment.

142. Moreover, the masses that form as a result of PAH often reoccur even after a patient undergoes the necessary liposuction surgery to have the masses removed from her body.

143. Defendants contend that PAH is a rare and a temporary potential complication. But the CoolSculpting device can permanently damage the tissue in the area it targets causing healthy tissue to become fibrinous, creating a deformity on the patient's body much larger in size than the original "stubborn fat bulge."

144. The condition does not resolve on its own, and unlike regular fat tissue, tissue affected by PAH does not respond to weight loss. Thus, the only method of removing PAH is through invasive surgery. The condition is solely attributed to the CoolSculpting device.

145. Defendants named the condition "Paradoxical Hyperplasia" and still uses this term to describe the condition. Internally, Defendants have also referred to the condition as Paradoxical *Tissue* Hyperplasia.

146. In 2012, Defendants created their own diagnosis criteria for the condition, which they require CoolSculpting providers to use to diagnose PAH.

147. Defendants knew the risk of PAH associated with use of their CoolSculpting System but failed to adequately warn consumers and physicians and intentionally omitted and/or concealed material information about the incidence and occurrence of PAH following CoolSculpting treatment

and/or deemphasized the actual risk of PAH associated with use of the CoolSculpting System and the fact that invasive surgery would be required to treat any PAH that develops.

148. Although Defendants knew, since at least 2007, that PAH was a significant and serious adverse effect of its CoolSculpting device, Defendants failed to disclose these risks to the FDA until 2016, when they informed the FDA of six cases of severe PAH in the abdomen, back, and flanks, asserting the risk of PAH was 0.13% out of 4,792 treatments in published studies.

149. By 2013, Defendants knew that the disfiguring bulges had to be removed surgically, through procedures such as liposuction and included abdominoplasty, excision, and panniculectomy.

150. By 2013, Defendants calculated that the incidence rate of PAH had become 1 in 3,500 patients, demonstrating that the number of people developing the condition was increasing exponentially.

151. Defendants publicly claim that PAH is a rare adverse effect, occurring in 0.033% of treatments, or about 1 in 3,000.

152. But in recent years, it has become increasingly evident that Defendants manipulate statistics to underreport incidence rate and give patients a false sense of security.

153. Upon information and belief, Defendants' reported risk is based on number of treatment applications rather than the number of patients (with patients typically undergoing multiple treatment applications), creating the misconception that PAH risk from CoolSculpting was low.

154. As the New York Times explained: if 2 patients received 10 treatments of CoolSculpting, and 1 developed PAH, the manufacturers reported 1 in 20 (5%) treatments as the risk of developing PAH, even though 1 in 2 patients developed 50%.

155. Defendants advise and promote getting at least two treatments, and many providers suggest more, thereby exponentially increasing the patients' actual chances of ultimately developing PAH.

156. A multicenter study of 2,114 patients showed a per-patient incidence of PAH as high as 0.43%, more than ten times greater than the 0.033% risk originally stated by Defendants.[30]

[30] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8279305/

157. The per-treatment incidence rate was much higher. In a recent retrospective case series of 4 patients diagnosed with PAH after cryolipolysis at a large academic medical center calculated the incidence of PAH as 0.67%.[31]

158. In March 2016, a group of independent authors addressed the incidence rate of PAH as reported in the 2014 JAMA article, stating "Our reported [per patient] incidence is 0.78 percent [1 in 129], more than 100 times higher than the device manufacturer reported incidence of 0.0051 percent. Ours is not a unique experience, as a dermatology practice in Whiting, Texas, recently reported a paradoxical adipose hyperplasia incidence of 0.47 percent [1 in 213]. Although our treatment numbers are low when considering the popularity of the procedure, we believe that paradoxical adipose hyperplasia is underreported."[32]

159. Another independent study published in November 2017 found that although Defendants had reported thirty-three cases of PAH worldwide, estimating an incidence rate of 0.021%, the rate is "underestimated." The authors of the study, who were not associated with the manufacturer, found that the incidence rate of PAH in their study was 1% (4 out of 398 patients developed PAH). They noted that "many of the more than 2 million patients treated with cryolipolysis worldwide are affected by PAH."[33]

160. Though Defendants performed its own studies on PAH to determine the cause of the condition, the findings of these studies were never distributed to CoolSculpting providers. Defendants' intentional choice to misrepresent and understate the risk of PAH not only misled consumers about the safety and efficacy of CoolSculpting in favor of sales, but also deprived patients of the necessary information to make an informed decision about their health care by keeping that information out of the hands of treatment providers.

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[31] Cox EA, Nichols DS, Riklan JE, Pomputius A, Mehta SD, Mast BA, Furnas H, Canales F, Sorice-Virk S. Characteristics and Treatment of Patients Diagnosed With Paradoxical Adipose Hyperplasia After Cryolipolysis: A Case Series and Scoping Review. Aesthet Surg J. 2022 Dec 14.

[32] Emma Kelly et al., *Paradoxical Adipose Hyperplasia after Cryolipolysis®: A Report on Incidence and Common Factors Identified in 510 Patients,* 137 Plastic and Reconstructive Surgery 639e-40e (2016), https://pubmed.ncbi.nlm.nih.gov/26809032/.

[33] Stroumza, Nathaniel MD; Gauthier, Nelly MD; Senet, Patricia MD; Moguelet, Philippe MD; Nail Barthlemy, Raphael MD; Atlan, Michael MD. Paradoxical Adipose Hypertrophy (PAH) After Cryolipolysis. *Aesthetic Surgery Journal.* 2018; Vol 38(4): 411-417, 414. DOI: 10.1093/asj/sjxl59.

161. Defendants were aware of the actual incidence and occurrence of PAH, and other serious, adverse effects, and knew the liability it faced as a result at least as early as March 2013 when Zeltiq issued its 2012 10-K report to update its investors on its business activity and potential liability risks.

162. Defendants were also aware of their exposure – and the liability they faced – as a result of PAH associated with use of CoolSculpting and stated in their public filings: "We may also be subject to additional liability from claims related to known rare side effects such as late-onset pain, subcutaneous induration, hernia, and [PAH]. Product liability claims could divert management attention from our core business, be expensive to defend, and result in sizable damage awards against us. We currently have product liability insurance, but it may not be adequate to cover us against potential liability and it may be subject to material deductibles."[34]

163. Defendants went on to note in these SEC filings that "CoolSculpting may cause or contribute to adverse medical events that we are required to report to the FDA and if we fail to do so, we could be subject to sanctions that would materially harm our business." *Id.*

164. Defendants then reported to the SEC what it never reported in any of its advertising and/or marketing campaigns directed to consumers, including Mrs. Dwabe: "Rare side effects have been reported after receiving CoolSculpting treatments, such as late-onset pain, subcutaneous induration, hernia, and [PAH]."[35]

165. Defendants continued to report these "known rare side effects such as late-onset pain, subcutaneous induration, hernia, and [PAH]" in its subsequent public filings. However, in November 2016, Zeltiq's 10-Q updated their products liability contingency report to state:

> We **have historically been and continue to be predominantly self-insured for any product liability losses related to our products**. We currently have product liability insurance **to limit our exposure to these claims, but this insurance is subject to a cap reimbursement and, may not be adequate to cover us against all potential liability** and is subject to material deductibles. In addition, we may not be able

[34] U.S. Securities and Exchange Commission, Form 10-K Zeltiq Aesthetics, Inc. (2015) https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm (last visited Mar. 19, 2024).

[35] *Id.*

> to maintain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities.[36]

166. Despite their clear knowledge of the incidence and occurrence of PAH after use of the CoolSculpting System, Defendats failed to inform (or adequately warn) consumers, including Mrs. Dwabe, of the known risk of developing PAH as a result of using the CoolSculpting System.

167. Defendants continuously made affirmative representations in their direct-to-consumer advertising and marketing that the CoolSculpting System should be used by individuals seeking to avoid liposuction surgery by repeatedly using slogans like: "SAY **NO** TO SURGERY," "no surgery, no anesthesia, no downtime," "proven to be a safe and effective treatment for non-surgical fat reduction," and "eliminate stubborn fat without surgery."

168. Defendants failed to adequately warn and intentionally omitted and/or concealed material information about the serious health risks and adverse effects, including PAH, associated with use of its CoolSculpting System and/or the invasive surgeries that may be required to correct PAH following treatment, from consumers, including Mrs. Dwabe, in its direct-to-consumer advertising and overall marketing strategies and sales practices.

b. PAH Risk Was Suppressed in Provider Trainings

169. Defendants used PDMs to provide training to Mrs. Dwabe's CoolSculpting provider and inform the provider about PAH.

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

[36] U.S. Securities and Exchange Commission, Form 10-K Zeltiq Aesthetics, Inc. (2016) https://www.sec.gov/Archives/edgar/data/1415336/000162828017002057/zltq-12312016x10k.htm (last visited Mar. 19, 2024).

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

172. The presentation slide that described PAH used the term "Paradoxical Adipose Hyperplasia" even though Defendants knew that PAH was not an increase in healthy fat cells. In the slide, Defendants also misrepresented PAH as an "increase in subcutaneous adipose tissue," despite knowing that PAH causes fibroplasia or fibrosis of the subcutaneous tissue. Furthermore, the slide also inaccurately stated that "surgical intervention **may** be required," though the Defendant knew that surgery is required.

173. Defendants did not allow the PDMs to discuss PAH in detail with providers that posed specific questions. PDMs were instructed by Defendants to present only the misleading information about PAH from the training slide.

174. Through its training slide presentation, Defendants assured providers that the CoolSculpting device precisely targets fat cells and does not damage surrounding tissue or structures.

175. During training, Defendants PDMs verbally told CoolSculpting providers that the likelihood of CoolSculpting patients developing PAH is very low and that they would be unlikely to see a case of PAH in their practice.

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

177. Despite Defendant's extensive knowledge about PAH, the information released to CoolSculpting providers was de minimis and deceptive.

178. Importantly, Defendant did not provide information regarding PAH to CoolSculpting providers prior to their purchase of the medical device.

179. After the devices were purchased, Defendant downplayed the severity, permanency, and frequency of PAH to CoolSculpting providers.

180. Defendant also advised CoolSculpting providers not to mention "Paradoxical Adipose Hyperplasia" or "PAH" to patients who requested an evaluation for the condition until the

Defendant's claims department had an opportunity to review the patients' medical records and "confirm" the diagnosis.

181. Due to Defendant's failure to adequately warn CoolSculpting providers about PAH, the providers did not have an accurate understanding of the condition and were unable to properly inform their patients about its risks.

182. Due to Defendant's failure to adequately warn CoolSculpting providers about PAH, the providers did not have an accurate understanding of the condition and were unable to properly inform their patients about its risks.

183. Moreover, Defendant was aware that CoolSculpting providers did not understand PAH and were not properly informing their patients about the possibility of developing this serious condition after CoolSculpting. Defendants' direct communications with persons who developed PAH and posts from personal accounts online clearly demonstrated that CoolSculpting patients were not adequately informed on the risk of developing the condition.

184. Contrary to the statistics cited by CoolSculpting providers, a recent study suggested that the incidence rate of PAH in CoolSculpting patients is closer to 1 in 100, or 1%. Adverse events with an incidence rate of 1% or higher are considered "common," not rare, by the World Health Organization.

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

c. Defendants Used a "Medical Safety Team" To Suppress The Diagnosis of PAH

185. Defendants took an active role in helping CoolSculpting providers diagnose PAH and mitigated the provider's liability exposure by offering the patients a refund or a paid for single liposuction treatment in exchange for a release of liability.

186. Since PAH is a condition that was largely unknown by the medical community, CoolSculpting providers relied exclusively on Defendants for information about the condition.

187. Defendants guided providers in determining whether the patient should be diagnosed with PAH through its "Medical Safety Team." Defendants' employees reviewed the patients'

medical information and photographs and suggested to the CoolSculpting providers whether a patient should be diagnosed with PAH.

188. Defendants' "Medical Safety Team" did not examine any patients. Instead, they essentially diagnosed patients without performing any diagnostic tests or examination.

189. Defendants implemented a system that turned the adverse event reporting process into a de facto claims process. Defendants instructed providers to submit Clinical Event Forms and other documents, including a copy of the consent form signed by the patient that describes PAH.

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

191. Defendants designed a treatment "program" for patients that developed PAH. The Defendants offered to cover the cost of **single** liposuction surgery or give a refund for the CoolSculpting treatment in exchange for a release of liability for any future damages associated with the patients' PAH. Defendants included the CoolSculpting providers as parties released from liability in the settlement agreements.

192. Through the adverse event reports and its treatment program, Defendants became a centralized hub of information about PAH.

193. Through this program, Defendants had direct communications with CoolSculpting providers and CoolSculpting patients that developed PAH, allowing Defendants to collect information not available elsewhere.

194. Through this program, Defendants knew that the CoolSculpting providers used CoolSculpting consent forms that were either identical to or mirrored the language drafted by the Defendants in regard to PAH, which did not accurately represent the condition to the patients.

195. Through this program, Defendants provided assurance to CoolSculpting providers that if their patient developed PAH after CoolSculpting, the manufacturer would cover the cost to fix the condition.

196. Through this program, Defendants falsely led CoolSculpting providers to believe that a single liposuction surgery could successfully resolve patients' PAH.

197. If a CoolSculpting patient reported PAH directly to Defendants, Defendants required the patient to return to their CoolSculpting provider and request an evaluation of their condition.

198. Defendants instructed CoolSculpting providers to follow an extremely specific protocol for diagnosing patients with PAH, which resulted in many patients not being diagnosed with PAH despite suffering tissue damage. Defendants' diagnosis protocol only recognized fulminant cases with well demarcated masses as PAH, relying on the physicians' hand palpation of the affected tissue and a visual review of photographs taken of the patient before the procedure.

199. If the CoolSculpting providers did not agree to cooperate with the CoolSculpting patients in diagnosing PAH, the patients were left on their own. In many cases, patients sought medical evaluation from providers that did not have any experience with the CoolSculpting device, lacked knowledge about PAH, and could not effectively diagnose or treat the condition.

200. CoolSculpting providers benefited directly from Defendants' refund or free liposuction program because they were released from liability for future damages if the patient accepted the offer.

201. The liposuction program also incentivized CoolSculpting providers to fraudulently conceal the risk of PAH from the public, including Plaintiff. The liposuction program would refund patients or pay for them to undergo one liposuction procedure to correct the effect of PAH in exchange for a release of liability benefiting both the Defendants and the provider.

202. Not only did the "liposuction program" indemnify CoolSculpting providers, but it also misled CoolSculpting providers to believe that PAH was a condition that could be successfully corrected with a single liposuction procedure, if required, and assured the physicians and/or clinics they had no risk of liability to CoolSculpting patients.

203. And if the CoolSculpting provider was a plastic surgeon, the provider would benefit directly from the patient's development of PAH because Defendants would offer to pay the provider to correct the condition through plastic surgery.

204. Defendants' treatment program was insufficient to cover the true losses suffered by CoolSculpting patients. Defendants did not cover the cost of travel for surgery, any other surgeries required to remove PAH, lost wages during recovery, or any other damages directly resulting from the injury caused by their CoolSculpting device.

205. Defendants' conduct of suppressing PAH diagnosis with a "Medical Review Team" and its refund or free liposuction treatment program violates the duty to report adverse events to the FDA and/or voluntarily recall the CoolSculpting System.

d. Defendants Failed to Provide Accurate PAH Incident Data to the FDA

206. Defendants additionally downplayed the seriousness, permanency, and frequency of PAH to the FDA.

207. On March 14, 2016, Defendants submitted a 510(k) Summary of Safety and Effectiveness report to the FDA, citing to "literature review" and reporting that there have been only "6 cases" of "serious adverse events" which include PAH. But by 2016, Defendants were aware of thousands of PAH reports. Accordingly, Defendants failed to report all known incidents of PAH to the FDA, despite the FDA's repeated requests to do so.

208. PAH is a reportable adverse event under 21 C.F.R. § 803 due to the permanency and severity of the condition, and because surgical intervention is the only means to resolve it.

209. Since the CoolSculpting device went on the market through September 2019, Defendants have received thousands of reports of PAH. Defendants reported less than 70 to the FDA's public database, MAUDE (Manufacturer and User Facility Device Experience).

210. By failing to report, Defendants maintained exclusive control of the information about the number of patients suffering from PAH after CoolSculpting, as providers and the public cannot independently obtain the most current data via the FDA's public database.

F. Defendants Mislead Providers as to the Severity of PAH

211. Although Defendants provided some information regarding PAH to CoolSculpting providers, the information was misleading and led providers to believe that the condition causes a rare minor side effect which is not likely to occur or reoccur. The language used by Defendants did not relay the seriousness, permanency, and frequency of the condition.

212. Defendants' inadequate disclosure about PAH failed to inform the CoolSculpting providers that: (i) PAH is the opposite effect of CoolSculpting's advertised purpose of fat reduction; (ii) PAH is a disease of the tissue; (iii) CoolSculpting can damage the tissue of the treated area; (iv) PAH results in a physical deformity; (v) a single patient can suffer multiple deformities on the body from PAH; (vi) the deformity will never resolve on its own because it is permanent; (vii) PAH changes the microstructure of the tissue; (viii) multiple invasive surgeries are required to remedy the PAH affected tissue; (ix) surgery may not resolve PAH affected tissue; (x) CoolSculpting can cause cutaneous tissue laxity requiring surgery to cut, lift, and sew the skin; (xi) PAH has a wide range of physical effects on the body including lymphatic system issues; (xii) the frequency of occurrence of PAH is not rare and thousands of people have suffered from the condition after undergoing CoolSculpting; (xiii) PAH was the most commonly reported adverse effect of CoolSculpting; (xiv) CoolSculpting was FDA-cleared, which is not synonymous with FDA-approved.

213. Defendants falsely told CoolSculpting providers that using the device's smaller sized applicators eliminated or significantly reduced the occurrence of PAH.

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

215. Defendants knew that one liposuction treatment would not remedy PAH, and that multiple invasive surgeries would be required to do so.

216. Defendants kept record of the reported incidents of PAH which included important data such as place of treatment, date of treatment, area(s) of the body affected, date PAH was diagnose. This data gave Defendants key information about the incidence rate of the condition.

217. In 2012, soon after Defendants discovered that the CoolSculpting device could cause the development of PAH, Defendants commissioned the inventor of the cryolipolysis process, Dr. R. Rox Anderson and his colleague at Massachusetts General Hospital, Dr. Mathew Avram, to author a document about this serious and permanent adverse effect, to which Defendants referred to as the "White Paper."

218. The White Paper described PAH as follows: "[r]ecently, the manufacturer received eleven separately confirmed reports of patients who developed growth of soft tissue in the treated

site(s) over several months following treatment. The soft tissue growth is painless, firm, and visibly enlarged within the treated areas. The enlargement typically started two to three months post treatment, often after the expected reduction in fat, becoming visibly evident at four to five months post treatments. Because the soft tissue enlargement is a rare, unexpected growth of subcutaneous fat tissue, this phenomenon is being termed 'paradoxical hyperplasia.'"[37]

219. The White Paper also warned that "[p]atients who are considering undergoing this procedure should be counseled on the possibility of its occurrence, as well as the surgical options available should it occur."[38]

220. Defendants kept the White Paper a secret from CoolSculpting providers and did not disclose the document unless a provider insisted on obtaining additional information about PAH after one of their patients developed the condition.

221. In some instances, Defendants even required the CoolSculpting providers to sign a confidentiality agreement before it disclosed the White Paper.

222. When Defendants did share the White Paper with providers, it always disclosed the November 30, 2012, version of the document, which acknowledged only eleven cases of PAH and was never updated to include the most current information.

The White Paper, although more informative than the device's User Manual and Defendants' training presentations, was outdated and inadequate, failing to disclose the true risks of PAH.

G. Defendants Pressured and Incentivized Treatment Providers to Downplay PAH Risk

a. Aggressive Marketing Required CoolSculpting Providers to be Business Partners and/or Agents of Defendants

223. Zeltiq introduced the CoolSculpting System in 2011 and by the second quarter of 2012 had sold 84,072 treatment cycles. Zeltiq's 2016 SEC filings revealed that Zeltiq employed two different marketing groups, which identified 28.6 million consumers who would be interested in learning more about the CoolSculpting procedure after reading the product description.

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[37] R. Rox Anderson, MD & Matthew Avram, MD, Paradoxical Hyperplasia: A Rare Side Effect associate with Cryolipolysis 1 (2012), https://skinrenu.com.au/wp-content/uploads/2017/03/13.PH-white-paper-FINAL.pdf.

[38] *Id.* at. 4.

224. Based on market research, Zeltiq realized they were out of sync with market demand, reporting only 135,000 non-invasive fat reduction procedures in 2014. Zeltiq told investors: "when we compare our potential audience to the number of procedures conducted we find that our market penetration is lower than 1%."[39]

225. Zeltiq subsequently adopted an aggressive strategy to partner with physicians through a pricing model that rewarded overselling CoolSculpting procedures.

226. Beginning in 2014, Zeltiq laid out a methodical plan to selectively market and sell the CoolSculpting system, to dominate the body contouring market by simultaneously establishing cooperative customer partnerships (with physicians) and a direct-to-consumer program.

227. Zeltiq expanded its cooperative customer partnership program in 2016.

228. Zeltiq also implemented a five-step practice marketing program designed to help establish "best practices" relating to patient treatment, staff treatment, front desk operations, and internal and external marketing-essentially controlling the physician's practice.

229. At the core of this five-step program is Treatment-to-Transformation, or T2T, a customized assessment and treatment protocol, which Coolsculpting claims revolutionized the way customers use CoolSculpting to deliver improved outcomes and high patient satisfaction.

230. Effectively, Zeltiq controlled and implemented its own sales system in clinical physician practices.

231. By way of example, in late 2013, Zeltiq launched the first CoolSculpting training programs, CoolSculpting University ("CSU") to train non-medical and medical professionals in "the proper techniques for T2T, including a complete treatment assessment, applicator placement and patient consultation. Customers are also trained on specific practice enhancement execution protocols designed to accelerate utilization and maximize the use of their CoolSculpting offering that includes branding, grassroots initiatives and digital marketing tactics."[40]

[39] *Id*.

[40] *Id*.

232. CSU's curriculum included hands-on education, live treatments, and lecture-style presentations.

233. In 2015, Zeltiq hosted over 1,800 medical professionals from 865 offices worldwide at their CSU programs. Zeltiq held CSU trainings in Pleasanton, California and Reston, Virginia.

234. Zeltiq also hosted nine satellite CSU programs internationally in 2015.

235. Defendants have awarded several non-medical professionals a "CoolSculpting University Masters" and expressly allow and encourage the non-medical professionals to market themselves as a CoolSculpting Master Specialist to the general public.

236. As a result of these co-partnerships, Zeltiq's revenue increased from $255.4 million in 2015 to $354.2 million in 2016, a 38.7% increase.

b. Defendants Control CoolSculpting Providers' Messaging and Patient Information

237. Defendants also instruct both medical and non-medical professionals on how to engage patients, perform patient consultations, and sell CoolSculpting.

238. In Defendants' promotional brochure, "Preparing Your Practice for CoolSculpting," Defendants specifically instruct practices to prepare their staff with "CoolSculpting talking points" and a "phone script" to control the narrative surrounding CoolSculpting, such as:

> **"The Main CoolSculpting Message"** CoolSculpting is the safe, non-invasive way to reduce fat in common trouble areas that tend to be diet- and exercise-resistant;
>
> **"What happens during the procedure?"** Using a technology developed by Harvard scientists, CoolSculpting targets and freezes fat cells causing their natural death in the treatment area. It's completely non-invasive so there is no cutting, no needles and no anesthesia; and
>
> **"Is CoolSculpting safe? Painful? Are there side effects?"** CoolSculpting is medically cleared for the flanks and proven safe. Some patients may experience temporary pain or discomfort.

239. In Defendants' promotional brochure, "Reaching Your CoolSculpting Patient Segments," Defendants advise healthcare professionals on how to sell CoolSculpting to patients.

> **NO SURGERY. NO DOWNTIME. UNMISTAKABLE RESULTS** . . . the CoolSculpting procedure requires no surgery or downtime, so you're in and out of the office like always;

> **LET US INTRODUCE YOU TO SIMPLE NEW WAYS TO LOOK YOUR BEST, NO SURGERY REQUIRED** . . . the CoolSculpting procedure helps eliminate stubborn fat by freezing fat cells, safely and simply. Non-surgical treatments don't require downtime . . . .; and
>
> The CoolSculpting procedure eliminates fat cells safely and simply, without surgery or down time.

240. In a document prepared by Defendants entitled "CoolSculpting Consumer FAQ – US" that was labeled confidential and not for distribution, Defendants provided a Q&A about CoolSculpting that Defendants "intended to guide CoolSculpting Center physicians during media interviews." Among other things, Defendants stated that:

> **Q**: HOW DO PATIENTS FIND DOCTORS THAT OFFER COOLSCULPTING?
> **A**: CoolSculpting is made available only to premiere accredited doctors and treatment centers. Current distribution consists of dermatologists, plastic surgeons and other aesthetic specialists.... ZELTIQ encourages consumers to do their homework and ensure they accept no substitutes for CoolSculpting.
>
> **Q**: IS COOLSCULPTING SAFE? PAINFUL? SIDE EFFECTS?
> **A**: CoolSculpting is safe and generally comfortable for most patients … Approximately 50 reported cases out of 115,000 treatments, patients experienced more severe pain during and/or after treatment … In 100% of cases, pain has naturally subsided over time and there have been no long-term effects of treatment.
>
> **Q**: WHAT CAN PEOPLE EXPECT IN TERMS OF FAT REDUCTION – WHAT IS THE AVERAGE OUTCOME?
> **A**: In all CoolSculpting cases, patients will experience an undeniable reduction in fat in the area treated.

241. Defendants' narratives and promotional materials encouraged CoolSculpting providers to stress the safety, efficacy, and noninvasive nature of the CoolSculpting System and to minimize any possible side effects to "temporary pain or discomfort."

c. CoolSculpting Providers are Incentivized to Upsell CoolSculpting Treatments.

i. Rewards Program

242. A CoolSculpting provider must make a substantial upfront investment when purchasing a CoolSculpting device, and the device is specifically programmed to function only with

the use of consumable cards, or "cycles," that a provider must purchase in advance from Defendants to operate the CoolSculpting device at an average cost between $650 to $800 per cycle.

243. The CoolSculpting provider's financial investment in CoolSculpting and consumable cards, or "cycles," incentivizes the provider to upsell its CoolSculpting services and seek out clients on whom they can use the device and not exercise independent judgment based on the patient's needs.

244. Zeltiq created a rewards program which is both a marketing tool and client membership program, complete with an app where patients can monitor their account points and redeem points for CoolSculpting.

245. As part of the program, Defendants had patients sign a HIPAA release which, unknown to the patient, was used by Practice Development Managers ("PDMs") to shop the client to CoolSculpting providers.

246. Once the patient information was shared with a local physician partner, the patient received marketing materials from the physician partner and Defendants. The rewards program was aggressively used by Defendants' PDM to develop and grow physicians' CoolSculpting practices as well as to regulate pricing. The rewards program created a brand exclusive customer base and simultaneously exerted complete control over the pricing and physicians.

247. Potential patients sign up for the rewards program to gain a free cycle of CoolSculpting. However, Defendants also provided physicians with scripts to induce patients to treat other areas of the body and purchase additional cycles.

248. Strict physician compliance was demanded by the PDM, who had the power to punish physicians who offered lower pricing for CoolSculpting.

249. Defendants effectively became a business partner of each physician's practice and pricing could not be changed without the Defendant's permission.

250. Clients could not begin a cycle of treatment unless their physician or other provider uses the CoolConnect card which activates the Freeze-Detect software technology to provide the cycle of treatment.

251. The physician and Defendants share in the profits for each cycle. The financial interest of the physician coupled with scripted sales pitches from Defendants removed any independent medical decision making about the safety and efficacy of CoolSculpting.

ii. Control of Provider Profits

252. The global non-invasive fat reduction market size was estimated at $992.5 million in 2019 and is anticipated to register a compound annual growth rate of 16.4% from 2020 to 2027.

253. Defendants have masterminded a price-fixing system where they inject themselves into the provider's CoolSculpting practice and become entangled in the patient's medical treatment so they can control pricing and dominate the fat reduction market.

254. Defendants sell physicians the CoolSculpting machine and "CoolCards" starter packs for $189,062.50.[41]

255. Physician Partners purchased CoolCards to receive benefits from the Crystal Program. The Crystal Rewards program is comprised of three tiers (Crystal, Preferred Crystal and Premier Crystal), each with a distinguishing set of benefits based on CoolCard purchases.

256. CoolCards are inserted into the applicator to authenticate each CoolSculpting treatment. Qualifying practices will receive rebates on CoolCard purchases ranging from 2.5%-20% as well as special designation and listing status on coolsculpting.com's physician locator.[42]

257. Defendants also enticed physician partners by offering to pay for 50% of the physician's advertising costs to promote CoolSculpting—advertising that ultimately benefits Defendants through increased sales.[43]

258. The CoolSculpting business system is strategically designed to financially benefit both the physician owner of the device and the Defendants.

259. Defendants make more money selling the consumable cards to CoolSculpting providers than selling the actual CoolSculpting devices. In 2018, Allergan earned $235.3 million

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[41] *Tcheupdjian v. Zeltiq Aesthetics, Inc*., 1:16-cv-06787, DKT. 1, Compl. at 3.

[42] BusinessWire, ZELTIQ Aesthetics Introduces Crystal Rewards Program (2012) https://www.businesswire.com/news/home/20120821005567/en/ZELTIQ%C2%AE-Aesthetics-Introduces-Crystal-Rewards-Program (last visited Mar. 19, 2024).

[43] *Id.*

selling consumable cards and $126.3 million selling the CoolSculpting devices and applicators.[44] By controlling the consumable cards, the Defendants retains control of the CoolSculpting provider's clinical practice.

260. Defendants also closely controlled and continue to control the CoolSculpting providers' sales methods and pricing of CoolSculpting cycles. During training on the device, Defendants devote a substantial part of the training time boasting about the device's potential to substantially increase the providers' revenues and how to increase CoolSculpting sales by using various sales tactics.

261. Defendants' training materials include sample scripts to use on prospective CoolSculpting patients and describe upselling methods such as having the patients return for a "follow-up appointment" where the provider has an opportunity to sell additional cycles, or by pre-selling CoolSculpting packages where the patient pays for multiple cycles in advance for future uses.[45]

262. Defendants installed a cellular device inside each CoolSculpting machine that automatically reports information about each cycle administered by CoolSculpting providers directly to Defendants.

263. This platform, which is called CoolConnect, is used by the Defendants to obtain data from the CoolSculpting devices and use it to pressure CoolSculpting providers to sell more procedures.

264. According to Keith Sullivan, Zeltiq's former CEO, "[i]n this way, we know what we are doing, and we can show [the CoolSculpting providers] how they are doing such as if you're only

[44] Allergan, Allergan Reports Fourth Quarter and Full-Year 2018 Financial Results, https://allergan.gcs-web.com/news-releases/news-release-details/allergan-reports-fourth-quarter-and-full-year-2018-financial (last visited Mar. 19, 2024).

[45] Guidelines for CoolSculpting Success, https://docplayer.net/docview/26/9289425/#file=/storage/26/9289425/9289425.pdf (last visited Mar. 19, 2024).

treating flanks, why aren't you looking at their belly, and so on. The PDM has the data to bring back to those accounts on a monthly or quarterly basis and follow their progress."[46]

265. Likewise, at all times material, Defendants controlled how the CoolSculpting providers advertised their CoolSculpting services. Defendants established a minimum advertised price policy, restricting providers from independently setting and advertising prices for the CoolSculpting procedure and penalized providers that advertised a lower price for their CoolSculpting services.[47]

266. The physician and/or clinic pays Defendants a portion of the cycle price charged to the consumer for the CoolSculpting procedure, establishing the procedure as a clear joint venture between the healthcare provider and Defendants.

H. Defendants Misled Consumers Through Pervasive Direct Consumer Marketing

267. The CoolSculpting System has received substantial press coverage in the national media since its clearance by the FDA for non-invasive, cosmetic body-contouring, including features on television shows such as *The Today Show, Good Morning America, The CBS Early Show, The Rachel Ray Show, The Dr. Oz Show, Extra, Nightline, The Doctors,* and *E! News,* and in magazines such as *O, Elle, Marie Claire, Allure, Men's Fitness, Town & Country, Elevate, W,* and *Vie.*[48]

268. Defendants operated and still operates a website www.coolsculpting.com where they advertise CoolSculpting directly to the public and refers prospective patients to CoolSculpting providers in their geographical area.

269. In addition to intensely marketing the CoolSculpting device to the general public, Defendants aggressively pursue doctor's offices, medical spas, laser hair removal clinics, and other cosmetic procedure establishments to sell its CoolSculpting System device and induce them to add CoolSculpting to their list of medical procedures provided to their cosmetic patients.[49]

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[46] Wendy Lewis, *Fat Chance Building a Better Body the Cool Way,* Prime Journal (May 18, 2016), https ://www.prime-j oural.com/fat-chance-building-a-better-body-the-cool-way/.

[47] *Id.*

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

[49] U.S. Securities and Exchange Commission, Form 10-K Zeltiq Aesthetics, Inc. (2015) https://www.sec.gov/Archives/edgar/data/1415336/000162828016012690/zltq-12312015x10k.htm (last

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

271. Defendants' relationship with CoolSculpting providers differs from traditional relationships between medical device manufacturers and device users.

272. After a consumer sees a CoolSculpting advertisement, he or she is directed to visit www.coolsculpting.com, which refers the consumer to a local CoolSculpting provider. When a consumer arrives at a CoolSculpting provider's office, he or she sees CoolSculpting posters and brochures which describe the benefits of the CoolSculpting procedure.

273. The provider sells the procedure to the consumer using specific sales techniques according to the training that Defendants provided. The provider uses special forms depicting the CoolSculpting trademark logo in administering the procedure.

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

275. In 2012, Defendants launched "targeted and strategic" direct-to-consumer advertising campaigns, including social media, targeted blogs, television, radio, and print media to "generate awareness of CoolSculpting among aesthetic veterans and aesthetic neophytes" and "drive demand for CoolSculpting."

276. In 2015 "to further enhance and expand…brand awareness," Defendants launched a second large scale direct-to-consumer advertising campaign with the purpose of "build[ing] awareness in the marketplace by having consumers (a) go to existing local practices and request treatment and drive consumable revenue, or (b) go to their local physician who does not yet have consumable services, create the desire and drive system revenue."

277. Defendants' stated strategy was to drive consumer demand to induce providers to purchase a CoolSculpting System for use on the consumers who demanded the services.

visited Mar. 19, 2024).

278. In their CoolSculpting Consumer FAQ, Defendants explained to CoolSculpting providers that "Zeltiq encourages consumers to do their homework and ensure they accept no substitutes for CoolSculpting."

279. Defendants' direct-to-consumer marketing and advertising campaigns had the intended effect: consumers, including Mrs. Dwabe, learned about the CoolSculpting System through Defendants' aggressive direct-to-consumer advertising and marketing campaign and, like Mrs. Dwabe, made a decision, based on the information provided them by Defendants, to undergo CoolSculpting treatment.

280. Defendants' website even included a database of CoolSculpting providers that consumers could search using their city, state, or zip code to locate a provider where they could obtain CoolSculpting treatments.

281. Defendants directed and encouraged consumers, including Mrs. Dwabe, to seek out treatment using the CoolSculpting System and "accept no substitutes." CoolSculpting Consumer FAQ.

282. Defendants did not advise, encourage, or recommend consumers, including Mrs. Dwabe, to consult with his or her physician or CoolSculpting provider to determine whether CoolSculpting was the best treatment to achieve the consumer's weight loss goals based on his or her particular health needs.

283. In Defendants' "Fear No Mirror" direct-to-consumer campaign, in or around 2014 and 2015, Zeltiq made the following representations to consumers:

> The CoolSculpting procedure shapes what you see without surgery or downtime, so you'll look great from every angle;
>
> CoolSculpting technology safely delivers precisely controlled cooling to gently and effectively target the fat cells underneath the skin while leaving the skin itself unaffected. The treated fat cells are crystalized (frozen), then die. Over time, your body naturally processes the fat and eliminates these dead cells leaving a more sculpted you. No surgery, no anesthesia, no downtime.
>
> The CoolSculpting procedure is non-surgical, safe, effective, and best of all, the results are long-term.

284. Defendants' direct-to-consumer television and video ads made similar representations that CoolSculpting was safe and effective and intentionally omitted any mention of the incidence and occurrence of PAH following treatment (or how it is calculated):

> Defendants' 2015 CoolSculpting commercial ended with the text "it's as easy as getting a pedicure," commented that "rare side effects may occur," stated "typical side effects include temporary numbness, discomfort, and swelling," and made no mention of the incidence or occurrence of PAH despite their knowledge of the same, https://vimeo.com/126871210;
>
> Defendants' 2018 CoolSculpting commercial made no mention of any side effect, while again touting results without surgery, https://vimeo.com/283096862;
>
> Defendants' 2020 CoolSculpting commercial warned that rare side effects may occur, but does not mention the incidence or occurrence of PAH or that surgical correction is required, https://www.ispot.tv/ad/ZJZN/coolsculpting-you-crush-hills; and
>
> The video that Defendants prepared and posted to their Vimeo webpage celebrating its receipt of a NEWBEAUTY AWARD represents "NO SURGERY NO DOWNTIME" and does not indicate any incidence or occurrence of adverse effects, like PAH, https://player.vimeo.com/video/238677979.Xzz

285. Defendants also maintained a Facebook page where it interacted with consumers directly and made similar representations that CoolSculpting was safe and effective and intentionally omitted any mention of the incidence and occurrence of PAH following treatment:

> A July 29, 2015 post by ZELTIQ contains a patient testimonial that they were "SO GLAD THAT [THEY] TRIED THE COOLSCULPTING PROCEDURE BEFORE CONSIDERING A TUMMY TUCK OR LIPO. SURGERY AND THE RECOVERY TIME WOULD HAVE PUT ME OUT MONTHS, WHICH I COULD NEVER DO WITH WORK AND KIDS" with ZELTIQ's explanation that "the CoolSculpting procedure is perfect for those on-the-go because there is no surgery and no downtime!"; and
>
> A September 28, 2015 post by ZELTIQ represents that "with no downtime, Molly [Sims] can continue her job as a mom and supermodel post-procedure!"

286. Defendants' direct-to-consumer advertising, marketing, promotion, and/or sales practices misrepresents to consumers, including Mrs. Dwabe, that the CoolSculpting System is safe and effective for its intended use and omits material information by failing to disclose known health risks, including the incidence and occurrence of PAH following treatment.

287. Defendants' direct-to-consumer advertising was successful and Defendants reported in their 2015 10-K, p.15, that "CoolSculpting website traffic significantly increased in those markets, and local CoolSculpting providers experienced a significant increase in patient interest and treatments."

288. As a result of Defendants' failure to warn of the known health risks and serious adverse effects associated with use of its CoolSculpting System in their advertisements and marketing materials, those persons who used it, including Mrs. Dwabe, have suffered and may continue to suffer severe and permanent personal injuries, including, but not limited to, PAH.

I. Defendants Have Repeatedly Misrepresented the Nature and Scope of CoolSculpting's FDA Approval

289. Defendants have continuously and repeatedly advertised CoolSculpting as "the only non-invasive treatment FDA-cleared to freeze fat away. CoolSculpting targets unwanted fat so your body can eliminate it naturally – without surgery or downtime." Yet CoolSculpting has never received FDA approval as a method of "freezing fat," or indeed removing fat whatsoever.

290. CoolSculpting is a Class II medical device, as defined and categorized by the U.S. Food and Drug Administration ("FDA").

291. On or about May 31, 2006, the FDA first cleared CoolSculpting to be used as a skin cooling device to minimize pain and thermal injury during laser and dermatological treatments and as a local anesthetic for procedures that induce minor local discomfort. On or about August 24, 2010, the FDA cleared CoolSculpting to be used to induce lipolysis only for the flank area. On or about May 2, 2012, the FDA expanded its clearance for CoolSculpting to include inducing lipolysis in the abdomen.

292. The FDA has only approved CoolSculpting as a medical device that "reduce[s] the appearance of cellulite." No peer-reviewed studies, FDA reports, or any other authority support the premise that CoolSculpting "kills fat cells."

293. Notwithstanding, Defendants have launched a fraudulent marketing campaign that mischaracterized the FDA approval of CoolSculpting for "reducing the appearance of cellulite" into a full-scale misbranding of the device as capable of "[k]illing fat cells".

294. On October 25, 2016, Andrea Levine, Esq. representing the National Advertising Division ("NAD"), referred the untruthful advertising claims about CoolSculpting to the Federal Trade Commission.

295. Zeltiq agreed to discontinue fat elimination claims and follow most but not all the NAD's other recommendations. The NAD referred the matter to the FTC because Zeltiq refused to add the NAD's recommended disclosures to its advertising.[50]

296. In addition to mischaracterizing the FDA's clearance, Defendants' CoolSculpting device cannot ensure that any of the fat cells it targets will actually die and even if some fat cells did die, the effects are minimal and temporary.

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

298. When the CoolSculpting device does not kill the fat cells it targets during the procedure, and the cells survive the cryo-assault of CoolSculpting, the tissue goes into cellular adaptation mode.

299. The FDA approval specifically states that all device labeling must be truthful and not misleading.

300. Zeltiq coined the term CoolSculpting which is a marketing word for the scientific term "cryoliposis" or "freezing fat," a theory that cold temperatures will cause the slow death of fat cells

[50] https://www.ftc.gov/system/files/documents/public_statements/994093/coolsculpting_resolutio_letter.pdf

over a one-to-three-month period which will cause a visual reduction in fat bulges. However, in trials, no studies were performed to confirm a reduction in fat cells.

301. A 2012 National Clinical Trial was done to evaluate the feasibility of using cryoliposis on the inner thigh area. One of the problems with the study is how fat reduction was measured. The non-invasive reduction of the inner thigh study merely showed physicians' images of pre and post treatment areas of 45 female trial study participants. Efficacy and safety in male patients were not analyzed in this trial.

302. Additionally, trial participants were asked to maintain their weight and not lose or gain more than 5 pounds during the course of the study. Although follow-up visits were done over a 16-week period, the study does not document patient weight changes.

303. Success was defined as ultrasound confirmed 1mm or greater reduction in fat layer thickness for the treated region. An ultrasound was used to estimate the body fat percentage of clinical trial participants based on the assumption it correlates closely with those of DEXA in both females (r= 0.97, standard error of the estimate = 1.79) and males (r = 0.98, standard error of the estimate = 0.96).

304. A DEXA Scan is a dual-energy absorptiometry scanner that provides the body's composition of muscle and fat.

305. For the NCT 2012 study, success for CoolSculpting of the Inner Thigh was defined as a 1 mm reduction in fat thickness. A 1 mm reduction is the size of the tip of a pencil.

306. For the NCT 2012 study, success for CoolSculpting of the Inner Thigh was defined as a 1 mm reduction in fat thickness. A 1 mm reduction is the size of the tip of a pencil.

307. Defendants exceeded the scope of the FDA label by misrepresenting that fat loss should be expected, by advertising and continuing to advertise CoolSculpting as a "nonsurgical" procedure intended to reduce stubborn fat bulges with "up to 20-25% reduction in fat layer thickness after a single session."[51]

[51] Coolsculpting, https://www coolsculpting.com/coolsculpting (last visited Mar. 19, 2024).

308. Despite knowing that NCT 2012 trial study limited to the thigh area which only defined success as a 1mm fat reduction, the marketing literature shows abdominal photos of a much larger misleading picture of fat reduction.

FIRST CAUSE OF ACTION

(STRICT PRODUCT LIABILITY – DESIGN, MANUFACTURE AND FAILURE TO WARN)

309. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

310. The CoolSculpting System used on Mrs. Dwabe was designed and/or manufactured in violation of the Federal Food, Drug and Cosmetic Act ("FDCA") and regulations promulgated pursuant to it, including but not limited to improper workmanship, failure to update and validate Freeze-Detect Software, which caused defects in the CoolSculpting system during the manufacturing process and/or during use of the device. The failure of the Freeze-Detect Software has caused Mrs. Dwabe to incur additional costs, pain, scarring, deformity, and the need to undergo multiple surgeries.

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

312. At all times relevant to this action, Defendants had a duty to exercise reasonable care, and to comply with inspection, labeling, marketing, promotions, and sale of the CoolSculpting treatment, as well as a duty to ensure patients would not suffer from unreasonable, dangerous, or untoward side effects. Defendants introduced CoolSculpting into the stream of commerce.

313. At all times relevant to this action, Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of CoolSculpting treatment.

314. At all times relevant to this action, Defendants knew or reasonably should have known that CoolSculpting was unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following: (i) patients can develop PAH, at a higher rate than disclosed to the FDA, which will create disfigurement at the treatment site; (ii) PAH cannot be treated

immediately because patients must wait for tissue to soften from the CoolSculpting freeze; (iii) fat reduction is not as significant as advertised; (iv) fat reduction is not permanent; (v) Defendants, not the physician, controlled the CoolSculpting treatment through "Freeze Detect" software technology.

315. Defendants failed to exercise ordinary care in the creating, designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of its CoolSculpting device into interstate commerce. Defendants knew or should have known that its CoolSculpting device placed users at risk for developing serious and dangerous side effects, including but not limited to PAH, hernias, blood clots, nerve damage, permanent post-surgical growths, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

316. Based on what Defendants knew or should have known, Defendants deviated from principles of due care, deviated from standards of care, and were otherwise negligent. Defendants had a duty to comply with the FDCA and the regulations promulgated pursuant to it, but the Defendant, its agents, servants, and/or employees, violated the FDCA regulations by the following acts and/or omissions:

i. Failed to disclose to CoolSculpting providers and the FDA all known PAH adverse events in violation of 21 C.F.R. § 803. Through Defendants' White Paper and refund or free liposuction program, Defendants gathered data showing that CoolSculpting did not perform as expected and/or caused higher rates of PAH. Defendants have not reported the lack of fat reduction or true rate of PAH to the FDA or CoolSculpting providers;

ii. Defendants failed to conduct sufficient testing to determine whether its CoolSculpting devices were safe for use and failed to anticipate the effect the procedure would have on healthy tissue prior to releasing the device for commercial distribution, in violation of 21 C.F.R. § 820.30(c), (d), (e), (f) and (g). Defendants knew or should have known that its CoolSculpting devices were unsafe and unreasonably dangerous because CoolSculpting can convert healthy tissue to fibrinous tissue, a condition the Defendants coined as PAH. Mrs. Dwabe developed PAH due to CoolSculpting;

iii. Failed to conduct adequate bio-compatibility studies to determine the CoolSculpting system's propensity to cause PAH in violation of 21 C.F.R. § 820.30(b) and (c);

iv. Failed to Follow FDA Design Control Regulations promulgated by 21 C.F.R. § 820.30(a)(1)(2)(i), which holds "Each manufacturer of any class III or class II device... shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met." This includes devices like CoolSculpting with automated computer software. Upon information and belief, Defendants did have recorded software events with the CoolSculpting system. Changes were made to the predicate K 183514 system hardware and software to allow two treatments to be performed simultaneously. On July 5, 2021, Defendants issued a voluntary Class II recall of the CoolSculpting Elite System because the software had an incorrect error messaging system that could potentially lead to: 1) re-treating the affected anatomic area within 24 hours; or 2) failure to report a thermal event or other codes which would cause extended treatment in the affected anatomic area. As a result of the bugs, thermal events 1) may not lead to "thermal event" error message alert and treatment would not be stopped; or 2) the error text displayed may be unrelated and the provider would not know to avoid retreatment within 24 hours. These errors can result in cold-induced injury and second- or third-degree freeze bums. After sending two different Urgent Field Notices on July 13, 2021 and July 23, 2021, advising health care providers to update the software, a third notice was sent to healthcare providers via email on August 26, 2021 via email instructing them to cease use of the CoolSculpting Elite Devices until further notice. The updated communication instructed customers to refrain from using affected devices until the Recalling Firm notifies them because the software change needs to be submitted to FDA for review. The initial software updates in July of 2021 were not submitted to the FDA for review;

v. Defendants have misbranded the CoolSculpting System by advertising the device as "FDA-cleared" for the treatment of visible fat bulges in the submental (under the chin) and submandibular (under the jawline) areas, thigh, abdomen, and flank, along with

bra fat, back fat, underneath the buttocks (also known as banana roll), and upper arm. This is a clear violation of the misbranding statute codified at 21 C.F.R. § 807.97 that forbids any denotation of FDA approval of a Class I or Class II device simply because a manufacturer complies with "substantial equivalence." The misbranding statute further holds determination by the Commissioner that a device intended for introduction into commercial distribution because it is 1) substantially equivalent to a device in commercial distribution before May 28, 1976; or 2) substantially equivalent to a device introduced into commercial distribution after May 28, 1976 that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates the impression that a device is officially approved by complying with premarket notification regulations is misleading and constitutes misbranding. Mrs. Dwabe saw the following statements about CoolSculpting: "CoolSculpting is the world's #1 FDA-approved treatment option providers turn to for nonsurgical fat reduction," "CoolSculpting has been approved by the FDA," "Clinical trials have determined that CoolSculpting is a safe and effective way to reduce fat." These are fraudulently false representations made to Mrs. Dwabe, as the Defendants were not granted the right to market CoolSculpting based upon clinical trials nor is the device FDA approved;

vi. Failing to recall its dangerous and defective CoolSculpting devices at the earliest date it became known that the devices were dangerous and defective by failing to identify, capture, and/or correct the CoolSculpting discrepancy/discrepancies, in violation of 21 C.F.R. § 820.80(c);

vii. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, inter alia, complaints regarding the CoolSculpting system, returned components, and other quality problems associated with the components, in violation of 21 C.F.R. § 820.100;

viii. Failed to appropriately respond to adverse incident reports that strongly indicated the CoolSculpting system was malfunctioning, as defined in 21 C.F.R. § 803.3, or

otherwise not responding to their design objective intent, in violation of 21 C.F.R. § 820.198. Through its "Medical Review Team," refund or free liposuction program, and physician reports of PAH, Defendants were aware that PAH is a common adverse event but failed to report these events to the FDA and healthcare providers or initiate a voluntary recall;

ix. Failed to conduct complete device investigations on adverse events of PAH caused by CoolSculpting in violation of 21 C.F.R. § 820.198. Defendants has failed to investigate and analyze the cause and long-term effects of PAH;

x. Continued to inject the CoolSculpting system into the stream of commerce when Defendants knew, or should have known, that one or more were malfunctioning, as defined in 21 C.F.R. § 803.3, or otherwise not responding to their design objective intent; and

xi. Defendants otherwise failed to comply with the applicable statutory requirements and terms of the conditional approval issued by the FDA, including but not limited to the off-label marketing restrictions and post-market surveillance requirements.

317. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the subject device and components, as applied to Mrs. Dwabe, failed and directly caused and/or contributed to the severe and permanent injuries sustained by Mrs. Dwabe, as defined in 21 C.F.R. § 803.3, as well as other damages alleged herein.

318. As a consequence of Defendants' violations, Mrs. Dwabe endured pain and suffering, including humiliation, scarring, disfigurement, and additional invasive surgeries to remove fibrinous tissue. Mrs. Dwabe will continue to incur medical costs to treat the PAH.

319. Plaintiffs allege that at the time the subject device and components left Defendants' control: 1) one or more were defective because they deviated from the manufacturers or designer's specifications in a material way; 2) such defective condition rendered them unreasonably dangerous to the user; and 3) such condition proximately caused the damages for which recovery is sought.

320. Alternatively, Plaintiffs allege that at the time the subject components left Defendants' control: 1) one or more were designed in a defective manner; 2) such defective condition

rendered them unreasonably dangerous to the user; and 3) such condition proximately caused the damages for which recovery is sought herein. Further: 1) Defendants knew, or in light of reasonably available knowledge and/or the exercise of reasonable care should have known, about the danger for which recovery is sought; and 2) the CoolSculpting system collectively failed to function as expected and a feasible design alternative existed that would have, with reasonable probability, have prevented the harm and injury which occurred to Mrs. Dwabe.

321. Under California law, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of strict liability in tort. For a plaintiff to recover under strict product liability in tort, the manufacturer has to have placed an article on the market, with the knowledge that it is to be used without inspection for defects, and it proves to have a defect that cause injury to a human being. *Greenman v. Yuba Power Products, Inc.,* 377 P.2d 897 (Cal. 1963).

322. Through Defendants' conduct in failing to warn treatment providers, deceiving CoolSculpting providers, and pressuring providers and physicians to underreport PAH incidences, and incentivizing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

323. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

324. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

SECOND CAUSE OF ACTION

(NEGLIGENCE - DESIGN, MANUFACTURE, MISBRANDED)

325. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

326. Plaintiffs are in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by defectively designed CoolSculpting systems, as Mrs. Dwabe was the type of person for whom Coolsculpting was intended to be used.

327. At all times herein mentioned, Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed the CoolSculpting device that was used on Mrs. Dwabe.

328. That its CoolSculpting devices were expected to reach, and did reach, the usual consumers, handlers, and persons coming into contact with the device without substantial change in the condition in which they were produced, manufactured, sold, distributed, and marketed by Defendants.

329. At all times herein mentioned, Defendants' CoolSculpting device were in defective condition and unsafe, and Defendants knew or had reason to know that the devices were defective and unsafe, especially when used in the form and manner recommended by the Defendant.

330. When Mrs. Dwabe underwent a CoolSculpting treatment, the CoolSculpting System was a Class II medical device that was designed and/or manufactured by Defendants and placed into the stream of commerce.

331. Based on what Defendants knew or should have known, Defendants deviated from principles of due care, deviated from standards of care, and were otherwise negligent. It was the duty of the Defendants to comply with the FDCA and the regulations promulgated pursuant to it, but the Defendant, its agents, servants, and/or employees, included but violated the FDCA regulations by the following acts and/or omissions:

i. Failed to disclose to CoolSculpting providers or the FDA all known PAH adverse events in violation of 21 C.F.R. § 803. Through Defendants' Secret White Paper and liposuction program, Defendants knew that CoolSculpting did not perform as expected and/or caused higher rates of PAH. Defendants have not reported the lack of fat reduction or true rate of PAH to the FDA or CoolSculpting providers;

ii. Not conducting sufficient testing programs to determine whether CoolSculpting devices were safe for use by failing to validate the anticipated wear and/or reaction

on healthy tissue prior to their release into commercial distribution, in violation of 21 C.F.R. § 820.30(c), (d), (e), (f) and (g). Defendants knew or should have known that the CoolSculpting devices were unsafe and unreasonably dangerous because they can convert healthy tissue to fibrinous tissue which Defendants have coined PAH. Mrs. Dwabe developed fibrinous tissue (PAH) due to CoolSculpting treatment;

iii. Failed to conduct adequate bio-compatibility studies to determine the CoolSculpting system's propensity to cause PAH in violation of 21 C.F.R. § 820.30(b), (c);

iv. Failed to Follow FDA Design Control Regulations 21 C.F.R. § 820.30(a)(1)(2)(i) which holds "Each manufacturer of any class III or class II device…shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met." This includes devices like the CoolSculpting System with automated computer software. Upon information and belief, Defendants did have recorded software events with the CoolSculpting system. Changes were made to the predicate K183514 system hardware and software to allow two treatments to be performed simultaneously. On July 5, 2021, Defendants issued a voluntary Class II recall of the CoolSculpting Elite System because the software had an incorrect error messaging system that could potentially lead to: 1) Re-treating the affected anatomic area within 24 hours 2) Failure to report a thermal event or other codes which would cause extended treatment in the affected anatomic area where CoolSculpting provider would not be aware that a thermal event has occurred. As a result of the bugs thermal events 1) may not lead to "thermal event" error message alert and treatment would not be stopped; or 2) the error text displayed may be unrelated and the provider would not know to avoid retreatment within 24 hours. These could result in cold-induced injury and 2nd or 3rd degree freeze burns. After sending two different Urgent Field Notices on 7/13/21 and 7/23/21 advising health care providers to update the software, a third notice was sent to healthcare providers on 08/26/2021 via email informing its customers to cease use of the CoolSculpting Elite Devices until further notice. The updated communication instructed customers to refrain from using affected devices

until the Recalling Firm notifies them because the software change needs to be submitted to FDA for review. The initial software updates in July of 2021 were not submitted to the FDA for review;

v. Defendants have misbranded the CoolSculpting System in advertisements by alleging the device is "FDA-cleared" for the treatment of visible fat bulges in the submental (under the chin) and submandibular (under the jawline) areas, thigh, abdomen, and flank, along with bra fat, back fat, underneath the buttocks (also known as banana roll), and upper arm. This is a clear violation of the Misbranding statute 21 C.F.R. § 807.97 that forbids any denotation of FDA approval of a Class I or Class II device simply because a manufacturer complies with "substantial equivalence". The Misbranding statute further holds determination by the Commissioner that the device intended for introduction into commercial distribution because it is substantially equivalent to a device in commercial distribution before May 28, 1976 or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding. Mrs. Dwabe saw the following statements about CoolSculpting "CoolSculpting is the world's #1 FDA-approved treatment option providers turn to for nonsurgical fat reduction." CoolSculpting has been approved by the FDA. Clinical trials have determined that CoolSculpting is a safe and effective way to reduce fat. This is all fraudulently false representations made to Mrs. Dwabe because Defendants was not granted the right to market CoolSculpting based upon clinical trials nor is the device FDA approved.

vi. Failing to recall its dangerous and defective CoolSculpting devices at the earliest date that it became known that said its CoolSculpting devices were, in fact, dangerous and defective by failing to identify, capture and/or correct the CoolSculpting discrepancies, in violation of 21 C.F.R. § 820.80(c);

vii. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia,* complaints regarding CoolSculpting system, returned components, and other quality problems associated with the components, in violation of 21 C.F.R. § 820.100;

viii. Failed to appropriately respond to adverse incident reports that strongly indicated the CoolSculpting system was Malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to their Design Objective Intent, in violation of 21 C.F.R. § 820.198. Defendants "Medical Review Team", liposuction program and physician complaints reported adverse events of PAH as a common adverse event and Defendants have largely ignored the clinical evidence by not reporting them to the FDA, healthcare providers or initiating a voluntary recall;

ix. Failed to conduct complete device investigations on adverse events of PH caused by CoolSculpting in violation of 21 C.F.R. § 820.198. Defendants has failed to investigate and analyze the cause and long-term effects of PAH;

x. Continued to inject the CoolSculpting system into the stream of commerce when Defendants knew, or should have known, that one or more were Malfunctioning [as defined in 21 C.F.R. § 803.3] or otherwise not responding to their Design Objective Intent; and/or

xi. Defendants otherwise failed to comply with the applicable statutory requirements and terms of the conditional approval issued by the FDA, including but not limited to the off-label marketing restrictions and post-market surveillance requirements.

332. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the subject components, as applied to Plaintiff, failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained by Plaintiff, as defined in 21 C.F.R. § 803.3, as well as other damages alleged herein.

333. As a direct result, Plaintiff, Mrs. Dwabe, endured pain, and suffering, including pain, humiliation, scarring, disfigurement, additional invasive surgeries to remove fibrinous tissue, and will continue to incur medical costs to treat the PAH.

334. Plaintiffs allege that at the time the subject components left Defendants' control, (i) one or more were defective because they deviated in a material way from the manufacturers or designer's specifications, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein.

335. Alternatively, Plaintiffs allege that at the time the subject components left Defendants' control, (i) one or more were designed in a defective manner, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein. Further, (i) Defendants knew, or in light of reasonably available knowledge or in the exercise of reasonable care should have known, about the danger for which recovery is sought herein, and (ii) the CoolSculpting system collectively failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability have prevented the harm and injury which occurred to Plaintiff.

336. As a direct and proximate result of Defendants violations of one or more of these federal statutory and regulatory standards of care, the CoolSculpting system used on Mrs. Dwabe failed and directly caused and/or contributed to the severe and permanent injuries sustained and endured by Mrs. Dwabe, as defined in 21 C.F.R. § 803.3. Mrs. Dwabe has endured pain and suffering, including, but not limited to, additional debilitating and invasive surgeries, physical pain and suffering, mental anguish and emotional distress, humiliation, embarrassment, annoyance, and aggravation. Additionally, Mrs. Dwabe has incurred significant medical expenses, both past and present, and loss of wages, both past and present.

337. Under California law, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence.

338. As a direct and proximate result of Defendants aforementioned actions, Plaintiffs pray for judgment against Defendants.

339. Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective product which created an unreasonable risk to the health of consumers and to Mrs. Dwabe, in particular, and Defendants is liable for the injuries sustained by Mrs. Dwabe.

340. Through Defendants' conduct in deceiving CoolSculpting providers and/or convincing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

341. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

342. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

THIRD CAUSE OF ACTION

(BREACH OF EXPRESS WARRANTY)

343. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

344. Defendants knew that CoolSculpting treatment can cause tissue damage and permanent deformity to the user's body in the form of PAH. Defendants advertised CoolSculpting as a non-invasive procedure designed to reduce fat.

345. None of Defendants' advertising, marketing, or informational materials viewed by the Mrs. Dwabe mentioned that CoolSculpting procedures could cause a condition that results in permanent disfigurement to the body that can only be resolved through invasive surgeries, resulting in the opposite effect of the device's advertised purpose.

346. Mrs. Dwabe relied on the skill and judgment of the Defendants and Defendants' representations that the device was adequately tested and rendered safe for its intended use.

347. Mrs. Dwabe became interested in and underwent the CoolSculpting procedure based on the Defendants' representation that the procedure could remove and/or kill fat permanently.

348. Due to the innate defective nature of the CoolSculpting device, Mrs. Dwabe and the individuals performing the CoolSculpting procedure on her, through the use of reasonable care, could not have discovered the defective nature of the CoolSculpting System device or its risks.

349. As the direct and proximate result of Defendants' conduct, Mrs. Dwabe sustained serious injuries from the defective, unsafe, and unreasonably dangerous CoolSculpting device that could not safely be used for the purpose for which it was marketed, advertised, promoted, and intended. Specifically, Defendants' CoolSculpting device caused Mrs. Dwabe to suffer a permanent enlargement and hardening of fat tissue which can only be removed through invasive plastic surgery.

350. As the direct and proximate result of Defendants' wrongful conduct, Mrs. Dwabe has experienced, and continues to experience, serious and dangerous side effects including but not limited to, PAH, as well as other severe personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

FOURTH CAUSE OF ACTION

(BREACH OF IMPLIED WARRANTY)

351. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

352. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted, and sold its CoolSculpting devices to induce lipolysis.

353. At the time Defendants marketed, sold, and distributed the CoolSculpting device used on Mrs. Dwabe, Defendants knew the use for which its CoolSculpting device was intended and impliedly warranted the product to be of merchantable quality, safe, and fit for such use.

354. Defendants impliedly represented and warranted to users of its CoolSculpting devices, and/or their physicians/healthcare providers, and/or the FDA, that its CoolSculpting devices were of merchantable quality, safe, and fit for their intended purpose.

355. The aforementioned representations and warranties were false, misleading, and inaccurate as the CoolSculpting devices were unsafe, unreasonably dangerous, not of merchantable quality, and defective.

356. Mrs. Dwabe and/or members of the medical community and/or healthcare professionals relied on these implied warranties of merchantability and fitness for a particular use and purpose.

357. Mrs. Dwabe and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of the Defendants to determine whether the CoolSculpting devices were of merchantable quality, safe, and fit for their intended use.

358. Defendants injected its CoolSculpting devices into the stream of commerce in a defective, unsafe, and inherently dangerous condition. These products and materials were expected to and did reach users, handlers, and persons coming into contact with the products without substantial change from the condition in which they were sold.

359. Defendants herein breached the aforesaid implied warranties, as its CoolSculpting devices were neither merchantable nor fit for their intended purposes and uses.

360. As a direct and proximate result of the foregoing, Mrs. Dwabe has experienced, and continues to experience, serious and dangerous side effects including but not limited to, PAH, as well as other severe personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

FIFTH CAUSE OF ACTION

(STRICT LIABILITY- FAILURE TO WARN)

361. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

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

363. Defendants directly or through their agents, apparent agents, servants, or employees designed, manufactured, tested, marketed, and commercially distributed the CoolSculpting device that was used on Mrs. Dwabe.

364. Defendants knew that its CoolSculpting device was unreasonably dangerous, unsafe, and/or defective and could cause harm to those who used it, including Mrs. Dwabe. Specifically, Defendants knew that their medical device could cause the opposite effect of the device's advertised purpose in the form of PAH.

365. Defendants knew that PAH is not preventable and is unavoidable if undergoing the CoolSculpting procedure. Defendants also knew that there was a higher possibility that Mrs. Dwabe could develop PAH after undergoing the CoolSculpting procedure than they had communicated to consumers or to treatment providers.

366. Defendants had superior knowledge about PAH because they were in possession of facts and information about the condition not available to anyone else. As the manufacturer of the device, Defendants were a centralized hub of information about the device's adverse effects, including PAH. Defendants received thousands of reports of users developing the condition, had access to those users' medical records and information regarding diagnosis, treatment, and occurrence rate of PAH, which they did not disclose to the public or medical community.

367. Defendants had a duty to provide adequate warnings about PAH, a dangerous adverse effect of its CoolSculpting medical device, to La Bella. La Bella also had a duty to adequately warn Mrs. Dwabe about the true incidence rate of the procedure.

368. Defendants failed to provide adequate warnings to Mrs. Dwabe because the language used by Defendants to describe PAH in its materials:

i. Was inaccurate in content and ambiguous in manner of expression;

ii. Did not adequately inform about a condition which is: 1) unfamiliar to the medical community; 2) is only associated with the CoolSculpting device; and 3) about which Defendants had superior knowledge;

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

iv. Misrepresented facts about the condition;

v. Did not use concrete terms like "deformity" and "disfigurement" to describe PAH;

vi. Did not definitively state that PAH is a disease of the tissue;

vii. Did not definitively state that PAH can only be removed with invasive surgery;

viii. Did not warn that it is likely that multiple surgeries may be necessary to remove PAH;

ix. Did not disclose that a single patient can develop the condition in multiple areas;

x. Did not disclose that the incidence rate was calculated on a per-cycle basis, not per-patient;

xi. Did not disclose that PAH causes permanent cutaneous and subcutaneous tissue damage;

xii. Did not disclose that long term effects of PAH affected tissue are unknown;

xiii. Did not disclose that even with surgery, patients affected by PAH may still be left with deformities on their body; and

xiv. Used words such as "rare side effect" to imply that PAH is unlikely to occur, while knowing that the condition is not rare.

369. Defendants are strictly liable for Plaintiff's damages because their product was defective due to the failure to adequately warn about the danger of the CoolSculpting device, particularly the risk of PAH.

370. As the direct and proximate result of Defendants' wrongful conduct, Mrs. Dwabe has experienced, and continues to experience, serious and dangerous side effects including but not limited to, PAH, as well as other severe personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

371. Through Defendants' conduct in deceiving CoolSculpting providers and/or convincing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of

the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

372. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

373. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

SIXTH CAUSE OF ACTION

(NEGLIGENT ACTS/OMISSIONS OF AGENTS)

374. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

375. Defendants by and through contracts, distributorship agreements, and kickbacks to physicians and/or clinics, established a business partnership with the physicians and/or clinics. Physicians and other CoolSculpting providers had both express and apparent authority to act for Defendants acted in concert with the business objectives and instructions laid out by Defendant, thereby making them one entity. The nature of this relationship eliminated the independent medical judgment of the physician.

376. Defendants and their agents had superior knowledge about PAH because they were in possession of facts and information about the condition not available to anyone else. As the manufacturer of the device, Defendants were a centralized hub of information about the device's adverse effects, including PAH. Defendants received thousands of reports of users developing the condition, had access to those users' medical records and information regarding diagnosis, treatment, and occurrence rate of PAH, which they did not disclose to the public or medical community.

377. The CoolSculpting providers acted as the Defendants' agents in selling the CoolSculpting cycles, because Defendant, among other things, conducted itself in the following

ways: 1) maintained control over the CoolSculpting cycles through its consumable card system; 2) shared profits with the providers on each cycle administered to patients; 3) provided forms and documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting patients; 4) referred CoolSculpting patients to the CoolSculpting providers via its website; 5) controlled the advertised price of CoolSculpting; 6) controlled how patients were diagnosed with PAH resulting from CoolSculpting.

378. Defendants and their agents owed a duty to protect Mrs. Dwabe from the unreasonable risk of using its CoolSculpting medical device, which they knew had the ability to cause permanent injury resulting in the opposite effect of the device's advertised purpose.

379. **Duty to take Corrective and Preventive Actions.** Defendants had a duty to take corrective and preventive actions when they found out that the CoolSculpting device causes permanent deformities to patient's bodies.

380. Defendants failed to exercise ordinary care when they: 1) failed to acknowledge that PAH is a serious side effect of the CoolSculpting device; and 2) failed to update its labeling for the CoolSculpting device to adequately describe the risk of PAH when it discovered the serious and permanent side effect associated with the device; or 3) failed to take the CoolSculpting device off the market when it discovered the serious and permanent side effect associated with the device.

381. **Duty to Inform Providers.** Defendants had a duty to adequately inform Plaintiff's CoolSculpting provider that PAH, an adverse effect associated with cryolipolysis and the CoolSculpting device: 1) causes cutaneous and subcutaneous tissue damage; 2) is a permanent deformity; 3) which will never resolve on its own; 4) which may affect a single patient in multiple treatment areas; 5) requires multiple plastic surgeries, per affected area, to remove; 6) causes the opposite of the intended result of CoolSculpting; 7) is more likely to develop in males; 8) may have long term effects, due to tissue damage; 9) may require additional treatment in the future; and 10) may not be resolved with plastic surgery.

382. Defendants failed to exercise ordinary care by using misleading language to describe PAH to CoolSculpting providers/agents, failing to adequately inform them about the seriousness of the condition. Defendants concealed material facts about the condition from CoolSculpting

providers/agents. Defendants made ambiguous and inaccurate statements about the effect PAH has on the body, its permanency, treatment options, and rate of risk in the written materials it furnished to Plaintiff's CoolSculpting provider/agent.

383. The provider, due to conflict of interest and lack of disclosure, did not and/or refused to adequately inform Mrs. Dwabe about the risk of developing serious and permanent injuries from CoolSculpting. Consequently, Mrs. Dwabe and was induced to purchase CoolSculpting cycles, undergo the CoolSculpting procedure, and consequently suffered personal injuries and economic damages.

384. **Duty to be Honest in Advertising CoolSculpting.** Defendants also had a duty to be honest in their advertisement materials directed at Plaintiff, such as commercials, website content, and the brochures and posters that it furnished to the CoolSculpting providers to use in their offices. Specifically, Defendants had a duty:

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

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

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

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

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

vi. To disclose that even after an initial reduction in fat, a person may develop PAH.

385. Due to Defendants and their agent's failure to use ordinary care, Mrs. Dwabe was not aware that purchasing CoolSculpting cycles and undergoing the CoolSculpting procedure subjected her to a risk of developing permanent deformities of damaged fat tissue and skin laxity which require multiple invasive surgeries to remove. Consequently, Mrs. Dwabe was induced purchase CoolSculpting cycles, undergo the CoolSculpting procedure, and consequently suffered personal injuries and economic damages.

386. **Duty to Warn CoolSculpting Consumers.** Defendants and their agents created a system that forced CoolSculpting providers to rely on them to support their CoolSculpting business. Defendants was involved itself in every step of the CoolSculpting treatment, from attracting consumers through advertisement, furnishing CoolSculpting providers with patient-facing documents (including consent forms) that informed consumers about the procedure, profit-sharing with agents on each cycle sold to the consumers, diagnosing the consumer with PAH, and offering to settle PAH claims which protected the CoolSculpting providers from liability.

387. Defendants' participation and control of physician agents in the consumers' medical treatment gave rise to a duty to warn the consumers directly about the danger of its medical device. It was unreasonable for the Defendants to rely on CoolSculpting providers to properly inform their patients about the risk of PAH under the business partnerships created by Defendant.

388. Defendants failed to exercise ordinary care when they unreasonably relied on CoolSculpting providers to inform CoolSculpting patients about the risk of PAH, knowing that: 1) the consent language used by providers did not accurately and adequately explain PAH to consumers; 2) PAH was the most serious adverse effect of CoolSculpting; 3) PHA was the most frequently reported adverse effect of CoolSculpting; 4) PAH created the opposite of the intended effect of CoolSculpting; and 5) CoolSculpting providers were incentivized with increased sales to conceal the truth about PAH and other injuries from their patients.

389. Due to Defendants' failure to use ordinary care, Mrs. Dwabe was not aware that purchasing CoolSculpting cycles and undergoing the CoolSculpting procedure subjected her to a risk of developing permanent deformities of damaged fat tissue and skin laxity which require multiple invasive surgeries to remove.

390. As the direct and proximate result of Defendants and their agent's wrongful conduct, Mrs. Dwabe has experienced, and continues to experience, serious and dangerous side effects including but not limited to, PAH, as well as other severe personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

391. Through Defendants' conduct in deceiving CoolSculpting providers and/or convincing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

392. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

393. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

SEVENTH CAUSE OF ACTION

(NEGLIGENT MISREPRESENTATION AND CONCEALMENT)

394. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

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

396. The CoolSculpting providers acted as Defendants' agents in selling the CoolSculpting cycles, because Defendants, among other things: 1) maintained control over the CoolSculpting cycles through its consumable card system, 2) shared profits with the providers on each cycle administered to patients, 3) provided forms and documents to the CoolSculpting providers with the CoolSculpting logo to use for CoolSculpting patients, 4) referred CoolSculpting patients to the CoolSculpting

providers via its website, 5) controlled the advertised price of CoolSculpting, and 6) controlled how patients were diagnosed with PAH resulting from CoolSculpting.

397. Defendants made these statements and concealed material facts about PAH without regard for the truth of the statements they were making.

398. **Severity.** Defendants knew that PAH is a disfigurement and a deformity to the body that is completely different from a normal "enlargement of fat" because PAH permanently damages the tissue it affects. Defendants also knew that many PAH patients also suffered cutaneous tissue damage resulting in skin laxity, which requires additional surgeries to reconstruct. Defendants misrepresented the consequences of PAH by creatively using insufficient and ambiguous language to describe the condition and intentionally avoided using concrete terms that would fairly and accurately describe the adverse event, as well as concealing how they calculated the incidence rate.

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

400. **Frequency.** Based on the number of PAH reports Defendants received, they knew that the likelihood of developing PAH after CoolSculpting was not rare. Defendants concealed their knowledge of the unreasonably dangerous risks of Coolsculpting while simultaneously relying on words "rare" and "small number" to induce consumers to believe that it is unlikely that a patient will develop the condition. Defendants concealed the fact that PAH was the most frequently reported adverse effect of CoolSculpting.

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

402. Defendants knew that the CoolSculpting providers' lack of knowledge and understanding about PAH will result in consumers being uninformed about the serious and

permanent adverse effect. On the other hand, Defendants knew that if consumers knew that there was a risk of developing the opposite effect of CoolSculpting's advertised purpose, consumers would not likely undergo the elective procedure.

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

404. As the proximate result of Defendants' fraudulent conduct, Mrs. Dwabe suffered damages that include economic and non-economic losses.

405. Through Defendants' conduct in deceiving CoolSculpting providers and/or convincing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

406. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

407. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

EIGHTH CAUSE OF ACTION

(FRAUDULENT MISREPRESENTATION AND CONCEALMENT)

408. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

409. Defendants had superior knowledge about PAH because they were in possession of facts and information about the condition not available to anyone else. As the manufacturer of the device, Defendants were a centralized hub of information about the device's adverse effects, including PAH. Defendants received thousands of reports of users developing the condition, had access to those users' medical records and information regarding diagnosis, treatment, and occurrence rate of PAH, which it did not disclose to the public or medical community.

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

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

412. **Permanency.** Defendants knew that PAH will never resolve on its own and that the *only* means of removing it is through invasive plastic surgery. Despite this knowledge, Defendants used false language in describing PAH to CoolSculpting providers, downplaying the permanency of the condition, and stating that "surgical intervention may be required."

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

414. Defendants' material misrepresentations about PAH and concealment of material information was motivated by profits. Since the majority of the Defendants' CoolSculpting profits are gained from the use of the device on consumers rather than sales of the device to providers, Defendants' conduct was highly driven by consumers' purchase of the CoolSculpting cycles.

415. Defendants knew that the CoolSculpting providers' lack of knowledge and understanding about PAH would result in consumers being uninformed about the serious and permanent adverse effect. On the other hand, Defendants knew that if consumers knew that there was a risk of developing the opposite effect of CoolSculpting's advertised purpose, consumers would be unlikely to undergo the elective procedure.

416. As the result of Defendants' superior knowledge about PAH, CoolSculpting providers justifiably relied on Defendants' representations about the adverse effect solely associated with Defendants' medical device. Believing that the adverse effect is unlikely to occur and is not serious nor permanent, CoolSculpting providers did not properly inform CoolSculpting patients about the risk of PAH. Information regarding PAH was material and necessary for Mrs. Dwabe to make an informed decision about undergoing this elective procedure. Had Mrs. Dwabe known that there was a risk that she could suffer the opposite effect of the CoolSculpting device's advertised purpose, she would not have purchased cycles of CoolSculpting.

417. As the proximate result of Defendants' fraudulent conduct, Mrs. Dwabe suffered damages that include economic and non-economic losses.

418. Through Defendants' conduct in deceiving CoolSculpting providers and/or convincing providers to participate in the "pay to play" scheme, Mrs. Dwabe was not informed of

the seriousness, permanency, and frequency of PAH. Defendants' concealment of material information regarding the serious adverse effect of the CoolSculpting device, and deprivation of consumer access to important information about PAH, was so reckless that it constituted a conscious disregard or indifference to the life, safety, or rights of the device's users.

419. Defendant, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to its CoolSculpting device and PAH.

420. Defendants and their agents' malicious and fraudulent conduct must be punished to deter them from causing future harm to others. Exemplary damages are warranted under those circumstances.

NINTH CAUSE OF ACTION

(LOSS OF CONSORTIUM)

421. Plaintiffs incorporate herein by reference each and every allegation contained in the preceding and succeeding paragraphs as though herein fully restated and realleged.

422. The common-law action for loss of consortium is a civil action sounding in tort, and the action has four elements: (1) a valid and lawful marriage between the plaintiff and the person injured at the time of the injury; (2) a tortious injury to the plaintiff's spouse; (3) the loss of consortium suffered by the plaintiff; and (4) the loss was proximately caused by the defendant's act. *LeFiell Manufacturing Co. v. Superior Court* (2012) 55 Cal. 4th 275.

423. While triggered by the spouse's injury, the loss of consortium claim is separate and distinct, and not merely derivative or collateral to, the spouse's cause of action. *Rosencrans v. Dover Images, Ltd*. (2011) 192 Cal. App. 4th 1072.

424. Here, Mr. and Mrs. Dwabe are, and were at all relevant times, were in a valid and lawful marriage.

425. Mrs. Dwabe sustained a tortious injury as a direct result of the defective CoolSculpting procedure performed by the defendants. This injury has caused her significant physical and emotional suffering, as detailed in the preceding paragraphs.

426. As a result of the injury to his spouse, Mr. Dwabe has suffered a substantial loss of consortium. The physical and emotional changes in Mrs. Dwabe have led to a profound loss of companionship, affection, and emotional support in their marriage. The deformities caused by PAH and the resulting psychological impact have created a significant emotional distance between Mr. and Mrs. Dwabe, severely affecting their marital relationship.

427. Mr. Dwabe has had to assume additional responsibilities at home, providing care and support for his wife while coping with his own emotional distress. This has placed a considerable strain on his well-being and ability to perform his duties effectively, both at home and in his professional life.

428. Mrs. Dwabe has also experienced a loss of consortium with her husband. The emotional and physical toll of her condition has not only impacted her own well-being but has strained their relationship, leading to a diminished emotional connection and support from her husband. The mutual support and companionship that once defined their marriage have been significantly compromised due to the profound impact of her injuries on both of their lives.

429. The loss of consortium suffered by Mr. and Mrs. Dwabe was proximately caused by the defendants' act of marketing and distributing a defective product, failing to provide adequate warnings, and engaging in deceptive advertising practices. These actions directly led to the injuries sustained by Mrs. Dwabe, which in turn caused the significant loss of consortium experienced by Mr. and Mrs. Dwabe.

Prayer for Relief

Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth here in full and further prays:

1) All available compensatory damages for the described losses with respect to each cause of action;
2) Past and future medical expenses, as well as the cost associated with past and future life care;
3) Past and future lost wages and loss of earning capacity;
4) Past and future emotional distress;

5) Consequential damages;

6) All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

7) Disgorgement of profits obtained through unjust enrichment;

8) Restitution;

9) Punitive damages with respect to each cause of action to the extent such damages are recoverable under the law;

10) Reasonable attorneys' fees where recoverable;

11) Costs of suit this action;

12) Pre-judgment and all other interest recoverable; and

13) Such other additional, further, and general relief as Plaintiffs may be entitled to in law or in equity as justice so requires.

Demand for Jury Trial

Plaintiffs hereby demand a trial by jury as to all issues.

Dated: October 2, 2024

Haderlein and Kouyoumdjian LLP

By: _____
Krikor Kouyoumdjian
Jonathan Haderlein

Attorneys for Plaintiff

Dated: October 2, 2024

BACH MILI LLP

By: */s/Rami Bachour*
Rami Bachour

Attorneys for Plaintiff