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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

HEATHER WANKE, MIA JONES, and
JANICE NEWMAN,

Plaintiffs,

v.

INVASIX INC.,

Defendants.

CASE NO.

COMPLAINT FOR:

1. **BREACH OF WARRANTY**
2. **VIOLATION OF CALIFORNIA UNFAIR COMPETITION STATUTE, BUS. & PROF. CODE § 17200 et seq.**
3. **VIOLATION OF CALIFORNIA FALSE ADVERTISING LAW, BUS. & PROF. CODE § 17500 et seq.**
4. **NEGLIGENCE – FAILURE TO WARN**
5. **NEGLIGENCE – FAILURE TO TEST**
6. **STRICT PRODUCT LIABILITY**

DEMAND FOR JURY TRIAL

1 Plaintiffs Heather Wanke, Mia Jones and Janice Newman (collectively,
2 “Plaintiffs”), through counsel, file this Original Complaint against Defendant
3 Invasix Inc. (“Invasix” or “Defendant”) and respectfully state as follows:

4 **NATURE OF THE ACTION**

5 1. Plaintiffs seek redress for permanent facial disfigurement and
6 personal injury caused by the Fractora procedure, a radio frequency-based
7 cosmetic surgery performed with a Fractora device (the “Product”) designed,
8 manufactured and sold in North America by Invasix.

9 **JURISDICTION AND VENUE**

10 2. The Court has jurisdiction over the state law claims pursuant to 28
11 U.S.C. § 1332(a) because this is a lawsuit in which over \$75,000 is at issue and
12 Plaintiffs are citizens of states other than Defendant’s state of citizenship. The
13 Court has supplemental jurisdiction over Plaintiffs’ state law claims pursuant to
14 28 U.S.C. § 1367.

15 3. Venue is proper pursuant to 28 U.S.C. § 1391(a) because a
16 substantial part of the events giving rise to the claims asserted occurred in this
17 District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because
18 Defendant conducts substantial business in this District, has sufficient minimum
19 contacts with this District, and otherwise purposely avails itself of the markets
20 in this District, through the promotion, sale, and marketing of the Product in this
21 District.

22 **PARTIES**

23 4. Plaintiff Heather Wanke is a citizen of Tennessee, residing in
24 Murfreesburo, Tennessee.

25 5. Plaintiff Mia Jones is a citizen of Tennessee, residing in
26 Murfreesburo, Tennessee.

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1 equivalent to FDA ‘approval’ of a device. Instead, the FDA only clears such
2 devices for the limited uses identified by the manufacturer in the § 510(k)
3 application.” *U.S. v. Medtronics, Inc.*, 2017 US DIST. LEXIS 153887, at *6
4 (CD Cal. Sept. 11, 2017) (citing 21 CFR § 807.97 and 801.5)).

5 11. A manufacturer must submit a new 510(k) application or seek pre-
6 market approval if there is any “change or modification in the device that could
7 significantly affect the safety or effectiveness of the device” or “major change or
8 modification in the intended use of the device.” 21 CFR 807.81(a)(3).

9 12. Defendant obtained 510(k) clearance of the Product.¹

10 13. Since the Product received its 510(k) clearance, the FDA
11 announced its plan to overhaul this relatively lax procedure, acknowledging that
12 the 510(k) clearance “framework needs to be modernized to reflect advances in
13 technology, safety and the capabilities of a new generation of medical devices.”²
14 As is discussed in more detail below, Defendant markets the Product as just
15 such a revolution in medical devices, claiming it is a safer alternative to more
16 traditional, ablative and invasive procedures.

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19 ¹ Brian Lodwig, President of Invasix, confirmed that the 510(k) FDA clearance
20 application for the product included the February 2011 Operator’s Manual.
21 Invasix submitted that application, Fractora K102461, on or about March 25,
22 2011.

23 ² Statement of FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D.,
24 Director of the Center for Devices and Radiological Health, Nov. 26, 2018, at
25 [https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.h](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm)
26 [tm](https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm). CNBC associates the FDA’s announcement with “scathing investigations into
27 medical device failures and how the FDA’s accelerated review process may have
28 missed problems and put consumers at risk.” Angelica LaVito, CNBC, FDA to
Overhaul More than 40-Year old Process for Approving Medical Devices that
Some Say Puts Consumers at Risk, November 26, 2018, at
[https://www.cnbc.com/2018/11/26/fda-to-overhaul-510k-medical-device-](https://www.cnbc.com/2018/11/26/fda-to-overhaul-510k-medical-device-approval-process.html)
[approval-process.html](https://www.cnbc.com/2018/11/26/fda-to-overhaul-510k-medical-device-approval-process.html).

1 14. According to documents submitted by Defendant to the FDA as
2 part of the 510(k) clearance process, the Product is “composed of a console,
3 hand held applicator, and disposable tip, designed to deliver bipolar
4 radiofrequency electrical current to the skin surface, via an array of multi-
5 electrode pins.” The Product is intended for “dermatological procedures
6 requiring ablation and resurfacing of the skin.”

7 15. More specifically, the Fractora procedure performed by the Product
8 uses radio frequency energy to selectively vaporize columns of skin while
9 leaving adjacent skin relatively uninjured. The intentional injury stimulates the
10 body’s production of collagen, which leaves the skin looking and feeling
11 smoother. Because adjacent skin theoretically remains relatively uninjured,
12 Defendant claims the Fractora procedure is safer and requires less recovery time
13 than alternative procedures such as those performed with other ablative devices,
14 such as scalpels, lasers and chemicals.

15 **Defendant’s Failure to Disclose the Financial Interest of Doctors Recruited**
16 **to Assist in Sales**

17 16. Defendant sells the Product to doctors. In order to promote sales,
18 Defendant recruits well known and/or well-regarded doctors, doctors it
19 considers to be opinion leaders, to use and promote the Product through what
20 Defendant refers to as the Luminary Program. Luminary Program members
21 conduct trainings and demonstrations to prospective doctor-customers and the
22 media, prepare white papers, conduct so-called studies, provide testimonials
23 and create referrals in exchange for honoraria, extended training, product
24 discounts, compensation for referrals and other perks.

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1 17. However, Defendant does not disclose its connection to the
2 Luminary Program doctors, that the doctors have been compensated for their
3 participation or that the trainings, demonstrations, “studies,” white papers and
4 testimonials constitute no more than promotional materials.³ Instead,
5 Defendant present these materials as though they are independent and, in the
6 case of purported studies and papers, the result of objective scientific study,
7 which they are not.⁴

8 18. Defendant relies heavily on one opinion leader in particular, Dr.
9 Stephen R. Mulholland, a plastic surgeon with a private aesthetics practice in
10 Toronto, Canada. Mulholland co-invented the Fractora technology and co-
11 founded Invasix. He continues to own roughly 17% of the company.

12 ³ According to the FDA, any statement by a manufacturer to a third party is a
13 promotional activity, including, but not limited to statements made by sales
14 representatives to doctors or patients, statements made in marketing materials,
15 such as web and social media sites, sales brochures, direct-to-consumer
16 advertising, as well as statements made in press releases, training materials, or by
17 way of depictions and demonstrations. Use of health care providers to “train” on
18 a product is also promotional, particularly if the health care provider is chosen by
19 the company and receives compensation of any form for his or her assistance.
20 *See* Final Guidance on Industry-Supported Scientific and Educational Activities,
21 published by the FDA in December 1997, which is available at
22 [https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.](https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf)
23 pdf.

24 ⁴ The President of Invasix has confirmed the existence of the Luminary Program
25 and the company’s compensation of its members in exchange for Luminary
26 duties. However, specifics concerning the Luminary Program members—such as
27 the identity of its members, the compensation or other financial incentives
28 provided by Defendant in exchange for Luminary duties, and when and in what
form (i.e., demonstrations, so-called studies, white papers, etc.) the Luminaries
have made statements about the Product in Invasix-sponsored activities— is
exclusively within the knowledge of Defendant and the information unavailable
to Plaintiffs prior to discovery. An example of Luminary video and written
testimonials, demonstrations and white papers can be found on Defendant’s
website at inmodemd.com.

1 19. Invasix clearly sponsors the Dr. Mulholland demonstrations:
2 Invasix employees extend invitations and provide materials. Yet, rather than
3 disclose the financial interest of both Invasix and its owner, Dr. Mulholland, the
4 presentation aides and materials mention nothing of Dr. Mulholland’s ties to
5 Invasix and the Fractora technology, implying that Dr. Mulholland is no more
6 than an independent practitioner besotted with the Fractora procedure.⁵

7 20. The FDCA and California consumer protection statutes and
8 common law prohibit this type of deception in the sale of medical devices. *See*
9 21 USC §§ 331(b) and 352(f). FDA regulation also requires reporting of
10 annual payments to those conducting research regarding a medical device, like
11 Dr. Mulholland and many of the Luminary Program members, exceeding
12 \$25,000 a year or equity stakes in public companies worth more than \$50,000
13 and any equity stake in private companies, such as Invasix. *See* 21 C.F.R. §§
14 54.2(f) & 54.4 (1999) and 42 C.F.R. § 50.603.⁶ At a minimum, Invasix’s

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16 ⁵ Defendant makes these misrepresentations and omissions concerning Dr.
17 Mulholland and his connection to Defendant in, among other things, a
18 PowerPoint presentation and white papers used by Defendant and Dr. Mulholland
19 at the demonstrations. Because Defendant believes the PowerPoint document to
20 be proprietary and confidential, Plaintiffs do not attach it as an exhibit; however,
21 Plaintiff provided Defendant a copy prior to filing this Complaint (and in
22 Defendant’s possession prior to that time as well). A slide introducing Dr.
23 Mulholland refers only to his private aesthetics plastic surgery practice. A slide
24 introducing Invasix lists company “founders,” but fails to identify Dr.
25 Mulholland among them. The presentation also includes white papers authored by
26 Dr. Mulholland but in which his connection to Defendant goes undisclosed. Dr.
27 Mulholland’s curriculum vitae lists the dates and locations of his many Fractora
28 demonstrations. Because Defendant views the document as proprietary and
confidential, and because it is voluminous, Plaintiffs do not attach it as an exhibit.

⁶ *See also* FDA Guidance for Clinical Investigators, Industry and FDA Staff:
Financial Disclosure by Clinical Investigator, pt. IV.A.2 (2013), *available at*
<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>.
The Public Health Service has similar requirements; under its regulation, a
clinical investigator like Dr. Mulholland must disclose an equity interest in

1 failure to disclose Dr. Mulholland’s connection to the company violates the
2 FDCA and its implementing regulation.

3 **Defendant Impermissibly Endorses False, Misleading and Fraudulent**
4 **Promotion of Product and Fails to Disclose Increased Risk of Unintended**
5 **Injury**

6 21. Use of these types of opinion leaders is a powerful marketing tool
7 and Invasix spends a great deal of time, money and effort to utilize these
8 leaders. A growing body of empirical evidence suggests that even seemingly
9 trivial perks, such as pens and specialty promotional items, can exert undue
10 influence.⁷ Of course, Defendant offers its Luminaries much more than
11 trinkets.

12 22. Doctors subject to these kinds of manipulations are often blinded to
13 the objectively verifiable bias,⁸ including members of Defendant’s Luminary

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15 excess of \$5,000 in a public company and any ownership interest in a privately
16 held business. 21 C.F.R. § 54.2(b).

17 ⁷ See, e.g., Deborah Korenstein, Salomeh Keyhani & Joseph S. Ross, *Physician*
18 *Attitudes Toward Industry: A View Across the Specialties*, 145 ARCHIVES
19 SURGERY 570, 573, 577 (2010); see also ASS’N OF AM.MED. COLLS., THE
20 SCIENTIFIC BASIS OF INFLUENCE AND RECIPROCITY: A SYMPOSIUM
21 1 (2007) (discussing a “growing body of a neurobiological and psychosocial
22 evidence related to the effects of gifts on recipients’ choices and decisions”); see
23 also L. Lewis Wall & Douglas Brown, *The High Cost of Free Lunch*, 110
24 OBSTETRICS & GYNECOLOGY 169, 171 (2007) (noting that “[t]he provision
25 of food is an especially powerful tool in shaping perceptions and increasing the
26 sense of reciprocal obligation in cultures around the world”); Stephanie Saul, *Drug*
Makers Pay for Lunch as They Pitch, N.Y. TIMES, July 28, 2006, at A1 (reporting
that some physicians’ offices receive breakfast and lunch paid for by
pharmaceutical companies every day and that the companies spend hundreds of
millions of dollars each year on such meals); Jason Dana & George Loewenstein,
A Social Science Perspective on Gifts to Physicians from Industry, 290 JAMA 252,
253 (2003).

27 ⁸ See, e.g., Ann H. Harvey, Ulrich Kirk, George H. Denfield & P. Read Montague,
28 *Monetary Favors and Their Influence on Neural Responses and Revealed*
Preference, 30 J. NEUROSCIENCE 9597, 9600–01 (2010) (reporting on research

1 Program. Luminaries exaggerate the benefits of the Product by using it in a way
2 significantly more aggressive than proposed by Defendant in its 510(k)
3 submissions to the FDA. This allows for more dramatic results. It also
4 dramatically increases the risk of unintended injury to the patient. Yet Luminary
5 Program members downplay potential risks, such as burning, scarring and nerve
6 damage, and tout the Product as safer than alternative procedures.

7 23. Like the so-called studies, white papers, live demonstrations,
8 videos and other resources created by Luminary Program members, Dr.
9 Mulholland employs the Product device using much more aggressive parameters
10 and techniques than the FDA-cleared use instructions/warnings. And like the
11 Luminary Program members, Dr. Mulholland fails to warn new and potential
12 doctor-customers that the device parameters and techniques he is using are not
13 FDA-cleared and substantially increase the risks of unintended injury to
14 patients.

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16 demonstrating that “[a] monetary favor from a company was indeed capable of
17 robustly influencing preference for art paired with the logo of the sponsoring
18 company logo. . . . despite the fact that subjects were unfamiliar with the company
19 logos, subjects had no reciprocal interaction with the company, and the only
20 association between the art and the sponsoring company was visual juxtaposition
21 on a computer screen,” and despite the fact that the subjects of the research did not
22 believe “the presence of the logo influenced their ability to judge the paintings”);
23 *see also* Azgad Gold & Paul S. Appelbaum, *Unconscious Conflict of Interest: A*
24 *Jewish Perspective*, 37 J. MED. ETHICS 402, 404 (2011) (“It seems that the
25 Talmudic answer to this question is clear. On the psychological level, one cannot
26 escape the deleterious unconscious effects of receiving a gift. As a human being,
27 the recipient is biased, no matter how wise and otherwise reasonable the person
28 may be.”); Don A. Moore, Philip E. Tetlock, Lloyd Tanlu & Max H. Bazerman,
Conflicts of Interest and the Case of Auditor Independence: Moral Seduction and
Strategic Issue Cycling, 31 ACAD. MGMT. REV. 1, 2 (2006) (arguing that, with
specific regard to auditors, “[p]utting the most Machiavellian fringes of
professional communities aside, . . . the majority of professionals are unaware of
the gradual accumulation of pressures on them to slant their conclusions—a
process we characterize as moral seduction”).

1 24. More particularly, the purported studies, white papers, live
2 demonstrations, videos and other resources created by Luminary Program
3 members, Dr. Mulholland included, employ the following aggressive device
4 parameters and user techniques, all of which are at odds with Invasix's 510(k)
5 FDA application for the Product:

- 6 (a) Failure to use the lowest energy output setting necessary to achieve
7 the desired surgical effect, instead typically promoting the use of the
8 Product at or near the highest energy levels (i.e., 20-30 mJ/pin versus
9 40-62 mJ/pin, 62 mJ/pin being the highest setting);
- 10 (b) Failure to reduce Product energy output setting over bony areas, such
11 as the cheek bones and forehead, and further reduce the settings over
12 areas of thin skin, such as the neck and under the eyes;
- 13 (c) Use of unreasonable number and configuration of multi-electrode pins
14 (i.e., the 24 versus 60 or 126 pin tip);
- 15 (d) Unreasonable length of multi-electrode pins (i.e., 3000 micron versus
16 600 micron);
- 17 (e) Use of unreasonable lack of coating (versus coated) on multi-
18 electrode pins;
- 19 (f) Failure to use the output setting for the shortest amount of time
20 necessary to achieve the desired surgical effect, (i.e., use of
21 unreasonable number of passes with Product over the same area of the
22 body);
- 23 (g) Use of unreasonable amount of pressure with which the handpiece is
24 applied to the patient's skin; and
- 25 (h) Failure to overlap the applicator tip by 30-50%, thereby causing an
26 overlap of one negative electrode on top of another, resulting in too
27 much superficial positive current flowing up to the negative electrode
28 in that area.

1 25. By way of example, in the Power Point presentation used by Dr.
2 Mullholland at his demonstrations, a “Typical Parameters for Clinical Effects”
3 slide encourages use of the Product at energy levels significantly higher than
4 those presented to the FDA and with no reference to pin tip, reduction in energy
5 for bony areas or areas of thin skin, or any warning that usage at higher energy
6 levels increases the risk of burns, scarring and nerve damage. The presentation
7 also includes slides depicting Fractora treatment results using the machine at
8 the very highest energy settings, including on the neck and under the eyes, in
9 contradiction to FDA cleared parameters.

10 26. The white papers and testimonials also illustrate these
11 misrepresentations and omissions. These white papers summarize small, so-
12 called clinical studies of the Fractora procedure using the device at energy
13 settings of 60 mJ/pin—nearly the highest available setting—for the face and
14 neck. This setting is significantly higher than those in the FDA clearance
15 application materials, particularly in areas in which the FDA clearance materials
16 require a twenty percent reduction in energy setting for bony areas, such as
17 around the eyes, and another twenty percent reduction in areas of thin skin, such
18 as the forehead and neck. The white papers also include before and after photo
19 depictions of the patient subjects, indicating dramatic results in just one
20 treatment using these aggressive parameters.

21 27. Since the statements made by Dr. Mulholland and Luminaries are
22 promotional, they are imputed to Invasix even though Invasix does not directly
23 employ the doctors. The FDA considers off-label promotion by a device
24 manufacturer, whether express or implied, to be a violation of the FDCA,
25 particularly 21 USC §§ 331(b) and 352(f). *See also Carson v. Depuy Spine,*
26 *Inc.*, 365 F. App’x 812, 815(9th Cir. 2010) (“[W]hile doctors may use a drug or
27 device off-label, the marketing and promotion of a Class III device for
28 unapproved use violates Section 331 of the FDCA.”); *Schouest v. Medtronic,*

1 *Inc.*, 13 F. Supp. 3d 692, 703-706 (S.D. Tex. Mar. 24, 2014) (same).

2 28. Off-label use encompasses use of techniques and device
3 parameters that vary from the FDA approved instructions/warnings. *See, e.g.*,
4 *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1209-1210 (N.D. Cal. May 13,
5 2014) (noting that the FDA's approval letter for the device required
6 implantation from the anterior (front) abdomen using an LT Cage and finding
7 "Any operation that uses the Device in a manner other than that approved by
8 the FDA is called an "off-label" use. This includes operations in which the
9 spine is approached from the back and operation without the LT Cage."").
10 Similarly, it includes use of the device at odds with prohibitions found in the
11 FDA cleared instructions/warnings, such as the requirement of a prescription,
12 limiting use to within a hospital or clinic facility or, as in the case of the
13 Product, limiting use to licensed physicians. *See Coyne Beahm, Inc. v. United*
14 *States FDA*, 966 F. Supp. 1374, n. 27 (M.D.N.C. 1997) (citing legislative
15 history, H.R. 94-853 at 24-25 (1976)).

16 29. Since Dr. Mulholland and the Luminary Program members endorse
17 use of the Product in a way contrary to the FDA-cleared instructions/warnings
18 for use, and because these endorsements are imputed to Invasix, the
19 demonstrations and promotional materials offered by Dr. Mulholland and the
20 Luminary Program members constitute off-label promotion of the Product by a
21 manufacturer in violation of the FDCA.

22 30. Moreover, because these promotional demonstrations and
23 materials omit critical warnings about likely risks, they are also false,
24 fraudulent and misleading and in violation of California consumer protection
25 laws and the FDCA. More specifically, the opinion leaders used by Invasix to
26 promote the Fractora device fail to inform their audience that (1) use of the
27 device at a higher energy level increases the risk of burns, scarring and nerve
28 damage, (2) energy settings should be reduced on bony areas and areas of thin

1 skin, such as forehead and cheeks, and (3) users, like Plaintiffs’ doctors, could
2 achieve the same results by using less energy over multiple sessions, thereby
3 reducing the risk of injury.

4 31. Invasix makes the so-called studies, white papers, videos and other
5 resources created by Luminaries and other health care professionals financially
6 interested in the sale of the device available to prospective and new
7 buyers/users through its website, inmodemd.com, and an electronic portal,
8 access to which is given to new and potential owners/users by email.
9 Defendant reviews these materials, particularly those involving Dr. Mulholland,
10 with new and prospective doctor-customers during in-office demonstrations
11 and trainings. In other words, Defendant indoctrinates all new and prospective
12 Product owners with these false, fraudulent and misleading materials.

13 **False, Misleading and Fraudulent Promotion of Product and Product**
14 **Defect—Inconsistent and Inadequate Product Labeling**

15 32. Invasix’s Product labeling is equally flawed.⁹ A device is
16 “defective” if its instructions fail to provide those who can prescribe the device
17 with all the necessary information (approved by the FDA) to use their medical
18 expertise in deciding whether to prescribe the drug or device. Where this
19 information is inadequate or incomplete, the company may be liable under
20 theories of strict product liability (failure to warn), product liability (failure to
21 warn) and negligence (failure to act as a reasonable product device manufacture
22 by way of inadequate or poor warnings).

23 33. Since receiving 510(k) FDA-clearance in 2011, Invasix has issued
24 users new Product operator manuals and Clinical Bulletins with grossly
25 inconsistent and inadequate instructions/warnings regarding permissible energy

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27 ⁹ The FDCA defines labeling as “all labels and other written, printed, or graphic
28 accompanying any such article.” *See* 21 U.S.C. § 325(a).

1 settings, selection of the appropriate disposable tips and multi-electrode pins
2 and procedure techniques, such as the permissible amount of overlap and
3 pressure with which to apply the hand held applicator tip. Similarly, the
4 Product manuals and Clinical Bulletins fail to adequately warn users of known
5 risks associated with the Product, including, but not limited to, the risk of long
6 term nerve damage.

7 34. Details specific to each Plaintiff and their respective health care
8 providers follow.

9 **False, Misleading and Fraudulent Promotion of Product and Product**
10 **Defect—Promoting Use of Product by Non-Physicians**

11 35. The Product is a prescriptive device that may only be used upon a
12 physician's order. The FDA-cleared Product Operator Manual and all
13 subsequent manuals further restrict use of the Product to licensed physicians.
14 Nevertheless, Invasix regularly markets the Product to doctors for use by non-
15 physicians, encouraging existing and prospective buyers to increase their rate of
16 return by delegating Fractora procedures to nurses and, in some cases,
17 estheticians, who have no or little medical training. Invasix trains these non-
18 physicians on Product usage in direct contradiction to warnings and restrictions
19 included in the FDA-cleared product manual.

20 36. Defendant's practice of promoting use of the Product by non-
21 Physicians violates the FDCA as impermissible off-label promotion, renders the
22 Product defective under applicable product liability law, constitutes breach of
23 express and implied warranties and amounts to negligence and negligence per
24 se.

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1 **False, Misleading and Fraudulent Promotion of Product—Failure to**
2 **Report Adverse Events**

3 37. The FDA and California consumer protection laws require
4 manufacturers like Invasix to report adverse events related to use of its medical
5 devices. This requirement is key to the FDA’s role in patient safety. If
6 manufacturers fail to comply, the FDA cannot protect unsuspecting patients
7 from unsafe medical devices or procedures made unsafe by a manufacturer’s
8 false, misleading or fraudulent promotion of a medical device.

9 38. The Medical Device reporting regulation, 21 C.F.R. 80350(a),
10 requires manufacturers to report device-related adverse events within thirty (30)
11 days of “receiving or otherwise becoming aware of information, from any
12 source, that reasonably suggest that the device it markets” *may* have caused or
13 contributed to a death or serious injury. FDA guidance makes clear, adverse
14 event includes any undesirable experience, certainly including permanent
15 impairment to a body structure or when additional treatment was necessary to
16 prevent such impairment. *See* FDA guidance, available at
17 <https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm>.

18 39. The reporting requirement applies equally to situations where the
19 adverse event was or may have been the result of a device malfunction, a
20 device defect or user error. *See* FDA Guidance for Industry and Food and Drug
21 Administration Staff, Medical Device Reporting for Manufacturers, published
22 in 2016, available at
23 [https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/
24 guidancedocuments/ucm359566.pdf](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf).

25 40. Invasix has unlawfully suppressed reporting of adverse events that
26 may have prevented injury to Plaintiffs. Plaintiffs are aware of at least *eleven*
27 victims of the Fractora procedure—all of whom Invasix is aware—that fall
28 within the mandatory reporting guidelines. In some cases, the President of

1 Invasix has himself referred to the incidents as “adverse events.” Yet, Invasix
2 has yet to report a single adverse event related to the Fractora procedure. In so
3 doing, Invasix violated the FDCA and failed to follow its own internal Risk
4 Estimation and Evaluation of Customer Complaint guide.

5 41. Invasix further suppresses FDA adverse event reporting by its
6 practice of downplaying the seriousness of injuries suffered by Fractora
7 patients when contacted by concerned physicians. This practice emanates from
8 those in positions of highest authority within Invasix and is, thus, corporate-
9 driven and wide scale interference with the very FDA regulation meant to
10 protect unsuspecting consumers.

11 42. Defendant’s practice of suppressing adverse event reporting is a
12 form of impermissible off-label promotion under the FDCA and California
13 consumer protection laws; it also renders the Product defective under
14 applicable product liability law, constitutes breach of express and implied
15 warranties and amounts to negligence and negligence per se.

16 **FACTS RELATING TO PLAINTIFFS**

17 **Plaintiff Heather Wanke**

18 43. Prior to the Fractora procedure performed by Dr. Paulino E. Goco,
19 located in Nashville, Tennessee, on June 15, 2017, Heather was a young-
20 looking forty-three (43) year old dietician. She and her husband lived an active
21 and social life in Nashville. Heather sought treatment only to refresh her skin,
22 which was virtually wrinkle-free with small pores and a healthy-looking olive
23 complexion.

24 44. Dr. Goco recommended the Fractora procedure, claiming it was a
25 very safe, cutting edge, painless and non-invasive alternative to face lift and
26 other energy based (laser) procedures. He also assured Heather the procedure
27 was risk-free and would require little downtime. He failed to inform her that
28 the procedure rarely requires the general anesthesia he recommended for her

1 treatment or that he intended to use extremely aggressive treatment parameters
2 for the procedure despite Heather's nearly perfect skin condition.

3 45. Far from safe, the Fractora procedure left Heather with severe,
4 claw-like scarring on her right cheek, ice pick-like scarring to her entire face
5 and changes to the texture of her skin, leaving her with an orange peel look.
6 These scars persist despite over a year of healing and one additional, painful
7 Fractora procedure intended to improve the scarring.

8 46. Dr. Goco placed Heather under general anesthesia for her
9 treatment on June 15, 2017. According to a Clinical Bulletin published at or
10 around the same time as the 2011 Operator's Manual for which Invasix
11 received FDA clearance of the Fractora device, users select three parameters:
12 tip size, energy per pin (10-62 mj) and treatment mode (single or multiples
13 pulses). Dr. Goco selected nearly the most aggressive of the tip size and
14 treatment mode parameters for treatment on Heather's entire face and the
15 highest energy settings for areas in which the energy levels should have been
16 reduced, such as on Heather's sensitive eye and cheek areas.

17 47. More particularly, Dr. Goco used the 24 pin tip, with the 3000
18 micron presumably uncoated tips at two pulses, "double stacked" for two
19 passes over Heather's entire face. He administered the tissue destroying radio
20 frequency at 25 mj for Heather's forehead, brow and lower eye lid areas, at 50
21 and 45 on her cheeks and around her mouth and at 45 for between her brow,
22 crow's feet area and perioral. In all, Dr. Goco dispensed more than 1,400
23 pulses on Heather's face.

24 48. Invasix had not provided Dr. Goco an updated Quick Reference
25 Guide ("QRG") at the time of the procedure although it created a new QRG in
26 March 2017. So, Dr. Goco referred to the only QRG provided to him at the
27 time of the procedure: the January 2015 QRG. A comparison of the two
28 guides reveals the January 2015 instructions to be much more aggressive than

1 Invasix actually believed safe at the time. For the treatment of wrinkles, the
2 January 2015 QRG directs doctors to use the 24 pin 3000 micron uncoated tips
3 at the highest energy settings available on the machine, 40-62 mj, on soft tissue.
4 The March 2017 QRG, on the other hand, recommend use of only 25-50 mj.
5 (The March 2017 QRG also suggests use of the coated pin tip for people like
6 Heather with skin type IV.)

7 49. When another patient suffered similar injuries later that year, Dr.
8 Goco wondered in an email, “why did they not give us a notice [that the treatment
9 instructions had changed] and update training information???”

10 50. These outdated and unsafe instructions, closely followed by Dr.
11 Goco, were all the more dangerous because, as a May 2014 Invasix Clinical
12 Bulletin points out, the 24 pin tip delivers heat deeper than any of the other
13 Fractora pin tips and because of the doctor’s selection of multiple pulses and
14 passes. All of these parameters are in excess of those included in FDA-
15 reviewed 2011 Operator’s Manual. In particular, the Operators Manual warns:

16 Use the lowest output setting necessary to achieve the desired
17 surgical effect. Use of the RF energy only for the minimum time
18 necessary in order to lessen the possibility of unintended burn injury.
19 The higher the RF energy and the longer the RF energy is applied,
20 the greater the possibility of unintended thermal damage to tissue ...

21 51. Worse still, Dr. Goco employed a dangerous technique on both
22 passes of the Fractora. Rather than overlapping the hand piece, Dr. Goco
23 “double stacked.” That is, he applied one of the highest energy levels using a
24 pin tip delivering heat deeper than the alternatives, twice to the same area
25 without overlap. Dr. R. Stephen Mulholland, the co-founder of Invasix and co-
26 inventor of InMode/Fractora, wrote in 2015 that the Fractora handpiece should
27 be applied with overlap of “approximately 30-50%, with care taken not to
28 overlap one negative electrode on top of another.” He warned that failure to
overlap will result in unintended thermal damage.

1 52. Dr. David Goldberg, hired by Invasix to speak and train on its
2 InMode device and widely renowned as among the best cosmetic
3 dermatologists and energy-based device doctors, shares Dr. Mulholland's belief
4 that a failure to overlap the Invasix tip will lead to injuries such as those
5 suffered by Heather. Likewise, Invasix Fractora Quick Reference Guides dated
6 January 2013 (recommending approximately 20% overlap), December 2013
7 (same), January 2014 (recommending approximately 30-50% overlap), January
8 2015 (same) and May 2015 (same) echo Dr. Mulholland's instructions to use
9 overlap.

10 53. Nevertheless, the 2011 Operator's Manual (page 25) instructs
11 physicians to use minimal overlapping, suggesting that overlap should be
12 avoided.¹⁰ A Clinical Bulletin issued at approximately the same time also
13 instructs physicians not to overlap.

14 54. But Invasix has since issued multiple other "labeling documents"
15 (as that phrase is defined by the FDA) with inconsistent instructions/warnings
16 as to overlap. The most notable of these documents is the May 2014 Clinical
17 Bulletin, presumably relied upon by Dr. Goco, in which, contrary to the peer-
18 reviewed writing of Dr. Mulholland, Invasix told physicians, "Stacking pulses
19 in the same site may improve the results It is safe to stack with the 24 pin
20 tip, as the heat is deeper but be more careful with the non-coated tips." In the
21 Bulletin, Invasix acknowledged, "Stacking may increase the risk of side-
22 effects. Therefore, . . . On boney (sic) areas . . . treat with reduced energy, and
23 gradually increase energy **to a maximum of 25mJ/pin**. Avoid using 24 pin tip
24 if response of test pulse is excessive." (Emphasis added.)

25 55. Dr. Goco told Heather to expect less than five days downtime so

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27 ¹⁰ Invasix failed to update that manual until December 2015; nor has it submitted
28 the 2015 manual for FDA clearance. The 2011 Operator's Manual remains the
only FDA cleared instructions/warnings for the device.

1 Heather knew something had gone terribly wrong when she remained swollen
2 with puncture mark wounds all over her face at day 3 and 4 of her recovery.
3 She remained housebound at day 7. Her skin looked even worse beginning at
4 day 10—as the swelling subsided, Heather’s smooth, clear skin came to look
5 and feel like orange peel, the skin under her eyes darkened and burns left claw
6 and moon shaped scarring on her cheeks, upper lip and chin and between her
7 brow.

8 56. Dr. Goco shared Heather’s concern, requiring multiple follow up
9 appointments. In notes from July 12, 2017, Dr. Goco noted
10 “hyperpigmentation.” He repeated a VISIA Facial Assessment Report on
11 Heather that same day. As compared to an assessment taken June 9, 2017, just
12 before the Fractora procedure, Heather’s skin scored 60-90% worse in
13 assessments including “spots,” “wrinkles,” “texture” and “pores.”

14 57. Heather cried and cried in Dr. Goco’s treatment room. Neither the
15 doctor nor his staff could console her. Dr. Goco became so alarmed at
16 Heather’s distress, he left a personal voice mail message for her after the July
17 12, 2017 appointment. In it, Dr. Goco acknowledged that Heather would need
18 multiple additional treatments to address the injuries sustained as a result of the
19 Fractora treatment.

20 58. In a third follow up appointment on July 28, 2017, Dr. Goco
21 identified the injuries as “ice-pi[c]k type dimple scars,” “deeper around chin
22 and brow.” He instructed Heather to continue wound care and offered her a
23 (completely unsolicited) refund for the procedure.

24 59. In September 2017, Heather saw Dr. Natalie Curcio for restorative
25 treatment. Dr. Curcio noted extensive scarring, which she attributed to “a prior
26 laser resurfacing that was too aggressive.” Dr. Curcio encouraged Heather to
27 undergo a second Fractora procedure. The procedure caused Heather extreme
28 anxiety as a result of her prior bad experience. It did little to improve her scars

1 and discoloration.

2 60. While Heather should pursue further improvement through
3 additional restorative treatments, these procedures are expensive, painful and
4 risky. They also take an emotional toll. And no amount of additional treatment
5 will completely reverse the scarring and hyperpigmentation marking Heather's
6 face.

7 61. Heather's damages also include lost wages. Heather missed no
8 fewer than fifty-nine (59) from work as a nutritionist—approximately thirty
9 (30) days immediately following the procedure, another roughly twenty (20)
10 days in the month of August, when Heather researched her condition and
11 possible cures obsessively, and another nine (9) days for the second, restorative
12 Fractora procedure. Heather's daily rate of pay is \$240/day, making her
13 damages for lost wages at the time of filing \$14,160.

14 62. In addition, Heather has operated a virtual health and dietary
15 supplement franchise, YOY, since 2012. Her business, like the health and
16 wellness industry as a whole, grew exponentially between 2012 and 2016. In
17 2018, Forbes described growth in the health and wellness industry generally as
18 a "boom," particularly since 2015-2016. *See*
19 [https://www.forbes.com/sites/forbeslacouncil/2018/04/27/what-businesses-can-](https://www.forbes.com/sites/forbeslacouncil/2018/04/27/what-businesses-can-learn-from-the-health-and-wellness-boom/#490ad789341e)
20 [learn-from-the-health-and-wellness-boom/#490ad789341e](https://www.forbes.com/sites/forbeslacouncil/2018/04/27/what-businesses-can-learn-from-the-health-and-wellness-boom/#490ad789341e). In fact, YOY
21 enjoyed its largest increase in her revenue in 2016, despite Heather's inability
22 to promote the business for approximately nine (9) months due to family
23 obligations. Had Heather been actively working on YOY that year, we can
24 conservatively estimate her growth would have been more than double her
25 actual numbers, or a total increase of more than \$26,000.

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1 63. We would have expected YOY to increase by more than that
2 amount in 2017 and 2018 but for the injuries Heather sustained as a result of
3 the Fractora, when, instead, her sales became stagnant. Heather's lost profits
4 for YOY because of the Fractora total more than \$56,000, assuming only that
5 she would have matched her growth for 2016.

6 64. Heather also incurred \$4,005.10 in out of pocket expenses for
7 medications, ointments and other costs of treatment.

8 65. Thus, Heather's economic damages alone exceed \$75,000.00.

9 66. Heather has suffered emotionally, too. She is a young, beautiful
10 woman who, until her permanent scarring, enjoyed the good fortune of healthy,
11 young looking and virtually wrinkle and damage-free skin. The changes in
12 Heather's face cause her to appear older and less healthy. The scars around her
13 mouth actually look like smoker's lines. This is particularly hard for Heather,
14 who makes her living in the wellness and health industry. She is inconsolable
15 at the prospect of a lifetime of facial scars.

16 67. As a result of her disfigurement, Heather has experienced extreme
17 anxiety, depression, sleeplessness, loss of appetite, irritability and, worst of all,
18 a significant decrease in her self-esteem. Her lack of confidence has in many
19 ways changed the dynamics of daily life. She has retreated from what had been
20 a very active and happy social life: she stopped attending church; business
21 networking events; Pure Barre, her favorite exercise activity; coffee dates;
22 girls' nights; couples' events; and dates with her husband. She missed her
23 twenty-fifth high school reunion and her college homecoming game and
24 accompanying celebrations. She has declined public speaking engagements,
25 which she previously accepted and enjoyed. Her anxiety about being seen
26 publicly became overwhelming, turned Heather into a recluse. Friends began to
27 worry and inquire about her nearly total absence from their usual bustling
28 social scene.

1 **Plaintiff Janice Newman**

2 68. Plaintiff Janice Newman is a forty-seven year-old woman who
3 resides in Floral Park, New York. She is a public figure, working as a
4 broadcaster for twenty-five years, fourteen of them as a television
5 meteorologist. Most recently, Janice appears on Fox & Friends, a daily news
6 and talk program that airs weekdays nationally on the Fox News Channel
7 between 6:00 a.m.- 9:00 a.m. In addition, Janice appears on the Fox Business
8 Network, various radio programs and as a substitute for Fox News Live
9 headline anchors. Janice began her work with Fox News in 2003; before that,
10 she appeared on several radio and television stations in Canada and in the
11 United States, including Imus in the Morning, CHEZ-FM and WCBS-TV.

12 69. Janice is married to Sean Newman of the New York City Fire
13 Department. Together, she and her husband have two young sons, ages eight
14 and six.

15 70. Janice is young and extremely active. Her only issue was a few
16 wrinkles on her neck. She agreed to undergo a Fractora procedure performed
17 by Dr. Jon B. Turk on February 16, 2017 based on her doctor's
18 recommendation and claims made by Invasix in brochures, posters and in the
19 media that it is a safe, less invasive alternative to surgical and other energy-
20 based procedures and that she could expect to heal much more quickly than if
21 undergoing comparable procedures.

22 71. Far from safe, the Fractora procedure left Janice with severe—and,
23 to date, permanent— nerve damage, causing continuing facial paralysis,
24 drooping and an uneven smile. For months, Janice suffered symptoms so
25 severe, she could not speak clearly and had difficulty eating and drinking. Even
26 now her smile, which is critical to her role as a television broadcaster and
27 public media figure among other things, remains asymmetrical. In addition to
28 the severe nerve damage, she also suffered permanent scarring on her neck.

1 72. Dr. Turk placed Janice under general anesthesia for her treatments
2 on February 16, 2017. He began with another Invasix treatment, FaceTite,
3 applied to Janice neck. He followed the FaceTite immediately with the
4 Fractora procedure. Dr. Turk selected nearly the most aggressive of the
5 parameters available for the Product for both of two passes performed on
6 Janice’s sensitive neck area.

7 73. For the first pass, Dr. Turk used the 24 pin coated tip at 55 mJ/pin
8 with two pulses. As a May 2014 Invasix Clinical Bulletin points out, the 24 pin
9 tip delivers heat deeper than any of the other Fractora pin tips.¹¹ Similarly, the
10 55 mJ/pin energy setting is just shy of the device’s very highest setting of 62
11 mJ/pin and particularly aggressive given the doctor’s selection of multiple
12 pulses. All of these parameters are in excess of those included in FDA-
13 reviewed 2011 Operator’s Manual. In particular, the Operator’s Manual warns,
14 “Use the lowest output setting necessary to achieve the desired surgical effect.
15 Use of the RF energy only for the minimum time necessary in order to lessen
16 the possibility of unintended burn injury. The higher the RF energy and the
17 longer the RF energy is applied, the greater the possibility of unintended
18 thermal damage to tissue” For treatment of lax skin on Fitzgerald Skin
19 Types I-III, which applied to Janice, the May 2015 Quick Reference Guide
20 instructs physicians to use the 24-coated pin tip at no more than 30-40 mJ/pin
21 on soft tissue and 20-30 mJ/pin when working on bony areas.

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26 ¹¹ Prior to discovery, Janice cannot be sure what materials Invasix had provided
27 to Dr. Turk at the time of her procedure; that information is known to Defendant.
28 Based on representations made about Dr. Turk’s experience with the procedure,
Janice believes he received all of the materials cited in the section of this
Complaint detailing her procedure and injuries.

1 74. Worse still, Dr. Turk employed a dangerous technique on his first
2 pass of the Fractora. Rather than overlapping the handpiece, Dr. Turk “triple
3 stacke[d].” That is, he applied one of the highest energy levels using a pin tip
4 delivering heat deeper than the alternatives, not just once or twice, but three
5 times to the same area without overlap.

6 75. Again, Invasix has provided Product users inconsistent instructions
7 with regard to use of overlapping. Both the 2011 and updated 2014 Operator
8 Manuals instruct physicians to use minimal overlapping, suggesting that
9 overlap should be avoided. A Clinical Bulletin issued at approximately the
10 same time also instructs physicians not to overlap.

11 76. But Invasix has since issued multiple other “labeling documents”
12 (as that phrase is defined by the FDA) with inconsistent instructions/warnings
13 as to overlap. The most notable of these documents is the May 2014 Clinical
14 Bulletin, presumably relied upon by Dr. Turk, in which, contrary to the peer-
15 reviewed writing of Dr. Mulholland, Invasix told physicians, “Stacking pulses
16 in the same site may improve the results It is safe to stack with the 24 pin
17 tip, as the heat is deeper but be more careful with the non-coated tips.” In the
18 Bulletin, Invasix acknowledged, “Stacking may increase the risk of side-
19 effects. Therefore, . . . On boney (sic) areas . . . treat with reduced energy, and
20 gradually increase energy **to a maximum of 25mJ/pin**. Avoid using 24 pin tip
21 if response of test pulse is excessive.” *Id.* (emphasis added).

22 77. Dr. Mulholland warned in 2015 that failure to use approximately
23 30-50% overlap would result in unintended thermal damage. This risk includes
24 the nerve damage Janice has suffered; nevertheless, Invasix has utterly failed to
25 warn doctors and patients of the risk of prolonged facial paralysis due to nerve
26 injury—not in its Operator Manuals, Clinical Bulletins or elsewhere.

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1 78. Dr. Turk followed up with a second pass of Janice’s “central
2 neck,” selecting a 50 mJ/pin energy level but using the 60 pin tip with a single
3 pulse. Here again, Dr. Turk selected much too aggressive parameters.
4 According to the May 2015 Quick Reference Guide, when treating even deep
5 wrinkles, the 60 pin tip should be used at no more than 30-45 mj on bony areas,
6 which should be reduced by 20% when working on areas of thin skin, such as
7 the neck.

8 79. For months, Janice suffered symptoms so severe, she could not
9 speak clearly and had difficulty eating and drinking. Even now her smile,
10 which is critical to her role as a television broadcaster and public media figure
11 among other things, remains asymmetrical. In addition to the severe nerve
12 damage, she also suffered permanent scarring on her neck.

13 80. Janice noticed a problem right away. The morning after the
14 procedure, she wrote Dr. Turk’s office manager to ask “if it’s normal that one
15 side of my face is more swollen than the other? It’s a little challenging to talk
16 out of the side of my mouth that’s swollen.” Later that day, she explained,
17 “my face is a bit droopy and I’m lisping a bit when I talk and my smile is off
18 center.” A few days later, February 20, 2017, she wrote, “Still [a] little worried
19 about the swelling and the left side of my mouth. I have this weird lopsided
20 smile!”

21 81. By March 1, 2017, Janice had attempted to return to work. She
22 finished one segment before Fox News producers pulled her off the air because
23 her appearance and inability to speak clearly. Janice conveyed the news to Dr.
24 Turk’s office, saying, “The recovery is so slow. Starting to get anxious.”
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1 82. Her anxiety grew still when, by March 20, 2017 (more than a
2 month after the procedures), she was “still not a hundred percent and I’m still
3 nervous that when I bite into things I have to move my lower lip so I don’t bite
4 my lip. I also have a hard time flossing my teeth and now I find when I drink
5 something it spills out of the corner of my mouth a bit. I am wondering if I
6 should see a facial nerve specialist?”

7 83. Dr. Turk seemed to share Janice’s concern, requesting that she
8 send photos on a regular basis for months and prescribing her steroids and
9 further recommending Botox to reduce swelling and improve her appearance.
10 Yet he assured Janice time and again that “100% this is temporary. It is just
11 hard to predict at what rate the muscles/nerves return to normal. . . . Sorry you
12 have to go through this.” On March 13, 2017, he claimed, “Could be just a few
13 days now.” But, by March 28, 2017, Dr. Turk admitted, “Thought it would be
14 happening a bit faster” On April 3, 2017, he thought the “needle [had]
15 start[ed] to move and the week after next sounds realistic.” Nevertheless, he
16 shared Janice’s sense of helplessness, explaining that in the face of the serious
17 physical and emotional impediments Janice was suffering, he had “meditated
18 and sent good thoughts, and maybe the universe listened.”

19 84. When, five weeks after the procedure which promised to require
20 less than a week’s downtime, Janice’s face continued to droop, her lip paralysis
21 persisted and talking, eating and drinking remained difficult and embarrassing,
22 she sought a second opinion from Dr. Michael C. Kane, a well-regarded New
23 York City plastic surgeon. Dr. Kane noted, “A[ssessment]: Prob[able] thermal
24 marg[inal] mand[ibular] n[erve] injury.” In other words, the aggressive
25 parameters used by Dr. Turk resulted in just the sort of thermal injury we would
26 expect from use of too much radio frequency over too long a period, failing to
27 utilize the overlapping technique of which Dr. Mulholland has written in a
28 peer-reviewed book chapter. He also observed that, at five weeks after the

1 procedure, Janice’s neck remained red and swollen.

2 85. Janice experienced great pain and suffering as the result of the
3 Fractora procedure and subsequent treatment. But the lasting effects are far
4 more devastating. Dr. Kane expressed concern that Janice’s nerve and muscle
5 injury may be permanent. This concern has borne true. Her face remains
6 droopy and her smile uneven eight months after the procedure. She also has
7 permanent scarring on her neck.

8 86. When Janice’s symptoms failed to improve as Dr. Turk indicated,
9 she worried that they could be related to Multiple Sclerosis (referred to
10 commonly as “MS”), a condition with which she was diagnosed in 2005 but for
11 which she has not had a major flare up for ten (10) years. The possibility that
12 she may have relapsed into an active state of the condition, an indication that
13 the condition was worsening, caused Janice a great deal of anxiety and distress
14 as a mother, a wife and a broadcaster. So, in addition to getting a second
15 opinion from Dr. Kane, Janice also visited the physician caring for her MS.
16 She also asked Dr. Turk his opinion. Both doctors agreed that the Fractora
17 procedure, not the MS, caused Janice’s symptoms.

18 87. While this offered Janice some solace, her inability to work—and
19 the uncertainty of when or if she would be able to return to work— caused
20 severe anxiety, panic attacks and depression common to those who have
21 suffered a medical trauma. These serious conditions reflected a number of
22 thoughts and feelings stirred by Janice’s physical injuries. She feared she may
23 not be able to return to work either on television or the radio, in which case, she
24 would lose not only the fulfillment and sense of achievement and identity one
25 gets from a successful career attained only after many, many years of hard
26 work and dedication, but also, as the primary breadwinner, the financial
27 stability of her family. She dreaded telling her supervisors, embarrassed for
28 having undergone a cosmetic procedure and worried at how they would react to

1 her inability to do her job after having just recently received the promotion to
2 her dream job on Fox & Friends.

3 88. Her concerns about career made her desperate for assurance. She
4 paid particular heed to Dr. Turk's promises that her injuries would resolve and
5 was all the more disheartened when those promises proved untrue.

6 89. In total, Janice missed two months of work. Her humiliation at
7 having been pulled off air by producers after her first attempt to return was
8 compounded by the requirement that she submit to weekly screen testing,
9 during which her producers would intensively scrutinize her face. They also
10 shared the screen tests with others who were unaware of Janice's situation for
11 feedback about her face and speech. This continued until, by her producers'
12 estimation, the balance between their and viewers' desire to have Janice return
13 to work and placing Janice back on air while still suffering effects from the
14 procedure tipped in favor of the former.

15 90. Fox News continued to pay Janice's salary during her time off air;
16 however, her career and career opportunities suffered. In broadcasting,
17 dependability is paramount. Viewers crave continuity, consistency and routine.
18 Although it was through no fault of her own, Janice disappointed both her
19 producers and viewers when her injuries required a long leave of absence. She
20 also missed career building opportunities during that time, including coverage
21 of a major winter storm, attendance with her team at the State of the Union
22 Address and multiple news pieces for which she would be the reporter. In
23 addition, the injuries required that Janice cancel all other public appearances.

24 91. During this period, she also received thousands of emails from
25 concerned viewers. They wanted to know why she was off air, when she would
26 return, if she was sick and, more particularly, if she was experiencing a MS
27 relapse. Viewers were not the only ones concerned that Janice may be
28 struggling with MS. She learned of rumors among co-workers of exactly that.

1 This was itself a source of worry because broadcasting, like so many careers in
2 the public eye, places a great deal of emphasis on health, youth and beauty.
3 Janice’s career would suffer—she would be less marketable both to viewers
4 and news groups—if she were even perceived as ill.

5 92. Consequently, Janice felt compelled to write and speak publicly
6 about what happened to her to dispel this misperception. This compounded her
7 feelings of embarrassment. It required that she again discuss the issue with Fox
8 producers. It also required that she share with a large audience her decision to
9 undergo an elective cosmetic procedure, something about which she felt a great
10 deal of shame. She had not told even her closest friends and family members
11 about the procedure. Now she was forced to tell everyone, including strangers.

12 93. Janice struggled personally with feelings of self-doubt and extreme
13 self-consciousness. Her injuries markedly changed her physical appearance.
14 For many months, she looked as though she may have suffered a stroke or some
15 other serious illness. She feared she would never regain her former identity—
16 or the ability to speak clearly and eat and drink without difficulty. Her lack of
17 confidence changed the dynamics of daily life. She has retreated in large part
18 from what had been a very active and happy social life. Janice lost sleep, lost
19 weight and became easily irritable. She suffered terrifying panic attacks during
20 which she could not breathe, shook, cried uncontrollably and felt nauseas.

21 94. These attacks, and her depression and anxiety in general, in turn,
22 affected her husband and sons. From her husband’s perspective, a loving one
23 to be sure, the procedure had been completely unnecessary. He felt anger at the
24 pain the injuries were causing his wife and family. Janice’s sons were nothing
25 short of traumatized by their mother’s panic attacks and initial appearance after
26 the procedure. At eight and six years old, their sense of security and
27 contentment depended almost wholly on their mother’s health and happiness.
28 The change in her appearance—especially something so fundamental as her

1 smile—also shook them to their core.

2 95. For her and her family’s sake, Janice began counseling. While it
3 has helped, she continues to struggle. She still receives emails from viewers,
4 who point out that her smile remains crooked.

5 **Plaintiff Mia Jones**

6 96. Prior to the Fractora procedure performed by an aesthetician at the
7 office of Dr. Paulino E. Goco, located in Nashville, Tennessee, on November
8 15, 2017, Mia was an extremely young-looking forty-nine (49) year old
9 aesthetician and hair stylist. She is mother of two children, nine (9) and fifteen
10 (15) years of age. She enjoyed an active work and social life in Nashville. Mia
11 sought treatment only to refresh her skin, which was virtually wrinkle-free and
12 healthy-looking.

13 97. Invasix representatives Heather Acquire and Trip Hutson sold the
14 InMode machine to Dr. Goco. Acquire, Hutson and, Invasix trainer, Cheryl
15 Hazing, visited with Mia and the other office aestheticians and staff in that
16 process, explaining and demonstrating the procedures that can be performed by
17 the machine. With regard to the Fractora, they claimed the procedure was an
18 extremely safe, painless and non-invasive alternative to face lift and other
19 energy based (laser) procedures. They also assured Mia the procedure was risk-
20 free and would require little downtime. They did not reveal to Dr. Goco or his
21 staff that, by that time, in late 2016-early 2017, no fewer than eleven other
22 women had been burned and permanently disfigured by the Fractora procedure.

23 98. At the recommendation of Acquire, Hutson and Hazing, Dr. Goco
24 had Mia and two other office aestheticians, Tricia King and Mandi Perry,
25 trained to perform the Fractora procedure. Acquire, Hutson and Hazing did not
26 disclose to Dr. Goco or to his staff that the FDA clearance for the Fractora
27 machine was for physician’s use only.
28

1 99. Mia’s injury occurred the third time she underwent the Fractora
2 procedure. Tricia King and Mandi Perry, Mia’s fellow aestheticians, performed
3 the first Fractora treatment using the 24 pin coated tip for two, single pulse
4 passes at 15 mj. Perry performed the second approximately six (6) weeks later,
5 using the 24 pin coated tip for a single, double pulse pass at 20 mj. Mia
6 tolerated those procedures well.

7 100. The third procedure, performed roughly six (6) weeks later,
8 differed from the first two only in that King followed the first pass with a
9 second, using the 60 pin tip at 30 mj. This third procedure left Mia’s face
10 extremely red and a little swollen even after using a cooling device. Her
11 redness turned to scabbing of the forehead and cheeks. The condition of her
12 face required Mia take three days off work after the third procedure.

13 101. Mia and King selected these parameters after training by Hazing
14 and reference to the January 2015 Quick Reference Guide (“QRG”). This QRG
15 indicates the “short 60 pin tip,” is safe for use on “full face” to treat superficial,
16 moderate and deep texture, tone and wrinkles. It also recommends energy
17 parameters for the 60 pin tip of up to 62, the highest energy setting.

18 102. Given these indications—which were reiterated in the Invasix
19 training—Mia and King understood the 60 pin tip is less aggressive than the 24
20 pin tip. However, Dr. R. Stephen Mulholland, the co-founder of Invasix and co-
21 inventor of InMode/Fractora, testified in October 2015 that the 60 and 126 pin
22 tips are more aggressive than the 24 pin tip counterpart in terms of the very
23 adverse effects suffered by Mia, possible unintended changes in skin color and
24 texture.

25 103. Moreover, had Invasix provided Dr. Goco the most updated QRG
26 at the time of Mia’s third procedure—the QRG dated March 2017—she would
27 have seen that Invasix actually recommended against using the 60 pin tip for
28 her Fitzpatrick Skin Type, Type IV. The March 2017 QRG also recommends

1 the 60 pin tip be used at much less aggressive energy settings, never more than
 2 30 mj.

3 104. After the fact, Wanda Cummings, an Invasix trainer, told Mia her
 4 injuries were the result of using the 60 pin tip given her skin Type IV.
 5 Cummings conclusion about the cause is corroborated by the March 2017
 6 QRG.

7 105. Dr. Goco expressed frustration at Invasix’s failure to provide him
 8 and his staff updated training information. In a January 22, 2018 email from
 9 him to Mia, Dr. Goco wondered, “Why did they not give us a notice [that the
 10 treatment instructions had changed] and update training information???” In the
 11 same email chain, Mia shares with Dr. Goco to what Wanda Cummings, the
 12 Invasix trainer, attributed her injuries:

106.

Dr. Goco on January 17, 2018	“Did she give any idea why that happened to you??? I think we should get [a]nother trainer out for every to get the latest parameters[.]
Mia on January 22, 2018 at 9:03 a.m.	<u>“[She said] I shouldn’t have used a 60 pin on my face.</u> The chart though said it was okay for type IV skin. Would it be okay if I ask her to come? She said she was going to pop by when she was near Nashville when I spoke with her.” (Emphasis added)
Dr. Goco on January 17, 2018 at 9:24 a.m.	“Yes, [i]t would be nice to have her come by and refresh everyones[’] training. Why did they not give us a

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	notice and update the training notice information????
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107. Again, the procedure left Mia’s face extremely red and swollen. Her face then scabbed to the point Mia could not work for three days. Mia’s scabbing ultimately turned to scarring over her entire face. It resulted in volume loss in Mia’s cheeks. The skin in Mia’s cheeks, around her smile lines and under her eyes is thin, loose and crepey. In addition, Mia suffered collapsed pores and other changes in her skin texture.

108. Mia has seen multiple doctors to address her disfigurement. Dr. Natalie Curcio has performed a few laser genesis treatments, all to no avail. Mia has also seen (and, in some cases, incurred consultation charges for) Drs. Williams Stebbins, John Bingham, Brian Beisman and Steven Bengelsdorf. She has also purchased medications, ointments and other over the counter treatment products.

109. Mia has suffered emotionally, too. She is a young, beautiful woman who, until her injuries, enjoyed the good fortune of healthy, young looking and virtually wrinkle and damage-free skin. The changes in Mia’s face add ten to fifteen years to her appearance and cause her to look less healthy. The loss of volume and crepey skin even appear to be smoker’s lines. This is particularly hurtful to Mia, who makes her living in the aesthetic and health industry.

110. As a result of her disfigurement, Mia has experienced extreme anxiety, depression, sleeplessness, loss of appetite, irritability and, worst of all, a significant decrease in her self-esteem. She finds mornings particularly difficult. She often suffers panic attack symptoms in the mornings, including loss of breath, rapid heartbeat and a sense of dread. Mia lost more than ten (10) pounds from her already small frame (she weighed as little as 116, down from her normal weight of 128 pounds).

1 111. Mia's inability to focus on work has resulted in loss of clients, loss
2 of revenue in the form of gratuities from clients and the loss of credibility with
3 her co-workers and Dr. Goco. She estimates her total lost earnings to be
4 \$8,100, which represents loss of nine (9) long-term clients who Mia had
5 previously seen every six to eight weeks for roughly \$150/appointment in
6 services.

7 112. She has also become obsessive in her research of the Fractora
8 procedure and doctors who specialize in treating injuries like hers. She has
9 extreme anxiety about undergoing additional treatments given her experience.
10 She will only feel comfortable using the best doctors in the area of scar
11 treatment, whom she believes to be Dr. Peter Rullan in Chula Vista, CA and
12 Dr. David Lim in Brisbane, Australia.

13 113. Dr. Rullan has recommended 2-3 erbium (\$500 per treatment) and
14 at least 3 Vbeam (\$300 per treatment) laser treatments, 1-3 CROSS (Chemical
15 Reconstruction of Skin Scars) (\$100-\$250 per treatment, depending upon
16 provider) treatments and 2 vials of Sculptra filler (\$1,250 per vial). The laser
17 treatments will have to be repeated multiple times and the Scuptra filler will
18 require lifelong retreatment.

19 114. Dr. Lim has recommended approximately 3 Fraxel 1927 and Co2
20 laser treatments for an estimated cost of \$3,000-\$5,000.

21 115. Thus, the total estimated cost of immediate (within a year) future
22 treatments is \$3,000-5,650, with another \$10,000 for Scuptra filler replacement
23 every 3 years for 15 years—a total that will exceed \$65,650 in Mia's lifetime.

24 116. Mia's lack of confidence has also affected her daily life. She has
25 retreated from what had been a very active and happy social life. She stopped
26 attending church. She has yet to return to a singles-type social group in Franklin,
27 TN. She even missed her son's soccer games, fearing what the other soccer
28 moms would think. Mia nearly passed on a trip to Italy she and her friends had

1 been planning (and for which she had paid) months in advance. As it was, she
2 kept her plans but the entire trip—like all Mia’s social and professional
3 experiences since the injuries—was shrouded in the sadness and grief she now
4 feels all the time.

5 117. For the first time, Mia began seeing a counselor, Tammy Dickerson,
6 for symptoms of medical treatment-related Post Traumatic Stress Disorder,
7 anxiety and depression. Her treatment has been helpful but, alas, her symptoms
8 persist. In fact, had it not been for her sessions with Lee, Mia believes she would
9 have become completely disabled. These sessions have come at great expenses,
10 more than \$1,600, and time off work.

11 118. Altogether, Mia’s out of pocket expenses exceed \$3,771.36. Her
12 total economic damages alone total more than \$75,000.

13 **Federal Law Does not Preempt Plaintiffs’ Claims**

14 119. Plaintiffs’ claims are not preempted by federal law for multiple
15 reasons. As a preliminary matter, the FDCA preemption provision applies only
16 to state law claims that create different or additional requirements and relate to
17 either safety and efficacy of the device or some other device specific
18 requirement. 21 U.S.C. § 360k(a). The FDA 510(k) clearance process, also
19 called a “premarket notification process,” focuses on whether the Product is
20 substantially equivalent to a predicate product and does not require the rigorous
21 “premarket approval” process by which the FDA determines the safety and
22 efficacy of other Class III medical devices. To the contrary, “Section 510(k)
23 clearance is not equivalent to FDA ‘approval’ of a device.” *U.S. v. Medtronic,*
24 *Inc.*, 2017 US DIST. LEXIS 153887, at *6. Courts have found preemption does
25 not apply to common law failure to warn product defect claims in 510(k)
26 clearance cases. *See e.g., Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 484-98,
27 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996).

1 120. Similarly, regulation implementing the FDCA clarifies the Act’s
2 preemption provision, which “does not preempt State or local requirements that
3 are equal to, or substantially identical to, requirements imposed by or under the
4 act.” 21 C.F.R. § 808.1(d). The Ninth Circuit borrowed language from the
5 Eighth Circuit in describing the “narrow gap” through which a state law claim
6 must fit to avoid express preemption: “The plaintiff must be suing for conduct
7 that violates the FDCA (or else his claim is expressly preempted by § 360k(a)),
8 but the plaintiff must not be suing because of the conduct violates the FDCA
9 (such a claim would be impliedly preempted under *Buckman [Co. v. Plaintiffs’*
10 *Legal Committee*, 531 U.S. 341, 350, 121 S. Ct. 1021, 148 L. Ed. 2d 854
11 (2001)].” *Perez v. Nidek, Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

12 121. Plaintiffs’ state law claims fall squarely within this gap, “parallel or
13 ‘genuinely equivalent’ to federal law,” and, thus, fall outside the express
14 preemption of the FDCA.¹² *See Stengal v. Medtronics, Inc.*, 704 F.3d 1224, 1233
15 (9th Cir. 2013) (holding state common law claims, including negligence,
16 premised on Medtronics failure to report adverse events to the FDA or otherwise
17 warn of prior failures of the device not preempted because the state paralleled
18 federal law inasmuch as it incorporated federal law as setting the standard of
19 care); *Houston v. Medtronics, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013)
20 (holding fraud-based and express warranty claims predicated on manufacturer’s
21 promotion of off label use without disclosing the risks associated with that use
22 to fall outside express and implied preemption).

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27 ¹² California law applies as Invasix’s wrongful conduct emanates in California.
28 *See, e.g., Sullivan v. Oracle Corp.*, 51 Cal. 4th 1191, 1207, 127 Cal. Rptr. 3d
185, 254 P.3d 237 (2011) (holding California’s consumer protection laws
“reach[] any unlawful business act or practice committed *in California*”).

1 122. State law claims fall outside implied federal preemption if not
2 barred by express preemption and “moored in traditional state common law that
3 exists independently from the FDCA.” *Houston*, 957 F. Supp. 2d at 1179.
4 California consumer protection laws create a duty independent of the FDCA on
5 manufacturers to refrain from false and deceptive advertisement even when the
6 truth of that advertisement “may be generally within the purview of the FDA.”
7 *See In re Epogen & Aransep Off-Label Marketing & Sales Practices Litig.*, 590
8 F. Supp. 2d 1282, 1291 (C.D. Cal. 2008) (“[I]nsofar as Plaintiffs can identify
9 specific representations by Defendants that are literally false, misleading, or
10 contain material omissions, the claims are actionable” under state and federal
11 consumer protection laws.). Thus, Plaintiffs’ state law claims are not impliedly
12 preempted.

13 **FIRST CAUSE OF ACTION**
14 **(Breach of Express Warranty)**

15 123. Plaintiffs hereby incorporate the above allegations by reference as
16 though fully set forth herein.

17 124. The owners of the Product used on Plaintiffs formed a contract
18 with Defendant at the time they purchased the Products. Plaintiffs are in privity
19 with those owners. The terms of that contract include the promises and
20 affirmations of fact made by Defendant on the Product’s labeling and through
21 Defendant’s promotional activities, marketing and advertising. The affirmations
22 of fact made in the promotional activity, marketing and advertising constitute
23 express warranties and became part of the basis of the bargain, and are part of
24 the standardized contract between Plaintiffs and Defendant.

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1 125. The affirmations of fact made by Defendant include, but are not
2 limited to, claims:

- 3 (a) Product is safe; effective; safer, more effective and requires less
4 recovery time than alternative procedures such as face lifts, laser
5 surgeries and chemical processes;
- 6 (b) Product is recommended by physicians with no financial interest in
7 promoting the Product;
- 8 (c) Product “promotes more superficial ablation and is more focused on
9 non-coagulative dermal residual heat” than alternative procedures;
10 “relatively comfortable;” “a complete single treatment solution for
11 aging patients;”¹³
- 12 (d) “Fractora is considered a non-invasive skin resurfacing and restoration
13 treatment that has been approved by the FDA and Health Canada;”
14 “Fractora does a better job [than traditional fractional procedures]
15 because it goes deeper and combines ablative and non-ablative RF;”
16 “[Fractora’s] RF influences all of the skin underneath, not just where
17 the pins penetrate and heat the skin [unlike traditional laser fractional
18 therapy;” Fractora’s secondary heating next to where the pins
19 penetrate and heat the skin is better controlled than with traditional
20 laser fractional therapy;
- 21 (e) “Fractora is the most advanced fractional radio-frequency treatment;”
22 “Fractora is light years ahead of traditional CO2 laser or Fraxel;”
23 “Part of the advantage of Fractora is the ability to treat the neck;”
24 Fractora can be safely performed by a non-physician “technician;”
25 using test spots is optional or only for patients “worried about

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27 ¹³ See “Fractora: A Novel Method for Deep Radio-Frequency Fractional
28 Resurfacing and Total Skin Rejuvenation” white paper included in promotional
materials provided at demonstrations conducted by Dr. Mulholland.

1 otherwise perform as represented.

2 132. Plaintiffs notified Defendant the Product was not merchantable
3 within a reasonable time after the defect manifested to Plaintiffs and other
4 consumers.

5 133. As a result of the non-merchantability of the Product, Plaintiffs and
6 other consumers sustained damages.

7 **THIRD CAUSE OF ACTION**

8 **(Fraud--Violation of California Unfair Competition Statute ("CUCS"))**

9 **Cal. Bus. & Prof. Code § 17200 et seq.**

10 134. Plaintiffs hereby incorporate the above allegations by reference as
11 though fully set forth herein.

12 135. Plaintiffs, as purchasers of the Fractora procedure performed with
13 the Product, are consumers within the meaning of the CUCS given that
14 Defendant's business activities involve trade or commerce, are addressed to the
15 market generally and otherwise implicate consumer protection concerns.

16 136. As detailed above, Defendant, through its promotional activities,
17 advertisements and Product labeling, used false advertising to sale the Product.
18 More specifically, and as described with particularity above, the following of
19 Defendant's wrongful conduct violates CUCS: (1) the undisclosed use of
20 physicians with a financial interest in promoting the Product; (2) promotion of
21 the Product for off-label use, an act which is prohibited under the FDCA; (3)
22 false, misleading or fraudulent off-label promotion of the Product without
23 proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4)
24 false, misleading or fraudulent labeling of the product through inconsistent and
25 inadequate instructions/warnings found in Product manuals and Clinical
26 Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and
27 affirmative acts to suppress reporting of—adverse events concerning the
28 Product, acts that are prohibited by the FDCA; (6) promotion of use of the

1 Product by non-physicians in contradiction of Defendant’s own instructions for
2 the safe use of the Product and, therefore false, misleading or fraudulent and
3 prohibited by the FDCA; and (7) other false, misleading or fraudulent
4 representations concerning the Product in advertisements provided by
5 Defendant to health care providers, such as claims the Product provides in just
6 one treatment better, safer, more effective results than can be achieved with
7 alternative procedures.

8 137. Defendant also knowingly concealed, suppressed, and consciously
9 omitted material facts in promotional activities, advertisements and labeling to
10 Plaintiffs and to the users of the Products used on Plaintiffs knowing that the
11 users and Plaintiffs would rely on the promotional materials, advertisements and
12 labeling in, on the part of the Plaintiffs, purchasing the Fractora procedure and,
13 with regard to the users, purchasing and using the Products.

14 138. Once defects in the Product and its tendency to cause unintended
15 injuries despite use as instructed by Defendant became apparent to Defendant,
16 Defendant had a duty to disclose that fact—and adverse events— because this
17 risk would be a material fact in the decision making process of Plaintiffs and
18 those performing the Fractora procedure, and, without Defendant’s disclosure,
19 Plaintiffs and those performing the Fractora procedure would not necessarily
20 know that there is such a risk.

21 139. Defendant intended that Plaintiffs and those performing the
22 Fractora procedure would rely on the continued deception by purchasing the
23 Fractora procedure and using the Product, unaware of these material facts and
24 omissions. Defendant further knew that Plaintiffs and those performing the
25 Fractora procedure would continue to rely on Defendant’s representations and
26 silence as to any known risk of unintended injuries as evidence that the Product
27 was safe and would perform as represented. Defendant’s wrongful conduct,
28 which emanates in California, where Defendant maintains is principal and sole

1 place of business, constitutes breaches of express and implied warranties, and,
2 as such and independently, constitutes consumer fraud within the meaning of
3 the CUCS.

4 140. Defendant's material non-disclosure constitutes an unconscionable
5 commercial practice, deception, fraud, false promise, misrepresentation and/or
6 omission of material facts as to the nature of the goods in violation of the
7 CUCS.

8 141. Defendant is the producing and proximate cause of Plaintiffs'
9 injuries.

10 **FOURTH CAUSE OF ACTION**

11 **(Fraud—Violation of California False Advertising Law (“CFAL”)**

12 **Bus. & Prof. Code § 17500 et seq.)**

13 142. Plaintiffs hereby incorporate the above allegations by reference as
14 though fully set forth herein.

15 143. Plaintiffs, as purchasers of the Fractora procedure performed with
16 the Product, are consumers within the meaning of the CFAL given that
17 Defendant's business activities involve trade or commerce, are addressed to the
18 market generally and otherwise implicate consumer protection concerns.

19 144. Defendant knowingly concealed, suppressed, and consciously
20 omitted material facts in promotional activities, advertisements and labeling to
21 Plaintiffs and to the users of the Products used on Plaintiffs knowing that
22 Plaintiffs and users would rely on the promotional activities, advertisements and
23 labeling in, on the part of the Plaintiffs, purchasing the Fractora procedure, and,
24 with regard to the users, purchasing and using the Products. More specifically,
25 and as described with particularity above, the following of Defendant's
26 wrongful conduct violates CFAL: (1) the undisclosed use of physicians with a
27 financial interest in promoting the Product; (2) promotion of the Product for off-
28 label use, an act which is prohibited under the FDCA; (3) false, misleading or

1 fraudulent off-label promotion of the Product without proper disclosure of
2 attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or
3 fraudulent labeling of the product through inconsistent and inadequate
4 instructions/warnings found in Product manuals and Clinical Bulletins, an act
5 that is prohibited by the FDCA; (5) failure to report—and affirmative acts to
6 suppress reporting of—adverse events concerning the Product, acts that are
7 prohibited by the FDCA; (6) promotion of use of the Product by non-physicians
8 in contradiction of Defendant’s own instructions for the safe use of the Product
9 and, therefore false, misleading or fraudulent and prohibited by the FDCA; and
10 (7) other false, misleading or fraudulent representations concerning the Product
11 in advertisements provided by Defendant to health care providers, such as
12 claims the Product provides in just one treatment better, safer, more effective
13 results than can be achieved with alternative procedures.

14 145. Once the defects in the Products and their tendency to cause
15 unintended injuries despite use as instructed by Defendant became apparent to
16 Defendant, Defendant had a duty to disclosure that fact—and adverse events—
17 because this risk would be a material fact in the decision making process of
18 Plaintiffs and those performing the Fractora procedure, and, without
19 Defendant’s disclosure, Plaintiffs and those performing the Fractora procedure
20 would not necessarily know that there is such a risk.

21 146. Defendant intended that Plaintiffs and those performing the
22 Fractora procedure would rely on the continued deception by using and
23 purchasing the Product and performing and undergoing the Fractora procedure,
24 unaware of these material facts and omissions. Defendant further knew that
25 Plaintiffs and those performing the Fractora procedure would continue to rely on
26 Defendant’s representations and silence as to any known risk of unintended
27 injuries as evidence that the Product was safe and would perform as represented.
28 Defendant’s wrongful conduct, which emanates in California, where Defendant

1 maintains is principal and sole place of business, constitutes breaches of express
2 and implied warranties, and, as such and independently, constitutes false
3 advertising within the meaning of the CFAL.

4 147. Defendant's material non-disclosure constitutes false advertising in
5 violation of the CFAL.

6 148. Defendant is the producing and proximate cause of Plaintiffs'
7 injuries.

8 **FIFTH CAUSE OF ACTION**

9 **(Fraud—Common Law)**

10 149. Plaintiffs hereby incorporate the above allegations by reference as
11 though fully set forth herein.

12 150. Defendant knowingly concealed, suppressed, and consciously
13 omitted material facts in promotional activities, advertisements and labeling to
14 Plaintiffs and to the users of the Products used on Plaintiffs knowing and
15 intending that Plaintiffs and users would rely on the promotional activities,
16 advertisements and labeling in, on the part of the Plaintiffs, purchasing the
17 Fractora procedure, and, with regard to the users, purchasing and using the
18 Products. More specifically, and as described with particularity above, the
19 following of Defendant's wrongful conduct constitutes common law fraud: (1)
20 the undisclosed use of physicians with a financial interest in promoting the
21 Product; (2) promotion of the Product for off-label use, an act which is
22 prohibited under the FDCA; (3) false, misleading or fraudulent off-label
23 promotion of the Product without proper disclosure of attendant risks, an act that
24 is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the
25 product through inconsistent and inadequate instructions/warnings found in
26 Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA;
27 (5) failure to report—and affirmative acts to suppress reporting of—adverse
28 events concerning the Product, acts that are prohibited by the FDCA; (6)

1 promotion of use of the Product by non-physicians in contradiction of
2 Defendant's own instructions for the safe use of the Product and, therefore false,
3 misleading or fraudulent and prohibited by the FDCA; and (7) other false,
4 misleading or fraudulent representations concerning the Product in
5 advertisements provided by Defendant to health care providers, such as claims
6 the Product provides in just one treatment better, safer, more effective results
7 than can be achieved with alternative procedures.

8 151. Defendant's fraud is the proximate cause of Plaintiffs' injuries.

9 **SIXTH CAUSE OF ACTION**

10 **(Negligence, Negligence Per Se and Gross Negligence)**

11 152. Plaintiffs hereby incorporate the above allegations by reference as
12 though fully set forth herein.

13 153. Defendant owed Plaintiffs a duty to use due care in their
14 development, testing, planning, design, marketing and sale of the Product.

15 154. Under the FDCA, CUCS, CFAL and the applicable common law,
16 Defendant owed Plaintiffs a duty of care to refrain from the false, misleading or
17 fraudulent off-label promotion and labeling of the Product. Under the FDCA,
18 CUCS, CFAL and the applicable common law, Defendant also owed Plaintiffs a
19 duty to report adverse events related to use of the Product. Finally, under the
20 FDCA, CUCS, CFAL and the applicable common law, Defendant owed
21 Plaintiffs a duty to refrain from promoting use of the Product by non-physicians.
22 The statutory schemes of the FDCA, CUCS and CFAL are designed to protect
23 vulnerable patients like Plaintiffs and, therefore, set the standard of care in these
24 regards.

25 155. Defendant breached these duties by (1) failure to exercise due care
26 in producing, processing, manufacturing, distributing and/or offering for sale the
27 Product and, therefore, selling the Product in a defective condition that was
28 unsafe for use as promoted by Defendant, namely the failure to warn; (2) false,

1 misleading or fraudulent off-label promotion of the Product; (3) false,
2 misleading or fraudulent labeling of the product through inconsistent and
3 inadequate instructions/warnings found in Product manuals and Clinical
4 Bulletins; (4) failure to report—and affirmative acts to suppress reporting of—
5 adverse events concerning the Product; and (5) promoting use of the Product by
6 non-physicians.

7 156. Defendant further breached its duty of care to Plaintiffs by failing
8 to use sufficient quality control, perform adequate research or testing, proper
9 manufacturing, production or processing, and failing to take sufficient
10 measures to prevent the Product from being offered for sale in an unsafe and
11 hazardous form.

12 157. In addition, Defendant breached its duty of due care by failing to
13 properly and adequately inform consumers, including Plaintiffs, health care
14 providers and the FDA once risks of unintended injuries such as burns, scars
15 and nerve damage were brought to the Defendant's attention.

16 158. Defendant knew, or in the exercise of reasonable care should have
17 known, that the Product presents an unacceptable risk to consumers, including
18 Plaintiffs, and would result in damages that were foreseeable and reasonably
19 avoidable.

20 159. As a direct and proximate result of Defendant's above-referenced
21 negligence, negligence per se and/or gross negligence, Plaintiffs have suffered
22 and are entitled to recover damages, both compensatory and punitive.

23 **SEVENTH CAUSE OF ACTION**

24 **(Strict Liability)**

25 160. Plaintiffs hereby incorporate the above allegations by reference as
26 though fully set forth herein.

27 161. Defendant is the producer, manufacturer, marketer, distributor
28 and/or seller of the Product.

1 162. The Product is defective in design or formulation due to
2 inconsistent and inadequate instructions/warnings and the promotion of off-label
3 use of the Product employing aggressive settings and techniques in order to
4 exaggerate the effectiveness of the Product while failing to disclose the dramatic
5 increase in risks of unintended injuries when using the Product in such an
6 aggressive manner.

7 163. The Product is also defective due to inadequate post-market
8 instruction/warnings because, after Defendant knew or should have known of
9 the risk of injury from the Product, Defendant failed to immediately provide
10 adequate instruction/warnings and report adverse events to Plaintiffs, health care
11 providers and the FDA.

12 164. As the direct and legal result of the defective condition of the
13 Product as produced, manufactured, designed, marketed, distributed and/or sold
14 by Defendant, and of the negligence, carelessness, other wrongdoing and actions
15 of Defendant described herein, Plaintiffs suffered damages.

16 **ATTORNEYS' FEES, EXPENSES AND COSTS**

17 165. Plaintiffs hereby incorporate the above allegations by reference as
18 though fully set forth herein.

19 166. Plaintiffs have been forced to secure the assistance of counsel to
20 protect their legal rights and mitigate their damages as a result of the
21 Defendant's wrongful conduct.

22 167. Having made proper presentment and provided actual and
23 sufficient notice of their claims to Defendant, Plaintiffs seek recovery of their
24 reasonable attorneys' fees, expenses and costs pursuant to all applicable statutes,
25 regulations and agreements.

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PRAYER

WHEREFORE Plaintiffs pray for Judgment against Defendant as follows:

1. For an award of actual, consequential and punitive damages according to proof;
2. For an award of reasonable attorneys' fees, costs and pre- and post-judgment interest; and;
3. For all other relief to which they may be justly entitled.

Respectfully submitted,

CHRISTIANSEN DAVIS, LLC
ESENSTEN LAW

By: /s/ Robert L. Esensten
Amy E. Davis
Robert L. Esensten
ATTORNEYS FOR PLAINTIFFS

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury.

Respectfully submitted,

CHRISTIANSEN DAVIS, LLC
ESENSTEN LAW

By: /s/ Robert L. Esensten
Amy E. Davis
Robert L. Esensten
ATTORNEYS FOR PLAINTIFFS