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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

JANICE NEWMAN, **Plaintiff,** **v.** **INVASIX INC. and INMODE LTD.,** **Defendants.**	**CASE NO. 1:19-CV-07494** **FIRST AMENDED COMPLAINT:** **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** **HON. NAOMI REICE BUCHWALD**

Plaintiff Janice Newman ("Plaintiff"), through counsel, files this First Amended Complaint against Defendant Invasix Inc. and Defendant InMode Ltd. and respectfully state as follows:

NATURE OF THE ACTION

1. Plaintiff seeks redress for permanent facial disfigurement and personal

injury caused by the Fractora procedure, a radio frequency-based cosmetic surgery performed with a Fractora device (the "Product") designed, manufactured and sold in North America by Invasix.

JURISDICTION AND VENUE

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

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

PARTIES

4. Plaintiff Janice Newman is a citizen of New York, residing in Floral Park, New York.

5. Defendant Invasix, Inc. is a corporation formed under the laws of Delaware, with its principal North American office in Ontario, Canada. Defendant Invasix, Inc. has appeared in this lawsuit.

6. Defendant InMode Ltd. is an Israeli corporation with a principal place of business at Tavor Building, Sha'ar Yokneam, P.O. Box 533, Yokneam 2069206, Israel. Pursuant to Federal Rule of Civil Procedure 4(f) and Article 10(a) of the Hague Convention, Plaintiff may serve Defendant InMode Ltd. by certified mail at this location, attention Moshe Mizrahy, the company's Chief Executive Officer and Chairman of the Board of Directors.

FACTUAL BACKGROUND

7. Defendant Invasix, Inc. acts as the North American division for Defendant InMode Ltd. Plaintiff, therefore, refers to these defendants collectively as "Defendant." Defendant designed, manufactured, marketed, sold and distributed the Product throughout the United States at all times relevant to this Complaint.

Product Received 510(k) FDA Clearance

8. Under the Food, Drug and Cosmetic Act of 1938, as modified by the Medical Device Amendments of 1976 (the "FDCA"), the U.S. Food and Drug Administration ("FDA") has authority to regulate medical devices. If a device "support[s] or sustain[s] human life" or "presents a potential unreasonable risk of illness or injury," it is designated a "Class III" device for which pre-market approval by the FDA is required. 21 U.S.C. § 360c(a)(1)(C)(ii). The FDCA presumes all devices are Class III devices unless a manufacturer demonstrates otherwise. To obtain pre-market approval, a device manufacturer typically must show the "safety and effectiveness [of the device] under the conditions of use set forth on the label." § 360c(a)(2)(B).

9. However, a device may also be cleared for sale by the manufacturer if found by the FDA to be substantially equivalent to a "predicate" device that was legally marketed prior to May 28, 1976. 21 CFR § 807.92(a)(3). To obtain FDA-clearance under the substantially equivalent standard, a procedure commonly referred to as 510(k) clearance and the least stringent of all processes for FDA-approval of a medical device, a manufacturer must submit, among other things, a statement of intended use and proposed labeling and instructions for use of the device. "Section 510(k) clearance is not equivalent to FDA 'approval' of a device. Instead, the FDA only clears such devices for the limited uses identified by the manufacturer in the § 510(k) application." *U.S. v. Medtronics, Inc.*, 2017 US DIST. LEXIS 153887, at *6 (CD Cal. Sept. 11, 2017) (citing 21 CFR § 807.97 and 801.5)).

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

11. Defendant obtained 510(k) clearance of the Product.[1]

12. Since the Product received its 501(k) clearance, the FDA announced its plan to overhaul this relatively lax procedure, acknowledging that the 501(k) clearance "framework needs to be modernized to reflect advances in technology, safety and the capabilities of a new generation of medical devices."[2] As is discussed in more detail below, Defendant markets the Product as just such a revolution in medical devices, claiming it is a safer alternative to more traditional, ablative and invasive procedures.

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

[1] Brian Lodwig, former President of Invasix, confirmed that the 510(k) FDA clearance application for the product included the February 2011 Operator's Manual. Invasix submitted that application, Fractora K102461, on or about March 25, 2011.

[2] Statement of FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, Nov. 26, 2018, at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm626572.htm. CNBC associates the FDA's announcement with "scathing investigations into medical device failures and how the FDA's accelerated review process may have 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-approval-process.html.

skin."

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

Defendant's Failure to Disclose the Financial Interest of Doctors Recruited to Assist in Sales

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

16. However, Defendant does not disclose its connection to the Luminary Program doctors, that the doctors have been compensated for their participation or that the trainings, demonstrations, "studies," white papers and testimonials constitute no more than promotional materials.[3] Instead, Defendant present these

[3] According to the FDA, any statement by a manufacturer to a third party is a promotional activity, including, but not limited to statements made by sales representatives to doctors or patients, statements made in marketing materials, such as web and social media sites, sales brochures, direct-to-consumer advertising, as well as statements made in press releases, training materials, or by way of depictions

materials as though they are independent and, in the case of purported studies and papers, the result of objective scientific study, which they are not.[4]

17. Defendant relies heavily on one opinion leader in particular, Dr. Stephen R. Mulholland, a plastic surgeon with a private aesthetics practice in Toronto, Canada. Mulholland co-invented the Fractora technology and co-founded Invasix. He continues to own shares in the entity that owns and controls the company.

18. Invasix clearly sponsors the Dr. Mulholland demonstrations: Invasix employees extend invitations and provide materials. Yet, rather than disclose the financial interest of both Invasix and its owner, Dr. Mulholland, the presentation aides and materials mention nothing of Dr. Mulholland's ties to Invasix and the Fractora technology, implying that Dr. Mulholland is no more than an independent

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and demonstrations. Use of health care providers to "train" on a product is also promotional, particularly if the health care provider is chosen by the company and receives compensation of any form for his or her assistance. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, published by the FDA in December 1997, which is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM125602.pdf.

[4] The President of Invasix has confirmed the existence of the Luminary Program and the company's compensation of its members in exchange for Luminary duties. However, specifics concerning the Luminary Program members—such as the identity of its members, the compensation or other financial incentives 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.

practitioner besotted with the Fractora procedure.[5]

19. The FDCA and California consumer protection statutes and common law prohibits this type of deception in the sale of medical devices. *See* 21 USC §§ 331(b) and 352(f). FDA regulation also requires reporting of annual payments to those conducting research regarding a medical device, like Dr. Mulholland and many of the Luminary Program members, exceeding $25,000 a year or equity stakes in public companies worth more than $50,000 and any equity stake in private companies, such as Invasix. *See* 21 C.F.R. §§ 54.2(f) & 54.4 (1999) and 42 C.F.R. § 50.603.[6] Invasix's failure to disclose the connection between Dr. Mulholland and other physicians to the company violates the FDCA and its implementing

[5] Defendant makes these misrepresentations and omissions concerning Dr. Mulholland and his connection to Defendant in, among other things, a PowerPoint presentation and white papers used by Defendant and Dr. Mulholland at the demonstrations. Because Defendant believes the PowerPoint document to be proprietary and confidential, Plaintiff does not attach it as an exhibit; however, Plaintiff provided Defendant a copy prior to filing this Complaint (and in Defendant's possession prior to that time as well). A slide introducing Dr. Mulholland refers only to his private aesthetics plastic surgery practice. A slide introducing Invasix lists company "founders," but fails to identify Dr. Mulholland among them. The presentation also includes white papers authored by Dr. Mulholland but in which his connection to Defendant goes undisclosed. Dr. Mulholland's curriculum vitae lists the dates and locations of his many Fractora demonstrations. Because Defendant views the document as proprietary and confidential, and because it is voluminous, Plaintiff does 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 excess of $5,000 in a public company and any ownership interest in a privately held business. 21 C.F.R. § 54.2(b).

regulation.

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

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

21. Doctors subject to these kinds of manipulations are often blinded to the objectively verifiable bias,[8] including members of Defendant's Luminary

[7] *See, e.g.,* Deborah Korenstein, Salomeh Keyhani & Joseph S. Ross, *Physician Attitudes Toward Industry:A View Across the Specialties*, 145 ARCHIVES SURGERY 570, 573, 577 (2010); *see also* ASS'N OF AM.MED. COLLS., THE SCIENTIFIC BASIS OF INFLUENCE AND RECIPROCITY: A SYMPOSIUM 1 (2007) (discussing a "growing body of a neurobiological and psychosocial evidence related to the effects of gifts on recipients' choices and decisions"); *see also* L. Lewis Wall & Douglas Brown, *The High Cost of Free Lunch*, 110 OBSTETRICS & GYNECOLOGY 169, 171 (2007) (noting that "[t]he provision of food is an especially powerful tool in shaping perceptions and increasing the 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).

[8] *See, e.g.,* Ann H. Harvey, Ulrich Kirk, George H. Denfield & P. Read Montague, *Monetary Favors and Their Influence on Neural Responses and Revealed Preference*, 30 J. NEUROSCIENCE 9597, 9600–01 (2010) (reporting on research demonstrating that "[a] monetary favor from a company was indeed capable of robustly influencing preference for art paired with the logo of the sponsoring company logo. . . . despite the fact that subjects were unfamiliar with the company logos, subjects had no reciprocal interaction with the company, and the only association between the art and the sponsoring company was visual juxtaposition on

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

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

23. More particularly, the purported studies, white papers, live demonstrations, videos and other resources created by Luminary Program members, Dr. Mulholland included, employ the following aggressive device

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a computer screen," and despite the fact that the subjects of the research did not believe "the presence of the logo influenced their ability to judge the paintings"); *see also* Azgad Gold & Paul S. Appelbaum, *Unconscious Conflict of Interest: A Jewish Perspective*, 37 J. MED. ETHICS 402, 404 (2011) ("It seems that the Talmudic answer to this question is clear. On the psychological level, one cannot escape the deleterious unconscious effects of receiving a gift. As a human being, the recipient is biased, no matter how wise and otherwise reasonable the person 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").

parameters and user techniques, all of which are at odds with Invasix's 510(k) FDA application for the Product:

(a) Failure to use the lowest energy output setting necessary to achieve the desired surgical effect, instead typically promoting the use of the Product at or near the highest energy levels (i.e., 20-30 mJ/pin versus 40-62 mJ/pin, 62 mJ/pin being the highest setting);

(b) Failure to reduce Product energy output setting over bony areas, such as the cheek bones and forehead, and further reduce the settings over areas of thin skin, such as the neck and under the eyes;

(c) Use of unreasonable number and configuration of multi-electrode pins (i.e., the 24 versus 60 or 126 pin tip);

(d) Unreasonable length of multi-electrode pins (i.e., 3000 micron versus 600 micron);

(e) Use of unreasonable lack of coating (versus coated) on multi-electrode pins;

(f) Failure to use the output setting for the shortest amount of time necessary to achieve the desired surgical effect, (i.e., use of unreasonable number of passes with Product over the same area of the body);

(g) Use of unreasonable amount of pressure with which the handpiece is applied to the patient's skin; and

(h) Failure to overlap the applicator tip by 30-50%, thereby causing an overlap of one negative electrode on top of another, resulting in too much superficial positive current flowing up to the negative electrode in that area.

24. By way of example, in the Power Point presentation used by Dr. Mullholland at his demonstrations, a "Typical Parameters for Clinical Effects" slide encourages use of the Product at energy levels significantly higher than those

presented to the FDA and with no reference to pin tip, reduction in energy for bony areas or areas of thin skin, or any warning that usage at higher energy levels increases the risk of burns, scarring and nerve damage. The presentation also includes slides depicting Fractora treatment results using the machine at the very highest energy settings, including on the neck and under the eyes, in contradiction to FDA cleared parameters.

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

26. Since the statements made by Dr. Mulholland and Luminaries are promotional, they are imputed to Invasix even though Invasix does not directly employ the doctors. The FDA considers off-label promotion by a device manufacturer, whether express or implied, to be a violation of the FDCA, particularly 21 USC §§ 331(b) and 352(f). *See also Carson v. Depuy Spine, Inc.*, 365 F. App'x 812, 815(9th Cir. 2010) ("[W]hile doctors may use a drug or device off-label, the marketing and promotion of a Class III device for unapproved use violates Section 331 of the FDCA.");*Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 703-706 (S.D. Tex. Mar. 24, 2014) (same).

27. Off-label use encompasses use of techniques and device parameters that vary from the FDA approved instructions/warnings. *See, e.g., Eidson v.*

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

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

29. Moreover, because these promotional demonstrations and materials omit critical warnings about likely risks, they are also false, fraudulent and misleading and in violation of California consumer protection laws and the FDCA. More specifically, the opinion leaders used by Invasix to promote the Fractora device fail to inform their audience that (1) use of the device at a higher energy level increases the risk of burns, scarring and nerve damage, (2) energy settings should be reduced on bony areas and areas of thin skin, such as forehead and cheeks, and (3) users, like Plaintiff's doctors, could achieve the same results by using less energy over multiple sessions, thereby reducing the risk of injury.

30. Invasix makes the so-called studies, white papers, videos and other

resources created by Luminaries and other health care professionals financially interested in the sale of the device available to prospective and new buyers/users through its website, inmodemd.com, and an electronic portal, access to which is given to new and potential owners/users by email. Defendant reviews these materials, particularly those involving Dr. Mulholland, with new and prospective doctor-customers during in-office demonstrations and trainings. In other words, Defendant indoctrinates all new and prospective Product owners with these false, fraudulent and misleading materials.

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

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

32. Since receiving 510(k) FDA-clearance in 2011, Invasix has issued users new Product operator manuals and Clinical Bulletins with grossly inconsistent and inadequate instructions/warnings regarding permissible energy settings, selection of the appropriate disposable tips and multi-electrode pins and procedure techniques, such as the permissible amount of overlap and pressure with which to apply the hand held applicator tip. Similarly, the Product manuals and Clinical

[9] The FDCA defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying any such article." *See* 21 U.S.C. § 325(a).

Bulletins fail to adequately warn users of known risks associated with the Product, including, but not limited to, the risk of long term nerve damage.

33. Details specific to Plaintiff and her health care provider follows.

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

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

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

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

36. The FDA and consumer protection laws of California, where Invasix makes decisions concerning manufacture, distribution, marketing, promotion and sale of the Product, require manufacturers like Invasix to report adverse events related to use of its medical devices, even those adverse events the manufacturer believes is due to misuse of the Product. This requirement is key to the FDA's role in patient safety. If manufacturers fail to comply, the FDA cannot protect unsuspecting patients from unsafe medical devices or procedures made unsafe by a manufacturer's false, misleading or fraudulent promotion of a medical device.

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

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

39. Invasix has unlawfully suppressed reporting of adverse events that may have prevented injury to Plaintiff. Plaintiff is aware of at least *twelve* victims of the Fractora procedure—all of whom Invasix is aware—that fall within the mandatory reporting guidelines. In some cases, Brian Lodwig, the former President of Invasix, Inc. has himself referred to the incidents as "adverse events." Yet, Invasix has yet to report a single adverse event related to the Fractora procedure. In so doing, Invasix violated the FDCA and failed to follow its own internal Risk Estimation and Evaluation of Customer Complaint guide.

40. Invasix further suppresses FDA adverse event reporting by its practice of downplaying the seriousness of injuries suffered by Fractora patients when contacted by concerned physicians. This practice emanates from those in positions

of highest authority within Invasix and is, thus, corporate-driven and wide scale interference with the very FDA regulation meant to protect unsuspecting consumers.

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

FACTS RELATING TO PLAINTIFF

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

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

44. Janice is young and extremely active. Her only issue was a few wrinkles on her neck. She agreed to undergo a Fractora procedure performed by Dr. Jon B. Turk on February 16, 2017 based on her doctor's recommendation and claims made by Invasix in brochures, posters and in the media that it is a safe, less invasive alternative to surgical and other energy-based procedures and that she

could expect to heal much quicker than if undergoing comparable procedures.

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

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

47. For the first pass, Dr. Turk used the 24 pin coated tip at 55 mJ/pin with two pulses. As a May 2014 Invasix Clinical Bulletin points out, the 24 pin tip delivers heat deeper than any of the other Fractora pin tips.[10] Similarly, the 55 mJ/pin energy setting is just shy of the device's very highest setting of 62 mJ/pin and particularly aggressive given the doctor's selection of multiple pulses. All of these parameters are in excess of those included in FDA-reviewed 2011 Operator's Manual. In particular, the Operator's Manual warns, "Use the lowest output setting necessary to achieve the desired surgical effect. Use of the RF energy only for the minimum time necessary in order to lessen the possibility of unintended burn injury. The higher the RF energy and the longer the RF energy is applied, the

[10] Prior to discovery, Janice cannot be sure what materials Invasix had provided to Dr. Turk at the time of her procedure; that information is known to Defendant. 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.

greater the possibility of unintended thermal damage to tissue . . . ." For treatment of lax skin on Fitzgerald Skin Types I-III, which applied to Janice, the May 2015 Quick Reference Guide instructs physicians to use the 24 coated pin tip at no more than 30-40 mJ/pin on soft tissue and 20-30 mJ/pin when working on bony areas.

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

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

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

51. Dr. Mulholland warned in 2015 that failure to use approximately 30-50% overlap would result in unintended thermal damage. This risk includes the

nerve damage Janice has suffered; nevertheless, Invasix has utterly failed to warn doctors and patients of the risk of prolonged facial paralysis due to nerve injury—not in its Operator Manuals, Clinical Bulletins or elsewhere.

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

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

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

55. By March 1, 2017, Janice had attempted to return to work. She finished one segment before Fox News producers pulled her off the air because her appearance and inability to speak clearly. Janice conveyed the news to Dr. Turk's office, saying, "The recovery is so slow. Starting to get anxious."

56. Her anxiety grew still when, by March 20, 2017 (more than a month after the procedures), she was "still not a hundred percent and I'm still nervous that

when I bit into things I have to move my lower lip so I don't bite my lip. I also have a hard time flossing my teeth and now I find when I drink something it spills out of the corner of my mouth a bit. I am wondering if I should see a facial nerve specialist?"

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

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

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

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

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

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

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

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

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

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

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

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

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

68. These attacks, and her depression and anxiety in general, in turn, affected her husband and sons. From her husband's perspective, a loving one to be sure, the procedure had been completely unnecessary. He felt anger at the pain the injuries were causing his wife and family. Janice's sons were nothing short of traumatized by their mother's panic attacks and initial appearance after the procedure. At eight and six years old, their sense of security and contentment depended almost wholly on their mother's health and happiness. The change in

her appearance—especially something so fundamental as her smile—also shook them to their core.

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

Federal Law Does not Preempt Plaintiff's Claims

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

71. Similarly, regulation implementing the FDCA clarifies the Act's preemption provision, which "does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act." 21 C.F.R. § 808.1(d). The Ninth Circuit borrowed language from the Eighth Circuit in describing the "narrow gap" through which a state law claim must fit to avoid express preemption: "The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because of the conduct violates the FDCA (such a claim would

be impliedly preempted under *Buckman [Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 350, 121 S. Ct. 1021, 148 L. Ed. 2d 854 (2001)*]*." *Perez v. Nidek, Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013).

72. Plaintiff's state law claims fall squarely within this gap, "parallel or 'genuinely equivalent' to federal law," and, thus, fall outside the express preemption of the FDCA.[11] *See Stengal v. Medtronics, Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (holding state common law claims, including negligence, premised on Medtronics failure to report adverse events to the FDA or otherwise warn of prior failures of the device not preempted because the state paralleled federal law inasmuch as it incorporated federal law as setting the standard of care); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 (C.D. Cal. 2013) (holding fraud-based and express warranty claims predicated on manufacturer's promotion of off label use without disclosing the risks associated with that use to fall outside express and implied preemption).

73. State law claims fall outside implied federal preemption if not barred by express preemption and "moored in traditional state common law that exists independently from the FDCA." *Houston*, 957 F. Supp. 2d at 1179. California consumer protection laws create a duty independent of the FDCA on manufacturers to refrain from false and deceptive advertisement even when the truth of that advertisement "may be generally within the purview of the FDA." *See In re Epogen & Aransep Off-Label Marketing & Sales Practices Litig*., 590 F. Supp. 2d 1282, 1291 (C.D. Cal. 2008) ("[I]nsofar as Plaintiff can identify specific representations by Defendants that are literally false, misleading, or contain

[11] California law applies as Invasix's wrongful conduct emanates in California. *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*").

material omissions, the claims are actionable" under state and federal consumer protection laws.). Thus, Plaintiff's state law claims are not impliedly preempted.

FIRST CAUSE OF ACTION

(Breach of Express Warranty)

74. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

75. The owners of the Product used on Plaintiff formed a contract with Defendant at the time they purchased the Products. Plaintiff are in privity with those owners. The terms of that contract include the promises and affirmations of fact made by Defendant on the Product's labeling and through Defendant's promotional activities, marketing and advertising. The affirmations of fact made in the promotional activity, marketing and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and Defendant.

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

(a) The Product is safe; effective; safer, more effective and requires less recovery time than alternative procedures such as face lifts, laser surgeries and chemical processes;

(b) The Product is recommended by physicians with no financial interest in promoting the Product;

(c) The Product "promotes more superficial ablation and is more focused on non-coagulative dermal residual heat" than alternative procedures; "relatively comfortable;" "a complete single treatment solution for aging patients;"[12]

[12] *See* "Fractora: A Novel Method for Deep Radio-Frequency Fractional Resurfacing and Total Skin Rejuvenation" white paper included in promotional

(d) "Fractora is considered a non-invasive skin resurfacing and restoration treatment that has been approved by the FDA and Health Canada;" "Fractora does a better job [than traditional fractional procedures] because it goes deeper and combines ablative and non-ablative RF;" "[Fractora's] RF influences all of the skin underneath, not just where the pins penetrate and heat the skin [unlike traditional laser fractional therapy;" Fractora's secondary heating next to where the pins penetrate and heat the skin is better controlled than with traditional laser fractional therapy;

(e) "Fractora is the most advanced fractional radio-frequency treatment;" "Fractora is light years ahead of traditional CO2 laser or Fraxel;" "Part of the advantage of Fractora is the ability to treat the neck;" Fractora can be safely performed by a non-physician "technician;" using test spots is optional or only for patients "worried about discomfort and healing;" Fractora "allows patients to look 10-15 years younger;" Fractora is "industry leading transformation" and

(f) "Stacking pulses in the same site may improve the results of tightening and ablation. It is safe to stack with the 24 pin tip . . . ."

77. Plaintiff or the Product owners have performed all conditions precedent to Defendant's liability for breach of its express warranties. Plaintiff notified Defendant of these breaches of warranty before bringing this lawsuit and within a reasonable time after discovering the extent and severity of her injuries.

78. Defendant breached express warranties about the Product and its qualities because its statements about the Product were false and the Product does not conform to their affirmations and promises. Plaintiff would not have undergone

materials provided at demonstrations conducted by Dr. Mulholland.

the Fractora procedure had they known the true nature of the Product and procedure and Defendant's misstatements regarding the Product.

79. As a result of Defendant's breach of warranty, Plaintiff has been damaged in the amount of the purchase price of the Fractora procedure and any consequential damages resulting from the procedure, including the cost to treat the injuries and scarring caused by the Product.

SECOND CAUSE OF ACTION

(Breach of Implied Warranty)

80. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

81. At all times relevant hereto, there was a duty imposed by law which requires that a manufacturer or seller's product be reasonably fit for the purposes for which such products are used, and that product be acceptable in trade for the product description.

82. Notwithstanding the aforementioned duty, at the time of delivery, the Product used on Plaintiff was not merchantable because it contained defect(s) that cause unintended injuries, such as burning, scarring and nerve damage, even when employing device settings and techniques found on the Product labeling or in promotions of the Product by Defendant, and do not otherwise perform as represented.

83. Plaintiff notified Defendant the Product was not merchantable within a reasonable time after the defect manifested to Plaintiff and other consumers.

84. As a result of the non-merchantability of the Product, Plaintiff and other consumers sustained damages.

THIRD CAUSE OF ACTION

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

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

85. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

86. Plaintiff, as a purchaser of the Fractora procedure performed with the Product, is a consumer within the meaning of the CUCS given that Defendant's business activities involve trade or commerce, are addressed to the market generally and otherwise implicate consumer protection concerns.

87. As detailed above, Defendant, through its promotional activities, advertisements and Product labeling, used false advertising to sale the Product. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct violates CUCS: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6) promotion of use of the Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA; and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can

be achieved with alternative procedures.

88. Defendant also knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiff and to the users of the Products used on Plaintiff knowing that the users and Plaintiff would rely on the promotional materials, advertisements and labeling in, on the part of the Plaintiff, purchasing the Fractora procedure and, with regard to the users, purchasing and using the Products.

89. Once defects in the Product and its tendency to cause unintended injuries despite use as instructed by Defendant became apparent to Defendant, Defendant had a duty to disclosure that fact—and adverse events— because this risk would be a material fact in the decision making process of Plaintiff and those performing the Fractora procedure, and, without Defendant's disclosure, Plaintiff and those performing the Fractora procedure would not necessarily know that there is such a risk.

90. Defendant intended that Plaintiff and those performing the Fractora procedure would rely on the continued deception by purchasing the Fractora procedure and using the Product, unaware of these material facts and omissions. Defendant further knew that Plaintiff and those performing the Fractora procedure would continue to rely on Defendant's representations and silence as to any known risk of unintended injuries as evidence that the Product was safe and would perform as represented. Defendant's wrongful conduct, which emanates in California, constitutes breaches of express and implied warranties, and, as such and independently, constitutes consumer fraud within the meaning of the CUCS.

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

92. Defendant is the producing and proximate cause of Plaintiff's injuries.

FOURTH CAUSE OF ACTION

(Fraud--Violation of California False Advertising Law ("CFAL")

Bus. & Prof. Code § 17500 et seq.)

93. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

94. Plaintiff, as a purchaser of the Fractora procedure performed with the Product, is a consumer within the meaning of the CFAL given that Defendant's business activities involve trade or commerce, are addressed to the market generally and otherwise implicate consumer protection concerns.

95. Defendant knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiff and to the users of the Products used on Plaintiff knowing that Plaintiff and users would rely on the promotional activities, advertisements and labeling in, on the part of the Plaintiff, purchasing the Fractora procedure, and, with regard to the users, purchasing and using the Products. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct violates CFAL: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6) promotion of use of the Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA;

and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can be achieved with alternative procedures.

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

97. Defendant intended that Plaintiff and those performing the Fractora procedure would rely on the continued deception by using and purchasing the Product and performing and undergoing the Fractora procedure, unaware of these material facts and omissions. Defendant further knew that Plaintiff and those performing the Fractora procedure would continue to rely on Defendant's representations and silence as to any known risk of unintended injuries as evidence that the Product was safe and would perform as represented. Defendant's wrongful conduct, which emanates in California, , constitutes breaches of express and implied warranties, and, as such and independently, constitutes false advertising within the meaning of the CFAL.

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

99. Defendant is the producing and proximate cause of Plaintiff's injuries.

FIFTH CAUSE OF ACTION

(Fraud—Common Law)

100. Plaintiff hereby incorporates the above allegations by reference as

though fully set forth herein.

101. Defendant knowingly concealed, suppressed, and consciously omitted material facts in promotional activities, advertisements and labeling to Plaintiff and to the users of the Products used on Plaintiff knowing and intending that Plaintiff and users would rely on the promotional activities, advertisements and labeling in, on the part of the Plaintiff, purchasing the Fractora procedure, and, with regard to the users, purchasing and using the Products. More specifically, and as described with particularity above, the following of Defendant's wrongful conduct constitutes common law fraud: (1) the undisclosed use of physicians with a financial interest in promoting the Product; (2) promotion of the Product for off-label use, an act which is prohibited under the FDCA; (3) false, misleading or fraudulent off-label promotion of the Product without proper disclosure of attendant risks, an act that is prohibited by the FDCA; (4) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins, an act that is prohibited by the FDCA; (5) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product, acts that are prohibited by the FDCA; (6) promotion of use of the Product by non-physicians in contradiction of Defendant's own instructions for the safe use of the Product and, therefore false, misleading or fraudulent and prohibited by the FDCA; and (7) other false, misleading or fraudulent representations concerning the Product in advertisements provided by Defendant to health care providers, such as claims the Product provides in just one treatment better, safer, more effective results than can be achieved with alternative procedures.

102. Defendant's fraud is the proximate cause of Plaintiff's injuries.

SIXTH CAUSE OF ACTION

(Negligence, Negligence Per Se and Gross Negligence)

103. Plaintiff hereby incorporates the above allegations by reference as

though fully set forth herein.

104. Defendant owed Plaintiff a duty to use due care in the development, testing, planning, design, marketing and sale of the Product.

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

106. Defendant breached these duties by (1) failure to exercise due care in producing, processing, manufacturing, distributing and/or offering for sale the Product and, therefore, selling the Product in a defective condition that was unsafe for use as promoted by Defendant, namely the failure to warn; (2) false, misleading or fraudulent off-label promotion of the Product; (3) false, misleading or fraudulent labeling of the product through inconsistent and inadequate instructions/warnings found in Product manuals and Clinical Bulletins; (4) failure to report—and affirmative acts to suppress reporting of—adverse events concerning the Product; and (5) promoting use of the Product by non-physicians.

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

108. In addition, Defendant breached its duty of due care by failing to properly and adequately inform consumers, including Plaintiff, health care

providers and the FDA once risks of unintended injuries such as burns, scars and nerve damage were brought to the Defendant's attention.

109. Defendant knew, or in the exercise of reasonable care should have known, that the Product presents an unacceptable risk to consumers, including Plaintiff, and would result in damages that were foreseeable and reasonably avoidable.

110. As a direct and proximate result of Defendant's above-referenced negligence, negligence per se and/or gross negligence, Plaintiff has suffered and is entitled to recover damages, both compensatory and punitive.

SEVENTH CAUSE OF ACTION

(Strict Liability)

111. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

112. Defendant is the producer, manufacturer, marketer, distributor and/or seller of the Product.

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

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

115. As the direct and legal result of the defective condition of the Product as produced, manufactured, designed, marketed, distributed and/or sold by

Defendant, and of the negligence, carelessness, other wrongdoing and actions of Defendant described herein, Plaintiff suffered damages.

ATTORNEYS' FEES, EXPENSES AND COSTS

116. Plaintiff hereby incorporates the above allegations by reference as though fully set forth herein.

117. Plaintiff has been forced to secure the assistance of counsel to protect their legal rights and mitigate their damages as a result of the Defendant's wrongful conduct.

118. Having made proper presentment and provided actual and sufficient notice of their claims to Defendant, Plaintiff seeks recovery of her reasonable attorneys' fees, expenses and costs pursuant to all applicable statutes, regulations and agreements.

PRAYER

WHEREFORE Plaintiff prays 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.

DEMAND FOR JURY TRIAL

Plaintiff hereby demand trial by jury.

Respectfully submitted,

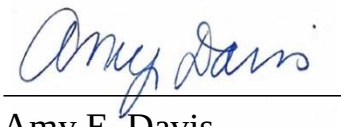
CHRISTIANSEN DAVIS, LLC

By: /s/ Amy E. Davis
Amy E. Davis

Amy E. Davis (*pro hac vice*)
1021 N. Bishop Ave.
Dallas, Texas 75208
Telephone: (214) 838-3501
adavis@cdfirm.com

CERTIFICATE OF SERVICE

This is to certify that on this 23rd day of October 2019, a true and correct copy of the foregoing document was served via electronic filing service upon counsel of record for Defendant Invasix, Inc. and by email on counsel for InMode Ltd.



Amy E. Davis