

## ADVANCED AESTHETIC CONCEPTS, LP AND MARK DURANTE

**IN THE DISTRICT COURT**

**Plaintiffs,**

**VS.**

**TARRANT COUNTY, TEXAS**

**PAIGE PETERSON, BELINDA WORLEY,  
SUSIE QUINN, FAIRWARNING, INC.,  
PUBLIC CITIZEN, INC., AND  
MEDICAL SPA MD**

**Defendants.**

**JUDICIAL DISTRICT**

**Amended**  
**PLAINTIFFS' VERIFIED PETITION**  
**AND APPLICATION FOR TEMPORARY RESTRAINING ORDER**

TO THE HONORABLE JUDGE OF SAID COURT:

NOW COMES, Advanced Aesthetics Concepts, LP, and Mark Durante, Plaintiffs herein, complaining of Paige Peterson, Belinda Worley, Susie Quinn, FairWarning, Inc. ("FairWarning"), Public Citizen, Inc. ("Public Citizen") and Medical Spa MD ("Medical Spa MD"), Defendants herein, and for cause of action would respectfully show unto this Court as follows:

## I. DISCOVERY CONTROL PLAN

1. This case is intended to be conducted under Level 3, TEX. R. CIV. P. 190.4 in that Plaintiff seeks damages from the Defendants in an aggregate amount of more than \$50,000.00. Further, discovery in this case is intended to be conducted under Level 3, TEX. R. CIV. P. 190.4.

## **II. PARTIES**

2. Plaintiff, Advanced Aesthetics Concepts, LP (“Advanced”), is a Texas limited partnership with its principal office and place of business in Tarrant County, Texas.

3. Plaintiff Mark Durante (“Mr. Durante”) is a Texas resident and is a principal in Advanced.

4. Defendant, Paige Peterson (“Peterson”) is a Texas resident and may be served herein by service of process by serving her personally at one of the addresses that she has used for her residence of 4373 W. Northwest Hwy, Dallas, TX, 75220, or at 6119 Greenville Ave., Apt 372, Dallas, TX 75206, or at 6119 Greenville Ave. Apt 37, Dallas, TX 75206, or at 5919 Greenville Ave., Dallas, Texas 75206, or at 402 Bickett Ln., Spring, TX 77373.

5. Defendant, Belinda Worley (“Worley”) is a Texas resident and may be served herein by service of process by serving her personally at one of the addresses that she has used for her residence of 4373 W. Northwest Hwy, Dallas, TX, 75220, or at 6119 Greenville Ave., Apt 372, Dallas, TX 75206, or at 6119 Greenville Ave. Apt 37, Dallas, TX 75206, or at 5919 Greenville Ave., Dallas, Texas 75206, or at 402 Bickett Ln., Spring, TX 77373.

6. Defendant, Susie Quinn (“Quinn”), upon information and belief is a foreign resident whose address is 2438 Hoskins Rd., North Vancouver, BC V7J3A3, and may be served herein by service of process by serving her through the Secretary of State. Because this suit arises out of Quinn’s purposeful contacts in this state as more specifically described below, including the repeated and direct contacts she has made in this forum to the clients of the Plaintiffs, the assumption of jurisdiction by this Court does not offend traditional notions of fair play and substantial justice. Since Quinn is a foreign resident, the Texas Secretary of State is an

agent for service of process upon Quinn. Pursuant to § 17.044 of the Texas Civil Practice and Remedies Code, Quinn can be served by certified mail, return receipt requested directed to Susie Quinn, through the Texas Secretary of State as an agent for service of process at the following address: Office of Secretary of State, Statutory Documents Section – Citations Unit, 1019 Brazos Street, Austin, Texas 78701. Susie Quinn's home address is 2438 Hoskins Rd., North Vancouver, BC V7J3A3.

7. Defendant FairWarning, Inc. ("FairWarning"), upon information and belief is a foreign entity that publishes its articles and comments from Encino, California. Because this suit arises out of FairWarning's purposeful contacts in this state as more specifically described below, including communicating with defendants Peterson and Worley, both of whom were and are residents of the state of Texas, as well as directly contacting Advanced and Mr. Durante in their Texas office requesting information for one of the publications that is the subject matter of this lawsuit, and in contacting counsel for Advanced concerning the same, the assumption of jurisdiction by this Court does not offend traditional notions of fair play and substantial justice. Since FairWarning is a foreign entity, the Texas Secretary of State is an agent for service of process upon FairWarning. Pursuant to § 17.044 of the Texas Civil Practice and Remedies Code, FairWarning can be served by certified mail, return receipt requested directed to FairWarning.org, attention Myron Levin, through the Texas Secretary of State as an agent for service of process at the following address: Office of Secretary of State, Statutory Documents Section – Citations Unit, 1019 Brazos Street, Austin, Texas 78701. FairWarning may be served with service of process by serving its registered agent and editor Myron Levin, at its business address of 17514 Ventura Blvd., Suite 103, Encino, CA 91316.

8. Defendant Public Citizen, Inc. ("Public Citizen"), upon information and belief is a foreign entity that publishes its articles and comments through its on-line website of [www.citizen.org](http://www.citizen.org), from Washington, D.C. Because this suit arises out of Public Citizen's purposeful contacts in this state as more specifically described below, the assumption of jurisdiction by this Court does not offend traditional notions of fair play and substantial justice. Further, Public Citizen maintains an office in Texas located at 1303 San Antonio St., Austin, Texas 78701. Public Citizen may be served with service of process by serving its Registered Agent, Thomas E. Smith at 1303 San Antonio St., Austin, Texas 78701.

9. Defendant Medicalspamd.org. ("Medical Spa MD"), upon information and belief is a foreign entity that publishes its articles and comments from Park City, Utah. Medical Spa MD may be served with service of process by serving its editor, Mr. Jeff Barson. Because this suit arises out of Medical Spa MD's purposeful contacts in this state as more specifically described herein, the assumption of jurisdiction by this Court does not offend traditional notions of fair play and substantial justice. Since Medical Spa MD is a foreign entity, the Texas Secretary of State is an agent for service of process upon Medical Spa MD. Pursuant to § 17.044 of the Texas Civil Practice and Remedies Code, Medical Spa MD can be served by certified mail, return receipt requested directed to Medical Spa MD, attention Mr. Jeff Barson, through the Texas Secretary of State as an agent for service of process at the following address: Office of Secretary of State, Statutory Documents Section – Citations Unit, 1019 Brazos Street, Austin, Texas 78701. Medical Spa MD may be served with service of process by serving its editor Mr. Jeff Barson, at its business address of Medical Spa MD, 2177 Monarch Drive, Park City, Utah, 84060.

**III.**  
**INTERESTED PARTIES**

10. RevecoMed International, Inc. ("RevecoMed") is a foreign corporation whose principal place of business is located in California.

**IV.**  
**VENUE**

11. Venue is proper in Tarrant County, Texas pursuant to TEX. CIV. PRAC. & REM. CODE § 15.001 et. seq. in that all or part of the causes of action for which Plaintiffs sue took place in Tarrant County, Texas and Plaintiffs are both residents of Tarrant County, Texas.

**V.**  
**BACKGROUND**

12. This case is a smear campaign being perpetrated by Peterson, Worley and Quinn against Mark Durante, Advanced and RevecoMed and is designed to cause economic harm to the Plaintiffs. The smear campaign is being waged in false statements that are being published by Peterson, Worley and Quinn to various individuals, companies and Advanced and Mr. Durante's clients. The statements are being posted in various e-mails, numerous on-line blogs, and are also being provided to various newswires, on-line and printed publications including Fair Warning, Public Citizen and Medical Spa MD, The Austin Statesman, The Orange County Register, Modern Medicine, Medican Device and Diagnostic Industry, NBC News.com and In These Times. The allegations were also "tweeted" via Twitter to various attorneys who later posted blogs seeking persons who were hurt or injured in an attempt to start lawsuits against Advanced. There have been literally hundreds of twitters initiated and directed to news media, public organizations and clients.

13. The smear campaign is being further waged by one or more of Peterson, Worley and Quinn contacting various government agencies, including the Food and Drug Administration (the "FDA") the Texas Department of State Health Services (the "TDSHS"), and numerous state medical agencies claiming that Advanced, Mr. Durante and RevecoMed have been selling equipment not registered for sale by the FDA and claiming that the FDA should order Advanced, Mr. Durante and RevecoMed to stop selling their products and call back equipment. The smear campaign has taken an ominous turn in that Quinn has now started making numerous direct, systematic and repeated contacts with many of Advanced and Mr. Durante's clients. Advanced and Mr. Durante's clients are licensed physicians, many of whom practice in the state of Texas. The statements being sent to these doctors by Quinn are meant to harm Mr. Durante and Advanced, by instilling into each doctor she contacts, fear and uncertainty about the products the doctors have purchased from Advanced, fear that the equipment is going to be seized, fear that the doctor is going to be investigated, and fear that these doctors may lose their business as a result.

14. The Court should duly note that the Defendants have intentionally used the terms Lipo-Ex and LipoTron throughout this smear campaign to confuse the public, the governmental agencies, and the media. Defendant Peterson is most specifically aware of the difference in that she was a LipoTron distributor. As set forth hereinafter, the Lipo-Ex Program is not a device and does not require FDA approval. It is a trademarked "program" of Advanced. The Lipo-Ex Program can and does encompass several different components and technologies, including diet, nutrition and nutritional supplements and may or may not incorporate colonics, the LipoTron and

the Celluderm. The LipoTron is a medical device which currently maintains a Class 1 registration with the FDA.

15. The initial root of this case dates back from 2007 to early 2009, when Peterson was the broker used by Advanced for the purchase of certain products which Peterson purchased from RevecoMed and later re-sold to independent distributors including Advanced. The products included the LipoTRON products that are at issue in this lawsuit. The business relationship between Peterson and Advanced ended in April 2009 when Advanced and RevecoMed entered into a direct distributorship relationship wherein neither Advanced nor RevecoMed required the services of Peterson or her company, P2, LLC. Since Peterson and RevecoMed parted ways, Peterson has sought out ways to hurt Advanced and Mr. Durante and has claimed that RevecoMed owes her money.

16. Also, as part of the underlying issues between Peterson and Advanced, is an issue concerning the inadvertent transfers of four wire transfers by Advanced which were supposed to be sent to RevecoMed, but were accidentally sent to Peterson in care of her company, P2. On December 31, 2009, Advanced sent a series of four (4) wire transfers from its bank, Compass Bank to pay for product which Advanced had purchased from RevecoMed. In the process of sending the wire transfers, Advanced inadvertently sent the wire transfers to Peterson's company, P2.

17. Subsequent to learning that the wire transfers had been inadvertently sent to P2, Advanced attempted to recall the wire transfers and was able to recall two of the four wire transfers, but were unable to recall the first two wire transfers. Advanced then attempted to call Peterson, about Peterson returning the wire transfers, however, Peterson refused to return the

funds from the wire transfers. The two wire transfers wrongfully retained by Peterson totaled \$62,250.00.

18. Advanced then filed suit against Peterson and her company, P2 for the return of the wire transfers in Cause No.: 342-242888-10, styled *Advanced Aesthetics, LLP vs. Paige Peterson, Individually and d/b/a/ P2 Ventures*, in the 342<sup>nd</sup> District Court, Tarrant County, Texas. Advanced was granted summary judgment against Peterson and P2 for the return of the wire transfer funds. In order to avoid the return of the money retained by Peterson, Peterson and P2 filed bankruptcy wherein they received a discharge under chapter 7 of the United States Bankruptcy Code.

19. However, for no reason but to disparage Advanced and to harm Mr. Durante, Peterson, prior to filing for bankruptcy and during the course of the first lawsuit, began calling the FDA claiming that Advanced and RevecoMed were allegedly improperly selling equipment that had not been authorized by the FDA to be sold.

20. The equipment at issue is a product known as the LipoTRON 3000. As detailed in Mr. Durante's Affidavit, the LipoTRON 3000 has been registered by the FDA as a Class 1 medical device. As stated on the FDA website, it is "*A therapeutic massager is an electrically powered device intended for medical purpose, such as to relieve minor muscle aches and pains,*" device and may be used by doctors for pain management. Additionally, the FDA does not regulate doctors' use of products, such as the LipoTRON 3000 for "off label" use.

21. Prior to the LipoTRON 3000 being registered as a Class 1 medical device, RevecoMed had made application with the FDA for the LipoTRON 3000 to be used in a number of indicated possible uses. Those applications were made in 2007 and 2009. Due to the length of



the time taken by the FDA in registering the LipoTRON 3000 under the 2007 and 2009 applications, RevcoMed filed a subsequent application with the FDA wherein the LipoTRON 3000 was recognized by the FDA as a Class 1 Medical device and was registered as same.

22. Despite the FDA having registered the LipoTRON 3000 as a Class 1 device, pursuant to Mr. Durante's Affidavit, Peterson, Worley and Quinn have contacted the FDA, the TDSHS, as well as various state medical agencies claiming that Advanced, Mr. Durante and RevecoMed are supposedly illegally selling the LipoTRON 3000.

***Paige Peterson, Belinda Worley - Business Disparagement***

23. Peterson and Worley have disparaged Advanced by publishing or causing the publication of statements about Advanced and its economic interests that were false and were published with malice and without privilege. Specifically, Peterson and Worley contacted the online publication FairWarning ([www.Fairwarning.org](http://www.Fairwarning.org)) claiming that one of the products sold by Advanced, the LipoTRON 3000, had not been approved by the FDA and that the Plaintiffs were selling it illegally. Peterson and Worley also stated that Advanced was the subject of a FDA criminal investigation. The statements made to the online publication though are false and have disparaged the economic interests of Advanced.

24. The elements to support a cause of action for business disparagement are: (1) an individual published disparaging words about the company's economic interests; (2) the words were false; (3) the individual published the words with malice; (4) the individual published the words without privilege; and (5) the publication caused special damages, such as the loss of sales or credit.

25. As evidenced in Mr. Durante's Affidavit, Advanced is in the business of selling various medical technologies and programs. Included in its product line is the LipoTRON 3000. Contrary to the disparaging statements made by Peterson and Worley that the LipoTRON 3000 may not be legally sold, the FDA has permitted the registration of the LipoTRON 3000 as a class 1 medical device. As such, the LipoTRON 3000 may be legally sold.

26. Included in the false statements to FairWarning were statements that the LipoTRON 3000 had not been approved by the FDA, that RevecoMed and Advanced were illegally marketing the LipoTRON 3000, and that the FDA was conducting a "criminal investigation" of Advanced. To cover their mis-statements, Peterson and Worley admitted that they had attempted to place telephone calls to the FDA from a hospital so that the call(s) could not be traced back to them. (See the attachments to Mr. Durante's Affidavit).

27. In the present instance, Peterson and Worley published disparaging words about Advanced and its economic interests; as evidenced in Mr. Durante's Affidavit, the words were false. Peterson and Worley published the words with malice because Peterson and Worley knew that the statements they were publishing were false and they acted with reckless disregard concerning their statements. Further, Peterson and Worley acted with ill-will toward Advanced and intended by their actions to interfere with Advanced's economic interest and published the words without privilege. Lastly, pursuant to Mr. Durante's Affidavit, the publication caused special damages to Advanced, including the loss of sales.

***Paige Peterson, Belinda Worley – Slander and Libel***

28. In addition to disparaging Advanced, Peterson and Worley have slandered and libeled Mr. Durante. At a minimum, in making their statements to the online publication

FairWarning that the LipoTRON 3000 had not been approved by the FDA and that the Plaintiffs were selling it illegally, and that Advanced and or Mr. Durante were the subject of an FDA criminal investigation, Peterson and Worley have slandered and libeled Mr. Durante and his good name and reputation. In another online publication (In The Times) Quinn stated the FDA was working with the DOJ to complete an intricate case spanning seven (7) years. The statements they made to FairWarning and In The Times are false and defamatory.

29. The elements to support a cause of action for slander and libel are: (1) a false statement of fact about a person or company; (2) publication of the false statement; (3) the false statement was at least negligently made; (4) damages that tend to injure a living person's reputation and thereby expose the person to public hatred, contempt or ridicule, or financial injury or to impeach any person's honesty, integrity, virtue, or reputation.

30. As evidenced in Mr. Durante's Affidavit, the LipoTRON 3000 is presently registered with the FDA as a class 1 medical device and as such, the FDA permits the sale and distribution of the LipoTRON 3000. Despite this fact, Peterson and Worley have instigated a smear campaign against Advanced and Mr. Durante by publishing their various false statements.

31. Further, upon information and belief, Peterson and Worley have collaborated with Quinn to defame Mr. Durante, as evidenced by the comments that each have made on various social media including statements by Quinn made on Med Spa MD's blogsite on July 20, 2012, stating that she would never quit, and asking Peterson if she would ever quit, as follows:

*"Paige, brave soul that you are... don't they know the most dangerous person in the room is the one who has nothing left to lose? .... I will never quit, will you?"*

32. In the present instance, Peterson and Worley have libeled Mr. Durante and the economic interests of Advanced by the publication of their false statements. Peterson and Worley

published the words with malice or at a minimum negligently because Peterson and Worley knew that the statements they were publishing were false. Further, Peterson and Worley were negligent because they permitted the statements to be published without regard to verifying any of the accuracy of the statements that they were making. Lastly, as a result of the slander and libel perpetrated against Mr. Durante, Mr. Durante has been exposed to public hatred, contempt, ridicule, and financial injury, and has had his honesty, integrity, virtue, and reputation impeached, as well as that of his Company, Advanced.

33. As such, Peterson and Worley have slandered and libeled Mr. Durante and Mr. Durante's reputation has been harmed.

***Fair Warning - Business Disparagement***

34. FairWarning has also disparaged Advanced by publishing and subsequently causing the re-publication of statements about Advanced and its economic interests that were false and were published with malice and without privilege. Specifically, FairWarning took the statements published to it by Peterson and Worley and published those statements even though the statements that the LipoTRON 3000 had not been approved by the FDA, that the Plaintiffs were selling it illegally, and that Advanced was the subject of an FDA criminal investigation were false. The statements published by FairWarning though are false and have disparaged the economic interests of Advanced.

35. As noted above, the elements to support a cause of action for business disparagement are identified in paragraph 24 and are incorporated herein for all purposes.

36. In the present instance, FairWarning published disparaging words about Advanced and its economic interests. This is despite that on or about the first week of June,

2012, Myron Levon, Editor of FairWarning, interviewed Mark Durante and was informed that the article FairWarning was preparing contained numerous factual errors. As evidenced in Mr. Durante's Affidavit, the words were false. FairWarning published the words with malice because it knew that the statements it was publishing were false as it took no effort other than to rely on Peterson and Worley. Such reliance is acting with reckless disregard concerning the statements that it published. FairWarning acted with ill-will toward Advanced and intended by its actions to interfere with Advanced's economic interest by publishing the words. Further, as noted in Mr. Durante's Affidavit, the publication caused special damages to Advanced, including the loss of sales.

37. Pursuant to Mr. Durante's Affidavit, FairWarning, published a report on its website titled "Fat-Melting Device a Weighty Subject for FDA" wherein FairWarning wrongfully claims that the LipoTRON "has never been cleared or approved by the U.S. Food and Drug Administration....." Such statement is a complete mis-representation of the truth. (A true and correct copy of the FairWarning Article is attached to Mr. Durante's Affidavit and is incorporated herein for all purposes). Pursuant to Mr. Durante's Affidavit, the LipoTRON 3000 has in fact been registered by the FDA as a Class 1 medical device, which permits the LipoTRON 3000 to be marketed and sold as a Class 1 medical device.

38. FairWarning has disparaged Advanced by improperly portraying Advanced and Mr. Durante as (1) breaking federal law, (2) by claiming or otherwise insinuating that Advanced is the subject of an ongoing criminal investigation, (3) by claiming or otherwise insinuating the LipoTRON 3000 is being sold without FDA approval, and (4) by claiming or otherwise insinuating that the LipoTRON 3000 is a dangerous device.

### ***Fair Warning – Libel***

39. In addition to disparaging Advanced, Fair Warning has libeled Mr. Durante. At a minimum, in publishing the statements that the LipoTRON 3000 had not been approved by the FDA and that the Plaintiffs were supposedly selling it illegally, and that Advanced and or Mr. Durante were the subject of a FDA criminal investigation, FairWarning has libeled Mr. Durante and his good name and reputation. The statements made by FairWarning are false and defamatory.

40. As noted above, the elements to support a cause of action for slander and libel are identified in paragraph 29 and are incorporated herein for all purposes.

41. In the present instance, FairWarning has libeled Mr. Durante and the economic interests of Advanced. As set forth in Mr. Durante's Affidavit, the statements published by FairWarning were false. At a minimum, FairWarning published the words negligently because FairWarning had made no effort to verify the accuracy of the statements other than taking the word of Peterson and Worley. In fact, FairWarning does state that it got its information from an anonymous call from Paige Peterson, whom it identified as a former Lipotron distributor, and Belinda W. Worley, "a marketing consultant who worked with her."

42. Thus, while FairWarning provides no proof of any actual investigation or that the LipoTRON 3000 is being sold improperly, FairWarning does take time to include a quote from an alleged FDA spokesperson who stated that if the device is not legally on the market, then a physician should not be able to obtain it or use it on a patient. The inference that FairWarning is making is clear that it meant the statement to mean that the LipoTRON 3000 was not legally on the market and thus Advanced and Mr. Durante could not legally sell it.

43. FairWarning goes onto to say that the “FDA is aware of the activity. But an investigation by FairWarning found that the agency had not taken any enforcement action-even though it has known about the situation since January, 2010 when two whistleblowers (Worley and Patterson) provided documents to the FDA.

44. FairWarning’s statements portray Advanced as actively selling the LipoTRON 3000 without FDA approval, when in fact Advanced is completely compliant within the guidelines set forth by the FDA. In contrast to the fact-less statements published by FairWarning, as provided in Mr. Durante’s Affidavit, Advanced promotes the LipoTRON 3000 as a FDA registered Class 1 medical device that may be used by its clients for its approved indications and which is frequently marketed in association with Advanced’s trademarked LipoEX program. The Lipo-EX program is a program implemented by Advanced and consists of a multitude of programs including diet, nutrition and exercise, as well as other measures. As one of the possible options of the LipoEX program, Advanced sells the LipoTRON 3000. As permitted by the FDA, licensed physicians may use the LipoTRON 3000 for its approved indications, as well as potential use in “off-label” treatment as the physician deems necessary as the FDA permits.

45. FairWarning also mis-represents statements made by Mr. Durante to the TDSHS when FairWarning stated that “Mark Durante, managing partner of Advanced Aesthetics Concepts, told state investigators that the LipoTRON had been cleared by the FDA, but later corrected himself to say paperwork had been filed but no clearance given.” In fact, the statements attributed to Mr. Durante are totally false as Mr. Durante never stated that the FDA had not approved the LipoTRON 3000. As noted herein, the FDA has already registered the LipoTRON 3000 as a Class 1 medical device.

46. As such, FairWarning has slandered and libeled Mr. Durante and Mr. Durante has been exposed to public hatred, contempt, ridicule, and financial injury, and has had his honesty, integrity, virtue, and reputation impeached, as well as that of his company, Advanced.

***Public Citizen- Business Disparagement***

47. Public Citizen has also disparaged Advanced by publishing and subsequently causing the re-publication of statements about Advanced and its economic interests that were false. The statements were published with malice and without privilege. Specifically, Public Citizen took the article published by FairWarning and re-published it even though the statements that the LipoTRON 3000 had not been approved by the FDA, that the Plaintiffs were selling it illegally, and that Advanced was the subject of a FDA criminal investigation were false.

48. As noted above, the elements to support a cause of action for business disparagement are identified in paragraph 24 and are incorporated herein for all purposes.

49. In the present instance, Public Citizen has published disparaging words about Advanced and its economic interests. Specifically, as evidenced in Mr. Durante's Affidavit, Public Citizen has published the Fair Warning article on its website, which as previously established, were false and malicious statements about Advanced, including statements to federal and state agencies claiming that the "apparently illegal marketing and promotion of this potentially dangerous device" (the LipoTRON 3000) must be stopped and the equipment immediately seized and the FDA complete its "criminal investigation". Included in those agencies, were letters to Margaret A. Hamburg, Commissioner, Food and Drug Administration and Jeffrey E. Shuren, Director, Center for Devices and Radiological Health of the Food and Drug Administration.



50. Public Citizen has disparaged Advanced by (1) improperly portraying Advanced as breaking federal law, (2) by claiming or otherwise insinuating that Advanced is the subject of an ongoing criminal investigation, (3) by claiming the LipoTRON 3000 is being sold without FDA approval, (4) by claiming the LipoTRON 3000 is a dangerous device, and (5) by demanding that the FDA order that the LipoTRON 3000 not be sold and that all existing LipoTRON 3000 equipment be seized. Statements like these are meant only to harm Advanced and its business interests as well as to instill doubt and fear into Advanced's clients. Such statements are disparaging by their very nature and were made with malice at the time that the statements were made because Public Citizen took no effort to investigate the truth of the statements that it was making.

51. Further, Public Citizen has claimed that the LipoTRON is being illegally sold and even provides an unsubstantiated e-mail allegedly from a FDA investigator that claims "RevecoMed and its distributor have been illegally marketing the LipoTron", yet its only source is as it cites its "whistleblower" who has already been identified as Peterson. As well, Public Citizen's portrayal that the LipoTRON 3000 is a dangerous device is not accurate as evidenced by its Class 1 registration, which indicates that it is not dangerous pursuant to the FDA's own guidelines for that Class.

52. Public Citizen has failed to verify any of the statements that it published about the LipoTRON 3000, Advanced or Mr. Durante. Public Citizen claims that it is an advocate "for a healthier and more equitable world by making government work for the people and by defending democracy from corporate greed" yet its lofty goals obviously do not include even making a cursory review of the facts before it launches an unwarranted attack on Advanced.

***Public Citizen – Libel***

53. In addition to disparaging Advanced, Public Citizen has also libeled Mr. Durante by publishing the negative statements about Advanced and Mr. Durante. At a minimum, in publishing the statements that the LipoTRON 3000 had not been approved by the FDA and that the Plaintiffs were supposedly selling it illegally, and that Advanced and or Mr. Durante were the subject of a FDA criminal investigation, Public Citizen has libeled Mr. Durante and his good name and reputation. The statements made by Public Citizen are false and defamatory.

54. As noted above, the elements to support a cause of action for slander and libel are identified in paragraph 29 and are incorporated herein for all purposes.

55. In the present instance, Public Citizen has libeled Mr. Durante and the economic interests of Advanced. As set forth in Mr. Durante's Affidavit, the statements published by Public Citizen were false. At a minimum, Public Citizen published the words negligently because it made no effort to verify the accuracy of the statements other than taking the word of FairWarning, who was taking the word of Peterson and Worley.

56. Specifically, Public Citizen has defamed Mr. Durante by (1) improperly portraying Advanced and Mr. Durante as breaking federal law, (2) by claiming or otherwise insinuating that Advanced is the subject of an ongoing criminal investigation, (3) by claiming the LipoTRON 3000 is being sold without FDA approval, (4) by claiming the LipoTRON 3000 is a dangerous device, and (5) by demanding that the FDA order that the LipoTRON 3000 not be sold and that all existing LipoTRON 3000 equipment be seized. Statements like these are meant only to harm Mr. Durante and his business interests as well as to instill doubt and fear into his

company's clients, prospective clients, associates, and his other business interests as a question as to his integrity.

57. Just like FairWarning, Public Citizen provides no proof of any of the statements that it makes. Instead, Public Citizen, negligently adopts the position in the FairWarning article and then negligently exposes Mr. Durante to scorn.

58. In addition to adopting the FairWarning position, Public Citizen has taken it upon itself to contact various state medical agencies in order to get public sentiment against Advanced and Mr. Durante. Public Citizen has done this even though it offers no proof of any of its or FairWarning's allegations.

59. As such, Public Citizen has slandered and libeled Mr. Durante and Mr. Durante has been exposed to public hatred, contempt, ridicule, and financial injury, and has had his honesty, integrity, virtue, and reputation impeached, as well as that of his company, Advanced.

60. Public Citizen claims that it is an advocate "for a healthier and more equitable world by making government work for the people and by defending democracy from corporate greed" but its lofty goals obviously do not include even making a cursory review of the facts, instead relying on negative and false journalism which has libeled Mr. Durante.

#### ***Medical Spa MD- Libel***

61. Medical Spa MD has also libeled Mr. Durante. Through its publication of the same reports published by FairWarning and Public Citizen, Medical Spa MD has elected to act with reckless disregard to the truth. Medical Spa MD is an online publication ([www.medicalspamd.com](http://www.medicalspamd.com)) that claims it is for physicians in cosmetic medicine. Without even attempting to verify the accuracy of the article published by FairWarning, Medical Spa MD re-

published the same exact article. As detailed above, the published statements included claims improperly portraying Advanced and Mr. Durante as breaking federal law, claiming or otherwise insinuating that Advanced is the subject of an ongoing criminal investigation, claiming the LipoTRON 3000 is being sold without FDA approval, and claims that LipoTRON 3000 is a dangerous device. Further, Medical Spa MD sent an “alarmist” e-mail to their 20,000 plus members stating “MEMBER ALERT: FDA Being Urged to Seize All LipoTron 2000 (Lipo-Ex) Devices in the US”. The statements published by Medical Spa MD were, at a minimum negligent and have caused Advanced and Mr. Durante harm.

62. Medical Spa MD was contacted as early as March 15, 2012 by Advanced regarding the blatantly false statements being made by “J Quinn” and was asked to remove the statements. Upon the advice of Jeff Barson of Medical Spa MD, Advanced then sent a letter to J Quinn asking that the comments be removed. Upon information and belief, J Quinn and Susie Quinn are one and the same. On April 9, 2012, Advanced e-mailed its letter to J Quinn. Advanced was notified shortly thereafter that the Texas Department of State Health Services received a complaint against Advanced on the same day, April 9, 2012. Advanced maintains that Medical Spa MD continued to take actions and actively participate in actions against Advanced, violating its own Terms and Conditions of Use to do so.

63. Medical Spa MD has defamed Mr. Durante by (1) improperly portraying Advanced and Mr. Durante as breaking federal law, (2) by claiming or otherwise insinuating that Advanced is the subject of an ongoing criminal investigation, (3) by claiming the LipoTRON 3000 is being sold without FDA approval, and (4) by claiming the LipoTRON 3000 is a dangerous device. Statements like these are meant only to harm Advanced and its business

interests as well as to instill doubt and fear into Advanced's clients. Such statements are defamatory by their very nature and go beyond any right Medical Spa MD may otherwise have.

64. Medical Spa MD has failed to verify any of the statements that it published about the LipoTRON 3000, Advanced or Mr. Durante. Medical Spa MD has engaged in the same negative and false journalism as FairWarning and Public Citizen with reckless disregard to the truth or to the effect its actions have had on Mr. Durante.

***Susie Quinn – Business Disparagement***

65. Susie Quinn has also instigated a smear campaign against Advanced, its d/b/a Profit Solutions, MD, and Mr. Durante. Susie Quinn has engaged in publishing numerous and malicious attacks against Advanced, including posting numerous on-line statements in response to the articles posted by FairWarning and Public Citizen.

66. As noted above, the elements to support a cause of action for business disparagement are identified in paragraph 24 and are incorporated herein for all purposes.

67. In the present instance, under the pseudonym of "J Quinn", Susie Quinn has made false and disparaging remarks about Advanced stating that "[t]he manufacturer and distributors of Lipo-EX, aka LipoTRON are currently under federal criminal investigation for marketing and selling without FDA approval." Quinn has made these statements on various on-line blogs, including the blog associated with Medical Spa MD. A true and correct copy of Susie Quinn's blogs are attached to Mr. Durante's Affidavit and are incorporated herein for all purposes.

68. Such statements though are false and are meant to harm and injure Advanced's business interests. As previously set forth, Advanced is not under any criminal investigation. Even assuming arguendo that the FDA were investigating anyone associated with the LipoTRON

3000, the FDA does not in fact publish its investigations. Quinn therefore provides no evidence of any of her baseless accusations. Her statements were made merely to disparage the economic interests of Advanced.

69. Further, Quinn opened a Facebook account and then tried to “friend” all of Advanced’s clients’ Facebook pages to disseminate the FairWarning article to all of their contacts. Advanced was contacted by various clients and Advanced had to issue directives to them as to how to file with Facebook and have the connection removed.

70. In addition to making many statements on-line, Quinn has disparaged Advanced by making direct contact with Advanced’s clients, many of whom reside in Texas. Specifically, on July 15, 2012, Quinn posted the FairWarning article “Fat Melting Device a Weighty Matter for the FDA” on all of Advanced’s Facebook accounts. On July 18, 2012, Quinn posted the Public Citizen article “FDA Being Urged to Seize All Lipo Tron 3000 (Lipo-Ex) Devices in the US” together with a link to the Medical Spa MD articles.

71. On July 23, 2012, Quinn sent e-mails to five doctors all of whom were clients of Advanced and all of whom had their medical practice in Texas claiming to provide “evidence about the ongoing federal and state criminal investigations of Advanced Aesthetics Concepts”. This e-mail was sent to: Remirez Internal Medicine Associates, Beaumont, Texas; Contour Derma Med Spa, San Antonio, Texas; PL Weight Loss Clinic, Santa Fe, Texas; Laser Rejuvenation & Family Medicine Associates, P.A. Joshua, Texas.

72. On July 31, 2012 Quinn sent e-mails to three additional clients of Advanced that were located in Texas telling them that the TDSHS had opened another case targeting Profit Solutions MD as another identity of Advanced Aesthetic Concepts. This e-mail was sent to:

Sabrina Mercer Skincare; Cypress, Texas, Vanity RX Medi-Spa, Longview, Texas, and Remirez Internal Medicine Associates, Beaumont, Texas.

73. On August 1, 2012 Quinn sent e-mails to seven more clients of Advanced that were located in Texas telling them that Public Citizen had urged the Texas Medical Board and the Texas Department of State Health to act on the “illegal Lipo-Ex/Lipotron”. This e-mail was sent to: Remirez Internal Medicine Associates, Beaumont, Texas; Dr. Harcharan Narang, Houston, Texas, Hidden Door Med Spa, Roanoke, Texas, Avante Medical Spa, The Woodlands, Texas, Vanity RX Medi-Spa, Longview, Texas, Family Medicine Associates, P.A., Joshua, Texas, Realis Medical Spa, Houston, Texas.

74. On August 6, 2012 Quinn sent an e-mail to another client of Advanced that was located in Texas telling them that Public Citizen had urged the Texas Medical Board and the Texas Department of State Health to act on the “illegal Lipo-Ex/Lipotron”. This e-mail was sent to: Facial Techniques, Dallas, Texas.

75. In other instances, Quinn proceeds to admonish anyone using the LipoTRON device to read the “FDCA and US CODE OF FEDERAL REGULATIONS” writing that “[t]his is a very serious matter for which the FDA is prosecuting to the maximum extent of the law.” As well as, Quinn further publishes that the OCI, DOJ and other federal investigative agencies are “interviewing Lipo-Ex/LipoTRON purchasers and other interested parties” and that she knows this because she is an “interested party.” Quinn though never explains how she is an interested party and that as a Canadian resident, what concern she has with the FDA and the products that it regulates.

76. In the present instance, Quinn has published disparaging words about Advanced and its economic interests; as evidenced in Mr. Durante's Affidavit, the words were false. Quinn has published the words with malice. Quinn knows that the statements she has published were false and she has acted with reckless disregard concerning the statements. Further, Quinn has acted with ill-will toward Advanced and intended by her actions to interfere with, and in fact have caused Advanced economic loss.

***Quinn – Slander and Libel***

77. In addition to disparaging Advanced, Quinn has slandered and libeled Mr. Durante. At a minimum, in making her statements to the various online publications that the LipoTRON 3000 had not been approved by the FDA and that the Plaintiffs were selling it illegally, and that Advanced and or Mr. Durante were the subject of a FDA criminal investigation, Quinn has slandered and libeled Mr. Durante and his good name and reputation. The statements they made by Quinn are false and defamatory.

78. As noted above, the elements to support a cause of action for slander and libel are identified in paragraph 29 and are incorporated herein for all purposes.

79. As evidenced in Mr. Durante's Affidavit, the LipoTRON 3000 is presently registered with the FDA as a class 1 medical device and as such, the FDA permits the sale and distribution of the LipoTRON 3000. Despite this fact, Quinn has participated in a smear campaign against Advanced and Mr. Durante by publishing her many false statements.

80. Further, upon information and belief, Quinn has collaborated with Peterson and Worley to defame Mr. Durante, as evidenced by the comments both she and Peterson have made



on various social media including statements Quinn made on Med Spa MD's blogsite on July 20, 2012, stating that she would never quit, and asking Peterson if she would.

81. Quinn is blatant in that she apparently has made it clear that she believes she is exempt from US jurisdiction.

82. In the present instance, Quinn has libeled Mr. Durante and the economic interests of Advanced by the publication of her false statements both to various on-line entities, but also in her publication of many e-mails to Mr. Durante's clients in July and August 2012. Quinn has published the words with malice or at a minimum negligently with reckless disregard for the truth. She has failed to verify any of the accuracy of the statements that she has made. As a result of the slander and libel perpetrated against Mr. Durante, Mr. Durante has been exposed to public hatred, contempt, ridicule, and financial injury, and has had his honesty, integrity, virtue, and reputation impeached, as well as that of his Company, Advanced.

## **VI.**

### **APPLICATION FOR TEMPORARY RESTRAINING ORDER**

1. As set out above, the actions of the Defendants have disparaged Advanced. Texas law provides that disparagement is a legal claim involving an individual publishing disparaging words about a company's economic interests; the words were false; the individual published the words with malice; the individual published the words without privilege; and the publication caused special damages, such as the loss of sales or credit. Defamation is a legal claim involving injury to a person's reputation caused by false statements and includes libel expressed in written or other graphic form that tends to injure a living person's reputation and thereby expose the person to public hatred, contempt or ridicule, financial injury or to impeach any person's honesty, integrity, virtue, or reputation or to publish the natural defects of anyone and thereby

expose the person to public hatred, ridicule, or financial injury. The elements require that the publication only be negligent.

2. The Defendants, in publishing the false and misleading comments, including the publication of false and misleading statements and by carrying on their attacks in repeated discussions in the various social media have disparaged Advanced's business reputation and interests and have tarnished Mr. Durante's personal reputation, have impeached his personal honesty and integrity, and have caused immediate financial harm which threatens Plaintiffs' business.

3. As set out herein, Plaintiffs are engaged in the lawful sale of equipment as permitted by the FDA. Plaintiffs have been subjected to the Defendants' repeated disparagement and defamation. Plaintiffs are entitled to injunctive relief without bond or with a de-minimus bond. As such, Plaintiffs seek a temporary restraining order, ordering the Defendants as follows:

a) Cease and desist from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

4. Upon a final hearing by this Court, Defendants be permanently enjoined from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

## **VII.** **VENUE**

5. It is probable Plaintiffs will recover from Defendants in that the Defendants have engaged in a systematic pattern of disparaging Advanced and in making false and libelous statements and comments concerning Mr. Durante and the Plaintiffs business practices, procedures, products, business and personal reputation. Defendants' repeated and numerous comments have been designed to harm Advanced and Mr. Durante. Defendants intentionally and or negligently have mislead the public to cause permanent and irreparable harm to the Plaintiffs. Upon information and belief, Defendants have conspired together to publish the false and misleading statements and to cause other organizations and publications to question the Plaintiffs' integrity, virtue, honesty and business practices. Plaintiffs are entitled to injunctive relief in order to protect their business including their personal and business reputation.

**VIII.**  
**IMMINENT HARM**

6. If Plaintiffs' application is not granted, the harm is imminent because Defendants' actions are designed to cause immediate and irreparable damage to the Plaintiffs. Plaintiffs have been made the subject of false and misleading comments, statements and publications designed to harm the Plaintiffs and their business. Plaintiffs' clients are being directly contacted by e-mail by one or more of the Defendants urging the Plaintiffs' clients that the Plaintiffs allegedly violated federal law. Plaintiffs are in grave risk of losing their business and their business and personal reputation has been harmed. Defendants constant publishing of the false and misleading statements about Advanced and Mr. Durante, including that there is an ongoing criminal investigation has caused and will continue to cause imminent harm to the Plaintiffs. As noted in the same articles in which the Defendants have published, even if the FDA were involved in an investigation, it does not comment on its investigations. The mere referring to the alleged investigation is causing significant harm to the Plaintiffs business and personal reputation. Thus in the event that the FDA is conducting some investigation which it has not informed the Plaintiffs of, there is no reason of any nature for the Defendants to constantly publish or otherwise make any reference, statement or comment any investigation.

**IX.**

Plaintiffs have no adequate remedy at law in that Defendants are active in their attempt to harm the Plaintiffs and their business interests.

**X.**

There is insufficient time to serve notice on the Defendants and to hold a hearing on the application.

**XI.**

Plaintiffs are willing to post bond if the Court deems it appropriate.

**XII.**

**REQUEST FOR TEMPORARY INJUNCTION**

Plaintiffs ask the Court to set this Application for Temporary Restraining Order for hearing, and after hearing the Application, issue a temporary injunction against Defendants, enjoining Defendants and anyone acting in concert with them, from the prohibited activities herein described and ordering the Defendants as follows:

1. Cease and desist from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

2. Upon a final hearing by this Court, Defendants be permanently enjoined from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or

observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

**XIII.**  
**REQUEST FOR PERMANENT INJUNCTION**

Plaintiffs ask the Court to set this Application for Temporary Restraining Order and Request for Temporary Injunction for hearing for a full trial on the issues in Plaintiffs' application, and after the hearing, issue a permanent injunction against Defendants enjoining and ordering the Defendants, and anyone acting in concert with them as follows:

1. Cease and desist from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

2. Upon a final hearing by this Court, Defendants be permanently enjoined from making, speaking, creating, commenting, or writing, anything about Advanced, Mr. Durante, the LipoTRON 3000, the Lipo-EX Program, including but not limited to making, speaking, creating, commenting, writing, referencing, insinuating, or alluding to in any manner, any false, misleading, disparaging, slanderous and or libelous comment or observation, to any person, publication, government agency, or organization, including but not limited to any internet domain, web site, on-line blog, twitter account, or any and all other social media account, of any nature, concerning any of the Plaintiffs' business practices, procedures and products in any form or manner, including any and all comments, statements, writings, concerning Mr. Durante's honesty, integrity, virtue, or reputation.

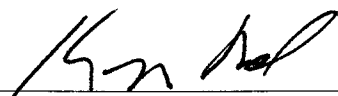
#### **XIV. ATTORNEY'S FEES**

As a result of Defendants actions, Plaintiffs were required to retain an attorney to file this application. The Plaintiffs have agreed to pay reasonable attorney's fees in connection with the filing and prosecution of this application. As such, Plaintiffs now sue to recover their attorney's fees pursuant to the Texas Civil Practice and Remedies Code.

WHEREFORE, PREMISES CONSIDERED, Plaintiffs, Advanced Aesthetics Concepts, LP and Mark Durante ask that the Court grant their Temporary Restraining Order, and set this Application for Temporary Injunction for hearing, and upon notice to Defendants, issue a temporary injunction, as requested above, and upon final trial, enter a permanent injunction against Defendants as set out above, and for such other and further relief to which Plaintiffs may be justly entitled at law or in equity.

Respectfully submitted,

GOODRICH POSTNIKOFF & ASSOCIATES, LLP  
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Fort Worth, Texas 76102  
(817) 347-5265 Telephone  
(817) 335-9411 Tele-copy

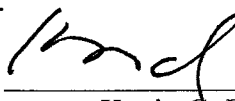


Michael S. Goodrich  
State Bar No. 08165100  
Kevin G. Herd  
State Bar No. 24027017  
Amanda B. Hernandez  
State Bar No. 24069911

ATTORNEYS FOR PLAINTIFFS

### **CERTIFICATE OF CONFERENCE**

I, Kevin G. Herd, certify that on August 22, 2012, I attempted to contact Clifford Womack, who was the last counsel for Paige Peterson concerning the relief sought herein, but was unable to confer with him. As for the remaining defendants, I am unaware as to whether any of the remaining Defendants have counsel in this matter. Due to the exigency of this matter, it is brought to the Court's attention ex parte.



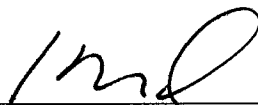
Kevin G. Herd

### **CERTIFICATE OF SERVICE**

I, Kevin G. Herd, certify that a true and correct copy of the foregoing was served in the manner indicated upon the following:

Clifford M. Womack  
Law Office of Clifford M. Womack  
2701 West Berry Street, Suite 123  
Fort Worth, Texas 76109

Certified Mail R.R.R. #7009 0960 0001 2178 3076



Kevin G. Herd






















**TARRANT COUNTY, TEXAS**

**VS.**

**JUDICIAL DISTRICT**

**AFFIDAVIT OF MARK DURANTE**

**STATE OF TEXAS** §  
§  
**COUNTY OF TARRANT** §

1) "My name is Mark Durante. I am over the age of 18 years and reside in Tarrant County, Texas. I am of sound mind and fully competent to make this affidavit. I have personal knowledge of the facts and statements stated herein, and they are true and correct.

2) I am the managing member of the general partner of Advanced Aesthetic Concepts, LP (“Advanced”), and I am authorized to make this affidavit on behalf of Advanced Aesthetic Concepts, LP (“Advanced”). In my position as managing member of the general partner of Advanced, I am a custodian of the business records maintained by Advanced. As custodian of

records maintained by Advanced, the records attached to this affidavit were made at or near the time by, or from information transmitted by me, and were kept in the course of a regularly conducted business activity and it is Advanced's regular practice to make the records in the regular course of business. I have personal knowledge of the events stated herein, including the prior business relationship between Advanced and Paige Peterson and Belinda Worley.

3) I also have personal knowledge of the business relationship between Advanced and RevecoMed, Inc. ("RevecoMed") including but not limited to equipment that Advanced purchases from RevecoMed including the LipoTRON 3000. I also have personal knowledge of the marketing of the equipment sold by Advanced to its customers.

4) Advanced is a Texas entity engaged in the business of providing wholesale aesthetic medical equipment, training, marketing, consulting and business solutions to physicians and medical spa owners.

5) Included in the consulting and services that Advanced provides is a program that Advanced created called the Lipo-EX Program. The Lipo-Ex Program is not a device and does not require FDA approval. It is a trademarked "program" of Advanced. The Lipo-Ex Program can and does encompass several different components to include such things as diet, nutrition and nutritional supplements, patient education on metabolic processes, colonics, and technologies which may include the LipoTron. Physicians are free to utilize which medical service, device or technology they might incorporate.

6) Included in the technologies that some physicians incorporate in addressing their patient's needs is the LipoTRON 3000. The LipoTRON 3000 is a Class 1 Medical Device registered with the United States Food and Drug Administration (the "FDA") for pain management.

7) The Lipo-EX Program and the LipoTRON 3000 are not the same thing and their

names cannot be used interchangeably.

8) On or about July, 2012, prior to the article's publication, I received a telephone call from Myron Levin who identified himself as the Editor of an on-line publication known as FairWarning. FairWarning's website is [www.Fairwarning.org](http://www.Fairwarning.org). In the conversation, I was informed by Mr. Levin that FairWarning intended to publish an article concerning the LipoTRON 3000 including the manufacturer of the LipoTRON 3000, RevecoMed, Inc. As well, I was informed by Mr. Levin that FairWarning intended to reference Advanced and the Lipo-EX Program in its article. During the course of the interview Mr. Levin informed me that his source was Paige Peterson (now known as one of the "whistleblowers" in this action) who had revealed to him that the LipoTRON 3000 was being sold without FDA approval and that the Lipo-EX Program was the same thing as the LipoTRON 3000. In the FairWarning article Mr. Levin identified the two "whistleblowers" as Paige Peterson and Belinda Worley, both of whom are named in this suit.

9) I informed Mr. Levin that Advanced had been involved in a lawsuit with Paige Peterson in 2009 concerning the return of a substantial sum of money that had been inadvertently sent to Paige Peterson via her company, P2, LLC via a misdirected wire transfer. I informed Mr. Levin that Advanced filed suit against P2, LLC and Paige Peterson for the return of the money in which Advanced was granted judgment for the return of the money. I further informed Mr. Levin that neither P2, LLC nor Paige Peterson returned the money, but instead filed bankruptcy.

10) On or about July 11, 2012 FairWarning published an article titled "Fat-Melting Device a Weighty Matter for FDA". A true and accurate copy of the FairWarning article is attached hereto and incorporated herein for all purposes as Exhibit "A". The FairWarning article is offensive to Advanced and to me personally and contains numerous factual errors and mis-statements which I believe were intentionally placed in the article to harm Advanced and its business interests and

reputation as well as my personal reputation.

11) Included in the factual errors in the article is FairWarning's statement that the "LipoTron 3000, or Lipo-EX" are the same thing. They are not. As noted herein, the Lipo-Ex Program is not a device and does not require FDA approval. It is a trademarked "program" of Advanced. The Lipo-Ex Program can and does encompass several different components to include such things as diet, nutrition and nutritional supplements, patient education on metabolic processes, colonics, and technologies which may include the LipoTron. The LipoTRON 3000 is a medical device manufactured by RevecoMed and which holds a class 1 registration with the FDA.

12) The FairWarning article is factually incorrect in its statement that the "The LipoTron, which targets fat with radiofrequency waves, has never been cleared or approved by the U. S. Food and Drug Administration, which would make it illegal under federal law to sell or promote it for weight loss." This statement is factually incorrect and I believe it intentionally misleads the reader. Contrary to the statement by FairWarning, the LipoTRON 3000 has been registered with the FDA as a Class 1 Medical Device. As such, federal law permits the sale and marketing of the LipoTRON 3000. As noted above, the LipoTRON 3000 is used for its proper indications and may be used by a licensed physician for same or in "off-label" treatment as the physician deems necessary.

13) The FairWarning article is factually incorrect in that misquotes the statements that I made to FairWarning. Specifically, FairWarning published that I had "told state investigators that the LipoTRON had been cleared by the FDA, but later corrected himself to say paperwork had been filed but no clearance yet given". This statement is factually incorrect. I did not make the aforementioned statement to FairWarning.

14) The FairWarning article is factually incorrect in its portrayal that there is a investigation of the LipoTRON 3000 and Advanced being conducted by the FDA. Advanced has not

ever received a target letter or telephone call from the FDA concerning any investigation, nor has Advanced ever been contacted by the FDA or any other federal governmental agency concerning any criminal investigation into the marketing of the equipment that Advanced markets to its clients.

15) After the publication of the FairWarning article, I was made aware that on or about July 12, 2012, Medical Spa MD had re-printed the FairWarning article in its entirety on its web site as an attachment to Medical Spa MD's article titled "Fairwarning: The LipoTron 3000 (Lipo-Ex) FDA UnApproved \$85k Massager" wherein Medical Spa Md adopted the same positions as stated in the FairWarning article including the factually incorrect statements in paragraphs 11-14 herein. A true and correct copy of the Medical Spa MD's article is attached hereto and incorporated herein as Exhibit "B".

16) The Medical Spa MD article is offensive to Advanced and to me personally and contains numerous factual errors and mis-statements which I believe were intentionally placed in the article to harm Advanced and its business interests and reputation as well as my personal reputation.

17) In addition to the factual errors contained in the FairWarning article identified in paragraphs 11-14 herein, in which Medical Spa MD adopted and published, the Medical Spa MD article is factually incorrect wherein it portrays the LipoTron 3000 as being the same as the Lipo-Ex. As noted herein, the LipoTRON 3000 is a medical device manufactured by RevecoMed whereas the Lipo-Ex Program is not a device and does not require FDA approval. It is a trademarked "program" of Advanced and encompasses several different components to include such things as diet, nutrition and nutritional supplements, patient education on metabolic processes, colonics, and technologies.

18) Medical Spa MD broadcast a special alert to 20,000 plus members of the medical community, a key marketing group of Advanced's, to alert them that "FDA Being Urged to Seize All LipoTron 2000 (Lipo-Ex) Devices in the US".

19) The Medical Spa MD article is factually incorrect in its portrayal of a “criminal investigation” and I believe it intentionally misleads the reader. As noted herein, Advanced has not ever received a target letter or telephone call from the FDA concerning any alleged criminal investigation of the LipoTRON 3000 or the Lipo-EX program.

20) On July 18, 2012, Medical Spa MD posted a second article on its web-site concerning the LipoTRON titled “ More bad news for LipoTron, RevecoMED (the manufacturer of LipoTron), and probably its resellers....” A true and correct copy of the second Medical Spa MD’s article is attached hereto and incorporated herein as Exhibit “C”.

21) In this publication, Medical Spa MD also posted a letter written by Public Citizen, Inc. (“Public Citizen”) who Medical Spa MD identifies as a “consumer watchdog”. The letter that Public Citizen sent to the FDA repeated many of the false statements from the FairWarning and the Medical Spa MD articles. A true and correct copy of Public Citizen’s letter is attached hereto and incorporated herein as Exhibit “D”. This is despite the fact that Medical Spa MD was contacted by Advanced as early as March 15, 2012 regarding the statements made by Susie Quinn a/k/a JQuinn wherein Advanced requested that Medical Spa MD remove the statements. In response, Mr. Jeff Barson of Medical Spa MD advised Advanced that it should contact Susie Quinn directly, and on April 9, 2012, Advanced mailed a letter and an e-mail to Susie Quinn asking her to remove her comments, which she has refused to do so far. Shortly thereafter, Advanced was notified by the Texas Department of State Health Services that it had received a complaint against Advanced, which was filed on April 9, 2012, the day Advanced asked Quinn to remove postings, for the same thing that Susie Quinn had complained.

22) Included in the factual errors in the Public Citizen letter, is its statement that “RevecoMED and its distributor have been illegally marketing the LipoTron.” As previously noted, the LipoTRON 3000 has been registered with the FDA as a Class 1 Medical Device, and as such, federal law permits the sale and marketing of the LipoTRON 3000. Accordingly, Advanced is in compliance with federal law concerning the marketing of the LipoTRON 3000.

23) The Public Citizen publication is factually incorrect in its portrayal that the LipoTRON is a “dangerous device.” Advanced has not ever received a target letter or telephone call from the FDA concerning any investigation, nor has Advanced ever been contacted by any user or the FDA or any other federal governmental agency concerning the LipoTRON allegedly being a dangerous device.

24) The Public Citizen publication is factually incorrect in its portrayal that the LipoTRON and Lipo-EX are one and the same and that “Lipo-EX uses bi-polar radio frequency (RF), which results in an electric field.....” As noted herein, the LipoTRON 3000 is a medical device manufactured by RevecoMed whereas the Lipo-EX is a trademarked “program” of Advanced and encompasses several different components to include such things as diet, nutrition and nutritional supplements, patient education on metabolic processes, colonics, and technologies. . Physicians using the Lipo-EX Program may use the LipoTRON within the guidelines set by the FDA, but the Lipo-EX program is not a machine as is portrayed by Public Citizen.

25) On or about July 12, 2012, Susie Quinn, under the pseudonym “jquinn” posted various comments on Medical Spa MD’s web-site in response to the Medical Spa MD article. Included in her postings were statements that “the manufacturer and distributors of Lipo-EX, aka LIPOTRON are currently under federal criminal investigation for marketing and selling without FDA approval, ....” Susie Quinn further posted that “If you are currently using this device or have

been approached to purchase this device, I urge you to read the FDCA and US CODE OF FEDERAL REGULATIONS from the FDA web site (link listed below along with the specific sections regarding why this device is being investigated).”

26) On or about July 14, 2012, Susie Quinn, under the pseudonym “jquinn” posted additional statements that “Today FDA urged to seize LipoTrons/Lipo-EXs, stop RevecoMED/AAC, and protect the public by Washington DC Public Citizen, and includes in her posting a link to the Public Citizen postings.

27) On or about July 15, 2012, Susie Quinn under the pseudonym “jquinn” posted the FairWarning article “Fat Melting Device a Weighty Matter for the FDA” on all of Advanced’s clients’ Facebook accounts, as well as on Advanced’s facebook account. A true and correct copy of the Facebook account postings made by Susie Quinn are attached hereto and incorporated herein as Exhibit “F”.

28) On July 18, 2012, Susie Quinn posted on facebook accounts and on Twitter and in the Medical Spa comment section, the Public Citizen article “FDA Being Urged to Seize All Lipo Tron 3000 (Lipo-Ex) Devices in the US” together with a link to the Medical Spa MD articles.

29) On July 18, 2012, Susie Quinn posted the Public Citizen article “FDA Being Urged to Seize All Lipo Tron 3000 (Lipo-Ex) Devices in the US” together with a link to the Medical Spa MD articles.

30) On July 23, 2012, Susie Quinn sent e-mails to five doctors all of whom were clients of Advanced, all of whom had their medical practice in Texas, wherein Susie Quinn claimed to provide “evidence about the ongoing federal and state criminal investigations of Advanced Aesthetics Concepts”. This e-mail was sent to: Remirez Internal Medicine Associates, Beaumont,



Texas; Contour Derma Med Spa, San Antonio, Texas; PL Weight Loss Clinic, Santa Fe, Texas; Laser Rejuvenation & Family Medicine Associates, P.A. Joshua, Texas.

31) On July 31, 2012 Susie Quinn sent e-mails to three additional clients of Advanced that were also located in Texas and claimed that the TDSHS had opened another case targeting Profit Solutions MD as another identity of Advanced Aesthetics Concepts. This e-mail was sent to: Sabrina Mercer Skincare; Cypress, Texas, Vanity RX Medi-Spa, Longview, Texas, and Remirez Internal Medicine Associates, Beaumont, Texas.

32) On August 1, 2012 Susie Quinn sent e-mails to seven more clients of Advanced that were located in Texas telling them that Public Citizen had urged the Texas Medical Board and the Texas Department of State Health to act on the "illegal Lipo-Ex/Lipotrn". This e-mail was sent to: Remirez Internal Medicine Associates, Beaumont, Texas; Dr. Harcharan Narang, Houston, Texas, Hidden Door Med Spa, Roanoke, Texas, Avante Medical Spa, The Woodlands, Texas, Vanity RX Medi-Spa, Longview, Texas, Family Medicine Associates, P.A., Joshua, Texas, Realis Medical Spa, Houston, Texas.

33) On August 6, 2012 Susie Quinn sent an e-mail to another client of Advanced that was located in Texas telling them that Public Citizen had urged the Texas Medical Board and the Texas Department of State Health to act on the "illegal Lipo-Ex/Lipotrn". This e-mail was sent to: Facial Techniques, Dallas, Texas. A true and correct copy of the e-mails that Susie Quinn sent to the various clients of Advanced are attached hereto and incorporated herein as Exhibit "G".

34) The statements made by Susie Quinn through her on line postings to the Facebook accounts of Advanced's clients, her on line postings to the Medical Spa MD and Public Citizen websites, and her numerous e-mails to Advanced's clients, are offensive to Advanced and to me personally and contain numerous factual errors and mis-statements which I believe were intentionally

placed in her postings, blogs and e-mails to harm Advanced and its business interests and reputation as well as my personal reputation.


35) The statements made by Susie Quinn through her on line postings to the Facebook accounts of Advanced's clients, her on line postings to the Medical Spa MD and Public Citizen websites, and her numerous e-mails to the clients of Advanced are factually incorrect.

36) As provided herein, the LipoTRON 3000 and Lipo-EX Program are not the same. LipoTRON 3000 and Lipo-EX Program are not illegal. Advanced does not illegally market the LipoTRON 3000, as the LipoTRON 3000 has been registered with the FDA as a Class 1 Medical Device, and as such, federal law permits the sale and marketing of the LipoTRON 3000. The Lipo-Ex Program is not a device and does not require FDA approval. It is a trademarked "program" of Advanced. The Lipo-Ex Program can and does encompass several different components to include such things as diet, nutrition and nutritional supplements, patient education on metabolic processes, colonics, and technologies which may include the LipoTron.

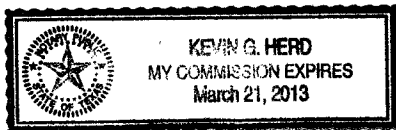
37) Advanced is not subject to a criminal investigation and has not ever received a target letter or telephone call from the FDA concerning any criminal investigation.


38) Advanced has been harmed by the numerous factual errors and mis-statements that were made by FairWarning, Medical Spa MD, Public Citizen, Paige Peterson, Belinda Worley and Susie Quinn. Since the negative and false information that has been published by FairWarning, Medical Spa MD, Public Citizen, Paige Peterson, Belinda Worley and Susie Quinn, Advanced has been economically harmed from the loss of sales and the damage to Advanced business reputation and I have been harmed from damage done to my personal reputation.

Further Affiant Sayeth Naught."

  
Mark Durante, Managing Member of AAC Gen-  
Par, LLC, the General Partner of Advanced  
Aesthetic Concepts, L.P.

SUBSCRIBED AND SWORN TO BEFORE ME, on the 22<sup>nd</sup> day of August, 2012, to  
certify which witness my hand and official seal.

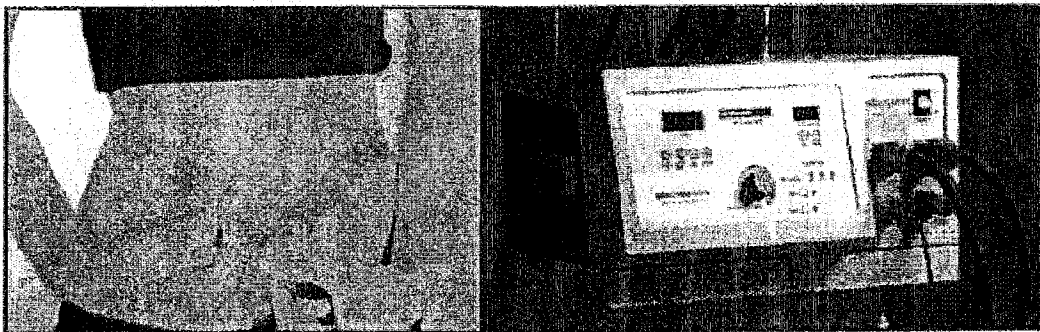


  
Notary Public in and for the State of Texas

July 11, 2012  
- FairWarning - <http://www.fairwarning.org> -

## Fat-Melting Device a Weighty Matter for FDA

By Myron Levin and Stuart Silverstein on July 11, 2012 in FairWarning Investigates | [3 Comments](#)



iStockphoto/LipoTron

For several years, doctors and medical spas around the country have touted a fat-melting device called the LipoTron 3000, or Lipo-Ex, as a revolutionary way for people to slim down.

Signature Medical Spa in Tampa, Fla., in an online pitch for its "Lipo-Ex Spring Fling Fat-Off!", described the technology as "truly the only non-invasive way to reduce fat."

### This story also published by:

[msnbc.com](http://msnbc.com)

[The Orange County Register](http://TheOrangeCountyRegister.com)

[TucsonSentinel.com](http://TucsonSentinel.com)

[Florida Center for Investigative Reporting](http://FloridaCenterforInvestigativeReporting.com)  
[100Reporters](http://100Reporters.com)

Praise also came from Sculpt Medical Spa in Chicago, which called the procedure "the most innovative, effective, and technologically advanced" non-surgical method of removing fat.

Doctors have appeared on TV news shows in Houston, Phoenix and Miami to promote LipoTron treatments.

These testimonials have translated into millions of dollars in sales for physicians, med spas, and the device's manufacturer, RevecoMED International of Fullerton, Calif.

But there's a problem: The LipoTron, which targets fat with radiofrequency waves, has never been cleared or approved by the U.S. Food and Drug Administration, which would make it illegal under federal law to sell or promote it for weight loss.

The FDA is aware of the activity. But an investigation by FairWarning found that the agency has not taken enforcement action—even though it has known about the situation at least since January, 2010. At that time, two whistleblowers, one a former LipoTron distributor, provided sales records and a trove of other documents to an FDA criminal investigator.

The case spotlights the booming, multi-billion-dollar business of aesthetic medicine—and the willingness of some doctors and med spas to use unapproved devices as they vie to be first with the latest technologies to smooth wrinkles, tighten skin and sculpt the body.

# Exhibit "Q"

EXHIBIT

A

The FDA won't say if it is investigating Reveco, citing a policy not to discuss investigations or acknowledge if there is one.

For his part, RevecoMED President James S. Rosen said the agency hasn't contacted the company. He asserted that, "As of today, we are compliant with the FDA."

Still, for observers such as Dr. Patricia K. Farris, a clinical associate professor of medicine at Tulane University and a spokesperson for the American Academy of Dermatology, the situation is baffling.

Told of the unauthorized sales, Farris responded: "It shocks me the FDA would not have cracked down on them."

"I mean, radiofrequency is an electrical device, and you can't just be throwing these things in the marketplace without doing the right studies to make sure that, A, the device is safe and, B, that the thing does something and has some benefit."



Paige Peterson

Dr. Suzanne Yee, a Little Rock, Ark., plastic surgeon whom Reveco asked several years ago to take part in a LipoTron study, said she was surprised to learn that the company already was selling the device.

She noted that some medical spas have falsely stated on their websites that the LipoTron is FDA-approved. "It's not FDA-approved," Yee said. "I think that's dishonest."

There have been scattered incidents of patients receiving minor shocks and burns from LipoTron treatments, but no known reports of serious injury.

While the FDA has failed to act, the Texas Department of State Health Services issued a warning letter last September to a Fort Worth distributor for marketing the LipoTron without FDA clearance. According to an agency report, Mark Durante, managing partner of Advanced Aesthetic Concepts, told state investigators that the LipoTron had been cleared by the FDA, but later corrected himself to say paperwork had been filed but no clearance yet given.



RevecoMED office in Fullerton, Calif. (Lilly Fowler)

Durante told FairWarning that, in response to the warning, his company changed some language on its website. However, a spokeswoman for the Texas agency said it recently opened a second complaint investigation of Advanced Aesthetic Concepts.

Selling for as much as \$85,000, the LipoTron passes radiofrequency waves through the body to heat, and destroy, fat cells. According to Reveco, the procedure targets subcutaneous fat, which is just below the skin, as well as visceral fat surrounding the vital organs, but without harming adjacent tissues. Spas typically

recommend six to eight treatments for about \$400 each.

According to interviews and records, Reveco first sought a green light from the FDA in 2007. It chose the FDA's market clearance procedure, which is less demanding than the formal approval process.

To get a new device cleared this way, the manufacturer must show it is similar in safety and effectiveness to products that are already on the market.

However, Reveco's bid failed. The company's initial application "wasn't in-depth enough," Rosen said, and the FDA repeatedly sought additional data. Finally, according to Rosen, "We said, 'You know what, it's not worth it.'"

According to interviews and a document reviewed by FairWarning, the FDA then told Reveco that the device could not be marketed.

LipoTron sales continued, however. Rosen wouldn't disclose how many of the devices have been sold, but the number is believed to be in the low hundreds.

In 2011, Reveco took another tack with the FDA. It classified the LipoTron as a massager used for relief of minor pain. That would make it, in FDA parlance, a Class 1 device — a category that includes such simple, low-risk items as elastic bandages and examination gloves.

The advantage for Reveco is that massagers can be sold without a green light from the FDA. They automatically are exempt from FDA review and can be put on the market once a notice is filed.

Yet doctors and med spas have been promoting the device on the Internet not for massages but for removing fat.

Rosen said that was not Reveco's responsibility, stating that the company can't dictate what doctors do or "police everything out on the Internet."

Asked who would pay \$85,000 for a massager, Rosen replied: "Anybody that wants to buy it."

Physicians are free under federal law to prescribe unapproved, or "off-label," uses of drugs or medical devices—but only if the products have been cleared or approved for another purpose, according to the FDA.

FDA spokeswoman Sarah Clark-Lynn said in an email that if a device is not legally on the market, "a physician should not have been able to obtain it, much less use it on a patient."

Dr. Sherwood Baxt, a New Jersey plastic surgeon who advertised the procedure in a promotional video, said that when he bought the LipoTron he wasn't troubled by its lack of FDA clearance. He explained that he had used unapproved devices before and, while he considered the agency's green light a marketing advantage, he didn't consider it necessary.

Besides, Baxt said, "We were told FDA approval was imminent." It didn't work out that way, however, and, he said, "After two years, I just stopped asking."

He continues to use the device for skin tightening on certain patients but quit using it for fat reduction. For fat reduction, Baxt said, "it wasn't as effective as I thought it was going to be."

The FDA was informed of the unauthorized sales through an anonymous call. Paige Peterson, a former LipoTron distributor, and Belinda W. Worley, a marketing consultant who worked with her, told FairWarning they dialed in from a hospital phone in hopes the call could not be traced.

But they agreed to meet with criminal investigator Evan Rae a few days later at a Hilton inn in Waco, mid-way between Rae's office in Austin and Dallas, where Peterson and Worley lived.

They found a quiet spot in the lobby bar, which was closed in the morning, and talked for a couple of hours. Peterson said she gave Rae a detailed statement, a computer flash drive and copies of records, including emails, memos and invoices. Rae taped the conversation and snapped photos of the LipoTron 3000 the women had brought along. Rae declined to be interviewed.

Peterson told FairWarning she had made 39 LipoTron sales, even though she was aware the device had not been cleared by the FDA. The evidence she gave Rae "was just as damning of me as everybody else. I have zero assurances that the FDA is not going to arrest me."

Peterson admitted there was no love lost between her and Revoco. She said she had paid out-of-pocket for some research costs aimed at getting FDA approval, but had not been reimbursed. And she said the company dumped her as a distributor in favor of another sales group.

But Peterson also said Revoco had misled her with repeated assurances it was taking all proper steps and FDA approval was imminent—and spread this misinformation to some anxious customers.

"I had run out of acceptable answers to give the doctors that had purchased the LipoTron," she said. "I needed to fall on my sword and tell the truth." Better to come clean, Peterson decided, than to wait for the FDA "to come knocking on my door."

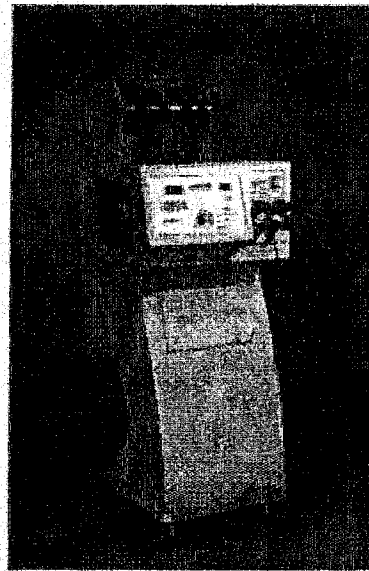
While declining to comment on Peterson's statements, Rosen said she had gone over to "the dark side."

"She's a person that's vindictive," he said. "She's doing it out of spite."

For her part, Peterson says that after 2½ years she is surprised and frustrated by the apparent lack of action.

"Why do we have an FDA?" she asked.

"I tried to do what I thought was right, and nobody's doing anything about it. Everybody gets to thumb their nose at the law."



LipoTron 3000, sometimes called the Lipo-Ex.

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**Printed from FairWarning.org:** <http://www.fairwarning.org/2012/07/fat-melting-device-a-weighty-matter-for-fda/>

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<http://medicalsparamd.com/the-blog/2012/7/12/fairwarning-the-lipotron-3000-lipo-ex-fda-unapproved-85k-mas.html>

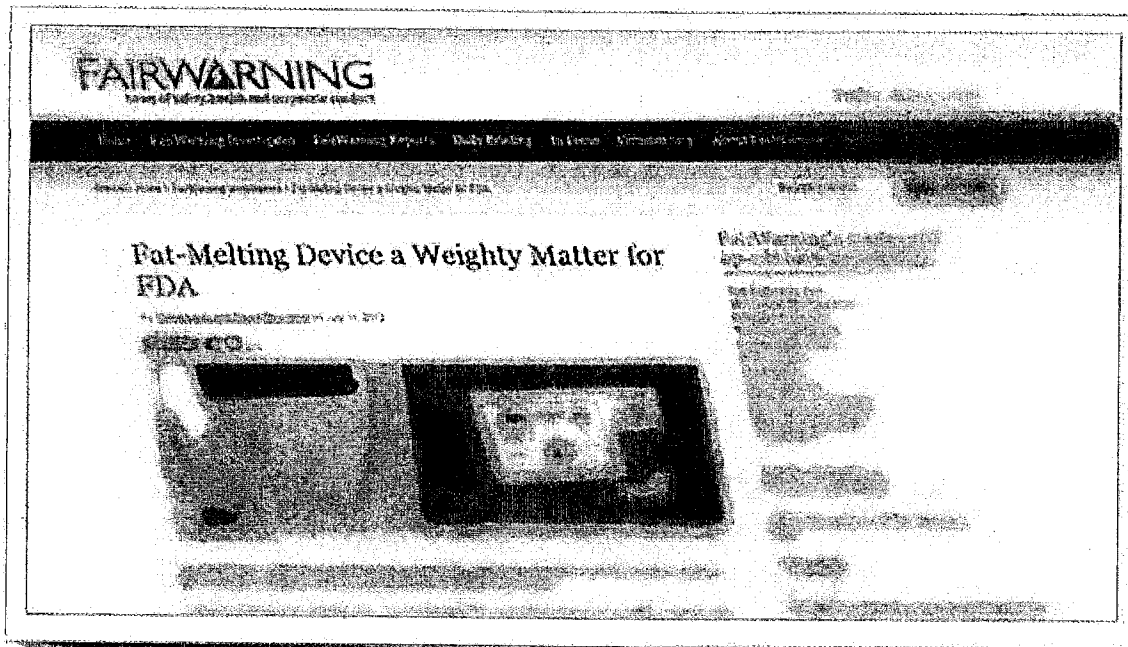
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Thursday

Jul122012

36 Comments | MEDICAL SPA MD on IPL & LASER MANUFACTURERS + LEGAL

## Fairwarning: The LipoTron 3000 (Lipo-Ex) FDA UnApproved \$85k Massager



According to a new story on Fairwarning.org, RevecoMED claims that their LipoTron (Lipo-Ex) is really being marketed and sold as an \$85,000 massager.

I just got off the phone with Myron Levin or Fairwarning.org who contacted me about Advanced Aesthetic Concepts attempts to have comments and reviews about the Lipotron 3000 and their business removed from Medical Spa MD claiming that some negative comments were costing them sales. It was an interesting discussion and Myron filled me in on some of the background that went into the story which has some interesting twists including anonymous calls to the FDA and secretive meetings with criminal investigators.

**Exhibit "B"**

**EXHIBIT**

**B**



Read the entire article here: [Fat-Melting Device a Weighty Matter for FDA on Fairwarning.org](#)

From the Fairwarning.org article:

According to interviews and records, Reveco first sought a green light from the FDA in 2007. It chose the FDA's market clearance procedure, which is less demanding than the formal approval process.

To get a new device cleared this way, the manufacturer must show it is similar in safety and effectiveness to products that are already on the market.

However, Reveco's bid failed. The company's initial application "wasn't in-depth enough," Rosen said, and the FDA repeatedly sought additional data. Finally, according to Rosen, "We said, 'You know what, it's not worth it.'"

According to interviews and a document reviewed by FairWarning, the FDA then told Reveco that the device could not be marketed.

LipoTron sales continued, however. Rosen wouldn't disclose how many of the devices have been sold, but the number is believed to be in the low hundreds.

In 2011, Reveco took another tack with the FDA. It classified the LipoTron as a massager used for relief of minor pain. That would make it, in FDA parlance, a Class 1 device — a category that includes such simple, low-risk items as elastic bandages and examination gloves.

The advantage for Reveco is that massagers can be sold without a green light from the FDA. They automatically are exempt from FDA review and can be put on the market once a notice is filed.

Yet doctors and med spas have been promoting the device on the Internet not for massages but for removing fat.

Rosen said that was not Reveco's responsibility, stating that the company can't dictate what doctors do or "police everything out on the Internet."

Asked who would pay \$85,000 for a massager, Rosen replied: "Anybody that wants to buy it."

Wow. It takes some really big cajones to claim that you're selling an \$80k+ device named LipoTron to cosmetic clinics from a company named RevecoMED but you're only marketing it as "a massager for minor pain" and that it's the doctors who are running around uncontrolled promoting it for fat-melting. I'm actually somewhat impressed. I guess the real lesson is that if

you can't get your device approved by the FDA as a medical device the first time, reclassify it as a band-aid and declare yourself in full compliance. That seems simple enough.

Of course it also seems fairly clear from the article that if you have one of these devices and you're promoting it as FDA approved or as a treatment for anything other than a 'massager' you might not be in lock-step with the FDA, a fact that might be exacerbated by the fact that this story has been picked up by major media outlets like MSN.com.

I'm curious; Does anyone have one of these Lipotron devices that they're using as a massager for minor pain? You might want to see if it works on yourself because I'm guessing you have a headache about now.

Update on 07-18-2012 by Medical Spa MD

**More bad news for LipoTron, RevecoMED (the manufacturer of LipoTron), and probably for it's resellers... as well as all the physicians and clinics who are offering LipoTron treatments.**

Public Citizen, a consumer watchdog organization with 300k members, has contacted the FDA urging, among other things, that all LipoTron devices should be seized immediately.

Here is what Public Citizen is asking for: from their letter to the FDA:

Immediately seize all LipoTron devices that have been manufactured by RevecoMED and either (a) are being held in inventory by the manufacturer in the U.S. or (b) have been sold and distributed to user facilities in the U.S.

(2) Immediately order RevecoMED and any distributors of the LipoTron device to cease and desist all activities involving the distribution, sale, and promotion of the LipoTron device.

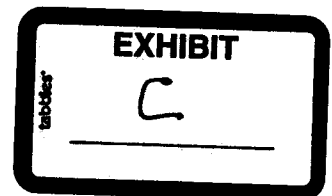
(3) Expeditiously complete its criminal investigation of the distribution, sale, and promotion of the LipoTron device and take appropriate legal action against those individuals, companies, and user facilities that are found by the agency to have engaged in any illegal marketing or promotion of this device

This can not be good news for any of the medical spas and clinics who already have this device.

Read the entire letter to the FDA

View attachments regarding the letter

View the Public Citizen press release



You might like:

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## Reader Comments (36)

Just read the article. It's amazing to me that they're selling the device as "fully compliant with the FDA" after failing to get approval. I guess that the real losers are the physicians who paid for this massage device for minor pain.

"Selling for as much as \$85,000, the LipoTron passes radiofrequency waves through the body to heat, and destroy, fat cells. According to Reveco, the procedure targets subcutaneous fat, which is just below the skin, as well as visceral fat surrounding the vital organs, but without harming adjacent tissues. Spas typically recommend six to eight treatments for about \$400 each."

I don't know who is still selling these but there seems to be some very serious questions about how ethical (or legal) it is to use something that the FDA didn't approve. I'm not conversant in FDA regs but it seems very odd that these guys could do this. Anyone have more insight?

07.13 | [Ligo](#)

Thank you, MedicalSpaMD, for posting this story front page. I am the person who has been posting about this federal criminal investigation on this site for about 30+ months. Mark Durante of Advanced Aesthetic Concepts, the exclusive distributor for RevecoMED and the LipoTron, threatened to sue me unless I deleted my posts about the investigation and contacted you to do the same. Thank you for staying strong for free speech.

Just to be clear, Lipo-EX is LipoTron, just in case anyone is confused. The whole purpose for calling the LipoTron by another name (Lipo-EX) was to stay under the radar of the FDA and make it look like something "legal".

You will be seeing more national coverage of this story in the weeks to come.

07.14 | Quinn

Regarding Jim Rosen's comment about not being able to police the Internet, the link below will take you to Rosen's / RevecoMED's web site for their medical clinic which features the LipoTron for fat reduction. So looks like he could police his own site, but chose otherwise.

<http://www.trinitymedclinic.com/aboutus.htm>

07.14 | Quinn

I took a look at that link and it's very clear that this clinic, (which the CEO of of RevecoMED, Jim Rosen, appears to own) is promoting this treatment specifically as what it is, a RF fat melting medical device.

<http://www.trinitymedclinic.com/services.html>

Copied and pasted from that page:

"How does it Work?

LipoTron uses radio frequency to specifically target fat cells. The treatment increases your body's core temperature to a point of dissolving fat cells, without causing damage to other internal organs. It is the first technology to melt the unhealthy and dangerous fat linked to heart disease and diabetes. CT scans, body circumference and weight measurements have confirmed that LipoTron results in the loss of 2-3 inches and 10 lbs of weight in just 6 weeks for most patients. It causes the disruption of fat cell membranes, thus causing the fatty content to leak out into the interstitial tissue...

Question & Answer

Q. What is LipoTron?

A. The LipoTron is a non-invasive aesthetic device that tightens skin, recontours the face and body, reduces cellulite. This safe treatment works for all the skin types and colors, and offers solutions to the inevitable problems of weight gain and aging skin.

Q. What is different between Thermage or Aluma Skin Renewal and LipoTron?

A. Their devices use high heat ( 65° C or more) for contraction of collagen but LipoTron uses low tissue heat between 39-42. Their application is limited to skin tightening.

Q. What is LipoTron Application?

A. Tighten the jaw line, reduce jowls, recontours chin line, and reduce eyes under bag. Smooth the orange peel look, tighten loosen skin and recontours body measurement. Firm the breast, tighten loosen skin under the arms or on stomach.

Q. What is LipoTron Radio Frequency- Assisted Lipoplasty (RFAL)?

A. Conventional liposuction is the invasive cosmetic plastic surgical procedure to remove pockets of fat that has not responded to diet and exercise. Also, Invasive liposuction was not intended as a means for weight loss or obesity treatment. LipoTron Noninvasive RFAL system provides all the advantages of a deep thermal increase to remove subcutaneous fat (cellulite) , visceral fat at the same time including weight loss and obesity treatment. This procedure has no downtime, side effect and maintenance."

I have no dog in this fight but it's obvious that this is both a medical device that should have FDA approval, and that they're promoting it as such.

07.14 | CHIMO

Let's connect the dots...

Dot 1

"State examining claims about LipoTRON device" was a story printed in the Austin Statesman on June 24th.

<http://www.statesman.com/news/texas/state-examining-claims-about-lipotron-device-2403609.html>

An early quote from Mark Durante (Advanced Aesthetic Concepts) from the Statesman article...

Durante said "that although the firm still distributes the LipoTRON, the website does not tout it for fat removal."

[www.lipoexprograms.com](http://www.lipoexprograms.com) is Advanced Aesthetic Concepts / Durante's website touting the Lipo-Ex program for fat removal. Later in the Statesman article, he admits Lipo-Ex contains the Lipotron RF device.

How can you conclude the site belongs to Durante?

1. Advanced Aesthetic Concepts website is [www.fromstarttoperfection.com](http://www.fromstarttoperfection.com).
2. Contact info on [www.lipoexprograms.com](http://www.lipoexprograms.com) is [info@fromstarttoperfection.com](mailto:info@fromstarttoperfection.com)
3. Physical address listed on [lipoexprograms.com](http://lipoexprograms.com) is the same address provided for Advanced Aesthetic Concepts.
4. Call the phone number listed on the Lipo-Ex site the website 800-337-0745. It is the same contact phone number on Advanced Aesthetic Concepts website.
5. Ask for Mark, Sommer, Shannon, Cindy, Webster, Jane or Samethi, all names under the about us tab as Team Leaders.

07.15 | dotconnector

Dot 2

More quotes from the Statesman article spoken by Durante.

"The LipoTRON is used "as a therapeutic massager for increased circulation," Durante said in an interview last week.

"The state did not understand there is a difference between the Lipo-Ex program and the LipoTRON," he said, adding that the company never promoted LipoTRON for weight loss. The Lipo-Ex program includes other medical devices, including the Celluderm System and Lightwave LED, but the LipoTRON is the only one that uses radiofrequency to heat body fat, Durante said."

As of early 2012 LipoTRON and Celluderm share the same exempted status under Regulation section 890.5660 Therapeutic Massager to relieve minor aches and pains.

The LipoTRON is a class 1 exempted massaging device registered to RevecoMED

The Celluderm is a class 1 exempted massaging device registered to Innovative Med Inc.

As of January 2010 Lightwave LED was cleared K082586 for 5 indications:

1. The LIGHTWAVE Deluxe Red light is indicated for use in dermatology for treatment of superficial, benign vascular, and pigmented lesions.
2. The LIGHTWAVE Deluxe Red and Blue light combination is intended to emit energy in the red and blue region of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.
3. THE LIGHTWAVE Deluxe Blue light is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.
4. THE LIGHTWAVE Deluxe Red and Blue light combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.
5. THE LIGHTWAVE Deluxe Infrared Light is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

The below is quoted from [www.lipoexprograms.com](http://www.lipoexprograms.com) under the Technology tab, but you won't see it unless you click on "read more" toward the end of the page.

"How does Lipo-Ex work and what kind of patient results can I expect?

Out of the synergy of technology and extensive research, a revolutionary formula for fat reduction, skin rejuvenation and body sculpting has emerged. Using a patented radio frequency (RF) technology, the benefits of RF are no longer limited to superficial conditions, but can now therapeutically extend to the visceral areas of the body. These technological advancements, unique to the Lipo-Ex program, are then blended with proprietary clinical techniques and education to help your patients reach their goals for fat reduction, skin tightening and body sculpting for the entire body. In international studies, the technology in the Lipo-Ex program became the first of its kind to demonstrate with CT scans the reduction of both visceral and subcutaneous fat. The studies also showed a total reduction of fat of approximately 0.8-1 quart per session with a total of 4-5 quarts after 5 sessions. Currently, our physicians nationwide are documenting an average circumference loss of 2 1/2 to 4 inches in eight weeks with some patients reaching as much as 8" in a single circumference reduction."

In the FDA market exemption of Therapeutic Massager or the Clearance for marketing indications did you see visceral fat reduction? Subcutaneous fat reduction? Skin tightening? Body sculpting for the entire body? Up to 1 quart per session fat reduction? Or Average circumference loss of 2.5 to 4 inches in 8 weeks listed as acceptable marketing claims?

Doctors can make these claims if they choose but only on the Lightwave LED because it is a "FDA 510K cleared device", making these claims "off label". Distributors cannot. Manufacturers cannot.

The other two devices are FDA Class I exempted devices. Any marketing claim other than therapeutic massage or minor ache and pain relief subject to FDA approval for marketing through the 510K or PreMarket Approval process.

07.15 | [dotconnector](#)

Dot 3

Continued Mark Durante quotes from the Statesman article:

"All they are doing is they are asking us to respond to a complaint," Durante said. "We don't believe the complaint is justified. We handled everything the state asked."

He (Durante) would not say how many LipoTRON devices his company distributes or how much they cost.

Then according to the FairWarning.org story link in the article above, Jim Rosen the CEO and President of RevecoMED International. "Rosen wouldn't disclose how many of the devices have been sold, but the number is believed to be in the low hundreds."

Rosen and Durante won't say how many LipoTRON devices have been sold by their companies in the US because all sales are illegal.

A repost of FairWarning's story on Medical Device and Diagnostic Industry Blog was correctly titled,

"Medical Device Offers Alternative to Liposuction...and a Middle Finger to FDA"

<http://www.mddionline.com/blog/devicetalk/medical-device-offers-alternative-liposuctionand-middle-finger-fda>

Here's how I found these details, using google.com search and the keywords Reveco, Advanced Aesthetic Concepts, Lipotron, and Lipo-EX.

07.15 | [dotconnector](#)

Today FDA urged to seize LipoTrons / Lipo-EXs, stop RevecoMED / AAC, and protect the public by Washington DC PublicCitizen.

Here's the link to the press release, transcript of the letter to the FDA, and supporting documentation:

<http://www.citizen.org/hrg2044>

07.18 | [JQuinn](#)

Just received your MEMBER ALERT email about FDA urged to seize LipoTrons. One clarification: the PublicCitizen letter to the FDA calls for the seizure of all RevecoMED LipoTron devices. There are a number of models besides the 3000.

including LipoTron 500, LipoTron 1000, LipoTron 2000, VitalRF, RecuDerm, FollicleStimulator, Lipo-EX, Lipo-EX Advanced, and a few others.

Distributors of these devices have included Advanced Aesthetic Concepts of Fort Worth, TX, DermaVista of Birmingham, AL, Qnyx Medical of Novato, CA, and, of course, the whistleblowers themselves.

07.18 | Jquinn

J Quinn otherwise known as Paige Pederson has failed to disclose the fact that she stole \$65K from a subcontractor. The subcontractor filed civil case against her and the subcontractor WON. She then declared bankruptcy to avoid paying back the monies and avoid criminal activity. This is not an honest person.

07.18 | LoisLane

Whether Jquinn is this person or not, or even if this person is "honest" is entirely beside the point. The real losers here are the docs that have been suckered in by these people with empty promises and what could very well put them at risk on multiple fronts, not to mention the money they'll lose as a result. Who cares which snake raised it's head first.

07.18 | Rangle

Since I own a machine I'm interested in what develops from all this finger pointing. does this watchdog group have a vendetta, do they really care about patients. do they know if any harm or good has come from these treatments with lipo-ex? I have not been using the machine for some time, but we did get fair results. It was marketed to me as a fat reduction tool. Advanced concepts may have promoted this product off label but was it illegal? we use alot of medications with good results off label. Just playing the devils advocate here, trying to get both sides of the story. Does anyone know if any independent legal action is planned against advanced concepts or M. durante?

07.18 | antiagingmd

@antiagingmd,

I think it's too early to tell if there will be any individual lawsuits that come out of this but I would bet that there may be a few. (I would guess that you would want some money back if the FDA comes in and takes your unit.) From what I'm reading the stories that are going up are not vendettas against any of the companies involved but are really pushing the FDA for what they feel are lax enforcement. However, just as with anything else, the US has an abundance of lawyers. If I were you I would contact one and get their take. I would also make absolutely sure that I wasn't promoting this device as FDA approved and I would be somewhat hesitant about even using the device. These guys got caught with their hand in the cookie jar and the FDA is going to be forced to sit on them. (jut my 2 bits)

07.18 | Rangle

See below for statute language concerning "off label". What I understand is it is okay for a medical practitioner to use off label as long as the device is/was "legally marketed". If it was not "legally marketed", off-label is a problem.

Here's the actual FDCA language along with a link to a really useful document written by Ellen J. Flannery of Covington & Burlington LLP, an FDA expert law firm in DC



"A health care practitioner can prescribe or administer a legally marketed device to a patient for an off-label use, but a manufacturer cannot promote unapproved uses of a device". FDCA § 906.

<http://www.aipia.org/learningcenter/library/papers/am/AM08Materials/Documents/Flannery-paper.pdf>

07.18 | [JQuinn](#)

I found this article very interesting. Thank you for writing and publishing it. I believe the FDA has a role to play in making sure devices are safe and effective. When it comes to medical devices, the FDA focuses more on safety than efficacy. But either I am a bit confused or I find this article a bit hypocritical given its context on this webpage. What I mean is that you are writing about a device being used without proper FDA clearance, but right next to this article, you are offering to sell re-imported Botox. Isn't that illegal and against FDA mandates?????? Seems a bit strange to me. Perhaps you can clarify my confusion on this subject. Or if I am correct, you should reconsider your illegal sale of re-imported Botox.

Brian Stolley, MD,

07.18 | [Brian Stolley, MD](#)

@Brian Stolley, MD

From your question I'm guessing that you may have just stumbled upon the site. Not wanting to speak for anyone but you'll find physicians and authors from outside the US all over the site and the header/footer state that. I don't think that there's any representation to purchase anything that's illegal or unethical and that is an advertisement. (Ok, I think I'm done with this thread.)

07.18 | [Rangle](#)

I also agree with Dr. Stolley, but this is the true nature of the unregulated "spa" business. We have spa owners without any type of medical background owning and performing treatments on patients. Also, machines being sold by sales reps who know full and well their machines do not yet have medical clearance, but fail to tell the physicians buying them. Then, when they get fired, elect themselves "whistleblowers" and pretend they care about safety and the public, after taking hundreds of thousands in commissions from unsuspecting physicians. The worst part is knowing the same whistleblowers are currently out there selling their snake oil with other non-cleared devices.

07.18 | [I believe in karma](#)

I haven't heard of any real issues with this device or any 'horror stories'. Is this device capable of real damage and have there been patients who have been harmed? Is this really more about FDA enforcing their approval process or are patients really at risk if this is being handled capably through real medical clinics? There is always a scale and from what little I've read there shouldn't be anything hear (by way of complications) that couldn't be said of something like Thermage. Are there risks above burns or localized lipolysis?

07.18 | Emeryo

If these LipoTron guys are smart, they'll take all necessary steps to swallow hard and try and fix this. Threatening the messenger is a no-win tactic as a business and sometimes you just have to admit your mistakes.

07.19 | Chabela106

Thanks but I WILL NOT buy this equipment. This country is doomed.

07.19 | MBracaldo

People should get their facts straight before they make statements which could harm others. There is nothing worse in this country than irresponsible reporting. The court case against Paige Pederson and the outcome are public record in Tarrant County, Texas, as is her bankruptcy filing to avoid jail and paying back monies she stole. Just as the fact the device is FDA approved. Why anyone would not take the proper steps to verify such information before making such a libelous statement is beyond the rational mind. Both, the bashing and the lost court case are related to Paige Pederson, who is nothing more than an angry, disgruntled ex-seller of the Lipotron device. There are no two snakes involved here...only a snake and a bunny...with Ms. Pederson being the two headed snake.

07.19 | LoisLane

@LoisLane.

It's clear that you are one of the players in this case and have no fondness for Paige Pederson, but I don't see what her history has to do with the FDA approval issue. (She admitted to much wrongdoing in the story already but that's how 'whistleblowing' works.) While everything you say to disparage this person may be true, the real topic is the representation/marketing of a medical device as being FDA approved when it apparently was not.

However, from your comment above it appears that you're claiming that the Lipotron device actually is FDA approved. Is that so? Are you claiming that the LipoTron actually is FDA approved? If the device actually has FDA approval (and not this hocus-pocus 'massager' Type 1 non-approval BS) then I would think that it would be provided to the media tout de suite. If not, I don't see how you can be mad at Fairwarning or others for reporting this. If I had one of these devices, which I do not, I would want to know about this.

@MBracaldo,

Like the comment.

07.19 | Chabela106

@MBracaldo,

I think Lois Lane is angry that Fairwarning as well as other news outlets published articles based on only what Paige Peterson was saying without bothering to check all the facts. I am an owner of a Lipotron, but have not used this machine for

a few years. Never did Reveco tell me that the machine was FDA approved. They applied for clearance to get FDA approval and FDA came back and needed more information. I think at this point Reveco did not have the money to pursue FDA clearance. Was I a fool for buying this machine when it was not FDA approved? Yes!, but I was so excited and happy with the results. Also, I don't agree that Paige "admitted to much wrong doing". I never once received an apology as she states she gave to the doctors she sold the Lipotron to in the fair warning article, even though she had my office, cell and email. Further, I have received numerous other email suggestions from Paige over the last few years to buy other pieces of equipment that are not currently FDA approved. Is she sorry about that too? Not to lay all the blame on Paige, because I think both her and Reveco are a bunch of snakes. It's no wonder that she was fired from this company. Their personalities are probably too similar to get along!

07.19 | ~~I believe in karma~~

The bottom line is negative press is not always a bad thing...in fact it's part of being successful. When you have a great product there will always be those who want to tear you down, protect their own interests, or try exploiting you for mere recognition. Advanced Aesthetic Concepts has always known that the forefront of any industry is as dangerous as it is rewarding. Fortunately, our desire to improve health with less risk, downtime and help physicians improve their economic situations in uncertain times had been the passion for continuing with non-invasive technologies that are near miraculous advancements in this decade. As old school surgical procedures make way to non-surgical procedures that were merely science fiction 20 years ago in movies like Star Trek, I know there will be those that will attempt to tear down the success of valuable programs, like Lipo-Ex for their own gain.

The fact of the matter is that the source and initiator of these attacks on Advanced Aesthetic Concepts and Revecomed is a disgruntled former distributor, who has been bitter and maliciously attacking both companies for three years ever since she lost her distributorship for both unethical and possible criminal behavior. The fact of the matter is that Paige Peterson, who initially contacted Fairwarning.com and is the person, mentioned above who anonymously called the FDA and held secret meetings with criminal investigators, was also proven in court to have misappropriated \$60,000 from Advanced Aesthetic Concepts. She is a vengeful person out to destroy anyone associated with Lipotron 3000 merely because she lost her opportunity to work with a great product because of unethical practices. Her attacks are merely the result of her anger about losing out on a great opportunity. If not, why would she be so diligent with her attack strategies for three years? In fact, according to a post on this page all comments posted here from jquinn, who is so adamant about bashing Lipotron technology and the Lipo-Ex program are on a hacked email account. So it can be assumed that jquinn, who refuses to be identified, is probably associated in some way with (or actually is) Paige Peterson.

In addition, from a factual standpoint neither Lipo-Ex and or Lipotron 3000 one of the devices used in the Lipo-Ex program is under investigation by the FDA or anyone else. The Lipotron 3000 was in the FDA approval process in the final stages until the FDA asked for more information last Fall. It was at that point that Revecomed decided to get the class 1 FDA clearance, so that in the interim the safety and therapeutic value of the technology was at least made certain to the public. However, the manufacturer is in diligent pursuit of other indications of use.

Another fact to consider is that most non-invasive fat reduction and skin tightening technologies on the market today, no matter how well they work or how safe they are, is currently approved or registered with the FDA for uses other than what doctors are promoting all over the nation. The majority of technology being use for fat reduction is actually cleared for

increased circulation and or muscle relief, skin tightening, etc. So why the attack on Lipotron, other than the bitter root in Paige Peterson, who is only interested in attacking the people who work with the Lipotron? She is not at all concerned with the patients, who benefit from the treatments, or the good for the medical community and the future of medicine.

Who is Jquinn and why does she continue to attack this technology? Jquinn has the same email address as a mysterious Susie Quinn, who started a Facebook page yesterday to post exaggerated claims about the device all over Lipo-Ex providers' Facebook pages. And why are respectable news sources dealing with someone as shady as a Paige Peterson or Jquinn, whose identity is hidden in a hacked email account for what they are calling news?

Medical Spa MD, instead of asking those who offer Lipotron services as part of their Lipo-Ex program if they have a headache, the article above should ask those same physicians how happy their patients are and what kind of great results they are getting. I guess, unfortunately as always bad news just sells better than good news especially for a publication like Fair Warning. In reality, the good news is that most Lipo-Ex program providers have gotten rid of the headache of managed care by providing a service that makes their patients happy.

07.19 | Jayne Wilks

Jayne Wilks, Marketing Director, Advanced Aesthetic Concepts, exclusive distributor of Lipo-EX / LipoTron.

07.19 | dotconnector

My apologies Jayne for misspelling your name...previous post facts stand Jayne Wilks, Marketing Director, Advanced Aesthetic Concepts, exclusive distributor of Lipo-Ex / LipoTron.

07.19 | dotconnector

Dot Connector.

Thank you for identifying me by title. The fact that I used my name surely indicates that I had no desire to hide my identity as an employee of Advanced Aesthetic Concepts. My only objection is the slash you used between Lipo-Ex and LipoTron, since LipoTron is only one of the devices used in a program that includes other protocols. Please stop indicating that they are one in the same in your posts.

A better question that might be answered than what is Jayne Wilk's exact title is who is Dot Connector and who is Jquinn for those answers would certainly help everyone CONNECT THE DOTS!

Sincerely,

Jayne Wilks

07.20 | Jayne Wilks

Dot Connector.

Thank you for identifying me by title. The fact that I used my name surely indicates that I had no desire to hide my identity as a an employee of Advanced Aesthetic Concepts. My only objection is the slash you used between Lipo-Ex and LipoTron, since LipoTron is only one of the devices used in a program that includes other protocol. Please stop indicating that they are one in the same in your posts.

A better question that might be answered than what is Jayne Wilk's exact title is who is Dot Connector and who is jquinn for those answers would certainly help everyone CONNECT THE DOTS!

Sincerely,  
Jayne Wilks

07.20 | Jayne Wilks

@DotConnector, Seriously? I guess you think we should be grateful that we have some one like you, with your uncanny ability to connect the dots, to point out the obvious to those of us who are not as sharp as you. Perhaps you think everyone else here is stupid and needs your help? Connect this: She, (Jayne Wilks) obviously is not afraid and does not need to hide behind a fake name like some people. Funny thing: When you speak the truth, there is no need to hide.

07.20 | Butch Quinn

Even without knowing all the details and facts, this intriguing Lipotron story is intriguing, not that anyone ever knows all the facts; it appears that numerous libelous statements have been made and continue to be allowed to be posted. Either the manufacturer is being investigated or it is not. The FDA documents everything it does and sends extremely detailed warning letters to manufacturers when they find issues that require correction. In my humble opinion, for the editors of this website to post an alert or update on this story stating "FDA urged to seize all Lipotrons" based on a letter supposedly sent to the FDA by some consumer watchdog group is extremely reckless and seriously erodes the credibility of this site as an objective, unbiased source of information. This group that supposedly sent a letter to the FDA is not a government agency; it has no official capacity or authority. So now the question becomes: How and why did this watchdog group become involved? I wonder who contacted them? It is one thing to allow others to comment, but now the editors are posting these articles? Have you picked up the phone and called and spoken with anyone to verify any of this information? Here's a good question to ask someone, "Could Paige Peterson possibly be out there peddling other Non FDA Approved devices to physicians right now?"

To the editors of this organ I would say, You seem to have forgotten that when you have the right to Freedom of Speech, it carries great responsibility. Whether the editors of this site know it or not, Medical Spa MD may have just become another pawn in this insidious game. Shame on you J.B.

07.20 | Shannon Wilks

Major national news media story in development. If you have been injured, had adverse events related to Lipo-EX / LipoTron, media producers have interest in talking with patients, physicians, medspa owners, technicians. You may be contacted directly by the producers of the show--not me. tweet to jquinn@gw55sq.

07:20 JQuinn

Largo – agree-- serious ethical and legal issues are at hand

JQuinn – give'em hell...wish I could say I am JQuinn, but she is in Vancouver in her ivory tower... god help us...she's relentless...

ChiMD – way to check things out on your own and report back...verified fact are hard to fight

DotConnector – the logic is killing us, but "thanks" for the 101 course on FDA regs & internet sleuthing

Lois Lane – think you still have some issues with the "sub-contractor" case, but thanks for the reference...loved the bunny

Rangle – thanks for getting back to the issue at hand and not continuing the whistleblower bashing – "hand in the cookie jar" IS the big issue

AntliagingMD – from what I read and understand, physicians can only promote "off label" IF the device is "legally marketed"

Karma believer – "snake oil", now watch out.... you are aligning yourself...and remember what goes around comes around...

Emery D – Stick around. there are several law groups soliciting on the internet for patients that had treatments... "if you build it, they will come"

MBaracaldo – "I wish no one else ever did"

Chabela106 – Thanks for sticking with the facts

Karria (again) – Obviously you missed some of the story published by FairWarning, AAC, RevecoMED, and Paige Peterson contributed. not to mention the FDA and American Academy of Dermatology!

Jayne – builet points for you

- If the device is not FDA cleared/approved/exempted to market for the claims you are marketing it for in 2007, 2008, 2009, 2010, 2011...IT IS NOT OK TO PROMOTE IT to physicians, med-spas, or patients in the United States of America.
- But, BOY, didn't it make "A LOT" of money!?,
- What happened to "First do no harm?"
- Lipo-Ex, LipoTRON, LipoTron 3000, Vital RF, Recuderm...all the same
- Your "program" contains 3 devices being promoted for non-indicated uses
- A distributor, consultant, manufacturer or ANYONE "soliciting" for business benefit CANNOT provide this info to the public, to physicians, to medical spas....Just ask Glaxo-Klein, I'm sure they have the MOST current position on this type of marketing...and they budgeted for the "hit" they are taking, so hope you are as well...

Butch – interesting you are joining the AAC group in asking for the names of only a few in a strand of more than 30 comments....what happened to "free speech"?

Shannon – at least some here (who have bothered to read), know what you and AAC have done – with and without Paige Peterson – so really Shannon, "turnabout is fair play"....

Wonder what your company name will be on Monday? (you have the whole weekend to morph into yet another identity to elude the law)...

07.20 | Paige

I was just recently told to look at this thread of comments in relationship to news in healthcare. After reading this entire thread, and seeing the last post, my only comment is to be careful!!! This reads like a battle between a past distributor with legal issues and two companies that have no love loss for this distributor. If anything comes out of these articles as defamatory and there is legal action, as posted by Jquinn earlier, you don't want to be caught in the middle by participating in any of those media outlets. Especially when that material is out there forever on the internet to be used by either sides discretion. Defamations is becoming a very big legal issue in today's society with social media giving voice to irresponsible comments. With that said, I only suggest that anyone who is thinking of tweeting Jquinn to be part of a news media story, "Be careful!!!"

07.20 | Be Careful

Paige, brave soul that you are... Don't they know the most dangerous person in the room is the one who has nothing left to lose?

FDA Office of Criminal Investigation, Texas Department of Health, Public Citizen (Citizen.com), FairWarning, and over 500 twitter follows have been notified of PROFIT SOLUTIONS MD as just another morph of AAC.

I will never quit, will you?

07.20 | JQuinn

JQuinn, looks like your very bitter and obviously have no life.. Quit spamming everybody with your nonsense and get a job.

07.23 | unknown

As part of the team working on the name change for Advanced Aesthetics Concepts for nine months, I feel compelled to set everyone at ease as to the thought that AAC is trying to hide behind a name change to Profit Solutions MD. Frankly, the negativity towards AAC only reared its ugly head in the last few weeks. Anyone who has ever launched a name change knows the time it takes to prepare for such a launch, such as web development, logo designs, trademarks, etc. We only wish we could have done it in a few weeks! Please don't insult those who have worked on it this long and hard.



1000 20th Street, NW • Washington, D.C. 20004 • 202/588-1000 • www.citizen.org

July 18, 2012

July 18, 2012

Margaret A. Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
Department of Health and Human Services  
WO 2200  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Jeffrey E. Shuren, M.D., J.D.  
Director, Center for Devices and Radiological Health  
Food and Drug Administration  
Department of Health and Human Services  
WO 66, Room 5442  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Dear Drs. Hamburg and Shuren:

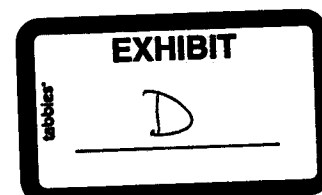
For several years, the Food and Drug Administration (FDA) has been aware of the apparent illegal distribution, sale, and promotion of the LipoTron medical device — also sometimes called Lipo-Ex, manufactured by RevecoMED International in Fullerton, California, and intended for use in removing subcutaneous and visceral fat — without the approval or clearance of the FDA. After reading about this matter in a July 11 story published in *FairWarning*,<sup>1</sup> Public Citizen obtained documents from one of the whistleblowers who was referenced in the story and who originally brought this matter to the attention of the FDA.

Most disturbing, the documents provided to us by the whistleblower indicate that the apparently illegal marketing and promotion of this potentially dangerous device was brought to the attention of the FDA's Office of Criminal Investigations more than two and a half years ago, but the FDA has failed to take action against the manufacturer and other entities involved in the distribution, sale, and promotion of the device, which is now being widely used throughout the U.S.

Therefore, Public Citizen, a consumer advocacy group representing more than 300,000 members and supporters nationwide, urges the FDA to take the following actions:

- (1) Immediately seize all LipoTron devices that have been manufactured by RevecoMED and either (a) are being held in inventory by the manufacturer in the U.S. or (b) have been sold and distributed to user facilities in the U.S.

**Exhibit "U"**





- (2) Immediately order RevecoMED and any distributors of the LipoTron device to cease and desist all activities involving the distribution, sale, and promotion of the LipoTron device.
- (3) Expediently complete its criminal investigation of the distribution, sale, and promotion of the LipoTron device and take appropriate legal action against those individuals, companies, and user facilities that are found by the agency to have engaged in any illegal marketing or promotion of this device.

#### **Overview of the LipoTron device**

The RevecoMED International website provides an overview of its LipoTron device.<sup>2</sup> This promotional website includes the following information:

##### **How does it Work?**

LipoTron uses radio frequency to specifically target fat cells. The treatment increases your body's core temperature to a point of dissolving fat cells, without causing damage to other internal organs. It is the first technology to melt the unhealthy and dangerous fat linked to heart disease and diabetes. CT scans[,] body circumference and weight measurements have confirmed that LipoTron results in the loss of 2-3 inches and 10 lbs of weight in just 6 weeks for most patients. It causes the disruption of fat cell membranes, thus causing the fatty content to leak out into the interstitial [sic] tissue. The fat is then absorbed by the lymphatic system and eventually eliminated naturally via the urine and feces. ...

##### **Q. What is LipoTron?**

A. The LipoTron is a non-invasive aesthetic device that tightens skin, recon tours [sic] the face and body, reduces cellulite. This safe treatment works for all the skin types and colors, and offers solutions to the inevitable problems of weigh[t] gain and aging skin. ...

##### **Q. What is LipoTron Radio Frequency-Assisted Lipoplasty (RFAL)?**

A. Conventional liposuction is the invasive cosmetic plastic surgical procedure to remove pockets of fat that has [sic] not responded to diet and exercise. Also, Invasive liposuction was not intended as a means for weight loss or obesity treatment. LipoTron Noninvasive RFAL system provides all the advantages of a deep thermal increase to remove subcutaneous fat (cellulite), visceral fat [sic] at the same time including weigh[t] loss and obesity treatment. This procedure has no downtime, side effect and maintenance.

The RevecoMED website also includes the following table summarizing the intended uses of the LipoTron device:

	Application	LipoTron Series	Biological Effect
Facial	Facial Tightening Wrinkle Reduction Freckle Acne and Blemishes Dark Circle Eye Bags Bruise	500 2000 3000	<ul style="list-style-type: none"> <li>• Stimulate Collagen Synthesis</li> <li>• Muscle relaxation</li> <li>• Increase Blood Flow</li> <li>• Increase Metabolism</li> <li>• Supply Oxygen</li> <li>• Reduce fatty deposits</li> </ul>
Cellulite Treatment	WIDER AREA OF: Abdominal Laxity Breast Firming Orange Peel Arms & Calves Face & Neck Double chin	2000 3000	<p>Lipotron-2000/3000 covers the three key elements to burn Subcutaneous fat deposits</p> <ul style="list-style-type: none"> <li>• Adipose dissolves at 41C</li> <li>• Supply Oxygen</li> <li>• Increase Blood Circulation</li> </ul>
Fat Reduction	Visceral Fat Reduction Obesity Treatment	3000	<ul style="list-style-type: none"> <li>• Heat treatment</li> <li>• Activating Cellular</li> <li>• Muscle relaxation</li> <li>• Increase blood Flow</li> <li>• Supply Oxygen</li> </ul>

#### Regulatory status of the LipoTron device

It is our understanding, based on information provided to us by one of the whistleblowers who contacted the FDA, that RevecoMED International has been selling and distributing the LipoTron since 2007 to user facilities throughout the U.S.

However, a search of the FDA website reveals no evidence that the LipoTron, which must be a class 2 or class 3 device, has ever been cleared or approved by the FDA under the 510(k) premarket notification process or under the premarket approval application process, respectively.

It is also our understanding, based on information provided to us by one of the whistleblowers who contacted the FDA, that in approximately 2007 and again in approximately 2009 RevecoMED International sought clearance from the FDA for the LipoTron under the 510(k) premarket notification process, and in both instances, the FDA did not grant clearance and requested additional information from the company. Despite this lack of clearance, RevecoMED International continued to market the device.

In approximately 2011, RevecoMED International registered the "LipoTRON; RFLipo System" as an electronic therapeutic massager (product code ISA), a class I device.<sup>3</sup> The listed registered establishment name and address for the LipoTron is:

RevecoMED International Inc.  
2491 E Orangethorpe Ave.  
Fullerton, CA 92831

The official correspondent for the RevecoMED International registration is Hong B. Kim. It is our understanding, based on information provided by one of the whistleblowers who contacted the FDA, that Mr. Kim is the owner of RevecoMED International and that he also goes by the name Michael Kim.

Remarkably, the FDA appears to have accepted this registration of the LipoTron as a class I device, even though (1) the uses of the device as promoted by the company on its website appear to be clearly inconsistent with, and go far beyond, those of an electronic therapeutic massager (the device type for which it was registered) and (2) the agency previously, on two occasions, had denied clearance of the device under the 510(k) premarket notification process.

#### **The FDA's criminal investigation regarding the marketing of the LipoTron device**

In January 2010, the whistleblowers who contacted the FDA presented allegations of illegal marketing of the LipoTron by RevecoMED and its distributor (Advanced Aesthetic Concepts [AAC]) along with supporting evidence to Mr. Evan Rae, a criminal investigator in the Austin Resident Office of the FDA's Office of Criminal Investigations. The following statements made by Mr. Rae in a series of emails sent over the past two years (copies enclosed) appear to confirm that RevecoMED and its distributor have been illegally marketing the LipoTron. Moreover, these statements demonstrate that multiple agency officials have been aware of these apparently illegal activities for several years but, by not taking appropriate action to remove these devices from the market and clinical practice, have recklessly failed to protect patients:

May 14, 2010: [Y]ou are correct, **not enough has been done to REVECOMED/AAC at this point** [emphasis added]. I have re-contacted our Headquarters (Office of Criminal Investigations), the Dallas District Office (Regulatory), the Center for Devices and Radiological Health, Office of Device Evaluation, and everyone else I have had contact with and advised them of the latest developments and the lack of action on our side. A conference call between all concerned is scheduled, which should speed things up when compared to email. I will do everything I can to get things moving. We will likely focus on AAC and other appropriate Texas entities, for ease of logistics.

---

<sup>3</sup> As recently as June 29, 2012, the RevecoMED International registration for the Lipotron device listed the proprietary name as "LipoTRON; RFLipo System." Subsequently, the registration was updated to list the proprietary name of the device as "RFLipo System."

March 17, 2011: [Y]es, I'm working on [the case involving your allegations about RevecoMED] almost every day. Reviewing 700+ page filing is taking a while, but I may have some specific questions soon. **The communications [to RevecoMED] from FDA could not be clearer. They prohibit any marketing of the [LipoTron] device and so state in specific language [emphasis added].** They are aware of everything I am, so I would anticipate that the extended period will expire without the deficiencies being corrected. Then, we will decide what action is called for.

April 10, 2012: ... I will add **that I have noted the [LipoTron] devices to be readily available for purchase and advertised (marketed) [emphasis added].** The fact that training and "informational seminars" are conducted also speaks to overtly having the device for purchase. **I have again contacted the Center for Devices and Radiological Health regarding their opinion, since they (as well as the State [of Texas]) have advised REVECOMED, if not AAC itself, in no uncertain terms that the device may not be marketed [emphasis added].** FDA put that paragraph in all caps on both denials of approval.

Among the numerous documents provided to Mr. Rae by the whistleblowers who contacted the FDA was a 2007 email to one of the whistleblowers. The email (copy enclosed) was sent from [revecomed@usa.com](mailto:revecomed@usa.com) and, according to the whistleblower, is from the owner of RevecoMED, Mr. Michael Kim. The email included the following:

Roger sold one set to customer in New Jersey month ago [sic] where I was there with Roger. Because of short trip I was not able to train them sufficiently. Eventually the device has to be replaced as the customer keeps creating problem after problem. They mentioned about burn damage and FDA while they were complaining the [sic] problem. **If they report to FDA what will happen is that FDA will order us to withdraw all the devices that we illegally sold, which is mandatory and if we don't come up with the order in time we go in treble [sic] right away, going to not civil court but crime court [emphasis added].**

So to avoid or minimize the disaster here is my suggestions until 510K

1. Sell the device to the doctors to make sure that they are good friends with Reps.
2. Sell the device only their backyard [sic] where they can reach maximum 5 hours by car to their customer.
3. Minimum one full day training before use.
4. No sell through sub-reps if you don't take a full responsibility of any accident or problem in sub-reps territory.
5. No Ad, publication, release of information. Use only manufacturer supplied printed material.
6. No Lipotron or RevecoMED's products, information in Rep's Website.

In the meantime what we are going to do is:

1. FDA preparation
2. R&D for more secure device
3. Clinical Study in several applications with doctors who you trust.

4. Prepare all necessary documents which you are working on
5. Sell the device in our community

The above statements, attributed by the whistleblower to Mr. Kim, appear to indicate (1) his awareness in 2007 that RevecoMED's marketing of the LipoTron device without the approval or clearance of the FDA was illegal and (2) his willful intent to continue to market the device despite this awareness.

#### **Risks of serious harm from the LipoTron device**

The following excerpt from the "Question & Answer" section on the RevecoMED webpage promoting the LipoTron device<sup>4</sup> appears to downplay the risks of treatment with the device:

##### **Q: Are there any risks involved with LipoTron RFAL?**

A: Every treatment procedure has risks and RFAL is no different, but according to our clinical study RFAL is the safest and effective [sic] method of removing localized fat areas among all Lipoplasty technologies so far.

This presentation of risks fails to disclose the potential for serious burns that can result from exposure of human tissue to radiofrequency radiation. Of note, the *FairWarning* story reported that "[t]here have been scattered incidents of patients receiving minor shocks and burns from LipoTron treatments."<sup>5</sup>

#### **Widespread promotion of the LipoTron device by multiple healthcare providers and clinics**

A simple internet search reveals that multiple physicians, clinics, and health spas throughout the U.S. are promoting treatment with the LipoTron device for indications that are consistent with those presented on the RevecoMED website and that go far beyond those of a simple electronic therapeutic massager. Examples of such promotion include the following:

- (1) The Altschuler Center for Weight Loss and Wellness, Novato, California: The center's website includes the following:<sup>6</sup>

Lipotron is a revolutionary system that effectively and painlessly eliminates body fat. Unlike other devices on the market that only target surface fat, Lipotron is the only device that reduces dangerous visceral fat as well. ...

##### **How does it work?**

Radio frequency currents recognize fatty tissue by its high water content, which makes it easy to selectively heat and dissolve fat cells. Bi-polar frequency of the RF current delivers heat to deep subcutaneous tissue without damaging the skin. Deep heating tightens tissue, melts fat, and stimulates collagen production. The deep heat reduces the orange peel or dimple look of cellulite.

### What can Lipotron do?

- Reduce large volumes of fat without liposuction or surgery
- Reduce visceral fat
- Reduce cellulite
- Diminish wrinkles
- Tighten and firm skin
- Contour specific areas of the body (love handles, abdomen, bra bulges, hips, butt, thighs, knees, arms)
- Smooth skin after liposuction

(2) Daniel Man, M.D., board-certified plastic surgeon, Boca Raton, Florida: His website includes the following:<sup>7</sup>

### What is LIPOTRON?

**LIPOTRON** uses a patented radio frequency technology for safe, pain-free treatments that are a non-surgical (non-invasive) alternative for skin tightening and fat reduction including: face, neck, body, hands, abdomen, contouring, cellulite removal, fat reduction and melting deep visceral fat associated in over weight and obese conditions. ...

### What can be treatment [sic] with the device?

- Cellulite anywhere on the body
- Weight loss (fat removal)
- Body Shaping- removal of love handles, abdomen, bra bulges, hips, thighs, groin pads, knee pads, arms
- Facial & Neck Contouring (double chin, jowls, eye pads)
- Non-surgical Breast Reduction
- Visceral Fat Reduction (melts fat around internal organs)
- Hand Rejuvenation
- Skin Tightening & Firming
- Stretch Marks

(3) Advanced Esthetics, Ann Arbor, Michigan: The company's website includes the following:<sup>8</sup>

### Lipotron Cellulite Reduction

The Lipotron cellulite reduction machine introduces a new era in the field of aesthetics and cosmetic medicine in treatments for cellulite. **The Lipotron RF uses radio frequency dermal technology for fat reduction in buttocks, abdomen, thighs, breast, neck and face [emphasis in original].**

The synergy of Capacitative Electrical Transfer (CENT) and Bi-Polar Frequency technology delivers heat to deep dermal tissue without damaging the epidermis. Endogenous Dermal Heating (EH) will tighten tissue, melt fat, and stimulate collagen production. The deep heat penetration targets adipose tissue to melt fat and reduce the orange peel or dimple look. Also an effective treatment in reducing stretch marks or sagging skin.

(4) The Signature Medical Spa, Tampa, Florida: The spa's website includes the following:<sup>9</sup>

**LIPO-EX (USES LIPOTRON) ...**

- Lipo-Ex expands surgical capabilities with its ability to help you reduce the dangerous visceral fat (shown by CT Scans) untreatable with liposuction. ...

**How Does Lipo-Ex Work?**

Lipo-Ex uses bi-polar radio frequency (RF), which results in an electric field that allows heating of tissue to be delivered at controlled temperatures into the treatment area. The Lipo-Ex apparatus uses 2 electrodes. One electrode is a grounding plate with a negative charge. The other electrode, having a positive charge, is manipulated by the practitioner over the treatment area. The opposing charges are met in the middle below the surface of the skin where the fat is located. When the two opposing charges encounter water in the fat, it slows down (encounters resistance). This heats up the water, which causes the fat to melt. The melted fat is then flushed away naturally by the lymphatic system.

**Conclusions and requested actions**

The information summarized above appears to clearly demonstrate the illegal, widespread distribution, sale, and promotion of the LipoTron medical device for removal of subcutaneous and visceral fat, among other promoted uses, by RevecoMED, its distributors, and multiple healthcare providers, clinics, and health spas, without the approval or clearance of the FDA over a period of several years. Most disturbing is the inexplicable failure of the FDA to take appropriate action to end these apparently illegal activities after they were brought to the attention of the agency's Office of Criminal Investigations more than two and half years ago. The FDA's failure to act has allowed numerous patients throughout the U.S. to be exposed to a potentially harmful medical device with unproven effectiveness.

Public Citizen therefore urges the FDA to take the following actions:

- (1) Immediately seize all LipoTron devices that have been manufactured by RevecoMED and either (a) are being held in inventory by the manufacturer in the U.S. or (b) have been sold and distributed to user facilities in the U.S.
- (2) Immediately order RevecoMED and any distributors of the LipoTron device to cease and desist all activities involving the distribution, sale, and promotion of the LipoTron device.

- (3) Expediently complete its criminal investigation of the distribution, sale, and promotion of the LipoTron and take appropriate legal action against those individuals, companies, and user facilities that are found by the agency to have engaged in any illegal marketing or promotion of this device.

Furthermore, we ask that you provide us with an explanation for the FDA's failure to act regarding this matter.

Sincerely,

Michael A. Carome, M.D.  
Deputy Director  
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.  
Director  
Public Citizen's Health Research Group

Enclosures

cc: The Honorable Kathleen Sebelius, Secretary of Health and Human Services

<sup>1</sup> Levin M, Silverstein S. Fat-melting device a weighty matter for FDA. FairWarning. July 11, 2012. Available at <http://www.fairwarning.org/2012/07/fat-melting-device-a-weighty-matter-for-fda/>. Accessed July 17, 2012.

<sup>2</sup> RevcoMED Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revcomed.com/lipo.html>. Accessed July 17, 2012.

<sup>3</sup> Food and Drug Administration. Establishment registration and device listing database; Proprietary name: LipoTRON; RFLipo System. Available at

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/r1.cfm?lid=304916&ipcd=ISA> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/r1.cfm?rid=133135>. Accessed June 29, 2012.

<sup>4</sup> RevcoMED Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revcomed.com/lipo.html>. Accessed July 17, 2012.

<sup>5</sup> Levin M, Silverstein S. Fat-melting device a weighty matter for FDA. FairWarning. July 11, 2012. Available at <http://www.fairwarning.org/2012/07/fat-melting-device-a-weighty-matter-for-fda/>. Accessed July 17, 2012.

<sup>6</sup> <http://www.marinweightloss.com/lipotron-body-contouring>. Accessed July 17, 2012.

<sup>7</sup> <http://www.drmann.com/body-procedures/lipotron/>. Accessed July 17, 2012.

<sup>8</sup> <http://www.advancedaestheticsmt.com/LipoTron---Fat-Reduction.html>. Accessed July 17, 2012.

<sup>9</sup> <http://www.painfreelipo.com/lipoex.php>. Accessed July 17, 2012.



Subject: RE: Summary Judgement  
Date: Fri, 14 May 2010 09:27:10 -0400  
From: [evan.rae@oci.fda.gov](mailto:evan.rae@oci.fda.gov)  
To: paige@ [REDACTED]

Heather, you are correct, not enough has been done to REVECOMED/AAC at this point. I have re-contacted our Headquarters (Office of Criminal Investigations), the Dallas District Office (Regulatory), the Center for Devices and Radiological Health, Office of Device Evaluation, and everyone else I have had contact with and advised them of the latest developments and the lack of action on our side. A conference call between all concerned is scheduled, which should speed things up when compared to email. I will do everything I can to get things moving. We will likely focus on AAC and other appropriate Texas entities, for ease of logistics. Thank you for your patience, Evan

Evan J. Rae  
FDA/Office of Criminal Investigations  
Austin Resident Office  
Phone: 512-349-2574  
Cell: 512-203-0571  
Fax: 512-349-2986  
[evan.rae@oci.fda.gov](mailto:evan.rae@oci.fda.gov)

---

From: [REDACTED] On Behalf Of Paige Peterson  
Sent: Wednesday, May 12, 2010 12:06 PM  
To: Rae, Evan  
Subject: Summary Judgement

Evan,

Last Friday the Judge found in favor of AAC on the summary judgment. AAC does not believe that there is an investigation of them or RevecoMED, their attorney submitted an affidavit stating that there is no investigation of AAC. They also said that P2 has made all of this up.

Thought you might find that interesting. Would you like a copy of all of Mark's affidavits and filings with the court?

Any news from your talk with the Justice Department?

It appears that AAC and Reveco get to continue unscathed, and P2 gets to pay the price for doing the right thing.

Paige

Copy of Emails  
Posted by Public Citizen.org

Subject: RE: touching base  
Date: Thu, 17 Mar 2011 09:39:33 -0400  
From: [evan.rae@oci.fda.gov](mailto:evan.rae@oci.fda.gov)  
To: [REDACTED]

Paige, yes, I'm working on it almost every day. Reviewing the 700+ page filing is taking a while, but I may have some specific questions soon. The communications from FDA could not be clearer. They prohibit any marketing of the device and so state in clear language. They are aware of everything I am, so I would anticipate that the extended period will expire without the deficiencies being corrected. Then, we will decide what action is called for. Thanks, Evan

---

**From:** Paige Peterson [REDACTED]  
**Sent:** Wednesday, March 16, 2011 10:32 PM  
**To:** Rae, Evan  
**Subject:** touching base

Hello Evan,  
Wanted to touch base and see if there are any developments since we spoke a couple of weeks ago.  
Are things still moving forward with the case?  
Best,  
Paige

*P2 LLC*  
*Paige Peterson*

Subject: RE: Lipo Ex - Advanced Aesthetic Concepts - Fort Worth  
Date: Tue, 10 Apr 2012 14:41:32 -0400  
From: evan.rae@oci.fda.gov  
To: Jonnetta.Wheaton@dshs.state.tx.us; [REDACTED]  
CC: Lori.Woznicki@dshs.state.tx.us; Torn.Brinck@dshs.state.tx.us

All,

I won't be available this afternoon for the discussion, but I will add that I have noted the devices to be readily available for purchase and advertised (marketed). The fact that training and "informational seminars" are conducted also speaks to overtly having the device for purchase. I have again contacted the Center for Devices and Radiological Health regarding their opinion, since they (as well as the State) have advised REVECOMED, if not AAC itself, in no uncertain terms that the device may not be marketed. FDA put that paragraph in all caps on both denials of approval. Please let me know what is decided this afternoon, thank you, Evan

---

**From:** Jonnetta.Wheaton@dshs.state.tx.us [mailto:Jonnetta.Wheaton@dshs.state.tx.us]  
**Sent:** Tuesday, April 10, 2012 11:37 AM  
**To:** [REDACTED]  
**Cc:** Lori.Woznicki@dshs.state.tx.us; Tom.Brinck@dshs.state.tx.us; Rae, Evan  
**Subject:** RE: Lipo Ex - Advanced Aesthetic Concepts - Fort Worth

Hello Paige,

I apologize for the delay in getting back to you with the complaint status. I need some clarification regarding the status of the spa you mentioned as well as information regarding the firm's marketing of the devices for unapproved uses (via the website and the letter you state your friend has received this month). Do you have some time today to discuss this with me? I can give you a call when you are available or you can call me (see contact information below).

Jonnetta Wheaton, Compliance Officer  
Drugs and Medical Devices Group  
Policy Standards and Quality Assurance Unit  
Environmental and Consumer Safety Section  
Division of Regulatory Services  
Texas Department of State Health Services  
Phone: (512) 834-6755 x2367  
Fax: (512) 834-6759  
E-mail: [jonnetta.wheaton@dshs.state.tx.us](mailto:jonnetta.wheaton@dshs.state.tx.us)

From: [revecomed@usa.com](mailto:revecomed@usa.com)  
To: [paige](#)  
Date: Wed, 22 Aug 2007 13:06:22 -0500  
Subject: Re: US market & others

Paige,

Any territory that tom and his reps do not cover is O.K. Please do not overlap the territories that they already in motion as I like to protect Tom's Reps who have been working hard for Lipotron. I want to keep basic business moral. They are innocent business person ells. So far I keep quite anything between you and myself in this office including Jim who is a close friend with Roger. It is premature to let them know and as far as business is concerned you don't want to make enemies.

I sent the following instruction to Jim to slow down their activities this morning. This will be part of your duties,too.

#### QUOTE

Jim, I was scared in Mexico where one of customer's staffs burned breast. It reminds me that when we sold U/S liposuction to couple of doctors before FDA one of patients had a burn damage. Patient sued the clinic and we came up with 100 K on behalf of the clinic. From that point we never attempt to sell the liposuction in USA even for clinical study.

Roger sold one set to customer in New Jersey month ago where I was there with Roger. Because of short trip I was not able to train them sufficiently. Eventually the device has to be replaced as the customer keeps creating problem after problem. They mentioned about burn damage and FDA while they were complaining the problem. If they report to FDA what will happen is that FDA will order us to withdraw all the devices that we illegally sold, which is mandatory and if we don't come up with the order in time we go in treble right away, going to not civil court but crime court.

So to avoid or minimize the disaster here is my suggestions until 510K

1. Sell the device to the doctors to make sure that they are good friends with Reps.
2. Sell the device only their backyard where they can reach maximum 5 hours by car to their customer.
3. Minimum one full day training before use.
4. No sell through sub-reps if you don't take a full responsibility of any accident or problem in sub-reps territory.
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6. No Lipotron or RevecoMED's products, information in Rep's Website.

In the meantime what we are going to do is :

1. FDA preparation
2. R&D for more secure device
3. Clinical Study in several applications with doctors who you trust.
4. Prepare all necessary documents which you are working on
5. Sell the device in our community

Michael

#### UNQUOTE

To place a new order direct it's up to you if they are not ware of it and not in their Reps territories.

and I am very happy we purchased this machine. I don't know where you are located, but come on down to South Texas. I will give you a session and you can make your own conclusions about how well this machine works.

10.20 | wendyh

careful...you get what you pay for by way of "free" advice here--too many of the posts/responses here are from salespeople selling this device who are not objective and are not running clinics as they profess.

11.9 | squinn

it's a scam...

04.13 | scott

Hi,

Is anyone interested in purchasing a lipotron machine? I have a practically new one that the company purchased in 2008, but we haven't used since 2008. Please let me know if anyone is interested. thanks

07.12 | N.N.

Is it the Lipotron 3000? For how much?

07.12 | LC

The manufacturer and distributors of Lipo-EX, aka LIPOTRON are currently under federal criminal investigation for marketing and selling without FDA approval. Investigators from the Office of Criminal Investigations are, as I post this, conducting interviews with LIPOTRON/LIPO-EX buyers/users throughout the US.

If you are currently using this device or have been approached to purchase this device, I urge you to read the FDCA and US CODE OF FEDERAL REGULATIONS from the FDA web site (link listed below along with the specific sections regarding why this device is being investigated).

<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>

- SEC. 301. [21 USC §331] Prohibited acts
- SEC. 302. [21 USC §332] Injunction proceedings
- SEC. 303. [21 USC §333] Penalties
- SEC. 304. [21 USC §334] Seizure
- SEC. 501. [21 USC §351] Adulterated Drugs and Devices
- SEC. 502. [21 USC §352] Misbranded Drugs and Devices

CODE OF FEDERAL REGULATIONS  
TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES  
PART 892 RADIOLOGY DEVICES

This is a very serious matter for which the FDA is prosecuting to the maximum extent of the law.

EXHIBIT

E

08.6 | jquinn

Jquinn,

First, your facts are incorrect. No one is under any type of "criminal investigation" by the FDA. Therefore your statements are libelous. Secondly, that you would make such a statement on a public forum indicates that you are a person lacking good judgement. Obviously, you are a person with a vested interest in the untruth that you are perputating, thereby corrupting any chance of gaining the respect you so desperately seek. Just looking at the venomous nature of your previous comments, a picture of a very bitter little person starts to develop and emerge.

08.6 | sw

Hi jquinn-

I have been interested in Lipotron for a while, but wanted to wait until it had finally received FDA approval, which I had believed was pending as they were in their 3rd FDA trials

It had been used in Asian and South America for the last decade, and has been in FDA clinical trials since 2006. I have heard both positive and negatives about it, but when reading through your postings it seems as though your biggest complaint is that it has been marketed to "beauty shops" that also offer teeth whitening and micros.

Well my Med spa offers BriteSmile teeth whitening and I pay a dentist some serious money to oversee it. We also offer micros as well as laser hair removal, fotofacials, sclerotherapy, Velashape etc.. and all of the injectibles. So how and where this device is sold and marketed to really doesn't concern me.

However, your claims of federal criminal investigation concern me greatly. Yet when I've followed the links that you've provided I don't see anything pending by the FDA or by the FDA's Office of Criminal Investigations.

I am confused by the drama and the controversy-what's your issue with this device and/or it's manufacturer other than marketing and sales tactics?

08.6 | BetterOffNow

You can sign up for the FDA Law Blog at [fdablog@hpm.com](mailto:fdablog@hpm.com), FDA NEWS at [enewsletters@fdanews.com](mailto:enewsletters@fdanews.com). In addition, the FDA and DOJ web sites post press releases concerning these matters once the OCI, DOJ, and other federal investigative agencies have completed their findings. Active FDA / OCI / FBI criminal investigations are not a matter of public record until they are ready to prosecute. Interested and vested parties can get objective information directly from these government web sites.

The OCI of the FDA is now currently interviewing Lipo-Ex / Lipotron purchasers and other interested parties. I know this because I am an interested party and have been interviewed and several purchasers and end users have called me concerning their talks with FDA / OCI investigators.

Here's a link where you can read an actual press release and access other pertinent information directly from the DOJ about similar cases: <http://www.justice.gov/usao/cas/press/cas90219-Folsom.pdf>

If you haven't done anything wrong by actively manufacturing, marketing and selling a device that is not FDA approved, you have

nothing to worry about. But the FDCA & USC 21 say otherwise,

We'll very shortly know the outcome of these issues.

08.10 | jquinn

In my previous Aug 06 posting, I inadvertently left out USC 18, Section 371 which is usually cited (see DOJ case referenced above where Count 1 was USC 18) in these types of medical device cases, along with the FDCA and USC 21:

Search 18 U.S.C. § 371 : US Code - Section 371: Conspiracy to commit offense or to defraud United States

If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any manner or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be fined under this title or imprisoned not more than five years, or both.

If, however, the offense, the commission of which is the object of the conspiracy, is a misdemeanor only, the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor.

Link: <http://codes.lp.findlaw.com/uscode/18/19/371>

08.10 | jquinn

I'm not worried.

I am concerned however, because this looked like it was a promising technology.

Ok- so I read through the press releases that you referred to and again I am confused.

Maybe someone more intelligent than myself can explain how this relates to Lipotron?

Or maybe SW is correct in stating that your statements are libelous.

\*NEWS RELEASE SUMMARY - February 17, 2009

United States Attorney Karen P. Hewitt announced that James Folsom was found guilty by a federal jury earlier today in United States District Court in San Diego of twenty-six felony counts relating to his sale of an unapproved medical device.

The verdict follows a two-week trial before the Honorable John A. Houston, United States District Judge. According to evidence presented at trial, from 1997 through August 11, 2008, James Folsom conspired with others to ship adulterated and misbranded Rife-type biofrequency devices in interstate commerce.

The device, sold under the names "NatureTronics," "AstroPulse," "BioSolutions," "Energy Wellness," and "Global Wellness," consisted of a micro-current frequency generator with a digital readout, two stainless steel cylinders, two personal application plates with connectors and lead wires connecting the device to the cylinders and the plates.

Users were provided with an operating manual that set forth hundreds of digital settings for the device, directed to specific conditions from AIDS, diabetes, stroke, and ulcers to worms. Users were advised to connect the cylinders or plates to the machine and touch them to the body for a recommended run time to treat each condition.

According to testimony at trial, the defendant purchased over 9,000 units, which he sold to distributors for approximately \$1000-1200 and to retail customers for \$1995, with sales of over \$8 million. The devices were manufactured by the defendant and others in a San Diego location, which he failed to register with the Food and Drug

Administration (FDA) as a device manufacturing establishment. The defendant used the false name "Jim Anderson" when selling the device and used post office boxes, self-storage units, and bank accounts opened in the names of others to conduct his business, all in an effort to avoid detection by the FDA. The defendant also marketed his device "for investigational purposes," deceiving consumers into the false belief that he possessed a valid investigational device exemption from the FDA.

According to Assistant U.S. Attorney Melanie K. Pierson, who prosecuted the case, the devices were adulterated in that they were marketed without a valid investigational device exemption, without pre-market approval, and in violation of an electrical performance standard set by the FDA prohibiting lead wires that come into contact with patients from being able to come in contact with potentially hazardous voltages. The devices were also misbranded in that they were marketed without valid clearance from the FDA, did not bear the name and address of the manufacturer on the labeling, and were produced in an unregistered manufacturing establishment. "

08.10 | BetterOffNow

Okay JQuinn. Your previous post did not make a whole lot of sense to me when I read them and when I tried to look at your multiple web address "proof" nothing came up except what BetterOffNow posted. I'm a little baffled. I guess this is supposed to be some kind of scare tactic for the purchasers of Lipotron, such as myself, to not use the machine or get a lawyer or something. The thing is, when I called the FDA's toll-free line at 1-800-463-6332, I was told there was nothing on file and nothing pending. My question to you is why are you writing that you are "an interested party" to the supposed OCI and FDA interviews? Why are you interested? Did you file a complaint against Revecomed? All the posts you have written on here pertain only to Lipotron/Lipo-Ex and are negative in nature. Are you a disgruntled employee? Umm the plot thickens...

My guess from what you have posted is that you most likely have filed a complaint with the FDA and you believe that RevecoMed is going to get into serious trouble based on your complaint. Good luck with that. Anyone can report to the FDA about any adverse reactions, false advertising, etc. I'm sure they get thousands of complaints and have to spend countless hours looking into them only to toss them out if their is no evidence. Judging from the lack of evidence provided by yourself, I am quite sure you provided no supporting facts to prove your claim.

As for Lipotron not getting FDA approval yet, I think where Revecomed went wrong was not getting FDA approval for a side effect such as pain reduction. Correct me if I am wrong, but there is no non-invasive "fat melting" machine on the market that is FDA approved for melting of fat. Zeltiq is FDA approved for thermal cooling and Zerona was FDA approved for "use during liposuction." Once a medical device is labeled FDA approved, then it seems like physicians feel more comfortable purchasing the equipment and patients feel better having have services performed on them even though the machine is being used "off-label".

JQuinn, you seem to be on a life-long mission to slander the makers of Lipotron for the last three years. At least if you have some honest and verifiable issues, by all means share them. Otherwise, it just seems like you are unwisely opening yourself up for future litigation.

08.11 | wendyh

I have used this technology at another office and it works. I do have to say though, it works in the right hands. The user must be able to perform lymphatic drainage correctly so that once the treatment is over, the lymphatic system doesn't get blocked. The body must be heated to the necessary temp for there to be results. PLUS the patient must do their homework and go work out - walk briskly for 30



\* July 15th + 18th  
Facebook

Jayne Wilks

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Wednesday, August 08, 2012 2:36 PM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Read below, Laser Rejuvenation in Joshua, TX - cites there being Facebook stuff too.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** Laser Rejuvenation [laserrejuvenation@hotmail.com](mailto:laserrejuvenation@hotmail.com)  
**To:** Webster Lodge III [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 15:23  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen  
This is really becoming cumbersome to receive emails and Facebook stuff.... It certainly causes doubt.. I sure hope this ends soon!

Sent from my iPhone

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Date:** August 1, 2012 2:23:55 PM CDT  
**To:** undisclosed-recipients;;  
**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.  
letters and attachments:

Here are the links to the

<http://www.citizen.org/documents/2054.pdf>  
<http://www.citizen.org/documents/2055.pdf>  
[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5186 - Release Date: 08/08/12



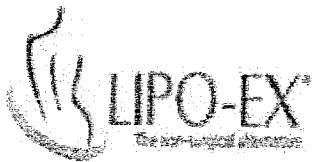
\* July 23rd Email

**Jayne Wilks**

---

**From:** Shannon Wilks <shannon@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:30 AM  
**To:** 'Jayne Wilks'  
**Subject:** FW: ProfitSolutionsMD aka AdvancedAestheticConcepts

Shannon Wilks  
Business Development  
Advanced Aesthetic Concepts  
(800) 337-0745 ext. 105  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



*Liberty is the Right to Choose... Freedom comes from making the Right Choice.*

---

**From:** Carla Minton [<mailto:lipoexbeaumont@gt.rr.com>]  
**Sent:** Tuesday, July 24, 2012 9:42 AM  
**To:** [shannon@fromstarttoperfection.com](mailto:shannon@fromstarttoperfection.com)  
**Subject:** Fw: ProfitSolutionsMD aka AdvancedAestheticConcepts

**From:** J Quinn  
**Sent:** Monday, July 23, 2012 10:12 PM  
**To:** undisclosed-recipients:  
**Subject:** ProfitSolutionsMD aka AdvancedAestheticConcepts

Link to PublicCitizen's letter today urging FDA to target ProfitSolutionsMD aka Advanced Aesthetic Concepts:  
<http://www.citizen.org/documents/2047.pdf>

In other documents submitted today by PublicCitizen to the FDA, to state medical examiners, and to state legislators, here are highlights of PublicCitizen's evidence of an ongoing, existing federal and state of Texas criminal investigations of AdvancedAestheticConcepts (AAC):

"It is our understanding that the FDA's Office of Criminal Investigations is investigating

allegations of illegal marketing of the LipoTron by RevecoMED and its distributor (Advanced

Aesthetic Concepts [AAC]). In a series of emails sent over the past two years (copies enclosed), statements made by Mr. Evan Rae, a criminal investigator in the Austin Resident Office of the FDA's Office of Criminal Investigations, appear to confirm that RevecoMED and its distributor have been illegally marketing the LipoTron:

May 14, 2010: [Y]ou are correct, not enough has been done to REVECOMED/AAC at this point [emphasis added]. I have re-contacted our Headquarters (Office of Criminal Investigations), the Dallas District Office (Regulatory), the Center for Devices and Radiological Health, Office of Device Evaluation, and everyone else I have had contact with and advised them of the latest developments and the lack of action on our side. A conference call between all concerned is scheduled, which should speed things up when compared to email. I will do everything I can to get things moving. We will likely focus on AAC and other appropriate Texas entities, for ease of logistics.

March 17, 2011: [Y]es, I'm working on [the case involving your allegations about RevecoMED] almost every day. Reviewing 700+ page filing is taking a while, but I may have some specific questions soon. The communications [to RevecoMED] from FDA could not be clearer. They prohibit any marketing of the [LipoTron] device and so state in specific language [emphasis added]. They are aware of everything I am, so I would anticipate that the extended period will expire without the deficiencies being corrected. Then, we will decide what action is called for.

April 10, 2012: ... I will add that I have noted the [LipoTron] devices to be readily available for purchase and advertised (marketed) [emphasis added]. The fact that training and "informational seminars" are conducted also speaks to overtly having the device for purchase. I have again contacted the Center for Devices and Radiological

Health regarding their opinion, since they (as well as the State [of Texas]) have advised REVECOMED, if not AAC itself, in no uncertain terms that the device may not be marketed [emphasis added]. FDA put that paragraph in all caps on both denials of approval."

Here is the link to the copies of the actual emails quoted above:

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

jquinn

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5172 - Release Date: 08/02/12

**Jayne Wilks**

---

**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:24 AM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: ProfitSolutionsMD aka AdvancedAestheticConcepts

Belinda,

This is the first email that jquinn sent out forwarded back to us by PL Weight Loss in Texas. The address is below. Pam Pixley is the owner.

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



---

**From:** PL Enterprises [mailto:plenterprisesllc@hotmail.com]  
**Sent:** Tuesday, July 24, 2012 4:51 PM  
**To:** mark@fromstarttoperfection.com; Jayne Wilks  
**Subject:** FW: ProfitSolutionsMD aka AdvancedAestheticConcepts

**A Message From PL Weight Loss**

**12422 Hwy 6  
Santa Fe, Texas 77510  
Phone: (409) 939-7726  
Fax: (409) 316-9336**

If you have any questions, comments or suggestions please feel free to reply to this email or to send an original message to [plweightlossclinic@comcast.net](mailto:plweightlossclinic@comcast.net) or [plenterprisesllc@hotmail.com](mailto:plenterprisesllc@hotmail.com)

If you are more than 15 minutes late to your appointment, please contact us to reschedule.  
You can also contact us at (409) 939-7726 between the hours of 1pm and 7pm Monday through Thursday.

***Thank You and Have an Awesome Day!***

**NOTICE OF CONFIDENTIALITY:** This electronic mail transmission may contain **CONFIDENTIAL INFORMATION**, belonging to the sender and recipient, which is legally privileged. The information is intended only for the use of the individual or entity listed above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, use, or taking of any action on reliance of the contents of this electronically-mailed confidential information is strictly prohibited and may violate PL Enterprises LLC policy (legal) and Health and Insurance Patient Privacy Act( HIPPA). If you have received this electronic mail in error, please notify us by telephone immediately to arrange for return and correction of internal records; in addition, please delete the original message. (409)939-7726: PAM

---

Date: Mon, 23 Jul 2012 22:12:03 -0500  
Subject: ProfitSolutionsMD aka AdvancedAestheticConcepts  
From: [jquinnwrites@gmail.com](mailto:jquinnwrites@gmail.com)  
To:

Link to PublicCitizen's letter today urging FDA to target ProfitSolutionsMD aka Advanced Aesthetic Concepts: <http://www.citizen.org/documents/2047.pdf>

In other documents submitted today by PublicCitizen to the FDA, to state medical examiners, and to state legislators, here are highlights of PublicCitizen's evidence of an ongoing, existing federal and state of Texas criminal investigations of AdvancedAestheticConcepts (AAC):

"It is our understanding that the FDA's Office of Criminal Investigations is investigating allegations of illegal marketing of the LipoTron by RevecoMED and its distributor (Advanced Aesthetic Concepts [AAC]). In a series of emails sent over the past two years (copies enclosed), statements made by Mr. Evan Rae, a criminal investigator in the Austin Resident Office of the FDA's Office of Criminal Investigations, appear to confirm that RevecoMED and its distributor have been illegally marketing the LipoTron:

May 14, 2010: [Y]ou are correct, not enough has been done to REVECOMED/AAC at this point [emphasis added]. I have re-contacted our Headquarters (Office of Criminal Investigations), the Dallas District Office (Regulatory), the Center for Devices and Radiological Health, Office of Device Evaluation, and everyone else I have had contact with and advised them of the latest developments and the lack of action on our side. A conference call between all concerned is scheduled, which should speed things up when compared to email. I will do everything I can to get things moving. We will likely focus on AAC and other appropriate Texas entities, for ease of logistics.

March 17, 2011: [Y]es, I'm working on [the case involving your allegations about RevecoMED] almost every day. Reviewing 700+ page filing is taking a while, but I may have some specific questions soon. The communications [to RevecoMED] from FDA could not be clearer. They prohibit any marketing of the [LipoTron] device and so state in specific language [emphasis added]. They are aware of everything I am, so I would anticipate that the extended period will expire without the deficiencies being corrected. Then, we will decide what action is called for.

April 10, 2012: ... I will add that I have noted the [LipoTron] devices to be readily available for purchase and advertised (marketed) [emphasis added]. The fact that training and "informational seminars" are conducted also speaks to overtly having the device for purchase. I have again contacted the Center for Devices and Radiological Health regarding their opinion, since they (as well as the State [of Texas]) have advised REVECOMED, if not AAC itself, in no uncertain terms that the device may not be marketed [emphasis added]. FDA put that paragraph in all caps on both denials of approval."

Here is the link to the copies of the actual emails quoted above:  
[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

jquinn

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5151 - Release Date: 07/24/12

## Jayne Wilks

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**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:25 AM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: Lipo-Ex Investigation  
  
**Importance:** High

Here's is the email from Dr. Dan Powell who owns Contour Derma in Texas.

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



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**From:** Dan Powell [mailto:dpowmd@hotmail.com]  
**Sent:** Tuesday, July 24, 2012 4:59 PM  
**To:** Jayne Wilks  
**Cc:** Webster Lodge; Cindy Kapel  
**Subject:** RE: Lipo-Ex Investigation  
**Importance:** High

Dear Jayne,

It has just come to my attention this afternoon that RevecoMED and AAC (now ProfitSolutionsMD) have apparently been under investigation by the FDA's Office of Criminal Investigations dating back over two years ago??? Is this true? Reference below web pages:

<http://www.citizen.org/pressroom/pressroomredirect.cfm?ID=3662>

<http://www.citizen.org/documents/2046.pdf>

<http://www.citizen.org/documents/2047.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

If true, and it does appear to be true, I will have some very serious decisions to make as I was unaware of ANY such controversy. As you will note in the above New Jersey letter, they are urging the New Jersey State Board of Medical Examiners to not only go after distributors but to go after the end-users as well (aka the physicians), which could affect a physician's medical license and/or career.

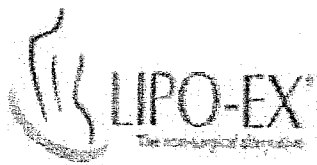


*\* July 31st email*

**Jayne Wilks**

**From:** Shannon Wilks <shannon@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:29 AM  
**To:** 'Jayne Wilks'  
**Subject:** FW: ProfitSolutionsMD Targeted in New Investigation

Shannon Wilks  
Business Development  
Advanced Aesthetic Concepts  
(800) 337-0745 ext. 105  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



*Liberty is the Right to Choose... Freedom comes from making the Right Choice.*

---

**From:** Carla Minton [<mailto:lipoexbeaumont@gt.rr.com>]  
**Sent:** Thursday, August 02, 2012 10:28 AM  
**To:** [shannon@fromstarttoperfection.com](mailto:shannon@fromstarttoperfection.com)  
**Subject:** Fw: ProfitSolutionsMD Targeted in New Investigation

**From:** J Quinn  
**Sent:** Tuesday, July 31, 2012 3:52 PM  
**To:** undisclosed-recipients:  
**Subject:** ProfitSolutionsMD Targeted in New Investigation

Texas DSHS has today opened another case targeting Profit Solutions MD, another identity of Advanced Aesthetic Concepts. The complaint number is 1525120590. The investigation for complaint #1525120415 for Advanced Aesthetic Concepts is still ongoing.

Contact info for DSHS:  
Compliance Officer  
Drugs and Medical Devices Group  
Policy Standards and Quality Assurance Unit  
Environmental and Consumer Safety Section  
Division of Regulatory Services  
Texas Department of State Health Services  
Phone: (512) 834-6755 x2367  
Fax: (512) 834-6759

jquinn

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5172 - Release Date: 08/02/12

**Jayne Wilks**

---

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 9:57 AM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: ProfitSolutionsMD Targeted in New Investigation  
**Attachments:** PastedGraphic-5.tiff; \_Certification\_.htm

reply from Sabrina Mercer.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

**PastedGraphic-5.tiff (72.1 Kb) attached**

----- Original Message -----

**From:** Sabrina Mercer [sabrina@sabrinamercer.com](mailto:sabrina@sabrinamercer.com)  
**To:** Lodge III [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Tue 31/07/12 17:25  
**Subject:** Fwd: ProfitSolutionsMD Targeted in New Investigation  
PastedGraphic-5.tiff (72.1 Kb) attached

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Subject:** ProfitSolutionsMD Targeted in New Investigation  
**Date:** July 31, 2012 3:52:17 PM CDT  
**To:** undisclosed-recipients;;

Texas DSHS has today opened another case targeting Profit Solutions MD, another identity of Advanced Aesthetic Concepts. The complaint number is 1525120590. The investigation for complaint #1525120415 for Advanced Aesthetic Concepts is still ongoing.

Contact info for DSHS:  
Compliance Officer  
Drugs and Medical Devices Group  
Policy Standards and Quality Assurance Unit  
Environmental and Consumer Safety Section  
Division of Regulatory Services  
Texas Department of State Health Services  
Phone: (512) 834-6755 x2367

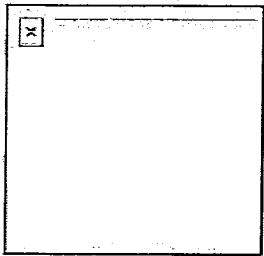
Fax: (512) 834-6759

jquinn

Sabrina Mercer

Sabrina Mercer Skincare  
25282 Northwest Freeway, Suite 160  
Cypress, TX 77429  
281.256.1003

[www.SabrinaMercer.com](http://www.SabrinaMercer.com)



**Jayne Wilks**

---

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 9:27 AM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: ProfitSolutionsMD Targeted in New Investigation

Vanity RX - Kelly Yohn

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** Vanity Rx [vanityrx@gmail.com](mailto:vanityrx@gmail.com)  
**To:** [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 12:50  
**Subject:** Fwd: ProfitSolutionsMD Targeted in New Investigation  
What is this???

Kelly Yohn

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Date:** July 31, 2012 3:52:17 PM CDT  
**To:** undisclosed-recipients;;  
**Subject:** ProfitSolutionsMD Targeted in New Investigation

Texas DSHS has today opened another case targeting Profit Solutions MD, another identity of Advanced Aesthetic Concepts. The complaint number is 1525120590. The investigation for complaint #1525120415 for Advanced Aesthetic Concepts is still ongoing.

Contact info for DSHS:  
Compliance Officer  
Drugs and Medical Devices Group  
Policy Standards and Quality Assurance Unit  
Environmental and Consumer Safety Section  
Division of Regulatory Services  
Texas Department of State Health Services

Phone: (512) 834-6755 x2367  
Fax: (512) 834-6759

jquinn

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5170 - Release Date: 08/01/12

\* AUG 1st email

**Jayne Wilks**

---

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 9:28 AM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

From Dr. McKenzie.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** Laser Rejuvenation [laserrejuvenation@hotmail.com](mailto:laserrejuvenation@hotmail.com)  
**To:** Webster Lodge III [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 15:23

**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

This is really becoming cumbersome to receive emails and Facebook stuff.... It certainly causes doubt.. I sure hope this ends soon!

Sent from my iPhone

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Date:** August 1, 2012 2:23:55 PM CDT  
**To:** undisclosed-recipients;;  
**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.  
letters and attachments:

Here are the links to the

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5170 - Release Date: 08/01/12

## Jayne Wilks

---

**From:** Stacey <stacey@avantemedispa.com>  
**Sent:** Wednesday, August 01, 2012 3:40 PM  
**To:** 'Mark Durante'  
**Cc:** 'Jayne Wilks'  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Mark,

And yet more emails just keep coming.

We definitely need to talk. Whoever this person is, has named us, Avante, directly in their documents. See below. Mary Ann and I are beside ourselves. Who is this person? Why are they naming us specifically? Are we doing this procedure illegally? Do we need to take the Lipo Ex info off our website? Are they going to come and confiscate our machine? Is the machine harmful to our patients?

We cannot afford a lawsuit. We don't even have the machine paid off yet.

Talk tomorrow,

S

---

**From:** J Quinn [mailto:jsquinnwrites@gmail.com]  
**Sent:** Wednesday, August 01, 2012 2:24 PM  
**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.  
are the links to the letters and attachments:

Here

<http://www.citizen.org/documents/2054.pdf>  
<http://www.citizen.org/documents/2055.pdf>  
[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5169 - Release Date: 08/01/12



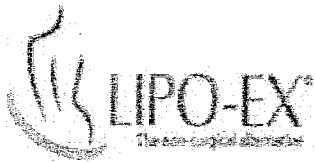
## Jayne Wilks

---

**From:** Shannon Wilks <shannon@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:40 AM  
**To:** 'Jayne Wilks'  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

From Carla

Shannon Wilks  
Business Development  
Advanced Aesthetic Concepts  
(800) 337-0745 ext, 105  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



*Liberty is the Right to Choose... Freedom comes from making the Right Choice.*

---

**From:** Carla Minton [<mailto:lipoexbeaumont@qt.rr.com>]  
**Sent:** Thursday, August 02, 2012 10:39 AM  
**To:** [shannon@fromstarttoperfection.com](mailto:shannon@fromstarttoperfection.com)  
**Subject:** Fw: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

**From:** J Quinn  
**Sent:** Wednesday, August 01, 2012 2:23 PM  
**To:** undisclosed-recipients:  
**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.  
are the links to the letters and attachments:

Here

<http://www.citizen.org/documents/2054.pdf>  
<http://www.citizen.org/documents/2055.pdf>  
[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5172 - Release Date: 08/02/12

## Jayne Wilks

---

**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:42 AM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: [Fwd: TX Medical Board & TX Dept of State Health Urged to Action byPublicCitizen]  
**Attachments:** untitled-[2].html; \_Certification\_.htm

Here's a quinn email that went to Lori Dale the owner of Hidden Door Medspa in TX,

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



**From:** Webster Lodge III [<mailto:webster@fromstarttoperfection.com>]  
**Sent:** Thursday, August 02, 2012 9:29 AM  
**To:** [jayne@fromstarttoperfection.com](mailto:jayne@fromstarttoperfection.com)  
**Subject:** Fwd: [Fwd: TX Medical Board & TX Dept of State Health Urged to Action byPublicCitizen]

Jayne - from Lori Dale at Hidden Door.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

untitled-[2].html (1.2 Kb) attached

----- Original Message -----

**From:** [hellosouthlake@hiddendoorspa.com](mailto:hellosouthlake@hiddendoorspa.com)  
**To:** [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 15:54  
**Subject:** Fwd: [Fwd: TX Medical Board & TX Dept of State Health Urged to Action byPublicCitizen]  
untitled-[2].html (1.2 Kb) attached How do I get a hold of this person and tell them to quit emailing me??

## Jayne Wilks

---

**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 10:32 AM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Here's one of the jquinn emails that went to Dr. Narang in Houston TX.

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexprograms.com](http://www.lipoexprograms.com)

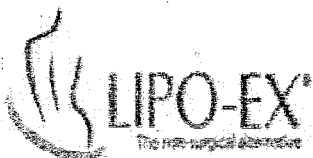


---

**From:** Shannon Wilks [<mailto:shannon@fromstarttoperfection.com>]  
**Sent:** Thursday, August 02, 2012 10:28 AM  
**To:** 'Jayne Wilks'  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Shannon Wilks  
Business Development  
Advanced Aesthetic Concepts  
(800) 337-0745 ext. 105

MailFilterGateway has detected a possible fraud attempt from "www.fromstarttoperfection.com" claiming to be www.lipoexprograms.com



*Liberty is the Right to Choose... Freedom comes from making the Right Choice.*

---

**From:** [hapr17@yahoo.com](mailto:hapr17@yahoo.com) [<mailto:hapr17@yahoo.com>]  
**Sent:** Wednesday, August 01, 2012 3:14 PM

**To:** Shannon Wilks

**Subject:** Fw: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Sent via BlackBerry from T-Mobile

---

**From:** harcharanFirst Name Narang <cypressoffice98@yahoo.com>

**Date:** Wed, 1 Aug 2012 12:30:37 -0700 (PDT)

**To:** <hapr17@yahoo.com>

**Subject:** Fw: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

--- On Wed, 8/1/12, J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)> wrote:

From: J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>

Subject: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

To:

Date: Wednesday, August 1, 2012, 7:23 PM

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal

Lipo-EX / Lipotron.

Here are the links to the letters and

attachments:

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5172 - Release Date: 08/02/12

**Jayne Wilks**

---

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Thursday, August 02, 2012 9:29 AM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: [Fwd: TX Medical Board & TX Dept of State Health Urged to Action byPublicCitizen]  
**Attachments:** untitled-[2].html; \_Certification\_.htm

Jayne - from Lori Dale at Hidden Door.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

untitled-[2].html (1.2 Kb) attached

----- Original Message -----

**From:** [hellosouthlake@hiddendoorspa.com](mailto:hellosouthlake@hiddendoorspa.com)  
**To:** [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 15:54  
**Subject:** Fwd: [Fwd: TX Medical Board & TX Dept of State Health Urged to Action byPublicCitizen]  
untitled-[2].html (1.2 Kb) attached How do I get a hold of this person and tell them to quit emailing me??

Lori

----- Original Message -----

**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen  
**From:** "J Quinn" <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Date:** Wed, August 1, 2012 1:23 pm  
**To:** undisclosed-recipients;;

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.

Here are the links to the letters and attachments:

<http://www.citizen.org/documents/2054.pdf>  
<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

## Jayne Wilks

---

**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Wednesday, August 01, 2012 3:25 PM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexprograms.com](http://www.lipoexprograms.com)



**From:** Webster Lodge III [<mailto:webster@fromstarttoperfection.com>]  
**Sent:** Wednesday, August 01, 2012 3:08 PM  
**To:** [jayne@fromstarttoperfection.com](mailto:jayne@fromstarttoperfection.com)  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

received this from two providers: Skinstar and Vanity RX.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** Vanity Rx [vanitvrx@gmail.com](mailto:vanitvrx@gmail.com)  
**To:** [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 14:39  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen  
They just sent this one too

Kelly Yohn

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>

**Date:** August 1, 2012 2:23:55 PM CDT

**To:** undisclosed-recipients::

**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX /

Lipotron.

Here are the links to the

letters and attachments:

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5169 - Release Date: 08/01/12



**Jayne Wilks**

---

**From:** Webster Lodge III <webster@fromstarttoperfection.com>  
**Sent:** Wednesday, August 08, 2012 2:36 PM  
**To:** jayne@fromstarttoperfection.com  
**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Read below, Laser Rejuvenation in Joshua, TX - cites there being Facebook stuff too.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** Laser Rejuvenation [laserrejuvenation@hotmail.com](mailto:laserrejuvenation@hotmail.com)  
**To:** Webster Lodge III [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)  
**Sent:** Wed 01/08/12 15:23

**Subject:** Fwd: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

This is really becoming cumbersome to receive emails and Facebook stuff.... It certainly causes doubt.. I sure hope this ends soon!

Sent from my iPhone

Begin forwarded message:

**From:** J Quinn <[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)>  
**Date:** August 1, 2012 2:23:55 PM CDT  
**To:** undisclosed-recipients;;  
**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX /

Lipotron.

Here are the links to the

letters and attachments:

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5186 - Release Date: 08/08/12

**Jayne Wilks**

---

**From:** Cindy Kapel <cindy@fromstarttoperfection.com>  
**Sent:** Wednesday, August 08, 2012 4:07 PM  
**To:** 'Jayne Wilks'  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Warm regards,

Cindy Kappel  
Advanced Aesthetic Concepts, L.P.  
307 W. 7th Street, Suite 220  
Fort Worth, TX 76102  
Tel # 817-386-5021 Ext 104  
Fax # 817-386-5024  
[cindy@fromstarttoperfection.com](mailto:cindy@fromstarttoperfection.com)

---

**From:** Marian McClendon [<mailto:info@realismedicalspa.com>]  
**Sent:** Monday, August 06, 2012 1:19 PM  
**To:** 'Cindy Kapel'  
**Subject:** RE: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

You would think/hope that at some point their anger will wear out and they will move on. How long can people stay upset?!?!

---

**From:** Cindy Kapel [<mailto:cindy@fromstarttoperfection.com>]  
**Sent:** Monday, August 06, 2012 11:51 AM  
**To:** 'Marian McClendon'  
**Subject:** RE: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Hi Marian! How are you? I will, of course, be glad to forward these to Mark. It really is absurd Marian. I just cannot believe the lengths these people have gone to. But, what I more cannot believe is the irresponsible reporting and lack of fact checking. Thanks for keeping us informed! We appreciate you!

Warm regards,

Cindy Kappel  
Advanced Aesthetic Concepts, L.P.  
307 W. 7th Street, Suite 220  
Fort Worth, TX 76102  
Tel # 817-386-5021 Ext 104  
Fax # 817-386-5024  
[cindy@fromstarttoperfection.com](mailto:cindy@fromstarttoperfection.com)

---

**From:** Marian McClendon [<mailto:info@realismedicalspa.com>]  
**Sent:** Monday, August 06, 2012 11:25 AM  
**To:** 'Cindy Kapel'  
**Subject:** FW: TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Cindy,  
Could you please forward this to Mark. I don't have his email handy. Thanks.  
Marian

---

**From:** J Quinn [mailto:[jsquinnwrites@gmail.com](mailto:jsquinnwrites@gmail.com)]

**Sent:** Wednesday, August 01, 2012 2:24 PM

**To:** undisclosed-recipients:

**Subject:** TX Medical Board & TX Dept of State Health Urged to Action by PublicCitizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron.

are the links to the letters and attachments:

Here

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

---

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 10.0.1424 / Virus Database: 2437/5181 - Release Date: 08/06/12

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No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 10.0.1424 / Virus Database: 2437/5181 - Release Date: 08/06/12

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5186 - Release Date: 08/08/12

*\* Aug 6th email*

**Jayne Wilks**

---

**From:** Jayne Wilks <jayne@fromstarttoperfection.com>  
**Sent:** Monday, August 06, 2012 1:36 PM  
**To:** Belinda@profitsolutionsMD.com  
**Subject:** FW: Facial Techinques, Laura Foster

Here's another one in Texas that Webster just received. The email is below.

Here's the address:

Facial Techniques  
Laura Foster, owner  
8140 Walnut Hill Lane, Suite 106  
Dallas, TX 75231  
(214) 346-5438

To Greater Success,  
Jayne Wilks  
Director of Marketing  
Profit Solutions MD  
Ph: 800.337.0745  
fax: 817.386.5024  
[jayne@profitsolutionsmd.com](mailto:jayne@profitsolutionsmd.com)  
[www.profitsolutionsmd.com](http://www.profitsolutionsmd.com)  
[www.lipoexpressprograms.com](http://www.lipoexpressprograms.com)



**From:** Webster Lodge III [<mailto:webster@fromstarttoperfection.com>]  
**Sent:** Monday, August 06, 2012 1:34 PM  
**To:** [belinda@profitsolutionsmd.com](mailto:belinda@profitsolutionsmd.com); [jayne@fromstarttoperfection.com](mailto:jayne@fromstarttoperfection.com)  
**Subject:** Fwd: Facial Techinques, Laura Foster

Another one, Facial Techniques in Dallas, TX.

To Greater Success,

Webster Lodge, III  
Business Development Director  
Profit Solutions MD  
Office (800) 337-0745  
Mobile (407) 923-8389

----- Original Message -----

**From:** "Facial Techniques" [office@facialtechniques.com](mailto:office@facialtechniques.com)

**To:** [webster@fromstarttoperfection.com](mailto:webster@fromstarttoperfection.com)

**Sent:** Mon 06/08/12 12:38

**Subject:** Fwd: Facial Techinques, Laura Foster

TX Medical Board & TX Dept of State Health Urged to Action by Public Citizen

Today Texas Medical Board and the Texas Department of State Health urged by Public Citizen ([www.citizen.org](http://www.citizen.org)) to act immediately on apparently illegal Lipo-EX / Lipotron. Here  
are the links to the letters and attachments:

<http://www.citizen.org/documents/2054.pdf>

<http://www.citizen.org/documents/2055.pdf>

[http://www.citizen.org/documents/2044\\_attachments.pdf](http://www.citizen.org/documents/2044_attachments.pdf)

No virus found in this message.

Checked by AVG - [www.avg.com](http://www.avg.com)

Version: 2012.0.2177 / Virus Database: 2437/5181 - Release Date: 08/06/12

[Share](#) [Report Abuse](#) [Next Blog](#) [Create Blog](#) [Sign In](#)

# jsquinnwrites

FRIDAY, JULY 20, 2012

## FDA Urged to Seize Lipo-EX / LipoTron

30+ month federal investigation finally coming to the public eye:


<http://www.citizen.org/hrg2044>

<http://www.fairwarning.org/2012/07/fat-melting-device-a-weighty-matter-for-fda/>

<http://100r.org/2012/07/fat-melting-device-a-weighty-matter-for-fda/>

<http://medicalspamd.com/the-blog/2012/7/12/fairwarning-the-lipotron-3000-lipo-ex-fda-unapproved-85k-mas.html>

Posied by JQuinn at 2:55 PM No comments:

 Recommend this on Google


BLOG ARCHIVE

▼ 2012 (1)

▼ July (1)

FDA Urged to Seize Lipo-EX / LipoTron

ABOUT ME



JQuinn

[View my complete profile](#)

[Home](#)

[Subscribe to Posts \(Atom\)](#)

Picture Window template. Powered by Blogger.

Twitter interface showing the profile of JQuinn (@jw55sq). The profile includes a bio: "WRITER @ Chicago Herald". The page displays a list of tweets, including one about "New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed". The interface also shows a "Follow JQuinn" section with fields for email and password, and a "Tweets" section with a list of recent tweets.

**JQuinn**  
@jw55sq  
WRITER @ Chicago Herald

917 Tweets  
280 Followers  
21 Following

**Follow JQuinn**

Full Name  
Email  
Password

**Tweets**

JQuinn (@jw55sq) 12 Aug  
@LDSBorg New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed bit.ly/whistleblower...

JQuinn (@jw55sq) 12 Aug  
@StevenSternberg New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed bit.ly/whistleblower...

JQuinn (@jw55sq) 12 Aug  
@Spelling New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed bit.ly/whistleblower...

JQuinn (@jw55sq) 12 Aug  
@Anna\_Rothschild New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed bit.ly/whistleblower...

JQuinn (@jw55sq) 12 Aug  
@Scheerba New Appointee at DOJ To Ensure Whistleblower Complaints Are Promptly Addressed bit.ly/whistleblower...

Twitter interface showing a list of tweets. The tweets are about "Blood of Christ" trumping FDA state agencies and protecting ProfSolutionsMD TX distributor. The interface also shows a "Follow JQuinn" section with fields for email and password, and a "Tweets" section with a list of recent tweets.

**JQuinn** (@jw55sq) 6 Aug  
@mpmcarmey "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@WMArtics "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@MackinNews "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@Pharmaceutical "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@AlaindeBotton "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@WashingtonPost "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron

**JQuinn** (@jw55sq) 6 Aug  
@MiamiNewswatch "Blood of Christ" trumps FDA state agencies & protects ProfSolutionsMD TX distributor says re apptmty illegal Lipo-EX/LipoTron



Point #8 The Same black African Mask that is on Jquinn's twitter page is the Facebook profile picture that was sent to Dr. Lyons email. (The Facebook account for Susie Quinn has since been closed.)

Twitter account for Susie Quinn is: <https://twitter.com/JournoSusie> as seen Below:



Point #9 Susie Quinn is the Editor at the Alberni Valley News: (See Below)

[http://www.albernavalleynews.com/about\\_us/9664547.html](http://www.albernavalleynews.com/about_us/9664547.html)