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Dear Ms. Tootle and Dr. Rosenberg:

Public Citizen, a consumer advocacy group representing more than 300,000 members and supporters nationwide, recently became 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 and in performing a variety of other cosmetic procedures — without the approval or clearance of the Food and Drug Administration (FDA).

After reading about this matter in a July 11 story published in *FairWarning*¹ and obtaining documents from one of the whistleblowers who was referenced in the story and who originally brought this matter to the attention of the FDA, Public Citizen wrote a letter to the FDA urging the agency to immediately seize all LipoTron devices that have been manufactured by RevecoMED and order the manufacturer and its distributors to cease and desist all activities involving the distribution, sale, and promotion of the LipoTron device.²

However, the active promotion of the use of the LipoTron device by some physicians in Florida, including Dr. Daniel Man (license number ME37381) and Dr. Emily Helm (license number ME101814), require the urgent attention of the Florida Board of Medicine. The widespread promotion and routine use of a potentially harmful class 2 or class 3 device of unproven effectiveness that has not been cleared or approved by the FDA are unethical, demonstrate a reckless disregard for the health and welfare of patients, and must not be tolerated.

Public Citizen therefore urges the Florida Board of Medicine to take the following actions:

- (1) Conduct a thorough investigation into the medical activities of Dr. Man and Dr. Helm that involve treatment with the LipoTron device;

- (2) If the investigation confirms the promotion of, and treatment of patients with, the LipoTron device by Dr. Man or Dr. Helm, institute appropriate disciplinary actions; and
- (3) Direct Dr. Man and Dr. Helm to cease all activities promoting the LipoTron device.

Overview of the LipoTron device

The RevecoMED International website until very recently provided an overview of the LipoTron device (copy of webpage enclosed).³ This promotional website included 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"> ● Stimulate Collagen Synthesis ● Muscle relaxation ● Increase Blood Flow ● Increase Metabolism ● Supply Oxygen ● Reduce fatty deposits
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"> ● Adipose dissolves at 41C ● Supply Oxygen ● Increase Blood Circulation
Fat Reduction	Visceral Fat Reduction Obesity Treatment	3000	<ul style="list-style-type: none"> ● Heat treatment ● Activating Cellular ● Muscle relaxation ● Increase blood Flow ● Supply Oxygen

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 moderate- to high-risk 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 1 device.⁴ The listed registered establishment name and address for the LipoTron is:

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

Remarkably, the FDA appears to have accepted this registration of the LipoTron as a class 1 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.

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

* 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.”

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.

Risks of serious harm from the LipoTron device

Serious burns can result from exposure of human tissue to radio frequency radiation. Of note, the *FairWarning* story reported that “[t]here have been scattered incidents of patients receiving minor shocks and burns from LipoTron treatments.”⁵

Promotion of the LipoTron device by Dr. Man

Dr. Man, a board-certified plastic surgeon in Boca Raton, Florida, has established a website that includes a webpage (copy enclosed) promoting treatment with the LipoTron for multiple indications.⁶ A review of this webpage reveals that Dr. Man has been 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. The webpage includes the following written content:

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. ...

How does LIPOTRON work?

Radio frequency currents recognize fatty tissue because of their high water content. It makes it easy to selectively heat and release melted cells. Using Bi-polar frequency of the RF current, the heat is delivered to deep subcutaneous fatty tissues without damaging surface skin. The deep heating effect also tightens skin by stimulating collagen production. The deep heating effect also reduces the orange peel, dimpled look of cellulite. It is an effective treatment in reducing stretch marks and firming of the sagging skin. Radio frequency has been reported to dissolve fat up to 8 inches deep, around internal organs (called visceral fat). Visceral fat is particularly unhealthy since it increases the risk of heart disease. ...

The following may be experienced after the treatment: redness for several hours post treatment; dryness; itching; skin irritation; remote risk of a burn to the skin; and possible increase in menstrual flow. ...

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

Promotion of the LipoTron device by Dr. Helm

According to a webpage (copy enclosed) from one of two websites for the Signature Medical Spa in Tampa, Florida, Dr. Helm is affiliated with this medical spa and provides treatment with the Lipo-Ex (LipoTron) device:⁷

Meet Dr. Helm, Board Certified M.D.

If you're looking for a Tampa liposuction doctor, you want to make sure that you find someone who is fully licensed and well-trained in the procedure. At The Signature Medical Spa, our board certified physician, Dr. Helm, is a graduate of the highly acclaimed Wright State University of Medicine. ...

At The Signature Medical Spa, we put patient comfort, safety, and satisfaction above all else. Dr. Helm has the experience and the expertise to provide high-quality cosmetic treatments to our patients while maintaining a strict standard of excellence in safe and effective medical care. **Our emphasis here is on non-invasive or minimally invasive cosmetic procedures, including Lipo-Ex, which is a safe and effective alternative to traditional liposuction** [emphasis added]. We want to help you with the areas of your body that you can't seem to improve with diet or exercise, and we want to make sure that we do so safely, without you having to experience discomfort or downtime. Many things can contribute to problem areas on your body, mostly stubborn fat deposits and cellulite that doesn't seem to budge. These things include genetics, pregnancy and childbirth, and the inevitable consequences of aging.

Dr. Helm and the rest of the staff are here to help, and we approach each cosmetic procedure with complete focus on the patient. We'll consult with you about what you'd like to improve on your body and discuss the options that we can provide, and we'll make sure that you are fully informed about any procedure that you're interested in. Weight loss, cellulite reduction and wrinkle reduction through non-invasive procedures are our specialties, and helping you to feel better about the way you look is our goal! Call us today and we'll set you up with an appointment for a free consultation with the doctor.

Another webpage (copy enclosed) from the second website for the Signature Medical Spa promotes treatment with the Lipo-Ex (LipoTron).⁸ A review of this webpage reveals that the spa has been 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. The webpage includes the following written content:

Lipo-Ex (Uses Lipotron)

Lipo-Ex Breaks the Liposuction Barrier

The Lipo-Ex Process is a combination of Diet, Exercise and the use of the Lipotron Device

- Lipo-Ex expands surgical capabilities with its ability to help you reduce the dangerous visceral fat (shown by CT Scans) untreatable with liposuction.
- Lipo-Ex is a great assist to correcting the lumpy, bumpy appearance and scar tissue often left by liposuction. ...

Lipo-Ex Breaks the Results Barrier

- 2½ to 6 inches lost in a single circumference measurement in less than [sic] 8 weeks.
- CT scans show between 16 to 25.1 in.² total of visceral and subcutaneous fat loss in 5 treatments.

Lipo-Ex Breaks the Depth of Penetration Barrier

- With penetration depths up to 20 times deeper than any other non-surgical technology, Lipo-Ex is perfect for reducing subcutaneous and visceral fat, tightening skin and getting rid of cellulite. ...

Lipo-Ex FAQ's

Lipo-Ex is a painless, non-surgical fat removal technique that uses bi-polar radio frequency (RF) energy to heat up tissue and melt away the fat beneath the skin. The tissues are gently warmed and massaged and heated slowly and gradually, at a low temperature. The melted fat is removed by the body's lymphatic system through natural processes of elimination. This non-invasive procedure is designed to safely increase your body's core temperature just enough to dissolve fat cells without affecting any other structures in your body. It is done with no downtime and no recovery time.

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.

The Lip-Ex Procedure:

- Burns Fat
- Tightens skin
- Stimulates Collagen Production
- Reduces Cellulite

Lipo-Ex is able to reach the kind of visceral fat around the organs that cause serious health problems. This is all done without any pain or discomfort. At the start of a treatment session, the electrode is massaged on the treatment area. This causes the surrounding lymph nodes to be gently warmed. As the process is continued, the deeper subcutaneous tissue is gradually warmed until it reaches a temperature where the fat is melted. This is all done without damaging the surface tissue.

Conclusions and requested actions

Dr. Man and Dr. Helm have promoted the use of the potentially harmful LipoTron device for multiple indications, despite a lack of FDA approval or clearance and a lack of sufficient evidence that treatment with the device was effective for any indication, thus unnecessarily exposing numerous patients to costly and time-consuming treatments that posed risks of harm that were not justified by any benefits.

Such widespread promotion and routine use of a potentially harmful class 2 or class 3 device of unproven effectiveness that has not been cleared or approved by the FDA are unethical, demonstrate a reckless disregard for the health and welfare of patients, and must not be tolerated.

Public Citizen therefore urges the Florida Board of Medicine to take the following actions:

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- (3) Direct Dr. Man and Dr. Helm to cease all activities promoting the LipoTron device.

We look forward to your prompt attention to this important 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

¹ 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.

² Carome, MA, Wolfe SM. Letter to the Food and Drug Administration regarding the LipoTron medical device. July 18, 2012. Available at <http://www.citizen.org/hrg2044>. Accessed July 18, 2012.

³ Revecomed Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revecomed.com/lipo.html>. Accessed July 17, 2012.

⁴ 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/rl.cfm?lid=304916&lpcd=ISA> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=133135>. Accessed June 29, 2012.

⁵ 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.

⁶ Website for Daniel Man, M.D. Webpage promoting the Lipotron. Available at <http://www.drman.com/body-procedures/lipotron/>. Accessed July 24, 2012.

⁷ Website for the Signature Medical Spa. Webpage introducing Dr. Emily Helm. Available at http://www.signaturelipo.com/dr_helm.html. Accessed July 24, 2012.

⁸ Website for the Signature Medical Spa. Webpage promoting treatment with Lipo-Ex (LipoTron). Available at <http://www.painfreelipo.com/lipoex.php>. Accessed July 24, 2012.