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August 1, 2012

David L. Lakey, M.D.
Commissioner of Health
Texas Department of State Health Services
P.O. Box 149347
Austin, Texas 78714-9347

Dear Dr. Lakey:

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 promotion and use of the LipoTron device by multiple health spas and clinics throughout Texas require the urgent attention of the Texas Department of State Health Services. 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 Texas Department of State Health Services to take the following actions:

- (1) Conduct a thorough investigation into the activities of any health spa or clinic operating in Texas that involve promotion of, and treatment of patients with, the Lipo-Ex (LipoTron) device; and
- (2) If the investigation confirms the promotion of, and treatment of patients with, the Lipo-Ex (LipoTron) device by any health spa or clinic operating in Texas, take appropriate actions to terminate these activities.

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

Furthermore, a consent form for treatment with the Lipo-Ex (LipoTron) device posted on the website of the Blush Aesthetics and Skincare health spa in Dallas (copy enclosed) includes the following description of the risks of the procedure:⁶

I have been informed of the potential risks and side effects of RFAL including but not limited to redness, swelling, heat sensitivity, pain, increase[d] bowel movements, increased urination, increased menstrual flow, flu like symptoms and “arch” burns. I understand the nature of the proposed procedure; the risks and potential damages and adverse sequelae (side effects) have been explained to me.

Promotion of the Lipo-Ex (LipoTron) device by health spas in Texas

One example of the promotion of the Lipo-Ex (LipoTron) device can be found on one of the webpages from the website for the Avante Laser and MediSpas located in Houston and The Woodlands (copy enclosed).⁷ 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- Non-Surgical Fat/Cellulite Reduction Procedure

Lipo-Ex is a painless, non-surgical fat/cellulite reduction technique that uses bi-polar radio frequency (RF) energy to heat up tissue and melt away the non-surgical fat beneath the skin. The tissues are gently warmed and massaged and heated slowly and gradually, at a low temperature. The melted non-surgical 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 non-surgical 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 non-surgical 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 non-surgical fat to melt. The melted fat is then flushed away naturally by the lymphatic system.

The Lipo-Ex Procedure:

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

Lipo-Ex is able to reach the kind of visceral non-surgical fat around the organs that cause serious health problems. This is all done without any pain or discomfort to the patient.

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 non-surgical fat is melted. This is all done without damaging the surface tissue.

Other health spas in Texas promoting treatment with the Lipo-Ex (LipoTron) device include the following:

- Blush Aesthetics and Skincare in Dallas (see <http://blushaestheticsandskincare.com/services/cellulite-circumference-reduction-dallas-texas-viora-reaction-lipoex/>)
- Body Focus Laser and Longevity Center in Midland (see <http://www.askdranna.com/procedures/weight-loss/lipo-ex>)
- Realis Medical Spa in Houston (see <http://www.realismedicalspa.com/body-contouring/lipo-ex/>)
- Envy medical day spa in Weatherford (see <http://myenvyspa.com/lipoex.htm>)
- Forever Fit and Wellness Center in Cypress (see http://www.houstonlipoandaesthetics.com/lipo_ex.html)
- Hidden Door Medspas in Roanoke and Southlake (see <http://hiddendoorspa.com/medspa/lipo-ex/>)
- Laser Rejuvenation in Joshua and Cleburne (see <http://www.laserrejuv.com/lipoex.html>)
- Le Salon Medical Spa in San Antonio (see <http://www.lesalonsa.com/services/non-invasive-rf-lipoplasty-lipo-ex/?pid=24>)
- Lipo-Ex of Beaumont (see http://www.beaumontlipoex.com/lipo_ex.html)
- NuGenesis Medical Spa in Waco (see <http://www.nugenesismedical.com/lipoex.html>)

- ReNew Medical Spa in Texarkana (see http://www.renewmedicalsapa.net/lipo_ex.html)
- Renovo MedSpa in El Paso (see http://www.renovomedspa.com/lipo_ex.html)
- Vanity RX Health and Beauty Clinic in Longview (see <http://www.vanityrx.com/lipo-ex-fat-reduction.html>)
- Wellness MedSpa and Laser Center in Bedford (see <http://wellnessii.com/Services/Body/Lipo-%20Ex%20Fat%20Melting%20Technology.shtml>)

Conclusions and requested actions

The above-referenced health spas and clinics have promoted the use of the potentially harmful Lipo-Ex (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 Texas Department of State Health Services to take the following actions:

- (1) Conduct a thorough investigation into the activities of the above-reference health spas and clinics and any other health spa or clinic operating in Texas that involve promotion of, and treatment of patients with, the Lipo-Ex (LipoTron) device; and
- (2) If the investigation confirms the promotion of, and treatment of patients with, the Lipo-Ex (LipoTron) device by of the above-reference health spas and clinics or any other health spa or clinic operating in Texas, take appropriate actions to terminate these activities.

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 the Blush Aesthetics and Skincare health spa. Webpage providing consent form for treatment with the Lipo-Ex (LipoTron) device. Available at <http://blushaestheticsandskincare.com/perch/resources/1337371276rfalconsent.pdf>. Accessed July 25, 2012.

⁷ Website for the Avante Laser and MediSpa. Webpage promoting Lipo-Ex (Lipotron). Available at <http://www.avantemedispa.com/services-lipo-ex.cfm>. Accessed July 25, 2012.