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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.

- (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.

### **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<sup>\*\*</sup>” as an electronic therapeutic massager (product code ISA), a class 1 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 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.

### **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.

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\* 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>

**LIPOTRON (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) Expeditiously 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

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<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> RevecoMED Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revecomed.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/rl.cfm?lid=304916&lpcd=ISA> and <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=133135>. Accessed June 29, 2012.

<sup>4</sup> RevecoMED Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revecomed.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.drman.com/body-procedures/lipotron/>. Accessed July 17, 2012.

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

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