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Larry D. Dixon
Executive Director
Alabama Board of Medical Examiners
P.O. Box 946
Montgomery, Alabama 36101-0946

George C. Smith, Jr., M.D.
Chairman
Alabama Board of Medical Examiners
P.O. Box 946
Montgomery, Alabama 36101-0946

Dear Mr. Dixon and Dr. Smith:

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 and use of the LipoTron device by some physicians in Alabama, including Dr. William R. Staggers (license number MD.15283) and Dr. Michael B. Lyons (license number MD.10323), require the urgent attention of the Alabama Board of Medical Examiners. 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 Alabama Board of Medical Examiners to take the following actions:

- (1) Conduct a thorough investigation into the medical activities of Dr. Stagers and Dr. Lyons and any other doctor in Alabama 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. Stagers, Dr. Lyons, or any other doctor in Alabama, institute appropriate disciplinary actions; and
- (3) Direct Dr. Stagers and Dr. Lyons, and any other doctor in Alabama engaged in activities promoting treatment with the LipoTron device, to cease all activities promoting this 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

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 Dr. Stagers

Dr. Stagers, a board-certified plastic surgeon in Fairhope, Alabama, has established a website for Eastern Shore Plastic Surgery that includes a webpage (copy enclosed) promoting treatment with the Lipo-Ex (LipoTron) device for multiple indications.⁷ A review of this webpage reveals that Dr. Stagers has been promoting treatment with the Lipo-Ex (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 Melts Fat Without Diet, Needles or Surgery!

Now available at Eastern Shore Plastic Surgery, PC

With Lipo-Ex you can Melt up to 3 inches in body fat circumference in 6 weeks. This relaxing procedure can help you achieve the following with no downtime:

- Fat Reduction
- Body Sculpting
- Skin Tightening
- Wrinkle Reduction

Lipo-Ex feels like a hot stone massage, so relax, enjoy and melt away the unhealthy visceral fat that not even liposuction can treat or get long term cellulite reduction or tighten loose, sagging skin.

Promotion of the Lipo-Ex (LipoTron) device by Dr. Lyons

Dr. Lyons, a board-certified plastic surgeon in Mobile, Alabama, has established a website for his medical practice that includes a webpage (copy enclosed) promoting treatment with the Lipo-Ex (LipoTron) device for multiple indications.⁸ A review of this webpage reveals that Dr. Lyons has been promoting treatment with the Lipo-Ex (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:

Advanced Alternatives to Liposuction

Dr. Lyons recently acquired the latest advancement in Non-Invasive Body Sculpting technology that practically leap frogs all known liposuction treatments available today.

Called LIPO-EX, this new technology melts fat, not only under your skin, but also reduces deep abdominal fat (Visceral fat) located inside the abdomen (untreatable with traditional liposuction).

A procedure that requires no needles and no drugs or medications for pain, treatment visits can now be scheduled during lunch hours and at other convenient times without affecting the rest of your day. ...

Take 10 years Off

Take 10 years off your face and body and add it to your life ... the Lipo-Ex is a Radio Frequency device that effectively treats the face, neck, lower eyelids, arms, feet, calf, thigh, abdomen and back.

It virtually melts the fat.

CT SCANS (catscans) used in international studies reveal that deep abdominal fat (visceral fat) reductions of 30% to 40% is achieved in as little as 8 - 10 treatments. These same studies show reductions of over 3 inches and weight loss exceeding 10 pounds after 6 treatments.

Visceral fat is the deep abdominal fat found under our deep layer of abdominal skin. An excess of visceral fat creates the pot belly or beer belly effect.

Visceral-fat accumulation has been associated with hypertension, glucose intolerance, coronary artery disease, insulin resistance and dyslipidemia. Since visceral fat is one of the key indicators of morbidity and mortality, Dr. Lyons' treatments to reduce this fat accumulation will improve a person's health overall.

Conclusions and requested actions

Dr. Stagers and Dr. Lyons 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 Alabama Board of Medical Examiners to take the following actions:

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- (3) Direct Dr. Stagers and Dr. Lyons, and any other doctor in Alabama engaged in activities promoting treatment with the LipoTron device, to cease all activities promoting this 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

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- 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 RevcoMED Asia. LipoTron: noninvasive lipoplasty and skin tightening. Available at <http://www.revcomed.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 26, 2012.
- ⁷ Website for Eastern Shore Plastic Surgery, P.C. Webpage promoting the Lipo-Ex (Lipotron) device. Available at <http://www.easternshoreplasticsurgery.com/whats-new/>. Accessed July 26, 2012.
- ⁸ Website for Dr. Michael B. Lyons. Webpage promoting the Lipo-Ex (Lipotron) device. Available at http://www.lyonsmd.com/lipo_ex.asp. Accessed July 26, 2012.