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July 23, 2012

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President
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P.O. Box 183
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Dear Mr. Roeder and Dr. Jordan:

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, one aspect of the *FairWarning* story requires the urgent attention of the New Jersey State Board of Medical Examiners (NJSBME). Dr. Sherwood A. Baxt (New Jersey License Number 25MA02815300), a New Jersey plastic surgeon, was identified in the story as one physician who is actively promoting the use of the LipoTron device on his medical group's website. Most troubling, the story indicates that Dr. S. A. Baxt (1) has been aware for a period of years that the LipoTron device lacks FDA approval, (2) openly admits to having used other devices unapproved by the FDA, and (3) does not consider FDA approval to be necessary before using a medical device to treat patients. The widespread promotion and routine use of potentially harmful devices of unproven effectiveness that have not been 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 NJSBME to take the following actions:

(1) Conduct a thorough investigation into the medical activities of Dr. S. A. Baxt and any of his physician colleagues (which include Dr. Saida H. Baxt [New Jersey License Number 25MA0281700] and Dr. Rebecca D. Baxt [New Jersey License Number 25MA06657800]) at the Baxt CosMedical center in Paramus, New Jersey, that involve treatment with the LipoTron device or any other device lacking FDA approval or clearance;

(2) If the investigation confirms the promotion of, and treatment of patients with, the LipoTron — or any other medical device — by Dr. S. A. Baxt and any of his physician colleagues at the Baxt CosMedical center for uses not approved or cleared by the FDA, institute appropriate disciplinary actions; and

(3) Direct Dr. S. A. Baxt and his colleagues to cease all activities promoting the LipoTron and any other medical device that has not been approved or cleared by the FDA.

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 interstial [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	● 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	Lipotron-2000/3000 covers the three key elements to burn Subcutaneous fat deposits ● Adipose dissolves at 41C ● Supply Oxygen ● Increase Blood Circulation
Fat Reduction	Visceral Fat Reduction Obesity Treatment	3000	● 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

[*] 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."

> 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.

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. S. A. Baxt and the Baxt CosMedical center in Paramus, New Jersey

The Baxt CosMedical website includes a webpage (copy enclosed) promoting treatment with the LipoTron 3000 for multiple indications.[6] A review of this webpage reveals that Baxt CosMedical and Dr. S. A. Baxt have 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:

> **Lipotron 3000** is one of several devices utilizing radiofrequency technology to heat the layer just beneath the skin and cause new collagen formation with its secondary skin tightening effect. As of this writing we have been using the product for almost 2 years with a very satisfied patient following. It is a non-surgical treatment taking approximately one hour and we suggest a minimum of 6 to 8 treatments. Under ideal conditions would do at least 12 treatments. The treatment is completely non-painful and it's performed by one of our highly trained technicians. A paddle is run over the surface of the skin and a sensor within the paddle reads the temperature just beneath the skin. We know that by heating this layer to a certain level it causes contraction of the collagen bands and the body's response is to also form new collagen. Results are often noticed after about 6 sessions, however they will continue to improve for the length of the treatments and will further improve for three months to a year. There is no downtime at all except for possibly a very slight redness to the skin lasting a few hours.

The webpage also provides a promotional video featuring Dr. S. A. Baxt discussing use of the LipoTron 3000 for fat reduction and other indications. Sounding like a snake-oil salesman, he makes the following statements during the video:

> We're talking nonsurgical. We're talking completely different — almost a fantasy phase that the field is going through now. We're using radiofrequency technology, which is administered by our trained technicians. And these are a series of treatments, once a week, about one hour at a time. … And we're doing two things with it. We're able to actually shrink and reduce fat and tighten skin with it. … We use this on every part of the body. We use it on the abdomen, … thigh, upper arms, etc.

The following excerpt from the July 11 *FairWarning* story about the LipoTron device presents additional public comments made by Dr. S. A. Baxt about his use and promotion of this and other devices:[7]

> 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 above statements clearly indicate that Dr. S. A. Baxt (1) has been aware for a period of years that the LipoTron device lacks FDA approval, (2) openly admits to having used other devices unapproved by the FDA, and (3) does not consider FDA approval to be necessary before using a medical device to treat patients.

Conclusions and requested actions

Over a period of years, the Baxt CosMedical center and Dr. S. A. Baxt 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 potentially harmful devices of unproven effectiveness that have not been 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 NJSBME to take the following actions:

(1) Conduct a thorough investigation into the medical activities of Dr. S. A. Baxt and any of his physician colleagues (which include Dr. Saida H. Baxt [New Jersey License Number 25MA0281700] and Dr. Rebecca D. Baxt [New Jersey License Number

25MA06657800]) at the Baxt CosMedical center in Paramus, New Jersey, that involve treatment with the LipoTron device or any other device lacking FDA approval or clearance;

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(3) Direct Dr. S. A. Baxt and his colleagues to cease all activities promoting the LipoTron and any other medical device that has not been approved or cleared by the FDA.

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

cc: The Honorable Loretta Weinberg, Majority Leader, New Jersey State Senate
The Honorable Joseph F. Vitale; Chair; Health, Human Services and Senior Citizens Committee, New Jersey State Senate

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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] 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] Baxt CosMedical. Webpage promoting the Lipotron 3000. Available at http://www.cosmedical.com/lipotron.php#mn-main. Accessed July 19, 2012.
[7] 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.