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July 23, 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:

As you are aware, on July 18 Public Citizen sent you a letter regarding 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 Food and Drug Administration (FDA). In its letter, Public Citizen urged the FDA to, among other things, immediately seize all LipoTron devices in the U.S. 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.<sup>1</sup>

The letter identified Advanced Aesthetic Concepts (AAC) as a distributor of Revecomed's LipoTron device. Since submitting its July 18 letter, Public Citizen has learned that AAC now appears to be illegally — and more blatantly — promoting use of the LipoTron (using the name Lipo-Ex) under a new company name: Profit Solutions MD (a copy of the company's home page is enclosed).<sup>2</sup> We therefore now urge the FDA to include Profit Solutions MD as a target when conducting its ongoing criminal investigation of this matter and when implementing actions to terminate the apparent illegal distribution, sale, and promotion of the LipoTron medical device.

**AAC and Profit Solutions MD are the same company**

A review of the websites for AAC and Profit Solutions MD indicate that they share the same business address and telephone number<sup>3,4</sup> (copies of the contact information webpages for each are enclosed):

307 W. 7th Street, Suite 220  
Fort Worth, Texas 76102  
800-337-0745

Moreover, one webpage from the Profit Solutions MD website citing testimonials from physicians who have used the LipoTron (Lipo-Ex) device to treat patients (copy enclosed) includes the following:<sup>5</sup>

The assistance my aesthetic consultant from Advanced Aesthetic Concepts (AAC) [now Profit Solutions MD] made it even easier to slide Lipo-Ex right into my practice. ... In addition, AAC [now Profit Solutions MD] helped us get all of our marketing started, so I could start adding new patients immediately [bracketed text in the original].

**Profit Solution MD's promotion of the LipoTron (Lipo-Ex) device**

The webpage on the Profit Solutions MD website that promotes use of the LipoTron (Lipo-Ex) device (copy enclosed) includes the following:<sup>6</sup>

**How does Lipo-Ex work and what kind of patient results can I expect?**

Out of the synergy of technology and extensive research, a revolutionary formula for fat reduction, skin tightening and body sculpting has emerged. **Using a patented radio frequency (RF) technology, the benefits of RF are no longer limited to superficial conditions, but can now therapeutically extend to the visceral areas of the body** [emphasis added]. These technological advancements, unique to the Lipo-Ex program, are then blended with proprietary clinical techniques and education to help your patients reach their goals for fat reduction, skin tightening and body sculpting for the entire body. In international studies, **the technology in the Lipo-Ex program became the first of its kind to demonstrate with CT scans the reduction of both visceral and subcutaneous fat** [emphasis added]. The studies also showed a total reduction of fat of approximately 0.8-1 quart per session with a total of 4-5 quarts after 5 sessions. Currently, our physicians nationwide are documenting an average circumference loss of 2 ½ to 4 inches in eight weeks with some patients reaching as much as 8" in a single circumference reduction.\*

\*The radiofrequency technology used in the Lipo-Ex Programs is classified by the FDA as an electronically powered therapeutic massager device intended for medical purposes, such as to relieve minor muscle aches and pains and increase circulation.

A separate page on the Profit Solutions MD website includes the following testimonials from physicians endorsing treatment with the LipoTron (Lipo-Ex) device (copy enclosed):<sup>7</sup>

“We began offering Lipo-Ex to our clients in July, 2008, and it has quickly surpassed any other procedure we perform in terms of added revenue... our clients have been extremely pleased with the results they are achieving with Lipo Ex. Many of our clients have seen the circumference of their waists drop 3-4 inches with up to 10 lbs of weight lost. The reduction in cellulite has also been something we have never been able to achieve before Lipo Ex. This procedure has generated a significant amount of additional traffic to our facility, which has translated into other procedures as well. Overall, we are very pleased with our Lipo Ex system...”

**Dr. Bruce McClendon**

Realis Medical Spa  
Houston, TX

“Lipo-Ex offers our patients more options to remove fat and tighten skin than were previously available. Because it is non-surgical, it is very cost effective and it is especially beneficial for patients who have medical conditions and may not be good candidates for surgery or traditional liposuction. This means we can treat more patients and a greater variety of patients in less time with more convenience. Patients love the results. They report loss of inches and tighter skin after only a few treatments. I have personally witnessed my patients’ results getting better and better over time.”

**Daniel Man, M.D., Board Certified Plastic Surgeon**

Daniel Man, M.D  
Boca Raton, Florida

“I enjoy offering our patients Lipo-Ex because of the fast and amazing results we see. Faces tighten in just one treatment, and patients are thrilled with the immediate improvement. We are currently treating two men for visceral fat. One lost 6 lbs. and the other 8 lbs. in just one week. Both lost one pant size in just three treatments. We’ve used several fat reduction technologies, but Lipo-Ex is by far the best non-invasive fat melting/skin tightening treatment we’ve seen.”

**Barbara D. Marino, MD, FACOG**

Body Design By Marino  
Houston, TX

**Conclusions**

Profit Solutions MD (formerly known as AAC) clearly is 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. Furthermore, RevecoMED

International, not the FDA, inappropriately self-classified the LipoTron as an electronic therapeutic massager device.

We therefore now urge the FDA to include Profit Solutions MD as a target when conducting its ongoing criminal investigation of the apparent illegal distribution, sale, and promotion of the LipoTron (Lipo-Ex) medical device and when implementing actions to terminate these activities.

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> 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.

<sup>2</sup> Profit Solutions MD home webpage. Available at <http://profitsolutionsmd.com/>. Accessed July 20, 2012.

<sup>3</sup> Profit Solutions MD contact information webpage. Available at <http://profitsolutionsmd.com/contact/>. Accessed July 23, 2012.

<sup>4</sup> Advanced Aesthetic Concepts contact information webpage. Available at <http://www.fromstarttoperfection.com/contactus.php>. Accessed July 20, 2012.

<sup>5</sup> Profits Solutions MD webpage providing physician testimonials endorsing the LipoTron (Lipo-Ex) device. Available at <http://profitsolutionsmd.com/testimonials/>. Accessed July 20, 2012.

<sup>6</sup> Profit Solutions MD webpage promoting the LipoTron (Lipo-Ex) device. Available at <http://profitsolutionsmd.com/programs/lipo-ex/>. Accessed July 20, 2012.

<sup>7</sup> Profits Solutions MD webpage providing physician testimonials endorsing the LipoTron (Lipo-Ex) device. Available at <http://profitsolutionsmd.com/testimonials/>. Accessed July 20, 2012.