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August 22, 2012

Kevin G. Herd
Goodrich Postnikoff & Associates, LLP
777 Main Street, Suite 1360
Fort Worth, Texas 76102

Re: Advanced Aesthetic Concepts LP, also d/b/a Profit Solutions MD

Dear Mr. Herd:

I write in response to your August 3, 2012 letter to Drs. Michael Carome and Sidney Wolfe, asserting that Public Citizen has published false and misleading information concerning your clients Advanced Aesthetic Concepts and Mark Durante. The Public Citizen statements of which you complain are neither false and misleading nor defamatory. Public Citizen will, therefore, not retract its statements. Moreover, if you carry through on your threat to file suit, we will invoke Texas' new anti-SLAPP statute to seek an award of attorney fees.

To begin with, nothing in Public Citizen's letters to the FDA, or in any other public statement to date, said anything about Mark Durante. Consequently, Mr. Durante can have no defamation claim against Public Citizen.

As for Advanced Aesthetic Concepts, your letter specifically complains about Public Citizen's July 18 and July 23, 2012 letters to Dr. Margaret Hamburg, the Commissioner of the Food and Drug Administration (FDA) and Dr. Jeffrey Shuren, Director of the FDA's Center for Devices and Radiological Health. Those letters address the apparent illegal distribution, sale, and promotion of the LipoTron medical device, manufactured by Revecomed International, for use in removing subcutaneous and visceral fat—a use not approved or cleared by the FDA. Our letters identified Advanced Aesthetic Concepts as a distributor and, through Profit Solutions MD, a promoter of the device.

Your letter makes the following key assertions:

- (1) Public Citizen's statements that the LipoTron device is in violation of the FDA's standards and guidelines are false, misleading, defamatory, and libelous.
- (2) Public Citizen based its accusations on applications that were made to the FDA in 2007 and 2009, without acknowledging that the FDA later registered the LipoTron 3000 as a class I medical device.

- (3) Public Citizen's allegation that the FDA is conducting a criminal investigation into the marketing of the LipoTron medical device is baseless because, you say, there is no criminal investigation and no illegal marketing.
- (4) Public Citizen's characterization of "LipoTron 3000" and "Lipo-Ex" as two names for the same thing is false because the LipoTron is a device, and Lipo-Ex is a program designed for weight management.

None of these assertions provides any support for your libel claims, for the following reasons:

- (1) Public Citizen's allegations are based on a large volume of information and documents unrelated to the 510(k) premarket notifications apparently submitted to the FDA by RevecoMED International in 2007 and 2009. Many of the documents on which the letters were based appeared on the websites of RevecoMED, the FDA, and Profit Solutions MD, but some were taken down or modified after the July 11 *FairWarning* article and after Public Citizen sent its letters.
- (2) Public Citizen's investigation revealed that RevecoMED International registered the LipoTron device with the FDA, and its July 18 letter (at page 4) mentioned that registration, stating that in approximately 2011, RevecoMED International registered with the FDA the "LipoTRON; RFLipo System" as an electronic therapeutic massager (product code ISA), a class I device. With respect to this registration, it is important to note the following:

- (a) The registration of a medical device is accomplished by the manufacturer and can be done electronically via the FDA's website. Contrary to your suggestion, under the Food, Drug, and Cosmetic Act, the FDA does not "approve" class I devices. *See* 21 U.S.C. §§ 360(k), 360e(c).
- (b) Although the website has since been altered, the uses of the LipoTron medical device that were promoted by RevecoMED International on its website as recently as July 19, 2012, are inconsistent with, and go far beyond, those of an electronic therapeutic massager. (Public Citizen has copies of the web pages as they existed on July 19.)

Registration of a device in class I does not make legal marketing of the device for uses outside the scope of the class I designation, regardless of whether the FDA is aware of the broader marketing.

- (c) Based on RevecoMED descriptions of the LipoTron medical device and its uses, as promoted on the RevecoMED website, it appears the device would be properly classified as a class II or III device. The 2007 and 2009 attempts to obtain

marketing clearance through the 510(k) premarket notification process support this opinion.

- (d) Even before Revecomed registered the LipoTron in approximately 2011, Revecomed International and its distributors, including Advanced Aesthetic Concepts, marketed the device throughout the U.S. It did so without either FDA clearance under the 510(k) premarket notification process or FDA premarket approval.
- (3) The fact that the FDA does not comment on any ongoing investigation does not mean that an investigation is not taking place. Public Citizen's reference to the FDA's criminal investigation of the apparent illegal marketing of the LipoTron device is based on extensive conversations and communications with one of the whistleblowers who first contacted the FDA's Office of Criminal Investigations about these allegations, and on a series of emails dated May 14, 2010, March 17, 2011, and April 10, 2012, that were written by Mr. Evan Rae, a criminal investigator in the Austin Resident Office of the FDA's Office of Criminal Investigation. These emails were quoted extensively in our letters to the FDA, and were attached to them. The emails belie your denial that there is a criminal investigation. Below are pertinent excerpts from these emails:

May 14, 2010: [Y]ou are correct, **not enough has been done to REVECOMED/ [Advanced Aesthetic Concepts (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 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.

The above emails provide a substantial basis for Public Citizen's statements that the FDA has been conducting a criminal investigation into the marketing of the LipoTron medical device for more than two years and appear to confirm that RevecoMED and its distributors have been illegally marketing this device despite explicit communications from the FDA prohibiting such marketing.

- (4) To the extent that your claim of defamation is based on a distinction between the name of the device and the name used for the treatment using the device, that distinction cannot form the basis for a meritorious defamation claim. Specifically, your letter states that your client uses Lipo-Ex to denote a weight management program, not to refer to the LipoTron device. The evidence shows, however, that the centerpiece of the Lipo-Ex program is the improper use of the LipoTron device, and, moreover, that your client sells that device. That is, the Lipo-Ex treatment is treatment with the LipoTron medical device. Thus, the distinction made in your letter does not render Public Citizen's statements defamatory, regardless of whether Lipo-Ex treatment solely involves use of the LipoTron medical device or whether it is the fundamental component of a broader "weight loss program." For example:
- (a) Although your August 3 letter denies that Advanced Aesthetic Concepts is selling the LipoTron medical device (the LipoTron 3000), Public Citizen has copies of multiple purchase orders and invoices documenting sales of the LipoTron 3000 by Advanced Aesthetic Concepts for amounts ranging from \$35,000 to \$99,500.
 - (b) Some of the invoices explicitly describe the LipoTron device as a component of Lipo-Ex, and many of the purchase orders and invoices included a line item for "LIPO-EX Training," which variably included one or two days of training, a jar of HFD cream or conductive cream, a technical manual, and a CD. The training and creams were presumably related to use of the LipoTron 3000 to treat patients.
 - (c) As previously noted, the RevecoMED International website had a page promoting use of the LipoTron device. At the top of page was posted a link to a video entitled "LIPO-EX: The non-surgical alternative." Below the video was the following text describing treatment with the LipoTron:

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.

- (d) Your own client's website for Profit Solutions MD previously included a page describing its Lipo-Ex product. (Public Citizen has a copy of this page as it appeared on July 20). This webpage read in part as follows:

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.

The above description is consistent with treatment using the LipoTron medical device.

- (e) The website for Profit Solutions MD as recently as August 15 included a page citing and linking to a news article published by Cosmetic Surgery Today on October 25, 2011 (available at http://www.cosmeticsurgerytoday.com/liposuction_/lipo-ex/) that described Lipo-Ex (Public Citizen has printed hard copies of the Profit Solutions MD web page and the Cosmetic Surgery Today web page). Both the Profit Solutions MD webpage and the referenced Cosmetic Surgery Today article includes the following text:

What is the technology of Lipo-Ex?

This form of liposuction eliminates body fat faster than other fat reduction procedures. In this treatment, the problematic areas are exposed to radio frequencies with high penetration capacities. The intense energy creates high temperatures within the fat cells themselves and causes the release of their contents. The body's lymphatic system absorbs the released contents and flushes them out.

The referenced Cosmetic Surgery Today article includes the following additional information:

How long does one session take?

It takes about one hour to complete a **Lipo-Ex treatment** session [emphasis in original]. However, the duration of the procedure can vary from thirty to ninety minutes, depending on the area and scope of treatment. The procedure has to be done at least eight times to garner the best results

What side effects should one expect from the procedure?

Lipo-Ex side effects include redness, itching and dryness of the skin [emphasis in original]. These effects are only temporary. Swelling or bruising are not regular side effects.

Again, the above description is consistent with treatment using the LipoTron medical device.

- (f) The website for Profit Solutions MD as recently as August 15 included a page citing and linking to a news article published on April 29, 2010 on the Plastic Surgery website (available at <http://guidetoplasticsurgery.com/how-does-using-lipo-ex-get-rid-of-cellulite/>) that described Lipo-Ex (Public Citizen has printed hard copies of the Profit Solutions MD webpage and the Plastic Surgery webpage). The referenced article was written by Dr. Alexandra Lambrou who, according to one of the Advanced Aesthetic Concepts purchase orders provided to Public Citizen, purchased a LipoTron 3000 device in late 2009. The Profit Solutions MD webpage referencing Dr. Lambrou's article included the following content:

05/19/12

How Does Using Lipo Ex Get Rid Of Cellulite?

One of the biggest benefits of Lipo Ex is that it can do so much at one time. Whereas cosmetic surgery patients in the past may have needed to undergo separate procedures for fat removal, cellulite reduction, and skin tightening, men and women who use Lipo Ex can improve all three conditions at once, explains Dr. Alexandra Lambrou. As the medical director at Sculpt Medical Spa in Chicago, Lambrou has shifted the [sic] her practice to focus exclusively on patients undergoing Lipo Ex now that she has seen how much this technology can do.

Although Lipo Ex is primarily known as a procedure to get rid of fat in patients, less is known about its benefits in getting rid of cellulite, increasing collagen production, and improving skin tone.

The referenced Plastic Surgery article by Dr. Lambrou includes the following additional information:

When undergoing Lipo Ex for the purpose of fat reduction, Lambrou explains that a physician will place a hand piece that emits radio frequency waves on top of the specific area of the body that is being treated, such as the stomach or thighs. Depending on the density of the region, the device may be adjusted to work more effectively. This leads into how cellulite reduction is handled with the machine as well, because adjusting the depths of radio wave penetration will depend on which area is being treated.

“The way the device works is that a physician puts a grounding plate on one side of the body and places a hand piece on the other. As the radio waves pass through the body, we begin heating up the fat cells and making them more porous,” Lambrou explains. Different hand pieces are used to

treat different types of fat. For example, a wider hand piece would be used to treat deeper levels of visceral fat, whereas a hand piece that emits a more shallow frequency would be used in treating cellulite. “When we treat cellulite, we used a bi-polar hand piece and we don’t even need the grounding plate,” she explains. “Whereas with areas like the thighs or hips we would use a mono-polar hand piece for the procedure.”

When a patient is most interested in having cellulite removed, the hand piece used during the Lipo Ex procedure only needs to penetrate into the body a half-centimeter to a centimeter deep. Rather than using a flat metal grounding plate, which is placed on the opposite side of the body for patients undergoing Lipo Ex with a bi-polar hand piece, Lambrou says that she would use a series of four smaller, miniature plates for someone whose main interest was on cellulite reduction only. “With the monopolar hand piece we can get the area that we are working on heated to a much deeper level, which helps us penetrate deeper and dissolve the fat in a deeper area,” Lambrou explains.

After undergoing Lipo Ex to treat cellulite, patients may not notice significant changes right away. “Usually patients won’t start noticing any major changes until they have come in for three or four treatments,” she says. “The second half of the treatments is where the progress and cellulite reduction really start accelerating.” Although every patient is different, most can expect to see a significant reduction in the amount of cellulite with six to 12 Lipo Ex treatment sessions.

The above description indicates that Lipo-Ex treatment involves undergoing treatment with a radiofrequency device in discrete sessions and is consistent with treatment using the LipoTron medical device.

- (g) The website for Profit Solutions MD as recently as August 15 included a page with testimonials about Lipo-Ex from several physicians and one medical spa owner (Public Citizen has a printed hardcopy of this webpage). Kristy Murrow, the owner of the Mariposa Med Spa in Oklahoma City, Oklahoma, is quoted as saying the following regarding Lipo-Ex:

We are very pleased with our patient results from Lipo-Ex. Our device is often busy 6-8 [hours] a day! We’ve had many patients complete treatment on one area and begin additional areas because they are so satisfied with the initial results.

This testimony indicates that Lipo-Ex treatment is delivered by a device, i.e., the LipoTron device.

- (h) Public Citizen has printed copies of multiple websites from physicians and medical spas throughout the country promoting treatment with the Lipo-Ex or LipoTron device. For those websites promoting treatment with Lipo-Ex, the description of the treatment in all cases is consistent with treatment using the LipoTron medical device. In at least one case, the website states: “Lipo-Ex (Uses Lipotron).” Furthermore, promotional videos for Lipo-Ex treatment posted on the website for Mariposa Med Spa in Oklahoma City and on YouTube for Signature Medical Spa in Tampa, Florida, include segments showing the LipoTron 3000 and patients appearing to be treated with this device.
- (i) A consent form for treatment with Lipo-Ex posted on the website of the Blush Aesthetics and Skincare health spa in Dallas, Texas, is entitled “RADIO FREQUENCY ASSISTED LIPOPLASTY (RFAL)” and includes the following description of the procedure:

I understand that **Lipotron, radio frequency assisted lipoplasty (RFAL), is a technology currently seeking FDA clearance** [emphasis added]. The concept of this treatment is to use radio frequency technology to maintain a pre-determined temperature in the treatment zone over a necessary period of time to help tighten skin and/or to help reduce the volume content of the fat cells. Cosmetic indications for these procedures include but are not limited to cellulite reduction, treatment of problem fat areas, skin tightening, and skin rejuvenation. Depending upon the area to be treated, each treatment takes approximately 20 - 55 minutes. You may experience increased redness to the area for up to 12 hours. You will be able to return to most normal activities following the treatment ...

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] bowl [sic] movements, increased urination, increased menstrual flow, flu like symptoms and “arch” burns ...

I am aware that this procedure is considered cosmetic and is considered “**experimental or investigational**” and therefore will not be covered by insurance [emphasis added] ...

- (5) Your letter acknowledges that Dr. Carome and Dr. Wolfe relied on a whistleblower who had inside knowledge of the problems with the device. You provide no reason why they should have given less than full credence to the whistleblower’s information, which was confirmed by extensive documentary evidence that we reviewed before publishing our statements about the LipoTron.

In summary, overwhelming evidence supports Public Citizen’s public statements about Advanced Aesthetic Concepts and about the LipoTron medical device. The statements are not false, misleading, or defamatory. Accordingly, Public Citizen rejects your demand that it

immediately cease and desist communicating about this matter in a variety of media. And Public Citizen stands by its request that the FDA 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.

Moreover, Public Citizen urges you to advise your clients to stop marketing the LipoTron medical device for weight management and any weight-loss programs that rely on that device.

Sincerely,



Allison M. Zieve
General Counsel
Public Citizen Foundation