

# GOODRICH POSTNIKOFF & ASSOCIATES, LLP

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August 3, 2012

Public Citizen  
1600 20<sup>th</sup> St.,  
Washington, DC 20009

Attn:

✓ Michael A. Carome, M.D., Deputy Director  
Sidney M. Wolfe, M.D., Director

VIA CM-RRR#: 7010 3090 0001 3343 6288  
VIA CM-RRR#: 7010 4090 0001 3343 6127

**Re: Advanced Aesthetic Concepts LP, d/b/a Profit Solutions MD (collectively  
"Advanced Aesthetics") and Mark Durante**

Dear Sirs:

Please be advised that this law firm represents Advanced Aesthetics and Mark Durante. It has come to our attention that on one or more occasions you have published false and misleading information concerning Advanced Aesthetics and Mark Durante, including to but not limited to comments concerning the LipoTRON 3000 and or the LipoEX program. Included in your statements are allegations that the LipoTRON 3000 is being sold without having been approved by the U.S. Food and Drug Administration ("FDA"). You have further stated or otherwise insinuated that as a result, my clients are engaged in illegal and unethical business practices.

For your information, the LipoTRON 3000 has been registered by the FDA as a Class 1 medical device. Your statements that the LipoTRON 3000 is in violation of the FDA standards and guidelines are false and misleading. In your publication dated July 18, 2012, you urge that the FDA "should act immediately to end the distribution, sale and promotion of an unapproved medical device that could pose a risk of harm to patients." You base your accusations on applications that were made to the FDA in 2007 and 2009. You apparently have failed to investigate or otherwise verify that the FDA, has subsequent to the dates you reference, registered the LipoTRON 3000 as a Class 1 medical device.

You state further that the FDA should immediately order RevecoMED (the Maker of the product) and any distributors of the LipoTRON device to cease and desist all activities involving

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the distribution, sale and promotion of the LipoTRON device. And for the FDA to expeditiously complete its criminal investigation (your words) 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. Your allegation that there is a criminal investigation is baseless. As I am sure that you are aware, the FDA does not comment on any investigation. Your use of words such as "criminal investigation" "illegal marketing" and "pose a risk of harm" are used to incite fear into the public and into Advanced Aesthetics' clients when there is no criminal investigation or illegal marketing.

You then follow up with a letter to Margaret Hamburg, Commissioner of the FDA on July 23, 2012 wherein you make blanket misrepresentations that the LipoTRON 3000 is also know as the LipoEX. This is blatantly false. The LipoTRON is a device, while the LipoEX is a program designed for weight management. While you correctly quote Profit Solutions web-site that the radio-frequency 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, you fail to distinguish that there is a difference between a physical machine and a weight management program. Instead, you misinform the FDA and your readers and are merely implementing a smear campaign against my clients. Further, Profit Solutions has never marketed the LipoTRON, it only has marketed the LipoEX program.

Your statements are based on assumptions and false information provided to you that you have failed to verify. You have never contacted Advanced Aesthetics or Mark Durante to investigate any portion of the statements that you made about them, instead you merely took the statements of a former employee of the manufacture and created a smear campaign against my clients. Your statements are defamatory and libelous and their publication has caused my clients considerable harm to their business and personal reputation.

Accordingly, demand is hereby made that you immediately cease and desist from:

1. making, speaking, creating, writing, and posting, in any manner, to any person, internet medium, publication, organization, social media of any nature, in any form or manner, concerning the business practices, procedures, operations and products associated with Advanced Aesthetics and Mark Durante, or any of their affiliations, and employees;
2. making, speaking, creating, writing, and posting, in any manner, to any person, internet medium, publication, organization, social media of any nature, in any form or manner, concerning any alleged investigation of

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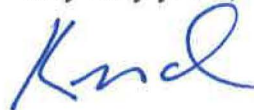
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Advanced Aesthetics and Mark Durante, or any of their affiliations, and employees by the FDA or any other state or federal agency;

3. communicating with third parties, either orally or in writing via the internet, social media, or any recognized postal delivery method concerning any information regarding Advanced Aesthetic, Mark Durante, or any of their affiliations, and employees.

Please be advised that in the event that you do not immediately cease and desist from the above activities, my clients will seek all remedies, available to them whether at law or in equity including issuance of an injunction and a lawsuit for the recovery of all costs and attorney's fees incurred.

Very truly yours,



Kevin G. Herd

KGH:tb