



Oklahoma State Department of Health  
Creating a State of Health

June 17, 2013

Michael A. Carome, M.D.  
Sidney M. Wolfe, M.D.  
Public Citizen's Health Research Group  
1600 20<sup>th</sup> Street N.W.  
Washington, D.C. 20009

Dear Drs. Carome and Wolfe:

This letter is to summarize the Oklahoma State Department of Health's follow up activities to your letter of August 3, 2012, requesting a thorough investigation of the use of the LipoTron device by the Mariposa MedSpa in Oklahoma City and Edmond and Restorations Medical Spa in Bartlesville. After reviewing the Department's licensure and regulatory authority, it was determined that neither the medical spas nor the LipoTron medical device fell under the Department's jurisdiction.

We commend you for submitting similar letters to the Oklahoma Board of Medical Licensure and Supervision and the Oklahoma Board of Osteopathy. Since receipt of your letter, we have communicated periodically with the Oklahoma Board of Medical Licensure and Supervision and the Oklahoma State Board of Osteopathic Examiners regarding the status of their respective investigations based on your complaint letter. Both boards have subsequently indicated to us they have addressed the concerns you raised in your letter with the respective physicians falling under their authority.

Our Department has also communicated regularly with the Region VI Food and Drug Administration (FDA) Office since receipt of your letter regarding the status of their investigation into the manufacturer's promotion of off-label use of the LipoTron. With the issuance of the recent FDA Warning Letter #25-13 of March 1, 2013, to RevocoMED, the manufacturer of the LipoTron device, we contacted both professional licensure boards to notify them about this ruling and shared copies of the warning letter.

In closing, we believe any further investigation and subsequent disciplinary action for improper advertisement and/or use of medical devices by licensed practitioners in Oklahoma appropriately falls under the jurisdiction of the State's respective professional licensure boards.

Sincerely,

Terry Cline, Ph.D.  
Commissioner  
Secretary of Health and Human Services

cc: Lyle R. Kelsey, M.B.A., C.M.B.E., Executive Director  
Oklahoma Board of Medical Licensure and Supervision

Deborah J. Bruce, J.D., Executive Director  
Oklahoma State Board of Osteopathic Examiners