From: Lyle Kelsey [mailto:lkelsey@okmedicalboard.org]
Sent: Thursday, January 31, 2013 6:44 PM
To: Michael Carome
Cc: Sidney Wolfe
Subject: Oklahoma Medical Board – LipoTron

Dr. Carome:

I have been looking through some older emails looking for some information and I realized that I never contacted you since my October 5 email about the end results of our investigation and discussions with the 3 physicians in Oklahoma.

On 10/17/12, the Oklahoma Medical Board Executive Staff, Eric Frische, MD, Board Medical Advisor; Kathryn Savage, Assistant Attorney General; Gayla Janke, RN, Board Investigator, myself and invited guest, Margaret Annes, FDA Division, Oklahoma City met with each physician group involved in the use and/or promotion of the LipoTron Medical Device. The executive board staff met with Ms. Annes first to make sure of our discussion content and expectations with the doctors. Ms. Annes said specifically that she was not authorized to tell the doctors that they are in violation [of the FDA regulations] and to cease. She would take the information from the meeting with the doctors and turn it into a complaint and look at the manufacturer. **After our discussion, the medical board staff decided to instruct the physicians that they are currently in violation of the FDA non-approved LipoTron (Lipo-Ex) for cosmetic uses by promoting and marketing its use to the general public for medical services outside the FDA approval as a Class 1 massage device only**

At 9:00 AM October 17th, we met with **JOSEPH BLOUGH, MD AND KRISTINE MURROW, PA** ON LIPO-EX / LIPOTRON in the medical board office. After much discussion, we told them that we were of the opinion that they were in violation of the intent of the FDA classification of medical devices by advertising the device (LipoTron) for anything other than a Class 1 massage device. We told them they needed to remove all reference to the LipoTron for cosmetic/weight loss purposes from their website and printed material. We told them they could use it off label for patients in their office only if they used informed consent to tell them that the device was not FDA approved for anything other than a massage device and that the patient gave consent for off-label use. They agreed to do that and in fact presented new promotional material that was void of any mention of the LipoTron. We have monitored his website and feel satisfied that he and his clinic are not promoting the LipoTron and we understand from the investigator that he is using it off-label on select, informed patients. http://broadwayclinic.com/

On October 17 at 11:30 AM, the same medical board staff & Ms. Annes met by Telephone Conference with **MICHAEL VaCLAW, MD and ELIZABETH SHERROCK, MD AND LEGAL COUNSEL** on LIPOTRON issue We had the same conversation with them and while they were much more guarded in their conversation than Dr. Blough, we presume with the lawyer present, they understood the position of the Medical Board and that if they did not cease in advertising and marketing the LipoTron as anything other than a class 1 massage devise and with the same instructions for off-label use that the medical board would have to look closer as what type of action would be taken. (With Ms. Annes earlier comments, we were not sure we could make a clear and convincing citation work so we talked about a cease order) They, through their lawyer, said they understood the concerns and that they would look over their options and take the necessary actions. We have monitored their websites and it appears that both physicians Dr. VaClaw & Dr. Sherrock have gone into primary care practice and are no longer utilizing or marketing the LipoTron. http://www.primarycarebartlesville.com/

**Conclusion**: As of October 2012, the Oklahoma Medical Board Executive Staff feels comfortable that the public is being protected and not mislead by the limited proper off label use of the LipoTron (Lipo-Ex) medical device. We have periodically checked with these physicians to verify this conclusion. We are also preparing a generic newsletter article about the misuse and consequences of use of non-FDA approved medical devices and medications.

Sincerely,


***Lyle Kelsey***
Executive Director
**Map & Directions on website:** www.okmedicalboard.org

**Oklahoma State Board of Medical Licensure and Supervision**
101 Northeast 51st Street (51st & Oklahoma)
Oklahoma City, Oklahoma 73105
**Office:** 405-962-1400
**Fax:** 405-962-1499
**Direct:** 405-962-1414
Cell: 405-250-5341
**Email:** lkelsey@okmedicalboard.org
P.O. Box is: 18256 - OKC 73154