DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FEB 28 2011

Sidney Wolfe, M.D.
Director

Michael Carome, M.D.
Deputy Director

Public Citizen's Health Research Group
1600 20th Street, NW
Washington, D.C. 20009

Dear Drs. Wolfe and Carome:

Thank you for your letter of February 17, 2011 concerning a members-only webinar held by the American Society of Plastic Surgeons (ASPS) and the American Society of Aesthetic Plastic Surgery (ASAPS) on February 3, 2011 to discuss the possible association between breast implants and the development of anaplastic large cell lymphoma (ALCL), a rare type of non-Hodgkin's lymphoma. You expressed concern that the webinar "urged members to inaccurately downplay the significance" of the risks of ALCL associated with breast implants.

As you know, the FDA is committed to providing patients and health care providers with accurate health-related information. On January 26, 2011, we publicly released the most current information, including our analysis and findings concerning ALCL and its possible association with breast implants. The FDA believes that women with breast implants may have a very low but increased risk of developing ALCL adjacent to the breast implant. FDA's analysis of the data and steps we plan to take to better understand and characterize the possible association can be found at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm

While ASPS and ASAPS are independent organizations that the FDA does not regulate, we are committed to assuring that health care providers and patients receive accurate information. We did view the ASPS/ASAPS webinar and spoke with representatives of both organizations. They informed us of their plans to remove the webinar from their website.

In your letter, you also note that your review of the 34 ALCL cases published in the literature demonstrated that some patients were diagnosed with recurrent and/or systemic ALCL and that some patients received radiation and/or chemotherapy for treatment. Furthermore, you state that "there are no data to support that surgery alone is curative."

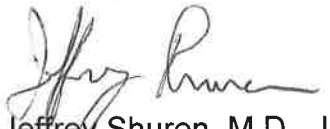
In our January 26 report, we described in detail the clinical presentation, prognosis and treatment options for women with breast implants and ALCL.

While some in the scientific community believe that ALCL associated with breast implants has a more benign course, the FDA believes the optimal treatment regimen has not been established and that additional data collection is needed to fully understand the possible relationship between ALCL and breast implants, as well as the risk factors, optimal treatment plan, and prognosis.

Currently, we are asking health care providers to report all confirmed cases of ALCL in women with breast implants through FDA's MedWatch Program. ASPS and other experts in the clinical and scientific communities have agreed to pursue a collaboration with the FDA to develop a registry to gather additional information to better characterize ALCL in women with breast implants. The details of the collaboration are still being developed, however FDA is committed to assuring the integrity of the data and the scientific validity of the information collected.

We appreciate your interest in the issue of ALCL in women with breast implants.

Sincerely,



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