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CANCER CENTER

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Mark B. McClellan, MD, PhD.
 Food and Drug Administration
 5600 Fishers Lane
 Rockville, MD 20857

Dear Dr. McClellan:

I feel compelled to respond to the recent letter addressed to you and widely circulated by Dr Thomas Whalen in which he expressed his views regarding the conduct of the General and Plastic Surgery Devices Panel that met on October 14 and 15, 2003, to consider the Inamed Corporation PMA pertaining to silicone gel breast implants. In that letter, he described the panel's decision as "misguided" and suggested that the plastic surgeons on the panel were somehow compromised by the possibility of personal gain based on the outcome of the vote. I take strong exception with his views and personal offense at this challenge to my integrity and that of the other plastic surgeons on the panel. I view Dr. Whalen's actions as an attempt to undermine the credibility of the panel, bypass its advice, and distort the FDA process by mobilizing social and political forces to influence the final decision regarding the Inamed PMA.

The panel was charged with making a recommendation regarding the safety and efficacy of Inamed's silicone gel breast implant product. The FDA defines safety as a balance between risks and benefits. Contrary to Dr. Whalen's opinion, the risks of the devices--both short-term and long-term--have been well characterized. Additional data of the kind being gathered by Inamed under current guidelines will be informative but will add nothing more upon which the conditional approval voted by the panel should be contingent. Questions about the long-term risk of systemic disease have been answered satisfactorily by numerous studies that are considered by the Institute of Medicine, a body with unassailable credibility, to be of sufficient quality to reach reliable conclusions. There is no evidence of a causal link between silicone gel implants and systemic disorders.

With most medical devices, determining safety is largely a matter of assessing risks because the perceived benefits are not controversial. With breast implants, however, the opposite is true. The risks at this time are well characterized, but there is disagreement about the benefits. This is why different individuals can arrive at opposite conclusions about safety based on the same set of risk data. The role of the FDA, in my opinion, should not be to make decisions for people on the question of benefits. The personal benefits derived from aesthetic and reconstructive breast surgery are very subjective and different for each woman. Because of this, each woman should be allowed to determine for herself whether the benefits outweigh the risks.

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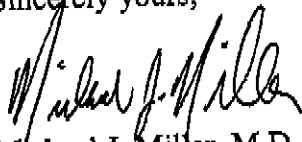
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Particularly troubling to me is Dr. Whalen's statement that "it serves the reputation of the FDA...and standing of the panel process... exceeding poorly to have had all of the plastic surgeons vote the PMA approvable." The plastic surgeons on the panel had the greatest experience and training in using these devices of all the panelists. I am committed to acting in good faith as an advocate for patients, and I am certain that each of my plastic surgery colleagues feels the same way. That the plastic surgeons voted unanimously for approval only strengthens the validity of the vote. To suggest that the plastic surgeons had any motivation other than a genuine concern for safety and that they did not base their vote solely on a responsible and competent analysis of the data is presumptuous and inappropriate.

I am confident that you and your staff at the FDA will thoughtfully weigh the body of data and recommendations of the advisory panel as you come to a decision regarding this issue. I appreciate the thorough way the FDA has addressed this issue over the past decade. It has been an honor for me to serve on the General and Plastic Surgery Devices Panel.

Sincerely yours,



Michael J. Miller, M.D.
Professor and Deputy Chairman

cc: David W. Feigal, Jr., MD
Celia Witten, MD, PhD
Senator John Cornyn
Senator Jon Corzine
Senator Kay Hutchison
Senator Edward Kennedy
Senator Frank Lautenberg
Representative Roy Blunt
Representative James Greenwood
David Krause, PhD

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