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Department of Materials Science and Engineering

Biomaterials Center

March 4, 2003/by Priority Mail

Ms. Samie Allen
Dockets Management Branch - CDRH
Food & Drug Administration
5630 Fishers Lane - Room 1061 (HFA-305)
Rockville, MD 20852

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Re: Docket No.: 01D-0318
Guidance for Saline, Silicone Gel, and Alternative Breast Implants

Dear Ms. Allen:

This guidance document was issued February 11, 2003 and was viewed on-line. In the context of the request for public comment, it may be helpful for you to be aware of 3 relevant scientific papers we have recently published (one of which is still in press to appear this year).

Reprints for the 2 that have been published in *J Biomed Mater Res (Applied Biomater)* [48:354-364, 1999] and *Ann Plast Surg* [2002:49:227-247] are enclosed as is a privileged copy of our paper in press in *Op Techn Plastic Surg*.

These, and other, studies raise serious questions concerning the time-dependent rupture of gel implants and the relatively frequent need for additional surgeries following primary implants. In the context of women's health care, it would seem appropriate that more quantitative information be provided to women contemplating augmentation or revision surgery as part of the normal informed consent.

I would of course be pleased to provide any further information which may be helpful to the CDRH concerning our research on breast implant safety.

Sincerely,

Eugene P. Goldberg
Genzyme Professor
Biomaterials, Materials Science & Engineering
Director, Biomaterials Center

enclosures

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