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2004 February 20

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

To Whom It May Concern:

This refers to the Draft Guidance for Industry and FDA Staff:
Saline, Silicone Gel, and Alternative Breast Implants, issued
January 13, 2004.

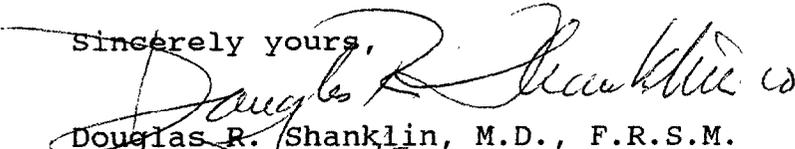
This is an extension of my letter of February 18, 2004. A copy
is attached. The literature on the immunopathology of silicones
is extensive and complex. It occurred it might assist your eval-
uation to have marked copies of our own publications on the sub-
ject as a means to enter the larger literature. These are:

1. My contribution to the Silicone in Medical Devices Confer-
ence Proceedings, F.D.A., **February 1-2, 1991**, pp. 103-125
2. Quantitative aspects of cellular responses to silicone.
Int.J.Occup.Med.Toxicol. 4:99-111, 1995 (Especially well
illustrated are the lesions of immunovascularitis.)
3. Microscopic technics and histologic findings in silicone
mammary implant capsules and regional paranodal tissues.
Curr.Topics Microbiol.Immunol. 210:253-261, 1996
4. The immunopathology of siliconosis. *Immunol.Res.* 18:125-173,
1998 (The sections most pertinent are marked.)
5. Dynamics of wound healing after silicone device implantation.
Exper.Molec.Pathol. 67:26-39, 1999. (Especially pp. 35-36
and Figure 5, a biopsy of a patch test.)

The journal for item #4 did not permit alphabetical references.
We have that list and will send a copy should you want one.

Thanking you for your attention to this matter, I remain,

Sincerely yours,


Douglas R. Shanklin, M.D., F.R.S.M.
Professor of Pathology and of
Obstetrics and Gynecology

drs/hwp
\FDA-04.002

2004D-0002

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