

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Rm 1061
5630 Fishers Lane
Rockville MD 20852
USA

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January 5, 2004

Silicone Gel-filled Breast Implants

Dear Sirs

The European silicone victims are looking with interest and great concern to the developments in the USA. The result of the Public Meeting of October 14/15, 2003 did indeed shock all those women, who suffer from complications after breast implantation.

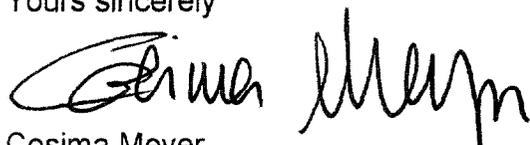
After the presentation of Inamed Corp. results of symptoms and complications, we were speechless about the fact, that the Advisory Panel did vote 9 to 6 in favor of this medical device. What you find in this report as statistics including 3-years, is in fact our painful experience in vivo for countless of years!

As we never had a ban of silicone gel-filled breast implants in Europe (except in France), the European Support Groups have been contacted by many, many women, who have received this very "new" implant, which is now under consideration to be approved by the FDA. We assure you, that women complain about the same complications and symptoms as the patients did with former implant generations. Manufacturers may have done some improvements, the list of reported side effects still is very long!

We strongly support Marlene Keeling's Citizen Petition submitted to you on November 18, 2003 and ask you not to approve Silicone Gel-filled Breast Implants, until we have long-term scientific data. Every a delay will safe Thousands of women in the USA from experiencing the well-known and therefore unnecessary complications. For the European women the US-ban (since 1992) stays for hope, that the European authorities will follow your example in acting responsible towards their citizens. Lifting the ban would play this very serious situation down and stigmatize all silicone victims worldwide.

Thanking you in advance, we remain,

Yours sincerely



Cosima Meyer
SSF Switzerland

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