

To: Divisions of Dockets management (HFA A-305)
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Re: SILICONE GEL BREAST IMPLANTS

1: Gel Bleed.

Gel bleed occurs from the moment of insertion. Gel bleed can be seen by simply laying the implant on sterile paper or on the drapes even before insertion. The health consequences have never been addressed, nor has any research been presented on the rate of bleed, quantity of gel bleed lost from the implant and its end site in the body. Gel bleed has simply been dismissed as non-consequential.

The manufacturer should present a comprehensive protocol as to how they intend to address this issue. A minimum would be biopsy of all capsules removed, and some form of quantitative measurement be presented on how much is being bled out.

2: Clinical data.

Their physicians dismiss most women who complain of symptoms. A program must be set up listing, tabulating and reporting symptoms by women with implants who complain thereof. These must, as a minimum, include the common "typical" symptoms: fatigue, short term memory loss, muscle pains (myalgia), joint pains (arthralgia), dry eyes, skin rashes, hair loss. Those women who have been diagnosed with fibromyalgia, atypical connective tissue disorders, scleroderma and atypical MS must be followed and reported

As most of these problems manifest from 7-10 years on, data and research must be a minimum of this time period. Three years is not sufficient time to know these end points

3: Rupture.

Most reported series show an incidence of rupture of 50-70% after 7-10 years post insertion. Any proposal to consider so-called "new" implants must allow for this period of time. The incidence of rupture prior to 3 years is insufficient in evaluating the long-term durability of the product, especially if these are to be inserted into young and teen women.

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