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EXHIBIT A

St. John's Regional Health Center

MEMORANDUM

To: IRC Members

From: Sr. Kathryn Slaughter, Tom Tally, and Tobias Meeker (reporting)

Date: 9/25/92

Subj: Mentor Adjunct Study of silicone gel breast implants

Our subcommittee had a number of concerns about the design of this study and the consent form: The protocol did not appear to us to be a "research study" in any familiar sense of that term. a) There is no accrual goal. The study is simply open for five years to any women who qualify. Participants are to be followed for five years. b) There are few exclusion criteria. In addition to the standard exclusions for any type of breast implant, women would be excluded if they merely desired augmentation, or if they had a qualifying condition and saline implants were deemed "medically unsuitable" by the surgeon. c) Inclusion criteria are very subjective and general. The consent form omitted a good deal of information that we believed should be revealed. In one section we found an outright error (when compared to information given in the protocol itself).

Tobias Meeker called Dr. Grant Bagley of the FDA (301-443-5470), one of the designers of the study, and Joyce Danny of Mentor (800-258-3494), the study coordinator. Here is a brief report of his conversations with them:

Dr. Bagley said that he participated in the "conceptual development" of the Mentor protocol. The FDA and Mentor worked together to devise the study and the consent form. Dr. Bagley represented "the clinical point of view" for the FDA team.

He said that this protocol is like nothing we've seen before because of the history of these devices. When the FDA requirements went into effect in 1976, requiring PMAs (pre-market approvals) for medical devices, breast implants were grandfathered in. That means they were "unapproved but legally marketed." By law, this would be the status of such grandfathered devices unless or until the FDA would have reason to require a PMA.

Following the media furor last year about side effects among women who had received silicone implants, a National Advisory Commission (NAC) was formed to review the status of silicone breast implants. The NAC recommended that a PMA should be required for marketing of silicone gel-filled breast implants. BUT the NAC also states that these devices should continue to be widely available to persons in unusual circumstances who would have medical need for them. To this end, the commission recommended that there be a limited core study that would be quite controlled and an adjunct study that would make the devices widely available (since not everyone with medical need -- due to location or whatever -- would be able to qualify for a traditional clinical trial.) The Mentor "study" is designed to serve this latter purpose. Dr. Bagley

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said of this protocol: "It is an administrative device to continue to make these devices widely available to those who have such need that the lack of established safety can be overlooked if there is a good informed consent process and the oversight of an IRC."

It is for these reasons that there are no accrual goals/limits and that more stringent criteria are not given for the "medical indications" that justify inclusion in the study. Dr. Bagley said that the FDA accepts that judgements of medical need will be very subjective, arrived at by a physician and patient in the context of an informed consent process.

Dr. Bagley said that he, personally, does not understand why "medically" the saline implant would not be an implant option in some cases. Yet, he said, at the hearings of the National Advisory Commission "it was successfully argued that such medical indications exist -- and this assertion was not successfully challenged;" hence the NAC's recommendations.

Dr. Bagley said that local hospitals could use their own peer review and other policies to set medical criteria standards for these cases, but these measures would be outside the protocol.

Joyce Denny, adjunct study coordinator at Mentor, said that the consent form had been "negotiated" between Mentor and the FDA and could not be changed. Nor may it be transferred to the letterhead of any institution -- the form must be used as provided by Mentor. I told her that we had concerns about the form. She said that she has received many calls from other IRCs expressing concerns. If an institution wishes it may devise an addendum on its own letterhead that the patient signs in addition to the Mentor form.

I told her that we were not only concerned that the patient be given more information than appeared in the Mentor form, but that the present form contains a discrepancy with information given in the protocol. Section B.2.c, paragraph 2 of the consent form, last sentence says:

"While no guaranteed method to detect breakage now exists without surgically opening the pocket containing the implant, mammography, ultrasound and physical examination can usually make the diagnosis" [emphasis added].

On page 1 of the protocol it is stated:

"No reliable method to detect rupture or leakage now exists, although mammography, ultrasound and physical examination may be helpful in diagnosing rupture" [emphasis added].

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Our subcommittee believes there is a great difference between a diagnostic work-up being effective "usually" and it being unreliable and merely "helpful." "We might have to send out an amendment on that," Ms Denny said.

Our subcommittee sees three reasonable courses of action: 1) refuse the protocol and consent form, 2) accept them with an addendum to the consent [and possibly require our researchers to define medical indications (and possibly require our researchers to define medical indications), or 3) table this protocol.

while we speak with other centers around the country of our concerns.

Arguments for refusing this protocol: a) The safety of these devices is unproven and has been called into question. b) The design of this protocol lacks rigor. This makes these devices widely available on the one hand and, on the other hand, calls into question the validity of data that will be collected. c) As the public becomes aware of this "study" and how it differs from traditional clinical trials, many will share the subcommittee's concerns that the very subjective determination of "medical need" opens the door for conflict of interest by researchers and that it is irresponsible to widely disseminate these untested devices. St. John's will appear irresponsible if its IRC reviews and approves this protocol.

Arguments for accepting the protocol and amending the consent: a) The harmfulness of these devices is unproven. b) The FDA has been intimately involved in the design of this protocol and the wording of its consent. We should trust that adequate consideration has been given of potential for risk versus potential for benefit. c) Physicians on staff who are convinced of the safety of these devices will be alienated if St. John's refuses to accept an FDA-approved (and designed!) study.

Arguments for tabling this protocol while conferring with other centers: a) It would strengthen the IRC's position if we can demonstrate that other centers share our concerns and will also act to refuse the protocol. b) It may be possible to generate a significant response to Mentor and the FDA to cause them to reconsider offering this protocol. c) Widespread consultation may cause us to modify our assessment.

Addendum: Our IRC met 9/25. One of the surgeons who hopes to do these procedures met with us. The discussion was lively. The surgeon gave his understanding that this protocol was designed "to give the illusion of a study" so that these devices could remain on the market. In subsequent closed session the IRC took the following action: We unanimously agreed that this protocol does not meet criteria that we normally expect of a clinical study. We are going to table the request for its approval while we continue to speak with other IRCs and groups around the country. In the meanwhile, we are instructing the surgeons who have been operating under "Urgent Need" to continue to do so.

Our IRC sees no role for itself in this "study." We feel that we are being asked to rubber-stamp a political solution to this highly politicized issue. This "study" will recklessly put many women at risk. Asking IRCs to behave in this manner violates their mandate and calls into question their integrity. It appears to us that the FDA has lost its objectivity. We hope this whole approach will be reconsidered.

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