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a mastectomy. Unlike patients who have undergone mastectomy, they still have breast tissue, and the presence of an implant complicates the use of mammography for the detection of breast cancer....In the end, it comes down to this: in our opinion the risk-benefit ratio does not at this time favor the unrestricted use of silicone breast implants in healthy women." The design of the Mentor adjunct "study" belies the concerns you expressed. This "study" makes these devices widely available to women who have not had mastectomies. If women are to be offered these implants outside of scientifically valid studies, we believe this offer should be restricted to the present "Urgent Need" population.

An FDA official (who shall remain unnamed) said to one of us (Tobias Meeker) that this adjunct protocol "is an administrative device to continue to make these implants 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 IRB."

To assume that a good consent process (with Institutional Review Committee oversight) will protect subjects from unjustified risks strikes us as a faulty assumption. This implant is a product with unproven safety and demonstrated (but unproven) risks. Further, we are concerned that misrepresenting this "administrative device" as a legitimate scientific study misleads potential recipients, making it more difficult for them to assess risk.

We see no role for an Institutional Review Committee in this "study." We feel that we are being asked to be participants in a political solution to this highly politicized issue. Asking IRBs to behave in this manner violates their mandate and calls into question their integrity. We hope the FDA will reconsider this whole approach.

Sincerely,

Tobias Meeker, M.Div., M.A.
Director, Ethics Program

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These persons have given permission, by ~~signed~~ ^{signed} letter, for their names to appear here:

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KSP

enclosure: Mentor letter re consents
Consent Form concerns

*please send copy of this letter &
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