

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division**

In re:)
SILICONE GEL BREAST IMPLANT) Master File No. CV 92-P-10000-S
PRODUCTS LIABILITY LITIGATION)
(MDL 926))

ORDER No. 31E
(Directions to National Science Panel under FRE 706)

This order supplements Orders No. 31, 31A, 31B, 31C, and 31D, as well as the directions under Fed. R. Evid. 706(a) given orally at a conference held on October 24-25, 1996, to the court-appointed experts serving on the National Science Panel.

1. The questions to which the court-appointed experts are asked to respond are the following:

(a) Issues. To what extent, if any—and with what limitations and caveats—do existing studies, research, and reported observations provide a reliable and reasonable scientific basis for one to conclude that silicone-gel breast implants cause or exacerbate any of the conditions described in (b) below? If, in the process of making these findings, you believe that there are related or subordinate issues that should be separately addressed, please do so.

(b) Scope. You are asked at this time to consider the relationship, if any, between implants and the following:

- "classic " connective tissue diseases, such as systemic lupus erythematosus, Sjogren's syndrome, etc.
- "atypical" presentations of connective tissue diseases or symptoms
- immune system dysfunctions

Listed in the appendix to this order are various diseases, symptoms, conditions, or complaints that have sometimes been asserted as possibly associated with silicone-gel implants. To the extent you believe appropriate—and without being asked to address separately each of these diseases, symptoms, conditions, and complaints—you are encouraged to comment on the scientific basis, if any, for any such claimed linkage. You are not being asked to consider purely local complications, such as breast disfigurement, tenderness, or capsular contracture.

(c) Contrary Opinions. To what extent, if any, should any of your opinions referenced in (a) above be considered as subject to sufficient genuine dispute as would permit other persons, generally qualified in your field of expertise, to express opinions that, though contrary to yours, would likely be viewed by others in the field as representing legitimate and responsible disagreement within your profession?

2. General guidance and procedural directions were developed and recorded during the conference with respect to such matters as initial submission by the parties of potentially relevant studies, research,

and reports; the process of individual review by the experts and consultation among them; procedures for the panel to present questions to the parties and/or to hear presentations from the parties at a future point; procedures to be followed if panelists need to address inquiries to authors of studies or to obtain special assistance or advice from other experts; preparation of joint or separate reports by the panelists; and potential procedures for presenting testimony through depositions. These directions should be viewed as tentative and preliminary, subject to being refined and altered by the court, after input from the panelists and the parties, as the work of the panel proceeds.

3. After the experts have received the initial submissions by the parties and have consulted among themselves, they should provide the court and the parties with their views regarding realistic schedules regarding such matters as preparation of reports and readiness for depositions.

4. It is anticipated that at least one representative of the plaintiffs and one representative of the defendants will either be privy to, or be provided with a copy of or access to, communications between the experts and the court.

This the 31st day of October, 1996.

/s/ Sam C. Pointer, Jr.
Chief Judge Sam C. Pointer, Jr.

APPENDIX TO ORDER NO. 31E
DISEASES, SYMPTOMS, CONDITIONS, PRIMARY AND SECONDARY COMPLAINTS

Abnormal biomarkers (antinuclear antibodies, immunoglobulins, NK cell activity, etc.)
Alopecia
Allergies
Arthralgias
Breathing difficulties/shortness of breath/pulmonary symptoms
Bruising easily
Burning in chest/heartburn/esophageal symptoms
Cognitive dysfunctions/memory problems/neurologic deficits/concentration difficulties
Chronic fatigue/low energy
Chronic inflammation
Constipation/diarrhea/incontinence
Coughing/sore throat/swallowing difficulties/dysphagia
Decrease in sex drive
Fever (low grade)
"Flu-like" feelings
Headaches
Heart palpitations
Hot flashes
Infections
Lymphadenopathy
Malaise (general)
Mood swings/irritability/anxiety/panic attacks
Mucosal ulcers
Muscle weakness/muscle cramps
Myalgias
Nausea/vomiting
Night sweats
Pain (abdominal, back, chest, intestinal, joint, muscle)
Sensitivity to heat/cold
SICCA symptoms (dry eyes/mouth/skin/vagina)
Skin changes/rashes/hives/paresthesia/numbness and tingling
Sleep disorders
Stiffness
Swelling/fluid retention/bloating
Tenderness/tender points
TMJ problems
Urination--frequency/burning/incontinence
Vertigo/dizziness/ringing in ears/vestibular dysfunction
Vision problems--blurred vision/light sensitivity
Weight loss/gain