Exhibit E

SECOND JUDICIAL DISTRICT COURT
COUNTY OF BERNALILLO
STATE OF NEW MEXICO

ENDORSED
FILED IN MY OFFICE
FEB 23 1998
CLERK DISTRICT COURT

LORRAINE JOHNSON vs. BAXTER HEALTHCARE CORP, ET AL.
Case No. CV-92-07501.

CONSTANCE BURCH vs. SURGITEK, INC., ET AL.,
Case No. CV-92-10922.

MARILYN GRACE vs. CUI CORPORATION.
Case No. CV-92-10930.

EMILY BUFORD vs. SURGITEK, INC., ET AL.,
Case No. CV-93-05887.

DECISION

This matter came before the Court for a combined hearing in the above captioned breast implant cases on Defendants' Motion to Exclude Causation Testimony of Plaintiffs' Clinicians and specific motions to exclude the testimony of Plaintiffs' witnesses Silver, Blais, O'Donnell and Pusztai. The hearing was held on January 7, 8, and 9, 1998. Since all of the witnesses had previously testified, either at trial or in deposition, the Court decided that judicial economy, as well as the economy of the parties, would be best served by reference to prior testimony and the documents relied upon by the various experts. The parties supplied the Court with the documents and testimony which they believed relevant to the issues at hand. In addition the parties fully briefed the issues before the Court. The Court was extremely impressed with all of the presentations and the obvious amount of work that went into those presentations.

The motions were essentially challenges to the Plaintiffs' evidence under the standards set out in the Daubert, Alberico and Anderson cases. I will not recite in detail the applicable law as

the standards set out therein, as counsel are all aware of the cases and the standards to be applied. For the reasons that follow I am going to grant Defendants' motions and exclude all expert evidence concerning general causation of any systemic disease alleged to be caused by breast implants. The Court was heavily influenced by the methodology and opinion of U.S. District Court Judge Robert E. Jones in the consolidated case of Hall v. Baxter Healthcare Corp. in the District of Oregon.

Initially, the Court notes that the burden is on the proponent of expert testimony to establish admissibility. In the Court's opinion the Plaintiffs are unable to meet that burden in these cases. The key issue is simply whether the Plaintiffs' proposed scientific evidence is good science. Is it derived by scientific method or is it merely a hypothesis yet to be proven by the use of reliable scientific method? Applying the factors set out in the Anderson case to the Plaintiffs' proposed expert testimony, the evidence is not reliable. The theories advanced by the Plaintiffs' experts have not been tested, nor subjected to peer review or publication. With no testing, it is virtually impossible to determine any rate of error. The testing that has been done in the area does not support Plaintiffs' experts' theories. Their theories are currently not accepted as valid in the medical community. Lastly, their theories are not capable of supporting opinions based upon reasonable probability.

Plaintiffs argue for judicial recognition of a new systemic disease, which for the sake of simplicity I will refer to as atypical connective tissue disease (ACTD). ACTD is, at best, a constellation of symptoms yet to be defined and, therefore, yet to be subjected to scientific testing. Dr. Goldsmith, an expert used by Plaintiffs in other cases, has stated that ACTD is not yet even a hypothesis. He acknowledges that he is in the initial process of determining a suitable

hypothesis to subject to epidemiological testing. Faced with this problem, Plaintiffs' counsel candidly argues that the law does not have to await final scientific testing before allowing their experts to go before a jury with their theories and let that jury sort out the science. This Court rejects that argument.

The law cannot lead science. Allowing experts to testify as to their opinions, when those opinions are as yet untested conclusions, would be inviting juries to speculate, something they are specifically instructed not to do. Allowing experts to testify just because they are technically qualified in a scientific field, without requiring that their theories and conclusions be subjected to scientific testing and peer review, leaves a lay jury to base their decision on speculation, guess or conjecture. The Court's role is to act as gatekeeper and ensure that only sound science is admitted into evidence. It may well be that future advances in medical science will validate Plaintiffs theories concerning breast implant diseases. Until those advances occur, the courts must apply sound science as it exists, not as it might develop. To do otherwise subjects the courts and our system of justice to justifiable criticism from the public. We in the legal system cannot live in our own little world oblivious to the laws of science and nature. The Daubert/Alberico/Anderson line of cases recognizes this reality.

Plaintiffs' experts in this case admit they have done no epidemiological testing of their theories. In addition Plaintiffs attack the epidemiological studies which have been done. Attacking the validity of the studies which do exist, however, does not aid Plaintiffs in their burden of establishing the admissibility of their experts' opinions. In the Court's opinion, in order to establish that breast implants cause ACTD, Plaintiffs' experts must have epidemiological studies which show that the Plaintiffs' disease (presuming it has been actually defined in order to

be tested) was, more likely than not, caused by breast implants. In this regard, with few exceptions not relevant here, the studies must show a relative risk greater than 2.0 in order to state that breast implants are more likely than not the cause of the disease. None of the studies which currently exist have met that standard. Anything short of 2.0 means that Plaintiffs' medical problems are more likely caused by something other than breast implants.

Plaintiffs' experts appear to rely on anecdotal reports, individual case studies, and differential diagnosis. In the Court's opinion, anecdotal reports and case studies without scientific testing of the conclusions drawn therefrom cannot support their conclusions. Differential diagnosis is also a flawed approach, in that it does not by itself prove the cause of a disease. Differential diagnosis assumes that the cause being considered has been proven to cause the disease in question.

For the reasons stated above and as more thoroughly set out in Judge Jones' opinion in the Hall case, I will not allow evidence of general causation in these cases.

With respect to the specific witnesses, Dr. Silver, for the reasons set out above, will not be allowed to testify as to any general causation matters. Dr. Blais is a troubling witness. Normally bias is matter for the jury. Here, however, it appears that Dr. Blais is so biased it affects his objectivity and his ability to give an honest opinion. Notwithstanding this problem, Dr. Blais' theories as to breast implants in general are totally unscientific and therefore unreliable. He publishes nothing, keeps no set of systematic records of his tests or observations, and his opinions are peculiarly his own without any general acceptance in the scientific community and without any ability of testing or peer review. Even if his testimony had some probative value, the prejudice to the Defendants would outweigh that testimony. Any glib expert who has an opinion and nothing

to support it can never be effectively cross-examined by an opponent, thus to allow such testimony would be prejudicial. He will not be allowed to give general opinions on the manufacture or design of implants, any immunological effects or responses, nor the issues of implant failure. Defendants concede that he may be able to testify as to his observations of the implants at issue, depending on the proffer. Accordingly, I am not deciding that issue at this time.

I am not going to allow the testimony of Dr. O'Donnell. Dr. O'Donnell is pharmacist with a masters in nutrition, who claims expertise in pharmacology. He has conceded that he has no education, training, or experience in the areas of medical devices, silicone or breast implants. He has conceded that he is not an expert in virtually every field that could have application to breast implants and their failure, from immunology to toxicology to biomaterials. Nevertheless, he is offering opinions on whether silicone is toxic, whether certain materials should be used in implant manufacture, whether implants were properly tested before offered to the public, and whether the FDA should have classified implants as a drug rather than a medical device.. He has no expertise to give opinions on those subjects, other than that gained as a testifying expert in breast implant cases. The one area where he may have expertise is in the area of the warnings which should accompany drugs. His expertise in that area, however, does not transfer to the area of breast implants, an area where he concedes that he has no education, training or experience. Even if warnings were not tied to general causation issues, generalizations about the warnings needed on drugs does not "fit" with the warning issues that might exist in a breast implant, medical device case. In addition to all of the above, like the other experts offered by Plaintiffs, none of Dr. O'Donnell's theories have been tested, subjected to peer review, or accepted by the scientific community. Any value his testimony might have would be outweighed by its prejudicial effect.

The court will also exclude the testimony of Dr Puszkin. In addition to his appalling lack of candor as to his credentials, Dr. Puszkin's theories fail all of the tests set out in Anderson He ignores scientific method, his theories cannot be tested, they have not been peer reviewed, and they enjoy no acceptance in the scientific community

In conclusion, the Court is aware that studies are ongoing in the area of breast implants and a federal 706 panel is soon to issue a report. The results of the ongoing studies may lend support to the as yet unsubstantiated theories of the Plaintiffs and their experts. This Court will reconsider this decision should such support be forthcoming. In the interim, the cases filed should go forward. The Court also realizes the impact of this decision on Plaintiffs' cases and the articulated intention to appeal from an adverse ruling. I lean toward certifying this question for interlocutory appeal should Plaintiffs so request, however, I will also listen to Defendants on this issue before I decide. Lastly, the Burch case is set for my next jury trial docket. While I do not intend to indefinitely stay the breast implant cases pending before me to await the results of ongoing studies, I will consider continuing the Burch case until my summer docket should Plaintiffs need additional time to determine their next course of action.

I would ask counsel to immediately consult with each other as to their respective positions on the appeal and the continuance issues and inform the Court of your positions. If we need a quick hearing on those matters I will accommodate. I do again want to express my appreciation to all counsel for their impressive preparation and presentation of these very complicated issues.

W. DANIEL SCHNEIDER

W. DANIEL SCHNEIDER
District Court Judge, Division VII