



FOR US POSTAL SERVICE DELIVERY:

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October 26, 2000

Dr. Jay A. Gershen
Executive Vice Chancellor
University of Colorado Health Sciences Center
Chancellor's Office
4200 East Ninth Avenue
Denver, Colorado 80262

**RE: Human Research Subject Protections Under Multiple Project Assurance (MPA)
M-1494**

**Research Project: Brent J, McMartin K, Phillips S, *et al.* Fomepizole for the Treatment
of Ethylene Glycol Poisoning. *N Engl J Med* 1999;340:832-8.
Related HHS Project number: FDR-001256**

Dear Dr. Gershen:

The Office for Human Research Protections (OHRP), formerly the Office for Protection from Research Risks (OPRR), has reviewed Dr. James Shore's July 7, 1999 report regarding the above referenced research. OHRP apologizes for the delay in responding to Dr. Shore's report.

Dr. Shore's report was submitted in response to OPRR's May 19, 1999 letter which expressed a concern that the informed consent procedures used to enroll subjects in the above referenced research failed to comply with the requirements of HHS regulations at 45 CFR 46.116.

Based upon its review of Dr. Shore's report, OHRP finds that the procedures for obtaining informed consent that were approved by the University of Colorado Health Sciences Center (UCHSC) Institutional Review Board (IRB) for the above referenced research were in compliance with the requirements of HHS regulations at 45 CFR 46.116.

Furthermore, OHRP commends the UCHSC IRB for recognizing that the procedure initially proposed by the investigators for obtaining "consent" for patients who were not lucid from two physicians uninvolved with the trial was not permissible under HHS regulations at 45 CFR 46.116.

As a result of the above determination, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,



Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Dr. William Hiatt, Executive Director, The Colorado Prevention Center
Dr. Doris J. Biester, President and CEO, The Children's Hospital, Denver
Mr. Ed Thorsland, Jr., Medical Center Director, Denver Veterans Affairs Medical Center
Dr. Patricia Gabow, CEO and Medical Director, Denver Health
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