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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Southwest Regional Office
4040 N. Central Expressway Suite 900
Dallas, Texas 75204

August 21, 2003

WARNING LETTER

CERTIFIED MAIL
Return Receipt Requested **03-SWR-WL-01/8**

Re: MQSA Facility ID #230540

Hannah L. Chung, MD
Davis Hospital and Medical Center (Outpatient Services)
1660 West Antelope Drive, Suite 120
Layton, UT 84041

Dear Dr. Chung:

On April 17, 2003, a representative of the Food and Drug Administration (FDA) visited your facility. This investigation revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA), which is codified in Section 263b of Title 42 of the United States Code (42 U.S.C. 263b), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Your facility was found to be performing mammography from October 1, 2001 through February 25, 2003 without a valid certificate as required by the MQSA [see 42 U.S.C. 263b(b)(1); 21 CFR § 900.11 (a)].

Because of this serious problem at your facility, we believe that the quality of mammography may have been compromised and may present a serious risk to human health. Therefore, in accordance with 21 CFR 900.12(j)(1), FDA is requiring that your facility undergo additional mammography review (AMR) of mammograms performed during the time your facility operated uncertified. The entity designated by FDA for this purpose is the American College of Radiology (ACR). The ACR will contact you regarding the selection of films for their review.

If FDA determines that the quality of mammography performed at your facility presents a significant risk to individual or public health, FDA regulations at 21 CFR 900.12(j)(2) authorize us to require your facility to notify patients and their referring physicians of the deficiencies presenting such risk and other relevant information.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to the violation related to the recent investigation of your facility and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or you may access information through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have any questions, please contact LCDR Scotty Hargrave of the Food and Drug Administration's Southwest Region at (214) 253-4930.

Sincerely yours,

for Dennis E. Baker, DRFDD
Regional Food and Drug Director