



Transmitted via Facsimile

JUL 25 2000

Food and Drug Administration
Rockville MD 20857

Delivery via Federal Express

WARNING LETTER

Steven J. Bier, M.D.
New York Diagnostic Medical Services, Inc.
102 Park Avenue
Yonkers, New York 10703

Re: MQSA Facility ID# 216861
CFN# 2438053

Dear Dr. Bier:

I am writing to you to let you know that the Food and Drug Administration (FDA) has been advised that the American College of Radiology (ACR) revoked your facility's mammography accreditation effective July 5, 2000.

The Mammography Quality Standards Act of 1992 (MQSA) provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility obtains an FDA certificate (42 USC 263b(b)(1)(A)) and meets and maintains quality standards for personnel qualifications, equipment, quality assurance programs, and record keeping and reporting.

We are aware that New York State Health Commissioner Antonio C. Novello, M.D., M.P.H., Dr.P.H. summarily suspended your medical license on May 25, 2000. Dr. Novello also suspended the authorization of the professional service corporation Steven J. Bier, M.D., P.C. to practice medicine. Dr. Novello determined that your continued practice of medicine poses an imminent danger to public health.

The charges against you include ones that involve the quality of the clinical images performed at Steven J. Bier, M.D., P.C. (FDA MQSA ID# 140780). It has been alleged that you performed mammograms on patients that were not of diagnostic quality due to deficiencies including improper equipment adjustments, improper positioning of patients, inadequate labeling, and inadequate film processing. You have also been charged with interpreting non-diagnostic mammograms and reporting the results without any documentation or evidence of repeating mammograms or attempting to repeat mammograms.

We are also aware that the New York State Department of Health reviewed clinical images taken at Steven J. Bier, M.D., P.C. The results of the review indicated that the quality of mammography produced at that facility posed a serious risk to human health. In view of these allegations, FDA has serious concerns about the quality of mammography that you performed at New York Diagnostic Medical Services, Inc. (New York Diagnostic). Therefore, FDA is requiring New York Diagnostic to undergo an Additional Mammography Review (AMR) to assess the quality of the mammography performed at the facility pursuant to 21 CFR 900.12(j)(1). The purpose of the review is to assess whether there has been a compromise of quality sufficient to pose a serious risk to human health.

Therefore, FDA is requesting that New York Diagnostic contact the ACR and arrange to have an AMR conducted to assess the quality of the mammography performed at this facility pursuant to 21 CFR 900.12(j)(1). You will be responsible for the payment of all fees charged by ACR for conducting the AMR. The review will assess whether there has been a compromise of quality sufficient to pose a serious risk to human health. If the results of the AMR indicate that the quality of mammography produced by your facility poses a serious risk to human health, FDA may require that your facility submit a plan for a physician and patient notification program under 42 USC 263b(h)(2) and 21 CFR 900.12(j)(2).

Within 15 working days after receiving this Warning Letter, you should notify FDA in writing of:

- whether you intend to contact the ACR to arrange the AMR and, if the results of the AMR reveal that there has been a compromise of quality sufficient to pose a serious risk to human health, if you intend to conduct a patient notification program; and
- your future plans for conducting mammography at this facility.

Please send your written response to:

Ellyce F. Ratskoff, R.Ph., J.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
1350 Piccard Drive (HFZ-240)
Room 220H
Rockville, Maryland 20850

Additionally, FDA regulations do not preclude States and local jurisdictions from independently enforcing their own laws and regulations. In some cases, those requirements may be more stringent than FDA's. Therefore, when you plan your corrective actions, you should consider the more stringent State or local jurisdictional requirements, if any.

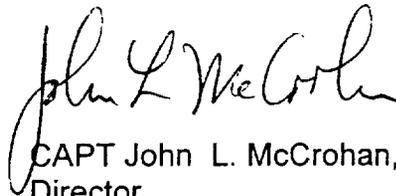
FDA may, without further notice, initiate further regulatory action(s) such as:

- Assessing civil money penalties in an amount not to exceed \$10,000 against an owner, operator, or any employee of a facility required to have a certificate, for:
 - each failure to substantially comply with the quality standards (21 USC 263b(b)(h)(3)(B)),
 - each failure to notify a patient of risk (42 USC 263b(h)(3)(C)), and
 - each violation, or for aiding or abetting in a violation of, any provision of the MQSA or FDA's implementing mammography regulations, 21 CFR Part 900 (42 USC 263b(h)(3)(D)).
- Suspending or revoking a facility's certificate (42 USC 263b(i)).
- Seeking an injunction in federal court to prohibit any mammography activity by a facility that constitutes a serious risk to human health (42 USC 263b(j)).

If you have any questions regarding the content of this letter, specifically the AMR, or your response, please contact Ms. Ratskoff at (301) 827-2980.

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Sincerely yours,



CAPT John L. McCrohan, USPHS
Director
Division of Mammography Quality
and Radiation Programs (HFZ-240)
Office of Health and Industry Programs
Center for Devices and Radiological Health

cc: Jeffrey Rubin, Esq.
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Ms. Maryanne Harvey, Chief
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Bureau of Environmental Radiation Protection
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