



Transmitted via Facsimile

JUL 25 2000

Delivery via Federal Express

WARNING LETTER

Steven J. Bier, M.D.
L. Mario DiBlasio, M.D.
Steven J. Bier, M.D., P.C.
2488 Grand Concourse
Suite 329
Bronx, New York 10458

Re: MQSA Facility ID# 140780
CFN# 2436435

Dear Drs. Bier and DiBlasio:

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 the medical licenses of Steven J. Bier, M.D. and L. Mario DiBlasio, M.D. on May 25, 2000. Dr. Novello also suspended the authorizations of the professional service corporations Steven J. Bier, M.D., P.C. and Mario DiBlasio, 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 your facility's clinical images. It has been alleged that you performed mammograms on patients that were not of diagnostic quality due to deficiencies including improper equipment adjustments and improper positioning of patients, inadequate labeling, 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.

FDA has serious concerns about the quality of mammography performed by your facility. FDA normally would have required your facility to undergo an Additional Mammography Review (AMR) to assess the quality of the mammography performed at your facility pursuant to 21 CFR 900.12(j)(1). The purpose of this review is to assess whether there has been a compromise of quality sufficient to pose a serious risk to human health. However, we are aware that the New York State Department of Health has reviewed clinical images taken by your facility. The results of the review indicated that the quality of mammography produced by your facility posed a serious risk to human health.

Accordingly, FDA is requiring your facility to submit a plan for a patient and physician notification program under 42 USC 263b(h)(2) and 21 CFR 900.12(j)(2). FDA is requiring you to notify all patients, and their referring physicians, that had mammography examinations performed at your facility from June 1, 1998 through May 25, 2000, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and other relevant information.

You must immediately conduct a complete review of your patient logs and billing records for this period of time and identify all patients that received mammography services at Steven J. Bier, M.D., P.C. Within 15 working days after receiving this letter, you must notify FDA in writing of the results of your review. Your written response must include the complete list of the names and addresses of all patients who received mammography examinations during this period as well as the name and address of each patient's referring physician.

To assist you in the notification program, we have enclosed samples of patient and physician notification letters for you to use. We strongly encourage you to closely follow the enclosed samples when you prepare your notification program. FDA will oversee the notification process, including the review and approval of the patient and physician notification letters before you mail them. Therefore, we ask that you share your draft letters with us within 15 working days after receiving this letter, as directed below. Upon receipt of your proposed letters, we will review them and provide you with our comments by mail or facsimile. **Under no circumstances should you send letters to the physicians or to the patients until FDA has reviewed and sent you written approval of the finalized documents.** Additionally, FDA will monitor and audit your notification process.

Physician Notification

The following recommendations must be taken into consideration in the preparation and implementation of the physician notification program:

- Each patient's referring physician must receive a notification letter.
- The notification letters must be issued on your facility's stationary.
- The notification letters must be sent by certified mail and return receipt.

- The notification letters must include an explanation of the problems with your facility's mammography services. If your facility intends to pay for having the films re-read or a repeat examination at another FDA-certified facility, this information should be communicated to the physician.
- You must mail the physician notification letters no later than five (5) business days after the FDA has approved the finalized letter.
- You must collect and retain all of the physician notification certified mail return receipt cards. FDA will review the return receipt cards as part of our monitoring and auditing activities.

Patient Notification

The following recommendations must be taken into consideration in the preparation and implementation of the patient notification program:

- Each patient must receive a notification letter written in English and Spanish, as appropriate.
- The notification letters must be issued on your facility's stationary.
- The notification letters must be sent by certified mail and return receipt.
- You must begin mailing the patient notification letters five (5) business days after the last physician notification is mailed.
- If a patient's letter is returned because the patient no longer lives at the address and you are unable to obtain a new address, you must take reasonable steps to locate the patient through her referring physician.
- If a patient has already had a mammogram since the [INSERT DATE of the patient's last examination] taken at Steven J. Bier, M.D., P.C., there is no need for her to take any action other than to continue to get routine mammograms.
- If a patient has not had a mammogram since the [INSERT DATE of the patient's last examination] taken at Steven J. Bier, M.D., P.C., we suggest that she contact her doctor or health care professional to discuss this situation and her need for any medical follow-up. If the patient elects to have her films re-read or have a repeat examination performed, we are enclosing a list of FDA-certified facilities in your area to assist your patient in locating the closest alternative certified mammography facility.
- If a patient needs to schedule a repeat mammogram but her health insurance will not pay for it, she may wish to contact the National Cancer Institute's (NCI)

information number at 1-800-422-6237. Experts at this number can determine whether there is a facility in or near her area that provides free or low cost mammograms. These experts can also answer questions about breast health and mammograms.

- If your facility intends to pay for having the films re-read or for a repeat examination, this information should be communicated to the patient. For example, "If you choose to have your films re-read or have a repeat mammogram, we will pay for it."
- You must collect and retain all of the patient notification certified mail return receipt cards. FDA will review the return receipt cards as part of our monitoring and auditing activities.
- You must prepare and retain a log for each of the patients to record the activities/steps that you have taken in your efforts to notify the patient. FDA will review the logs as part of our monitoring and auditing activities.

Within 15 working days after receiving this letter, you must send FDA a written response to this Warning Letter including:

- your intent to conduct the required patient and physician notification program, described above;
- a copy of your patient logs from June 1, 1998 through May 31, 2000;
- a list of the names and addresses of all the affected patients and their referring physicians;
- copies of your proposed patient and physician notification letters; 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

You can request an internal FDA review of our decision to require your facility to conduct a patient and physician notification program. Information about having this decision reviewed can be found in 21 CFR §10.75 (enclosed). Should you decide to

request a review of this decision, your written request must be submitted within 15 working days of receipt of this letter to:

Lireka P. Joseph, Dr. P.H.
Director
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive (HFZ-200)
Rockville, Maryland 20850

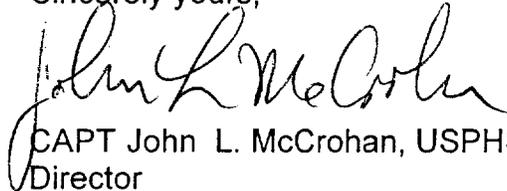
Additionally, FDA regulations do not preclude States and local jurisdictions from independently enforcing their own laws and regulations. In some cases, those requirements may be more stringent than FDA's. Therefore, when you plan your corrective actions, you should consider the more stringent State 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 procedures for conducting the patient and physician notification program, or your response, please contact Ms. Ratskoff at (301) 827-2980.

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

Enclosures:

1. Sample Physician Notification Letter
2. Sample Patient Notification Letter
3. List of FDA-certified facilities
4. Copy of 21 CFR §10.75 (Internal agency review of decisions)

cc: Jeffrey Rubin, Esq.
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Ms. Maryanne Harvey, Chief
Radiation Equipment Section
Bureau of Environmental Radiation Protection
New York State Health Department
547 River Street
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Mr. Joseph M. Aufrichtig, Assistant Director
Radiation Equipment Division
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New York City Health Department
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Ms. Priscilla F. Butler, M.S., FAAPM, FACR
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