



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

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August 13, 2004

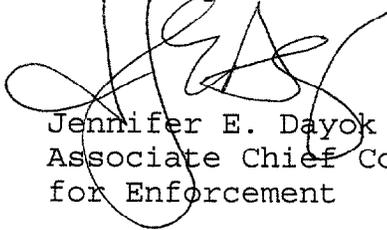
Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20857

Re: In re Korangy Radiology Associates, P.A., et al.
FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Complainant's Proposed Findings of Fact and Request for Cross-Examination. If you have any questions, please call me at (301) 827-5523. Thank you.

Sincerely,



Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz, Esq.

2003H-0432

FF 2

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of)
) FDA Docket: 2003H-0432
KORANGY RADIOLOGY ASSOCIATES, P. A.,)
trading as BALTIMORE IMAGING CENTERS,)
a corporation,)
)
and)
)
AMILE A. KORANGY, M.D.,)
an individual .)

COMPLAINANT'S PROPOSED FINDINGS OF FACT AND
REQUEST FOR CROSS-EXAMINATION

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), submits the following findings of fact pursuant to the Administrative Law Judge's Orders of November 13, 2003. Due to the May 27, 2004, Order granting Complainant's Motion for Partial Summary Judgment and finding Respondents Korangy Radiology Associates, P.A., and Amile Korangy, M.D. each liable for 193 violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, the following findings of fact are limited to issues relating to the amount of penalty to be imposed, including mitigating or aggravating factors, as set forth in 21 C.F.R. § 17.34.

FINDINGS OF FACT

THE MQSA'S RELATIONSHIP TO PUBLIC HEALTH

1. The effectiveness of mammography screening in the detection of breast cancer depends on consistently high-quality

mammograms. Declaration of Michael P. Divine, M.S. (Divine Decl.; attached as Ex. G-D to Complainant's Motion for Partial Summary Judgment (Complainant's Motion)).¹ Breast cancer is a leading cause of death among women in the United States. Id. Because successful treatment of breast cancer often depends on early detection, and because accurate mammograms can detect breast cancer two years before the patient or her doctor could feel a lump, high-quality mammography screening can greatly enhance the chances for survival. Id. On the other hand, low-quality screening can result in the failure to detect early lesions, delayed treatment, and an increased likelihood of death or mastectomy. Id.

2. The MQSA was enacted to establish uniform mammography standards and a certification process to ensure that only those mammography facilities providing high quality mammograms would remain in operation. See 62 Fed. Reg. 55852 (Oct. 28, 1997). The MQSA became effective on October 1, 1994. Id.

3. The MQSA was enacted in response to findings that the quality of mammography at certain facilities was inadequate, resulting in missed diagnoses of early lesions, delayed treatment, and otherwise avoidable increases in mortality. See 58 Fed. Reg. 67565 (Dec. 21, 1993). These concerns prompted the establishment of various private, state, and federal programs for

¹ Exhibits G-A through G-E along with their attachments, Exhibits G-1 through G-12, are attached to Complainant's Motion.

ensuring quality mammography. Id. These programs, however, suffered from several disadvantages. First, many of these programs were either voluntary, or they were mandatory but did not apply to all facilities in the United States. Id. Second, most of the programs lacked important mammography quality evaluation criteria or oversight mechanisms, such as clinical image review and on-site inspection of facilities. Id.

4. In order to rectify this situation, the MQSA was enacted to establish uniform, national quality standards for mammography. Id. The MQSA achieves this objective by making operation of a mammography facility contingent on the receipt of a certificate that the facility meets minimum mammography quality standards. Id. Thus, the success of the MQSA in ensuring safe, high-quality mammography services depends on, among other things, compliance with the certification requirement. Id.

KNOWLEDGE AND INTENT

5. Respondent Korangy Radiology Associates is a professional corporation organized and existing under the laws of the state of Maryland. See Answer of Respondents, Korangy Radiology Associates, P.A., T/A Baltimore Imaging Centers, and Amile A. Korangy, M.D. (Answer) ¶ 3.

6. Korangy Radiology Associates is engaged in the business of conducting mammography examinations, and it owns and operates a mammography facility doing business as Baltimore Imaging Centers (BIC) at 724 Maiden Choice Lane, Suite 102, Catonsville,

Maryland 21228. Id.

7. Respondent Amile A. Korangy, M.D., is the President, Director, and sole owner of Korangy Radiology Associates. See Ex. G-A, G-B, and G-C.

8. Dr. Korangy is also the Supervising Radiologist and Lead Interpreting Physician of the BIC mammography facility. Devince Decl. ¶ 17 and Ex. G-6 thereto; Declaration of Elizabeth A. Laudig (Laudig Decl.; attached as Ex. G-E to Complainant's Motion) ¶ 8.

9. Dr. Korangy directs the "day-to-day" operations of BIC and is responsible for maintaining BIC's certification under the MQSA. Laudig Decl. ¶ 8; Divine Decl. ¶ 17 and Ex. G-6 thereto. FDA issued a mammography certificate to Respondents on May 6, 1999. Divine Decl. ¶ 11 and Ex. G-4 thereto. The certificate, which enabled Respondents to lawfully perform mammography at the BIC facility, was scheduled to expire on May 6, 2002. Id. In fact, the May 6, 2002 expiration date was listed on the certificate itself. Ex. G-4.

10. FDA advised Respondents by letter dated April 1, 2002, that BIC's certificate would expire on May 6, 2002, unless BIC was re-accredited by an FDA-approved accreditation body. Divine Decl. ¶ 11 and Ex. G-1 thereto. The letter also informed Respondents that BIC could no longer perform mammography services after its certificate expired. Id.

11. FDA's April 1, 2002, letter was properly addressed. The

letter was sent by first-class mail and personally addressed to: Amile A. Korangy, M.D., Drs. Wityk, Goad, Korangy and Associates, 724 Maiden Choice Lane, Suite 102, Baltimore, MD 21228. Divine Decl. ¶ 11 and Ex. G-4 thereto. This address is the same one that is identified on BIC's certificate, which expired on May 6, 2002. Divine Decl. ¶ 14 and Ex. G-4 thereto. It is also the same address that Dr. Korangy identified as BIC's address in the facility's reinstatement application, which ultimately led to BIC's receipt of a provisional certificate on July 26, 2002. See Reinstatement Application at 3, 6-7 (attached to Divine Decl. as Ex. G-6). Dr. Korangy transmitted the reinstatement application to the American College of Radiology (ACR), an FDA-approved accreditation body, by letter dated July 22, 2002. Id. ¶ 17 and Ex. G-7 thereto. Dr. Korangy's letter was drafted on BIC stationary, which also identified BIC's address as 724 Maiden Choice Lane, Suite 102, Baltimore, MD 21228. Id.

12. By letter dated April 29, 2002, ACR informed Respondents that BIC failed to qualify for re-accreditation as a mammography facility. Id. ¶ 12 and Ex. G-2 thereto. As the basis for this decision, ACR found that the mammograms produced by BIC failed to comply with ACR's standards for clinical image quality. Id. ACR also strongly recommended that BIC immediately cease performing mammography examinations.² Id. In addition, ACR

² Although ACR denies accreditation when a facility fails to meet accreditation standards, FDA is charged by statute with bringing enforcement actions against entities and individuals

advised BIC that it could appeal the failure, but cautioned that an appeal might not be completed before BIC's certificate expired. Id. ACR then reminded Respondents of the statutory requirements, **"Furthermore, you may not lawfully conduct mammography if your MQSA certificate expires."** Id. (emphasis in original).

13. Dr. Korangy and BIC have acknowledged receipt of the April 29, 2002, letter. See Pre-Filed Direct Testimony of Amile A. Korangy, M.D. (Korangy Testimony) ¶ 11; Laudig Decl. ¶ 11 and Ex. G-11 thereto. In fact, Dr. Korangy discussed the April 29, 2002, letter from ACR with Barry J. Henderson, BIC's Vice President. Id. Dr. Korangy and Mr. Henderson decided that the mammograms produced by BIC were acceptable, and that BIC would continue to perform examinations. Id.

14. By letter dated May 1, 2002, FDA confirmed to Respondents that BIC had been denied accreditation due to its failure to meet ACR accreditation standards. Divine Decl. ¶ 13 and Ex. G-3 thereto. Accordingly, FDA advised that it was unable to recertify BIC as a mammography facility and instructed Respondents to cease performing mammography. Id.

15. It is undisputed that Respondents' representative received FDA's May 1, 2002, letter. See Respondents' Memorandum in Support of Opposition to Complainant's Motion ¶ 2. The letter was sent to Respondents via UPS Next Day Air service. Divine Decl. ¶ 13 and Ex. G-3 thereto. The UPS delivery notification

that violate the MQSA.

states that the letter was delivered on May 2, 2002, and was received by "Sonier," who signed for its receipt. Id. In a signed affidavit obtained by FDA investigators during an inspection of BIC, Barry J. Henderson, BIC's Vice President, admitted that an individual named "Sonier" signed for the receipt of the letter, and that Sonier is employed as a technician at BIC. Affidavit of Barry J. Henderson, dated September 3, 2002, at 8 (attached as Ex. G-11 to Laudig Decl.).

16. BIC's certificate expired on May 6, 2002. Divine Decl. ¶ 14 and Ex. G-4 thereto.

17. On July 22, 2002, Dr. Korangy applied for reinstatement of BIC's accreditation by submitting a reinstatement application to ACR. See Answer ¶ 16; Divine Decl. ¶ 17 and Ex. G-6 and G-7 thereto. In the application, Dr. Korangy indicated that BIC had corrected its clinical image deficiencies by, among other things, purchasing a new mammography unit. Divine Decl. ¶ 17 and Ex. G-6 and G-7 thereto.

18. On July 26, 2002, FDA issued a provisional certificate to BIC and informed Dr. Korangy that BIC was certified to lawfully provide mammography services. See Answer ¶ 17; Divine Decl. ¶ 19 and Ex. G-8 and G-9 thereto.

19. FDA investigators conducted an inspection of BIC during August 8, 12, 21-22, and September 3, 5-6, 2002. Laudig Decl. ¶ 5. During the inspection, investigators collected documents showing that, despite repeated notice of the certificate's

expiration and that they could not lawfully conduct mammograms without a certificate, Respondents conducted 192 mammography examinations while they were uncertified, between and including May 7, 2002, and July 25, 2002. Divine Decl. ¶ 21. Notably, approximately 165 of these examinations were conducted before the new mammography unit was installed on or about June 28, 2002. Id. ¶ 21 and Ex. G-10 thereto.

20. Respondents do not deny in their memorandum or supporting declarations that they knew their certificate expired on May 6, 2002.

ABILITY TO PAY

21. It is not clear from the exhibits submitted by Respondents what their financial circumstances are; there are many unanswered questions and the picture is incomplete.

22. Dr. Korangy has earned employment income of \$129,746 for 2001, \$147,000 for 2002, and \$116,025 for 2003. See Korangy Testimony ¶ 27 and Ex. R-5 thereto. However, Dr. Korangy reported adjusted gross income of \$17,009 for 2001 and \$165,477 for 2002. Korangy Testimony ¶ Ex. R-6 thereto.

23. BIC reported gross receipts of \$2,571,918 in 2001 and \$4,037,853 in 2002. BIC claimed a net loss of \$407,311 in 2001 and a net profit of \$188,364 in 2002, portions of both of which Dr. Korangy appears to have reported on his individual return. Korangy Testimony ¶¶ 22, 23, and 28 and Ex. R-2, R-3, and R-6 thereto.

24. Neither Dr. Korangy, nor BIC have submitted any documents to show income for 2003. Respondents' counsel has represented that Respondents filed for an extension to file their 2003 tax returns. The only document submitted by Respondents for 2003 is a profit and loss statement on BIC letterhead that is limited to the performance of mammography only. See Korangy Testimony Ex. R-4. The statement is not supported by any documentation and does not reflect the overall profit and loss of the corporation as a whole.

25. Also missing are any documents showing the overall assets and liabilities of either Dr. Korangy or BIC. While Dr. Korangy claims that he personally has no assets "that are of any significance in the sense that they are represented by a deed, certificate of title or other type of ownership document," see Korangy Testimony ¶ 32, there is nothing to show his net worth. BIC did not even make such a claim. According to BIC's letterhead, the corporation owns seven facilities throughout Maryland, which perform various procedures in addition to mammography. See, e.g., Korangy Testimony Ex. R-4. Moreover, Complainant has learned that Respondents have recently acquired new facility in Frederick, Maryland. See Ex. G-13 attached hereto. This business expansion suggests that the corporation is financially viable and has the ability to pay a fine.

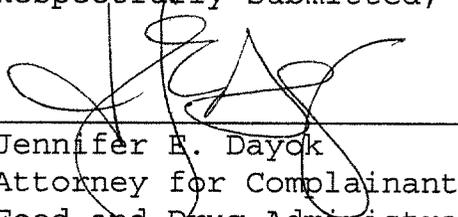
26. Complainant has recently requested that Respondents submit net worth statements listing assets and liabilities.

Respondents counsel has represented that these are forthcoming. Such statements should clarify the issue of Respondents' ability to pay.

REQUEST FOR CROSS-EXAMINATION

Complainant respectfully requests an opportunity to cross-examine Amile A. Korangy, M.D. and Barry Henderson. Complainant anticipates that cross-examination of Dr. Korangy will last for approximately 30 minutes and cross-examination of Mr. Henderson will last for approximately 20 minutes.

Respectfully submitted,

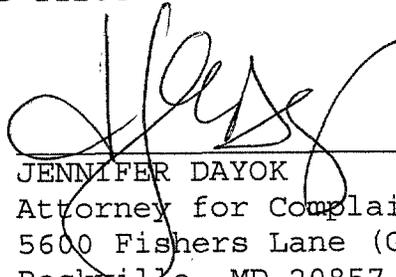


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CERTIFICATE OF SERVICE

I hereby certify that, on this 13th day of August, 2004, I have caused a copy of the foregoing COMPLAINANT'S PROPOSED FINDINGS OF FACT AND REQUEST FOR CROSS-EXAMINATION to be served by United States Mail, postage prepaid, on:

Henry E. Schwartz
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