



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

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

April 2, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration, Room 1061
5630 Fishers Lane
Rockville, MD 20852

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 Motion for Partial Summary Judgment and Complainant's Memorandum in Support of Motion for Partial Summary Judgment.

If you have any questions, please call me at (301) 827-7138. Thank you.

Sincerely yours,

Douglas A. Terry
Assistant Chief Counsel
for Enforcement

Enclosure

cc w/enc.:

Hon. Daniel J. Davidson, A.L.J.
Henry E. Schwartz
Thomas M. Jakub, CDRH
Louis J. Kaufman, CDRH
Heyward L. Rourk, CDRH
Michael P. Divine, CDRH
Pamela B. Schweikert, DCMO
Karen Schifter, OCC

2003H-0432

MD 5

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

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

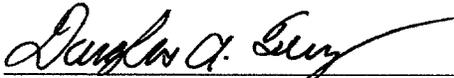
COMPLAINANT'S MOTION FOR
PARTIAL SUMMARY JUDGMENT

Complainant, the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services, moves for partial summary judgment on the issue of liability pursuant to 21 C.F.R. § 17.17. The ground for this motion is that, based on the undisputed facts, Respondents Korangy Radiology Associates, P.A., and Amile A. Korangy, M.D., performed mammography without a certificate in violation of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. Accordingly, summary judgment should be entered in favor of Complainant and against Respondents on the issue of liability.

A memorandum of law in support of this motion is attached.

DATED: April 2, 2004.

Respectfully submitted,



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UNITED STATES OF AMERICA
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a corporation,)	
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and)	FDA Docket: 2003H-0432
)	
AMILE A. KORANGY, M.D.,)	
an individual.)	

COMPLAINANT'S MEMORANDUM IN SUPPORT OF
MOTION FOR PARTIAL SUMMARY JUDGMENT

I. INTRODUCTION

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), brought this action for administrative civil money penalties against Respondents Korangy Radiology Associates, P.A. (Korangy Radiology Associates), the owner and operator of a mammography facility doing business as Baltimore Imaging Centers, and Amile A. Korangy, M.D., the President and owner of Korangy Radiology Associates and the Lead Interpreting Physician and Supervising Radiologist of Baltimore Imaging Centers. In the Complaint, Complainant alleges that Respondents conducted mammography examinations without proper certification in violation of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. Complainant has moved for partial summary judgment, pursuant to 21 C.F.R. § 17.17, on the issue of Respondents'

liability for these violations. Complainant is not now asking the Presiding Officer to determine the amount of the penalty; that determination can be resolved after further appropriate proceedings.

II. STATEMENT OF THE CASE

A. Respondents

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. 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.

Respondent Amile A. Korangy, M.D., is the President, Director, and sole owner of Korangy Radiology Associates. See Stock Purchase Agreement, dated October 30, 1998 (evidencing Dr. Korangy's purchase of all the outstanding shares of Drs. Wityk, Goad, Korangy & Associates, P.A., from two former shareholders) (Ex. G-A); Informal Action of the Stockholders and Board of Directors of Drs. Wityk, Goad, Korangy & Associates, P.A., dated October 30, 1998 (evidencing Dr. Korangy's appointment as President and Director of Drs. Wityk, Goad, Korangy & Associates,

P.A.) (Ex. G-B); Certified Copy of Articles of Amendment, Drs. Wityk, Goad, Korangy & Associates, P.A., dated December 10, 1998 (evidencing change of corporate name from Drs. Wityk, Goad, Korangy & Associates, P.A., to Korangy Radiology Associates, P.A.) (Ex. G-C). Dr. Korangy is also the Supervising Radiologist and Lead Interpreting Physician of the BIC mammography facility. Declaration of Michael P. Divine, M.S. (Divine Decl.; Ex. G-D) ¶ 17 and Ex. G-6 thereto at 1, 3, 6; Declaration of Elizabeth A. Laudig (Laudig Decl.; Ex. G-E) ¶ 8. 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.

B. Mammography And The MQSA

Breast cancer is a leading cause of death among women in the United States. See 62 Fed. Reg. 55852 (Oct. 28, 1997). 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. Prior to the enactment of the MQSA, there were no national mandatory standards for ensuring safe and reliable

mammography examinations. Id.

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. Id. The MQSA became effective on October 1, 1994. Id.

Under the MQSA, no mammography facility may conduct a mammography examination or procedure unless it possesses an effective certificate that has been issued or renewed under the MQSA. 42 U.S.C. § 263b(b)(1). In order to obtain or renew a certificate, the MQSA, and its implementing regulations, require a facility to apply to, and be accredited by, an FDA-approved accreditation body. 42 U.S.C. § 263b(d)(1)(A)(iv); 21 C.F.R. §§ 900.11(a) and (b). Once FDA receives notification of the accreditation body's decision to accredit a facility, FDA may issue a certificate to the facility or renew the facility's existing certificate. 21 C.F.R. § 900.11(b)(ii).

Where a previously certified facility has allowed its certificate to expire or has been refused a renewal, as in this case, the facility may apply to an accreditation body to have its certificate reinstated. 21 C.F.R. § 900.11(c). FDA may issue a provisional certificate to the facility once the accreditation body notifies FDA that the facility has corrected the deficiencies that led to the lapse of its certificate. 21 C.F.R.

§ 900.11(c)(2). A facility may lawfully perform mammography services once it receives a provisional certificate. 21 C.F.R. § 900.11(c)(3).

C. The BIC Mammography Facility

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, 2002.¹ Id. 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 once its certificate expired. Id.

By letter dated April 29, 2002, the American College of Radiology (ACR), an FDA-approved accreditation body, 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. Dr. Korangy

¹A certificate is effective for a period of three years after the date that it is issued or renewed. 42 U.S.C. § 263b(c)(1); Divine Decl. ¶ 9.

discussed the April 29, 2002, letter from ACR with Barry J. Henderson, BIC's Vice President. See Laudig Decl. ¶ 11 and Ex. G-11 thereto. Dr. Korangy and Mr. Henderson decided that the mammograms produced by BIC were acceptable, and that BIC would continue to perform examinations. Id.

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.

BIC's certificate expired on May 6, 2002. Divine Decl. ¶ 14 and Ex. G-4 thereto. On July 18, 2002, ACR sent a letter to Complainant describing ACR's concern that, despite its lack of certification, BIC was continuing to perform mammography. Id. ¶ 15 and Ex. G-5 thereto. As a result of this letter, Complainant contacted FDA's Baltimore District Office and requested that it conduct an inspection of BIC. Id. ¶ 16.

Respondents installed a new mammography unit in the BIC facility on or around June 28, 2002. Laudig Decl. ¶ 13 and Ex. G-12 thereto. Several weeks later, on July 22, 2002, Dr. Korangy applied for reinstatement of BIC's accreditation by submitting a

²Although ACR denies accreditation when a facility fails to meet accreditation standards, it is FDA that brings enforcement actions against entities and individuals that violate the MQSA. Divine Decl. ¶ 9.

reinstatement application to ACR. See Answer ¶ 16; Divine Decl. ¶ 17 and Exhibits 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 Exhibits G-6 and G-7 thereto. On July 24, 2002, ACR notified FDA that BIC's application for accreditation reinstatement was sufficiently complete for review, and that BIC was eligible for provisional reinstatement. Id. ¶ 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 Exhibits G-8 and G-9 thereto.

FDA investigators conducted an inspection of BIC during August 8, 12, 21-22, and September 3, 5-6, 2002. Laudig Decl. ¶ 5. The purpose of the inspection was to determine whether Respondents had performed mammography without a valid certificate. Id. During the inspection, the investigators collected documents for mammography examinations that Respondents conducted between May 7, 2002, and July 25, 2002, the period in which BIC was uncertified to perform mammography. Laudig Decl. ¶ 10; Divine Decl. ¶ 21 and Ex. G-10 thereto.³ These reports show that Respondents conducted 192 mammography examinations,

³Exhibit G-10 to the Divine Declaration consists of patient records that contain personal identifying information. Complainant has redacted this information in the copies filed with Dockets Management Branch.

while they were uncertified, between and including May 7, 2002, and July 25, 2002. Divine Decl. ¶ 21.

III. ARGUMENT

A. Standard For Summary Judgment

Under the regulations governing this action, "a party may move . . . for a summary decision on any issue in the hearing." 21 C.F.R. § 17.17(a) (emphasis added). The Presiding Officer "shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue of material fact and that the party is entitled to summary decision as a matter of law." 21 C.F.R. § 17.17(b).

Furthermore, where "a motion for summary decision is made and supported as provided in [21 C.F.R. § 17.17], a party opposing the motion may not rest on mere allegations or denials or general descriptions of positions and contentions; affidavits or other responses must set forth specific facts showing that there is a genuine issue of material fact for the hearing." 21 C.F.R. § 17.17(c).

Resolution of the liability issue before the hearing would promote the efficient resolution of this case by narrowing the issues requiring testimony to be considered at the hearing. Specifically, resolution of the liability issue would narrow the remaining issues to be considered to the amount of penalties for

which Respondents are liable.

B. Respondents Are Liable For Violations Of The MQSA As A Matter Of Law

No genuine issue of material fact exists as to whether Respondents Korangy Radiology Associates and Dr. Korangy violated the MQSA. Korangy Radiology Associates, doing business as BIC, conducted 192 mammography examinations between and including May 7, 2002, and July 25, 2002, while it was uncertified, in violation of 42 U.S.C. § 263b(b)(1). Dr. Korangy, as the most responsible person at Korangy Radiology Associates, is liable for the same violations. Alternatively, Dr. Korangy aided and abetted Korangy Radiology Associates in each of these violations. Respondents are liable for failing to obtain a certificate pursuant to 42 U.S.C. § 263b(h)(3)(A). In addition, Respondents are liable, pursuant to 42 U.S.C. § 263b(h)(3)(D), for 192 violations of the MQSA for conducting mammography examinations without a certificate, in violation of 42 U.S.C. § 263b(b)(1).

1. Korangy Radiology Associates Is Liable For 193 Violations Of The MQSA As A Matter Of Law

The MQSA, 42 U.S.C. § 263b(b)(1), provides that no mammography facility may conduct a mammography examination or procedure unless it possesses a certificate that has been issued or renewed under the MQSA.⁴ The MQSA places the duty of

⁴42 U.S.C. § 263b(b)(1) provides:

No facility may conduct an examination or procedure . . . involving mammography after October 1, 1994, unless the facility obtains -

obtaining a certificate upon the owner or lessee of the facility, or an authorized agent of either. 42 U.S.C. § 263b(d)(1). Under 42 U.S.C. § 263b(h)(3)(A), FDA may assess civil money penalties for a "failure to obtain a certificate as required by" 42 U.S.C. § 263b(b). Korangy Radiology Associates is the owner of the BIC facility. See Answer ¶ 3. Korangy Radiology Associates failed to obtain a certificate for the period between May 7, 2002, and July 25, 2002, during which BIC performed mammography in violation of 42 U.S.C. § 263b(b)(1). Divine Decl. ¶ 21 and Ex. G-10 thereto. Korangy Radiology Associates is therefore liable for a violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A).

Korangy Radiology Associates is also liable for conducting 192 mammography examinations while BIC was uncertified. Under 42 U.S.C. § 263b(h)(3)(D), FDA may assess civil money penalties in an amount not to exceed \$10,000 for each violation of, or for aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to

-
- (A) a certificate -
 - (i) that is issued, and if applicable, renewed, by the Secretary . . . ;
 - (ii) that is applicable to the examination or procedure to be conducted; and
 - (iii) that is displayed prominently in such facility; or

 - (B) a provisional certificate -
 - (i) that is issued by the Secretary . . . ;
 - (ii) that is applicable to the examination or procedure to be conducted; and
 - (iii) that is displayed prominently in such facility.

have a certificate.⁵ It is axiomatic that a corporation can act only through its officers and employees, whose actions are imputed to the corporation.⁶ The undisputed facts show that, between and including May 7, 2002, and July 25, 2002, Korangy Radiology Associates conducted 192 mammography examinations while the BIC mammography facility was uncertified, in violation of 42 U.S.C. § 263b(b) (1). Divine Decl. ¶ 21 and Ex. G-10 thereto. Accordingly, Korangy Radiology Associates is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (D).

⁵42 U.S.C. § 263b(h) (3) provides:

The Secretary [of Health and Human Services] may assess civil money penalties in an amount not to exceed \$10,000 for-

(A) failure to obtain a certificate as required by [Section 263b(b)],

* * * and

(D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

The Secretary of Health and Human Services has delegated his authority under the MQSA to the Commissioner of Food and Drugs. 21 C.F.R. § 5.10(a) (37). The authority to assess civil money penalties under the MQSA has been redelegated to various officials within FDA's CDRH. 21 C.F.R. § 5.1000(n).

⁶See, e.g., Magnum Foods, Inc. v. Continental Cas. Co., 36 F.3d 1491, 1499 (10th Cir. 1994) ("Since a corporation is only a legal entity, it cannot act or have a mental state by itself. It can act only through its officers and employees, and these acts are attributed to the corporation under basic principles of agency."); Conklin Bros. of Santa Rosa, Inc. v. United States, 986 F.2d 315, 318 (9th Cir. 1993) ("A corporation acts only through its agents and employees."); Shapo v. O'Shaughnessy, 246 F.Supp. 2d 935, 969 (N.D. Ill. 2002) ("There can be no doubt, however, that a corporation acts only through its directors, officers, and agents. A corporation is therefore liable for the intentional acts of its agents acting within the scope of his

2. Dr. Korangy Is Liable For 193 Violations Of The MQSA As A Matter Of Law

As noted, Korangy Radiology Associates is liable for 193 violations of the MQSA for performing mammography without a valid certificate. Dr. Korangy, as the sole owner and most responsible person at Korangy Radiology Associates, is also liable for these violations.

It is well established that responsible corporate officers are individually liable for violations of public health legislation. See United States v. Dotterweich, 320 U.S. 277, 285, 64 S.Ct. 134, 138 (1943) ("Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing an illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless."); United States v. Park, 421 U.S. 658, 672, 95 S.Ct. 1903, 1911 (1975) ("The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."); United States v. Hodges X-Ray, Inc., 759 F.2d 557, 560

authority.").

(6th Cir. 1985) ("[T]he Supreme Court decided that corporate officers could be held individually liable for violations of public health legislation.") (citing Park and Dotterweich); United States v. DeHaven and Assoc., Inc., No. 95-1177, 1996 U.S. Dist. LEXIS 22355, at *12 (E.D. La. Feb. 9, 1996) ("Corporate officers can be held individually liable for violations of public health legislation.") (also citing Park and Dotterweich).

Accordingly, a corporate officer who is in a position to prevent violations of statutes affecting public health is personally responsible for such violations:

[T]he Government establishes a prima facie case when it introduces evidence sufficient to warrant a finding by the trier of facts that the defendant had, by reason of his position in the corporation, responsibility and authority either to prevent in the first instance, or promptly to correct, the violation complained of, and that he failed to do so.

Park, 421 U.S. at 673-74, 95 S. Ct. at 1912; see also DeHaven and Assoc., Inc., 1996 U.S. Dist. LEXIS 22355, at *12 (quoting Park).

Dr. Korangy is the Supervising Radiologist and Lead Interpreting Physician of the BIC mammography facility. Divine Decl. ¶ 17 and Ex. G-6 thereto at 1, 3, 6; Laudig Decl. ¶ 8. Dr. Korangy is responsible for maintaining BIC's certification under the MQSA. Id. Dr. Korangy also directs the "day-to-day" operations of the facility. Laudig Decl. ¶ 8. Most importantly, Dr. Korangy is the President, Director, and sole owner of Korangy Radiology Associates, the owner of the BIC mammography facility.

Accordingly, Dr. Korangy has the authority to determine whether Korangy Radiology Associates, and its three physicians, continue to perform mammography. Laudig Decl. ¶ 11 and Ex. G-11 thereto; Divine Decl. ¶ 21. Dr. Korangy, by virtue of his position, had the authority to prevent Korangy Radiology Associates from performing uncertified mammography examinations in violation of 42 U.S.C. § 263b(b) (1). Because he failed to prevent these violations, Dr. Korangy is liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A) for failing to obtain a certificate. Dr. Korangy is also liable, as the owner of, and most responsible person at, Korangy Radiology Associates, for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (D), for his role in conducting 192 uncertified mammography examinations.

3. Alternatively, Dr. Korangy Is Liable For Violating The MQSA Because He Aided And Abetted Korangy Radiology Associates In Conducting Uncertified Mammography

As described above, FDA may assess civil money penalties for each violation of, or for each aiding and abetting in a violation of, any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate. 42 U.S.C. § 263b(h) (3) (D). A person is liable as an aider and abettor if (1) the underlying violation was committed by a principal; (2) the person knew of the violation; and (3) the person participated or assisted in the execution of the violation.⁷ In this case,

⁷Cf. United States v. Keene, 341 F.3d 78, 84 (1st Cir. 2003) ("A defendant may be convicted as an aider and abettor if the

Dr. Korangy aided and abetted Korangy Radiology Associates in conducting 192 examinations while the BIC facility was uncertified.

Korangy Radiology Associates conducted 192 mammography examinations without a valid certificate in violation of 42 U.S.C. § 263b(b)(1). Divine Decl. ¶ 21 and Ex. G-10 thereto. Dr. Korangy knew that Korangy Radiology Associates was performing mammography without a certificate. FDA advised Dr. Korangy by letter dated April 1, 2002, that BIC's certificate would expire on May 6, 2002, and that BIC could no longer perform mammography once the certificate expired. Divine Decl. ¶ 11 and Ex. G-1 thereto. By letter dated April 29, 2002, ACR informed Dr. Korangy that BIC failed to qualify for re-accreditation due to the poor clinical image quality of its mammograms. Id. ¶ 12 and

evidence shows: (1) that the underlying offense was committed by a principal; (2) that the defendant consciously shared the principal's knowledge; and (3) that he 'willfully associated himself in some way with the crime and willfully participated in it as he would in something he wished to bring about.'"); United States v. Ramirez-Velasquez, 322 F.3d 868, 880 (5th Cir. 2003) ("To establish aiding and abetting . . . , the government must show that the defendant (1) associated with a criminal venture, (2) participated in the venture, and (3) sought by action to make the venture successful."); United States v. Davis, 306 F.3d 398, 401 (6th Cir. 2002) ("To be convicted as an aider and abettor, the government had to prove that Defendant 'offered assistance or encouragement to his principal in the commission of a substantive offense.'"); United States v. Hunt, 272 F.3d 488, 493 (7th Cir. 2001) ("Aiding and abetting has three elements, requiring 'knowledge of the illegal activity that is being aided and abetted, a desire to help the activity succeed, and some act of helping.'") (all interpreting "aiding and abetting" under 18 U.S.C. § 2, which makes punishable as a principal one who aids or abets the commission of a federal offense).

Ex. G-2 thereto. Dr. Korangy decided to disregard the information from the accreditation body and continued to perform mammography. Laudig Decl. ¶ 11. By letter dated May 1, 2002, FDA confirmed to Dr. Korangy that it was unable to renew BIC's certificate due to BIC's failure to obtain accreditation.⁸ Divine Decl. ¶ 13 and Ex. G-3 thereto. In addition, BIC's certificate stated that it expired on May 6, 2002.⁹ Id. ¶ 14 and Ex. G-4 thereto. It is inconceivable that Dr. Korangy was unaware that BIC lacked certification between May 7, 2002, and July 25, 2002.

Dr. Korangy also participated and assisted in the performance of uncertified mammography examinations. Dr. Korangy himself read and interpreted the mammograms from at least 116 of the uncertified examinations. Divine Decl. ¶ 21 and Ex. G-10 thereto. The mammograms from the remaining uncertified examinations were read and interpreted by Irfan S. Shafique, M.D., and Robert J. Hage, D.O. Id. Dr. Korangy, however, remains liable for aiding and abetting with respect to these examinations because he possessed the authority to decide whether Drs. Shafique and Hage performed them.

Dr. Korangy knew of, and participated and assisted in, the

⁸A technologist at BIC named "Sonier" signed for the receipt of FDA's May 1, 2002, letter to Dr. Korangy. Laudig Decl. ¶ 12; Divine Decl. ¶ 13 and Ex. G-3 thereto.

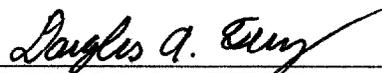
⁹The MQSA requires mammography facilities to prominently display

performance of mammography examinations while the BIC facility did not have a valid certificate. Dr. Korangy is the owner, operator, and an employee of Korangy Radiology Associates. Dr. Korangy aided and abetted Korangy Radiology Associates in conducting 192 mammography examinations while BIC was uncertified, in violation of 42 U.S.C. § 263b(b)(1). Dr. Korangy is therefore liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D), and for one violation of 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate.

IV. CONCLUSION

No genuine issue of material fact exists as to whether Korangy Radiology Associates and Dr. Korangy violated the MQSA. As a matter of law, Korangy Radiology Associates and Dr. Korangy are each liable for 193 violations of the MQSA. Accordingly, the Presiding Officer should grant summary judgment in favor of Complainant on the issue of Respondents' liability.

Respectfully submitted,



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their certificates. 42 U.S.C. § 263b(b)(1)(A)(iii).

CERTIFICATE OF SERVICE

I hereby certify that, on this second day of April, 2004, I have caused a copy of the foregoing Complainant's Motion For Partial Summary Judgment and Memorandum In Support Thereof to be served by Federal Express overnight delivery, on:

Henry E. Schwartz
Henry E. Schwartz LLC
Attorney for Respondents
901 Dulaney Valley Road, Suite 400
Towson, MD 21204



DOUGLAS A. TERRY
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