



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

May 21, 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 Reply To Respondents' Opposition To Complainant's Motion For Partial Summary Judgment and amended Proposed Findings Of Fact, Conclusions Of Law, And Order.

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  
Heyward L. Rourk, CDRH  
Michael P. Divine, CDRH

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

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In the Matter of )  
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KORANGY RADIOLOGY ASSOCIATES, P.A., ) FDA Docket: 2003H-0432  
trading as BALTIMORE IMAGING CENTERS,) )  
a corporation, )  
 )  
and )  
 )  
AMILE A. KORANGY, M.D., )  
an individual. )  
 )  
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COMPLAINANT'S REPLY TO RESPONDENTS' OPPOSITION  
TO COMPLAINANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), submits this Reply to Respondents' Opposition To Complainant's Motion For Partial Summary Judgment (Res. Mem.), which was filed on April 30, 2004.

Respondents make four primary arguments as to why the Presiding Officer should deny Complainant's Motion For Partial Summary Judgment. First, Respondents argue that they should not be held liable for violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, because they did not receive the letters from FDA warning them that their mammography certificate would expire on May 6, 2002, and instructing them to cease performing mammography. Res. Mem. at 1-2. Continuing on this argument, Respondents assert that they were unaware that FDA intended that they cease performing mammography. Id. at 2.

Second, Respondents argue that they cannot be held liable for each of the 192 uncertified mammography examinations that they conducted pursuant to 42 U.S.C. § 263b(h) (3) (D). Id. at 2-4. In support of this argument, Respondents claim that FDA may only assess civil money penalties for their conduct pursuant to 42 U.S.C. § 263b(h) (3) (A). Id.

Third, Respondents argue that Respondent Korangy Radiology Associates, P.A. (Korangy Radiology Associates), may not be held liable for its MQSA violations pursuant to 42 U.S.C. § 263b(h) (3) (D). Res. Mem. at 3-4. In support of this argument, Respondents contend that 42 U.S.C. § 263b(h) (3) (D) only applies to natural "individuals" and not to mammography facilities.

Finally, Respondents contend that Complainant is not permitted to assess penalties against both of them pursuant to 42 U.S.C. § 263b(h) (3) (D). Res. Mem. at 2.

As described below, none of these arguments is valid as a matter of law. Accordingly, Complainant's Motion For Partial Summary Judgment should be granted. An amended Proposed Findings of Fact, Conclusions of Law, and Order that addresses the issues raised in Respondents' Opposition is attached hereto (incorporating new paragraphs 46-95).

I. RESPONDENTS' ALLEGATION THAT THEY DID NOT RECEIVE FDA'S LETTERS IS NO DEFENSE TO THE MQSA VIOLATIONS.

Respondents have failed to raise a genuine issue of material fact or a valid legal defense in asserting that they did not

receive FDA's notices. As described in Complainant's Memorandum In Support Of Motion For Partial Summary Judgment (Complainant's Memorandum or Compl. Mem.), FDA advised Respondents by letter dated April 1, 2002, that the certificate issued to Respondents' mammography facility – Baltimore Imaging Centers (BIC) – was scheduled to expire on May 6, 2002, unless BIC was re-accredited by an FDA-approved accreditation body. Compl. Mem. at 5. The letter also informed Respondents that they could no longer perform mammography services once their certificate expired. Id. By letter dated May 1, 2002, FDA confirmed to Respondents that BIC had been denied accreditation due to its failure to meet the standards of its accreditation body, the American College of Radiology (ACR). Id. at 6. The letter also instructed Respondents to cease performing mammography. Id.

Respondents claim that they did not receive these letters, and that they were therefore unaware that they should cease performing mammography. Res. Mem. at 1-2, 4. As a matter of law, however, Respondents' claim, even if true, lacks legal significance. There is no requirement in the MQSA that FDA issue a prior warning. 42 U.S.C. § 263b et seq. Moreover, whether or not the individual Respondent, Dr. Korangy, actually read or recalls reading the FDA letters, the undisputed facts demonstrate that Respondents did receive FDA's May 1, 2002, letter, and that FDA properly addressed its April 1, 2002, letter. In addition,

Respondents do not deny that they were aware that their certificate had expired and that they were operating in violation of the MQSA. Finally, all persons, including Respondents, are presumed to know the law, and their alleged ignorance thereof does not constitute a valid defense. Accordingly, Respondents fail to create any genuine issue of material fact as to their liability under the MQSA.

A. The Undisputed Facts Demonstrate That Respondents Received Notice From FDA.

1. Respondents' Employee Received The May 1, 2002, Letter.

It is undisputed that Respondents' representative received FDA's May 1, 2002, letter. Declaration of Michael P. Divine (Divine Decl.; attached to Compl. Mem. as Ex. G-D) ¶ 13 and Ex. G-3 thereto; Declaration of Elizabeth A. Laudig (Laudig Decl.; attached as Ex. G-E to Compl. Mem.) ¶ 12 and Ex. G-11 thereto; Res. Mem. ¶ 2 at 1. That letter, which was addressed to Dr. Korangy and BIC, advised Respondents that FDA was unable to re-certify their facility because the facility had been denied accreditation by ACR. Divine Decl. ¶ 13 and Ex. G-3 thereto. The letter also instructed Respondents to cease performing mammography. Id.

FDA's May 1, 2002, letter was sent to Respondents via UPS Next Day Air service. Id. The UPS delivery notification 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.). Respondents do not dispute these facts. Res. Mem. ¶ 2 at 1.

Under well-established law, an employer is deemed to have received notice or knowledge that was acquired by an employee acting within the scope of her employment, regardless of whether the information was actually communicated to the employer.<sup>1</sup>

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<sup>1</sup>See, e.g., River Colony Estates Gen. P'ship v. Bayview Fin. Trading Group, Inc., 287 F. Supp. 2d 1213, 1227 (S.D. Cal. 2003) ("Under the doctrine of imputed knowledge a principal is charged with and is bound by the knowledge or notice received by his or her agent while the agent is acting within the scope of his or her authority. The law imputes the knowledge to the principal, regardless of whether the agent actually communicates the knowledge to the principal."); DGM Investments, Inc. v. New York Futures Exch., Inc., 265 F. Supp. 2d 254, 262 (S.D.N.Y. 2003) ("The general rule is that knowledge acquired by an agent acting within the scope of his agency is imputed to his principal and the latter is bound by such knowledge although the information is never actually communicated to it."); Associated Indem. Corp. v. Am. Ins. Co., 248 F. Supp. 2d 629, 649 (E.D. Mich. 2003) ("[I]f an employee of a corporation acquires knowledge within the scope of his employment, then that knowledge is imputed to the corporation"); Vigortone AG Products, Inc. v. PM AG Products, Inc., 217 F. Supp. 2d 858, 865 (N.D. Ill. 2001) ("Knowledge gained by a corporate agent while acting within the scope of his or her agency is normally imputed to the corporation if the knowledge concerns a matter within the scope of the agent's authority."); United States v. Josleyn, 206 F.3d 144, 159 (1st Cir. 2000) ("As to the legal principle, we clarify that there is no requirement that a person be a 'central figure' at a company

Accordingly, Respondents should be deemed to have received FDA's May 1, 2002, letter confirming that Respondents' facility failed the requirements for re-certification and instructing Respondents to cease performing mammography.

2. The April 1, 2002, Letter Was Properly Addressed.

FDA's April 1, 2002, letter was sent by first-class mail 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 letter was directed to the proper address. It is the same address 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 ACR 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,

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in order for that person's knowledge to be imputed to the company. The person whose knowledge is to be imputed must have some relationship to the company -- whether director, officer, agent, or employee -- which allows the person to obtain the knowledge in the course of the engagement with the company and within the scope of his or her authority." (citations omitted).

Baltimore, MD 21228.<sup>2</sup> Id.

Respondents argue, however, that the April 1, 2002, letter was sent to a "defunct corporate entity." Res. Mem. at 1. Respondents assert that Drs. Wityk, Goad, Korangy & Associates, P.A., was a corporate entity that preceded Respondent Korangy Radiology Associates, P.A, and that Respondents' office practice was to direct correspondence addressed to Drs. Wityk, Goad, Korangy & Associates, P.A., to the physicians who managed that corporation. Korangy Decl. ¶ 11. In other words, Respondents argue that the April 1 letter was sent to the wrong corporation.

Respondents' argument is flawed in two respects. As an initial matter, the letter was specifically addressed to Amile A. Korangy, M.D. It cannot be seriously contended that Dr. Korangy has no obligation to read mail that is specifically addressed to him. Thus, Dr. Korangy should not be permitted to claim lack of receipt of FDA's April 1 letter, even if the letter had been addressed to the wrong corporation.

The letter, however, was not addressed to the wrong corporation. Dr. Korangy purchased the entire interests of Dr.

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<sup>2</sup>As described above, FDA properly directed its April 1, 2002, letter to Dr. Korangy at 724 Maiden Choice Lane, Suite 102, Baltimore, MD 21228, because that was the address identified in BIC's accreditation materials, certificate, and stationary. In its Complaint, however, Complainant alleges that Respondents' place of business, and BIC's address, is 724 Maiden Choice Lane, Suite 102, Catonsville, Maryland 21228. Complaint ¶¶ 3-4. Although this is the address that BIC uses on its website, it is not the address it uses in all other circumstances.

Joseph J. Wityk and Dr. Francis A. Goad in Drs. Wityk, Goad, Korangy & Associates, P.A., on October 30, 1998. See Stock Purchase Agreement (attached as Ex. G-A to Compl. Mem.). Dr. Korangy changed the name of Drs. Wityk, Goad, Korangy & Associates, P.A., to Korangy Radiology Associates, P.A., by filing Articles of Amendment with the Maryland Department of Assessments and Taxation on December 10, 1998. See Articles of Amendment (attached as Ex. G-B to Compl. Mem.). Thus, rather than being a defunct corporate entity, Drs. Wityk, Goad, Korangy & Associates, P.A., is the same corporation as Korangy Radiology Associates, P.A.<sup>3</sup> Thus, FDA did direct its April 1, 2002, letter to the proper corporation. There is no legal significance to the fact that the letter was addressed to the corporation's former name, especially given that Respondents continued to employ that name in its dealings with FDA.<sup>4</sup> Accordingly, Respondents should

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<sup>3</sup>See 6 Fletcher Cyclopedia of Private Corp. § 2456 (2003) ("A mere change in the name of a corporation does not destroy the identity of the corporation, nor in any way affect its rights and liabilities. A change of a name by a corporation has no more effect upon the identity of the corporation than a change of name by a natural person has upon the identity of such person. It is the same corporation with a different name. The nature and character of the corporation does not change, nor do the rights and liabilities of its shareholders."); In the Matter of Torch, Inc., E.D. La. No. 94-2300, 1996 U.S. Dist. LEXIS 5053, at \*17 (E.D. La. April 16, 1996) ("The corporation, upon a change in its name, is in no sense a new corporation, nor the successor of the original one, but remains and continues to be the original corporation. It is the same corporation with a different name, and its character is in no respect changed.") (citations omitted).

<sup>4</sup>Indeed, Respondents' certificate, which expired on May 6, 2002,

not be able to rely on the fact that they refused to read mail addressed to Drs. Wityk, Goad, Korangy & Associates, P.A., and they should be deemed to have received FDA's April 1, 2002, letter.

Thus, Respondents received, at a minimum, constructive notice that their continued operation would violate the MQSA. Whether or not they had actual notice, the law is clear that no notice is necessary to hold Respondents accountable for their violations because they are presumed to know the law. Thus, Respondents' assertion that they were unaware that FDA intended that they cease performing mammography is immaterial and fails to create a genuine issue of material fact.

B. Even If Respondents Had Not Received Notice From FDA, Respondents Violated The MQSA.

It is well established that all persons are presumed to know the law, and that ignorance of the law is no defense to an action seeking redress for its violations.<sup>5</sup> The MQSA, 42 U.S.C.

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was issued to Drs. Wityk, Goad, Korangy & Associates. Divine Decl. ¶ 14 and Ex. G-4 thereto.

<sup>5</sup>See, e.g., 29 AM. JUR. 2D *Evidence* § 283 (2003) ("A rule frequently stated is that everyone is presumed to know the law, and this rule has been deemed applicable whether the law involved is state or federal. This presumption is merely a restatement of the substantive rule that ignorance of the law is not a defense, or excuses no one, or is wholly irrelevant."); Jet Line Services, Inc. v. M/V Marsa El Hariga, 462 F. Supp. 1165, 1176 (D. Md. 1978) ("It has frequently been stated that all persons are presumed to know the law of the land, regardless of whether the law involved is state or federal."); In re Chapman, 228 B.R. 899, 910 (Bankr. N.D. Ohio 1998) ("It is well established that all persons are presumed to know the law. Any conduct which violates

§ 263b(b) (1), provides that 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. Respondents do not, and cannot, dispute that they performed 192 mammography examinations after their certificate expired on May 6, 2002, but before they received a provisional certificate on July 26, 2002, permitting them to lawfully perform mammography. This fact – in and of itself – establishes Respondents' liability for the alleged violations of the MQSA.

Furthermore, it is undisputed that Respondents were on notice that their continued operation would violate the MQSA. Respondents admit that they received an April 29, 2002, letter from ACR, which advised them that BIC failed to qualify for re-accreditation due to the poor clinical image quality of its mammograms and strongly recommended that Respondents cease performing mammography. Declaration of Amile A. Korangy, M.D. (Korangy Decl.; attached to Res. Mem. as Ex. R-1) ¶ 7; Declaration of Barry Henderson (Henderson Decl.; attached to Res. Mem. as Ex. R-2) ¶ 3. In addition, Respondents' certificate explicitly stated that it expired on May 6, 2002. Compl. Mem. at 16. Thus, Respondents were on notice that they were violating the MQSA.

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the provisions of a law must be considered to have been done with knowledge of the fact that the conduct is unlawful.") (citations omitted).

Tellingly, Respondents do not deny in their memorandum or supporting declarations that they knew their certificate expired on May 6, 2002. Nor do Respondents deny that they conducted 192 mammography examinations after their certificate expired because of the poor image quality of their mammograms, but before they were re-certified on July 26, 2002. As a matter of law, this conduct constitutes a violation of 42 U.S.C. § 263b(b)(1) for which Respondents may be held liable, regardless of whether Respondents actually read the letters sent to them by FDA. Accordingly, Respondents' assertion that they were unaware that they should cease performing mammography, even if supported by the evidence, which it is not, does not create a valid legal defense.<sup>6</sup>

II. COMPLAINANT'S ASSESSMENT OF PENALTIES IS AUTHORIZED BY THE MQSA AND IS APPROPRIATE.

Respondents claim that Complainant has inappropriately utilized 42 U.S.C. § 263b(h)(3)(D) to assess penalties for

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<sup>6</sup>For the same reasons, Dr. Korangy may be held liable for aiding and abetting Korangy Radiology Associates in conducting 192 uncertified mammography examinations. Compl. Mem. at 16-17. As discussed above, it is undisputed that Dr. Korangy knew that Korangy Radiology Associates was performing mammography without a certificate. Despite Respondents' argument to the contrary, see Res. Mem. ¶ 5 at 4, Dr. Korangy did commit an "affirmative act contrary to law" – he read and interpreted the mammograms from at least 116 of the uncertified examinations, and he permitted the remaining uncertified examinations to be performed by other BIC physicians. Compl. Mem. at 16. As a matter of law, Dr. Korangy may be held liable for aiding and abetting Korangy Radiology Associates in performing uncertified mammography. Compl. Mem. at 16-17.

conduct that they consider to be solely violations of 42 U.S.C. § 263b(h) (3) (A). Res. Mem. at 2-3. Specifically, Respondents argue that Complainant's allegations concern Respondents' failure to obtain a certificate during the period between and including May 7, 2002, and July 25, 2002, during which Respondents conducted 192 mammography examinations. Res. Mem. at 2. Respondents assert that this conduct is specifically covered by the express terms of 42 U.S.C. § 263b(h) (3) (A), which permits FDA to assess civil money penalties for a "failure to obtain a certificate." Res. Mem. at 3. Respondents finally contend that 42 U.S.C. § 263b(h) (3) (A) would be rendered meaningless if Complainant is permitted to assess penalties, pursuant to 42 U.S.C. § 263b(h) (3) (D), for each uncertified examination that Respondents conducted. Id. at 3. Thus, Respondents argue that 42 U.S.C. § 263b(h) (3) (A) provides the exclusive remedy for their conduct.

Respondents' argument is flawed for two reasons. First, the plain language of the MQSA authorizes the penalties that Complainant seeks. Second, Respondents' argument relies on the mistaken assumption that 42 U.S.C. § 263b(h) (3) (A) provides the exclusive means for holding them responsible for their conduct.

A. Respondents Are Each Liable For 193 Violations Of The MQSA Pursuant To The Plain Language of 42 U.S.C. §§ 263b(h) (3) (A) and (D).

Under the most basic canon of statutory construction, the

plain meaning of a statute controls unless it would lead to absurd results.<sup>7</sup> As relevant to this case, 42 U.S.C.

§ 263b(h) (3) provides:

[FDA] 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. (Emphasis added).

As reflected by the plain meaning of the foregoing language, FDA may assess a penalty for a "failure to obtain a certificate as required by" 42 U.S.C. § 263b(b); and for each violation of any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

As discussed in Complainant's Memorandum, Respondents are liable for penalties pursuant to both 42 U.S.C. § 263b(h) (3) (A)

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<sup>7</sup>Cf. Siddiqui v. United States, 359 F.3d 1200, 1202 (9th Cir. 2004) ("The plain meaning of a statute is always controlling 'unless that meaning would lead to absurd results.'"); United States v. Jennings, 323 F.3d 263, 266-267 (4th Cir. 2003) ("The sole function of the courts is to enforce [the statute] according to its terms. Consequently, we cannot go beyond the plain meaning of the statute unless there is 'a clearly expressed legislative intent to the contrary, a literal application of the statute would thwart its obvious purpose, or a literal application of the statute would produce an absurd result.'"); Rhoads v. FDIC, 257 F.3d 373, 385 (4th Cir. 2001) ("[W]e recognize that 'under the most basic canon of statutory construction, we begin interpreting a statute by examining the literal and plain language of the statute.'" (citations omitted)).

and 42 U.S.C. § 263b(h) (3) (D). Compl. Mem. at 9-17. Respondents failed to obtain a certificate, as required by 42 U.S.C.

§ 263b(b), for the period between and including May 7, 2002, and July 25, 2002, during which Respondents performed mammography.

By its terms, 42 U.S.C. § 263b(h) (3) (A) authorizes FDA to assess a civil money penalty against each Respondent for their "failure to obtain a certificate."

In addition, 42 U.S.C. § 263b(h) (3) (D) plainly states that FDA may assess a penalty for each violation, 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.<sup>8</sup> In this case, the violation for which Complainant seeks to hold Respondents accountable is that of 42 U.S.C.

§ 263b(b) (1), which states:

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

(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 . . . ;

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<sup>8</sup>As discussed in Complainant's Memorandum, Respondent Korangy Radiology Associates is the owner and an operator of the BIC mammography facility. Compl. Mem. at 2, 10. Respondent Amile A. Korangy, M.D., is the sole owner of Korangy Radiology Associates, and an employee and operator of the BIC facility. Compl. Mem. at 2-3, 12-14, 16. Respondents do not dispute these facts. Res. Mem. ¶ 5 at 4.

- (ii) that is applicable to the examination or procedure to be conducted; and
- (iii) that is displayed prominently in such facility.

According to its literal terms, 42 U.S.C. § 263b(b) (1) is violated each time that "an examination or procedure" is conducted while a facility lacks an effective certificate. Respondents conducted 192 mammography examinations while their facility lacked a valid certificate, in violation of 42 U.S.C. § 263b(b) (1). Accordingly, Respondents are liable, pursuant to 42 U.S.C. § 263b(h) (3) (D), for 192 violations of 42 U.S.C. § 263b(b) (1). Based on its plain meaning, the MQSA authorizes the penalties that Complainant seeks to assess.

This interpretation does not lead to absurd results. In fact, it is entirely consistent with, and furthers the purposes of, the MQSA. The MQSA was enacted in response to findings that the quality of mammography at certain facilities was inadequate, resulting in missed diagnosis 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 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.

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 compliance with the certification requirement. Id.

The plain meaning interpretation of the MQSA provides to FDA a reasonable enforcement mechanism to penalize violations of the statute's most fundamental requirement – that a facility obtain a certificate to perform mammography. Under that interpretation, FDA may assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(A), for a failure to obtain a certificate during any period in which a facility performs uncertified mammography. It also permits FDA to assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(D), against a facility's owner, operator, and employee for each uncertified examination that the facility performs. The plain meaning interpretation encourages compliance with the certification requirement, provides to FDA the discretion to enforce the objectives of the MQSA, and does not lead to absurd results.

On the other hand, the interpretation urged by Respondents is inconsistent with the purposes of the statute and verges on absurdity. Under Respondents' proposed interpretation, FDA is only authorized to assess a civil money penalty for a failure to obtain a certificate in an amount not to exceed \$10,000, regardless of whether the facility performs one uncertified examination or 192 uncertified examinations. Clearly, Congress did not intend to limit the penalties for such egregious violations to a maximum amount of \$10,000 because this result is unlikely to provide a sufficient deterrent effect for failing to comply with the MQSA's basic certification requirement.

The penalties sought by Complainant comport with the plain meaning and objectives of the MQSA. As a matter of law, each Respondent is liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A), and for 192 violations pursuant to 42 U.S.C. § 263b(h) (3) (D).

- B. Respondents Incorrectly Assert That 42 U.S.C. § 263b(h) (3) (A) Provides The Exclusive Remedy For Their Conduct Because No Conflict Exists Between 42 U.S.C. § 263b(h) (3) (A) and 42 U.S.C. § 263b(h) (3) (D).

Respondents argue that Complainant has inappropriately utilized 42 U.S.C. § 263b(h) (3) (D) to assess penalties for violations that are based solely on 42 U.S.C. § 263b(h) (3) (A). Res. Mem. at 2. Respondents reason that Complainant's allegations involve Respondents' performance of mammography without a certificate. Id. at 3. Respondents assert that this

conduct is specifically and expressly addressed by 42 U.S.C. § 263b(h) (3) (A), which authorizes penalties for a "failure to obtain a certificate." Id. Respondents continue that, because their conduct is specifically addressed by 42 U.S.C. § 263b(h) (3) (A), it is not subject to 42 U.S.C. § 263b(h) (3) (D). Id.

Although not specifically articulated, Respondents appear to rely on the canon of statutory construction that provides that a specific statutory provision prevails over a general provision. Respondents essentially argue that the specific reference to "failure to obtain a certificate" in 42 U.S.C. § 263b(h) (3) (A) prevails over the general language in 42 U.S.C. § 263b(h) (3) (D), which authorizes penalties for any violation of the MQSA. Respondents' reliance on this rule, however, is misplaced because there is no irreconcilable conflict between the two provisions that would preclude Complainant from assessing penalties under both.

Specific and general provisions of a statute should be construed to give effect to both unless an irreconcilable conflict exists. This principle, in a similar context, is well illustrated in Padberg v. McGrath-McKenchie, 108 F. Supp. 2d 177 (E.D.N.Y. 2000). In Padberg, the New York City Taxi and Limousine Commission ("TLC") developed an initiative to penalize taxicab drivers who refused service for racially motivated

reasons. Padberg, 108 F. Supp. 2d at 179. To enforce this initiative, TLC began issuing summonses to taxicab drivers for service refusals under a specific rule and a general rule contained in the Rules of the City of New York. Id. at 180. The specific rule, 35 RCNY § 2-50(b), provided that "a driver shall not refuse by words, gestures, or any other means . . . to take any passenger to any destination within the City of New York . . . ." Id. at 179. A violation of 35 RCNY § 2-50(b) carried a maximum fine of \$350.00. Id. The general rule, 35 RCNY § 2-61(a)(2), prohibited "any willful act of omission or commission which is against the best interests of the public." Id. at 180. A violation of 35 RCNY § 2-61(a)(2) could result in license revocation. Id.

TLC observed the plaintiff, a taxicab driver, refuse to provide service to an African-American customer. Id. at 182. TLC issued two summonses to the plaintiff for violating both 35 RCNY § 2-50(b) and 35 RCNY § 2-61(a)(2) and revoked the plaintiff's license. Id. Seeking an injunction restoring his license, the plaintiff argued that he could not be penalized under the general rule of 35 RCNY § 2-61(a)(2) because his conduct was specifically covered by 35 RCNY § 2-50(b):

[The plaintiff] states correctly that under traditional principles of statutory construction, where two provisions purporting to cover the same matter are contradictory, the more specific will supplant the more general. He then claims that this principle requires the more specific § 2-50(b) to displace the more general § 2-61(a)(2) concerning the penalty for service

refusals.

Id. at 186.

The court rejected this argument, holding that "'the mere existence of a specific statute carrying a lighter penalty' does not by itself undermine the applicability of a more general rule, 'unless they cannot coexist independently.'" Id. (citation omitted). Finding that Sections 2-50(b) and 2-61(a)(2) did not contradict each other, the court concluded that the plaintiff's statutory construction argument was inapplicable. Id.

The court further held that it was appropriate for TLC to penalize the plaintiff under the general rule and the specific rule because the plaintiff's conduct fell within the scope of both rules:

Furthermore, [the plaintiff] ignores another principle of statutory construction: insofar as possible, statutes which cover the same matter should be construed together. In this case, § 2-61(a)(2) arguably applies to service refusals; indeed, at oral argument, [the plaintiff's] counsel conceded that a racially-motivated service refusal implicates the 'public welfare.' Since § 2-50(b) and § 2-61(a)(2) do not conflict, there appears to be no reason why TLC should not be permitted to penalize drivers who are found to have refused service under either rule. Therefore, [the plaintiff's] claim that TLC has acted unlawfully in revoking his license pursuant to § 2-61(a)(2) also fails to meet the 'likelihood of success' standard.

Id. (citation omitted).

The same analysis applies in this case. In particular, the terms of 42 U.S.C. § 263b(h)(3)(D) do not contradict the terms of

42 U.S.C. § 263b(h) (3) (A). As an initial matter, 42 U.S.C. § 263b(h) (3) provides that FDA may assess civil money penalties for (A) failure to obtain a certificate, and (D) each violation of, or for each aiding and abetting in a violation of, any provision of the MQSA. Pursuant to its literal language, the MQSA does not make 42 U.S.C. § 263b(h) (3) (A) the exclusive means for assessing penalties for performing uncertified mammography.

In addition, the two provisions can be construed in such a manner as to give effect to both. Under 42 U.S.C. § 263b(h) (3) (A), FDA may assess civil money penalties for a failure to obtain a certificate during any period in which a facility performs uncertified mammography. This interpretation in no manner contradicts 42 U.S.C. § 263b(h) (3) (D), which authorizes FDA to assess penalties for each violation of any provision of the MQSA, including 42 U.S.C. § 263b(b) (1). In short, Respondents' conduct falls within the scope of 42 U.S.C. §§ 263b(h) (3) (A) and 263b(h) (3) (D), and Respondents can be held liable under both provisions.

III. RESPONDENT KORANGY RADIOLOGY ASSOCIATES MAY BE HELD LIABLE FOR CIVIL MONEY PENALTIES UNDER 42 U.S.C. § 263b(h) (3) (D) BECAUSE IT IS THE OWNER AND AN OPERATOR OF THE BIC MAMMOGRAPHY FACILITY.

Respondents argue that Respondent Korangy Radiology Associates may not be held liable under 42 U.S.C. § 263b(h) (3) (D) because that provision only applies to natural individuals and not to facilities. Res. Mem. ¶ 4 at 3-4. In support,

Respondents explain that the term "facility" is defined under the MQSA as a "hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility . . . that conducts breast cancer screening or diagnosis through mammography activities." 42 U.S.C. § 263b(a)(3).

Respondents argue that "facilities" themselves are not subject to liability under 42 U.S.C. § 263b(h)(3)(D), which authorizes the assessment of penalties only against an "owner, operator, or any employee of a facility required to have a certificate." Res. Mem. ¶ 4 at 4. Respondents conclude that, because 42 U.S.C. § 263b(h)(3)(D) fails to specifically address the "facility" itself, the provision only applies to "individuals" having a connection to the facility. Id.

Respondents' argument reflects a misunderstanding of the structure and operation of the MQSA. As recognized by Respondents, 42 U.S.C. § 263b(b)(1) provides that no "facility" may conduct an examination or procedure unless it obtains an effective certificate that has been issued or renewed under the MQSA. The term "facility," however, is not defined to include legal entities to which FDA can assess a civil money penalty and collect a judgment. See 42 U.S.C. § 263b(a)(3) (e.g., a hospital, outpatient department, clinic, radiology practice, or mobile unit, or an office of a physician). Thus, the MQSA places liability for violations of the certification requirement on

those individuals and entities to which FDA can assess a civil money penalty and collect a judgment – i.e., the "owner, operator, or any employee of a facility required to have a certificate." 42 U.S.C. § 263b(h) (3) (D). Nothing in that definition limits the applicable class to natural persons.

It is undisputed that Korangy Radiology Associates is the owner and operator of the BIC mammography facility, which conducted 192 mammography examinations without a certificate in violation of 42 U.S.C. § 263b(b) (1). Korangy Radiology Associates, as the owner and operator of the facility, is therefore liable for 192 violations of 42 U.S.C. § 263b(b) (1), pursuant to 42 U.S.C. § 263b(h) (3) (D).

IV. COMPLAINANT MAY ASSESS PENALTIES AGAINST BOTH RESPONDENTS PURSUANT TO 42 U.S.C. § 263b(h) (3) (D).

A. The MQSA Authorizes Complainant To Assess Penalties Against Both Respondents For The Violations That Each Committed.

Respondents contend that Complainant is inappropriately utilizing 42 U.S.C. § 263b(h) (3) (D) to assess penalties totaling \$20,000 per violation, while that section only authorizes penalties in an amount not to exceed \$10,000 per violation. Res. Mem. ¶ 2 at 2. Respondents reason that Complainant is attempting to assess penalties totaling \$20,000 per violation by charging each Respondent for each MQSA violation under 42 U.S.C. § 263b(h) (3) (D). Id.

Respondents' argument overlooks the plain language of 42

U.S.C. § 263b(h) (3) (D), particularly the portion that defines the actors that may be subject to civil money penalties: i.e., "an owner, operator, or any employee of a facility required to have a certificate." Respondents' argument focuses solely on the "violation" portion of the statute and then concludes that there are two penalties for each individual violation. This conclusion, however, ignores the entire substance of 42 U.S.C. § 263b(h) (3) (D), which links the "violation" to the "owner, operator, or employee" that committed it. In short, Complainant is properly attempting to assess one penalty for each MQSA violation committed by each Respondent.

Respondents' interpretation is simply not permissible in light of the plain language of 42 U.S.C. § 263b(h) (3) (D). By its terms, that section permits FDA to assess penalties in an amount not to exceed \$10,000 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. Complainant seeks to assess penalties in an amount not to exceed \$10,000 against each Respondent for each violation of, or for each aiding and abetting in a violation of, the MQSA that each Respondent committed. The assessment of penalties in this manner is entirely consistent with the plain meaning of the statute.

B. The MQSA Authorizes Complainant To Assess Penalties For Violating, And Aiding And Abetting In Violations Of, The MQSA.

Finally, Respondents contend that Complainant is not permitted to assess penalties under 42 U.S.C. § 263b(h) (3) (D) both for violating the MQSA and for aiding and abetting in a violation of the MQSA. Res. Mem. ¶ 2 at 2. Respondents explain that 42 U.S.C. § 263b(h) (3) (D) provides that FDA "may assess civil money penalties in an amount not to exceed \$10,000 for . . . each violation, 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." (Emphasis added in Respondents' Memorandum.) Thus, Respondents argue that FDA may assess penalties for direct violations of the MQSA, or for aiding and abetting violations of the MQSA, but not for both. Res. Mem. ¶ 2 at 2. Respondents continue that, because Complainant seeks to assess penalties against Korangy Radiology Associates for violating the MQSA, it cannot assess penalties against Dr. Korangy for aiding and abetting violations of the MQSA. Id.

Respondents' argument fails for two reasons. First, the plain language of 42 U.S.C. § 263b(h) (3) (D) does not, as Respondents claim, place a limitation on FDA's ability to assess penalties for violating, or for aiding and abetting a violation

of, the MQSA. Rather, the provision simply clarifies that FDA may assess penalties against a facility's owner, operator, or employee that has violated, or aided and abetted in a violation of, any provision of the MQSA. Contrary to Respondents' argument, the provision enlarges the scope of conduct that gives rise to liability rather than diminishing it. In so doing, the provision authorizes FDA to hold responsible those owners, operators, and employees who are responsible for MQSA violations. Again, this result makes sense – it provides to FDA the authority to comprehensively enforce the MQSA and to encourage compliance with its requirements.

On the other hand, Respondents' interpretation would require that FDA ascertain the identity of the owner, operator, or employee that violated, or aided and abetted a violation of, the MQSA. FDA would then be required to choose between assessing penalties against: (1) the individuals or entities that violated the MQSA; or (2) the individuals or entities that aided and abetted in a violation of the MQSA. In either case, FDA would have to forego an action against responsible parties – either the direct violator or the aider and abettor. Respondents fail to explain how this seemingly arbitrary result makes sense.

Second, Respondents mistakenly assume that Dr. Korangy can only be held liable for aiding and abetting violations of the MQSA. As discussed above, Respondents incorrectly assert that

penalties can be assessed either for violating, or for aiding and abetting violations of, the MQSA. Based on this faulty premise, Respondents conclude that, because Complainant seeks to assess penalties against Korangy Radiology Associates, it cannot assess penalties against Dr. Korangy. Respondents therefore imply that Dr. Korangy may only be held liable for aiding and abetting violations of the MQSA.

As discussed in Complainant's Memorandum, however, Dr. Korangy, as the sole owner and most responsible person at Korangy Radiology Associates, is directly liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate. Compl. Mem. at 14. Dr. Korangy is also directly liable 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.<sup>9</sup> Id. Thus, Dr. Korangy remains liable for 193 violations of the MQSA, even if 42 U.S.C. § 263b(h)(3)(D) did preclude Complainant from assessing penalties for violating the MQSA and for aiding and abetting a violation of the MQSA.

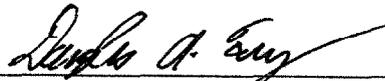
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<sup>9</sup>As discussed above, Dr. Korangy is directly liable for 193 violations of the MQSA. In the alternative, and as detailed in Complainant's Memorandum, Dr. Korangy is liable for 193 violations of the MQSA for aiding and abetting Korangy Radiology Associates in failing to obtain a certificate and in performing uncertified mammography. Compl. Mem. at 14-17.

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. For the reasons stated above and in Complainant's Memorandum, the Presiding Officer should grant summary judgment in favor of Complainant on the issue of Respondents' liability.

Respectfully submitted,

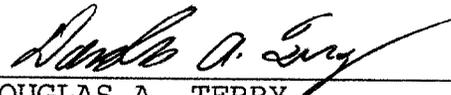


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**CERTIFICATE OF SERVICE**

I hereby certify that, on this 21st day of May, 2004, I have caused a copy of the foregoing Complainant's Reply To Respondents' Opposition To Complainant's Motion For Partial Summary Judgment and attached Proposed Findings Of Fact, Conclusions Of Law, And Order 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



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5600 Fishers Lane (GCF-1)  
Rockville, MD 20857

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

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

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PROPOSED FINDINGS OF FACT,  
CONCLUSIONS OF LAW, AND ORDER

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., and Amile A. Korangy, M.D., alleging violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. Complainant filed Complainant's Motion For Partial Summary Judgment (Complainant's Motion) on April 2, 2004, moving for partial summary judgment on the issue of Respondents' liability for these violations. Complainant's Motion having been fully briefed, the Presiding Officer now makes the following findings of fact and conclusions of law:

FINDINGS OF FACT

1. 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.

2. 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.

3. 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 (attached as Ex. G-A to Complainant's Motion); Informal Action of the Stockholders and Board of Directors of Drs. Wityk, Goad, Korangy & Associates, P.A., dated October 30, 1998 (attached as Ex. G-B to Complainant's Motion); Certified Copy of Articles of Amendment, Drs. Wityk, Goad, Korangy & Associates, P.A., dated December 10, 1998 (attached as Ex. G-C to Complainant's Motion).

4. 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.; attached as Ex. G-D to Complainant's Motion) ¶ 17 and Ex. G-6 thereto at 1, 3, 6; Declaration of Elizabeth A. Laudig (Laudig Decl.; attached as Ex. G-E to Complainant's Motion) ¶ 8.

5. 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.

6. 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.<sup>1</sup> Id.

7. 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.

8. 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.<sup>2</sup> Id.

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<sup>1</sup>A 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.

<sup>2</sup>Although 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.

9. Dr. Korangy 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.

10. 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.<sup>3</sup> 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.

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

12. 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.

13. Respondents installed a new mammography unit in the BIC facility on or around June 28, 2002. Laudig Decl. ¶ 13 and Ex. G-12 thereto.

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<sup>3</sup>A 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.

14. Several weeks later, 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 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. These reports show that Respondents conducted 192 mammography examinations, while they were uncertified, between and including May 7, 2002, and July 25, 2002. Divine Decl. ¶ 21.

#### CONCLUSIONS OF LAW

20. 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). 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).

21. 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).

22. 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.

23. 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).

24. 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).

25. 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).

26. No genuine issue of material fact exists as to whether

Respondents Korangy Radiology Associates and Dr. Korangy violated the MQSA.

27. The undisputed facts show that each Respondent is liable for 193 violations of the MQSA. Each Respondent is liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A), and for 192 violations pursuant to 42 U.S.C. § 263b(h) (3) (D).

A. Korangy Radiology Associates

1. Failure To Obtain A Certificate

28. 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).

29. The MQSA places the duty of obtaining a certificate upon the owner or lessee of the facility, or an authorized agent of either. 42 U.S.C. § 263b(d) (1).

30. Korangy Radiology Associates is the owner of the BIC facility.

31. Korangy Radiology Associates failed to obtain a certificate for the period between and including May 7, 2002, and July 25, 2002, during which BIC performed mammography in violation of 42 U.S.C. § 263b(b) (1). Korangy Radiology Associates is therefore liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A).

2. Performance Of 192 Uncertified Mammography Examinations

32. 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 have a certificate.

33. 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).

34. Accordingly, Korangy Radiology Associates is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (D).

B. Dr. Korangy

35. Dr. Korangy, as the sole owner and most responsible person at Korangy Radiology Associates, is liable for violating the MQSA to the same extent as Korangy Radiology Associates.

36. 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); United States v. Park, 421 U.S. 658, 672, 95 S.Ct. 1903, 1911 (1975); United States v. Hodges X-Ray, Inc., 759 F.2d 557, 560 (6th Cir. 1985); United States v. DeHaven and Assoc., Inc., No. 95-1177, 1996 U.S. Dist. LEXIS 22355, at \*12 (E.D. La. Feb. 9, 1996).

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

38. Dr. Korangy is the President, Director, and sole owner of Korangy Radiology Associates, the owner of the BIC mammography facility. Dr. Korangy has the authority to determine whether Korangy Radiology Associates, and its physicians, continue to perform mammography. 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).

39. Because he failed to prevent these violations, Dr. Korangy is liable for one (1) 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).

40. As an alternative ground for holding Dr. Korangy liable for 193 violations of the MQSA, Dr. Korangy aided and abetted Korangy Radiology Associates in failing to obtain a certificate and in performing 192 uncertified mammography examinations.

41. 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. Cf. United States v. Keene, 341 F.3d 78, 84 (1st Cir. 2003); United States v. Ramirez-Velasquez, 322 F.3d 868, 880 (5th Cir. 2003); United States v. Davis, 306 F.3d 398, 401 (6th Cir. 2002); United States v. Hunt, 272 F.3d 488, 493 (7th Cir. 2001) (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).

42. Dr. Korangy aided and abetted Korangy Radiology Associates in conducting 192 examinations while the BIC facility was uncertified, in violation of 42 U.S.C. § 263b(b)(1).

43. 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. 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. Dr. Korangy disregarded the information from the accreditation body and continued to perform mammography. 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. In addition, BIC's certificate stated that it expired on May 6, 2002. It is inconceivable that Dr. Korangy was unaware that BIC lacked certification between and including May 7, 2002, and July 25, 2002.

44. Dr. Korangy 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.

45. Dr. Korangy is liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D), and for one (1) violation pursuant to 42 U.S.C. § 263b(h)(3)(A) for failing to obtain a certificate.

RESPONDENTS HAVE FAILED TO  
CREATE A GENUINE ISSUE OF MATERIAL FACT

46. Respondents failed to create a genuine issue of material fact or raise a valid legal defense in Respondents' Opposition To Complainant's Motion For Partial Summary Judgment (Res. Mem.), which was filed on April 30, 2004.

A. Respondents' Allegation That They Did Not Receive FDA's Letters Is No Defense To The MQSA Violations.

1. The Undisputed Facts Demonstrate That Respondents Received Notice From FDA.

47. It is undisputed that Respondents' representative received FDA's May 1, 2002, letter. The letter was sent to Respondents via UPS Next Day Air service. Divine Decl. ¶ 13 and Ex. G-3 thereto. The UPS delivery notification 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.). Respondents do not dispute these facts. Res. Mem. ¶ 2 at 1.

48. Under well-established law, an employer is deemed to have received notice or knowledge that was acquired by an employee acting within the scope of her employment, regardless of whether the information was actually communicated to the employer. See, e.g., River Colony Estates Gen. P'ship v. Bayview Fin. Trading Group, Inc., 287 F. Supp. 2d 1213, 1227 (S.D. Cal. 2003); DGM Investments, Inc. v. New York Futures Exch., Inc., 265 F. Supp. 2d 254, 262 (S.D.N.Y. 2003); Associated Indem. Corp. v.

Am. Ins. Co., 248 F. Supp. 2d 629, 649 (E.D. Mich. 2003);  
Vigortone AG Products, Inc. v. PM AG Products, Inc., 217 F. Supp.  
2d 858, 865 (N.D. Ill. 2001); United States v. Josleyn, 206 F.3d  
144, 159 (1st Cir. 2000).

49. Accordingly, Respondents are deemed to have received FDA's May 1, 2002, letter confirming that Respondents' facility failed the requirements for re-certification and instructing them to cease performing mammography.

50. FDA's April 1, 2002, letter was properly addressed. The letter was sent by first-class mail 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 ACR 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.

51. Respondents' argument that they did not receive and read FDA's April 1, 2002, letter because it was sent to a "defunct corporate entity" is invalid. Res. Mem. at 1; Declaration of Amile A. Korangy, M.D. (Korangy Decl.; attached to Res. Mem. as Ex. R-1) ¶ 11. As an initial matter, the letter was specifically addressed to Amile A. Korangy, M.D. It cannot be seriously contended that Dr. Korangy has no obligation to read mail that is specifically addressed to him. Thus, Dr. Korangy may not claim lack of receipt of FDA's April 1 letter.

52. In addition, the letter was not was not addressed to a defunct corporate entity. Dr. Korangy purchased the entire interests of Dr. Joseph J. Wityk and Dr. Francis A. Goad in Drs. Wityk, Goad, Korangy & Associates, P.A., on October 30, 1998. See Stock Purchase Agreement (attached as Ex. G-A to Complainant's Motion). Dr. Korangy changed the name of Drs. Wityk, Goad, Korangy & Associates, P.A., to Korangy Radiology Associates, P.A., by filing Articles of Amendment with the Maryland Department of Assessments and Taxation on December 10, 1998. See Articles of Amendment (attached as Ex. G-B to Complainant's Motion). Thus, rather than being a defunct corporate entity, Drs. Wityk, Goad, Korangy & Associates, P.A., is the same corporation as Korangy Radiology Associates, P.A. See 6 Fletcher Cyclopedia of Private Corp. § 2456 (2003). FDA therefore directed its April 1, 2002, letter to the proper

corporation. There is no legal significance to the fact that the letter was addressed to the corporation's former name, especially given that Respondents continued to employ that name in its dealings with FDA. Accordingly, Respondents may not rely on the fact that they refused to read mail addressed to Drs. Wityk, Goad, Korangy & Associates, P.A., and they are deemed to have received FDA's April 1, 2002, letter.

53. Respondents received, at a minimum, constructive notice that their continued operation would violate the MQSA. Thus, Respondents' assertion that they were unaware that FDA intended that they cease performing mammography is immaterial and fails to create a genuine issue of material fact.

2. Even If Respondents Had Not Received Notice From FDA, Respondents Violated The MQSA.

54. It is well established that all persons are presumed to know the law, and that ignorance of the law is no defense to an action seeking redress for its violations. See, e.g., 29 AM. JUR. 2D Evidence § 283 (2003); Jet Line Services, Inc. v. M/V Marsa El Hariga, 462 F. Supp. 1165, 1176 (D. Md. 1978); In re Chapman, 228 B.R. 899, 910 (Bankr. N.D. Ohio 1998).

55. The MQSA, 42 U.S.C. § 263b(b)(1), provides that 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.

56. Respondents do not dispute that they performed 192

mammography examinations after their certificate expired on May 6, 2002, but before they received a provisional certificate on July 26, 2002, permitting them to lawfully perform mammography. This fact – in and of itself – establishes Respondents' liability for the alleged violations of the MQSA.

57. Furthermore, it is undisputed that Respondents were on notice that their continued operation would violate the MQSA. Respondents admit that they received an April 29, 2002, letter from ACR, which advised them that BIC failed to qualify for re-accreditation due to the poor clinical image quality of its mammograms and strongly recommended that Respondents cease performing mammography. Korangy Decl. ¶ 7; Declaration of Barry Henderson (Henderson Decl.; attached to Res. Mem. as Ex. R-2) ¶ 3. In addition, Respondents' certificate explicitly stated that it expired on May 6, 2002. Divine Decl. ¶ 11 and Ex. G-4 thereto. Thus, Respondents were on notice that they were violating the MQSA.

58. Respondents do not deny in their memorandum or supporting declarations that they knew their certificate expired on May 6, 2002. Nor do Respondents deny that they conducted 192 mammography examinations after their certificate expired because of the poor image quality of their mammograms, but before they were re-certified on July 26, 2002. As a matter of law, this conduct constitutes a violation of 42 U.S.C. § 263b(b)(1) for

which Respondents may be held liable, regardless of whether Respondents actually read the letters sent to them by FDA.

59. Accordingly, Respondents' assertion that they were unaware that they should cease performing mammography does not create a valid legal defense.

B. Complainant's Assessment Of Penalties Is Authorized By The MQSA And Is Appropriate.

1. Respondents Are Each Liable For 193 Violations Of The MQSA Pursuant To The Plain Language of 42 U.S.C. §§ 263b(h) (3) (A) and (D).

60. Under the most basic canon of statutory construction, the plain meaning of a statute controls unless it would lead to absurd results. Cf. Siddiqui v. United States, 359 F.3d 1200, 1202 (9th Cir. 2004); United States v. Jennings, 323 F.3d 263, 266-267 (4th Cir. 2003); Rhoads v. FDIC, 257 F.3d 373, 385 (4th Cir. 2001).

61. As relevant to this case, 42 U.S.C. § 263b(h) (3) provides:

[FDA] 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. (Emphasis added).

62. Under the plain meaning of the foregoing language, FDA may assess a penalty for a "failure to obtain a certificate as

required by" 42 U.S.C. § 263b(b); and for each violation of any provision of the MQSA by an owner, operator, or any employee of a facility required to have a certificate.

63. As discussed above, Respondents are liable for penalties pursuant to both 42 U.S.C. § 263b(h) (3) (A) and 42 U.S.C. § 263b(h) (3) (D). Respondents failed to obtain a certificate, as required by 42 U.S.C. § 263b(b), for the period between and including May 7, 2002, and July 25, 2002, during which Respondents performed mammography. By its terms, 42 U.S.C. § 263b(h) (3) (A) authorizes FDA to assess a civil money penalty against each Respondent for their "failure to obtain a certificate."

64. In addition, 42 U.S.C. § 263b(h) (3) (D) plainly states that FDA may assess a penalty for each violation, 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.

65. In this case, the violation for which Complainant seeks to hold Respondents accountable is that of 42 U.S.C. § 263b(b) (1), which states:

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

- (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.

66. According to its literal terms, 42 U.S.C. § 263b(b) (1) is violated each time that "an examination or procedure" is conducted while a facility lacks an effective certificate.

67. Respondents conducted 192 mammography examinations while their facility lacked a valid certificate, in violation of 42 U.S.C. § 263b(b) (1).

68. Accordingly, Respondents are liable, pursuant to 42 U.S.C. § 263b(h) (3) (D), for 192 violations of 42 U.S.C. § 263b(b) (1).

69. This interpretation does not lead to absurd results. In fact, it is entirely consistent with, and furthers the purposes of, the MQSA. The MQSA was enacted in response to findings that the quality of mammography at certain facilities was inadequate, resulting in missed diagnosis 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 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.

70. 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 compliance with the certification requirement. Id.

71. The plain meaning interpretation of the MQSA provides to FDA a reasonable enforcement mechanism to penalize violations of the statute's most fundamental requirement – that a facility obtain a certificate to perform mammography. Under that interpretation, FDA may assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(A), for a failure to obtain a certificate during any period in which a facility performs uncertified mammography. It also permits FDA to assess penalties, pursuant to 42 U.S.C. § 263b(h)(3)(D), against a facility's owner, operator, and employee for each uncertified examination that the facility performs. The plain meaning interpretation encourages compliance

with the certification requirement, provides to FDA the discretion to enforce the objectives of the MQSA, and does not lead to absurd results.

72. On the other hand, the interpretation urged by Respondents is inconsistent with the purposes of the statute and verges on absurdity. Under Respondents' proposed interpretation, FDA is only authorized to assess a civil money penalty for a failure to obtain a certificate in an amount not to exceed \$10,000, regardless of whether the facility performs one uncertified examination or 192 uncertified examinations. Clearly, Congress did not intend to limit the penalties for such egregious violations to a maximum amount of \$10,000 because this result is unlikely to provide a sufficient deterrent effect for failing to comply with the MQSA's basic certification requirement.

73. The penalties sought by Complainant comport with the plain meaning and objectives of the MQSA. As a matter of law, each Respondent is liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A), and for 192 violations pursuant to 42 U.S.C. § 263b(h)(3)(D).

2. 42 U.S.C. § 263b(h)(3)(A) Does Not Provide The Exclusive Remedy For Respondents' Conduct.

74. Respondents contend that Complainant has inappropriately utilized 42 U.S.C. § 263b(h)(3)(D) to assess penalties for violations that are based solely on 42 U.S.C.

§ 263b(h) (3) (A). Res. Mem. at 2. Respondents essentially argue that the specific reference to "failure to obtain a certificate" in 42 U.S.C. § 263b(h) (3) (A) prevails over the general language in 42 U.S.C. § 263b(h) (3) (D), which authorizes penalties for any violation of the MQSA. Id. at 2-3.

75. Specific and general provisions of a statute should be construed to give effect to both unless an irreconcilable conflict exists. See, e.g., Padberg v. McGrath-McKenchie, 108 F. Supp. 2d 177, 186 (E.D.N.Y. 2000).

76. The terms of 42 U.S.C. § 263b(h) (3) (D) do not conflict with the terms of 42 U.S.C. § 263b(h) (3) (A). As an initial matter, 42 U.S.C. § 263b(h) (3) provides that FDA may assess civil money penalties for (A) failure to obtain a certificate, and (D) each violation of, or for each aiding and abetting in a violation of, any provision of the MQSA. Pursuant to its literal language, the MQSA does not make 42 U.S.C. § 263b(h) (3) (A) the exclusive means for assessing penalties for performing uncertified mammography.

77. In addition, the two provisions can be construed in such a manner as to give effect to both. Under 42 U.S.C. § 263b(h) (3) (A), FDA may assess civil money penalties for a failure to obtain a certificate during any period in which a facility performs uncertified mammography. This interpretation in no manner contradicts 42 U.S.C. § 263b(h) (3) (D), which

authorizes FDA to assess penalties for each violation of any provision of the MQSA, including 42 U.S.C. § 263b(b) (1).

78. Respondents' conduct falls within the scope of 42 U.S.C. §§ 263b(h) (3) (A) and 263b(h) (3) (D), and Respondents can be held liable under both provisions.

.C. Respondent Korangy Radiology Associates May Be Held Liable For Civil Money Penalties Under 42 U.S.C. § 263b(h) (3) (D) Because It Is The Owner And Operator Of The BIC Mammography Facility.

79. Respondents' incorrectly assert that 42 U.S.C. § 263b(h) (3) (D) applies only to natural individuals and not to legal entities. Res. Mem. ¶ 4 at 3-4.

80. The term "facility" is defined under the MQSA as a "hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility . . . that conducts breast cancer screening or diagnosis through mammography activities." 42 U.S.C. § 263b(a) (3).

81. The MQSA, 42 U.S.C. § 263b(b) (1), provides that no "facility" may conduct an examination or procedure unless it obtains an effective certificate that has been issued or renewed under the MQSA.

82. The term "facility," however, is not defined to include legal entities to which FDA can assess a civil money penalty and collect a judgment. See 42 U.S.C. § 263b(a) (3) (e.g., a hospital, outpatient department, clinic, radiology practice, or mobile unit, or an office of a physician).

83. Thus, the MQSA places liability for violations of the certification requirement on those individuals and entities to which FDA can assess a civil money penalty and collect a judgment — i.e., the "owner, operator, or any employee of a facility required to have a certificate." 42 U.S.C. § 263b(h) (3) (D). Nothing in that definition limits the applicable class to natural persons.

84. It is undisputed that Korangy Radiology Associates is the owner and operator of the BIC mammography facility, which conducted 192 mammography examinations without a certificate in violation of 42 U.S.C. § 263b(b) (1).

85. Korangy Radiology Associates, as the owner and operator of the facility, is therefore liable for 192 violations of 42 U.S.C. § 263b(b) (1), pursuant to 42 U.S.C. § 263b(h) (3) (D).

D. Complainant May Assess Penalties Against Both Respondents Pursuant To 42 U.S.C. § 263b(h) (3) (D).

1. The MQSA Authorizes Complainant To Assess Penalties Against Both Respondents For The Violations That Each Committed.

86. The plain language of 42 U.S.C. § 263b(h) (3) (D) defines the actors that may be subject to civil money penalties: i.e., "an owner, operator, or any employee of a facility required to have a certificate."

87. The provision links the MQSA "violation" to the "owner, operator, or employee" that committed it.

88. By its terms, 42 U.S.C. § 263b(h) (3) (D) permits FDA to

assess penalties in an amount not to exceed \$10,000 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.

89. Complainant seeks to assess penalties in an amount not to exceed \$10,000 against each Respondent for each violation of, or for each aiding and abetting in a violation of, the MQSA that each Respondent committed.

90. The assessment of penalties in this manner is entirely consistent with the plain meaning of the statute.

2. The MQSA Authorizes Complainant To Assess Penalties For Violating, And Aiding And Abetting In Violations Of, The MQSA.

91. Respondents mistakenly argue that Complainant is not permitted to assess penalties under 42 U.S.C. § 263b(h)(3)(D) both for violating the MQSA and for aiding and abetting in a violation of the MQSA. Res. Mem. ¶ 2 at 2.

92. The plain language of 42 U.S.C. § 263b(h)(3)(D) does not, as Respondents claim, place a limitation on FDA's ability to assess penalties for violating, or for aiding and abetting a violation of, the MQSA. Rather, the provision simply clarifies that FDA may assess penalties against a facility's owner, operator, or employee that has violated, or aided and abetted in a violation of, any provision of the MQSA. Contrary to Respondents' argument, the provision enlarges the scope of

conduct that gives rise to liability rather than diminishing it. In so doing, the provision authorizes FDA to hold responsible those owners, operators, and employees who are responsible for MQSA violations. This result makes sense – it provides to FDA the authority to comprehensively enforce the MQSA and to encourage compliance with its requirements.

93. On the other hand, Respondents' interpretation would require that FDA ascertain the identity of the owner, operator, or employee that violated, or aided and abetted a violation of, the MQSA. FDA would then be required to choose between assessing penalties against: (1) the individuals or entities that violated the MQSA; or (2) the individuals or entities that aided and abetted in a violation of the MQSA. In either case, FDA would have to forego an action against responsible parties – either the direct violator or the aider and abettor. Respondents fail to explain how this arbitrary result makes sense.

#### CONCLUSION

94. No genuine issue of material fact exists as to whether Korangy Radiology Associates and Dr. Korangy violated the MQSA.

95. As a matter of law, Korangy Radiology Associates and Dr. Korangy are each liable for 193 violations of the MQSA.

\* \* \*

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:

Complainant's Motion For Partial Summary Judgment is  
GRANTED;

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for one (1) violation of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (A);

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h) (3) (D); and thus

Respondents Korangy Radiology Associates and Dr. Korangy are each liable for 193 violations of the MQSA.

Further appropriate proceedings regarding the appropriate amount of the penalties will follow.

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