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April 30, 2004

VIA HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1051
Rockville, Maryland 20852

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

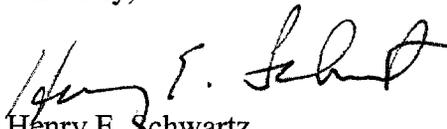
Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of the following documents:

- a. Opposition of Respondents to Complainant's Motion for Partial Summary Judgment;
- b. Memorandum in Support of Opposition of Respondents to Complainant's Motion for Partial Summary Judgment; and
- c. Proposed Order.

Thank you for your attention to this filing. Please contact me with any questions.

Sincerely,


Henry E. Schwartz

Enclosures

cc: Amile Korangy, M.D.
Douglas A. Terry, Esquire
Hon. Daniel J. Davidson, ALJ

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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 *

KORANGY RADIOLOGY ASSOCIATES, P.A., * ADMINISTRATIVE
Trading as BALTIMORE IMAGING CENTERS, * COMPLAINT FOR
A corporation, * CIVIL MONEY PENALTY

And FDA Docket: 2003H-0432

AMILE A. KORANGY, M.D., *
An individual *

* * * * *

**MEMORANDUM IN SUPPORT OF OPPOSITION OF RESPONDENTS
TO COMPLAINANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

Respondents, Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers ("BIC") and Amile A. Korangy, M.D. ("Dr. Korangy"), by their attorneys, Henry E. Schwartz, and Henry E. Schwartz LLC, oppose Complainant's Motion for Partial Summary Judgment for the reasons stated herein.

A. Factual Disputes.

1. Respondents did not receive the letter of April 1, 2002, allegedly sent by FDA. Declaration of Amile Korangy, M.D. (Korangy Decl.; Ex. R-1). This letter was addressed to a defunct corporate entity, and there is no record of anyone representing the Respondents having received this letter. (Ex. R-1). Dr. Korangy never received a copy of this letter. (Ex. R-1).

2. Respondents did not receive the letter of May 1, 2002, allegedly sent by FDA. (Korangy Decl.; Ex. R-1). There is no record of anyone representing the Respondents having received this letter, other than a signature of an individual who may have been employed as a radiology technician. (Ex. R-1). Dr. Korangy never received a copy of this letter. (Ex. R-1).

3. Dr. Korangy and Mr. Barry Henderson did not decide, as alleged by FDA, that the quality of the pre-existing mammography equipment was acceptable. In fact, Dr. Korangy ordered a replacement machine in March of 2002. (Korangy Decl.; Ex. R-1); Declaration of Barry Henderson (Henderson Decl.; Ex. R-2). Mr. Henderson did not tell FDA investigators that he and Dr. Korangy determined that the quality of the pre-existing mammography equipment was acceptable. (Ex. R-2).

4. Respondents contacted Complainant's agent, American College of Radiology ("ACR") on two occasions in May, 2002, for the purpose of reporting the purchase of a new mammography machine, and to obtain clarification of the process required to maintain certification to perform mammography procedures, and in neither conversation did ACR inform Respondents that Baltimore Imaging Centers was to have ceased performing mammography procedures on May 6, 2002. (Korangy Decl.; Ex. R-1).

5. Respondents took their existing mammography equipment out of service in May of 2002, and replaced it at that time with the equipment ordered in March, 2002. (Korangy Decl.; Ex. R-1).

6. Respondents believed, in May, June and July of 2002, that they were following ACR and FDA procedures in replacing their existing mammography equipment with new equipment, and were unaware that FDA intended that they cease performing mammography services. (Korangy Decl.; Ex. R-1). Prior to July of 2002, Respondents had received no notice from FDA indicating that they should cease and desist mammography, nor had ACR indicated to them, orally or otherwise, to that effect. (Ex. R-1).

B. Legal Disputes.

1. Respondents did not receive a written communication from FDA indicating that they would be in legal violation to continue to perform mammography during the time period in question, nor were they so informed by FDA's agent, American College of Radiology, when Respondents telephoned them for advice on the matter. Therefore, Respondents did not operate mammography equipment in the face of orders or instructions to cease and desist. In fact, Respondents believed that they were complying with FDA requirements through reporting to ACR their acquisition of new mammography equipment prior to any final determination by ACR or FDA.

2. Complainant has inappropriately utilized 42 USC 263b(h)(3) to levy fines totaling \$20,000 per "incident," when the statute limits any such fines to \$10,000 per "incident." 42 USC 263b(h)(3)(D) states that fines may be levied for "each violation, or for each aiding and abetting in a violation ..." (Emphasis added). The statute expressly provides that fines "not to exceed" \$10,000 are authorized. 42 USC 263b(h)(3). Therefore, all 193 charges against one Respondent should be denied on this basis. For the reasons stated below in paragraph 5, the charges against Respondent Korangy should be denied.

3. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) as a basis for levying fines that are based solely on alleged violations of 42 USC 263b(h)(3)(A), and are therefore limited by statute to a total of \$10,000 for "failure to obtain a certificate." Therefore, 192 counts against each Respondent should be denied on this basis.

The pertinent parts of Section (h)(3) are provided:

“(3) Civil money penalties

The Secretary may assess civil money penalties in an amount not to exceed \$10,000 for --

(A) failure to obtain a certificate as required by subsection (b) of this section,

...

(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.”

Clearly, Congress singled out, in subsection (3)(A), the failure to obtain a certificate, as an offense to be treated separately, as it is the only specific offense that merited its own subsection of the Act, or even any specific mention in the civil money penalties section of the Act. Clearly, Respondents are each charged with a violation of (3)(A), as operation of mammography equipment accurately describes the acts that create the offenses alleged in the Complaint in the instant case.

Complainants have attempted to utilize subsection (3)(D) to create 384 (192 x 2) additional punishable offenses out of the same act that created the alleged violation of subsection (3)(A). If we assume, arguendo, that the Respondents did operate mammography equipment without a certificate, as alleged by Complainants, their offenses are fully described by the express terms of subsection (3)(A). Complainants would presumably read subsection (3)(D) to allow additional penalties for “each violation” of the FDA regulations - read each time a piece of equipment is used without certification being properly in place. This argument fails on three bases. First, it would elevate FDA regulations above the express terms of the Act itself - by creating multiple penalties for an act limited to one fine by statute. Second, it would render meaningless section (b)(2) of the Act, which requires that a facility obtain a certificate “in order to” operate radiological equipment to image breasts, provide for interpretations of mammograms, and provide for the processing of mammography film. In other words, the offense under the Act is not owning mammography equipment without a certificate - it is using mammography equipment without a certificate. Therefore, the “failing to obtain a certificate” under subsection (3)(A) can only be an offense if the equipment is actually used, and to charge a separate violation for each use of the equipment under subsection (3)(D), is to render the terms of subsection (3)(A) meaningless. Third, such a reading would fly against the plain wording of the Mammography Act, in that subsection (3)(A) specifically creates one maximum \$10,000 fine for failure to obtain a certificate. Attempting to expand this penalty to each time the equipment in question is used for a procedure would render meaningless Congress’ express treatment of the failure to obtain a certificate as a separate offense. Such a reading of the law would render subsection (3)(A) as total surplussage, by merging it into subsection (3)(D), as Complainant attempts to do.

4. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) to levy fines upon the corporate entity that is the facility providing and billing for the services in

question, when that section of the law can, at best, only apply to the “owner, operator, or any employee” of the “facility.” Therefore, 192 charges against Respondent Korangy Radiology Associates, P.A., should be denied on this basis.

Complainant seeks 192 counts of \$10,000 fines against Korangy Radiology Associates, Inc., (“the Corporation”) under subsection (h)(3)(D) of the Mammography Act. This subsection, by its explicit terms, applies only to violations committed by “an owner, operator, or any employee of a facility required to have a certificate.” Put into context, the Act defines a “facility” in subsection (a)(3), as a “hospital, outpatient department, clinic...or other facility ...that conducts breast cancer screening or diagnosis through mammography activities.” The term “facility” is then utilized to describe the certification requirement - “no facility may conduct...unless the facility obtains a certificate. 42 USC 263b(b)(1). The term is used to describe the purposes for which a certificate must be obtained. 42 USC 263b(b)(2). The term is used to describe the “actor” who may not operate equipment without a valid certificate. 42 USC 263b(d)(3). And last, the term “facility” is used in the civil money penalties provision of the Act to define whose failure will create a quality of care violation. 42 USC 263b(h)(3)(B).

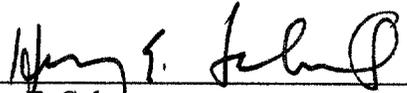
With this background, turning again to subsection (h)(3)(D), we see that this subsection was not intended to apply to “facilities.” It is clearly meant only to apply to “an owner, operator, or any employee of a facility.” This section, prominently featuring the phrase “aiding and abetting” was, by its plain language, intended by Congress to apply as a “supplement” to other provisions of the Act, allowing for the possibility of violations, direct, or through “aiding and abetting,” by individuals who are connected to a facility otherwise having violated the Act. Congress, as the other provisions of the Act clearly show, was perfectly capable of addressing “facilities” where appropriate, and pointedly failed to do so in subsection (h)(3)(D), except to point to a connection that the individual in question must have to a “facility” covered by the terms of the Act.

5. Respondent Korangy was unaware of the issuance of “cease and desist” letters by the FDA, and having committed no knowing violations, should not have been charged personally with violations of federal law, given that the corporation that owned and operated the equipment in question was also charged. Dr. Korangy did not “aid and abet” an activity that he had no knowledge of, and he was unaware that FDA had ordered the cessation of mammography activities with the equipment in question. It is true, as Complainant points out in footnote 6 of its Memorandum in Support of Motion for Partial Summary Judgment, that a corporation is liable for the deliberate acts of its agents. It is not true, however, that an owner, director or employee is automatically responsible for the acts attributed to a corporation. Such acts can be attributed only to those agents who otherwise are personally responsible for them. This is borne out by the “aiding and abetting” language in the Mammography Act cited by Complainants. An affirmative act contrary to law is required to bring charges against an individual. Therefore, all charges against Respondent Korangy should be denied on this basis.

C. Conclusion.

In sum, based upon the factual and legal disagreements noted above, the maximum charge that can be brought in this case is one \$10,000 civil money penalty against the corporate Respondent for operation of mammography equipment without certification. For the above-stated reasons, Respondents request that Complainant's Motion for Partial Summary Judgment be denied, as the existing factual and legal disputes require that the issues in this case be subject to hearing prior to decision.

Respectfully submitted on behalf of Respondents, by:

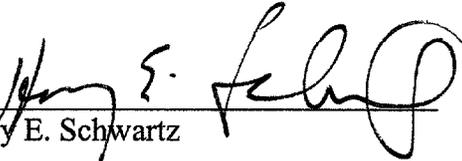


Henry E. Schwartz
Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
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Phone: 410.938.8703
Fax: 410.823.6017
henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 30 day of April, 2004, a copy of the foregoing Memorandum in Support of Opposition of Respondents to Complainant's Motion for Partial Summary Judgment was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Douglas A. Terry, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
Telephone: 301.827.1141



Henry E. Schwartz

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.,
Trading as BALTIMORE IMAGING CENTERS,
A corporation,

*

ADMINISTRATIVE
COMPLAINT FOR
CIVIL MONEY PENALTY

And

FDA Docket: 2003H-0432

AMILE A. KORANGY, M.D.,
An individual

*

* * * * *

**OPPOSITION OF RESPONDENTS TO COMPLAINANT'S MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Now come Respondents, Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers ("BIC") and Amile A. Korangy, M.D. ("Dr. Korangy"), by their attorneys, Henry E. Schwartz, and Henry E. Schwartz LLC, and oppose Complainant's Motion for Partial Summary Judgment for the reasons stated herein.

A. Factual Disputes.

1. Respondents did not receive the letter of April 1, 2002, allegedly sent by FDA. Declaration of Amile Korangy, M.D. (Korangy Decl.; Ex. R-1).

2. Respondents did not receive the letter of May 1, 2002, allegedly sent by FDA. (Korangy Decl.; Ex. R-1).

3. Dr. Korangy and Mr. Barry Henderson did not decide, as alleged by FDA, that the quality of the pre-existing mammography equipment was acceptable. In fact, Dr. Korangy ordered a replacement machine in March of 2002. (Korangy Decl.; Ex. R-1); Declaration of Barry Henderson (Henderson Decl.; Ex. R-2).

4. Respondents contacted Complainant's agent, American College of Radiology ("ACR") on two occasions in May, 2002, for the purpose of reporting the purchase of a new mammography machine, and to obtain clarification of the process required to maintain certification to perform mammography procedures, and in neither conversation did ACR inform Respondents that Baltimore Imaging Centers was to have ceased performing mammography procedures on May 6, 2002. (Korangy Decl.; Ex. R-1).

5. Respondents took their existing mammography equipment out of service in May of 2002, and replaced it at that time with the equipment ordered in March, 2002. (Korangy Decl.; Ex. R-1).

6. Respondents believed, in May, June and July of 2002, that they were following ACR and FDA procedures in replacing their existing mammography equipment with new equipment, and were unaware that FDA intended that they cease performing mammography services. (Korangy Decl.; Ex. R-1).

B. Legal Disputes.

1. Respondents did not receive a written communication from FDA indicating that they would be in legal violation to continue to perform mammography during the time period in question, nor were they so informed by FDA's agent, American College of Radiology, when Respondents telephoned them for advice on the matter. Therefore, Respondents did not knowingly or intentionally operate mammography equipment without current certification.

2. Complainant has inappropriately utilized 42 USC 263b(h)(3) to levy fines totaling \$20,000 per "incident," when the statute limits any such fines to \$10,000 per "incident." Therefore, all charges against one Respondent should be denied on this basis.

3. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) as a basis for levying fines that are based solely on alleged violations of 42 USC 263b(h)(3)(A), and are therefore limited by statute to a total of \$10,000 for "failure to obtain a certificate." Therefore, 192 counts against each Respondent should be denied on this basis.

4. Complainant has inappropriately utilized 42 USC 263b(h)(3)(D) to levy fines upon the corporate entity that is the facility providing and billing for the services in question, when that section of the law can, at best, only apply to the "owner, operator, or any employee" of the "facility." Therefore, all charges against Respondent Korangy Radiology Associates, P.A., should be denied on this basis.

5. Respondent Korangy was unaware of the issuance of "cease and desist" letters by the FDA, and having committed no knowing violations, should not have been charged personally with violations of federal law, given that the corporation was also charged. Therefore, all charges against Respondent Korangy should be denied on this basis.

C. Conclusion.

For the above-stated reasons, Respondents request that Complainant's Motion for Partial Summary Judgment be denied, as the existing factual and legal disputes require that the issues in this case be subject to hearing prior to decision.

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., Trading as BALTIMORE IMAGING CENTERS, A corporation,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
And		FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., An individual	*	

* * * * *

DECLARATION OF AMILE A. KORANGY, M.D.

Amile A. Korangy, M.D. declares as follows:

1. I am currently the sole owner of Korangy Radiology Associates, P.A.
2. Prior to 2002, the mammography equipment subject to FDA charges had been continuously certified since 1990, and was last certified in 1999.
3. I was not personally involved in any of the recertification activities that occurred prior to 2002.
4. In March of 2002 we received a report from the American College of Radiology ("ACR") raising questions about the quality of the films taken by the machine in question.
5. In March of 2002, I authorized the purchase of new equipment to replace the machine in question.
6. In March of 2002, Korangy Radiology Associates, P.A., ordered the new machine.
7. I did review the letter sent by ACR on April 29, 2002, and understood it to contain a recommendation that we not continue to use the old machine, but I also understood the letter to say that we should not permanently discontinue providing mammography.
8. At my request, a staff member called ACR on May 1, 2002, to clarify our situation with respect to the use of the old and new machines.

9. The staff member reported to me that ACR had instructed her to take films with the new machine, and forward them to ACR for review.

10. Prior to the charges being brought in this case, I never received nor heard about the letters of April 1, 2002 and May 1, 2002, that FDA alleges to have sent regarding the use of the old machine.

11. The letter dated April 1, 2002, was addressed to Drs. Wityk, Goad, Korangy & Associates, P.A., the corporate entity that preceded Korangy Radiology Associates, P.A. in 1998. It was the practice of our office to refer such correspondence to the physicians who managed that corporation.

12. The receipt for the letter dated May 1, 2002, alleged by the FDA to have been sent, contains a signature that I do not recognize. I never saw that letter.

13. In May or June of 2002, a staff member again called ACR, and informed them that we were prepared to obtain approval of the new machine. The staff member informed me that ACR instructed her to send film to them for evaluation.

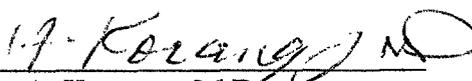
14. Korangy Radiology Associates, P.A. retired the old machine upon the installation of the new machine, in May or June of 2002, and began to utilize the new machine. The films were forwarded to ACR for evaluation.

15. At no time did I authorize the use of any mammography equipment at Korangy Radiology Associates, P.A., knowing that FDA believed such use to be in violation of the law.

16. At all times between May and July of 2002, I believed that we had responded appropriately to ACR's concerns by promptly ordering a new mammography machine, and installing it as soon as possible. I further believed that our contacts with ACR in May had assured us that the process that we were following comported with FDA requirements.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 29, 2004.


Amile A. Korangy, M.D.

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., Trading as BALTIMORE IMAGING CENTERS, A corporation,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
And		FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., An individual	*	
* * * * *		

DECLARATION OF BARRY HENDERSON

Barry Henderson declares as follows:

1. During ²⁰⁰² ~~1992~~ I was employed in an administrative capacity by Korangy Radiology Associates, P.A. 

2. In March of ²⁰⁰² ~~1992~~ we received a report from the American College of Radiology ("ACR") raising questions about the quality of the films taken by the machine in question. 

3. I did review the letter sent by ACR on April 29, 2002, and understood it to contain a recommendation that we not continue to use the old machine.

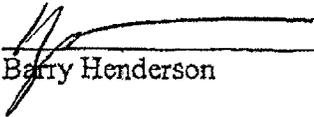
4. I never received nor heard about the letters of April 1, 2002 and May 1, 2002, that FDA alleges to have sent regarding the use of the old machine.

5. At no time did Dr. Korangy and I discuss the quality of the films taken by the mammography machine that was replaced in May of 1992. I have no specialized knowledge in that area, and quality issues were not part of my job charge or description. Any discussions that we had at that time pertained only to our efforts to ascertain from ACR the correct procedure to implement the change in mammography machines.

6. At all times between May and July of 2002, I believed that we had responded appropriately to ACR's concerns by promptly ordering a new mammography machine, and installing it as soon as possible. I further believed that our contacts with ACR in May had assured us that the process that we were following comported with FDA requirements.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on April 27 2004.


Barry Henderson

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
Trading as BALTIMORE IMAGING CENTERS, COMPLAINT FOR
A corporation, * CIVIL MONEY PENALTY
And FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., *
An individual *
* * * * *

PROPOSED ORDER

Complainant filed a Motion for Partial Summary Judgment on April 2, 2004, and Respondents filed an Opposition to said motion on April 30, 2004. Both the motion and the opposition were accompanied by declarations proffering factual assertions.

Accordingly, the Presiding Officer now finds that there exist genuine issues of material fact, and that the moving party is therefore not entitled to summary decision as a matter of law. 21 C.F.R. §17.17(b).

Accordingly, it is ORDERED, ADJUDGED, AND DECREED, that:
Complainant's Motion for Partial Summary Judgment is DENIED.

Daniel J. Davidson
Administrative Law Judge
U.S. Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

Proposed by:

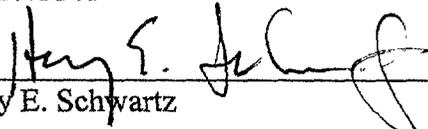


Henry E. Schwartz
Attorney for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 12th day of April, 2004, a copy of the foregoing Proposed Order was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

Douglas A. Terry, Esquire
The Center for Devices and Radiological Health
United State Food and Drug Administration
5600 Fishers Lane (GCF-1)
Rockville, MD 20857
Telephone: 301.827.1141


Henry E. Schwartz