



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

August 27, 2004

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

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

Dear Sir or Madam:

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

Sincerely,



Jennifer E. Dayok
Associate Chief Counsel
for Enforcement

Enclosure

cc w/encl.:

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

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

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

COMPLAINANT'S OPPOSITION TO RESPONDENTS' PROPOSED FINDINGS OF FACT

Complainant, the Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), submits the following critique of Respondents' Proposed Findings of Fact pursuant to the Administrative Law Judge's Order of November 13, 2003:

1-2. This background information has no bearing on the penalty issue before the Administrative Law Judge.

3-4. No comment.

5. This background information has no bearing on the penalty issue before the Administrative Law Judge.

6. The record belies Dr. Korangy's claim that he was not personally involved in the FDA certification process until 2002. Dr. Korangy admits that he became sole owner of Korangy Radiology Associates trading as Baltimore Imaging Centers (BIC) in October 1998. The certificate at issue in this case was issued to BIC in May 1999 and expired in May 2002. Dr. Korangy was the Supervising Radiologist and Lead Interpreting Physician during that period. Given this role, Dr. Korangy **should** have been involved in the certification process as early as

May 1999. Indeed, Barry Henderson, the Vice President of BIC informed FDA investigators that Dr. Korangy was responsible for maintaining BIC's certification. See Declaration of Elizabeth A. Laudig (Laudig Decl.; attached as Ex. G-E to Complainant's Motion for Partial Summary Judgment (Complainant's Motion)) ¶ 8.

Dr. Korangy's claim that he did not participate in the process until 2002 should not be considered to be a mitigating factor; if it is true, it shows that Dr. Korangy was remiss in his duties. It is well established that the responsibilities of corporate officials whose products may affect the health of consumers are "cast in rigorous terms." United States v. Park, 421 U.S. 658, 673 (1975). Such officials are in a position to devise measures necessary to ensure compliance with FDA law, and cannot rely on lack of knowledge or lack of participation as a defense. Id. at 671-73.

7. Exhibit R-1 appears to be a quotation for new equipment but does state when the equipment was actually ordered. In any event, the date of the order is not relevant to the penalty issue. It is notable, however, that the new equipment was not installed until at least June 28, 2002 and Respondents conducted 165 of the 192 uncertified examinations underlying this Court's finding of liability on the old equipment. See Declaration of Michael P. Divine, M.S. (Divine Decl.) (attached as Ex. G-D to Complainant's Motion) ¶ 21 and Ex G-10 thereto. Accordingly, Respondents' purchase of new equipment should be given little weight as a mitigating factor relevant to the penalty imposed.

8. Respondents were not charged with failing to cease mammography in response to the April 29, 2002 letter from the American College of Radiology (ACR); they were charged with failing to obtain a certificate for the BIC facility and for conducting 192 examinations after the facility's certificate expired on May 6, 2002. Thus, the relevant inquiry is whether or not

Respondents understood that they had to cease mammography when their certificate expired. Dr. Korangy admits reviewing the April 29, 2002 letter. In addition to "strongly recommend[ing]" that they discontinue mammography immediately because of various clinical image deficiencies,¹ the letter reminded Respondents of the statutory requirements, **"Furthermore, you may not lawfully conduct mammography if your MQSA certificate expires."** See Divine Decl. ¶ 12 and Ex. G-2 thereto (emphasis in original).

9-10. Any testimony of Dr. Korangy's understanding of a discussion between one of his staff members and ACR is inherently unreliable because it is based on hearsay. Respondents have not submitted any direct testimony into the record from such a staff member, and therefore Complainant will not be afforded an opportunity to explore the issue through cross-examination.

The only evidence in the record about such a communication appears in Complainant's Exhibit G-5, a letter dated July 18, 2002, from ACR to FDA, which listed BIC's then-recent contacts with ACR. The contact listed for May 1, 2002, states in full, "ACR staff received a phone call from Kim asking for the status of the facility's review on their repeat cycle, she was informed that a report had been written and FedEx overnight to the facility." Divine Decl. Ex. G-5. There is no mention in that document of any discussion between ACR and "Kim" about whether or not Dr. Korangy could continue performing mammography.

Although Respondents listed "Kim Gephart" as a witness, they never submitted any written direct testimony from her. Accordingly, Complainant respectfully requests that Respondents be precluded from introducing her testimony at the penalty hearing pursuant to 21

¹ ACR acknowledged in the letter that the official notice to discontinue mammography had to come from FDA. Although ACR can deny accreditation when a facility fails to meet accreditation standards, it is FDA that is charged by statute with bringing enforcement actions for violations of the MQSA.

C.F.R. §§ 17.25 and 17.35. In the alternative, should this Court allow her to testify, Complainant respectfully requests an opportunity to present a rebuttal witness pursuant to 21 C.F.R. § 17.39.

11. Respondents neglect to mention that the April 1, 2002 letter from FDA was addressed personally "Amile A. Korangy, M.D." The letter was properly addressed to the same address listed on BIC's letterhead and its MQSA certificate and the address identified by Dr. Korangy in the reinstatement application that he submitted to ACR. While Complainant has no way of knowing for certain whether Dr. Korangy read the letter, these facts strongly suggest that he should have received it and reviewed it. In any event, as this Court found in its Partial Summary Decision, Dr. Korangy had notice from the expiration date listed on the MQSA certificate itself, that BIC was performing mammography without a certificate during the period at issue. He also had notice that this was unlawful from the April 29, 2002 letter that he admitted reading.

12. Again, there is no way to know for certain whether Dr. Korangy read the May 1, 2002 letter, but it is undisputed that an employee of BIC, a technician name "Sonier," signed for receipt of the letter. See Respondents' Memorandum in Support of Opposition to Complainant's Motion ¶ 2; Divine Decl. ¶ 13 and Ex. G-3 thereto; Affidavit of Barry J. Henderson, dated September 3, 2002, at 8 (attached as Ex. G-11 to Laudig Decl.). It is well established that an employer is deemed to have received notice or knowledge that was acquired by an employee acting within the scope of his employment, regardless of whether the information was actually communicated to the employer. See, e.g., United States v. Josleyn, 206 F.3d 144, 159 (1st Cir. 2000); DGM Investments, Inc. v. New York Futures Exchange, Inc., 265 F. Supp. 2d 254, 262 (S.D.N.Y. 2003).

13. The claim in ¶ 13 is again based on hearsay and is inherently unreliable. See ¶¶ 9-10 above. Ex. G-5 lists only on other contact between ACR and BIC in May or June 2002. According to ACR's records, on May 23, 2003, "Kim from the facility called to inform the ACR that the facility would reinstate once it received the new unit." Divine Decl. Ex. G-5. Again, there is no record of any discussion of conducting mammography while the facility was uncertified, which is not surprising, given that by that time, the facility had been notified no less than three times that it could not lawfully conduct mammography examinations without a certificate.

14. See ¶ 7 above.

15-16. See ¶¶ 8, 11-12 above.

17. Contrary to the assertion in this paragraph, BIC received a Warning Letter from FDA after an inspection on September 12, 2001. The letter was issued due to the facility's failure to perform daily processor quality control testing in violation of the MQSA regulations. In March 2003, before this action was initiated, FDA imposed a Directed Plan of Correction on the facility, pursuant to 42 U.S.C. 42 263b(h)(1)(A), due to continuing serious violations discovered during an FDA inspection in August and September 2002.

18. No comment.

19. This is a conclusion of law.

20-23. As set forth in ¶¶ 21-26 of Complainant's Proposed Findings of Fact, the financial information submitted by Respondents do not paint a complete picture of their ability to pay a fine. In sum, while there are tax returns from 2001 and 2002, there are none from 2003. In addition, there are no documents to show either of the Respondents' net worth. The Respondents have recently expanded their operations by acquiring a new facility. Respondents' counsel has

represented that documents listing the assets and liabilities of Respondents, which would clarify the issue of ability to pay, are forthcoming.

24. In the Community Medical Imaging, Inc. civil money penalty case, FDA initially sought penalties in the amount of \$80,000 for each of the 3 respondents (two individuals and one corporation). This amount represented a penalty amount of \$10,000 for each violation alleged, specifically two violations of 42 U.S.C. § 263b(h)(2)(A) for failure to obtain a certificate for two different time periods and six violations of 42 U.S.C. § 263b(h)(2)(C) for each of six mammograms performed while the facility was uncertified. The penalties sought in that case were consistent with those sought here in that \$10,000 was sought for each violation. In this case, however, the facility conducted 192 mammograms while uncertified, rather than six. It appears from the Consent Decree in that case that the penalty was reduced based on complete documentation of the respondents' inability to pay. Such documentation has not been submitted here.

25. As stated in these objections, CDRH believes that the evidence contradicts Respondents' assertions that such mitigating factors as lack of notice and intent or prompt installation of new equipment apply. At the time that CDRH initiated this case, it had no evidence regarding Respondents' financial position and, as stated above, those facts remain unclear. Furthermore, although FDA's guidance provides that civil money penalties may be reduced for small entities, it also states that such a reduction may not be available for violations involving willful conduct, such as those supported by the evidence here.

26-27. See ¶¶ 20-23 above. The civil money penalties requested by CDRH were not designed to bankrupt the company or prevent them from providing services to patients.

However, the burden is on Respondents to come forward with evidence of their inability to pay before a reduction in the penalty amount is made.

28. This is a conclusion of law. As this Court recognized in its Partial Summary Decision, 42 U.S.C. § 263b(h)(3)(D) authorizes FDA to assess civil money penalties in an amount of up to \$10,000 for each violation of the MQSA. This Court found that each of the Respondents were liable for 193 violations. Accordingly, the penalty sought comports with the statute.

The MQSA, like all legislative acts, is presumed to be constitutional. Flemming v. Nestor, 363 U.S. 603, 617 (1960); see also New York State Club Ass'n v. City of New York, 487 U.S. 1, 17 (1988); Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1975). The burden of showing a statute to be unconstitutional is on the challenging party, New York State Club Ass'n, 487 U.S. at 17; Usery, 428 U.S. at 15, and "only the clearest proof" will suffice to establish its unconstitutionality. Flemming, 363 U.S. at 617; see also Walters v. National Ass'n of Radiation Survivors, 473 U.S. 305, 319 (1985) ("[j]udging the constitutionality of an Act of Congress is properly considered 'the gravest and most delicate duty that this Court is called upon to perform.'") Respondents' bald allegation that the civil money penalties sought represent an excessive fine clearly does not meet the required burden.

29. Complainant objects to a reduction in the penalty amount to a total of \$50,000.00 for both Respondents and respectfully requests that the Court impose the penalty amount of \$1,930,000 for each Respondent as authorized by the MQSA and sought in the Complaint for the 193 violations for which each Respondent is liable.

- a. See ¶ 25 above.
- b. See ¶¶ 19 and 25 above.

c. See ¶¶ 8, 11-12 above

d. See ¶ 7 above.

e. Respondents have not submitted any documentation to support this assertion, and their profit and loss statement for mammography examinations does not reflect the overall profit and loss for the corporation as a whole.

f. See ¶¶ 20-23 above.

g. See ¶¶ 26-27 above.

h. See ¶ 24 above.

i. See ¶ 28 above.

Respectfully submitted,



Jennifer E. Dayok
Attorney for Complainant
Food and Drug Administration
5600 Fishers Lane, Rm. 6-71
Rockville, MD 20857