

Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
Phone: 410.938.8703 / Fax: 410.823.6017
henryeschwartzllc@verizon.net

August 9, 2004

VIA UPS NEXT DAY AIR

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

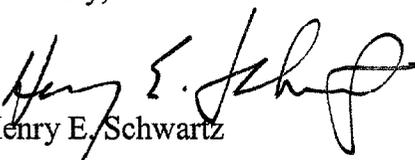
RE: In re Korangy Radiology Associates, P.A., *et al.*
FDA Docket No. 2003H-0432

Dear Sir/Madam:

Enclosed for filing in the above-referenced matter please find an original and one copy of Respondents' Proposed Findings of Fact.

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

Sincerely,


Henry E. Schwartz

Enclosures

cc: Amile Korangy, M.D.
Jennifer E. Dayok, Esquire
Honorable Daniel J. Davidson, ALJ

2003H-0432

RFF 1

a replacement machine. In evidence is the equipment order, dated March 19, 2002. (Exhibit R-1; Korangy, p.2).

8. That Dr. Korangy reviewed the ACR letter of April 29, 2002, and did not understand it to require that KRA cease utilizing the Equipment. (Korangy, p.2).

9. That Dr. Korangy, on May 1, 2002, requested that a staff member contact ACR to clarify the situation with respect to the use of the Equipment and the ordered replacement machine. (Korangy, p.2).

10. That Dr. Korangy understood the ACR's instructions to be to take films with the new machine, and forward them to ACR for review, and that he did not understand that KRA was being instructed to cease utilization of the Equipment. (Korangy, ppg. 2 and 3).

11. That FDA addressed a letter dated April 1, 2002 to "Drs. Wityk, Goad, Korangy and Associates, P.A.," and that Dr. Korangy had not seen a copy of that letter prior to the institution of charges in this case. (Korangy, p. 3).

12. That FDA addressed a letter dated May 1, 2002 to KRA, and that Dr. Korangy had not seen a copy of that letter prior to the institution of charges in this case. (Korangy, p.3).

13. That KRA staff again called ACR in May or June of 2002, and that again Dr. Korangy was not given to understand that KRA had been given instructions to cease utilizing the Equipment. (Korangy, p.3).

14. That KRA began utilizing the new machine in place of the Equipment as soon as the new machine was installed and operational. (Korangy, p.3).

15. That KRA did not knowingly violate the law by intentionally operating the Equipment during a period of de-certification. (Korangy, ppg. 3 and 4).

16. That Korangy did not knowingly violate the law by intentionally approving the operation of the Equipment during a period of de-certification. (Korangy, ppg. 3 and 4).

17. That neither KRA nor Korangy have ever been previously accused of any regulatory violations by any agency of government, either federal, state or local. (Korangy, p.5).

18. That KRA's gross receipts for 2001 and 2002 were [REDACTED] and [REDACTED], respectively. (Exhibits R-2 and R-3; Korangy, p.4).

19. That KRA's gross receipts for 2001 and 2002 qualify KRA as a "Small Business Entity" under federal law. 13 CFR Part 121.

20. That KRA's net profit/loss, as reported to the Internal Revenue Service for 2001 and 2002 were [REDACTED] and [REDACTED], respectively. (Exhibits R-2 and R-3; Korangy, ppg. 4 and 5).

21. That KRA's net profit/loss for the performance of mammography in 2003 was -\$172,473.61, as applicable expenses exceeded reimbursement by that amount. (Exhibit R-4; Korangy, p.4).

22. That Dr. Korangy, as reported to the Internal Revenue Service, received the following employment income:

- a. 2001: \$ [REDACTED]
 - b. 2002: [REDACTED]
 - c. 2003: [REDACTED]
- (Exhibits R-5 and R-7).

23. That Dr. Korangy's adjusted gross income, as reported to the IRS, for the years 2001 and 2002 was \$ [REDACTED] and \$ [REDACTED], respectively. (Exhibits R-5, R-6 and R-7).

24. That the only prior civil money penalty case brought by FDA to enforce the Mammography Quality Standards Act consisted of fines sought of \$80,000.00, and resulted in a settlement. A \$30,000.00 fine was paid by the respondent in that case. Community Medical Imaging, Inc., FDA Docket No. 97H-0379. (A copy of the Consent Decree is herewith enclosed as Exhibit R-8).

25. That, in the instant case, FDA imposed the maximum possible civil money penalties consistent with FDA's understanding of their authority, and undertook no consideration of the appropriateness of the penalty vis-à-vis the offenses charged, nor any possible mitigating circumstances. 21 CFR 17.34; 13 CFR Part 121; Reduction of Civil Money Penalties for Small Entities, Guidance for Industry and FDA Staff, US FDA, Office of Regulatory Affairs, Office of Enforcement, Division of Compliance Policy (Enclosed as Exhibit R-9).

26. That both Respondents have demonstrated their inability to pay the fines as assessed, and would likely resort to bankruptcy filings should the civil money penalties imposed be upheld. (Exhibits R-2 through R-7; Korangy, ppg. 4-6).

27. That the "intermediate sanction" of civil money penalties as imposed in this case is far more severe than the "ultimate sanction" of program disqualification that it was intended to replace, in that the civil money penalties as imposed would prevent Respondents from providing any services to any patients. MSQA, 42 USC 263b(h); Senate Report No. 102-448, S. Rep. No. 448, 102nd Cong., 2nd Sess. 1992, 1992 WL 322480 (Page 16 of Senate Report, a copy of which is enclosed as Exhibit R-10).

28. That the civil money sanctions as imposed in this case are grossly disproportionate to the offenses charged, and harsher than permanent disqualification, making the sanctions “excessive fines” under the Eighth Amendment to the United States Constitution. United States v. Bajakajian, 524 U.S. 321, 118 S. Ct. 2028, 1998; United States v. Ahmad, 213 F.3rd 805 (4th Cir., 2000); and Vasudeva v. United States, 214 F.3rd 1155 (9th Cir., 2000). (Copies enclosed herewith as Exhibits R-11 to R-13, respectively).

29. That the civil money penalties in the instant case be reduced to the amount of \$50,000.00, in consideration of the following factors:

- a. That the FDA did not consider mitigative factors in levying the penalty in the instant case;
- b. That KRA is a Small Business Entity under federal law;
- c. That KRA and Korangy did not deliberately violate the MSQA;
- d. That KRA and Korangy took decisive and immediate corrective action once advised of the problem by ACR, and prior to the issuance of formal notifications by ACR and FDA;
- e. That KRA sustains a net loss every time that it provides a mammography service to a patient;
- f. That KRA and Korangy do not have the ability to pay a civil money penalty remotely related to the fines issued in this case by FDA;
- g. That the fines issued in this case by FDA as an “intermediate sanction” are far harsher than would be the “ultimate sanction” of program disqualification.
- h. That FDA has issued civil money penalties in only one prior MSQA certification case, and that settlement in that case resulted in the payment of a fine in the amount of \$30,000.00; and
- i. That the civil money penalties issued in the instant case are disproportionate to the offenses charged, and therefore “excessive” under the Eighth Amendment to the United States Constitution.

REQUEST FOR CROSS-EXAMINATION OF WITNESSES

Respondents hereby request the opportunity to cross-examine Mr. Michael P. Divine, as well as any rebuttal witnesses called to testify by Complainant. It is anticipated that the cross-examination of Mr. Divine will last for approximately 20 minutes.

Submitted by:

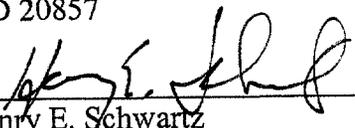

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Towson, MD 21204

Phone: 410.938.8903
Fax: 410.823.6017
henryeschwartzllc@verizon.net
Attorneys for Respondents

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 9 day of August, 2004, a copy of the foregoing Respondents' Proposed Findings of Fact was mailed, postage prepaid, to:

Jennifer E. Dayok, Esquire
Associate Chief for Enforcement
Office of the General Counsel
Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane, GCF-1
Rockville, MD 20857


Henry E. Schwartz