

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 PENALTIES
and)	
AMILE A. KORANGY, M.D., an individual.)	FDA Docket No. 2003H-0432
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INITIAL DECISION¹

Respondents Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers, and Dr. Korangy are each liable for one violation of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(A). Respondents Baltimore Imaging Centers and Dr. Korangy are each liable for 192 violations of the MQSA pursuant to 42 U.S.C. § 263b(h)(3)(D). Civil Money penalties in the amount of \$579,000 ordered for each of the Respondents.

Henry E. Schwartz for the Respondents Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers, and Amile A. Korangy, M.D.

Jenifer E. Dayok, and Marci Norton for the Center for Devices and Radiological Health of the Food and Drug Administration.

By **Daniel J. Davidson**, Administrative Law Judge

¹ Pursuant to 21 C.F.R. 17.45(d) this Initial Decision will become final and binding unless it is appealed within thirty (30) days of issuance.

Complainant, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), brought this action on September 22, 2003 seeking Civil Money Penalties (CMPs) against Respondents Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers (BIC), and Amile A. Korangy, M.D. The Complaint alleged that Respondents violated the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. A Partial Summary Decision issued May 27, 2004, found each of the Respondents liable for 193 violations of the (MQSA). That decision is incorporated by reference here. Subsequent proceedings, limited solely to the issue of the amount of the CMPs, included an oral hearing for purposes of cross-examination held on September 20, 2004, and post-hearing briefs filed on December 3, 2004.

The CDRH initially sought CMPs in the amount of \$10,000 for each of the 386 violations found in this proceeding. In its brief the CDRH indicated that the appropriate penalty should be \$1,158,000 or \$3,000 for each violation.

Respondents maintain that there should be no Civil Money Penalties assessed in this proceeding because the FDA failed to establish required procedures and standards for the issuance of such penalties. Specifically, Respondents rely on 42 USC 263b(h), subsection (4) which requires that “[t]he Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed...” Respondents assert the FDA has no authority to impose civil penalties in absence of the requisite clearly defined standards.

Respondents' argument that the Secretary failed to devise procedures as required under the MQSA is unconvincing. In addition to the FDA's Compliance Program Guidance Manual, (CPG 7382.014, September 30, 1999), FDA's regulations in 21 C.F.R.

Part 17 set forth practices and procedures for hearings concerning the administrative imposition of civil money penalties. The regulations specify that CMPs under “Section 354(h)(2) of the [Public Health Service] Act, as amended by the [MQSA], among other things, are governed by the Part 17 procedures [21 C.F.R. § 17.1(e)]. The regulations in Part 17 indicate what information must appear in a CMP complaint, explain how the hearing will be conducted and how the amount of penalties and assessments are determined, and provide for both interlocutory and final appeals. These regulations and FDA's CPG regarding mammography inspections constitute the procedures required under 42 U.S.C. § 263(h)(4).

Respondents also contend that CDRH has not established the appropriateness of the penalties sought in this matter as required by 21 C.F.R. § 17.33, in that the maximum \$10,000 per count was sought without consideration of mitigating circumstances including the Respondents' ability to pay. Respondents assert that since 21 C.F.R. § 17.33(b) places the burden of establishing the appropriateness CMP on the Center, “[t]he Administrative Law Judge may not substitute his discretion for that of the agency in this matter, as it is the Center that is required by regulation to prove its case.” (Respondents' Post Hearing Brief, p.3) The Respondents seem to be arguing that a determination of the appropriate amount of the CMP can only be made by the Center. Such a finding however, would undermine the entire hearing process. The CDRH has the burden of presenting evidence as to the appropriateness of the amount of the CMPs sought. The ultimate determination as to the sufficiency of the evidence presented and the appropriateness of the CMPs, clearly lies within the province of the deciding official(s) as provided in 21 C.F.R. § 17.34.

Reference is also made to an ongoing proceeding in which CDRH is only seeking penalties of \$1,000 per count where there were over 1200 alleged violations of the MQSA. Since a determination of CMPs necessarily involves consideration of only those factors present in each individual proceeding, Respondents' comparison is totally irrelevant. Even if there were some basis for making such a comparison, it is entirely inappropriate here because the matter referred to (FDA Docket No. 2004H-1322) is an ongoing proceeding in its early stages pending discovery and the introduction of evidence.

Additionally, Respondents claim that the CMPs sought in this proceeding "... are grossly disproportionate to the offenses charged, and thus are invalid as violative of the 8th Amendment to the United States Constitution." The Eighth Amendment provides that "[e]xcessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." (U.S. Const. amend. VIII).

The CMP sanctions in the MQSA, like the CMP sanctions the Federal Food, Drug, and Cosmetic Act, are not intended to be punitive. CMP authority is intended to take the profit out of non-compliance. CMPs are considered to be remedial, not punitive. "This means it is designated to influence future conduct..., either directly, by affecting current violative conduct, or indirectly, by serving to deter future violative conduct." (See Guidance for FDA Staff, Civil Money Penalty Policy, SMDA Civil Money Penalty Decision Tree, June 8, 1999, found at www.fda.gov/cdrh/comp/penalty.pdf, at 1).

Since CMP sanctions under the MQSA are remedial, they are not "fines" within the meaning of the Excessive Fines Clause of the Eighth Amendment. Even if the CMPs could be considered as fines, they would not be considered excessive, as they do not

exceed the statutorily established limit of \$10,000 for each violation. Accordingly, the CMPs in this case do not violate the Eighth Amendment to the Constitution.

Throughout this proceeding Respondents have maintained their inability to pay as one basis for the reduction or the elimination of the CMPs. Under 21 C.F.R. §17.33(c), the Respondents have the burden of proving their inability to pay and they have not done so. On the contrary, the record indicates that Respondents have been less than forthcoming with respect to relevant financial information.

Complainant's brief included Exhibit Nos. G-15 through G-31². These documents were either recently provided by Respondents or found in the Public Records of which Official Notice is taken. Pursuant to 21 C.F.R. § 17.41(b), these Exhibits are part of the Administrative Record. Documents provided in response to CDRH's requests, as well as the information contained in public tax and real property records appear to indicate that Respondents have access to more assets than they have revealed. For illustrative purposes, some of this information is included here.

Dr. Amile Korangy has maintained throughout this proceeding that he owns no real property in his name (Hearing Transcript at 39). While this appears to be technically correct, the information of record paints a different picture. Since 1996, it appears that Dr. Korangy has removed property from his name by, transferring it to his wife and children, into trusts, or into the name of another company. Activities regarding the ownership of his residence at 13607 Sheepshead Court, Clarksville, MD, 21029, are indicative.

² On December 8, 2004, Respondents filed a Motion to Strike Exhibit Nos. G-15 through 25, Exhibit Nos. G-27 through 29 and Exhibit No. G-31 on the grounds that they were late filed, inappropriate and/or prejudicial. The Motion was denied by Order issued December 15, 2004.

On December 23, 2003, (two months after this action was initiated) Dr. Korangy transferred this home out of his name into a trust with his wife, Parvane S. Kornagy, as trustee (Exhibit G-16, at 5). Dr. Korangy, nevertheless appears to maintain control over this residence. As of January 1, 2002, this property was valued for tax purposes at \$987,580 (Exhibit G-15). The market value of this home is arguably more than the tax assessment value. Based on public records, the property is probably worth well over one Million Dollars. A house at 13600 Sheepshead Ct., Clarksville, MD, is currently under contract and was listed for \$1,299,000. A comparable house is under contract for \$1.5 million (Metropolitan Regional Information Systems, Inc. Reports, Exhibit G-18).

A similar picture is reflected with respect to automobile registrations. At the September 20, 2004 hearing, Dr. Korangy stated that he does not have a car and that he did not have a car in his name (Hearing Transcript, at 40-41). Respondents had previously furnished Purchase Orders and Bills of Sale for a used 2000 Toyota Corolla registered in the name of BIC and a used 1998 Volkswagen Jetta GLX registered in the name of KRA (Exhibit G-19). Subsequently, Respondents produced evidence of two additional cars: a 2003 Mercedes Benz E500 purchased for \$72,525.60 on April 28, 2003, in the name of BIC and a GMC Yukon XL purchased for \$49,085.20 on June 21, 2003, in the name of "Baltimore Imagine (sic) Center, Michael Shahram Korangy (Exhibit G-20). It therefore appears that in the year 2003, two cars worth over \$120,000 were purchased, although neither is registered in Dr. Korangy's name.

It also appears that, on December 1, 1999 and January 24, 2000, Dr. Korangy transferred real property in Indian River County, Florida, to a company called Paskor,

LLC (Paskor). (Property Transfer Records for Indian River County, FL, Exhibit G-21).

This company was registered with the Florida Department of State, Division of Corporations on December 6, 1999, and the registered mailing address for the company is 13607 Sheeps Head Court, Clarksville, MD 21029 — Dr. Korangy's residence (Florida Department of State, Division of Corporations, Corporations Online Public Inquiry, Exhibit G-22). In the Florida filing, Dr. Korangy is listed as the MGRM (Managing Member) of Paskor. The property owned by Paskor, consists of multiple lots along Highway AIA in Vero Beach, and was assessed in 2004 at \$249,260 (Exhibit G-21 and Indian River County Online, History of Parcel owned by Paskor, Exhibit G-23).

Dr. Korangy and KRA own condominiums at 724 Maiden Choice Lane, Baltimore, MD, 21228, Units C1B, C1C, and C1D, which were assessed for tax purposes as of January 1, 2003, at \$114,500, \$209,100, and \$137,900, respectively. (MD Dept. of Assessments and Taxation, Real Property Data Search, Exhibit G-27). Through his company Pikesville Properties, LLC, Dr. Korangy also owns property at 6609 Reisterstown Road, Baltimore, MD, 21215, that he bought for \$1,000,000 on January 22, 2002 (Property Transfer Record for Baltimore City, MD, Exhibit G-28).

On July 30, 2004, Dr. Korangy registered another radiology facility in Frederick, Maryland, called Frederick Imaging Center, LLC (MD Dept. of Assessments and Taxation, attached hereto as Exhibit G-29). In total, Dr. Korangy operates at least six radiology facilities, three of which perform mammography examinations (Hearing Transcript, at 38).

KRA's 2003 tax return states that the company began tax year 2003 with buildings and other depreciable assets worth [REDACTED] and ended that tax year with

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buildings and other depreciable assets worth \$ [REDACTED] 2003 1120S for KRA, Exhibit G-30). It therefore appears that KRA acquired an additional \$1.2 million worth of appreciable assets in the 2003 tax year. However, Respondents have not introduced any information concerning those assets. Although the tax returns provided by Respondents indicate that Dr. Korangy and his wife make only \$ [REDACTED] (Exhibit G-25), and that KRA is operating at a loss, (Exhibit G-30), it seems that Respondents have numerous assets available to them.

Respondents have not demonstrated an inability to pay the CMPs sought by Complainant here. In fact, Respondents' financial activities and numerous asset transfers constitute an aggravating factor for consideration under 21 C.F.R. § 17.34(a). Pursuant to 21 C.F.R. §17.33(c), Respondents have the burden of proving any mitigating factors by a preponderance of the evidence. To the extent that inability to pay may be considered a mitigating factor, Dr. Korangy's financial manipulations would appear to preclude any finding that Respondents' burden has been sustained.

Congress in enacting the MQSA established the CPM at \$10,000 per violation, while providing for the reduction of that amount based on various considerations. A determination of Respondents' ability to pay and the consequences of the payment thereof has been hampered by the apparent reluctance to produce a complete picture of their financial situation. Mindful of the fact that CMPs are remedial in nature and based on the financial information that is available, Complainant (indicating that there is no intention to bankrupt the Respondents) has lowered the CMPs sought to \$3,000 per violation.

It therefore appears that CDRH, has met its burden of proving Respondents' liability, and the appropriateness of the amount of the CMPs sought as required by 21 C.F.R. § 17.33(b), as well as their ability to pay as required under 21 C.F.R. § 17.34. Under the circumstances presented, Civil Money Penalties in the amount of \$3,000 per count against each of the Respondents is deemed appropriate in this matter. Accordingly,

It is **ORDERED** that Respondent Amile A. Korangy, M.D., pay a total civil money penalty of \$579,000, comprised of \$3,000 for each of the 193 violations of the Mammography Quality Standards Act for which this Respondent has been found liable in the Partial Summary Decision issued May 27, 2004;

It is **further ORDERED** that Respondent Korangy Radiology Associates, P.A., trading as Baltimore Imaging Centers, pay a total civil money penalty of \$579,000, comprised of \$3,000 for each of the 193 violations of the Mammography Quality Standards Act for which this Respondent has been found liable in the Partial Summary Decision issued May 27, 2004.

Dated this 17th day of December, 2004

/s/ Daniel J. Davidson
Daniel J. Davidson
Administrative Law Judge