Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	)	DATE: May 31, 2006
Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers, Respondents,	)	FDA Docket No. 2003H-0432
	)	App. Div. Docket No. A-05-35
- v. -	)	Board Ruling No. 2006-2
Food and Drug Administration.	)	

RULING ON REQUEST FOR RECONSIDERATION

On March 20, 2006, Korangy Radiology Associates, P.A. (KRA), and Amile A. Korangy (collectively referred to here as Korangy) requested reconsideration of the decision issued by the Departmental Appeals Board (Board) on September 26, 2005. Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers, and Amile A. Korangy, DAB No. 1996 (2005) (Board Decision). On February 1, 2006, the Board notified Korangy that the Board had discovered that the Food and Drug Administration (FDA) had omitted attachments to some documents when preparing the record for transfer to the Board after Korangy appealed the decision of FDA Administrative Law Judge (ALJ) Daniel J. Davidson. Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers, and Amile A. Korangy, FDA Docket No. 2003H-0432 (2004) (ALJ Initial Decision). The Board reopened the case sua sponte and ordered the FDA to transmit the complete record of all proceedings before the ALJ, with a sealed supplement reflecting the unredacted versions of those documents sealed by the ALJ. The Board then provided Korangy an opportunity to review that record for completeness and accuracy and to indicate whether Korangy contended that the omitted attachments would have altered the Board's decision. Board letter to Korangy, dated February 1, 2006. Upon review of the omitted materials, Korangy's

reconsideration request, and the responsive briefing, we conclude that nothing in the omitted attachments requires us to modify the original Board Decision, which we hereby incorporate by reference as part of this ruling.

Background

The factual background and applicable legal authority relevant to this matter are fully set out in the Board Decision, and we will not repeat them here. To summarize for the benefit of the reader, the Board affirmed the FDA ALJ Decision imposing civil money penalties (CMPs) on Korangy in the combined amount of $1,158,000 ($579,000 for each respondent). Board Decision at 2. The CMPs were calculated based on $3,000 for each of 193 violations of the Mammography Quality Standards Act of 1992 (MQSA). 42 U.S.C. § 263b; see also 21 C.F.R. Parts 17 and 900. The violations arose from allegations that Korangy operated a mammography facility (KRA) after its FDA certificate expired on May 6, 2002, and performed 192 mammograms without a valid certificate contrary to the requirements of the MQSA.

The Board was not aware that the record was incomplete when the Board issued its decision. First, the index to the record originally forwarded from the ALJ to the Board did not fully identify attachments to some of the documents, so it was not evident to the Board that certain attachments had not been included. Second, after the matter had been transferred to the Board, Korangy sought and received a protective order from the ALJ to seal certain documents. Neither party notified the Board of these further proceedings before the ALJ after jurisdiction was transferred, and the FDA did not then forward the record of those additional proceedings to the Board. Third, it was not evident from the parties' discussion of certain tax documents that the copies that the Board had were not complete. Finally, the Board's review was limited to the narrow exceptions raised by Korangy to the ALJ Initial Decision and did not include making original findings of fact. The problems with the record were discovered when the Board's record was being prepared for certification to the United States Court of Appeals for the Fourth Circuit subsequent to Korangy's appeal to that court. The Board then reopened the case in order to assure a complete and accurate record of the administrative proceedings. The FDA then transferred its record of all proceedings before the FDA ALJ to the Board. Counsel for both parties had an opportunity to review the record to verify its completeness and accuracy. Both parties agreed to substitute the newly transmitted record (with sealed supplement) for the record previously transmitted to the Board by the FDA.

As noted, Korangy was also permitted an opportunity to notify the Board if he contended that the material omitted from the record would have altered the Board Decision, and, if so, to seek reconsideration. Korangy's reconsideration request contends that two items omitted from the record would have materially altered the Board Decision: (1) the complaint in another case before the FDA, In re Ecumed Health Group, FDA Docket No. 2004H-0322 (Ecumed), and (2) certain financial information, particularly Korangy's personal and business tax returns from 2001 and 2002.

Analysis

The general standard which the Board uses to evaluate whether to reconsider a decision is whether "a party promptly alleges a clear error of fact or law." Cf. 45 C.F.R. § 16.13. Korangy alleges here that the omission of certain documents from the record transmitted by the FDA would have caused the Board to decide differently. Below, we discuss why we conclude, after reviewing each of the items, that the omission did not result in any error in the Board Decision, much less any clear error.

1) The Ecumed complaint

Korangy presented the Ecumed complaint to the ALJ to document his claim that the FDA was arbitrary and capricious in setting the amount of its CMPs, as evidenced, in Korangy's view, by the "drastic difference" in the amounts imposed in Ecumed as opposed to those levied on Korangy. Korangy Reconsideration Request at 2. Although a copy of the Ecumed complaint was not included in the record originally transferred to the Board, the parties briefed the facts the FDA alleged in Ecumed (the nature of which was not disputed by the parties), and the Board Decision discussed those facts and the CMP the FDA sought in that matter. See Board Decision at 14, 19-20. Korangy contends that the Board "should have had the benefit of reviewing the Ecumed complaint as part of the record," but fails to demonstrate that anything in the complaint itself should alter the Board's rationale.

In Ecumed, the FDA proposed a $1,000 CMP for each procedure performed in violation of the MSQA, while for Korangy the FDA initially proposed the maximum $10,000 CMP per procedure and then reduced the CMP to $3,000 per procedure during the course of the proceedings before the ALJ. The Board noted that the FDA explained that the difference in CMP amounts sought in the two cases was "based on separate considerations of relevant factors in each case," and that the factors the FDA identified included "the prior history of the facility, individual respondents' roles and qualifications, and respondents' experience with the MSQA,

not to mention mitigating circumstances." Board Decision at 20. Neither initial complaint sets out the detailed information on each of the factors which the FDA considered in setting the proposed CMP amounts, and Korangy has not shown any legal requirement that the FDA detail the bases for its considerations in the complaint.

Korangy's reliance on the complaint in Ecumed as "significant . . . precedent" reflects a fundamental misunderstanding of the administrative adjudication process. Cf. Korangy Request for Reconsideration at 2. Despite Korangy's occasional reference to Ecumed as a "decision," neither party has provided any documentation of any proceedings in that matter beyond the filing of the initial complaint by the FDA. The complaint alone cannot serve as precedent in any sense. The regulations provide that the ALJ and the Board ultimately look independently at the statutory factors and any other factors "that in any given case may mitigate or aggravate the offense for which penalties and assessments are sought." 21 C.F.R. § 17.34(c). Even if we were convinced that the FDA irrationally sought inconsistent CMP amounts in two separate cases (which we are not), the ALJ and the Board on appeal are competent to assess whether the amount sought in any individual case is reasonable under all the relevant circumstances. Cf. Western Care Management Corporation, d/b/a Rehab Specialities Inn, DAB No. 1921, at 94 (2004) (In nursing home CMP case, Board noted that "[c]ase-to-case comparisons generally have little value given the unique circumstances of each case and the myriad factors that must be considered.").

Korangy's claim is that the only inference to be drawn from the difference in the initial proposed CMPs in the two complaints is that the greater the number of violations and the longer the period of noncompliance, the lower the per-violation CMP the FDA will seek, resulting in a perverse incentive to persist in committing violations. Korangy Reply Letter at 2. As noted in the Board Decision and confirmed by review of the complaint, Ecumed involved allegations of 1,201 violations over 17 months, while Korangy was charged with 193 violations over less than two months. Board Decision at 20. While Korangy is mathematically accurate in observing that the per-violation CMPs sought in Ecumed are lower than those sought in this case, we do not infer that the reason for the difference is that the FDA will seek lower per-violation CMPs whenever the number of violations

increases.[1] Korangy ignores the individualized factors mentioned above which the FDA cites as the considerations for setting different amounts. Nothing in the text of the Ecumed complaint is inconsistent with the Board's reliance on the FDA's explanation that such factors led to the selection of different per-violation CMPs in the two cases.

Korangy further claims that the "only 'aggravating' factor in this case appears to be that Dr. Korangy has availed himself of the estate planning techniques approved by Federal law." Korangy Request for Reconsideration at 2. The apparent point is either that the only reason for imposing a higher per day CMP on Korangy is that the respondents could afford it, or that the fact that Korangy had transferred assets to his family was the only basis for the higher amount.

Korangy's position is in error. The aggravating factors actually relied on by the ALJ were not related to any financial issues. In addition to the concerns inherent in the violations (including endangering almost 200 women's lives), the Board recognized a number of aggravating factors emphasized by the FDA, such as Korangy's knowledge that KRA was operating in violation; the poor quality images Korangy knew to be produced by the equipment KRA was using which caused the facility to fail quality standards of the accrediting authority; Korangy's prior history of violations and poor quality control; the presence of additional quality problems during the period in which Korangy performed mammograms without certification; and indications that Korangy attempted to mislead the accrediting authority about whether KRA was continuing to perform mammography without a certificate. Board Decision at 14-17. The Board also found that none of the mitigating factors asserted by Korangy had any merit. Id. at 18-30. While the Ecumed complaint indicates that the facility in that matter had also received notice of poor image quality, it is silent as to other potential aggravating circumstances, such as any prior history or attempts to mislead, and also does not set forth whether any mitigating factors applied.

Indeed, Korangy's financial claims were not in fact treated as an aggravating factor. The ALJ did find that Korangy was "less than forthcoming" about his assets and other financial information and, therefore, was not entitled to the benefit of any

---

[1] We also observe that the Korangy respondents committed violations at a higher rate per month (approximately 96 versus 70) during the time that the facilities operated without valid certificates.

affirmative defense based on ability to pay. ALJ Initial Decision at 8. While the ALJ commented further that Korangy's financial manipulations would constitute, if anything, an aggravating not mitigating factor, the Board noted that neither the ALJ nor the FDA relied on any assertion that Korangy's financial arrangements were improper or created to avoid payment of the CMPs as an aggravating factor in setting the final CMP amounts. Board Decision at 22-23, n.13. It is thus not true that Korangy would have been "better off not raising any defenses." Cf. Korangy Reply Letter at 2. Instead, Korangy simply failed to prove his defense by credible evidence.

The ALJ found, and we continue to agree, that the amounts imposed on Korangy were reasonable. Nothing in the Ecumed complaint causes us to reconsider or alter that evaluation.

2) Korangy's 2001 and 2002 tax returns

Korangy contends that the tax returns and supporting documents from 2001 and 2002 demonstrate the inability of either respondent to pay the CMP amounts imposed. Korangy Request for Reconsideration at 3. Korangy argues that these documents were "highly relevant" to the Board's consideration in order to have "a complete picture of that which was presented to the ALJ." Id. at 4. According to Korangy, what these documents establish is that "KRA operated at a loss in 2001, obtained modest gain in 2002, and that Dr. Korangy and his wife's income is not anywhere close to sufficient," while the business is "heavily leveraged." Id. at 3.

The issue is not whether the tax returns and supporting documents are relevant but whether the conclusion reached in the Board Decision was in error as a result of the omission of this material from the record before decision. Parts of these documents were in the record originally transmitted by the ALJ. The complete copies of these documents which we now have before us do little to illuminate the ability of either respondent to pay the CMP amounts imposed.

The full documents, like the partial ones the Board examined before, raise as many questions as they answer. See Board Decision at 29. Dr. Korangy insists that his asset transfers and other transactions were lawful under estate planning laws. Korangy Reply Letter at 3. This may well be true, but transactions within the family or with a wholly-owned business which are legal for tax or estate purposes do not necessarily immunize the assets at issue in those transactions from consideration by the FDA or the ALJ when the respondents claim

they have no assets or income to pay the CMPs without being driven out of business. Cf. id.

First, the returns are from 2001 and 2002, which are time periods before and during the period of the violations but not necessarily indicative of the financial status of the respondents at the time the CMPs were first assessed or at the present time when Korangy may be required to begin paying them. At the time of the Board Decision, the record did contain Korangy's personal and business tax documents from 2003, which is closer to the relevant time period.

Second, the tax records from 2001 and 2002 do not clarify the full picture of the net assets and income streams to which Korangy has access to satisfy the CMPs. Instead, they highlight unanswered questions. For example, Dr. Korangy's personal W-2 statements show wages paid by KRA in the amounts of $129,746 and $147,000 respectively for 2001 and 2002. In 2001, Dr. Korangy's personal return then deducts a loss of $109,919 but omits the supporting Schedule E that would explain the assets which generated this claimed loss. The amount does not appear to track the amount from KRA's Schedule K-1 for the shareholder's share of income, credit, deductions, etc. On both personal returns, Dr. Korangy reports substantial income in dividends from Legg Mason ($1,154 in 2001 and $2,869 in 2002) but has not, despite repeated requests from the FDA, ever offered an explanation of what underlying asset or assets generate this dividend income. In 2002, Dr. Korangy claimed capital losses in the amount of $3,000 but failed to provide a Schedule D which would have identified the assets that generated the claimed losses. We refer to these questions not to parse or resolve the details of Korangy's financial status, but merely to illustrate that the documents on their face do not provide a transparent or comprehensive overview of available sources of payment.

Finally, although Korangy dismisses FDA's point that the financial documents "lack independent verification," we find that point important. Compare FDA Response to Reconsideration Request at 7 with Korangy Reply Letter at 3. As explained in the Board Decision, the ALJ clearly evaluated Dr. Korangy's credibility on the issue of his financial status negatively after observing his demeanor at the hearing and reviewing all the financial documentation in the record, including the complete 2001 and 2002 tax documents inadvertently omitted when the record was transferred to us. Board Decision at 28, 30. The procedural events set out in the Board Decision may also have impacted the ALJ's assessment of the weight to be given these documents. Briefly, during the proceedings before the ALJ, Korangy signed an

agreement withdrawing any claim of inability to pay in order to avoid complying with discovery orders regarding Korangy's financial status. Id. at 24. The agreement provided that the ALJ should exclude any evidence offered by Korangy on inability to pay unless the documents sought were produced 60 days before the claim was raised. Id. Korangy breached this agreement by claiming inability to pay in his written direct testimony and by submitting exhibits without prior notice or compliance with the discovery order. Id. at 24-25. We generally defer to an ALJ in assessing the credibility of witnesses who have appeared before the ALJ and in assigning relative weight to the evidence, so long as substantial evidence on the record as a whole supports the ALJ's resolution of disputed facts. 21 C.F.R. § 17.47(k). Reviewing the full 2001 and 2002 documentation does nothing to alter our conclusion that the ALJ's evaluation of the evidence on ability to pay was supported by substantial evidence. Board Decision at 30.

Conclusion

For the reasons explained above, we decline to reconsider the Board Decision.

/s/
Donald F. Garrett

/s/
Sheila Ann Hegy

/s/
Judith A. Ballard
Presiding Board Member