

Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
Phone: 410.938.8703 / Fax: 410.938.8378
henryeschwartzllc@verizon.net

March 4, 2005

VIA OVERNIGHT DELIVERY

Departmental Appeals Board
Appellate Division, MS 6127
Room G-644, Cohen Building
330 Independence Avenue, SW
Washington, D.C. 20201

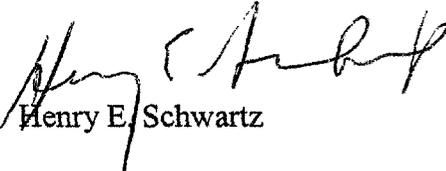
RE: In Re: Korangy Radiology Associates, et al.
FDA Docket: 2003H-0432
DAB Docket: A-05-35

Dear Sir/Madam:

Enclosed please find an original and two copies of Respondents' Reply Memorandum for filing in the above-referenced case.

Thank you for your attention to this filing. Please let me know if anything additional is needed from Respondents.

Sincerely,


Henry E. Schwartz

Enclosures

cc: Division of Dockets Management (HFA-305) {via overnight mail}
Amile Korangy, M.D.
Marci Norton, Esquire, FDA
Jennifer Dayok, Esquire, FDA

2003H-0432

~~2003H-0432~~
RBF 2

BEFORE THE DEPARTMENTAL APPEALS BOARD
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of: * FOOD AND DRUG ADMINISTRATION
*
KORANGY RADIOLOGY ASSOCIATES, ADMINISTRATIVE COMPLAINT
P.A., t/a BALTIMORE IMAGING * FOR CIVIL MONEY PENALTY
CENTERS, *
* FDA Docket: 2003H-0432
And *
* DAB Docket: A-05-35
AMILE A. KORANGY, M.D. *
*

* * * * *

RESPONDENTS' REPLY MEMORANDUM

The following responses of FDA are briefly addressed:

1. Express Terms of Mammography Act.

FDA alleges the promulgation of guidelines consistent with the mandate of 42 USC §263b(h)(4). Nevertheless, the statute specifically requires the development and implementation of procedures "with respect to when and how each of the sanctions" (emphasis added) contained in the Mammography Act is to be imposed. FDA admits, as did its expert compliance witness admit (Tr. at p. 13), that no such guidelines exist for the imposition of Civil Money Penalties. Accordingly, the CMPs issued in the instant case are illegal.

2. Burden of Proof.

FDA alleges that it has met its regulatory burden of proof under 21 CFR 17.33. The record, as indicated in Respondents' Memorandum before the DAB, indicates otherwise. FDA did not attempt to prove the "appropriateness" of the penalties imposed through the hearing process. It did, in fact, unilaterally decrease the penalties sought, during the hearing process, by approximately two-thirds. That both numbers are essentially arbitrary is not controverted by any evidence presented by FDA. The details of this position are presented in Respondents' Memorandum, and will not be repeated here, except to point out that FDA deliberately refuses to compare the instant case to the Ecumed case, based on totally spurious rationales. The Ecumed complaint is admitted as evidence in this case, and it contains minute details relating to the facts and circumstances of that case. Nevertheless, FDA refuses to recognize any need to conform their decisions in these matters to bases that are not arbitrary and capricious. This relates back to FDA's refusal to adopt statutorily mandated standards. A government agency cannot insist on behaving in a manner that is beyond evaluation.

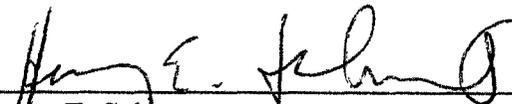
3. Administrative Law Judge's Discretion.

a. The ALJ had no power to revise proposed sanction, as the FDA's action did not conform to its statutory mandate, nor did FDA meet its regulatory burden of proof. The ALJ, unaware of the legal requirements in this case, stated on the record (Tr. at pages 31 and 32) that he expected FDA to seek the maximum penalty, and that he would then decide whether less was warranted. He then accepted FDA's lowered penalty offer without discussion or evaluation. The ALJ abused his discretion in this matter, and his decision should be reversed.

b. The ALJ accepted, over Respondents' objection, evidence presented by FDA in its post-hearing brief. The ALJ then denied Respondents' request to reply. The importance of this is emphasized by the amount of ink devoted to these "financial" documents by both the ALJ and by FDA in their DAB Memorandum. FDA attempts to characterize this evidence as "rebuttal testimony." This is a totally inaccurate characterization. Respondents' pre-filed testimony contained assertions of inability to pay the \$3.8 million dollar fine. Respondents were made available for cross-examination at the hearing on this subject by FDA. Documentary evidence could have been presented at that time. Had that occurred the proffer would have been subject to possible objection and ruling, and to possible response/rebuttal. The fact that these documents were presented post-hearing, and accepted as critical evidence by the ALJ while denying any opportunity for Respondents to address them at all, can only violate the conscience of anyone familiar with due process principles.

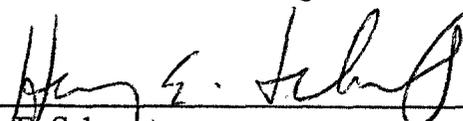
For the foregoing reasons, Respondents' respectfully request that the Board reverse the findings of the ALJ in this case, and determine and order that the CMPs issued by the FDA be stricken.

Respectfully Submitted;


Henry E. Schwartz
Henry E. Schwartz LLC
901 Dulaney Valley Road, Suite 400
Towson, Maryland 21204
410. 938.8703
henryeschwartzllc@verizon.net

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 4th day of March, 2005, a copy of the foregoing Respondents' Reply Memorandum was mailed, postage prepaid, to Marci Norton, Esquire, and Jennifer Dayok, Esquire, Office of the General Counsel, Food and Drug Administration, 5600 Fishers Lane, GCF-1, Rockville, MD 20857.


Henry E. Schwartz