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

----- x	:	Administrative
In the Matter of:	:	Complaint for
	:	Money Penalties
KORANGY RADIOLOGY ASSOCIATES,	:	
P.A., trading as BALTIMORE	:	
IMAGING CENTERS,	:	
	:	FDA Docket No.
a corporation,	:	2003H-0432
	:	
and	:	
	:	
AMILE A. KORANGY, M.D.,	:	
	:	
an individual.	:	
	:	
----- x	:	

Monday, September 20, 2004

5600 Fishers Lane  
Hearing Room F  
Rockville, Maryland

The hearing in the above-entitled matter  
convened, pursuant to notice, at 9:30 a.m.

BEFORE:

DANIEL J. DAVIDSON  
Administrative Law Judge

2003H-0432

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## APPEARANCES:

On behalf of the Complainant:

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Associate Chief Counsel for  
Enforcement  
5600 Fisher Lane  
Rockville, Maryland 20857

On behalf of the Respondent:

HENRY E. SCHWARTZ, ESQ.  
901 Dulaney Valley Road  
Suite 400  
Towson, Maryland 21204

C O N T E N T S

<u>WITNESS</u>	<u>DIRECT</u>	<u>CROSS</u>	<u>REDIRECT</u>	<u>RECROSS</u>
Michael P. Divine	--	10	26	--
Barry Henderson	--	33	--	--
Amile A. Korangy	--	35	--	--

P R O C E E D I N G S

JUDGE DAVIDSON: This is the United States of America, Food and Drug Administration, Administrative Complaint for Civil Penalties, FDA Docket No. 2003H-0432, in the matter of Korangy Radiology Associates, trading as Baltimore Imaging Centers, a corporation, and Amile A. Korangy, an individual.

The purpose of this hearing is for cross-examination of witnesses dealing with the--primarily with the determination of any mitigating circumstances with respect to the amount of the penalty to be determined, since I've already issued a partial summary decision on the merits.

I'll now proceed to take appearances. For the record, please state your name, address, the capacity in which you appear, and indicate the jurisdictions in these United States to which you've been admitted to practice if you are an attorney. We'll start with the appearances for the Food and Drug Administration Center. Go right ahead.

MS. DAYOK: Good morning, Your Honor. My name is Jennifer Dayok. I'm with the Office of the Chief Counsel for FDA, and I'm appearing today on behalf of FDA's Center for Devices and Radiological Health. I am admitted to practice law in Pennsylvania, and my address is 5600 Fishers Lane, Rockville, Maryland 20857, and that's mail code GCF-1.

JUDGE DAVIDSON: Okay. Who appears for Dr. Korangy or Korangy Medical--Baltimore Imaging Centers?

MR. SCHWARTZ: Good morning, Judge. My name is Henry Schwartz. I'm appearing today on behalf of both respondents. I am a member of the bar of the State of Maryland, and my address is 901 Dulaney Valley Road, Suite 400, Towson--T-o-w-s-o-n--Maryland 21204.

JUDGE DAVIDSON: Any preliminary matters?

MS. DAYOK: Your Honor, I have a preliminary matter. I want to object for the record to any new financial documents that respondents are seeking to introduce into evidence,

including the documents that they sought to introduce by letter as Exhibits, I believe, 15 and 16, on the grounds that we had requested these as part of discovery. We had requested all financial information including statements of assets and all documents related to annual receipts and basically all financial records of each respondent.

When they moved--the respondents moved for a protective order and then we filed a joint agreement to resolve discovery, the discovery dispute, and where the government agreed to withdraw its request on the condition that if respondents sought to allege inability to pay, they would produce these financial documents and produce documents responsive to the request 60 days before the filing in which they alleged their inability to pay or this hearing.

Having said that, Your Honor, in the alternative, I would like to state that FDA does not wish to impose a penalty that would bankrupt these respondents, and if you are to allow the documents, we would respectfully request that we be

allowed to fully brief the issue of inability to pay or ability to pay in post-hearing briefs, and also be permitted to supplement the record with any appropriate rebuttal evidence.

MR. SCHWARTZ: If I may, I'd start by responding backwards to Ms. Dayok. We don't have any objection certainly to briefing the issue or their providing rebuttal evidence, should there be any. We're fine with a free and open discussion on the subject.

And to address the first part of Ms. Dayok's comments, the documents that she's discussing did not exist at the time that the FDA's request was originally made, and that we asked our CPA to create these documents in an effort, during an ongoing discussion with the FDA, to provide them with additional information that we thought was relevant and that we also understood that they were interested in seeing. And so having produced those documents, we believe that they are relevant. Obviously, we apologize that they weren't introduced earlier, but as I said, they didn't

exist previously.

JUDGE DAVIDSON: All right. Well, as far as I'm concerned, the statute and the rules, 21 C.F.R., require me to take into consideration all of those documents before I can determine, at least initially, what the penalty, what the civil penalty would be. Therefore, it's kind of--it would be remiss for me to rule out anything, so I've got to look at it. By the same token, I've got to allow time for both sides to fully brief and consider what's available.

I will indicate that I've had a little bit of a problem with this proceeding, primarily because it's the first one that I've had--I've had maybe 15 or 20 civil penalty cases. It's the first one that's gone to this point without having more serious negotiations on a settlement basis when it comes to the penalty. I don't know what's been going on or what hasn't been going on, but what you're talking about now, both of you, is briefing something that you should be discussing between yourselves and arguing over whether the documents

are valid or invalid or whether they represent a basis for me making a determination or not.

Now, I'm willing to make the decision. I think you'd both be better off if I didn't make the decision. So we'll hear what you have to say today. We'll give you an opportunity to brief it. But I encourage you to get together frequently, if necessary, to reach a common settlement in this matter because you'll be taking your chances if you leave it up to me.

MR. SCHWARTZ: Yes, sir.

JUDGE DAVIDSON: Okay.

MS. DAYOK: Thank you, Your Honor.

JUDGE DAVIDSON: Okay. I think the way this should go, I believe the witnesses for the agency went first, so you will have your opportunity to cross-examine those witnesses first.

MR. SCHWARTZ: Shall we proceed then?

JUDGE DAVIDSON: Who is the first witness available for cross-examination?

MS. DAYOK: The first witness is Michael Divine.

JUDGE DAVIDSON: All right. Mr. Divine, are you present? Hurry up here, sir.

Whereupon,

MICHAEL P. DIVINE

was called as a witness and, after having been first duly sworn, was examined and testified as follows:

JUDGE DAVIDSON: Please be seated. Give your full name and address for the reporter, and then your counsel will take over from there.

THE WITNESS: My name is Michael P. Divine. I work for the Food and Drug Administration. My address is 1350 Picard Drive, Rockville, Maryland 20850.

JUDGE DAVIDSON: Ms. Dayok, do you have any preliminary matters before the witness is available for cross-examination? Do you have any qualification or other material you want the witness to state, or do you just want him ready for cross--let him answer the questions?

MS. DAYOK: Your Honor, I'd like to let him answer the questions. His qualifications are

listed in his declaration.

JUDGE DAVIDSON: That's okay. I just always give you an opportunity.

MS. DAYOK: Thank you.

JUDGE DAVIDSON: Go ahead.

MR. SCHWARTZ: Thank you, Judge.

CROSS-EXAMINATION

BY MR. SCHWARTZ:

Q Good morning, Mr. Divine. Obviously we have read your direct testimony, and so I'm content to ask you some questions based upon that. I understand you've been involved with mammography compliance for the FDA since approximately 1993; is that correct?

A Yes.

Q Okay. And if I understood your testimony, you are the FDA's compliance expert with regard to mammography; is that correct?

A That's correct.

Q Have you been personally involved in the case that was developed against the two respondents in this matter?

A Yes.

Q Okay. Did the development of the fines levied by FDA in this case follow FDA's procedures with respect to assessing civil money penalties?

A Yes, I believe so.

Q Okay. And what are those procedures?

A The procedure is to--the district office that investigates the case makes a recommendation to the center where I work, the Center for Devices and Radiological Health, in terms of the number of violations that were committed, that were found during the investigation, and they make a recommendation that is sent into my office, which is the Division of Mammography Quality and Radiation Programs. Our office evaluates the recommendation. That recommendation goes to our management, which either approves that recommendation or turns it down. Regardless of that decision, the recommendation is sent over to our Office of Compliance, and they also do a recommendation that goes through a similar process where it's evaluated by a compliance officer and

then it has to be approved by their management.

Once those two reviews have been done and it's sent over, from there it goes to the Office of Enforcement, which is part of our Office of Regulatory Affairs. They do an evaluation, and they make a decision whether they think there's any problems with the case or not. If they think it's an acceptable case, then it goes to our Office of Chief Counsel, where they look at it; and if they think it's a viable case, it's assigned to an attorney. And if they approve the case, then it's sent to our Center Director who makes the final decision, and he has to sign the letter that goes to the facility with the complaint.

Q And that's the process?

A Yes.

Q So you have described an internal FDA procedural process for the--basically describing the people and the agencies that develop and review the matter before it goes out.

A Right.

Q Okay. Are there any substantive

guidelines that the FDA follows with respect to the issuance of civil money penalties?

A We don't have any formal guidance at this time for civil money penalty cases that I'm aware of. We have some draft guidance, but we don't--it's not official.

Q Is that the draft guidance from 1999 that you're referring to?

A Yeah, I believe so.

Q Okay. That would be--that's--well, okay.

How many civil money penalty cases has the FDA initiated against mammography providers?

A Well, as far as being actually--sending a complaint to a facility, this is, I believe, the third one.

Q The third one?

A I think there's--there was one several years ago, and there's one that was recently sent out, other than this one.

Q The one that you mentioned was several years ago, is that the Community Radiology case?

A Community and Medical Imaging.

Q Okay, Community and Medical Imaging. And is the most recent one in a stage where you can publicly describe it?

A Yeah, it's--it's similar to this case. It's a facility in Florida charged with civil money penalties based on performing mammography without a certificate.

Q In that case, were the penalties issued of the \$10,000 per violation category?

A I'm not exactly sure of the numbers.

Q Okay.

A But it's of comparable level, I think.

Q Okay. And they were of the \$10,000 per violation level in the Community case; is that correct?

A I think initially when it was sent out, yeah, they were in the \$10,000 range.

Q You've indicated the FDA doesn't have substantive guidelines concerning the development of civil money penalties. Do you have a position or a belief as to whether the FDA's policies in this matter are to consider to civil money

penalties to be remedial or punitive?

A I would say remedial.

Q Okay. And could you describe what you mean by that?

A I think that what we're trying to accomplish with civil money penalties is when we believe there's a serious violation of the law, that the penalty be significant enough that the facility won't have serious violations in the future; that we're not trying to shut down facilities, we're trying to get them to correct violations.

Q With respect to--we talked a little bit about FDA process, but that was internal process that you described within the FDA. With respect to, again, civil money penalty cases for mammography, does the FDA have policies or procedures with regard to the actual dealings that it has with the regulated entity?

A I'm not sure I understand the question.

Q Okay. For example, the manner in which a warning or a notice of the possibility of being

subject to civil money penalties is provided to the regulated entity, does the FDA have a policy or procedure that would address that?

A Yes, we do.

Q Okay. And what is that policy?

A Well, I can describe it in a general sense, and then I can describe it specifically in this particular case.

Q Okay.

A In a general sense, when FDA uncovers violations of the law, our policy is to use something called prior notice where we give the regulated entity an opportunity--they're warned of the violations and then given an opportunity to respond. And that's usually done in most cases where--before taking regulatory action.

In the specific case where we have a mammography facility that is accredited and their certificate is about to expire, we have a process where we send out letters to the facility in advance of that expiration date indicating that their certificate will expire, and that if they do

perform mammography once it expires, that they could be subject to sanctions.

Q And does the FDA policy in this area extend to directing the manner in which those warning letters, if I can call them that, are to be delivered to the provider?

A Yes. We send--the last letter we send the facility before their certificate expires is usually sent by some type of accountable mail. We usually direct a contractor to send that mail by some kind of overnight mail, which would get some confirmation that it had been received by the facility.

Q Okay. Two questions, I think, about that. The first is you--you indicated that you--the process you described is what is usually done. Is there actually a policy or procedure written--

A Yes, we have a contract with the company that specifies what they have to do.

Q And what you just described, is that the requirement? Or is--

A Yes.

Q That is the requirement.

A Yes. Several years ago, we realized that we needed to do that to make sure that there was proper warning and that we knew there had been proper warning, so that if they did operate uncertified, you know, we knew that they had known about it in advance.

Q Now, let's talk just for a moment about your description of accountable mail, which is the standard, as I understand it.

A Right.

Q If I understood, you indicated that the concept or requirement is that someone--that there be evidence that someone at the facility received the document; is that correct?

A That's correct.

Q Okay. But does it matter who that person is who received the document?

A No, we don't specify that it has to be actually delivered to an individual. We just have to have acknowledgment that it was received.

Q Well, don't you think it would better suit

your purposes if you knew, for example, that the administrator or CEO of a facility received the letter as opposed to a secretary or a technologist?

A Well, FDA sends a letter--correspondence, a warning letter, for instance, is sent usually by the same method, and if it was addressed to the CEO or the president of the company, it would be sent. And then we considered that if it's received by the company and it's signed for, we considered it to be delivered.

Q Regardless of who--

A Regardless of who signed for it.

Q What if it was a security guard in the outside of a commonly shared building who signed for it? Would that also be acceptable?

A I don't really know. I'm not familiar with all those procedures. All we want to make sure is that it's received by the facility.

Q Okay. Now, in this case, obviously you're aware that the charges and the fines were brought not only against the facility, which is a corporation, but also Dr. Korangy personally. And

as far as I understand, certainly the FDA alleges--and I don't know that we disagree--this procedure that you described was followed in this case. Someone did sign for this.

On the other hand, that notice, as I understand it, was sent to the facility. There was--despite Dr. Korangy being a respondent in this case who's charged with offenses, there was, as I understand it, no effort to send any separate correspondence to Dr. Korangy himself. Is that correct?

A We consider by sending that letter to the facility addressed to him and received by the facility, we consider that to be acceptable.

Q Okay. Now, in this particular case, obviously we have a list of alleged violations, and what the FDA did was assess--and correct me if I'm wrong--what I believe to be the maximum possible penalty under the law against both the corporation and Dr. Korangy individually for each of the alleged violations, correct?

A Correct.

Q Okay. Can you tell us what factors were considered by the FDA in determining to charge two respondents with the maximum possible fines for the alleged violations?

A Okay. Well, when we decide to--obviously there are other violations of the law at various facilities, so we basically pick what we consider to be the most serious violations in a particular case. If we want to take a case, then it's based on the merits of the case and all the other factors that can be considered.

In this particular case, when we found that the facility had violated MQSA, we looked at that and we looked at other factors aside from the fact that they operated uncertified. We looked at the history of the facility. We knew that the facility had gotten a warning letter for quality control violations. In the most recent investigation which uncovered the fact that they operated uncertified, we found additional violations, and so we considered those as other factors and considered to take this particular case

for civil money penalties. And the recommendation was based on what they considered to be violations, and the final decision on the complaint was based on the various reviews and the decisions made by different people in the review of the case that was finally sent out.

Q Okay. Again, back for a moment to FDA policy, if you have an opinion, does the FDA consider the civil money penalty provision to provide intermediate sanctions that it can use against providers?

A Intermediate sanctions? I'm not sure I understand--

Q Okay. That's not a term that's utilized by the FDA?

A What do you mean--

Q Well, if you're not familiar with it, that's an acceptable answer.

A Well, we do--there are other things besides civil money penalties, if that's what you're asking. I mean, we can use suspension of a facility's certificate, which will close them down.

Q I really wasn't--let me just--I'll give one shot at sort of reinterpreting that, again, if it means anything to you. Obviously, the FDA has what could be considered by some perhaps the ultimate sanction, which is it can always de-certify, permanently de-certify a provider.

A Right.

Q And so the question that I was attempting to get at was whether the FDA considered the authority to impose civil money penalties as something that was as an alternative to the ultimate sanction or not.

A Yes, it is an alternative.

Q A couple more questions about, I think, the actual case here. In assessing the fine, did the FDA consider the fact that the respondents ordered a new machine to replace the one that ACR had problems with actually over a month prior to the findings that ACR officially provided to them? Was that considered?

A I'm sure that whatever information was collected during the investigation was available

and evaluated. I believe that the machine in question was purchased--or was actually started to be used somewhat later after the facility had already had their certificate expire.

Q But you don't know if the FDA actually considered the fact that that machine was ordered well before the April 29, '02, letter that was received by ACR?

A Well, it's--the facility failed to become accredited, and I'm not exactly sure what the reasons were. Most facilities who fail to become accredited, usually that's relating to performance of the technologist, but it could be the equipment, but--

Q I'm sorry for interrupting, but I wasn't asking for a general response. If you don't know whether it was considered or not, then that's really all I--

A I believe it was available, and the--I don't think we discussed it very much. I don't think we really considered it relevant.

Q Okay. Before the FDA levied the fines in

this case, did it consider the ability or not of the respondents to pay the fine?

A I believe considering the fact that the facility had several different operating locations, that was considered in terms of this not being a single facility, they had the assets to pay the penalty.

Q So, again, I'm not trying to put words in your mouth, but I think I understood you to say that the FDA considered the financial issue and determined that the respondents did have the assets?

A Yeah, I wasn't personally involved in that kind of analysis, but I believe that it was done during the process of review.

Q And do you know what information was utilized? You indicated that there was more than one service site that the respondents have.

A Right.

Q Do you know if there was any other information that was considered in making that determination?

A I'm not sure.

Q Again, correct me if I'm wrong, but I understood, I think, you to say when you described the purposes of--or the exercise of FDA's fining ability, that you would not personally recommend the fines that were levied in this particular case against these respondents if, in fact, they would bankrupt Dr. Korangy and the corporation; is that correct?

A It's not our intention to drive them out of business.

MR. SCHWARTZ: I understand. Okay. Thank you. I don't have any further questions.

JUDGE DAVIDSON: Redirect?

MS. DAYOK: Yes, Your Honor. May I remain seated?

JUDGE DAVIDSON: Certainly.

MS. DAYOK: Thank you.

REDIRECT EXAMINATION

BY MS. DAYOK:

Q Mr. Divine, I believe you talked about many of these issues during cross. At the time the

action was brought, did you have any specific financial documents that indicated the financial condition of the respondents?

A The original case?

Q At the time the case was initiated.

A No.

Q And you said you were aware--were you aware of how many facilities--

A Yes. The facility's letterhead indicates the locations.

Q Do you know how many? Can you estimate how many?

A I think it was eight, but I'm not exactly sure.

Q To your knowledge, do those facilities offer services in addition to mammography?

A Yes, they do. Those are also listed on the letterhead.

Q Do you know what kind of procedures--

A I believe they have magnetic resonance imaging, ultrasound, computed tomography, general radiography, and fluoroscopy. That's--I'm not

exactly sure, but that's my recollection.

Q And in your experience in over ten years of dealing with mammography facilities and radiologists, you've had contact with many radiologists that--

A Yes. In fact, we have two radiologists in our division.

Q And in your experience, do you have any opinion of how lucrative the radiology practice is in comparison with some other medical specialties?

MR. SCHWARTZ: Objection, Your Honor.

JUDGE DAVIDSON: Sustained.

BY MR. SCHWARTZ:

Q Did you have any reason to believe, based on the services provided and the number of facilities, that these respondents had any inability to pay civil money penalties?

A I didn't believe they had a problem.

Q And the agency--would the agency be willing, if receiving such documentation, to reduce the amount of penalties that they're asking for?

A I'm sorry. Could you repeat that?

Q If the agency received credible documentation of such inability to pay, would that be something that the agency would consider in reducing the amount of penalty?

A Yes, we would.

Q Now, FDA itself, do they get any money from any civil money penalty paid?

A It's my understanding that the penalty is paid to the U.S. Treasury. FDA doesn't get the money.

Q You described the practice of serving notice or warning letters on firms. When you did that in this case, who was the notice addressed to?

A Dr. Korangy.

Q And how did you initially learn that these respondents were performing mammography without a certificate?

A We received a letter from the American College of Radiology. The letter indicated that they believed this facility was operating uncertified based on their contacts with the facility.

Q And did you consider as part of bringing this action, as part of--did you consider the length of time that the facility remained uncertified?

A Yes, and also the number of mammography examinations they did while uncertified.

Q And in comparison with other cases, was that time period long? Can you describe how it--

A There are some facilities that may operate for a few days or maybe a week or longer. Most of those facilities don't have other problems. They seem to be fairly cooperative and seem very apologetic when they find out that the problem has occurred, and they quickly try to rectify the situation with the American College of Radiology or the other accreditation bodies that they may be accredited with.

Q And how many mammographies did this facility perform while uncertified?

JUDGE DAVIDSON: It's of record. A lot of what you've both gone into is of record. I've been kind of patient.

MS. DAYOK: I apologize, Your Honor.

JUDGE DAVIDSON: It's running out quickly. I don't need anything on the record that's already on the record. I certainly am willing to listen to arguments about things I've already decided, but I don't think there's any point in reiterating the things I've already decided on the record per se.

One more thing, if you're going to get into this with any other witnesses, the FDA, as you're well aware, is not a single-headed operation. It's got lots of different facets. At this point I represent the FDA in determining the amount of the penalty. An appeal from what I decide will go to the Appeals Board that is delegated. If the FDA brings this proceeding as the center, they're an advocate. When you're an advocate, you also would go for the highest award you can get. You may not have any chance of getting that, but you'd certainly go for it. So all these questions about whether he considered mitigating circumstances don't impress me very much because it's up to me to consider the mitigating

circumstances. I expect them to ask for the maximum. All right? Let's go.

MS. DAYOK: I have no further questions.

JUDGE DAVIDSON: Do you have any recross?

MR. SCHWARTZ: No, Judge.

JUDGE DAVIDSON: Okay. Next witness.

You're excused, sir.

[Witness excused.]

MR. SCHWARTZ: Judge, there were no other witnesses which we requested.

JUDGE DAVIDSON: You'll make your witness available for cross?

MR. SCHWARTZ: Certainly.

MS. DAYOK: First I'd like to cross-examine Barry Henderson, please.

JUDGE DAVIDSON: All right. Mr. Henderson?

Whereupon,

BARRY HENDERSON

was called as a witness and, after having been first duly sworn, was examined and testified as follows:

JUDGE DAVIDSON: Please be seated. Give your full name and address to the reporter.

THE WITNESS: Barry Henderson. My address is 2750 N.E. 183rd Street in Aventura--A-v-e-n-t-u-r-a--Florida.

CROSS-EXAMINATION

BY MS. DAYOK:

Q Good morning, Mr. Henderson.

A Good morning.

Q Just a few questions for you. You were the vice president or you currently are the vice president?

A I was.

Q You were? But you are no longer?

A I'm no longer employed by Baltimore Imaging.

Q And you were present at an FDA inspection of Baltimore Imaging Centers Maiden Choice Lane facility in August of 2002, correct?

A Yes.

Q At that time you spoke with Elizabeth Laudig from the district office?

A Yes.

Q And you gave an affidavit at that time?

A Yes.

Q And that affidavit was under oath; is that correct?

A It was presented to me. I read it and signed it in places.

Q You read it and signed it?

A Yes.

Q And you were given the opportunity to make corrections?

A Yes.

MS. DAYOK: I have no further questions.

MR. SCHWARTZ: Nor have I.

JUDGE DAVIDSON: You're excused.

[Witness excused.]

MR. SCHWARTZ: Are you ready for Dr. Korangy?

MS. DAYOK: Yes, I am.

Whereupon,

AMILE A. KORANGY, M.D.

was called as a witness and, after having been

first duly sworn, was examined and testified as follows:

JUDGE DAVIDSON: Please be seated. Give your name and address to the reporter.

THE WITNESS: My name is Amile Korangy. I live at 13607 North Sheepshead Court, Clarksville, Maryland 21029.

JUDGE DAVIDSON: I'm sorry. Where in Maryland?

THE WITNESS: Clarksville, Maryland.

JUDGE DAVIDSON: Clarksville, okay. Thank you.

#### CROSS-EXAMINATION

BY MS. DAYOK:

Q Good morning, Dr. Korangy.

A Good morning.

Q When you bought--after you bought all the shares of Drs. Wityk, Goad, Korangy & Associates in 1998, you didn't dissolve the corporation, correct?

A Correct.

Q You didn't break off and form a new corporation; is that correct?

A Yes, I did. The corporation was Wityk, Goad, Korangy & Associates, P.A. The new corporation was Korangy Radiology Associates, P.A.

Q You just changed the name, though. It was the same entity. Isn't that correct?

A Right.

Q Okay. And shortly after that, you had to renew your mammography certification for the Maiden Choice facility?

A Yes, in April or May of 2002.

Q I'm talking about May of 1999.

A I was not involved in that.

Q You weren't involved in that?

A As far as I know, Dr. Wityk was still involved getting the certifications done.

Q And isn't it correct that Dr. Wityk was not part of the corporation at that time?

A No. He still was working for the corporation. They sold their share, but they were employees of the corporation. They were working with the corporation.

Q Isn't it true, Dr. Korangy, that when the

facility applied to renew its mammography certification in April of 1999, you signed the application as supervising radiologist?

A Yes, I did, but Dr. Wityk was--because he knew about the procedure and he was doing it before, he was handling everything and just getting me to sign the papers.

Q Okay. So you did sign it.

A Yes.

Q And that certificate was issued in the names of Drs. Wityk, Goad, Korangy & Associates; is that correct?

A I don't know which name was it. I don't have the record.

Q You just opened--you just applied for accreditation for a new facility; isn't that correct?

A Right.

Q In Frederick, Maryland?

A Yes.

Q Are you renting that facility?

A Yes.

Q Renting the office space?

A Yes.

Q And you're the supervising radiologist for that, correct?

A Yes.

Q How many of your facilities offer mammography?

A We had six facilities before. We closed half of them. There is only three facilities doing mammography.

Q You closed the facilities altogether, or you just stopped doing mammography?

A We stopped doing mammography.

Q And for the ones that remain doing mammography, are you still the supervising radiologist?

A Yes.

Q Do you have any involvement in the hiring of employees at your facilities?

A No. We have other employees to interview and hire.

Q And you don't personally take part in

that?

A No.

Q Do you own a home, Dr. Korangy?

A No.

Q So the residence you described at 13607 North Sheepshead Court in Clarksville is not in your name?

A No.

Q Was it in your name in December of 2003?

A No.

Q Isn't it correct that you transferred that out of your name in December 2003?

A This was in a trust with my family and it's not in my name.

Q When you transferred it in 2003, did you receive any money or anything of value for that to transfer it out of your name?

A I told you I did not transfer it at that time. It was already in the name of the trust.

Q You submitted a statement of financial condition recently, in the last month. That was for yourself and for--one personally and one for

Korangy & Associates?

A Yes.

Q Now, that wasn't audited, was it?

A No.

Q So basically what that means is the accountant took all the documents that you gave him; is that correct?

A Right.

Q But he didn't do his own investigation?

A I don't know what he did. I gave him all the documents, the ones he asked for.

MS. DAYOK: May I have one moment, Your Honor?

JUDGE DAVIDSON: Certainly.

[Pause.]

BY MS. DAYOK:

Q And you own one building which is where the--you own a building--not you personally, but the Korangy Radiology Associates owns a building where the Maiden Choice office is?

A Yes.

Q Do you personally have a car?

A No, I don't have a car.

Q You don't have a car in your name?

A No.

MS. DAYOK: Your Honor, I have no further questions at this time.

MR. SCHWARTZ: I have no questions for Dr. Korangy.

JUDGE DAVIDSON: All right. Dr. Korangy, you're excused.

THE WITNESS: Your Honor, I was ready to answer a lot of questions, but that's okay.

[Witness excused.]

JUDGE DAVIDSON: Okay. Anything else you gentlemen or lady care to address me with at this point?

MR. SCHWARTZ: If I may?

JUDGE DAVIDSON: Certainly.

MR. SCHWARTZ: Yes, Your Honor, there's no more evidence on our part to be presented. Two things. First is I would like permission to file a post-hearing brief because I think it's essential--

JUDGE DAVIDSON: I'll grant you that.

MR. SCHWARTZ: And the other thing is if you would entertain maybe four minutes of argument at this point, preparatory to handing in the brief, I think just a summarization, I would be more than happy to do that.

JUDGE DAVIDSON: Can you do it without repeating what's already on the record?

MR. SCHWARTZ: I believe so.

JUDGE DAVIDSON: If so, okay. Otherwise, no, because--

MR. SCHWARTZ: I believe so.

JUDGE DAVIDSON: --I don't like to hear it over and over and over again.

MR. SCHWARTZ: Understood.

JUDGE DAVIDSON: Stuff has been presented to me for almost over a year now.

MR. SCHWARTZ: Understood, Judge. Yes, I think I can.

JUDGE DAVIDSON: Okay. Any objection?

MS. DAYOK: No objection, Your Honor.

JUDGE DAVIDSON: Do you care to also present a rebuttal argument?

MS. DAYOK: I would like to reserve my right to present a rebuttal.

JUDGE DAVIDSON: Okay. Thanks. You can do it in four minutes?

MR. SCHWARTZ: I think so.

JUDGE DAVIDSON: I'll give you five. Go ahead.

MR. SCHWARTZ: Thank you, Judge. I appreciate that. Yes, as I said, just a summarization. Obviously everything will be set out--

JUDGE DAVIDSON: I understand.

MR. SCHWARTZ: I wanted to give you a preview, I think, so that you would understand, I think, where we're coming from with this case.

First let me say if we can successfully conclude talks with FDA, you won't see us again and everyone will be happy. In the meanwhile, I've got my job to do with respect to legal representation, and I think I have some credible issues that I intend to put forward and that I think will be appropriate for the record in this case if we are

so unfortunate as to need to get to a point where we're trotting out the record somewhere along the line.

First of all, I would point out that 21 C.F.R. 17.33 indicates that the center must prove appropriateness of penalty by a preponderance of the evidence. I will argue that that has not been done in this case. We're not going over the facts today. We're pointing out the argument.

I would also like to point out that 42 U.S.C. 263 b(h)(4) states that the Secretary shall develop and implement procedures with respect to when and how each of the sanctions in this particular case is to be imposed. I would point out and I will argue in the brief that this has not been done, that the Secretary has not carried out his obligation under the law, and that the sanctions are inappropriate in any amount in this case for that very reason.

I would point out and I will argue that the sanctions in this case are grossly disproportionate to the offenses charged and,

therefore, violate the Eighth Amendment to the Constitution of the United States.

I will obviously make these arguments in more detail in the brief. I will, of course, also address the various mitigation factors that we would have hoped the FDA would have considered and that we do hope, of course, that Your Honor will consider if, of course, you are called upon to make a substantive judgment with regard to the merits of this case.

Thank you.

JUDGE DAVIDSON: Thank you.

Anything?

MS. DAYOK: Your Honor, I have nothing further except to say that I look forward to reading counsel's brief and preparing my own. Thank you.

JUDGE DAVIDSON: All right. First of all, we've got a couple of dates to establish. Let's go off the record for a second.

[Discussion off the record.]

JUDGE DAVIDSON: According to 21 C.F.R.

1741(a), the parties are given 30 days to file any corrections in the transcript with the FDA Dockets Management Branch, copies to each other, obviously, and myself. As pointed out, and I'll emphasize, in that section the corrections of the transcript are for errors of transcription only, not for something that should have been said differently or might have been said differently or was understood differently. It's only if it's transcribed incorrectly. So considering the eight days will bring us close to the end of this month--has someone got a calendar handy?

This is on my own system. I forgot to provide one for myself here.

MR. SCHWARTZ: I have that problem also, Judge.

MS. DAYOK: Okay, Your Honor. We have an electronic calendar here.

JUDGE DAVIDSON: I have one.

MS. DAYOK: Okay.

JUDGE DAVIDSON: All right. So October 28th--make it Friday, the 29th, will be the due

date for corrections of transcript.

Now, while I've noticed in the past that some of you--and I won't--some of you weren't even involved in--one of you wasn't even involved in this proceeding in the early part. But for some reason, my order of, I think it was, November 13, 2003, which set the schedule for this proceeding, Item 6 required the filing of a draft order with respect to any motion. I received several motions that didn't have draft orders attached. Maybe that's why I didn't rule, for your information and edification.

I'm going to require that your briefs also include a draft order for the conclusion of--and it can be in the form of an initial decision if you wish, but an order will be sufficient, setting forth the determinations that you think I ought to make with respect to the amount of the penalty.

The due date for your briefs, November 19th.

MS. DAYOK: Your Honor, I will be out of the country for most of November.

JUDGE DAVIDSON: Oh, yes? So we'll make it earlier?

[Laughter.]

MS. DAYOK: Could we make--

JUDGE DAVIDSON: All right. If that's a problem, you suggest a date. Go ahead.

MS. DAYOK: I would suggest it be the following--

JUDGE DAVIDSON: Don't start with the schedule, because there's not going to be briefs and reply briefs. Simultaneous briefings.

MS. DAYOK: November 29th, Your Honor? I won't be returning until the--probably the 23rd, and then that Thursday is Thanksgiving.

MR. SCHWARTZ: Judge, if I may, I have no desire to rush counsel for FDA.

JUDGE DAVIDSON: That's okay. So you want to make it the 29th or you can go another week, an additional week.

MS. DAYOK: Well, an additional week would be wonderful. Even that Friday would be fine, Your Honor.

JUDGE DAVIDSON: December 3rd?

MS. DAYOK: Yes.

JUDGE DAVIDSON: Okay. I would hope that before that you get together and enter into settlement negotiations on this.

MR. SCHWARTZ: If Ms. Dayok is going someplace interesting, I may try to join her.

[Laughter.]

JUDGE DAVIDSON: She didn't tell me where she was going.

MS. DAYOK: That's non-negotiable.

[Laughter.]

JUDGE DAVIDSON: I will expect, according to my rules, that if you get--if you find a need to postpone the schedule I'm going to issue in the form of a notice following this oral phase of the hearing, if you need to postpone the schedule, you can't postpone the--I mean for the briefing schedule, due to the fact that you are engaged in fruitful negotiations, that you'll let me know significantly in advance of the due date, because I don't appreciate being in the position of filing an

order, postponing a due date that has already passed. That's why I have a five-day rule in the first place. All right?

MR. SCHWARTZ: Yes, sir.

JUDGE DAVIDSON: If nothing further to come before us at this time--anybody have anything else?

MR. SCHWARTZ: No, sir.

MS. DAYOK: No, Your Honor.

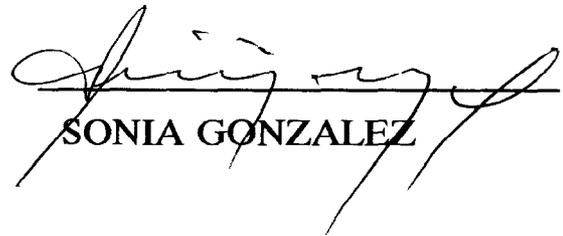
JUDGE DAVIDSON: All right. This hearing is adjourned.

[Whereupon, at 10:25 a.m., the hearing was adjourned.]

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***C E R T I F I C A T E***

I, **SONIA GONZALEZ**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



SONIA GONZALEZ