STATE OF OHIO

COUNTY OF CUYAHOGA

IN THE COURT OF COMMON PLEAS

* * * * * * * * *

BONNIE WEISS, *

Executrix of the * Case No. 326275

Estate of EDITH *

JAMES, *

Plaintiff *

vs. *

HENRY W. EISENBERG, *

M.D., et al., *

Defendants *

* * * * * * * *

DEPOSITION OF

KENNETH SCOTT MCCARTY, JR., M.D.

JULY 27, 1998

DEPOSITION

OF

KENNETH SCOTT MCCARTY, JR., M.D., taken on behalf of the Plaintiffs herein, pursuant to the Rules of Civil Procedure, taken before me, the undersigned, Jackie Hazlett, a Court Reporter and Notary Public in and for the Commonwealth of Pennsylvania, at Biomedical Science Tower, 200 Lothrop Street, Pittsburgh, Pennsylvania, on Monday, July 27, 1998, at 1:23 p.m.

APPEARANCES

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I N D E X

EXHIBIT PAGE

NUMBER	DESCRIPTION	PAGE IDENTIFIED

NONE OFFERED

OBJECTION PAGE

ATTORNEY	PAGE
Goldwasser	25
Goldwasser	102

P R O C E E D I N G S

KENNETH SCOTT MCCARTY, JR., M.D., HAVING FIRST BEEN DULY SWORN, TESTIFIED AS FOLLOWS:

EXAMINATION

BY ATTORNEY MALIK:

Q. How are you today, Doctor?

A. I'm okay. How about yourself?

Q. Well, thank you. I have some questions to ask you. I know you've done this before so if there's something you don't understand just let me know, okay?

For the record would you please state your full name?

A. Kenneth Scott McCarty, Jr.

Q. And is the CV which you gave Mr. Goldwasser accurate as of this date?

A. I don't have it. I gave it to you.

OFF RECORD DISCUSSION

A. The CV attached to the report appears to be dated 9/96, so it would be accurate through that date.

BY ATTORNEY MALIK:

Q. Is there a more recent one that's been prepared?

A. Yes, there should be. And there is --- subsequent to 9/96, yes, there are more recent CVs.

Q. Is there anything on the new one that's related to the subject of colorectal cancer?

A. No.

Q. What would be different between the two, just briefly?

A. I think the format was changed. Their --- meaning the format which it is. The official document frowns on people putting their children on the front page. I frown on people who frown on people who frown on people who put their children on the front page. The previous positions is in a separate job format, but its substance --- no difference in substance.

Q. Okay. Do you intend to publish any articles before the trial date which is presently set for September 14th regarding colorectal cancer?

A. No.
Q. Do you intend to give any talks or teach any classes regarding that subject?
A. What's the trial date?
ATTORNEY GOLDWASSER:
September 14th.
BY ATTORNEY MALIK:
Q. September 14th.
A. No, I don't think that will be the case. There is the general oncology covered in the path course, but I don't think that's before the September date.
Q. Are there any articles contained in the CV that relate to the topic of colorectal cancer, specifically?
A. I don't think so, no.
Q. Are you personally familiar with Doctor Eisenberg?
A. No.
Q. Have you ever met him?
A. No.
Q. Now, I noticed from your CV that you're Board Certified in both pathology and internal medicine?

A. Yes.
Q. What percent of your practice is devoted to each one?
A. You mean the internal medicine versus ---?
Q. Pathology.
A. Well, my pathology practice --- you're asking what percent of time probably.
Q. Yes.
A. Generally two days a week average in internal medicine, the remainder in pathology and related. As a general rule, there is overlap in the sense that I may see a patient because of a specialized pathologic finding and then see them clinically to put it in context. This afternoon I'll be seeing somebody who came because of pathologic abnormalities observed and then wants to discuss what the implications of those are.
Q. Do you spend more than 50 percent of your professional time in a clinical practice?

A. Between pathology --- you're saying clinical practice --- clinical means at the bedside, which would mean internal medicine as opposed to pathology which is also a clinical practice?

ATTORNEY GOLDWASSER:

Well, that's not what the law says, but is that what you're asking?

BY ATTORNEY MALIK:

Q. No, no, no. Either --- together, combined.

A. We didn't get into the pathology practice, but, yes, I do.

Q. What percentage of your time, then, do you spend on the pathology practice?

A. I think I'm 40 percent right now in actual clinical practice and then for pathology it's about 20 percent in internal medicine and then in teaching and research and related to those practices additional 30 percent.

Q. In your internal medicine practice, do you perform sigmoidoscopies?

A. No.
Q. Have you ever?
A. Yes.
Q. And when did you stop doing that?
A. 1992, probably.
Q. Did you ever perform colonoscopies?
A. No. You mean being the colonos --- the operator or the scop, no.
Q. Correct. With respect to sigmoidoscopies, do you think that that 1992 date is accurate, when you stopped doing sigmoidoscopies? I want you to be certain about that.
A. No. I don't --- I had a practice at the Durham Clinic. The last time --- and so that we're clear, and I made the distinction on colonoscopy and I walked right through your sigmoidoscopy question, I am not the operator for a sigmoidoscopy through that period of time. The Durham clinic, which I practiced in in Durham, we had surgeons as well as internists practicing together. Had several patients in which

the procedures were done, that I participated in the procedures. You're asking, do I do them. I should answer that, no, so that we're very clear.

Q. Okay.

A. And in that sense, do I operate a sigmoid scope, the answer is clearly, no.

Q. So you've participated in them with --- being in the room when the procedures have been done?

A. That's correct. And viewing the findings and also evaluating what might best be biopsied.

Q. What's important to me now is when you stopped doing that?

A. The last time I would have done it would have been '92.

Q. Okay. Have you in --- or do you in your internal medicine practice treat patients with colorectal cancer?

A. No, not now.

Q. Did *you?*

A. Yes.

Q. Up until when?

A. Probably 1991 or '92. That is

patients may have had colorectal cancer as part of their clinical picture. The primary medical oncology in the colorectal carcinoma and the primary surgery would have been by the other associates.

Q. In your internal medicine practice, then, am I correct in understanding you did not perform the task of diagnosing colorectal cancer?

A. No. That would not be correct. You mean making the diagnosis or more importantly doing the screening procedures. No, that would not be correct. I did do rectal exams. I did --- I don't know if they're right.

Q. Let me stop you right there. When you said rectal exam, digital rectal exams?

A. Digital rectal exams. And then ordering GI series. In that period of time I don't think there was a primary colon cancer for which I was responsible for the initial and primary diagnosis as an internist.

Q. In your internal medicine practice, can you tell me then what percentage of patients you have screened for colorectal cancer?
A. What percentage of patient have I screened for colorectal cancer?
Q. Right.
A. And we're talking in this time frame or the time frame of Durham Clinic?
Q. I believe through '92, anytime up through '92.
A. I tend to see patients who are referred either by themselves or others for specific problems. And in that regard, many of those patients are not, you know, patients who are seeing me as their primary physician. I do see patients also in that group who I am --- or they treat me as, I treat them as, in the role of being their primary physician. And those patients, stool blacks were done, digital rectal exams were done. I don't know how to even guesstimate the proportion of those patients. Probably ---.

Q. Can you give me a range?
A. I mean, that would be a guesstimate. As I look back on that I can't remember a clinic day that we didn't do a couple of rectal exams. The purpose of those were generally relating to stool blacks, they may be by manual exams during a pelvic, so it would be ten percent that were screened.
Q. Okay.
A. But I mean, that's ---.
Q. I understand. And the screening is limited to digital exams and stool quaiac, basically?
A. No. Although their --- the situation in which you're doing the annual screening for colonoscopy and imaging studies, really, those are patients in whom the primary concern is as a generalist and seeing them as a primary physician, it's not a common component of my practice and I think I've --- I hope I've made it clear, the majority of the patients are not ones I saw as the primary physician.

Q. Then it's a very fair statement to say you do not consider yourself a gastroenterologist?
A. Gosh, that would be in the category of an understatement.
Q. Okay. Are you personally familiar with Doctor Lavery (phonetic) who has offered --- who has also offered opinions in this case?
A. No.
Q. Did you review his deposition?
A. No.
Q. Did you review Doctor Eisenberg's deposition?
A. No. What I can probably simplify things for you is what I reviewed as sitting before you right there.
Q. Okay. And would you tell me what that is?
A. This is a pictorial representation of the histologic slides and these are the protocols that go with the histologic slides. This is the medical records supplied to me relating to the treatment of Bonnie Weiss.

ATTORNEY GOLDWASSER:

Edith James, actually.

Bonnie Weiss is the daughter-in-law.

A. Correct, sorry. Mrs. James.

BY ATTORNEY MALIK:

Q. And then the last thing?

A. This is all. The last thing is letters.

Q. Have you had the opportunity to testify for Mr. Goldwasser before?

A. I've reviewed cases for him before, but the first time I ever met him was today.

Q. Have you testified for him or others in his firm before?

A. Reminger and Reminger?

Q. Yes.

A. I think I have. I'm not sure whether I have reviewed cases and given depositions, but I certainly have reviewed cases for them.

Q. Have you done so for cases in Ohio?

A. I'm unaware of them being

anywhere else.

ATTORNEY GOLDWASSER:

Yes, we're only in Ohio.

A. I didn't know that for sure, so.

BY ATTORNEY MALIK:

Q. Would you have and documentation with respect to other depositions that you've given?

ATTORNEY GOLDWASSER:

To anybody or just Reminger and Reminger?

ATTORNEY MALIK:

Reminger and Reminger.

A. I'm not aware of any. I have --- Jacobsen Manor, of course, is no longer in existence and I, frankly, in my mind don't distinguish Reminger versus Jacobsen for reasons that may be obvious to you. I don't know if I've ever given a deposition with any certainty for them, I just know I've reviewed cases for them.

BY ATTORNEY MALIK:

Q. Have you ever testified in Ohio before?

A. Yes.

Q. An Ohio case? Do you recall what?
A. On several occasions I know that I have --- the first time that I met someone from Reminger and Reminger, I was on the opposing side. And I think it was an asbestos-related case, but primarily related to neoplasm. There were breast cancer cases and by --- you were saying in Ohio, you're meaning either by trial or deposition?
Q. Yes. I mean an Ohio case. I mean deposition ---.
A. Right. I understand that, but you said in Ohio, you know. I'm just trying --- I know what it's going to --- I'm to answer your question as you're asking it, so it makes sense to me. I'm sure it makes sense to you. Breast cancer, there have been colon cancers for Neuremberg Plevin (phonetic), I think Ann Kilbain (phonetic) had a case. Then some cervical cancer issues in Ohio.
Q. What percentage of your practice would you say --- or of this work that

you do is Plaintiff oriented versus Defense oriented?

A. It probably comes as nearly 50/50 as anything that I know.

Q. With respect to the colorectal cancer case in Ohio, was there more than one?

A. I reviewed more than one. I think there's only one that went to trial.

Q. Did you testify in more than one by deposition?

A. I don't remember doing that, I just remember reviewing it.

Q. Do you remember giving any testimony in Ohio other than the trial testimony in a colorectal case?

A. I don't remember. But that doesn't mean that I didn't over the years. I think I said Ann Kilbain was the --- or Neuremberg Plevin was the firm. There may have been two, but I think only one went to trial because that's what I remember.

Q. And what are your cha'rges for

review of a file and your charges for deposition testimony?

A. It's an hourly rate of $280 an hour.

Q. Is that money that goes directly to you or money that goes to the university?

A. To me.

Q. Other than Mr. Goldwasser, have you spoken to anybody else about this case?

A. Nobody outside of his office. And I don't have any recollection of talking to anybody other than him in his office.

Q. To date, how much time would you say you've spent on this matter?

A. Four hours.

Q. With respect to the cases that you have reviewed, can you tell me what percentage were medical malpractice cases?

A. I'm missing this, as opposed to product ---?

Q. As opposed to product injury,

product liability.

No, I've --- product liability is the only other material that I've reviewed. I don't think I've been involved in any personal injury. I don't know ---.

ATTORNEY GOLDWASSER:

Is this personal injury --- are you talking about automobile kind of cases?

ATTORNEY MALIK:

I'm talking about automobile kind of cases.

A. I don't think I've ever been involved in an automobile kind of case.

BY ATTORNEY MALIK:

Q. So what percentage would be medical malpractice? Greater than 50 percent?

A. It depends on the time frame. In some --- I've been involved in cases relating to breast implants, and that varies according to the year.

Q. Within the last five years, let's say.

A. Well, in the last five years, more relating to medical mal up until the last year in which there's been a lot *of* breast implant material reviewed.

Q. So percentage-wise ---?

A. It's --- it probably doesn't translate real well into a type where --- this year, probably 30 percent. Med mal last year, a higher proportion, except for the very end of the year there were a couple of, I guess they're called cluster cases where they have multiple cases together.

ATTORNEY GOLDWASSER:

Class action.

A. Class action.

BY ATTORNEY MALIK:

Q. Just an average.

A. I don't think it's a class action. It's literally just multiple cases coming together under one thing. It probably averages out to the majority being medical malpractice, matters that I review.

Q. That's okay. That's fine. Of

those medical malpractice that you've reviewed, what percentage would be the Plaintiffs and what percentage would be Defendants?

A. About half and half. When I was answering you before, that was the answer relative to med mal, because I had understood that to be the question.

Q. What --- can you tell me what percentage of colorectal cancer patients end up dying?

A. It depends on the stages of the disease.

ATTORNEY GOLDWASSER:

I'm going to object.

This is ***so*** variable.

A. There's 138,000 or thereabouts new cases diagnosed, I guess, and the last time there was really good statistics for that were 130, 140 and, what, 50,000 thereabouts that die per year.

BY ATTORNEY MALIK:

Q. ***So*** that comes out to what?

A. I'm not sure that's the way one

should to do that math, but of new cases diagnosed by that statistic, if that were a valid way to do it, just under half.

Q. All right.

A. In fact, there's no reason to guess at that, is there? So what I'm doing is pulling up recent statistics on colorectal. We'll be doing this from Holland and Frei. 138,000, 1995, 57,195 deaths.

Q. Is it a fair statement to say that most colorectal cancers are believed to arise from an adenomatous polyp?

A. Well, you've got the key word in that sentence is believed to arise. Now there are --- probably the majority of colorectal cancer is diagnosed in which you do not appreciate and adenomatous polyp. The assumption of the stepwise progression is related to Bert Vogelstein (phonetic) work, in which the genetic alterations occur. There is an increased risk associated with a sessile polyp, but your question is, do they arise from, and I'm taking the word believe out, and I

would say, no, it's not fair to say that they arise from. It is fair to say that people believe that there is a progression from mucosal change to invasive cancer, and I think that bears with the observations. The genetic work that has been done bears out the fact that there probably is point mutations that are involved in the development of the tumors. But all of those statements are not the same as saying what you asked.

Q. So your answer to my question is no?

A. My answer, as I said, was no, it's not fair to say that they do arise from a little adenomatous polyp.

Q. What, in layman's terms, is an adenomatous polyp?

A. An adenomatous polyp is a --- you've got two words and the definition of adenomatous polyp relates to the meaning in both of those words. Adenomatous means glandular derived and polyp means growth or projection.

Q. Let me ask you this, is it a fair statement to say that a polyp is a grossly visible protrusion from the mucosal surface? It may be classified pathologically as non-neoplastic, hyperplastic, adneo --- how did you pronounce that?

A. Adenomatous.

Q. Adenomatous.

A. Sounds like something that I might have written, so ---.

Q. Maybe it was.

A. Sounds like something I wrote. Yes, I think that's a fair statement. It's a growth or projection. I was trying to put it in lay terms, but what you read is an artfully written statement of what an adenomatous polyp could be.

Q. Is it a fair statement to say that adenomas are clearly pre-malignant?

A. No.

Q. And what's the basis for that?

A. Well, premalignant --- to properly use the term, means there's an obligate relationship to the malignancy.

First of all, malignancies kind of rise without a predisposing or pre-existing adenoma.

Secondly, in many situations in many sites, adenomas occur without any malignancy ever occurring. So your statement misses in both directions. I can make it a correct statement.

Q. No. No. No. I didn't say that all adenomas cause cancer.

A. Right. You asked whether an adenoma is a premalignant state. And I said, the term premalignant properly used indicates it's an obligate precursor. It may be a function of time and/or residual mutations that leads to or not leads to the formation, but there are many situations and sites in which adenomas have no observable relationship to the development of a cancer.

Q. Is it a more accurate statement then to say that adenomas can be premalignant?

A. Yes. That's what I was going to correct your statement to.

Q. Okay. How do you differentiate between a premalignant adenoma and a malignant?

A. Under conventional methods?

Q. Yes.

A. And I'm going to make this distinction a priority, you may have a follow-up question, which is fine. Under conventional methods, and conventional being defined as nongenomic, nongenetic, the distinction is really made on to the degree of atypia that is observed or not observed and the polyp in terms of whether you are going to assign a low, medium or high probability for the development of a neoplasm --- cancerous neoplasm from that lesion.

If, in fact, you take the degree of atypia as one factor, the other factor is sometimes considered a size. That's much less of a reliable predictor than is the degree of atypia.

The nonconventional methods involve looking at point mutations and expression of oncogenes. The problem

with that is that that would --- that results in a change in the standard by which you make the diagnosis of carcinoma and/or, quote, precancerous condition. I don't think that's yet a standard practice.

Q. The latter that you're talking about deals with changes or possible changes in DNA; correct?

A. Simply put, yes. It's simplified in the extreme because it's really both changes in the DNA and changes in the way in which DNA is transcribed.

Q. I want to dumb this down a little bit.

A. Go ahead.

Q. And I'm more concerned about the conventional.

A. That's the way I interpreted you, and I hope I answered you that way. The degree of atypia is your primary and the second is size. There's a great deal more information in the degree of atypia.

Q. So when you're talking about atypia, are you addressing the issue of

visualization of the polyp by a colonoscopy?

A. I'm trying to think if I understand --- I don't understand your question.

Q. Atypia, poly --- how are you defining atypia, so I'm on the same page with you.

A. There are two pages. And the one page is whether it looks atypical in its gross appearance. And that's the loosest use of the term.

Q. Which is where my head was at.

A. That's okay. We have an understanding in terms --- I think we're communicating fairly here, which is all I'm here for. The second page, which is the page I was on, was the histologic atypia, which is a good correlation to probability of neoplastic transformation to cancer.

Q. Is that sessile versus pedunculated?

A. No. That's your page.

Q. Okay.

A. The sessile versus pedunculated is in the realm of pathologic evaluation. But the question of atypia as I'm discussing it is histologic, meaning microscopic cellular changes.

Q. Okay.

A. Sessile versus pedunculated --- by the way, this whole conversation as we went into the histologic atypical component made the assumption that we were dealing with across the board with a sessile polyp. The pedunculated are a lower probability of producing any kind of problem.

Q. I don't want to get ahead of myself so let me stop you right there. You're about light years ahead of me here.

A. I don't want to be. I'm trying to move at the same level, just whistle.

Q. I read a statistic that indicated adenomatous polyps may be found in the colons of about 30 percent of middle age or elderly people. Do you agree with that.

A. That's probably an understatement.
Q. What would you believe the percentage is?
A. If you run the bowel at autopsy associated with death from other causes, you are probably going to find some hint of an adenomatous polyp in the majority of people over the age of 70. Now, having --- those become arguable as to whether they're actually adenomatous polyps. You can get a polypoid outpouching due to submucosal lymphocytic infiltrate. You can have pseudopolyps due to actually outpouching where there's diverticular disease. So some looks like it's coming up, but that's not the case. In fact, it's not coming up, the area right next to it is going down, gives you the impression of something sticking out, it's not the case. So loosely used, some sort of polypoid change is very common.
Q. And so of that polypoid change, what percentage of those become.
A. Extremely small fraction. And

your number there is probably related to the incidence of colon cancer versus the incidence of natural death in a given year. But, gosh, that's a small fraction of a percent.

Q. Okay.

A. As I think --- assuming we're on the same page through that exchange.

Q. Yeah, I think we are.

A. Because we did change back and forth there a little bit.

Q. Would you agree that most colon polyps produce no symptoms?

A. Yes.

Q. Would you agree that's pretty common knowledge for anybody with a gastroenterologist?

A. I have no idea what's common knowledge for a gastroenterologist. It's certainly --- you know, we've already established that most structures that might be considered polyps, and you use that term, I'm talking from the same page that we left before, are of no clinical concern or import. It then follows that

most do not, therefore, produce clinical symptoms. Certainly those don't.

Q. Do you have any idea what percentage of stools --- stool testing results in positive occult blood findings?

A. Done a single time?

Q. Sure.

A. Single and this is like giving the patient or doing a rectal?

Q. Giving the patient.

A. Finish the sentence. Giving the patient --- we're having conversation without full words here so we're doing ---

Q. Giving the patient a hemacult slide.

A. A hemacult slide.

ATTORNEY GOLDWASSER:

Who was otherwise asymptomatic.

A. He didn't ---.

BY ATTORNEY MALIK:

Q. That wasn't even in the equation.

A. The range on that runs from **two**

percent to like fifteen to eighteen percent that you can get hemacult positivity. A lot of this I was involved in looking at material in terms of what effective screening for colorectal cancer might be from the MIH several years ago. And the problem became the hemacults interpreted as any degree of positivity done a single time, gave one result, done three times gave a higher result, then the false positives became --- that is false positive, we're on the same page, means it's positive when no subsequent significant finding is present. Not false positive that it's false positive and a hemorrhoid is found.

Q. Okay.

A. Because false positive means that ---

Q. Okay.

A. We're on the same page there? The problem became that it resulted in a tremendous increase in anxiety and potential for additional testing that was really unnecessary because the use of the

hemacult was not particularly specific.

Q. Do you have any opinion or are you going to give any opinion on whether or not it's a worthwhile test to give?

A. I think it's a worthwhile test to give. But I didn't know that I was going to be asked that question.

ATTORNEY GOLDWASSER:

Well, you won't know until I decide what to ask you in fairness to you.

A. All right. I hadn't formulated anything with regard to this case or in the context of this case with regard to worthwhile tests.

Now, having said what my personal and professional opinion was, I also recognize that in people with specific conditions like diverticulosis or known hemorrhoids or known anal fissures or other problems, it is a dastardly test that causes more problems than it solves and there are many, including people who have a lot of respect for, that don't like to use hemacults for that reason,

and others.

BY ATTORNEY MALIK:

Q. But in your practice as an internal medicine physician, you did administer those tests?

A. Yes. I think that they have a role to play.

Q. Did Mrs. James have colon polyps?

A. Did have what?

Q. Colon polyps.

A. Plural?

ATTORNEY GOLDWASSER:

When?

BY ATTORNEY MALIK:

Q. At any time from your review of the record.

A. Yes, 1985, she had a polyp.

Q. Is it your opinion that she's only had one polyp and that was the one in 1985?

A. I saw --- I looked for two things. One, evidence of other polyps in 1985 during that study, and subsequently at the time when the diagnosis was made for evidence that other polyps were

observed either by scope and reported or by the sectioning of the histologic material that was harvested. In both cases, that leads to the answer in 1985 we had a polyp. I don't find a polyp per se subsequent to that.

Q. Okay. Did that polyp become malignant?

A. No. That polyp became formalinized. Placed in formalin, formalinized.

Q. That's because it was removed; correct?

A. Correct.

Q. Where was the location of that polyp?

A. I have to look in the records for the number of centimeters, ---.

ATTORNEY GOLDWASSER:

I think it was 45 to 50.

A. Forty-five (45) to 50. I was going to say 50, but let's look and see.

DOCTOR REVIEWS RECORDS

ATTORNEY GOLDWASSER:

The one in '85, David?

ATTORNEY MALIK:

Yes.

ATTORNEY GOLDWASSER:

Forty-five (45) to 50 then.

A. I was going to say 50. I was looking for a typed form, which I know I have. All right. Looking specifically at the Mount Sinai Medical Center record relating to the colonoscopy and polypectomy dated 6/20/85, performed by H. Eisenberg, specifically in the procedure note it was, quote, polypoid lesion and approximately 45 to 50 centimeters from the anal verge. And I think and is probably a typo. It should be at approximately.

BY ATTORNEY MALIK:

Q. Can you tell me when that polyp developed?

A. No.

Q. Are there any tests that can be done to determine when that specific polyp developed?

A. That can be done ---

Q. Yes.
A. --- on the polyp or on any material ---?
Q. On any material. Let's assume there's slides.
A. No.
Q. At the time it was removed, could there have been any tests to determine when it developed?
A. You know, you're asking --- I'm answering you very much specific to your specific question. You cannot determine --- you're asking can you determine when it developed.
Q. I'm really talking about, not so much an exact date as a range.
A. I accept that. But you're saying when so as to give a range of dates when it developed.

ATTORNEY GOLDWASSER:

You're asking with reasonable medical.certainty, I assume?

ATTORNEY MALIK:

Yes. With reasonable

medical certainty.

ATTORNEY GOLDWASSER:

As he understands it.

A. I translated it there from your smile. The fact is that in a polyp --- in a benign polyp in which there's little in terms of proliferative activity, you --- it can be very slow and it may have periods in which it's no change --- no substantive change at all. **I** can't answer when it developed. You can, based on it's size, get an estimate of what its proliferative rate is, a reasonable guesstimate of the minimum time it might have taken to get to that size. I don't have from that polyp and assessment of what the proliferative rate really was.

You asked a second question, which was was there anything that could have been done at that time. The answer is, could have assessed proliferative rate to age when determining how long that's present. But the polyp itself had no atypia. The polyp itself would not be in the category of an atypical polyp.

And certainly in 1985, as in 1995, there would be no reason to try to do that kind of analysis.

BY ATTORNEY MALIK:

Q. Okay. I was listening carefully to what your testimony was earlier, and you had mentioned mucosal changes and the step --- I'm trying to think of the exact term. For lack of a better word, it's step-by-step process. Before these cancers develop, don't they start out as adenomatous polyps?

A. No. I mean, that's a corollary of your earlier question. You know, before --- there are too many uncertainties in the sentence you just gave to give an answer.

Q. Now, let's stop right there. Let me go on to more specific questions and then we'll eventually cover that. Can you tell me as a pathologist why these polyps develop in the first place, these adenomas? And remember, dumb it down.

A. I'm trying to dumb it down. You know, dumbing it down for the development

of the polyp is harder than dumbing it down for the development of the cancer. You can get polypoid projections. We define this in two forms earlier about what we mean about polypoid and the projection as being referred to as polyp. The amount of the projection that's due to something that may be in the submucosa as opposed to the mucosa can be very different from one polyp to the next. And that's why in some of these situations you may have little to no mucosal change.

I need to compartmentalize that for a moment. In the stepwise genetic mutations that are involved in the progression to colon cancer, those are mucosal changes that are being described that are remarkably known by what the --- let's try --- promised to dumb it down. You may develop polypoid change in inflammatory conditions. It has nothing to do with neoplastic process. You may develop polypoid change because there's actually atrophy next to where the mucosa

is being observed so it looks polypoid. And I use the O-I-D, polypoid there as opposed to polyp. Then your question was directly, what causes the polyp. The answer that I think we know at this point is many of them may have some oncogene changes, some DNA changes. But others do not. And which oncogene is a trigger oncogene ---.

Q. That's the subject of another deposition.

A. Yes, it's a subject of --- but that's why I'm saying that the dumbing it down on the polyp is harder than on the cancer.

Q. But you went where I needed you to ***go.*** Were you aware that Mrs. James had diverticulitis?

A. Itis, osis?

Q. Diverticulosis, okay.

A. That's a relatively important distinction even though the words get used interchangeably, yes.

Q. By saying diverticulosis, does that anticipate inflammation going on in

the bowel?

A. It anticipates the potential for diverticulosis can be associated with the development of diverticulitis. And, no, this --- I'm not very good at the memory tests, so ---.

Q. Okay.

A. But I think that this was predominantly diverticulosis described. It may have been diverticulitis, also described.

Q. Can diverticulosis lead to the formation --- no, strike that.

Are patients with diverticulosis at a higher risk for polyp formation than patients without diverticulosis?

A. I think the answer to that is yes.

Q. Okay. Now, let me go to the next one. In patients with diverticulitis ---

A. I've got to finish the thought process because the problem --- without --- careful in which page we're at, the histologic page or the colonoscopic page.

You're on the colonoscopic page.

Q. Yes, I am.

A. So let me make this distinction for you, and I hope it helps, it's intended to. The diverticul --- the question of whether there's increased incidence of polyps on the colonoscopic is that as you colonoscope an individual with significant diverticulosis, you may get what looks like polyps which is really islands between the outpouching. So on a colonoscopic page, meaning from the colonoscopic viewpoint, you'll think you have polyps. These things get biopsied and we've seen lots of those. They --- their mucosa, an unremarkable mucosa. So that's not the same thing as being a polyp. That's why I wanted to pause and see. I heard you as being on that page, I thought you were on that page, and you confirmed that for me, and I appreciate that. But that distinction then follows.

Q. Let me be a little more sterile in my questions statistically then.

A. Uh-huh (yes).
Q. Are patients with diverticulosis at a higher risk for the formation of polyps?
A. Statistically people with diverticulosis, I believe, are reported to have a higher incidence of polyps. Caveat that many times literature reports findings that soften the definition and confuse the practitioner because of the implications of a true polyp versus an outpouching polyp. I'm trying to find a better simple word for that.
Q. Now, statistically with respect to diverticulitis, are patients who have diverticulitis more at higher risk for colon polyps?
A. People with true diverticulitis will get a submucosal swelling and often develop polypoid projections. It's an inflammatory polyp, true inflammatory polyp in that setting. So as an inflammatory polyp, I think the answer is, yes, they are.
Q. I have photographs that were

given to me by Mr. Goldwasser of the colonoscopy done in October. Have you reviewed those?

ATTORNEY GOLDWASSER:

Do you want to see the original document?

A. I have seen these, sure.

BY ATTORNEY MALIK:

Q. Okay. Can you, with this pen, circle the cancerous area?

A. I can, with this pen, circle the area that is being protruded out. I know from the histology.

Q. Okay. That's fine.

WITNESS COMPLIES

A. See, that one --- well, this one's just as good. It's still the same area.

ATTORNEY GOLDWASSER:

Just don't mark this origina

A. Why not?

ATTORNEY GOLDWASSER:

I'm going to use that.

BY ATTORNEY MALIK:

Q. Okay. Can you do it on all of them, if it's shown on all of them?
A. Even in the original, this one I'm going to write an A in the upper right-hand corner. The lower left-hand corner photo really is not of a quality that let's me comfortably indicate that.
WITNESS COMPLIES
A. You're look --- what I've marked here is obviously a two-dimensional photograph and in outlining where I see a mucosal change, some of this is projected and there's a third dimension, which is here (indicating), and you're not --- so you have a two-dimensional outline around a three-dimensional structure --- a photographic representation of a three-dimensional structure. I've only made any markings on the upper two and the lower right-hand.
BY ATTORNEY MALIK:
Q. And the things that you're marking are all the same polyp; correct?
A. I don't know that. I don't --- you know, I'm looking here for your ---

usually you'll get a depth recording on those, seeing the date. You've got a time recording and the date recording and the patient's name. You know, someone's not putting in the --- obviously photo one, two, three, four, and that's consistent with the time recordings, which are 10:41 and 24 seconds, 10:41 and 59 seconds. You're fully two minutes later, one minute and 19 seconds, 20 seconds later, and then another seven seconds later after that. So I was going over this with Mr. Goldwasser in terms of recognizing what you see as you penetrate these things. Not as a colonoscopist, but as an observer in these, you're moving with these so that you ask whether these were all the same.

Q. Yes.

A. There is no way to report that as the same. On the other hand, I believe in the colonoscopy report, you put your hand on that statement in a minute or two here. It makes it clear that it probably is. The colon is fairly dynamic. Some

may be more dynamic than others.

Now, your question would appear to be answered is it's all a similar lesion. But to put the context of the dynamic nature of the colon, at any point you can have contracture --- that's not a --- is that meaningful to you if I say that?

Q. Yes.

A. Or relaxation. And ahead of this there is --- I don't know whether he's going in or coming out and there's a difference in how this looks as you go in versus comes out. ***So*** it could be, it may not be. From the report it would seem it would be.

ATTORNEY GOLDWASSER:

I have the copy marked.

Mark mine similarly. Thank you.

BY ATTORNEY MALIK:

Q. To follow up what you just stated, why does the polyp look different going in than going out?

A. I need a movie. This is one of these things, I'm trying to do this in

under a thousand words. I've got a picture here. As you're going in, you're insufflating in front of your scope. All right?

Q. Insufflating meaning?

A. You're opening the space.

Q. Okay.

A. Okay. And as you're coming out, it's closing behind you; right? And there are going to be different degrees of that closure depending upon individual, the rigidity of the colonic wall. Does that answer your question?

Q. Yes, that answers my question. I knew the answer, I just wanted you to say it for the record.

A. Okay.

Q. Now, there's obvious, for lack of a better word, play due to this contraction and closure of the colon; correct? In other words, you can put a scope to, let's say for example, 38 centimeters one day and 38 centimeters another day and see different parts of the colon because of its contractility;

correct?

A. I don't think that's completely correct. What you can say with comfort is that there's about a 20 percent absolute difference in what may be there and what may be seen in the best of hands. There was a good study that was put out --- I want to say Royal Marsden (phonetic), but it was the London Group in comparing air contrast barium enemas to colonoscopy. And it was really interesting because the air contrast won, no doubt about it. And they turned around and then said, that if you went and did the colonoscopy more than once in case of failure of the colonoscopy, then it improves. Well, gee, that's sort of like what you're saying. But if you put the colonoscopy plus the air contrast barium enema together you improve still further. Right?

So the answer to your question is that a dynamic observation of a colonic mucosa will and probably does in any given individual look different to both

the observer and to a movie camera if it was present during that procedure. So if that's your question, I think that's the answer. But is --- what I'm stuck up on is the reason for the difference.

Q. My question goes specifically to reference points, distance. In other words, if you're ---.

A. If you were to go to the same number of centimeters through the same colon, the actual length that you've penetrated may be different?

Q. Right.

A. Yes, that's true.

Q. By either what percentage or how many centimeters?

A. I don't know. I mean, can you --- I mean, this is like a sleeve and a sock; right?

Q. Correct.

A. That's the best metaphor I know for this and now I've gotten into discussions about this before. It may differ by considerable amounts depending upon the compliance and rigidity of that

person's colon. So I'll leave you with the sock metaphor, you know. I can put the same sock on my foot, my foot being the scope, and it will give different lengths, but I've actually covered the same length of the sock and my foot goes to the toe. So what you use is the end point of a colonoscopy is the cecum, not the number of centimeters. So you end up at the same point. It's just sometimes you have a perception of traveling greater distances versus lesser distances.

Q. You say then that you perform the colonoscopy to the cecum, is that what you're telling me?

A. You talking about full colonoscopy, yes.

Q. Right. Okay.

A. So if you'd go to some fiduciary point.

Q. Yes.

A. Then you've covered the ascending, transverse, descending, the reverses direction, to some fiduciary

point.
Q. When you have --- let's say you have a sigmoidoscopy, flexible sigmoidoscopy that will go to 60 centimeters, can you accept that part of my ---?
A. I'm listening to, I haven't accepted or rejected it. I'm just listening.
Q. Okay.
A. But I will raise my left hand and say, you do remember me saying that I'm not a gastroenterologist and that my presence thereby may reflect on knowledge on this. I don't know that I'm the right person to be asking all this.
Q. Okay. But you are a physician who is familiar with anatomy and familiar with what the colon looks like; correct?
A. Yes.
Q. The sigmoid colon; correct?
A. I think that's a fair statement, yes.
Q. Okay. And the rest of the colon; correct?

A. Yes.
Q. Okay. Can you tell me at, let's say, 38 centimeters, what the margin of error would be in terms of where you could look at one day and where you could look at the next day? If you're answer's no, just tell me no.
A. What was your question? Can I tell you what the margin of error would be?
Q. Right. I mean, how much ---?

ATTORNEY GOLDWASSER:

With regard as **to** the accuracy, the measurement?

A. No. I think he's talking just about the distance.

BY ATTORNEY MALIK:

Q. Right. I mean how much did the colon bunch up? Right.
A. The colon can bunch up dramatically. And I don't know what the ---
Q. I'm trying to get a ---.
A. I don't know what the number is. I don't --- you know, that's ---.

Q. More than ten centimeters?
A. Well, what don't you understand about no? You know, it's --- that's a question for the persons who do these and observe --- I mean, it's really a test of doing the same colon, not six years apart, but you know, a day apart, X number of days, and I'd love to see you get that through the LRB.
Q. Okay. Now, the more that you do colonoscopies, --- strike that. Let me just go to the next question.
How did this polyp or cancer appear to the naked eye when it was seen on colonoscopy? How would you describe it?
A. I don't know whether it was entry or exit through here except for the timing that I just identified to you and the number of minutes between that. I think it's probably taken about the same time. That's a question really to pose to the colonoscopy person. What I have is the representation photographically, which is at best a poor representation.

It's clearly abnormal. And at this point, it is clearly occluding or appears to be pressing into a significant portion of the lumen. Now, I don't know whether that was able to be displaced or not. My reading of the colonoscopy note says it's probably not. What I see here is trumped entirely by what I see on the histologic slides.

Q. What does that mean, trumped entirely?

A. I mean the histologic slides out --- while what you see here is a photographic representation that speaks for itself, the histologic slides tell me what it is that I do, in fact, see here only because I'm told that those slides are taken from a lesion from this location. And I know they're fixed in time and space.

Q. Okay. From the histologic slides, from your review of the records from your looking at the photographs, can you give me a range of time in which the mucosa started to change to when this ---

what would be the correct word, tumor, polyp, cancer, develop?

A. Most of the mucosal reddening there is not necessarily cancer. I've got these slides and actually, Goldwasser has them, brought them with him again today. The fact of the matter is that the tumor is, for the most part, undermining the mucosa. The amount of mucosal change here is remarkably little. When you look at this and know that fact, you're seeing this as a proud mucosa, proud meaning pushed up and reddened, But that's edematous and pushed up. You're not seeing the often frondy, F-R-O-N-D, frondy-like --- or F-R-O-N-D-Y, now that I made the new word up, the fronds of the mucosa that are often seen as you develop these polyps and then within the polyp develop a carcinoma. ***So*** this thing in the slides representing where this tumor was on the specimen is predominantly a tumor in the submucosa and muscularis, really pushing this thing up. **I** have no question, this

goes back to the dynamic assessment that this was a relatively rigid area of the colon. But that pressure and the partial occlusion, I think 80 percent was the number on the record there, is occurring because this thing is filling up underneath the mucosa. All of this is following from your question, how long ago did this mucosa change.

The mucosal changes that are predominantly present, are not that dramatic. The dramatic changes are the submucosal tumor. That tumor is an extremely high mitotic rate and a poorly differentiated. And it's not a matter of months to really develop into the kind of tumor mass that you're looking at.

Q. When you use the phrase, high mitotic rate, what are you talking about?

A. The number of cell divisions that are observed.

Q. Like in doubling?

A. No, no. Doubling --- you know my speedometer doesn't tell me how far I've traveled.

Q. Right.
A. My speedometer tells me how fast I'm going. Actually it doesn't tell me that, it tells me how fast my rear wheels are going in the particular vehicle I drive. A doubling of the tumor mass requires that you have a knowledge not only of the rate of cell division, but also what the rate of cell death is.

This particular tumor, in addition to a high rate of division, also has a fair amount of necrosis, death, in it. And so, that will actually cause you to slow the size enlargement, but not slow the rate of tumor burden --- I'm trying to find --- that's not the right term. Can I not dumb it down?

Q. Yes.
A. Okay. If you look at it in terms of the actual proliferation, it is a persistent proliferation at a particular mitotic or division rate. .But that is complicated in terms of doubling of tumor size by the presence and demonstrable existence of necrosis, or tumor death.

The tumor death on its surface would seem to slow the rate in which the tumor might enlarge. But you may, as a result of that tumor death, get edema and swelling and congestion, which contributes to mass effect. Most of the time when people glibly discuss doubling, they're talking about mass effect, as though there was a mathematical relationship between tumor size and number of cells present. There is a relationship, but that relationship is confounded by all those variables and more that I've discussed.

What you've got in that picture which is what stimulated this lecture.

Q. Thank you.

A. I mean, I don't know how else to characterize it. It's far beyond what I meant to deal with today, but the fact of the matter is, that picture is more red and edematous than it is strikingly abnormal mucosa. Even in the original picture, which is a better quality than the one that you've been given as a copy.

Q. Let me do this by level then and try to follow what you're telling me. How long were the changes in the submucosa going on?
A. I think weeks and months.
Q. Okay. Two months, three months?
A. I think that to get a perceptible mass like that would probably be in the last three to four months.
Q. Okay. For the entire tumor to develop?
A. No. For it to develop to where it's perceptible.
Q. To where it's perceptible, all right. And what about the changes going on before it was perceptible? Is there any way of knowing?
A. Whether there was significant mucosal change?
Q. Right, or submucosal change.
A. Well, I think there was submucosal change during that period of time, but it would be subrosa, does that word dumb it down? I mean, you know, under the surface in every sense. You

might be able to determine with a study that there's some difference in motility, but probably wouldn't. The mucosa that I'm finding in these sections is --- clearly has focal abnormality, but I don't think that the majority of what you have been able to see before it became a mass, which is principally due to the underlying --- that was not directed to you, sorry. The mucosal change wouldn't have been something that would have been readily apparent from what I see on the slides. And it's not real terribly off when I look at this. I mean, leave this to what we do when we examine and examine a gross specimen, you do have some mucosal alteration apparent through here (indicating). I can't tell you without examining it microscopically what of that would be due to edema versus actual tumor. You don't get the clear-cut erosion, at least in the shots that are taken here and there's too much reflection off of the lower right-hand corner shot to speak to it, that lets me

go much further than that. There's a superficial area in the upper right-hand one that may well be an erosive area. So that's about as far as I can go with that from the gross, which is what the photograph represents.

Q. So just so I'm clear, we're talking a period of maximum, a few months before there's any appearance of visible tumor.

A. Before would be perceptible. I think that's probably correct, yes. The metaphor that fits in the photograph that you have is, you may have nothing wrong with your skin and have an abscess under the skin, you'll get a big red bump here. But what's going on is really underneath and you won't see anything going on until something happens to make you aware of that.

Q. So then from the point where it first became visible to the point where it obstructed 80 percent of the bowel, can you assess a time period?

A. I think incorporated into that is

the assessment of what symptoms were or weren't reported. But from the point at which you begin to get the wall to be rigid and you start obstructing, it's very short. And that's contributed to by both the actual tumor mass and the edema, that's the swelling that's associated in the area of the tumor. And that's in terms of weeks to months.

Q. So from --- but to reach the point of 80 percent occluding that portion of the colon, what would you say that it took in terms of time?

ATTORNEY GOLDWASSER:

He said weeks or months, I think.

A. What I --- yeah. You mean from the first change or from ---?

BY ATTORNEY MALIK:

Q. From the time when it would have been perceptible or changes in the mucosa would have been perceptible by colonoscopy.

A. Well, that **is** weeks to months. That is the .answer to that.

Q. To the point where there's 80 percent obstruction in the bowel?
A. Yes. Because you're really looking at this thing with relatively little mucosal change aggressively invading and being found in the submucosal and the muscularis.
Q. Another, what, three months, can you say with certainty?
A. No. Not with --- another three months, I'm losing you on reference to ---
Q. Well, we have the changes leading up to the change --- the visible changes in the mucosa. And the changes from the point where it's first visible in the mucosa to where it obstructs 80 percent of the bowel. So it was my understanding we had an initial three months to where we saw changes in the mucosa and then we had a time period ---.
A. Oh, no. Actually what --- the word that we were using there and I think appropriately is perceptible. Now, you've moved it back to a change in the

mucosa. A change in the mucosa versus the perceptible change in the mucosa, perception requires that you be able to specifically visualize this. Small changes in the mucosa may be associated with really dramatic changes submucosal. You won't appreciate the mucosal changes. You have the submucosal changes existing, the tumor is invading down rather than up and then you get to where the wall becomes rigid and the tumor mass increases. It is not a great deal of time to get to that point from where you have relative rigidity to the wall to where the mass pushes up.

Now, the perceptible changes in the mucosa is the important distinction here wherein you look at this histologic section, there's not a lot of the mucosa that seems to be involved. It's all coming underneath it.

Q. But yet we have a tumor that's invaded 80 percent of the colon according to the records.

A. That occludes 80 percent of the

lumen, yes.
Q. Okay. Occludes 80 percent *of* the lumen. So my only remaining question is as far as that's concerned is, how long did it take from the point the colon became rigid to the point where it occluded 80 percent *of* the lumen?
A. Well, based on what I've seen on the slides, there was tumor extensively involved in the submucosa muscularis and then it also piled up, at least through the are I think is represented there, you know, that's the image from the colonoscopy as opposed to the specimen, but they should be related and **I** believe they are. That swelling, that extension is what I'm referring to when I'm talking about a matter of months. I don't know another --- I don't know what we're missing if we're not communicating on that.
Q. A matter of months from the mucosa upward. From the lumen ---.
A. Here's where I'm --- I'm searching as I'm looking at you trying to

see where we're failing to communicate here. There are many situations in which that --- which appears to be the primary site is minuscule compared to that which is the invasive and extensive spread and/or metastasis site. The tumor burden fraction is in fractions of fractions of percent in terms of the tumor burden. You are looking with a colonoscopy at a tool that is best directed to the appearance of the mucosa. If your process is underneath that mucosa and the only thing present on the mucosa is small to perhaps even microscopic, you may see nothing and that is imperceptible.

Q. Okay. I can accept all that. I'm just talking about when you look at those photographs, the area you visualize in those photographs as obstructing, as you said, 80 percent of the lumen.

A. Well, I'm reading that from the report.

Q. Okay. What --- can you tell me what period of time it took to obstruct 80 percent of the lumen as you visualize

those photographs?

ATTORNEY GOLDWASSER:

Are you talking about from when it was perceptible or from when it was first submucosally active?

BY ATTORNEY MALIK:

Q. I'm not talking about submucosa, I'm not ---.

A. I think the first point at which placing a scope, or if I were looking at the specimen pathologically, which is a much more --- to where I would have recognized something from the inner surface to where it's representing a occlusive --- not completely occlusive, but significantly obstructing, is generally a function because *of* the amount of edema that you can demonstrate in here, it's not a matter of more than two or three months. All right? Now, that doesn't mean that there hasn't been tumor extending through the muscularis and submucosa that wasn't building upwards and .pushing for some period

before that. And remarkably, and as I see it in the slides, the amount of changing occurring over the surface epitheilia is really not dramatic.

Q. Okay. So am I correct in understanding you that the tumor first grew downward before it grew through the lumen?

A. I answered you in the --- I don't have a question at the point at which you said that. Can't say, which is to say that it grew downward at some point in what I see, and the tumor/cancer cells grew through the lumen downward and pushed the mucosa up. That is --- also, you asked for the principal growth of the tumor is downward and disrupting that to push it up.

Q. Okay. So then as it's growing downward, it's pushing it up?

A. As it's growing, having grown downward, it's pushing it up.

OFF RECORD DISCUSSION

BY ATTORNEY MALIK:

Q. And again, just so I'm clear in

understanding, when it's grown downward and pushing upward, is it --- that's a period of a few weeks to a few months?

A. Correct. The time --- a few weeks to a few months was in response to the question of how long did it take to occlude 80 percent of the lumen. And the combination of both the growth and the edema and swelling happens very rapidly.

Q. But both the growth downward and the growth --- and the protrusion?

A. Correct.

Q. We're talking a few months ---.

A. It's centripetal growth, so, yes.

Q. All right. In Doctor Eisenberg's notes, you indicate May 22nd of '95, pinkish blood. Would that be an indicator of this tumor existing?

A. I don't know. I mean, it may be. It's a positive finding. This is in his ---

Q. Office note?

A. Yeah, office note. Occassional pinkish blood. I think that's a description of her, Mrs. James'

observation, that she occasionally saw pinkish blood. You know, at this level, which is 38, centimeters ---.

Q. Not then, 28 centimeters.

A. This is '95. I'm sorry, 28 centimeters for this lesion. Pink would be ---.

Q. Well, 38, I think 38 is where he went --- did the sigmoid scope at one time and then he went down to 20.

A. Right. That's right above us, the flex sig in '94 to 38 and this is a 28. We're on the same ---.

Q. Yes.

A. Now, the question is, is my ---.

ATTORNEY GOLDWASSER:

What's the question?

A. No, we're just making --- I gave him a response which was because my eye caught the upper part of the page here and he was just correcting me to the distance.

BY ATTORNEY MALIK:

Q. Right.

A. Which is 28 centimeters. Where

we were heading, he was asking --- let me go to the question. The question was, is the pinkish blood indicative of a tumor?

Q. That's right.

A. And what I was about to process is whether it's low enough to give you bright red blood or overt blood, and it is. I mean, it could be.

Q. The pinkish blood could be indicative?

A. Could be, yeah. Although usually at 28, you know, it's going to be more mixed.

Q. Are you going to render any opinions on the standard of care for Doctor Eisenberg?

ATTORNEY GOLDWASSER:

I'm going to ask him that. He doesn't know until I tell him what I'm asking. I didn't tell him today what I'm going to ask him at trial. You know I will ask him that.

ATTORNEY MALIK:

With respect to ---

ATTORNEY GOLDWASSER:

Standard of care.

ATTORNEY MALIK:

--- the colonoscopy?

ATTORNEY GOLDWASSER:

The appropriateness of not doing the repeat surveillance colonoscopies after 1985.

ATTORNEY MALIK:

Okay.

BY ATTORNEY MALIK:

Q. Assume, please, that you are asked whether or not it was within the standard of care to not do repeat colonoscopies after 1985, what would your thoughts on that be?

A. I don't think that the repeat colonoscopies are required. This was not an atypical adenoma. Nothing about the descriptors on the adenoma suggested that it was. There were no other polyps appreciated and that extended as we already discussed to the 1995 studies. No symptoms in between.

I don't think that one is really

meaning to do the interval. I'll finish the question after the thought.

SHORT BREAK TAKEN

A. Requirement for doing the colonoscopy. How far had I gotten with the answer?

ATTORNEY GOLDWASSER:

She'll read it back.

COURT REPORTER READS BACK PREVIOUS QUESTION

A. I don't think that the standard of care requires the performance of interval colonoscopies. The relative risk that this woman would have been identified as having was not that great. And I'm basing that on the fact that she really didn't show any atypia in the adenoma, that there were no other polyps appreciated, and in the interval from 1985 to 1995, more likely than not had one been done on a yearly basis or every three years, you would have been 1985, 1988, 1991 and then reassure her. And not many would have continued to do it in perpetuity.

BY ATTORNEY MALIK:

Q. Did the '85 polyp grow downward also?

A. No.

Q. Assume now the presence --- or the reporting of pinkish blood in May of 1995, ---

A. Right.

Q. --- would the standard of care require colonoscopy after that, given her history?

A. I think that you have a person who has had --- no, the history wouldn't have been a major contributing factor to the decision that she should be studied, but the finding of gastrointestinal bleeding is important. If it's determined that it's other than right at the anal verge, it needs to be evaluated. It's just not acceptable to have rectal bleeding and/or colon bleeding and not explain it.

ATTORNEY GOLDWASSER:

The testimony is going to be this was occasional pinkish

blood seen on toilet tissue.

A. I understand that, but I --- he asked me a question that was both related and abstract. Did I hear you correctly?

BY ATTORNEY MALIK:

Q. Yes.

A. So we're making assumptions somebody has some bleeding, and then to distill it down we'll see where --- that's where we'll be on the same page in the same church. If somebody has GI bleeding, is it appropriate not to evaluate it? Simple answer, no. And if there's rectal bleeding or bleeding in the stool, irrespective of previous history, you need to evaluate it.

Q. So now let's go to the ultimate question, assuming it was evaluated at the end of May, beginning of June, ---

A. Of '95.

Q. --- of '95, would the tumor for which we're here today had been detected or would any mucosal changes have been seen or would there be anything that would lead the examiner to question the

site?
A. Probably not.
Q. Okay. And the basis for that?
A. The pattern in which you can observe it in October of '95. So that we're also clear on the bleeding issue, Mr. Goldwasser obviously broke into that conversation, but that is an important distinction that it be more than just superficial bleeding, meaning superficial at the anus.
Q. Nevertheless, assuming that that is the testimony, that it's pinkish blood on toilet paper, would you still say it's within the standard of care to be safe and do the colonoscopy?
A. Pinkish blood on the toilet tissue and no blood in the stool?
Q. Well, there was no hemacult test done and apparently no blood on the stool was reported.

ATTORNEY GOLDWASSER:

'95 there was.

ATTORNEY MALIK:

I'm talking in May of

'95.

A. She reported blood at --- hemoglobin and everything is normal and not done.

BY ATTORNEY MALIK:

Q. I would have to double check that.

A. That would be a great comfort that that would be the case, because I can't remember as I sit here. Let me take a peek. Not great comfort for anything other than to know that ---.

Q. I'm not sure that just blood on the toilet tissue ---.

ATTORNEY GOLDWASSER:

This was from September of '95 there were four hemacult slides that were negative.

A. In September of '95.

ATTORNEY GOLDWASSER:

September of '95.

October of '94, there were two hemacult slides which were negative.

A. I think that your hemacult tends

to be too sensitive and not specific enough leading one to conclude that this would suggest there was not --- a reasonable clinician would conclude that there was not --- she had bleeding.

BY ATTORNEY MALIK:

Q. Okay. But just back to the original question. Should, even with the presence of pinkish blood on toilet tissue, a colonoscopy have been done in a woman with a history of a polyp that's 80 plus years old, diverticulosis.

A. No. That would actually reduce the --- an 80 year old that's just showing some pink blood on toilet tissue, hemacult negative, no.

Q. But with --- what about not hemacult, just the evidence of pinkish blood on the toilet tissue?

A. The reasonable thing at that point would be to determine whether there was blood in the stool or not, which is what the hemacult is doing. Would I go immediately to colonoscopy if that were the case? I would have had several

myself. So just pink streaking on toilet tissue I don't think would push you to perform a colonoscopy. It would reasonably warrant follow-up evaluation such as the verification as to whether there was blood in the stool.

Q. Would that be by sigmoidoscopy?

A. It could be by hemacult.

Q. Can this kind of cancer cause any cardiac problems?

A. Directly?

Q. Symptoms *of* cardiac problems. In other words, can the patient have tachycardia, can the patient have palpitations, can the patient ---?

A. The answer is, yes, if you have a, anemia. And anemia can lead to that. The answer is, yes, if you have pericardial metastasis. The answer could be, yes, if you had an obstruction and really performed a Valsalva, that you could block down. But in terms of the tumor directly, no.

Q. Is there any way to determine ---?

A. Are you thinking of a carcinoid or something?
Q. No, no, no. I'm not thinking of a carcinoid. I'm just thinking from the colon obstruction and from the tumor that she had.
A. Well, just the obstruction is, you know, you can get into troubles from obstruction.
Q. Cardiac-wise?
A. Yes, cardiac-wise.
Q. Is there any way to --- strike that.

Is there any way for a gastroenterologist to measure any of the molecular changes going on in the cells that doesn't require a big, elaborate process? In other words, we have colonoscopy for screening, we have sigmoidoscopy for screening, we have hemacult, is there anything else that can be done to check?
A. That's reasonably done? I mean, you know, there --- skeptologists have argued that you can actually measure the

DNA from the stool and Bert Vogelstein has actually proposed testing of stool for DNA oncogene changes. I don't think that's in the realm of diagnostic testing at this point. Your question was --- and look for mutations in peripheral white cells, but, you know, I think you'd do that as a routine. In fact, there are people who argue against doing that at all.

Q. There is a report I saw that you had that indicated the staging of this tumor? And on the bottom of the page --- right here (indicating).

A. TM and N.

Q. TM and N is the standard staging measurement; right?

A. Yeah, Duke systems or TM and N.

Q. Okay. Can you tell me what, as it's written there, what it means?

A. Well, T-3 means it's through the mucosa, through the serosa and to his nodule involvement, and MX is metastis unknown, X , unknown.

Q. What did you use to determine how

far down the tumor grew?
A. In terms of volume?
Q. In terms of volume, correct.
A. You use it from the mucosal --- well, that's --- you asked it following the TM and N question.
Q. Yes.
A. You can use it by histological landmarks, which is the presence of muscularis. As it, you know, through the muscularis and in the presence of the serosas, as it enter the serosa. And in this case also the pericolonic fat is it diffusely in and throughout the fat.
Q. But did any of the slides you looked at tell you how far down it went?
A. In terms of through the serosa muscula?
Q. Right.
A. Sure.
Q. Okay. Can you tell me what this document represents?
A. Sure. Whenever a process slides, I try to document what the slides that were received looked like. And there are

any different number of ways to do that varying from photomicrographs to histologic snapshots taken with a camera. This represents a demonstration of which slides I had received, looked at and returned and it was accomplished by simply putting them on a ---.

Q. Xerox machine?

A. Well, I don't think it was Xerox, it might have been an alter account. But it was a photocopy device.

Q. Are you going to make any photographs of any of those slides for trial?

A. I didn't think so. The slides allow for direct projection off the slide without having to photograph them.

Q. And which slides do you intend to use?

A. I don't know. It depends on the question I'm asked, but the three, four and five probably are the most readily --- probably give the most information vis a vis what we discussed here today.

Q. Could you just briefly, please,

tell me what three, what four and what five show?

A. Okay. Number three ---.

Q. Can you --- is this for us to write on?

A. I don't think it's the only one I made, but you want to photocopy them. The number, you know, the slide itself, it would be easier than that because this one --- this literally is just a document to show what slides were looked at.

Q. Three, four.

ATTORNEY GOLDWASSER:

I gave you the wrong one. Here's five.

A. Yes, this is 14.

ATTORNEY GOLDWASSER:

Yes, there's five.

A. Okay. What you're seeing here is, you have mucosa coming along through here. Readily appreciated, you have tumor nesting here, tumor nesting here (indicating). There's no further mucosa on that. You have the edema and the fibrosis.

BY ATTORNEY MALIK:

Q. That's five?

A. That's in five. And then in number four you have a similar appearance. The section is not --- what's the right word for that. You're limited in how much tissue you can place on a slide and it is cut off on one end, but you again have tumor located and extending through --- down through the muscularis and into the region of the serosa. In five you're able to see that.

In four, you don't really have a clean shot of the serosa, if I remember the microscopic appearance. And in number three, you really see the tumor predominantly down in the muscularis and down through the serosa.

Q. Okay. When could this tumor have been --- do you have an opinion as to when his tumor could have been resected earlier and have provided a greater life span for the patient?

A. Well, you would have had to recognize it in order to resect it, and

that's the problem. So I don't think that the point at which it really was able to be discerned would allow for a successful resection and treatment. The second component that's present is this really invading, the way it does is a very aggressive tumor. So even a small tumor can result in problems.

Q. Can you tell us when or approximately when within that three-month period of time it metastasized to the liver?

A. I'm not sure it was within that period of time. It may have been before that.

Q. Okay. Can you explain that for me, how that could occur?

A. Yes. I mean, this tumor is, as aggressive as it is, microscopic single cells or clusters of cells may actually be seeded extremely early on in the development of the tumor.

Q. If it were, in fact, in the liver early on in terms of blood values, what values would you look at to give you a

clue?
A. What blood values you would look at to give you a clue that's in the liver?
Q. Right.
A. The alkaline phosphatase might be alleviated as an obstructive, but that is much more tumor burden. The question I've heard in the page that we're on for the metaphor we've been using is microscopic individual cells. You may have them present with no changes whatsoever. And that had been made and not seed the liver, the seed --- the cells may be broken off and circulates and not implant.
Q. Just on an assumption, assume that the tumor had been discovered and safely resected, are you going to render an opinion or do you have an opinion as to whether or not Mrs. James would have had a normal lifespan?

ATTORNEY GOLDWASSER:

Would that be resected before it became metastatic?

ATTORNEY MALIK:

Right.

A. Seventy-nine (79) year olds subjected to major abdominal surgery are subject to any number of problems ranging from pneumonia to pulmonary embolism. And the need in a person of this age for major surgery and resection probably makes that question answerable by saying it's unlikely that she would have had --- I'm not sure what a normal lifespan is at 79, but she's otherwise doing fine, the event of hospitalizing her and operating on her may bring that to an abrupt change.

SHORT BREAK TAKEN

BY ATTORNEY MALIK:

Q. Can a colonoscopy be performed and biopsy samples be taken by colonoscopy?

A. Yes.

Q. Based on your knowledge of this patient with a history of previous polyps, would you ---?

ATTORNEY GOLDWASSER:

History of polyp.

BY ATTORNEY MALIK:

Q. Polyp. Would you say that that was within the standard of care to do that?

A. No.

Q. And the basis of that?

A. Well depending on what point in time, one might have done a colonoscopy and a biopsy and had more pressure to do it in 1986 and '87 and at that time and it probably would have been recommended annually. People relax the annual to every three years after that period of time.

And the fact of the matter is that if you look at the actual yield, I think the London Study had some 800 and plus patients and the ones who had no atypia in their polyp had only three or four cancers ever detected through ten years of follow-up. So you'd be putting people through a significant amount of potential morbidity in exchange for yield and it might be noted in their study the

people that had absolutely no symptoms, didn't have any further problems. So ---

Q. Given this cancer and the way that it developed in Mrs. James, is there any way to have detected it prior to October of 1995?

A. Yes, I think a CT of the abdomen, had there been an indication for it, might have. He probably would have observed mass effect. Same corollary would be an MRI although those coils for that region are less likely.

Q. And the symptoms that would trigger a CT or an MRI would be bleeding?

A. Well, if she had obstruction and bleeding --- if you're bleeding, you're --- it's an important distinction here. If you're actually bleeding, then you have some --- in the colon by the way, that's the second part of the sentence but I think --- I didn't mean to swallow that, understand each other.

That means that you've got something on the mucosa and imparting

blood to the stool if the blood is imparted to the stool. So you're more likely to go up and see that. But if you're not imparting blood to the stool, the likelihood that you've got a mucosal change is much less.

Ann Kilbain's case is an example, the one that was in Cleveland. It was two things. There was repeated blood on the stool and the second thing, if I remember it correctly, was the person was anemic. And that just said that is a bleeding that requires evaluation. We don't seem to have that here.

Q. Based on this case, though, and what you know about this patient, given the CT and the MRI, when could it have been detected?

A. I think --- I think a CT might have detected a mass three or four months earlier.

Q. At that point, could it have been successfully resected?

A. No.

Q. At any point, could this have

been successfully resected?
A. You have to know --- I mean, you have to have something that leads you to where you can do the resection. I mean, you could carry this all the way back and if you said, if you had done a colon --- colectomy at the time of the first polyp, you would have prevented this colon cancer. But that's reductio ad absurdum. And that would be a different set of circumstances today, probably precipitates your presence from the other viewpoint.
Q. So basically what you're telling me, at least what I hear you telling me is this developed in such a fashion as to be insidious and untreatable really.
A. Well, it's insidious and I think the insidious quality is not treatable. If you **look** at the impact of colonoscopies, the actual reduction in observed advanced colon cancer is like only six percent of the total number, and that's in screened populations.
You know, this is not an economic

issue and I'm not going to look at it as one, but I don't want a colonoscopy unless there's a real clear-cut, high risk or symptoms that I'm presented with, because the procedure itself has a real risk of morbidity. And if I'm 79 and have diverticulitis, the chances of a problem increase even greater.

Q. Okay. But what I hear you telling me is that you're saying to me, David, this was that kind of cancer which couldn't be detected early enough to do anything about.

A. No. This is a cancer that presented with a series of circumstances that that's the case for. And I don't think that the manifestations were there that would lead one to recognizing it in the time that any intervention would have made any difference. You know, that's probably not so different than what you just said. But what is different about it is, it's the individual set of circumstances that we're faced with here.

Q. And those being different

symptoms?
A. Well, the appearance and the pattern in which this grew.
Q. Would left lower quadrant pain be a symptom of this tumor?
A. It could.
Q. Would left lower quadrant pain have warranted a colonoscopy?
A. If persistent.
Q. Okay. When you talk about the patient being anemic, how anemic are we talking? Are we talking slightly anemic or to moderate?
A. Well, the best measure of an anemia is a comparison to what your baseline hemoglobins have been. You know, I pay attention to, I don't always find an answer for, why people are two grams below what they were five years ago. I certainly pay attention if they're four or five grams. That's, you know, eyes wide open, what's going on. You don't always get an answer, but it would bear an investigation.
Q. Prior to, let's say, May of 1995,

assume this patient was anemic ---.

ATTORNEY GOLDWASSER:

Do you have evidence of that? I don't know whether I should object or whether that's a fact in evidence. In October of '94 her hemoglobin was 15.7.

ATTORNEY MALIK:

Well, you can object to it. I can't seem to find it. I thought I saw somewhere in the records where she was slightly anemic. So why don't you object to it and we'll go from there.

ATTORNEY GOLDWASSER:

Okay. Go ahead.

BY ATTORNEY MALIK:

Q. Assume that the patient was anemic prior to October of '95, would that in and of itself have warranted a colonoscopy?

A. The anemia represents a change from previous measures, ---

Q. Right.

A. --- the answer is, I would

evaluate that anemia, yes.

Q. Would a CAT Scan or MRI be warranted?

A. If the anemia was significant and I had evidence to suggest it was GI tract, yes. If it was an intra-abdominal bleed, you would be in a lot more trouble. I don't think MRI or CAT Scan would have been how I would approach it.

Q. So it was a GI bleed.

A. I mean, you're going to end up with an anemia that's either an anemia due to metabolic disorders or anemia due to hematologic disorders or anemia due to bleeding.

ATTORNEY GOLDWASSER:

This is an aside. Her hemoglobin was 16 just the month before the diagnosis.

A. Now, that would be consistent with the histology on the slide which you don't have mucosal --- you don't have a mucosal pattern that's likely to have bled. I'm not sure I had that hemoglobin in the records.

ATTORNEY GOLDWASSER:

You don't have that. That's different records.

ATTORNEY MALIK:

Can I see it?

ATTORNEY GOLDWASSER:

Sure.

ATTORNEY MALIK:

Can you show me what you're looking at? Are you on September of '95?

ATTORNEY GOLDWASSER:

September 11, 1995.

ATTORNEY MALIK:

No, I have it.

ATTORNEY GOLDWASSER:

Do you have it?

Hemoglobin --- bottom half --- bottom part of the page.

ATTORNEY MALIK:

Okay. I think we're just about done.

BY ATTORNEY MALIK:

Q. Just let me go back and ask you just one or .two questions and then I'm

finished.

I know I asked you about pain in the left lower quadrant, but I see in my notes that the note on April 25th of '94 indicated that it existed for several months. In your opinion, would that have anything to do with this tumor that was ultimately found?

A. It's possible it might have.

Q. Okay. So when you have that for several months, and you have the pinkish blood on the toilet paper, you have a history of a polyp, would an MRI or a CT Scan be warranted?

A. The polyp was in '85. And you go back to --- well, the simple answer is probably not. No change in the stool, no evidence of blood in the stool, hemacult would have been warranted.

ATTORNEY GOLDWASSER:

No weight loss seen at the time.

A.. Weight loss is an ephemeral thing to many of us. Probably not.

BY ATTORNEY MALIK:

Q. So it would not have been within the standard of care to have done an MRI or a CAT Scan?

ATTORNEY GOLDWASSER:

Outside of the thermalcy (phonetic) or not? I mean, that's a wide range. Would it have been within the standard of care?

A. Oh, it would have been reasonable to do one.

ATTORNEY GOLDWASSER:

The question really want ---

A. It wouldn't have been wrong not to.

BY ATTORNEY MALIK:

Q. Then your answer is no.

A. Depending on which question I'm answering.

Q. That it would be reasonable not to do one. That would be okay.

an MRI is what I would be wanting to say. You got a double negative ---.

Q. And it's not a breach of the standard of care to have not done an MRI, that's what you're saying?

A. I think I would have evaluated more on terms of whether there was occult blood. But the answer to your direct question is, it would not have been a breach, no.

Q. Would the failure to have examined for occult blood at the time of the reporting of the left lower quadrant may have been a breach?

A. That's a little more difficult. I think that you really --- I think the thought to examine for occult blood, I think it would have been reasonable to do so. I need to see the record. Was there anything besides the left lower quadrant pain that was in --- I don't think so. And I thought that was what was in the background here. We're in April of '94?

Q. No. We're right ---.

A. April of '95?

Q. No. We're in April of '94.
A. Yes. In April of '94, we do a flex sig.
Q. We have complaints of pain in left lower quadrant times several ---.
A. Months, probably. M-O-S.
Q. Then we have pinkish smear.
A. She gets a pelvic ultrasound, which is appropriate. It's negative. The main concerns really regarding ovary and uterus are probably higher on your list, but that's negative.
Q. You wouldn't expect that pelvic ultrasound to show any impairment to the liver; would you?
A. No. I was thinking the pelvic ultrasound for uterine or ovarian cancer.
Q. And then you feel all of the testing was appropriate as of April 25th of '94?
A. I didn't hear what you asked.
Q. That the failure to do an MRI or a CT Scan at that point was not a breach of the standard of care?
A. That's correct.

ATTORNEY MALIK:

I don't have anything else.

BY ATTORNEY MALIK:

Q. Oh, one other thing. What is the formal name of the cancer that she had?

A. I would refer to it as an adenoma carcinoma and colon primary.

* * * * * * * * *

DEPOSITION CONCLUDED AT 4:00 P.M.

* * * * * * * * *

COMMONWEALTH OF PENNSYLVANLA :
: SS
COUNTY OF VENANGO

C E R T I F I C A T E

I, Jacqueline L. Hazlett, Notary Public in and for the State of Pennsylvania, do hereby certify:

That the witness was hereby first duly sworn to testify to the truth, the whole truth, and nothing but the truth; that the foregoing deposition was taken at the time and place stated herein; and that the said deposition was taken in Stenotype by me and reduced to typewriting, and constitutes a true and correct record of the testimony given by the witness.

I further certify that the reading and signing of said deposition were ~~(not)~~ waived by counsel for the respective parties and by the witness.

I further certify that I am not a relative, employee or attorney of any of the parties, nor a relative or employee of counsel, and that I am in no way interested directly or indirectly in this action.

IN WITNESS WHEREOF, I have hereunto set my hand and stamp this 5 day of Aug, 98.

Jacqueline L. Hazlett

NOTARIAL SEAL
Jacqueline L. Hazlett, Notary Public
Oil City, Venango County, PA
My Commission Expires Nov. 29, 1999

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