THE STATE of OHIO, :
: SS:
COUNTY of CUYAHOGA. :

IN THE COURT OF COMMON PLEAS

ELLA HOPKINS, et al., :
plaintiffs, :
:
vs. : Case No. 274355
:
KAISER FOUNDATION HEALTH :
PLAN OF OHIO, et al., :
defendants. :

Telephonic deposition of WILLIAM H. HINDLE, M.D. a witness herein, called by the plaintiffs for the purpose of cross-examination pursuant to the Ohio Rules of Civil Procedure, taken before Kelly Keyes a Notary public within and for the State of Ohio, at the offices of Donna Taylor-Kolis, Co., L.P.A., 1015 Euclid Avenue, Cleveland, Ohio on WEDNESDAY, APRIL 24TH, 1996, commencing at 1:00 p.m. pursuant to agreement of counsel..

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I N D E X

WITNESS : WILLIAM H. RINDLE, M.D.

(FOR COMPLETE WORD INDEX, SEE APPENDIX)

(IF ASCII DISK ORDERED, SEE BACK COVER)

MISS KOLIS: We're not going to swear in the witness, if that is okay with you. It's okay if he promises to tell the truth, how is that?

MR. BONEZZI: All right.

MISS KOLIS: Since we can't see you I suppose.

CROSS-EXAMINATION

BY MISS KOLIS:

Q. Doctor, for the record could you state your name and your business address?

A. William H. Hindle, my business address is Women & Children's Hospital, L.A. County, USC Medical Center, 1240 North Mission Road, Los Angeles, California.

Q. Currently who is your employer?

A. University of Southern California.

Q. What is your position with the university?

A. Professor of clinical obstetrics and gynecology.

Q. If at any time, Dr. Hindle, I ask you a question that you don t understand, tell me to rephrase it for you, all right? Whatever way I can communicate the question the best is what we'd like

to seek out today, okay?

A. That would be fine.

Q. I have reviewed your curriculum vitae, I assume that it is current. For the record, we don't have to go through it in too much detail, we will mark my copy of your CV Exhibit A,

Let me ask you this, we can see from your CV where you attended undergraduate school, medical school, et cetera: Subsequent to completing your residency have you had any specialty training, did you do a Fellowship?

A. No, I did not do a Fellowship,

Q. You are Board certified I gather?

A. Yes.

Q. In what specialties are you Board certified?

A. Obstetrics and gynecology.

Q. When did you obtain that Board certification, Dr. Hindle?

A. 30 years ago, it says on the CV.

Q. I'm not looking at your CV, I'm just asking short introductory questions,

MR. RICE: I don't have a CV, do you have an extra copy?

MISS KOLIS: Sure, I don't have an extra one,

Q. Sorry. I'm handing Mr. Rice your CV since he hasn't had an opportunity to look at it.

Dr. Hindle, because I'm not there, I can't see what materials you have. I assume that you have a file relative to this case?

A. I have reviewed a file that is in my office and then Mr. Bonezzi has the records.

Q. Basically speaking, can you tell me from your memory or whatever is in front of you what medical records you've reviewed in this matter?

A. The doctor's office records, his deposition and the --

THE WITNESS: What is the other one you told me about, the oncologist, the DS or something like that?

MR. BONEZZI: I sent some of the oncology records,

A. Some of the oncology records of her subsequent care.

Q. Did *you* review the Kaiser chart covering the period of time from January, 1992 through September of 1993?

A. No, not all of it, I was sent a portion of it.

Q. You did review selected records from Kaiser?

A. Some of them.
Q. I'm going to flip through here and we'll get you right to some of the more important questions.
First of all, the CV you provided to Mr. Bonezzi, are there any publications which you now have in process that are not listed on your CV?
A. That are in process?
Q. Right. Something that you are working on that has not yet been published.
A. About four different chapters for textbooks, but they are --
Q. Can I gather based upon my extensive review of the literature you've written that those are all going to be about breast cancer, the chapters that you're writing?
A. They are all about breast disorders.
Q. Breast disorders, okay.
In addition to the medical records that we have just discussed and Dr. Wisler's deposition, have you reviewed the depositions of any of the Kaiser employees?
A. No.
Q. How did you become involved in this matter, Dr. Hindle?

A. Mr. Bonezzi's office called me.
Q. Have you done work for Mr. Bonezzi's office previously?
A. No,
Q. Do you know how they came by your name?
A. It was a long time ago, I don't remember what he told me at the time.
MR. BONEZZI: I read your literature,
A. He now tells me he read my literature,
Q. I would suspect that may be how he got your name.
Do you recall when you were first contacted in this matter?
A. Several years ago.
Q. At the time that you were initially contacted, did Mr. Bonezzi give you a general description of what the issues were in this case?
A. My recollection is we had a telephone conversation where he went over the case in a general way and then he sent me a summary letter.
Q. By summary letter you mean that he summarized the facts of the case for you and put that in written form?
A. Yes.

Then subsequently he sent me the documents in the medical record and the deposition,

Q. To the best of your recollection, after you received the medical records and the deposition did you independently verify the factual summarization that Mr. Bonezzi gave you?

A. Oh, yes,

Q. Out of curiosity, by any chance do you know the defendant, Dr. Kevin Wisler?

A. I do not.

Q. Have you spoken with Dr. Wisler regarding this case?

A. I have not,

Q. What is your understanding of your role in this matter?

A. To be an expert witness on the standard of care for obstetricians and gynecologists in evaluating breast disorders.

Q. I would ask you at this time to provide to Mr. Bonezzi a photostatic copy of all correspondences between your office and his office, all right? I don't know if you can give it to him today or not before he leaves, but sometime within the next week I would like to see the basic correspondence file,

A. I assume he has it all in his office.
Q. He might, but between the two of you if I could have what would constitute the complete correspondences between the two of you regarding the case, I would appreciate it.
A. In any case, he will get that to you,
Q. That would be great.
You authored a report on August 8th, 1995, do you have that report with you?
A. I will in just a moment.
Q. Have you located your report?
A. I'm searching for it.
Q. No problem,
Since we are not there physically we can't tell what you are doing.
MR. BONEZZI: Are you there?
MISS KOLIS: Yes.
MR. BONEZZI: I thought I had it, I don't have it with me,
MISS KOLIS: Don't worry about it. It's not a real long report, I will just read some things to him I'm sure at some point.
Q. Subsequent to writing this report, Dr. Hindle, had Mr. Bonezzi shown you the reports written by other experts in this matter?

A. 1 don't have a record of the exact dates of when I received the different depositions and summary letters of other physicians.

Q. To clarify what information I was seeking: I was curious as to whether or not you have read the reports written by other experts in this case?

A. There was one by Dr. Rosenthal.

Q. Right.

A. That I recall.

MR. **BONEZZI:** As far as the other experts, those would be the Kaiser experts. I do not believe that I have provided those to him, but I know I didn't provide Dr. Spatzler.

MISS KOLIS: I will accept that answer, Mr. Bonezzi.

Q. After you reviewed the materials, Dr. Hindle, did you feel the need for additional material in order to reach your conclusion in this matter?

A. No, because my conclusions were based on the medical records I was asked to evaluate and the deposition of the doctor involved, and I have both those documents.

Q. That was all you felt you needed.

Did you ask at any time to see the film of the mammogram that was performed at

Dr. Wisler's request?

A. I did not.

Q. When you reviewed the medical records and the deposition did you make notes of some sort?

A. I did not.

Q. Do you recall when you arrived at your opinion in this matter?

A. In written form is when I wrote the letter as requested, or the statement of my opinion.

Q. Since you don't have your file today you are not very certain as to when you were initially contacted regarding the case?

A. I would say it was about two years ago, but I don't have that,

Q. That's all. right. As close as you can get it, I guess, at this point.

By the way, even though this has nothing to do with it, are you planning to come in for trial?

A. I will come in if requested and that is required.

Q. Can you, Dr. Hindle, at this time summarize for me what opinions you hold based upon your review of the records and the deposition of Dr. Wisler?

A. Yes.

I would say based on the medical record and his clarification in the deposition when he first saw the patient in regard to her breast complaint, his subsequent management of that and then her transfer of care to another facility -- that particular recording of her first issue of a breast complaint was on 8-25-90, and I have his office record in front of me.

Q. My specific question was: What opinions do you hold as to the care and treatment rendered by Dr. Kevin Wisler to Ella Hopkins?

A. In reviewing this record compared to other obstetricians and gynecologists his care was appropriate, and he met the standard of care for obstetrics and gynecology regarding breast disorders.

Q. Can you state with specificity the factual basis for that contention?

A. The medical records of the doctor, his findings and his evaluation, and the appropriate steps that he took to evaluate his findings.

Q. What I will probably do is ask you some specific fact questions to make this easier for myself.

First of all, can I gather that what you're saying -- even though you haven't used the word -- is that based upon the presentation of this breast complaint that Dr. Wisler undertook, what you call in your writings, the triad evaluation of the breast; is that what you're talking about?

A. Yes.

Q. That he did a clinical examination, he did a fine needle aspiration, and he did mammography, correct?

A. Yes.

Q. We will get back to those. I have all the facts listed out from his deposition that I'm going to want to talk to you about.

In your review of Dr. Wisler's chart do you have any criticisms of the conduct of the plaintiff, Mrs. Hopkins?

A. Any criticism of the patient?

Q. Yes, that's my question,

MR. BONEZZI: Her initial evaluation or her total care?

MISS KOLIS: Total care.

Q. I assume that you have Dr. Wisler's complete chart?

A. Yes.

It seems from the notes that were made by the doctor and his staff on the mammogram report that she was advised to return for a follow up and I find no record that she did that.

Q. Have you with particularity and specificity, I suppose, looked at Dr. Wisler's deposition as it regards what he feels may have happened regarding that follow-up appointment?

A. Yes, I have read the deposition.

Q. If the facts at trial or otherwise are establishe- t- -- that D-. Wisler'- office -id not schedule Mrs. Hopkins for a follow-up examination, would you be critical of her for not coming in on her own?

A. Would I be critical of her?

Q. Yes.

A. Just to the extent that the patient shares some responsibility of her care, particularly if there is an evaluation of an abnormal finding. The patient would have s(e responsibility in my opinion.

Q. at do you base that opinion on?

A. In other cases that I have reviewed and in clinic - cti - and i- my own practice, the

practice of other obstetricians and gynecologists across the country,

Q. Let me ask the question in a different way then, Dr. Hindle,

If the facts are that the patient was told that the cytology examination was negative and the mammogram was negative and no information regarding follow up was given in that regard, if those are the facts; do you have a criticism that the patient did not come back to Dr. Wisler?

MR. BONEZZI: Objection. Donna, are you suggesting that Mrs. Hopkins is going to testify that she was never told to come back in two or three months as the records indicate?

MISS KOLIS: That's correct, Bill.

MR. BONEZZI: Go ahead and answer.

A. It is difficult to say that of a woman who is being evaluated for a breast mass like she was.

She certainly is aware because of the diagnostic procedures that were carried out there was an abnormality and she is not in a position medically to evaluate the reports

themselves and be reassured by that; so if she has a persistent mass, in my opinion she has some responsibility to seek follow-up care.

Q. Are you stating that if a patient is assured that the results of the testing are negative, that she should not worry about the lump, that she has some independent responsibility to know to come back in for another evaluation?

A. The difficulty with that is the interpretation of medical reports, be they x-ray or laboratory reports, they are just reports, they are not infallible in any case.

If this patient has persistent symptoms or a persistent problem like a breast mass, in my opinion the patient has some responsibility to return somewhere to have further follow up.

Q. I think I understand what your answer is.

Do you have any criticisms of any other defendants in this matter?

MR. BONEZZI: Objection. Can you be more specific, please?

Q. I gather you have no criticisms of Dr. Wisler's initial evaluation and care of Mrs. Hopkins?

A. Correct.
Q. Based upon your review of the Kaiser records, do you have criticisms of any of the employees at Kaiser in terms of their subsequent care and treatment of Mrs. Hopkins?
A. I wasn't asked to evaluate Kaiser records, I do not have those records in their entirety, so I have not formed an opinion about that.
Q. At the time that you read the Kaiser records, what was your purpose in reading them?
A. I was reading all the records that were sent to me and some of them were included in the records that were sent to me.
Q. It is not in your report, of course, but can you recall today what you learned about her subsequent course of care in reviewing those Kaiser records?
MR. BONEZZI: I'm sorry, Donna. Would you repeat that, please?
MISS KOLIS: Sure. I'm asking him if he has a recollection of what he learned about Mrs. Hopkins' subsequent course of care from reviewing the Kaiser records,
A. She was diagnosed as having breast cancer and then treated for that subsequently.

Q. Do you have a recollection of reviewing portions of the medical records that related to the examinations of her breast that were performed by personnel at Kaiser prior to diagnosis?

A. My recollection is that there was an early report of the nurse who did an evaluation, and then subsequently the cancer was diagnosed and subsequently treated.

Q. We will probably get back to that later.

In reaching your conclusions in this matter did you do a literature search of any sort?

A. I did not.

and that which you have published, I would gather?

A. And the medical records that I have reviewed, yes.

Q. Prior to this particular case, Dr. Hindle, have you ever been asked to become involved as an expert witness in a medical negligence case?

A. Yes, I have.

Q. How frequently have you testified?

A. Testify in court?

Q. We can break it down that way.

How many times have you testified

in court?

A. Probably about four times in the last ten years.

Q. Other than testifying in court, with what regularity are you retained to review records?

A. Probably once a month.

Q. Whom do you review records for?

A. Attorneys.

Q. See, that's what I get for asking a loose question,

Are you predominately retained by attorneys who represent physicians?

A. Yes, predominantly.

Q. Have you ever testified for a plaintiff?

A. Yes, I have,

Q. What would you guess or if you know what is the percentage of the breakdown between plaintiffs and defendants?

A, Probably somewhere between 10 and 20 percent.

Q. So about 80 percent of the time it would be on behalf of a physician, correct?

A. Correct,

Q. Doctor, is greater than 50 percent of your current medical practice dedicated to actual clinical medicine?

A. Yes.

Q. Your CV indicates that you are a professor of clinical obstetrics and gynecology, and you are the director of the Breast Diagnostic Center?

A. Correct.

Q. Can you tell me approximately what amount of time you spend in your capacity as the director of the Breast Diagnostic Center?

A. The majority of it.

Q. So your teaching responsibilities are more limited, is that what your answer would be?

A. I no longer do obstetrics, I have some general responsibility in the department of gynecology, but my major focus is the Breast Diagnostic Center within the department of gynecology.

Q. What are your duties as the director of the Breast Diagnostic Center?

A. I established it and I supervise it. I supervise it and each of the resident physicians who are rotating through the service.

Q. Are you still doing hands-on medical practice, you are not just supervising?

A. I no longer do private practice, my own private patients; but I, of course, examine the

patients with the residents and do hands-on work, both with surgery and with examinations, continuously with fine needle aspirations,

Q. How many patients would you say you see a week?

A. In the clinic we see about 50 new patients a week.

Q. Can I gather that the primary purpose of the Breast Diagnostic Center is to evaluate abnormalities of the breast? I know that sounds redundant, but I just want to make sure that's what you guys do there,

A. Yes. I would say it is a referral clinic, it is within the county's health care system and the patients there have been referred by other physicians there, either inside the county system or outside of it, if they have a specific complaint.

When I say 50 patients, that's 50 new patients that have not previously been evaluated.

Q. Does your diagnostic center employee nurse practitioners?

A. We don't employ anybody directly, the nursing staff is provided by Los Angeles County

*. Let me ask the question a better way then.

In your facility do nurses do the breast evaluations, the clinical breast evaluations, or do the physicians?

A. Basically physicians do.

Recently with changes in the budget of the county, they have curtailed the nursing staff and they have provided a nurse practitioner who assists us with some of the follow up and referral of the patients, and the follow up with their diagnosis and those who are referred to surgery. She happens to be a nurse practitioner, but she wasn't hired by me nor anyone else to serve that function.

Q. So that I will be perfectly clear on it because I want to ask you some questions about that arena: When you are doing a primary evaluation of a breast mass, would you give that responsibility to a nurse practitioner?

MR. **RICE:** Objection.

You can answer.

A. Not in our setup because we are primarily set up to teach residents in obstetrics and gynecology to do exactly that, So the examinations and the fine needle aspirations are done by the residents

under supervision,

Q. You indicated that you do have a recollection when you initially looked at the Kaiser records that a nurse was involved in the initial evaluation of Mrs. Hopkins?

A. That's my recollection.

Q. Can you recall from the document what the nature of the breast examination was?

A. I don't have that record in front of me.

Q. Do you remember anything about the breast evaluation that was recorded in that document?

A. Just that the nurse examined the patient.

Q. Do you recall if there were any findings at that time?

A. I don't really recall and I don't have that record in front of me.

Q. Doctor, from your CV it seems that you have authored many publications, especially concerning fine needle aspirations; that would be a fair statement, correct?

A. Yes.

Q. You are prominent and we11 studied I guess on the subject of the diagnostic triad.

Can you explain to me as simply as possible what the diagnostic triad consists of?

A. It consists of a diagnostic approach to a patient with a breast disorder, obtaining a breast oriented history, doing a clinical breast examination. Then if there is a mass to do a fine needle aspiration and to do a mammogram, and then to base the evaluation on all of that information,

Q. When you say "if there is a mass," can you define for me so we don't have a language problem later what a mass means when you are using that, "If there is a mass to do a fine needle aspiration"?

A. What I mean by mass is the dominant breast mass which by definition is a three dimensional distinct mass that it different than the rest of the breast tissue and different from the tissue in the other breast,

Q. If someone described an area of thickening, what would that mean to you?

A. That would be an area of thickening, that would not be a dominant breast mass.

Q. This diagnostic triad that you described, how long would you say that this has been the standard of care in the evaluation of breast disorders?

A. I am not even sure of the standard of care everywhere in the United States at this time

because the application of fine needle aspirations by primary care providers such as gynecologists is different in different locations. It is something that's available to them, but some physicians who have not been trained in the technique are not comfortable in using and they do not utilize it; but it is something that is available.

Q. If a physician is not trained in fine needle aspiration or it is not something that's available at their facility and a person presents with a dominant palpable breast mass, what would that person then be required to do?

A, In my opinion they would be required to refer the patient to someone who either does fine needle aspirations or is an expert in examining the breast or does open surgical biopsies.

Q. Besides revealing the existence of a lump itself, what can a physician learn during an actual physical examination of a breast?

A, Nature of the breast, the rest of the breast tissue, whether there is a tenderness, whether there is changes in the skin, whether there is evidence of infection, whether there is any discharge, whether there are palpable lymph nodes.

Q. Can a physician ever reach a definitive

diagnosis based on physical examination of the breast only?

A. We are into semantics, and by definition it is my understanding that to establish a definitive diagnosis -- they can establish a clinical impression and they can call that a diagnosis, but it is the clinical diagnosis and not a definitive cause.

In my use of the word, definitive implies either a cytologic diagnosis with an adequate cell sample or a histologic diagnosis of history obtained by biopsy.

Q. So all the physical examination does is add to or subtract perhaps from a clinical impression of whether a lump or a mass is malignant or benign; do you agree with that?

A. The most important thing about physical examination is whether the mass is even there.

Q. Correct. All right.

If a lump is described as smooth to the feel of the physician, what does that indicate to you if anything about the status of the lump?

A. If it is smooth it is thought to be a more favorable characteristic by clinical impression, but there is no certainty about whether that

relates to a malignancy or benign condition,

Q. So it could be smooth and it could be malignant as well?

A, Correct.

Q. Same thing, the question regarding firmness of the palpable mass, what does that tell a physician clinically?

A. The typical breast cancer is ductile carcinoma and they typically infiltrate and have a lot of fibrous reactions, they are very hard and they are irregular.

There are other forms of cancer and even the ductile carcinoma sometimes will be related as having a smooth structure or not be firm to palpation, Though typically the most common type of breast cancer is firm and irregular and tends tu have lack of mobility,

Q. But you are also indicating by your answer that something that is eventually diagnosed as ductile carcinoma doesn't necessary present itself as a firm, hard lump on the first examination?

A* That's correct, and in clinical medicine there is exceptions to everything.

Q. Sure.

Once again, Doctor, can I assume

that your answer in this arena is the same as to the mobility of the lump at the time of examination, that it doesn't really tell you for sure one way or the other whether the lump itself is malignant or benign?

A. That's correct and those are all characteristics, the smoothness, the mobility, the lack of hardness that are assumed to be clinically "benign" characteristics, but they are currently not diagnostic.

Q. What does a complaint of breast pain or tenderness associated with a lump mean to *you* clinically, does it have any relevance in determining whether something is benign or malignant?

A. Yes, it is like the other characteristics that we have been describing, the firmness, the irregularity, the mobility in general and tenderness is considered a "benign" characteristic, and goes along with the others; but as we have been discussing, it is not diagnostic and the clinician would not rely on that as a final diagnosis in doing the management,

Q. What does retraction of the skin indicate t you in terms of the skin being retracted in the

area where the lump is palpated?

A. If there is some change the tissue has probably some scarring below that if it is new. Some women have had retraction for many, many years and that clinically is less significant, Either infections or trauma or tumors can underlie retraction.

Q. Do you have a recollection or you can look at Dr. Wisler's chart and see that he made a notation at the time of her presentation in August that there was retraction associated with the mass that he palpated?

A. The record I am looking at is dated May 25, '90 from Dr. Wisler and there is a diagram on it of the breast. On the left side there is part of a circularly mass, going through it with a squiggly line looks like it says "slight retraction afterwards" if I read his writing correctly.

Q. I would represent to you that he has testified that that's what he said it says, it says "slight retraction.

A. That's what he said in the deposition if I recall.

Q. He did.

What does thickening of the skin

above a lump indicate?

A. Thickening of the skin above the lump is like any finding in the breast: The more findings there are, the higher the suspicion is and the greater the need to proceed to a definitive diagnosis.

Q. In moving ahead -- and we might have to look at something that Dr. Wisler said.

He completed the diagnostic triad OR Mrs. Hopkins, correct?

A. Yes.

Q. We have established that,

What is your understanding of Dr. Wisler's impression at the conclusion of that procedure?

A. Well, the other information in the deposition that he had thought this was a benign breast mass that had some fluid in it, that would indicate some cystic changes of the breast that were responsible for the fluid that was obtained,

Q. Do you recall what he said about whether the lump still existed after the aspiration?

A. I don't have the deposition in front of me.

Q. You are going to have to hold on because we might have to read some information. While Anne's looking for that, I'm going to ask you some other

questions.

Following the diagnostic triad, if a physician is not assured that the lump that he has examined is benign, what is the next step?

A. In any situation a follow up of a breast abnormality is to follow it up, re-evaluate it in the future and see if it progresses or changes or subsides.

Q. Let me indicate to you -- I understand you don't have the deposition and Mr. Bonezzi can change this at a later time I suppose if he doesn't have it, but Dr. Wisfer was asked in his deposition whether or not the mass resolved followed --

MR. BONEZZI: Why don't you tell me where you're reading from first?

MISS KOLIS: Page 38, lines 7 through 11.

MR. BONEZZI: Go ahead.

Q. It says my standard thing is if it is completely resolved I put resolved, the context, Doctor, is where I asked him about the lump.

Question, what if it has not?

Answer, I don't put resolved.

Question, you don't put anything down?

Answer,. right, from looking at my notes I assume that the mass was still there subsequent to the aspiration,

That's what the testimony was, Dr. Hindle.

Now,. given that the mass did not resolve following the aspiration, that's what Dr. **Wisler's** testimony is, what should have been the next thing that should have happened to Mrs. Hopkins?

A. Two things that did happen, they did the mammogram and he advised her to come back for re-evaluation in I believe the note said two to three months; and then the note that's written on the mammogram report --

Q. If we can hypothesize in this matter, let's say for the sake of the question I want to ask is that she did come back in two to three months and the lump was still there.

A. Yes.

Q. What would the standard of care have required at that time happen to the lump?

A. Some further diagnostic procedure or referral to the patient.

Q. When you say some further diagnostic

procedure are you referring to a repeat FNA?
A. It could be, or it could be a needle tissue core biopsy, or it could be an open surgical biopsy.
Q. In any event something more definitive would need to occur at that point in time?
A, Something further,
Q. Something further than had occurred in August and September, correct?
A. The reason I say further is because this could include repeating the fine needle aspiration,
Q. I suggested that as a possibility.
A. Yes,
Q. If that fine needle aspiration was once again negative and the cytology was negative, at that point would the standard of care require in the face of a lump that persisted for there to be an open biopsy?
A. First, let me clarify that I never use the word or try never to use the words negative or positive because negatives are fine, but there is nothing there and both with mammograms and fine needle aspiration you either get specific information or you don't; and if you don't, then it doesn't prove that nothing is there because nothing

does that, it isn't even true of an open surgical biopsy.

You have to look at the report itself and see what he reports, and if he reports like this in this case that there was something there that was not malignant there, then that means that's benign with what you get from normal breast tissue.

Many of the lumps and bumps in the breast that are palpable as dominant breast masses are in fact a configuration of fibrocystic changes of normal breast tissue and you would get normal structural cells as they did in that situation.

Q. My question is -- and I understand now that you don't want me to use the words positive and negative, so I won't.

A* You can use --

Q. In order for you to answer my questions, I guess I should ask them in whatever way you are comfortable with them.

First of all, let me deal with the cytology that came from Dr. Wisler's FNA.

A* It was --

Q. I don't know what word you want me to use, It didn't say she had a cancer, let's put it that

way, right'?

A. Right.

Q. The finding itself does not indicate that she doesn't have cancer. In other words, I guess the issue I am addressing or that you are alluding to, I'm sure, is that there are false negatives?

A. Let's be clear about the false negatives. If you don't obtain any cells, then you don't know anything, it is as if you hadn't done the fine needle aspiration, The report says minimal number of epithelial cells present for adequate cytologic examination, no malignant cells identified.

Now, they have a normal breast tissue finding in the fine needle aspiration, which is a common finding in doing fine needle aspirations of dominant breast masses, so that is consistent with the benign process, So there is no evidence of malignancy there.

Now, this was done with a very small needle, usually a 22 gauge needle, so there could always be sampling error if the needle isn't where something is, then of course you have no sample; but that's true when you're evaluating the whole breast or doing biopsies, if the tissue comes from someplace where the lesion doesn't exist, then

you don't know about the lesion,,
Q. The question I asked was if you got a persistent lump and the FNA comes back not diagnostic for the cancer, you can't be sure that there is no cancer?
A. You can never be sure there is no cancer,
Q. At that point isn't it acceptable medical practice then to attempt to do a histological diagnosis by an open biopsy?
MR. BONEZZI: Objection. At what time following the fine needle aspiration?
Q. I'll give you the range, three to six months.
A. If I heard you correctly, is it acceptable medical practice to do a biopsy? I have to answer yes, it is certainly an acceptable process to do a biopsy and also acceptable practice not to do a biopsy, but to continue to follow the patient when you have concordance of the diagnostic triads that by clinical examination, by fine needle aspirations and by mammogram, they all indicate the benign process- It is perfectly acceptable and it is within the standard of care of obstetricians and gynecologists to continue to follow the patient and see if the palpable abnormality changes with time,

Q. Let me see if I understand this: You think concordance is obtained when a lump does not deflate, let me ask that first?

A. Well, deflating or not deflating is not the issue of concordance, Deflating or not deflating has to do, in my experience, with cysts and if you take cysts and evacuate the fluids then the mass will disappear to palpation.

Q. Sure. If you draw fluid and it doesn't deflate, can't you at least make a reasonable clinical conclusion that it in fact is not a cyst?

A. Well, we have to be careful about what we're using the term cyst for because what we have now is a fibrocystic disease and it is very common, and as common as the very lumpy, bumpy fibrous irregularity; and if the fine needle aspiration goes up through one of those microcysts, then you would get a small amount of fluid,

So it isn't a question of fluid and no fluid, if you have a large palpable cyst the size of a golf ball you're going to get a whole syringe full, but it is clear that you are dealing with a cyst and that should disappear.

Q. This was not a large cyst, a large mass at the time that Dr. Wisler palpated it, do you agree

with that? It was 1.5 by 2 by 1.5 I think,
A. That's fine.
Q. You agree with me that those were the dimensions that he recorded?
A. They are close to that, I would have to look at that again. 1.5 by 2 by 1.5 is what I see,
Q. That's what I just indicated,
A. Okay.
Q. If this had been a fluid filled cyst and he did an FNA, wouldn't you have expected it to completely collapse?
A. Yes,. if the entire mass was a cyst, but the fact that it doesn't collapse doesn't mean that they are what we call microcysts. Microcysts have an amount of fluid in the breast which is very common when you have fibrocystic changes in the breast, which is a very common palpable abnormality and then will be evaluated for dominant breast mass.
Q. In reading Dr. Wisler's deposition, do you recall that he stated that if Mrs. Hopkins had returned to him three months later and the mass was still there that he would have referred her out for an open biopsy?
A. That's my general recollection and I don't

have that in front of me.

Q. Do you take issue with the fact that he would have at that point have sent her out for open biopsy?

A. No, I believe I stated that the next step is appropriate to do some further procedure, whether that is repeat fine needle aspiration or a tissue core needle biopsy or an open surgical biopsy or whatever the consultant recommends.

I have seen similar cases where the consultant surgeon gives breasts oncologists such a strong feeling that the mass is a totally benign process, but the surgeons continue to follow the patient and that is the judgment of the consultant,

Q. You don't think that the standard of care requires that a biopsy be performed in the face of a persistent palpable lump?

A. No, I do not. When the patient has been referred tu a consultant, the consultant in evaluating the entire situation, examining the patient, taking their own history and evaluating the mammogram reports and the fine needle aspiration report, and if their impression of that is that that's totally a benign process, then in my opinion the consultant would be justified in

continuing to follow the patient and observe the patient in some future time like in two or three months.

Q. If you continue to observe and follow the patient, what would make you decide to do a biopsy?

A, If the patient had a character of a mass, particularly if it is getting larger, or in my opinion, if the patient continues to worry about it and they are concerned we might be dealing with a malignancy or if I have any suspicious whatsoever that it might be malignant.

Q. You would wait until it grew to biopsy it?

A, I didn't say that,

I said it is within the standard of practice if the consultant who is presumed to be a specialist in breasts on the initial evaluation thinks it is totally benign, then that consultant, particularly if the patient is a menstruating woman with breasts changing with her menstrual cycle, may wish to examine that patient again after another menstrual cycle or two months later, or more commonly what you are describing as what would be carried out if the patient would be biopsied.

Q. We would carry that biopsy out to make sure there is not carcinoma, a cancer, correct?

A. Well, even biopsies don't absolutely prove things aren't there, but that is the next step in the diagnosis of the breast and that is the one that is most commonly done.

Q. From your recollection, was Mrs. Hopkins a woman who was still menstruating?

A. I believe she had had a hysterectomy.

Q. I just wanted to make sure that you understood that.

When you do an FNA and you draw blood tinged aspirate, what does that mean to you?

A. It means one of two things, either that the trauma or the fine needle aspiration created some bleeding in the tissue so some of that blood is drawn out in the needle, or the syringe or the area that you are evaluating has some prior hemorrhage bleeding into it and you can get that out into the syringe.

Q. Is blood in the aspirate a concern to the clinician who is doing an FNA as being suggestive that there is a malignant process occurring?

A. It is a concern for two reasons because the blood affects the accuracy of the cytologic evaluation, it is harder to interpret cells that are in hemorrhage and causing blood clots; so

ideally you want to have an aspirate that is not bloody.

The paradox is that most carcinomas are vascular, so most aspirations out of carcinoma are bloody aspirates.

Q. You can correct me if I'm wrong, I know we are going to get it here because I have a stack here of references.

You have written in fact that if the aspirate is bloodied in some way that it really is an indication for an immediate open biopsy?

A. What are you quoting?

Q. Well, let's see if we can find it. I don't know if Ann wants to steal this, because I must have 30 pages of questions. So I'm going to let Ann look for that, she'll try to find the reference.

I'm asking you if that's something that you would have written?

A. Well, I'm having a problem with the context of something like that may have been written in because in aspirating cysts, if you get gross fluids that's a sign that there might be some intracystic neoplasm.

As I said, with aspiration of the

most common breast cancer, ductile carcinoma, in my experience, most of those aspirations are bloody aspirates but you can still make an adequate cytologic interpretation and make the -- finalize the diagnoses of carcinoma, and if you have that then it isn't required to do an open surgical biopsy.

Q. Right. If the cytology comes back positive; is that what you're saying?

A. If the cytology comes back as malignant.

Q. Right. In the instance where you have blood tinged aspirates and the cytology comes back negative, isn't that a circumstance which indicates the need for an open biopsy?

A. No.

Q. Why not?

A. Because it has to do with what cellular material is there. If you don't see cells, you haven't learned anything. If you see totally benign cells in the aspirate like Mr. Wisler did, epithelial cells and no signs of malignancy, that is what you get from normal breast tissue and also some blood from there.

Q. So that blood means nothing to you?

A. I didn't say blood meant nothing to me, it

complicates the procedure. In most malignancy there is blood there, and when there is blood in a cyst it is a sign of a gross cyst where you get a measurable amount of fluid and there might be an intracystic neoplasm and most of those are malignant. It is significant, but not in my opinion an indication for immediate open surgical biopsy,

Q. If it is significant but it is not an indication for an immediate surgical biopsy, when given that constellation of factors would a surgical biopsy be necessary?

A. If the issue is unresolved as to what the diagnosis is. Again, I would differentiate between a cystic mass where you aspirate blood out of a cyst which is very unusual, but when that happens it is a sign that you may be dealing with an intracystic neoplasm, that is one instance.

The other one is if you keep getting blood in the aspirate and you do not have other cellular material that's a normal epithelial cell, then you don't have any answer as to what the cytology indicates. This is if you have nothing in the smear,.then you have to proceed either with a repeat fine needle aspiration, tissue core biopsy,.

or open surgical biopsy.

Are you aware or can you recall that Dr. Wisler testified that when he aspirated this mass what he received was a scant amount of fluid slightly blood tinged?

A. That's my recollection. I would say that's normal, typical,

O Dr. Hindle, do you routinely observe mammogram films for your own benefit which have been read by the radiographer when you are evaluating breast disorders?

A. No, that is not the standard of practice across the country in my opinion.

d. I agree with you, it isn't. I simply asked if you did or didn't.

Is it possible in your opinion to make a definitive diagnosis of cancer versus a benign lesion based upon a mammographic reading?

A. A mammographic impression is like a clinical impression, When you look at a film you are looking at a three dimensional mass suspended in two dimensions of black and white shadows and mammographers do not -- mammographers get very good at the clinical correlation between what they see and perceive on the film and what the final

definitive diagnosis is.

It is the same as clinical evaluation, doctors who do breast examinations full time as their career activity gets a very high correlation between their impression and the final definitive diagnosis, but neither the clinical breast examination nor any mammogram is definitively diagnostic.

Q. What did the mammogram reading in this case that Dr. **Wisler** ordered add to determining whether or not Mrs. Hopkins' mass was benign or malignant?

A. I have the report in front of me where it says two areas of each breast show relatively dense breast with the dense region being in the upper and outer quadrant of the right breast, there is no detectable dominant mass, there is no tumor calcification,

Q. I know what the reading says. I'm asking you what that added to being able to determine whether or not the mass was malignant or benign?

A. It shows no evidence of malignancy by that description and no evidence of a cancer by mammography, We then go back to the diagnostic triad of putting that information together with the history, the clinical examination, the fine needle

aspirations and the mammogram,

The report that I just read is consistent with a benign process with no evidence of malignancy or no red flag called to action another procedure based on the mammogram report.

Q. Is it appropriate to definitively diagnose a palpable mass as benign on the strength of the mammograph reading alone?

A. No.

Q. Of course it's not,

Just by way of background, you're saying FNA is not the standard of care across the country, when did the theory or technique of fine needle aspirations first develop?

A. When were fine needle aspirations of the breast first done?

Q. Yes.

A, 1930.

Q. When did they become widely used, I guess is the phrase, in this country?

A. They became widely used in Europe after the Second World War and I'm not sure that they are widely used in this country even now except for surgeons use them and have traditionally for many, many years to determine whether a palpable mass is

a cyst or a solid mass, Only recently, in my experience, have surgeons done fine needle aspiration cytology of solid masses.

Q. Why has fine needle aspirations been added as one of the diagnostic tools for breast diagnosis?

A. Do I consider it one?

Q. I said why has it been added, what are the benefits of doing a fine needle aspiration?

A. Because in the 22 gauge needle with a procedure that takes no longer than a venous puncture and no more painful than a venous puncture, one can establish a cytologic diagnosis on 90 percent of the neoplasms of the breast if you get an adequate blood sample, it can also be done as an office procedure.

Q. You're saying 90 percent because -- we'll loosely go through different numbers in different reports -- in 10 percent of the cases the cytology diagnosis which would appear to be negative is in fact not negative, false negatives is what the topic is.

Are 10 percent of the findings of false negatives incorrect?

A. You have to be very specific when you talk about "false negatives" because if you do not have

an adequate cell sample then you don't know anything, and for statistical purposes that's considered inadequate or "false negative." It is like a mammogram that doesn't show anything, it doesn't prove that nothing is there, which is why I prefer not to use the terms negative or positive because it gets confusing to everyone involved,

Q. In your opinion based upon the cytology report that you saw in this matter, was there adequate cell materia1 to be evaluated?

A. The report says cells present for adequate cytologic evaluation.

Q. The fact that that cytology reports does not indicate a malignancy which is later found, what does that tell you if anything?

A. What does it tell me?

Q. Yes.

A. Where that fine needle aspiration was done there was not a cancer.

Q. Does fine needle aspiration cause scarring on the breast?

A. Only if there is a hematoma formation and bleeding of the tissue can you get secondary scarring.

Q. Based upon the use of a 22 gauge needle even

if there was a hematoma, let's assume there was a hematoma, where would the scarring extend, what would it look like?

A. I had one patient that had a blood desecration that covered her entire breast.

Q. That would be something that you could see pretty clearly, wouldn't it?

A. Not necessarily, because it is usually in the tissue, It is like when they do mammography needle localization procedures, you can see bleeding within the tissue but you can see nothing on t

Q. The size of the wound or the puncture, whichever you prefer to call it, is small enough that it can be covered by a circular bandage, correct?

A. Yes. In fact, we don't even put Band-Aids on them at all, it is the same size needle that is used to draw blood.

Q. Will fine needle aspiration cause a thickening of the skin?

A. Usually makes no change whatsoever.

Q. I'm skipping my whole page of fine needle aspiration questions because I think I know what you're going to say.

Dr. Hindle, fine needle aspiration is only an additional diagnostic technique and does not replace an incisional biopsy; would you agree with that statement?

A. They are different in their application.

I think we have discussed repeatedly, my approach is that the diagnostic triad, doing a clinical breast examination, fine needle aspiration, mammography, looking for concordance and if you have concordance of that then you can manage the patient on that basis, If you don't and you have a persistent palpable dominant breast mass, then you need to get a definitive diagnosis which you can get by tissue core biopsy or open surgical biopsy.

Q. I was able to locate the reference that we were talking about in terms of the blood tinged fluid, it is in your article, "Breast Aspiration Cytology," 1982 I think.

A. 1982?

Q. 1983 was actually the publication date, American Journal of Obstetrics and Gynecology, do you have that one?

A. We are looking for it. You can ask me the question.

Q. What I wanted to do was point out to you where in writing I drew my conclusion of things that you had said, and then you can explain to me the correct context if I have misinterpreted it.
A. Well, number one, you know, that was what, 13 years ago.
Q. Yes. Well, we'll go through it and if you want to disavow what you wrote, that's fine, I just want to know.
MR. BONEZZI: I will object, that's not what he's saying.
MISS KOLIS: I know that.
MR. BONEZZI: I am totally surprised that you would even comment on that.
MISS KOLIS: Well, he told me he wrote it 13 years ago.
It is on page 485 of that article.
Q. At the top of the page which is a continuation to the previous section is your comment, and the section that I read says as follows,.
"If the cyst recurs it should be aspirated again," I understand that, we have discussed that today. "If bloody fluid is obtained, induration or thickening is palpated

after aspiration of the breast cyst, the patient should be referred for open biopsy."

A. Right. Now, you remember my previous discussion to the previous question that I differentiated between whether the mass is a gross cyst or it is a solid mass and this entire paragraph reiterates to gross cysts.

It is totally consistent with what I have told you today, that if you have a gross cyst and you aspirate it and it is grossly bloodied fluid, it indicates that there may be an intracystic neoplasm, this is a different entity and a different approach than a solid dominant breast mass as we had in the case that we are discussing. So that paragraph does not apply to this case.

Q. Okay, that's fine. You clarified it so that I will know whether to deal with that or not.

Based upon your answer, you're saying we're not dealing with a cyst, we're dealing with a solid dominant mass?

A. We're not dealing with a gross cyst where the entire mass is a cyst. I have discussed previously that much of the nodularity of the breast is associated with microcysts and some fluid might be

obtained,

When the typical, say, surgeon is talking about a cyst, they are talking about a gross cyst, something the size of a ping-pong ball that you would get a whole syringe full of fluid out of, not just a small amount of fluid that you squirt out on the slide.

Q. So what you said in that particular paragraph only applies to a cyst of a larger size?

A. Right.

Q. It doesn't apply to a smaller cyst?

A. Correct.

Q. I think we have been through this, I just want to ask it as directly as I can.

After an aspiration if the lump collapses completely or significantly decreases in size, that is indicative that the lump -- I'll call it a lump -- was a cyst, correct?

A. The first thing would be that there would be a palpable mass to put the needle into the center to withdraw out a syringe full of fluid, and if the mass as you are palpating it and drawing out the fluid shrinks below your palpating fingers, and when you take out all the fluid it becomes therapeutic as well as diagnostic, and there is no

residual palpable mass you have aspirated a cyst,
Q. You can agree with me that in this situation what Mrs. Hopkins presented with was not a cyst because that didn t happen on aspiration?
A. Correct,
Q. You told me what bloody aspirate means, so I don't need to ask that.
Just so 3 have this established, your literature that you have written -- you have written a couple of different things but they are all pretty similar -- suggests that for patients being treated following this aspiration, they do need to be followed up on, especially when that mass does not disappear; what is your time period for a follow-up?
A. In my opinion, all patients with breast disorders ought to be followed up to be certain that the disorder resolves, whether it be pain, whether it be masses, whatever the situation is, so they should be followed up,
Q. I understood that and you probably misunderstood my question, which is okay.
Time frame for follow-up?
A. Depends on what the problem is. If the patient has an infection they need to be followed

up in a short period of time, three or four days to make sure they are responding to treatment. Patients who have big masses who are menstruating woman should be followed in the subsequent menstrual cycle or another cycle, so we are then talking about two months.

It depends on what index of suspicion clinically, when you are the one dealing with a benign or malignant process and get the impression it is a benign process, then three months is an adequate followup as most breast tumors do not grow rapidly, and if you're likely to see some change it takes several months.

Q. So in this particular case three months would have been the appropriate time to return for an evaluation?

A. That's correct in my opinion and my experience across the country.

Q. If that mass had not changed in that three month period, would you then schedule a person to come in again in another three months?

A. IS this a theoretical question on what I would do on a mass that has not changed in three months?

Q. Yes.

A. As long as everything else in my evaluation, going back to the diagnostic triad process and there is no suspicion of malignancy, then I would continue to follow it and see what happened; and if it changes in characteristic, if it gets larger or harder or firmer or less mobile or more irregular then I would proceed to a definitive diagnosis, not only by cytology but by a tissue core biopsy or an open surgical biopsy.

Q. When you say "tissue core biopsy," you are discussing another method of obtaining the material that you could get by an open biopsy, but it is a different method, correct?

A. Yes, you get a much smaller sample,

Q. What's the benefit of doing a tissue core sample versus an open biopsy?

A. Open biopsy is an outpatient surgical procedure that is usually done in a surgical facility, often in a hospital, requires at least a day of the patient's time and considerable cost is involved on the health care system,

The tissue core needle biopsy, it is an office procedure that is being done under local anesthesia and the patient can go home or continue her activities within an hour after that

procedure,

Q. If the lump itself doesn't change but the skin in the area begins to thicken, would that be an indication to do either the tissue core or an open biopsy?

A, Or to do a skin biopsy,

Q. So you agree with me that some sort of biopsy should be done if in addition to the lump there has been a thickening of the skin in the area?

A, In anything that is progressing you should evaluate the patient for further diagnostic studies.

Q. Doctor, when a pathologist is looking at a slide containing cells of infiltrating ductile carcinoma what will he see, if you know?

MR. BONEZZI: Objection. Donna, you are asking him for a pathologic interpretation or that which he has been provided with by a pathologist?

MISS KOLIS: No, I'm asking him if he knows -- some people who do what he does actually get an interest in pathology and can tell me what they would expect to see on a slide. If he doesn't know the answer, that's okay.

A. Certainly in teaching at an institution we

review all the slides, we do not make a definitive diagnosis or write definitive reports, that stuff is done by trained pathologists.

In the case of cancer a needle is used and kept within the cancer, the entire slide is usually covered with malignant cells and it is quite obvious looking at the slide in any of its aspects that you are dealing with malignancy,

Q. Dr. Hindle, do you agree with me that infiltrating ductile carcinoma is the most common type of breast cancer?

A. Yes.

Q. Infiltrating ductile carcinoma generally feels like a hard cell mass to the touch; do you agree with that?

A Typically the mass is a hard, irregular, dense mass with limited mobility.

Q. We are going to go back in this area that you don't like, sooner or later I think I will probably get the right answer.

Which is a bigger problem with fine needle aspirations: One, false positives, that is FNA saying there is cancer when there isn't any; two, false negatives, that is FNA failing to find cancer that is really there?

MR. **BONEZZI:** Objection.

Go ahead and answer,

A. In my experience, like I said, I don't agree with the definitive cytologic reports of this, but following them along in my experience of being associated with approximately 5,000 fine needle aspirations, a so-called cytology diagnosis of false positive is incredibly rare, there are biologic processes of everything that happens a few times.

If you get the so-called false negatives, then I go back to what I said before, that for statistical purposes those slides that don't have adequate cell samples are considered "false negative," In my opinion if you don't have adequate cells you haven't learned anything, you can't draw any conclusions from it.

There is a sampling problem with fine needle aspiration because you have a 22 gauge needle which is a relatively small needle and of course you have to get it in the appropriate place and the cells that you obtain do reflect where the needle has been; but if you don't have the needle in the right place then you are going to get misled because you will have different cytology than the

lesion if perchance you have sampling error and the needle misses the lesion.

I understand that, if *you* want to just explain this to me a different way.

I suppose referring you back to the article that I previously asked you to look at, the one that was in the ~~American~~ Journal of Obstetrics and **Gynecology**, 1983.

A. Yes.

Q. On page 484, I understand this was a retrospective review of a patient population that was a little higher than 1100 people, right, somewhere in that neighborhood?

A. Yes.

Q. On page 484 basically what you say is that 23 percent of cancers were not detected by aspiration cytologic evaluation in that particular retrospective group.

A. Where are *you* on this page 484?

Q. 484, my copy is probably highlighted I would think and it is page 484 -- let's see if we can find it for you real quickly,

Go to 483. Sorry.

A. Okay.

Q. 483, beginning of the last paragraph on the

page says of those lesions that proved to be malignant cytologically by open biopsy, 11 to 23 percent of your grouping were not detected by aspiration cytologic examination.

A. Yes, that's the statement.

Q. Then at a time later I think you have written that there is a range on that, there is no reference to the fact that that only happens when there is an inadequate amount of aspirate; is that a fair statement?

A. There is no reference in this article to that?

Q. No. If you can find it, let me know,,

A. If you looked I presume it is not there.

Q. I don't see it. I haven't seen it in any of your writings, that's why I'm asking you.

A. What are *you* asking me?

Q. In trying to answer these questions you seem to be -- and *you* correct me if I'm wrong -- seem to be saying that when I'm calling something a false positive, you seem to be implying that that can only exist if the sample size is not adequate?

A. Did you say what you meant to say, you just said false positive?

Q. False negative. I'm sorry.

A. I make that distinction with the experience that I had over the last 20 years. If you don't have adequate cells you can't come to any conclusion, and cytologically that's called false negatives.

Then I explained about sampling here, and if you haven't obtained the specimen in a tumor and some cancers are very dense, very thick, very fibrous -- and it is very difficult to get cells from the cancer, but that is very unusual in my experience, The typical infiltration ductile carcinoma that is using an abundance of cell and since the needle remains in the mass and all those cells are malignant cells.

Q. I think that I know -- you have added to the answer.

In other words, there is no such thing as sampling error where for whatever reason the physician when he does the fine needle aspiration in the lesion draws out materials that doesn't contain the cells in it even though there is a malignancy there, that does happen?

A. Yes.

Q. We'll go on to the next group of questions hopefully, if I can turn the page on my notes.

That study that I just quoted from, the average figure is around 10 percent of the cases that the physician gets incorrect information or no information at all from an FNA; would you agree with me on that?

A. I wouldn't say incorrect information. You either get cytologically meaningful information or you don't, and if you don't then you have to proceed.

Now, sometimes the size of a pathology -- there are borderline cases and they really can't make a decision, then you need either further cytology or histology by a biopsy or a tissue core biopsy.

Q. You know, in discussing sample errors when performing FNA to hit the target, is that more difficult when the tumor is small?

A. Yes.

Q. Even if someone is using good technique there is a possibility of sampling error when the tumor is of a smaller size; do you agree with that?

A. Yes, that's always true.

Q. Sorry, Doctor, I'm lining out questions as I have written them here.

This particular patient is

described on the mammography as having fibrocystic -- and I'm not sure if it says change or disease, Have you got the mammogram that Dr. Wisler ordered?

A. The copy I have says clinical diagnosis fibrocystic disease with cyst aspiration approximately one week ago, dated 9-1-90.

Q. Based on your experience in doing this, when a person has fibrocystic disease -- I don't know if I like the word disease or fibrocystic changes -- the mammogram can come back negative to see anything even though you can palpate a lump, correct?

MR. **BONEZZI:** Objection to the form of the question,

Go ahead and answer it, Doctor,

A. That's accurate, To take the fibrocystic changes out of it, that's true of all mammograms. Mammograms can come back and not show anything mammographically and there can be by clinical examination a dominant breast mass.

Q. Do you have an opinion what the percentage of breast cancer is that are missed by mammography?

A. Ten percent,

Q. Excuse me?

Ae Ten percent.

Q. Ten percent, okay.

A. We're talking about palpable breast cancer because non-palpable ones are only found by mammography.

Q. Right, I'm sorry. I should have included that, clearly I meant what percentage of palpable breast cancers are missed by mammography.

Have you seen the mammogram reading that was done at Kaiser in April of 1992?

A. I saw another mammogram report and I don't remember the date of it. In fact, I think there were two of them, there was one that didn't show anything and then there was one that finally showed it was cancerous; is that correct?

Q. I will represent to you that neither of the mammograms said anything about cancer if that helps you to remember,

My question is just --

Ae I don't have that record here.

MR. **BONEZZI:** He may have seen that, he may have only seen that which Dr. Rosenthal set forth in his June 9th, 1994 report, the mammograms and the impressions of those.

Dr. Hindle, as a clinician who is regularly practicing in diagnosing and treating breast disorders, if you receive a mammogram that indicates: Number one, fibrocystic disease; number two, the finding says there is distortion of the nipple possibly secondary to the previous surgery, assume that statement is out there, does FNA cause nipple distortion?

A. It would be very unusual in my experience. As I said, if you have secondary hemorrhage there might be some changes in the subsequent mammogram or some distortion of the nipple.

Q. What causes nipple distortion in a mammogram?

A. What causes it?

Q. Yes.

A. General causes are some sort of trauma like blood trauma, some sort of infection or a malignancy.

MR. BONEZZI: Can we take a one minute break?

MISS KOLIS: Yes.

(Recess had.)

BY MISS KOLIS:

Hindle, in evaluating this case did you read the surgical description in the eventual pathology of Mrs. Hopkins that was performed by Dr. Dietz?

MR. BONEZZI: Why don't you read it and refresh his memory, because I may have sent that to him and I don't recall as we sit here, Q. Ann is going to have to sift through the medical records,

Let me ask you this question, perhaps you don't know, but we can start it this way: In hindsight, do you have an opinion today whether or not the mass that was evaluated by Dr. Wisler in September of 1990 was in fact cancerous?

MR. **BONEZZI**: Objection to the term "mass."

Go ahead and answer, please.

My conclusion is that the mass he evaluated, the area that he evaluated showed no evidence of malignancy and therefore was not cancer.

At that time, is that what you're saying?

At that time.

But my question to you is this: In hindsight, given the eventual diagnosis, do you

have an opinion whether or not that lump -- we'll call it a lump or a mass, whichever you prefer to call it -- was in fact cancerous?

MR. BONEZZI: Objection, He just answered at the time that Dr. Wisler became involved with it it was not cancerous,

MISS KOLIS: What is the basis of --

MR. BONEZZI: Leads to subsequent -- you can answer that, but **that's** a different question.

Q. What's the basis of that opinion, Dr. Hindle?

A. Because the complete evaluation by the diagnostic triad revealed no evidence of malignancy when that evaluation was done by the physician when he saw the patient on the 25th of August, 1990.

Q. This may be a difficult question €or you to answer, but I'm going to try anyway: Do you feel that it is appropriate for an OB/GYN to fail to perform a breast examination of a patient based upon the fact that the exam had previously been performed by a nurse practitioner?

MR. RICE: Objection.

A. You are asking me a theoretical question, if a nurse practitioner does an examination and finds no abnormality, whether that examination needs to be repeated by a physician?

Q. I didn't use that phrase.

Let's say a nurse practitioner does an examination and records a notation of thickening in the breast, thickening is an abnormality, isn't it?

A. Yes.

Q. After five or so months down the road, if you are an OB/GYN and you are looking at a medical record that indicates that the nurse has done an exam and noticed thickening, at that time does the standard of care require that the physician independently examine the breast?

MR. RICE: Objection.

A. In my experience if some abnormality of the breast has been described there should be some follow up of that. The physician could do the examination, he could refer the patient to someone else; but if there is an abnormality detected and the physician was aware of that, then the physician has some responsibility to do some further evaluation or have some further evaluation done,

Q. By another physician?
A. Yes.
Q. In your opinion in the situation -- we will just stick with thickening. If there is a recorded thickening of a breast is it adequate in terms of the accepted standard of medical care for a physician to simply lay their hand on a patient's breast while the patient is laying down; is that a complete breast examination?
A. If I understand the question, you're asking me two different things.

A complete breast examination of course is an examination of both breasts, the fibril areas, the axillary area, the supraclavicular areas comparing one side to the other and those are the standard steps to go through.

If the patient complains of a specific problem localized to a specific place, like any physical examination then the physician may as well examine exactly what it is the patient or some other health care professional has pointed out as the problem and not do the complete breast examination.
Q. Let's ask the question a little more specifically.

Just assume for the sake of my question that the patient we're talking about is Mrs. Hopkins and that she has been reported to have thickening in the area of the breast where the fine needle aspiration had previously occurred. Would it be acceptable in terms of the standard of care of medical practice for a breast evaluation for a physician while the patient is lying down to simply put their hand on the area?

MR. RICE: Objection.

A. You mean to examine that area?

Q. Yes, just assume for the sake of my question that that's the extent of the examination,

A. Is the patient coming to this physician to have a breast evaluation?

Q. That's not part of my question, but if you want to assume that you can assume further that the patient is concerned about a persistent lump in their breast.

A. If the patient has that complaint and the patient has come for a breast evaluation, then in my opinion any primary care physician should do a complete breast examination or refer the patient to some physician who is going to do a complete breast examination.

Q. Do you know what this cancer was eventually staged by Dr. Dietz?
A. 1 don't have Dr. Dietz' report in front of me, different people put different stages in different reports.
Q. In the textbook which you have authored, I've got it laying here somewhere, you have a chart in there in terms of staging breast cancer, don't you?
A. Yes,
Q. would you agree with me that a breast cancer should be staged a TIV if there is chest wall and muscle involvement?
A. Yeah. I don't have the whole staging in front of me, but it is very specific about involvement or what the subclassifications are,
Q. The chart then that is in your textbook then is one that you would follow?
A. I believe now it has been revised, but it is essentially similar to what you are looking at.
Q. This is your 1990 textbook, you are telling me that there has been a revision since that one?
A, Not the textbook, but I think the staging process has been -- a more current staging process, but essentially it hasn't changed from what you are looking at,

Q. But do you basically agree with me that something would be staged a TII if there is chest wall and muscle involvement?

A. Yes.

Q. Did you note that Kaiser when they initially examined this lesion, I'm going to say August of 1993 included in the chart that it was a TIIb, does that sound familiar to you?

A. I don't have that record in front of me and I remember seeing different stages by different consultants and different physicians.

Q. If the doctor had staged it at TIIb based upon his physical examination of the lump at that time, and that cytology then later staged it at TIV. The person who actually had done the lumpectomy is the better person to know the extent of the tumor, aren't they?

MR. RICE: Objection.

A. Essentially, yes,

Q. I have a couple more questions if I can find them.

Let's see if you agree with this: When a ductile carcinoma becomes invasive and starts involving layers of skin, the physical exam will reveal thickening of the skin as a clinical

sign of the dermal involvement?

A. If the cancer is involving the skin?

Q. Yes.

A. In cancer involving the skin you can usually feel the induration or the mass right below that or the thickening of the skin, some change in the skin.

Q. Sometimes can you just feel the thickening of the skin, but not actually palpate the lump behind it?

A. That would be very unusual because the cancer should be superficial and should be below the skin to get involved with the skin. Everything is possible biologically, but in general you feel a palpable mass in my experience where there is skin involvement.

Q. Let's see what else I wanted to ask you.

Do you have any opinions based upon an invasive ductile carcinoma being diagnosed as a TIV what the five year life expectancy of that person would be?

A. No, I do not hold myself out as an oncologist about life expectancy of malignancy.

Q. So you won't be testifying at trial as to life expectancy based on diagnostic times or

stages?
A. That's correct, I will not be testifying as to that aspect,
Q. You have no opinions on that, you rely upon medical oncologists for that information?
A. Yes.
Q. Do you agree with me that a delay in diagnosis, generally speaking, impairs a person's ability for long-term survival?
A. What is your definition in this question of delay in diagnosis?
Q. Let's assume hypothetically that there is a 19 month delay in diagnosis of this particular carcinoma, do you have an opinion based on your experience as to whether or not that would diminish the person's chances of long-time survival?
MR. RICE: Objection.
A. I don't have direct experience because I don't follow these patients throughout their life as they have been treated; but in everything that I have read and all the consultants that I have talked to say that approaching a year in the progress of a cancer the prognosis is limited and certainly not as good as if it had been diagnosed two years previous to that.

Q. Let me ask it this way: What sources do you consider authoritative in determining life expectancy based on cancer staging?

A. I don't know of any.

Q. So no one is authoritative? I'm sorry I don't mean to laugh.

Let me ask a different question: I gather, and not happily I'm sure, that based upon what you do for a living that you end up diagnosing breast cancer?

A, Sure.

Q. At your facility do you perform chemotherapy?

A* Me personally or --

Q. Not you personally, the facility itself,

Are you a full service breast facility I guess is what I'm asking?

A. Yes and yes, when you are talking about the facility, and I personally do not do either.

Q. Once there is a diagnosis of breast cancer whether it is by fine needle aspiration or otherwise, you then refer your patients to a medical oncologist for treatment?

A. Yes, and we continue to follow them.

Q. Do you participate in the treatment decisions?

A. Only in giving the clinical information and following the patient along and raising questions if I have some of the clinician who initially managed the patient,

Q. Given that it is in the front of your textbook I gather that you agree that a patient who is a Stage III or IV with a breast cancer should receive systemic treatment by way of chemotherapy?

A. Each case is individual, but in general that's true.

Q. What would mitigate against a person receiving chemotherapy with a Stage 111 or IV carcinoma?

A, Certain types of malignancy that are very uncommon that are not ductile carcinoma, that there is no evidence of any systemic involvement; but in general most Stage II and III would have chemotherapy or hormonal therapy,

Q. In the case of an invasive ductile carcinoma is it standard for a person with Stage III and IV to receive chemotherapy systematically?

A. Well, they receive adjuvant therapy, it depends on -- in my experience of observing the care of these patients, it depends on their estrogen retention status and their lymph node

status and it is an individual decision and they would have adjuvant therapy of sorts, either they would have hormonal therapy or chemotherapy.

MISS KOLIS: We are done, but Mr. Rise may have some questions for you.

MR. RICE: Hi, Doctor, My name is Jay Rice and I just have a couple of questions and I think to some extent they are redundant of what you have already been talking about, I want to make sure I understand.

THE WITNESS: Just for my interest, who do you represent?

MR. RICE: In this particular case I represent Kaiser.

THE WITNESS: Thank you.

CROSS-EXAMINATION

BY MR. RICE:

Q. Can you just tell me, Doctor, what are the criteria that you use for determining whether a fine needle aspiration is needed?

A. Needed?

Q. Yes.

A. That is your question?

Q. Yes, what is the criteria that you use for

determining whether a fine needle aspiration is needed or appropriate?

A. In my opinion the indication for fine needle aspiration of the breast is a palpable dominant breast mass.

Q. Is that the only criteria?

A. That indication for fine needle aspiration and knowing that you can get a sample of cells, There are peripheral uses of it and where a patient complains of an area where the doctor doesn't feel anything or to follow up with patients who are concerned about it, but because you can get a sample of the cell in the area of the concern is the indication, the medical indication and why I think the physician should be doing it is a palpable dominant breast mass,

Q. Doctor, what criteria do you rely on to determine what results are negative? I understand we have had some discussion about what is meant by negative, but can you just tell me what criteria you rely upon to tell whether or not the results are negative?

A. I will. differentiate again, I don't use that term. They are either adequate cells or they are not, if they are not adequate cells then it is just

as if you've never done the fine needle aspiration and draw no conclusion whatsoever.

If there are no malignant cells they will report that as ductile epithelium and that will show fat tissue, that will show connective tissue, so that one will notice that the needle was in essentially normal breast tissue and not in a neoplasm, so that would be reported in some circles as "negative"; but you can see why I don't like to use that term because it is confusing to everybody.

aspiration of a palpable mass and the mammogram and look at a concordance of all of those findings and manage the patient then according to that evaluation,

MR. RICE: Doctor, I don't have anything further,

Thank you, Doctor.

MR. BONEZZI: Anything else?

MISS KOLIS: I have one

further question that I forgot to ask.

RECROSS-EXAMINATION

BY MISS KOLIS:

Q. Dr. Hindle, do you do hormone replacement therapy for woman who are post-hysterectomy?

A. Yes.

Q. As part of any evaluation that you do of a patient who you are going to be prescribing various medications for that purpose, do you do a complete breast exam at that time?

A. At the time that you are going to administer a hormone replacement?

Q. Right. If you got someone in and they need to be evaluated for hormone replacement therapy because of their hysterectomy, do you do a complete breast exam at that time?

A. Am I the physician taking care of the patient, is that your question?

Q. Yes, if you are the person taking care of the patient.

A. If I were personally taking care of the patient, I would.

Q. Why would you do that?

A. Any situation that I function in there are a

multitude doctors of involved and the patient may have been examined a week before or a month before or at some other time, and when our patients -- we do not do complete total workups every time we see the patient,

If the patient was corning in for hormone therapy and has already been evaluated, if I have that evaluation in her medical record, then in the clinical situation of taking care of the patient as we do at the county clinic, we would go ahead and write her a prescription.,

Q. But if she is in for that purpose, for a complete physical, what are the medical indications for doing a breast examination in conjunction with hormone replacement therapy?

A. For a complete physical, that would include a complete physical examination.,

MISS KOLIS: I don't have any further questions.

MR. BONEZZI: We will read.

(Discussion had off the record.)

BY MISS KOLIS:

Q. Dr. Hindle, it is my understanding from

Mr. Bonezzi's assistant, Maureen, that you are going to charge me $300 an hour for today's time, by my watch I now owe you about $600, right?

A. No. That's time out of my office, so it might be slightly more.

Q. Do you want to prepare a bill and send it to me?

MR. BONEZZI: What I'm going to do, Donna, is already arranged that he is going to send the bill to me and I will go ahead and pay it and then I will send the bill back to you, so there won't be any delay in payment.

MISS KOLIS: There wouldn't be, just tell me where and I'll address it today. I would send him a check today, I'm just trying to figure out how much I owe him.

MR. BONEZZI: I appreciate that, but it is the time out of his office also.

MISS KOLIS: You take care of everything and let me know what I owe him.

Thank you very much, Dr. Hindle.

(Dr. Hindle Deposition Exhibit A marked for identification.)

(Deposition concluded; signature not waived.)

ERRATA SHEET

NOTATION PAGE/LIME

I have read the foregoing transcript and the same is true and accurate.

_____

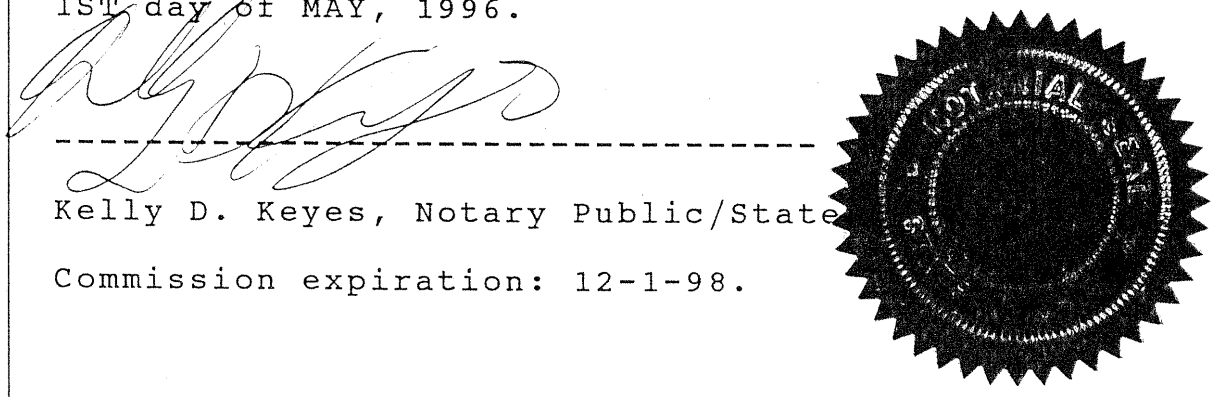
WILLIAM H. HINDLE, M.D.

The State of Ohio, .

County of Cuyahoga. : CERTIFICATE:

I, Kelly D. Keyes, Notary Public within and for the State of Ohio, do hereby certify that the within named witness, WILLIAM H. HINDLE, M.D., was by me first duly sworn to testify the truth in the cause aforesaid; that the testimony then given was reduced by me to stenotypy in the presence of said witness, subsequently transcribed onto a computer under my direction, and that the foregoing is a true and correct transcript of the testimony so given as aforesaid. I do further certify that this deposition was taken at the time and place as specified in the foregoing caption, and that I am not a relative, counsel or attorney of either party, or otherwise interested in the outcome of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, this 1ST day of MAY, 1996.



Kelly D. Keyes, Notary Public/State

Commission expiration: 12-1-98.

Look-See Concordance Report

UNIQUE WORDS: 1,382
TOTAL OCCURRENCES: 5,001
NOISE WORDS: 384
TOTAL WORDS IN FILE: 14,945

SINGLE FILE CONCORDANCE

CASE SENSITIVE

COVER PAGES = 4

INCLUDES ALL TEXT OCCURRENCES

DATES ON

INCLUDES PURE NUMBERS

POSSESSIVE FORMS ON

MAXIMUM TRACKED OCCURRENCE THRESHOLD: 50

NUMBER OF WORDS SURPASSING OCCURRENCE THRESHOLD: 6

LIST OF THRESHOLD WORDS:

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