COURT OF COMMON PLEAS
CUYAHOGA COUNTY

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NANCY FARKAS, Plaintiff,	)	
vs.	)	Case No. 393101
	)	Judge McCafferty
CLEVELAND CLINIC FOUNDATION, et al., Defendants.	)	

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Transcript of videotaped continued deposition of LOUIS D'AMICO, M.D., Witness herein, called by the Plaintiff as upon cross-examination, pursuant to Notice and Agreement of Counsel, pursuant to the Ohio Rules of Civil Procedure, before Denise C. Winter, a Registered Merit Reporter and Notary Public within and for the State of Ohio on Tuesday, July 11, 2000, at Reminger & Reminger, 113 St. Clair Building, Suite 700, Cleveland, Ohio, commencing at 3:15 p.m. and concluding at 5:00 p.m.

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Cleveland Clinic Foundation.

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Also present: Randall Buckosh, Litigaide, Inc.
Joanne Sysack

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I N D E X

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PROCEEDINGS

LOUIS D'AMICO, M.D.

Witness herein, called by the Plaintiff as upon cross-examination, having been first duly sworn, as hereinafter certified, was examined and testified as follows:

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MS. DIXON: Good afternoon, Dr. D'Amico. We're here to resume your deposition which was began on May 9th of this year, and I'm prepared to ask you a series of questions that I did not have the opportunity to ask you when we met the last time. I'll remind you, as the court reporter indicated, you are under oath, and if at any point in time you feel the need to refer to the medical records which I see you have a copy of in front of you, please feel free to do so.

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CONTINUED CROSS-EXAMINATION OF LOUIS D'AMICO, M.D.

BY MS. DIXON:

Q. Let me first ask you, since we last met, have you undertaken any additional review of medical records, deposition transcripts or expert reports?

A. No; I have not.

Q. Would it be fair to say that other than meeting with Counsel in preparation for today, you have not undertaken

any other efforts to prepare for today's deposition?
A. That's correct.
Q. Have you spoken to any of the Defendants in this case or individuals or entities that may have been Defendants in the past since we last met?
A. No; I have not.
Q. And just so that the record is clear, I'm not referring to day-to-day conversations that you may have with Dr. Noble. I'm inquiring regarding conversations specific to this litigation.
A. That's correct. I have not.
Q. In October of 1998, were you the director of the EMH urology group?
A. Yes.
Q. And you are currently the director of that group; correct?
A. Yes.
Q. Can you describe for me what your duties are as the director of the EMH urology group?
A. It's essentially a title. There are no specific duties since the administrative duties are essentially organized under the overall control of the main Department of Urology at the downtown Cleveland Clinic, so essentially the director is let's call it a figurehead or a contact person for any questions or problems that might arise in the

group's relationship with Elyria Memorial Hospital and the local hospital. It is not meant to imply I was an active administrator, meaning in control of hiring, firing, the actual day-to-day duties of the personnel within the office itself.

Q. Let me make sure I understand the chronology of events as it relates to the EMH urology group and its relationship with the Cleveland Clinic Foundation. As I understand it, I believe sometime in 1997 EMH established a relationship with the Cleveland Clinic Foundation; correct?

A. Yes. Except there's a similar contract that predated that with respect to cardiovascular surgery by about four years.

Q. At some point in 1997, you, as an individual physician, became an employee of the Cleveland Clinic; correct?

A. That's correct.

Q. And I'm assuming as part of establishing that relationship, there was some effort to coordinate efforts between the suburban outlets or suburban campus of the Cleveland Clinic such as Elyria Memorial Hospital and main campus, downtown Cleveland?

A. Yes.

Q. My question becomes, what steps have been put in place, to the best of your knowledge, to coordinate efforts

or ensure consistent care between the main campus Department of Urology of the Cleveland Clinic and the Elyria campus?

A. I'm not sure I understand your question. In reference to what, to specific care delivered by a physician? The physician care is the same both at the downtown campus and at the suburban affiliates.

Q. Let me go back. It wasn't a very well-worded question. I apologize.

Despite the fact your offices are physically located in Elyria, you are considered part of the Cleveland Clinic Foundation system; correct?

A. That's correct.

Q. And as part of that system, you are a member of the Department of Urology of the Cleveland Clinic Foundation?

A. That's correct.

Q. And when we met the last time, you indicated that your group, being the EMH urology group, is a true group?

A. Right.

Q. Meaning that you are physicians that function in the same office and may share charts, share responsibility in terms of call, but not withstanding that, you all are employees of the Cleveland Clinic and members of the Cleveland Clinic Department of Urology; correct?

A. That's correct.

Q. My question is, in terms of consistency of delivery of

patient care within the Department of Urology at the Cleveland Clinic Foundation, what steps, procedures or protocols are in place, to the best of your knowledge, to ensure that consistency or continuity?

A. I'm still not sure what you are referring to, seriously.

Q. In terms of delivery of patient care.

A. Patient care is delivered by each physician based on his training and our training is similar. Even though we are a group, each of us have private patients. We care for them as private patients.

The group structure is essentially an administrative, an administrative group that basically is there for sharing of overhead, employees, you know, billing and the business aspects of the practice, but the care that's delivered by each physician is the same as would be by a private urologist or a group urologist or an employee of an institution.

Q. As a urologist employed by the Cleveland Clinic Foundation, is there another physician within the Department of Urology that you would consider your direct supervisor?

A. We have a chairman of the department, you know, who essentially is not my direct supervisor, meaning directly overseeing my care to patient A or B, but is in control and in charge of the functioning of the department as a whole.

Q. Is that Dr. Novick?
A. That's correct.
Q. Have you been provided, since you became an employee of the Cleveland Clinic Foundation, any global practice or procedure guidelines as it relates to specific urological problems or dysfunction?
A. No.
Q. Have you ever received a copy of the 1997 "Clinical Practice Guidelines for Renal Cell Carcinoma'' that were authored by Dr. Novick and Dr. Bukowski?
A. Not specifically, but I'm aware they were published, and they may have been. I may have received them through the American Urologic Association as a separate mailing.
Q. You're not aware of any efforts independent of the American Urologic Society whereby you were provided those practice guidelines by the Cleveland Clinic Foundation?
A. In what way? In a direct mailing or --
Q. Whether it be by interoffice mail, United States mail, was there some effort to distribute that publication by virtue of your employment with the Cleveland Clinic Foundation?
A. I don't recall anything directly.
Q. Do you recall reviewing those guidelines?
A. I remember receiving them and scanning them a few years ago. There were similar guidelines for a number of

other disease entities.

Q. Do you know, generally speaking, what the purpose of the "Clinical Practice Guidelines for Renal Cell Carcinoma" published in 1979 by Dr. Bukowski and Dr. Novick were?

A. No, I don't right now.

Q. As just a generic, for generic purposes, would you agree that clinical practice guidelines are to define practice guidelines for the diagnosis and treatment of renal cell carcinoma?

MR. CONWAY: Objection.

A. I believe that's what their intent is.

Q. Would you agree that as it relates to renal cell carcinoma, confirmatory studies are always necessary whenever a renal mass is suspected, regardless of the presence or absence of symptoms suggestive of renal cell carcinoma?

A. Additional studies would certainly be indicated based on the clinical course of the presenting signs and symptoms, but whether all tests are done early or later would depend on the presenting signs and symptoms.

Q. So as it relates to the statement "confirmatory studies are always necessary whenever a renal mass is suspected regardless of the presence or absence of symptoms suggestive of renal cell carcinoma," do you agree or disagree with that statement?

MR. CONWAY: Objection. He answered it.

A. I need to know the presence of symptoms or signs, because if there are signs or symptoms present, that would clearly define the timetable or time frame with which to conduct the appropriate testing.

Q. So you believe without that additional information, you're unable to agree or disagree with that statement?

A. That's correct.

Q. So do you believe that Dr. Novick and Dr. Bukowski are in error making a statement such as that?

A. No. I believe their intent was to write a guideline which should be interpreted clinically with respect to each individual patient and situation.

Q. Would you agree with the statement, "because of the high mortality associated with renal cell carcinoma, screening for the disease is worthy of consideration"?

A. Yes. I agree it's worthy of consideration.

Q. Would you agree that a CT scan may be the single best study to clinically stage the primary tumor site and to exclude the possibility of intra-abdominal metastases as it relates to renal cell carcinoma?

A. Would you repeat that?

Q. Absolutely. As it relates to renal cell carcinoma, would you agree a CT scan may be the single best study to

clinically stage the primary tumor site and to exclude the possibility of intra-abdominal metastases?

A. I could conditionally agree, but I would just conditionally agree. I don't believe -- I believe the best staging procedure is a surgical removal with a pathologic study of the tumor itself.

Q. In terms of the conditional agreement you gave, was that based on clinical presentation?

A. Partly.

Q. And what's the other part of your reservation?

A. The fact that we do see intra-abdominal metastases from renal cell carcinoma is not a consistent first sign. The cancer may often skip the abdomen and spread elsewhere because of its nature by way of both lymphatic and vascular spread, so, you know, it's possible to have a patient with distant metastases and, frankly, a negative metastatic scan intra-abdominally but yet have disease in the chest, the lungs and so on.

Q. But you would agree that the CT scan would be the single best study to clinically stage both the primary tumor and to exclude the possibility of intra-abdominal --

A. No. The statement you read to me is maybe not -- it's not a definitive course. In other words, the implication of that statement is that you're defining a patient who you essentially know what the disease is and the extent of the

disease is and you're saying, in this particular patient, we picked up a renal mass and CT scan was consistent with a renal mass with no other CT findings of metastatic disease within the abdomen, and that statement basically doesn't say too much other than the fact that you have identified the presence or absence of a solid renal tumor and you have identified the absence of any significantly-sized tumor within the abdomen. It does not mean that that patient does not have metastatic disease is what I'm trying to say.

Q. But it would say whether or not the patient has metastatic disease in their intra-abdominal cavity; correct?

A. But that may not be clinically significant.

Q. Regardless of its clinical significance, a CT scan would tell you whether you had intra-abdominal metastases; correct?

A. Within the limit of the CT scan.

Q. Do you agree surgical excision is only effective therapy with patients with stage 1 or stage 2 renal cell carcinoma?

A. Yes, probably. There have been isolated instances of spontaneous remission in the past, but generally surgical removal is the best attempt at cure.

Q. Can you describe for me what nephron-sparing surgery is?

A. Nephron sparing simply is something that is actually

Dr. Noble's particular interest along with some other urologists around the country. It alludes to the fact that in some situations in which a very small tumor is identified, one may remove either the tumor itself or the tumor and only part of a kidney and allow the patient to spare a certain amount of kidney function which the patient may need later.

It is most critical in patients that have some degree of renal insufficiency or renal disease or perhaps who present with a solitary kidney -- with a tumor present within one kidney where obviously one would, if possible, want to preserve part of the kidney so that they can avoid dialysis. But that decision is always based on a discussion with the patient and a judgment of whether the benefit/risk ratio is present, namely, cure of the patient versus the potential for dialysis and serious complications from kidney failure.

Q. Would you agree with the Cleveland Clinic's own study that related to nephron-sparing surgery in its, specifically in its conclusions that for patients with a single, unilateral small, and small being defined as less than 4 centimeters, localized renal cell carcinoma, nephron-sparing surgery can have a 5-year survival rate *of* close to 80 percent?

A. That's correct. That's correct.

Q. Do you have any dispute with the Cleveland Clinic -- excuse me, with the Cleveland Clinic's practice guidelines if it quoted a 5-year survival rate of 57 and 60 percent for localized renal cell carcinoma even with inferior vena cava tumor thrombosis?

MR. CONWAY: Objection.

A. I would have to see the study to be able to agree. Generally, that's true. I can agree in a general sense.

Q. Do you use immunotherapy in the course of your practice?

A. I have, but I have referred those patients usually to the Clinic or a tertiary care center. Those are treatments that are not easily available in community hospitals.

Q. Those patients that you refer either to the main campus or another oncology department, do you continue to follow those patients, their course of care?

A. At appropriate times, I have, in the immediate -- during the treatment phase and in the immediate treatment phase. Afterwards, they're usually followed by the oncologist or the institution I referred them to. But if the patient survives for any length of time, they often refer to me for local care problems and some testing locally, and it's frequently a combined follow-up both locally as well as with the tertiary care institution.

Q. Would you agree that certain patient profiles appear

to predict -- excuse me, to better predict the likelihood of successful responses to immunotherapy?

A. I would have to have that clarified a little better.

Q. Would you agree that patients are likely to exhibit a more favorable clinical response if they have had a nephrectomy, exhibit non-bulky pulmonary and/or soft tissue metastases and are asymptomatic or minimal symptoms?

A. That's generally true; yes.

Q. And, again, doctor, feel free to review the medical record in front of you.

We talked the last time we were together regarding the final report of the IVP performed on Nancy Farkas on 10/20/98, and I believe at that time we agreed there were two separate findings on the IVP. One was an obstructive uropathy and the other was persistent filling defect suggestive of a cyst or mass.

Is that consistent with your recollection?

A. Yes. Yes; it is.

Q. Do you agree that by way of the 10/20/98 IVP, that second finding was suggestive or a sign of renal cell carcinoma?

A. No. I can't agree with that until I would have additional information. You mean the IVP report alone?

Q. Let me rephrase the question. The second finding on the IVP, the possible or probable cyst or mass.

A. That's correct.
Q. Would you agree that that is a sign or symptom suggestive of or suspicious of renal cell carcinoma?
A. No.
Q. Would you agree with the statement that was published by Dr. Bukowski and Novick that "it is of paramount importance that a patient with laboratory abnormalities, signs or symptoms suggesting renal cell carcinoma be promptly evaluated for the possible presence of this disease"?
A. Generally that's -- I would agree with that.
Q. Would you also agree with the statement published by Grs. Bukowski and Novick "diligence and prompt attention must be paid to individuals who present with the incidental findings of a solid renal mass without accompanying clinical signs or symptoms"?
A. Yeah; I would agree.
Q. Are you familiar with the clinical pathway or the decision pathway that related to the diagnosis of renal cell carcinoma that was published by Drs. Bukowski and Novick in 1997?
A. I don't recall the details right now, but I'm sure I reviewed it at the time.
Q. So that we're both using the same lexicon, if you will, is a decision pathway synonymous with a plan of care

as far as you're concerned?

A. No.

Q. How do you define a clinical pathway or decision pathway?

A. A decision and clinical pathway would essentially be generally helpful studies that would be ordered in a step-wise fashion to allow you to rule in or rule out more likely or less likely possibilities whereas a clinical care path, you already have established a diagnosis or a disease and you're establishing a specific detailed care plan with respect to that disease entity.

Q. Would you agree that a decision pathway provides a structured and reasonable general approach to patients presenting -- excuse me.

You indicated earlier that you believe you reviewed the decision pathway outlined in the 1997 Bukowski/Novick report; correct?

A. Uh-huh. Yes.

Q. Does your personal practice follow the decision pathway outlined in the Cleveland Clinic's "Journal of Medicine Guidelines'' that we have been discussing?

A. I'm not aware which pathway you are referring to now.

Q. I'm going to hand you what's marked, and I will mark it when we have an opportunity, page SI-34 of the "Renal Cell Carcinoma Report" authored by Drs. Bukowski and Novick

in 1997, specifically directing your attention to Figure 1.

A. Okay. Right. Okay.

Q. That pathway that is identified in Figure 1, is that a flow chart, if you will, that is familiar to you?

A. Yes. This is simply a compilation of currently accepted guidelines for the workup of a mass or cyst that's identified. However, I would note that the top of the chart indicates presenting signs and symptoms, namely, hematuria, abdominal mass and some laboratory studies and, therefore, this flow chart is based specifically on a presenting sign or symptom. It is not based strictly on the presence of, say, an abnormal IVP without a defined diagnosis with respect to the abnormal finding as in the case of this particular patient.

Q. My question, doctor, the pathway that's identified on Figure 1, is that consistent with a plan of care or a decision pathway, excuse me, that you utilize as part of your own personal practice?

A. Yes.

Q. And would you agree with me that that is a fairly mainstream decision pathway that's utilized by reasonably prudent urologists?

A. Yes.

MS. DIXON: And just for the record, we'll mark that as Exhibit 1, and when we have an

opportunity, I'll make a copy and provide it to the court reporter.

BY MS. DIXON:

Q. Doctor, would you agree that based on the Cleveland Clinic Foundation's own literature as well as generally known statistics, that only 30 percent of the patients who present with renal cell carcinoma have metastatic disease?

A. I believe that that statistic includes all patients, all presentations and all diseases and it's a retrospective analysis. In general, it will be true, but it would be difficult -- each individual patient, though, would be an isolated case, but, in general, it's true.

Q. You do not dispute that statistic on its face; correct?

A. Not when you are doing a statistical study looking at large numbers of patients. But it would be incorrect, for example, to take patient A and say patient A has a 30 percent chance of metastatic disease without a considerable amount of additional information.

Q. I assume that as part of your regular practice of urology, because you told me earlier you do both diagnose and treat patients with renal cell carcinoma; correct?

A. Yes.

Q. You are in the position oftentimes of quoting survival statistics; correct?

A. Yes.
Q. And do you personally undertake quoting survival statistics to patients, or do you refer them to an oncologist?
A. No. I frequently do myself.
Q. Do you likewise engage in the process of staging tumors?
A. Yes.
Q. Do you stage them both clinically and pathologically?
A. Yes.
Q. What classification of staging do you utilize in your own personal practice?
A. Well, generally we use both -- we use the clinical staging A, B, C for a more simpler discussion with the patient to help them understand as opposed to the TNM system which is a classification that is better for scientific study.
Q. As it relates to your conversation with patients, the more simplistic system, are you referring to the Robson System?
A. That's correct.
Q. Do you rely on statistics that have been gathered in conjunction with your utilization of the Robson System?
A. Yes.
Q. And would you agree with Dr. Bukowski and Dr. Novick

that, at least as of 1997, Robson's was the most widely utilized staging system?

A. That's correct.

Q. And, in fact, the TNM system is a fairly recent advent; correct?

A. That's correct.

Q. And would you likewise agree that even as we sit here today, the TNM system has undergone and continues to undergo modifications and modifications and changes to ensure the accuracy of that system?

A. Yes; it does.

Q. And that's particularly true as it relates to the TNM classification and/or staging of renal cell carcinoma; correct?

A. Many tumors are -- I'm not sure if that's the one that is the main focus of the changes in the TNM system, but they are all under review.

Q. You would agree with me as it relates to TNM classification of renal cell carcinoma, that the actual classifications of renal cell tumors has changed as recently as this year; correct?

A. I'm not sure what you are referring to.

Q. Would you agree with me as recently as this calendar year, on the tumor size alone, the size of a tumor has changed defining delineating between T1 and T2?

MR. CONWAY: Objection.

A. I would have to see the specific detail. I know there has been changes, yes, with respect to tumor size.

Q. And that as we sit here today, a T2 -- excuse me, a T2 tumor can be as large as 7 centimeters?

A. I would have to see the reference first.

Q. When you are quoting survival statistics to your patients, do you utilize a five-year survival rate?

A. Generally, yes. That's a rule of thumb that's used by many, if not most, physicians in a discussion on cure rates.

Q. A discussion of cure as it relates to renal cell carcinoma, you wouldn't dispute that five years equating a cure is mainstream thinking; correct?

A. With the caveat that there are many, many exceptions to that, though.

Q. But if we're having strictly a statistical conversation, would you agree with me that mainstream urologists would utilize a five-year survival rate equating a cure?

A. Generally, yes.

Q. Doctor, are you familiar with Dr. Robert Motzer from the Memorial Sloan Kettering and his writings?

A. I have heard the name. I'm not familiar with all of his writings.

Q. You are familiar with Memorial Sloan Kettering;

correct?

A. Yes; I am.

Q. And in publications authored by Dr. Motzer, who, again, I'll indicate is associated with that facility, he considered patients with survival times greater than five years as long-term survivors. You would agree with that; correct?

A. Yes.

Q. And would you likewise agree that if a patient with renal cell carcinoma is treated with a nephrectomy in stage 1 or stage 2, they have a more likely than not five-year survival rate?

MR. CONWAY: Objection.

A. That would strictly depend on the presentation of the tumor, the extent of metastatic disease and last but not least, the most important, the pathologic grading stage of the disease.

Q. Let's take a moment, doctor. If a patient has metastatic disease, they wouldn't be stage 1 or stage 2; correct?

A. You may not always know that ahead of time because there may be metastatic spread that is undiscoverable by routine CT scan in the chest, abdomen and so on.

Q. But in the statistics that we were speaking about earlier, those consider all patients; correct?

A. Those are all patients, and, again, just to remind you that those statistics are all retrospective studies, you know, that analyze, say, 100 cases of renal cell carcinoma at the end when one knows the course already, and the statistics usually are a way of identifying certain subgroups or subsets of patients that can be classified A, B and C. The purpose of that is essentially educative. It is not really to establish a, quote, 30 percent chance of metastatic disease with patient A with a tumor of 4 centimeters. That you cannot apply in the individual patient.

You can apply that later after the patient is part of a large group and you know the course of that patient's outcome, let's say. Then you can fit that patient into that subgroup, but you can't use that statistic to walk up to the patient and their family and say you only have a 30 percent chance of metastatic disease, 70 percent chance of a cure, therefore, you must do this.

Q. In the course of your practice, if you had a patient which you diagnosed with renal cell and were able to both clinically and pathologically stage as stage 1 --

A. That's correct.

Q. -- would you agree with me that that patient would more likely than not survive five years?

A. As a rule, as a general rule, I would say yes, but I

would with a number of reservations. First of all, I never discuss prognosis or cure rates until the treatment has already been established, meaning we have already done a nephrectomy and we have a pathology and the patient has had all the appropriate CT scanning and all that. Then and only then can you give a reasonable estimate of a prognosis and cure rate.

Q. Understood. My question is, once you had satisfied all those inquiries that you just identified for the record and you ultimately concluded both clinically and pathologically that patient was stage 1 and underwent a nephrectomy, more likely than not, that being defined as 51 percent, that patient would survive 5 years; correct?

A. Yes; I would agree.

8. My question then becomes, as it relates to stage 2, clinically and pathologically diagnosed and treated with a nephrectomy, would you agree with me that a patient would more likely than not survive 5 years?

A. Probably; yes.

Q. Would you agree with the statement that CT scanning has a 90 percent accuracy rate in defining the extent of a renal tumor pre-nephrectomy?

MR. CONWAY: Objection.

A. I would have to see the study. I would balk at the 90 percent. I think it's a good study, but I would hesitate to

say 90 percent. That's a very, very high accuracy. I'm not quite sure it's quite that high.

Q. Doctor, are you familiar with Dr. Nicholas Vogelzang?

A. No.

Q. I'll represent to you that Dr. Vogelzang is a hematologist/oncologist associated with the University of Chicago and that in 1998, he published an article in the Lancet regarding kidney cancer.

Do you disagree with the statement that is identified as part *of* that article that "long-term outcomes are reasonably good with 56 percent 5-year survival at 5 years for stage 3 tumors"?

A. What is the definition of a stage 3 tumor there?

Q. Stage 3 tumor being defined as a tumor extension to the renal -- perirenal tissue but confined to Gerota's fascia.

A. No. I would take issue with that, because that would depend on the age of the presentation of the patient as well as the exact pathologic and histological description of the cancer. That would be the main determinate.

Q. Doctor, let me ask you to turn to the IVP final report that is contained in Nancy's record.

A. Yes; I have it.

Q. Doctor, for the next series of questions, I would like you to assume hypothetically that you, not Dr. Noble, were

the one who saw Nancy Farkas for her follow-up visit after the October 20th emergency, excuse me, emergency room treatment she received.

Directing your attention to the second finding on the IVP which we discussed earlier, you would agree with me that that second finding is suspicious of a renal cancer; correct?

MR. CONWAY: Objection.

A. No. I couldn't say it with quite that degree of determination. It simply indicates an abnormality on the IVP that requires further evaluation. In fact, an IVP mass, based on the commonality of cysts versus tumors, you know, the incidence of renal cell carcinoma is actually very small whereas the incidence of finding cysts, even in the normal population, is at least 10 to 15 percent and in some studies approaches 20 plus percent.

Q. But for that very small percentage of the population that it is renal cell carcinoma, that is a very deadly finding; correct?

A. It can be.

Q. During the course of this litigation, I have had an opportunity to take the deposition of Dr. Ocampo who was the radiologist who signed the final report. During her deposition, I'll represent to you Dr. Ocampo stated that the finding of the mass on the lateral border of the right

kidney was the most serious finding on that report.

Would you agree with that statement?

A. No. I disagree.

Q. When we met the last time, you stated in your testimony that the painful obstructive uropathy was the most crucial finding on Nancy's October 20th IVP?

A. Absolutely. This was an emergency room visit, and when the patient presented with flank pain, there was an obstruction to the kidney. *An* obstruction potentially could lead to loss of the kidney and that is clearly -- in the immediate sense, and that is clearly the immediate finding that needs attention at that point.

Q. If the patient's pain, "the patient" being Nancy, resolved prior to the time she left the emergency department on October 20th, '98 and the IVP shows no signs of hydronephrosis, is your opinion the same?

A. You would have to define this a little better. By "resolve," is the pain improved but the cause is still undiscovered, or is the etiology uncovered and the problem resolved?

Q. Let me put it to you this way: The information you would have available to you, as the treating physician, is the information contained in the four corners of the IVP along with the patient's emergency room record and knowledge that her pain had resolved prior to departing the emergency

department on 10/20/98 and that IVP shows no signs of hydronephrosis.

A. Now, there is mild to moderate dilatation of the right ureter, so there is mild to moderate hydronephrosis. So are you discussing a different presentation or this presentation?

Q. My question is, if that IVP showed no signs of hydronephrosis, the patient was pain free at discharge, would that change your conclusion that painful obstructive uropathy was the most crucial finding?

MR. CONWAY: Objection as to form.

A. That presentation is inconsistent with -- if, if the hydronephrosis has resolved, the patient would not have pain, but you still haven't found the cause of the pain. You need to know the cause of the pain and the swelling and the bleeding and the presentation first.

Q. And that would mean that you would need to undergo additional studies as they relate to the obstructive uropathy; correct?

A. That's correct.

Q. And at the same time, at a minimum, you would also need additional evaluation of the persistent filling defect on the right, lower, lateral border of the kidney; correct?

A. At the appropriate point, yes.

Q. Would you agree with me that as to both of the

findings, the obstructive uropathy and the probable cyst or mass, that a CT scan would give you good information in further evaluating both of those conditions simultaneously?

A. It would be helpful, but it would not be necessary to do at this point since you already have an IVP that gives you enough initial information to proceed with your care plan and workup.

Q. My question is, would you agree with me following the findings obtained on the 10/20/98 IVP, that a CT scan would give you further diagnostic information not just on one of those findings but on both of those findings in order to assist you in crafting your plan of care?

A. As a hypothetical situation?

Q. Yes.

A. As a hypothetical situation, I would submit that if I could do all studies at one point, that would always be better than trying to select one or two, but the practical point is that people usually don't come in and get a shotgun approach and have, you know, two to five x-rays done of all different types.

You simply select the appropriate x-ray for the presenting symptoms, which in this case, by the way, because of the presence of hematuria, absolutely is the IVP. Because of the presence of gross hematuria, the IVP is clearly the traditionally indicated urologic study or

evaluation of this particular patient, meaning gross hematuria.

If the patient did not have hematuria and had perhaps vague or less defined pain, then one might shift to the CT scan because it gives an additional view of the remainder of the abdomen essentially to rule out other potential diseases such as appendicitis or colon diseases or gallbladder problems. Given the urologic presentation of the flank pain and gross hematuria, clearly the IVP is absolutely the single best study, not a CT scan, in the immediate sense.

Now, if your question is, you know, should I do both, well, possibly that's a consideration, but the IVP is absolutely the best step.

Q. Are you aware of whether or not the patient actually had hematuria at the time she presented to the emergency department?

A. I didn't examine the patient. It says, reason for exam, hematuria, low back pain.

Q. You indicated in your previous answer that the obstructive uropathy was the most crucial finding on the 10/20/98 IVP; correct?

A. That's correct.

Q. And would you agree with me that that finding of obstructive uropathy required further evaluation and diagnosis?

A. Yes.

Q. What test -- let me rephrase that.

I believe you told me the last time we met that the most likely cause of that obstructive uropathy was a kidney stone; correct?

A. Clinically and statistically, yes.

Q. And would you agree with me kidney stones present in an opaque and non-opaque format?

A. Yes. And note that this particular patient does have a stone in the other kidney, as well, which sort of immediately alerts you to the likelihood of stone disease.

Q. But would you agree that stones can present in an opaque and a non-opaque format?

A. Both; yes.

Q. Would you agree with me the best diagnostic tool available to you as a urologist in diagnosing non-opaque stones is a CT scan?

A. Not necessarily.

Q. What other test would you use?

A. I could use the IVP, retrograde pyelograms, ultrasounds. These are in such a way as to better define the presenting symptoms and, based on the patient's presenting situation, whether one did or did not wish to use radiographic studies involving radiation. But clearly you need to define the situation better.

Q. Would you agree with me as part of the 10/20/98 IVP, the radiologist was having difficulty determining whether or not the cause could be a non-opaque calculus?

A. I'm not sure how much difficulty the person was having, but the report simply states that there was not a definitive diagnosis, and apparently it states that the impression was that the obstruction at the level of the distal right ureter, which is well away from the kidney, by the way, was suspected as being due to either non-opaque or faintly opaque stone.

That is fairly straightforward. It seems to me that working diagncsis in the mind of the radiologist was a stone in the distal ureter and, therefore, additional studies were recommended.

Q. And if what is contained in the four corners of the 10/20/98 IVP final report as it relates to the obstructive uropathy was the best information available at that time regarding non-opaque calculus, would you agree that the next most sophisticated or diagnostic tool with the higher level of acuity would be the CT scan for better evaluating non-opaque stones?

A. No. The next study would be -- the next study that I, as a urologist, would need to carry out a care plan to treat this particular problem would be a retrograde pyelogram.

Q. Which is an invasive procedure; correct?

A. That's correct.
Q. You would agree with me an abdominal CT scan is a non-invasive procedure?
A. Yes.
Q. And based on the second finding, let me ask you this: You don't disagree with the notion that a CT, abdominal CT, scan would give you additional information as it relates to the obstructive uropathy; correct?
A. I disagree to the point that it does not help me any further. I have already discussed the fact that there is obstruction there. I don't need another x-ray to tell me there is obstruction there. You already have evidence of obstructive uropathy on the IVP, so why do you need a CT scan to tell me that, yes, I do have obstructive uropathy? I already know that.
Q. Well, you don't know where you may have non-opaque stones; correct?
A. I do. It says it's in the distal ureter at the level -- that says obstructive uropathy at the level of the distal right ureter which would mean the lower ureter near the bladder. And a second study with a cystoscopic urogram with retrograde is so you can outline the lower part of the ureter with contrast, which was done.
Q. Are all non-opaque stones appreciable on an IVP?
A. Non-opaque, not necessarily. They are visible or,

rather, not visible but rather suspected of being there by virtue of the fact they may be associated with obstruction.

Q. And are non-opaque stones able to be appreciated by way of CT scan?

A. They can be.

Q. I believe you indicated earlier that the focus on the kidney stone or the obstructive uropathy was for the purpose of saving or preserving the kidney and kidney function; correct?

A. The purpose of what now?

Q. The purpose of focusing initially on the kidney stone or obstructive uropathy was to preserve the kidney and kidney function?

A. That would be one consideration; yes.

Q. That would be the most serious consideration; correct?

A. If there was complete obstruction only, which this does not imply.

Q. Based on your review of this IVP, is this patient at risk for losing her kidney or kidney function based on that obstructive uropathy?

A. The best practical statement that could be made is that there is obstruction present to a mild to moderate degree of dilatation which increases the risk of some damage to the right kidney if attention is not directed to this in a timely manner, "timely" meaning days to perhaps a few

weeks.

Q. That finding in and of itself, the mild to moderate obstruction, is not consistent with this patient being in danger of losing the other kidney or kidney function; correct?

A. It only, if ignored, it could lead to, but ignored in the sense of long term, because we can actually leave a kidney completely obstructed for several days, perhaps even a week or two, and have complete recovery.

So I'm not sure what the point of your question is, but if there's mild to moderate obstruction present, the implication is that one would assume that that obstruction would become more and more severe and eventually lead to complete shutdown. And given the normal course *of* events, that's something that could occur over days to weeks to perhaps even months.

Q. So the risk of the first finding on the IVP is only in relation as it relates to loss of kidney function, or loss of the kidney relates to that condition being ignored in toto; correct?

A. Ignored in total and also the possibility of having sepsis in this case, because if the patient develops infection behind this area which is obstructed due to, by explaining it simply, due to increased back pressure, bacteria can be forced into the kidney, into the bloodstream

and make the person very, very ill which would be, actually, life threatening as opposed to simply threatening the renal kidney itself.

Q. In the face of a diagnosis of renal cell carcinoma, can we agree that focus is on removing that patient's kidney in order to save that patient's life?

A. Based on the stage and presentation, assuming the person does not have metastatic disease, and they should know that with reasonable certainty, then removal of the kidney, yes, can be and will be the main treatment plan for that.

Q. When we were together the last time, you used the term "renal colic CT scan." Can you tell me what that is or how it differs between a standard abdominal CT scan?

A. A standard abdominal CT scan is one that is carried out both with and without administration of intravenous contrast medium. This is essentially a radiologic entity, and I would defer to their expertise.

But in general, the addition of intravenous contrast helps to outline certain conditions, conditions within the abdominal cavity better because the iodine traveling within the vein offers a contrast between tissues that do not take up the dye and tissues that do. But renal colic CT is one where the -- in fact, it was specifically performed initially for kidney stones to help ease the diagnosis of

kidney stones, and the idea there was that you would not give dye. The patient did not need to be prepped. The risk of any contrast allergic reaction was lower, yet using fine cuts, which means numerous small cuts, with a CT scan would allow one to scan the urinary tract in a quick way to identify obstruction stones and also rule out any other confusing diseases that might affect your diagnosis like appendicitis, gallbladder disease and other intra-abdominal problems.

So the renal colic CT refers specifically to its use without dye. In an immediate sense, it's an easier test to do. It gives us a reasonable amount of information in a quick way without IV injection, and, specifically, it can be done without the presence of a radiologist, which was probably the most crucial factor. As opposed to calling a radiologist in in the middle of the night, a CT scan can be done by a technician and read by an ER physician.

And that was actually the background of utilizing the renal colic CT.

Q. And is the renal colic CT a diagnostic tool that is still used today?

A. Yes.

Q. And that would be a scan that would be part of a kidney stone evaluation?

A. Yes.

Q. Is that a diagnostic tool that is specifically requested by you, as the urologist, as opposed to a standard abdominal CT?

A. Yes.

Q. Can the renal colic CT scan appropriately -- be appropriately performed when a patient is having symptomatology such as renal colic associated with a stone?

A. Yes. The only limitation would be if the patient is in such severe pain that they cannot hold still. But assuming that they're medicated and are reasonably cooperative to hold still for the scan, yes, it can be done in just about any patient.

Q. Based on your review of the Nancy Farkas chart from EMH Urology, would you agree that when she presented to Dr. Noble on 10/26 of '98, she was not having flank pain?

A. I believe so. I believe that she was not having flank pain.

Q. Based on the fact that Nancy was not having flank pain, and do you know whether or not she also had -- if she continued to have gross hematuria on 10/26?

A. That I'm not aware of.

Q. I'll represent to you that the chart does not indicate gross hematuria on 10/26, and she is not experiencing flank pain. Is there anything to be gained in terms of patient management or care plan by not ordering a CT scan on 10/26?

A. Well, I would rather phrase that as saying what is there to be gained by doing the CT scan, and at that point there would be no additional information gained. The next step would be what was appropriately done which would be the retrograde and looking for a stone.

Q. Would you agree that performing the CT scan on 10/26/98 would have provided Dr. Noble with a variety of pieces of information as it relates to the second finding on the 10/20 IVP?

A. I think it would have provided additional information; yes.

Q. In a patient such as Nancy, in the manner in which she presented on 10/20/98, without flank pain and with no gross hematuria, is that a patient who, in your opinion, continues to be in urological distress?

A. If by distress you mean the absence of pain, yes, she was not in acute distress, but she still had not found the reason for her presenting symptoms.

Q. Is that a patient that you would still have concerns about regarding the integrity of her kidney and kidney function?

A. Yes, which is why I would do a retrograde pyelogram and proceed with further evaluation.

Q. And in what time frame would you expect that retrograde pyelogram to be performed?

A. Since her pain had improved and her hematuria is absent, based on the information you provided, I would not consider it an emergency, but I would plan to do it within the space of perhaps a few weeks or less.

Q. Is there anything medically speaking that would preclude you from simultaneously scheduling a CT scan to evaluate the second finding on the 10/20/98 IVP?

A. I would plan to do one at some point in the future, but my initial workup would be aimed at identifying the reason for the obstruction, bearing in mind that my clinical perception would be that there is a strong likelihood that a stone was still present in the distal ureter since she hadn't passed it and although the pain and bleeding had subsided which would mean that the stone was acquiescing if not moving.

Still, my main focus would be identifying and eliminating the stone which we presume is there at that point. Yes, I would certainly have some attention to working up the cyst or mass on the second finding, but at that point it would be a secondary factor which I would attend to later as my workup and plan continued.

Q. Based on Nancy's presentation on 10/26/98, is there any risk in not ordering the CT scan at that point?

A. Again, the question is not a risk but whether or not it's indicated at that point. Again, the focus was the

presenting symptomatology and the suspicion of an obstruction, a stone, a dilatation of the upper ureter, the potential for infection and, therefore, that clearly needs to be attended to first.

I understand what you're saying. Why didn't you order 20,000 other tests? I mean, to carry your point even further, why did we not order a CT of the chest or CT of the brain to look for metastatic disease just because there might be a less than 1 percent chance of having a renal cell carcinoma?

Q. Based on the findings on that IVP, there would be no doubt in your mind as a practitioner that a CT scan was indicated; correct?

A. Some form of additional test being the CT or ultrasound, and per the flow chart you showed me, would be appropriate in the workup indication.

Q. And my question is, is there any risk in not ordering a CT scan or an ultrasound on 10/26/98?

MR. CONWAY: Objection. He has answered that question.

MS. DIXON: Actually, he deferred and said --

BY MS. DIXON:

Q. Doctor, you said you would not deem it in terms of risk. You answered, actually, a different question. My

question this time is, specifically, is there any risk associated with not ordering a CT scan on 10/26/98?

MR. CONWAY: I still object.

A. A CT scan is not risky to the patient.

Q. Is there any risk in delaying diagnosis and treatment of renal cell carcinoma?

A. As a hypothetical question, yes, there would be.

Q. Had a renal colic CT scan been ordered on Nancy on or about 10/26/98, would that have further defined the mass which was identified in the October 20th IVP?

A. Probably; yes.

Q. When we met the last time, you indicated that you had the sense from reviewing Nancy's chart that Nancy was called by the staff of EMH Urology and asked to come back to the office but declined?

MR. CONWAY: At what time?

MS. DIXON: He wasn't actually clear.

BY MS. DIXON:

Q. I got the sense that you meant it towards the end of her treatment.

A. I believe so; yes.

Q. Is there a place in the chart that you can point me that fortifies or verifies your belief that Nancy was called by the EMH staff and asked to come back in for treatment and

she declined?
A. I don't believe I saw that written as you phrased it, but there clearly was contact with the patient and a request for follow-up or return.
Q. My question is, can you take a few moments and flip through the EMH urology group chart and show me where it was that Nancy was requested to return for an additional appointment or consultation?
A. Well, it's clearly implied in the discussions within Dr. Noble's progress notes that he discussed the appropriate workup.
Q. Would you agree with me that there's no place in the chart where there was an affirmative call placed by the staff of EMH urology group requesting Nancy to return for further treatment?
A. I'm not aware -- I'm not quite sure what you mean by that.
Q. Actually, I think when we spoke the last time, you indicated that when you, in the course of your practice, when you had a patient who, whether it be by way of misunderstanding or noncompliance, does not show for what you believe was an additional scheduled appointment, you have either directed your staff or you have personally called that patient to try and get them in; correct?
A. Yes.

Q. And I believe you indicated that it would be your practice to note that in the chart; correct?

A. No, not always, because, you know, for example, in this particular case, there is no documentation that anyone called Miss Farkas to come back to see Dr. Noble for her first appointment, and equally, when Dr. Noble first saw her, there's no documentation in there regarding any instructions on returning. After the surgery and the retrograde was done, there's nothing written asking her to come back for her post-op, which she did. There's an implied sense here where the patient will come back for follow-up. I don't have to actually write out a separate sheet, have the patient sign it and keep a duplicate. That is not standard of care.

Q. I'm not suggesting that, doctor. Maybe we're not communicating appropriately. The question I'm asking you relates to a patient who may have misunderstood instructions given by you or your staff regarding the need to schedule an additional follow-up appointment or has simply chosen to discontinue treatment against medical advice.

A. Okay.

Q. In those situations, when we spoke the last time, you indicated that you or your staff would make efforts to contact that person either by telephone or by letter to impress upon them the importance of an additional visit. Do

you remember that conversation?

A. Yes.

Q. And I believe when I asked you the last time, you said that you would expect there to be some record of that, those extra efforts.

A. Uh-huh.

Q. To impress upon the patient the importance of follow-up treatment contained in that patient's chart; correct?

A. Yes.

Q. My question becomes, is there anything contained in Nancy Farkas' chart that indicates to you or memorializes for you efforts undertaken by the staff of EMH Urology or Dr. Noble to suggest to Miss Farkas that she had either misunderstood instructions or she chose to discontinue treatment against medical advice and needed to schedule an additional appointment?

A. As I recall, there was, there was a call into the office and Dr. Noble replied by stating he had not finished his workup, specifically the metabolic stone profile, and recommended she have this done either by returning to us or there's some question about her moving out of the area and have it done by another urologist elsewhere. It was clear to me the communication to the patient was to encourage her to follow up on more than one occasion, and there's, I

believe on that last, one of the last routing sheets, there's the indication by the staff person or the secretary that she did note or give Mrs. Farkas an appointment for follow-up or noted the instruction to give her that, instruct her on following up.

Q. Is there any indication contained in the chart of a no show?

A. I don't know.

Q. And that's something you would want to be noted in the chart; correct?

A. Not always; no.

Q. Is there any letter indicated in the file indicating that Miss Farkas had not shown for an appointment which was medically indicated?

MR. CONWAY: Objection.

A. A letter by whom?

Q. A letter from the staff of EMH Urology or Dr. Noble indicating, Nancy Farkas, I instructed you, you need additional care, you discontinued treatment against medical advice, I suggest you contact the office and schedule an appointment?

A. We don't normally do that. Basically, if the condition is a benign problem, we don't normally write a letter quite with that strongly an emphasis.

Q. Would you agree with me in December of 1998, Dr. Noble

had not performed the tests necessary to give him the information as to whether or not the condition he was dealing with was benign?

A. In December was the presenting date?

Q. No. The presenting date was October. The purported telephone conversation with the staff was in December.

A. That's correct. Yeah. The workup was not finished at that point.

Q. No CT scan had been done, no ultrasound had been done; correct?

A. Well, secondarily. But, actually, the presenting symptoms had not essentially been diagnosed clearly either, meaning that the stone disease itself had not -- he had not completed his workup for stone disease. If he had completed his workup for stone disease, he would have proceeded to perform an ultrasound or CT scan.

And, in fact, I know Dr. Noble's routine because it's my routine, and any time there's an obstruction, we always obtain some additional study to be sure the obstruction has resolved. Even though we have done a retrograde pyelogram, we always obtain an IVP, ultrasound or a CT, whichever is appropriate, at a later point.

You know, usually it's within six to twelve weeks or within roughly that range of time to be sure that obstruction is clear, kidney is back to normal, functioning

normally and to evaluate for the presence or absence of other stones. That's part of the workup. That's a standard part of the workup.

Q. You would defer as part of good medical practice evaluation of a potentially-cancerous mass to undertake a stone risk profile?

A. 90 percent of renal cell cysts, 90 percent are benign, so I would question your use of the question of malignant. But in this patient's case, it was malignant. But at the point of presentation to Dr. Noble, there were no indications that this was a malignant cell carcinoma based on the workup at that point.

Q. Do you honestly believe it's fair to gamble with the patient's life that way?

MR. CONWAY: Objection. You don't have to answer, doctor. Objection. You don't. That's argumentative.

BY MS. DIXON:

Q. You told me earlier it can put the patient at risk delaying a CT scan; correct?

MR. CONWAY: Objection. That's not what he testified to, Debra.

A. I don't understand.

Q. Doctor, when we talked earlier regarding obtaining a CT scan on or about October 26th of 1998 --

A. Okay.
Q. -- I asked you if there was any risk to the patient, given the secondary finding on the IVP, in delaying that CT scan.
A. My answer was that the CT scan itself posed no risk to the patient, but the question was whether or not it was appropriate to do. Frankly, in a patient that has gross hematuria, your greater risks would be not doing an IVP and perhaps missing a transitional cell carcinoma or a cancer of the collecting system of the ureter which is at least frequent or as frequent as renal cell carcinoma.

The only way to diagnose that is with an IVP, so appropriately the IVP was done. So not doing the CT scan would have not placed this patient at the risk of death, so to speak, at that particular point.
Q. Doctor, let me ask you this: Is there any delay -- is there any risk to a patient in delaying the diagnosis of renal cell carcinoma?
A. In general, yes.
Q. Would you agree that the earlier a renal cell carcinoma is diagnosed and treated, the more likely a person's chances to avoid metastatic disease?
A. In general, yes.
Q. Are you aware of the fact that on November 23rd of 1998, when Nancy underwent a retrograde pyelogram, that that

pyelogram absolutely ruled out a kidney stone or obstruction in her ureter?

A. I would have to refer to the report.

Q. Feel free to do so.

A. Okay. Now, would you rephrase your question again?

Q. For the record, you now have in front of you the report relative to the November 23rd, 1998 retrograde pyelogram; correct?

A. Yes.

Q. Would you agree that the result of that retrograde pyelogram absolutely ruled out a kidney stone or obstruction in Nancy's ureter?

A. Well, essentially the report states that there are no stones or no visible stones or obstruction within the collecting system of the kidney, meaning the ureter and the inside part of the kidney. It does not essentially tell you about the kidney proper, meaning stone within the parenchyma or tissue of the kidney.

But the retrograde pyelogram indicates that the obstructive element that had been present on the IVP is now resolved and that they did not visibly see any signs of a visible stone on the films.

Q. As you read the term "visible stone" on the retrograde pyelogram, is that contrasting, if you will, an opaque versus a non-opaque stone?

A. Yes. A radiographically-opaque stone. The implication is that they did not see one that is calcified, therefore, radiographic low visibility, therefore, theoretically, there could be a non-opaque stone which was small enough not to cause obstruction which does occur at times. So the retrograde pyelogram theoretically still would not rule out a loosened or non-opaque stone in the absence of obstruction which would suggest perhaps a tiny stone -

Q. And likewise --

A. -- still present.

Q. I'm sorry. Likewise, the retrograde pyelogram, based on the findings you have in front of you, could not rule out the possibility of a stone contained within the kidney proper; correct?

A. No. Within the fleshy part or the parenchyma of the kidney itself, that's correct.

Q. Would you agree with me that a CT scan would assist Dr. Noble in ruling out a stone in the parenchyma *of* the kidney?

A. Yes. A renal colic CT scan would be appropriately performed at some point in the further workup of this patient as well as in general; yes.

Q. And, likewise, a renal colic CT scan would assist Dr. Noble in evaluating that right kidney and ureter for

non-opaque stones, as well; correct?

A. Yes; it would.

MS. DIXON: Doctor, I don't think I'm going to have too much more. I want to take a moment and review my notes.

THE WITNESS: Sure.

(Thereupon, a recess was taken.)

THE VIDEOGRAPHER: We're back on.

BY MS. DIXON:

Q. Doctor, before we went off the record, we talked about the findings on the November 23, 1998 retrograde pyelogram, and at the conclusion of that study, based on the findings you have in front of you, is it your opinion that it was not below the standard of care to proceed to a CT scan at that time?

MR. CONWAY: Objection. I don't understand that question. I don't know if he does. Can you repeat it?

MS. DIXON: Sure. I would be happy to rephrase it.

BY MS. DIXON:

Q. Doctor, you have reviewed the 11/23/98 retrograde pyelogram conclusions; correct?

A. Uh-huh. That's correct.

Q. You agree with the fact that there is no at least

overt obstruction at that point; correct?

A. That's correct.

Q. My question is once that information was available to Dr. Noble that there was no overt obstruction as of November 23rd, 1998, is it your opinion that it was not the standard of care to proceed to a CT scan at that time to further evaluate the second finding on the 10/20/98 IVP?

MR. CONWAY: Objection.

A. So the presumption is that you're saying it is the standard of care to do the CT at this point?

Q. My question to you is, is it the standard of care to proceed to a CT scan once you know there is no overt obstruction?

MR. CONWAY: Immediately?

BY MS. DIXON:

Q. Doctor.

MR. CONWAY: I'm just trying to be clear.

BY MS. DIXON:

Q. I'm not talking about later that afternoon, but is it the standard of care for the next active medical intervention, if you will, to be to proceed to a CT scan?

A. A CT scan would be appropriate and reasonable to perform as part of a continued kidney stone workup protocol. The only question is when to do it, and, as you said, it's

not necessary to do it on that particular day but within a reasonable amount of time. And follow-up, we normally would probably proceed with a CT renal colic at some point in the patient's workup.

Q. In your own personal practice, what time frame would you impose on yourself and your patient once you learned there had been no overt obstruction?

A. After an acute presentation similar to this particular patient's, a stone workup would reasonably carry from between one to perhaps three months as a rule or guide, as a rule of thumb, meaning within that time frame, one would have seen the patient back perhaps two or three times, done appropriate metabolic studies, have urine cultures, have other lab work available and some additional follow-up radiographic studies, one of which would be a CT renal colic, which I personally like, but one could also argue for an ultrasound, as well.

Q. And is there any medical text or treatise that you can direct me to that defines the appropriate time frame for obtaining that CT scan or ultrasound to further evaluate the cyst or mass?

A. No. Any statements referable would be similar to what you showed me as a flow chart, but that would always depend on the patient's presenting signs and symptoms and clearing up those signs and symptoms first and then proceeding to the

next level of the studies.

Q. Would you agree with me that as of the conclusion of the retrograde pyelogram on 10/23/98, there is no medical reason for not proceeding to a CT scan to evaluate the cyst or mass?

A. Well, there was -- I'm not sure what you mean by medical reason.

Q. Well, frankly, doctor, I got the impression based on your testimony up until this point that because of the concerns surrounding an obstructive uropathy and the potential kidney damage and all the sequelae that may follow that, it was critical to evaluate that obstruction; correct?

A. That's correct. In the immediate sense, that's true. And then electively, after one is sure that the obstruction is cleared up and you have all your other appropriate laboratory studies finished, then a follow-up scan, as I mentioned earlier, would be appropriate such as a CT renal colic or ultrasound or even an IVP, if necessary, at some point in the workup.

Q. My question, doctor, is once you had the information available to you that Dr. Noble did in conjunction with the November 23rd retrograde pyelogram, although you may have some preferences regarding additional metabolic workup and additional stone risk profiles, is there any reason, and what I mean by "reason" is any medical concern or

prohibition, that would cause you or cause you not to be able to order the CT scan at that time?

A. I'm sorry, I'm having trouble with your use of the negatives. We don't order things because it's not harmful not to order things. We order things for indications, so the indication here is that the obstruction is cleared, the obstruction is cleared and it is now appropriate to continue with further workup.

One of the things which we would include in that further workup would be a CT renal colic along with other metabolic studies.

Q. Is there any benefit to a patient such as Nancy Farkas, once the obstruction had been ruled out as of November 23rd, 1998, to reserve -- for a physician to reserve or hold off on obtaining a CT scan and obtain additional metabolic workup?

A. No. But I don't see any indication that Dr. Noble was -- did not plan to proceed with further workup either. Is this a hypothetical question?

Q. Well, you're the one who keeps telling me that after one completed the metabolic workup, they may then proceed to a scan such as a renal colic CT scan or abdominal CT scan.

A. Right. As part of the continued workup; right.

Q. My question is, is there any risk to the patient as of November 23rd, 1998 to defer on the further metabolic

testing and proceed directly to a CT scan?

A. Okay. I'm not sure what you mean by "risk." You mean is it risky for the patient -- is it harmful for the patient to have the CT? I don't understand your use of the word "risk."

Q. My question doesn't relate to the risk associated with undergoing a CT scan. As it relates to the two findings on the October 20th IVP.

A. Well, that's what I thought you meant. At this point you still do not know that the patient has renal cell carcinoma, so you can't make a case or argument stating that it's very risky not to do the CT scan because the patient is going to die from a cancer which we don't know is really there yet. Once you know the cancer is there, the answer to your question would be yes.

Q. But you have to do the test to know she has --

A. No. You have to do a needle biopsy of the mass to know whether or not it is there. The renal CT or the ultrasound simply shows the presence of a solid mass. It does not diagnose renal cell carcinoma. About 10 to 20 percent of solid renal masses are benign. There are renal oncocytomas and a few other benign tumors that exist.

You only know a person has renal cell carcinoma if you do an x-ray that gives you the suspicion of a solid renal mass, and then you proceed with a needle biopsy or some form

of surgical biopsy. Then you know the patient has renal cell carcinoma, then you can appropriately make statements regarding the patient's prognosis.

Q. And you would agree that the x-ray you were referring to is either a renal ultrasound or a CT scan?

A. Right. Which, again, is part of a normal kidney stone workup.

Q. My question becomes, doctor, once you had removed overt concern regarding obstruction, i.e. the findings on the 11/23 retrograde pyelogram, would you agree with me that at that point not turning to evaluation of the cyst or mass can place a patient at risk?

MR. CONWAY: Objection.

A. I think I answered that.

Q. Well, you have told me that --

A. Is it a little bit of risk or a lot of risk?

Q. Just risk as a general principle.

MR. CONWAY: Objection. Let me put on the record you have asked the same question about --

MS. DIXON: He hasn't answered it, Tom, and speaking objections are totally inappropriate.

MR. CONWAY: I have to speak, otherwise, I can't object. Objection. He's -- it's been asked and answered. You're phrasing it four or five different ways. He's given the same answer.

A. You're not establishing the risk. Are you speaking of risk of death from metastatic disease from cancer, or are you speaking of other forms of risk, the risk of the test itself, meaning that test is a benign test and, therefore, not risky for the patient to have done?

Q. Doctor, I appreciate that most medical procedures carry some risk independent of the disease they seek to diagnose. That being said, once an overt obstruction had been ruled out on 11/23/98 --

A. That's correct.

Q. -- would you agree that by a physician choosing to undergo additional metabolic testing and by virtue of doing that deferring a CT scan or ultrasound places the patient at greater risk for metastatic disease associated with renal cell carcinoma by virtue of failing to diagnose it in the timeliest or earliest, excuse me, at the earliest time possible?

MR. CONWAY: Objection. That is an impossible question. I know what you're trying to ask. That's an impossible question to answer. It's got four different parts in it, Debra. You want him to answer your ultimate issue of the case.

A. Part -- again, back up. As I mentioned earlier, part of a continued or proper kidney stone evaluation and workup is to do both radiographic studies and metabolic stone risk

testing if they are ongoing. I see no sign that this particular physician elected to simply stop at the metabolic part, so to speak, or stop at the retrograde or stop at the IVP. It was an ongoing relationship, and based on my own knowledge of the field as well as my knowledge of the way we were trained, there is no question that some form of the CT scanning or ultrasound would have been carried out at some point in the workup of this patient.

Now, whether it was on this particular day or the following week or the following month, I don't know, but it would have been done because that's part of the workup for the disease and, therefore, we would have uncovered the presence of a solid renal mass and then we would have followed the flow chart that you indicated and proceeded with a biopsy and appropriate therapy.

Q. You agree with me, based on review of that record, Dr. Noble, once he was armed with the findings of the November 23rd retrograde pyelogram, chose to defer the CT scan and --

A. I see no evidence --

Q. Excuse me. -- and undertake further metabolic studies?

A. I see no statements in the chart that says that I defer a CT scan and proceed with a metabolic stone profile.

Q. But he did, in fact, undertake additional metabolic

studies; correct? He ordered a pelvic sonogram and he requested a patient undergo a 24-hour urine test; correct?

A. Yes. I'm not sure of the date, but I do remember the urine collections; yes.

Q. So by virtue of ordering those, he made certain care decisions; correct? He ordered one test over another in terms of order?

A. Yes.

Q. My question is, once Dr. Noble had the findings of the November 23rd retrograde pyelogram and ruled out the kidney obstruction, is it your testimony that it was within the standard of care for Dr. Noble to further delay a CT scan in favor of further metabolic testing?

MR. CONWAY: Objection to the term "further delay."

A. We don't know that he delayed it. That's the issue here. You're using loaded terminology. Because when I or any physician approaches the workup of a patient, I do not always write down the next 100 things I'm going to do on a particular date. I may order a test number 1 and then order test number 2, but I may not write down that there is test number 10 which is to follow at a later date and that is what you are implying.

You are stating to me that, you know, a doctor intentionally delays treatment if he did not mention test

number 10 to do when he was doing test number 1 and 2 and that is not part of the standard of care. There is no standard of care that says that I, or any physician, have to write down 100 tests in order to be done for the coming year or ten years on a patient. You know, we order one test at a time in order based on the patient's clinical progress and presenting signs or symptoms and the timing of their follow-ups and so on.

Q. The pelvic sonogram that Dr. Noble ordered for Nancy Farkas, is that a test that would be utilized in furthering a metabolic workup?

A. Not normally. My understanding there, and it's somewhat limited, is that the patient apparently had not been or had not followed or been to medical physicians. I'm not clear why but had not had either a Pap smear or something, and he elected to proceed to do that as part of his continuing care of the patient. To me that means he was attending the patient and planned for continued follow-up not only of stone disease but also in general.

Certainly it's not an indication of a physician that intentionally would delay either diagnostic studies or treatment. But the selection of the pelvic sonogram itself was, I believe, to evaluate some other gynecologic problem which was extraneous to the stone workup itself, but it was just part of his continued offering of care to the patient.

That's why I say it's ridiculous to even infer that, you know, anyone elected to abandon this patient or not call the patient back. There's a sign that there was an effort made for continued care for follow-up of the patient not only for stone disease but also for medical problems, as well.

Q. Are you able to identify for me any advantage to purposefully or intentionally delaying the diagnosis of renal cell carcinoma?

MR. CONWAY: Objection. You don't have to answer that one either, doctor.

A. You answered it yourself.

Q. Is the answer no?

MR. CONWAY: Objection. Don't answer. That is argumentation. You know that's an improper question.

A. The answer is self-evident.

Q. Meaning no?

MR. CONWAY: Objection. Doctor, you don't have to answer the question.

MS. DIXON: Tom, I'll go back to the judge again. I'm sure she's still there.

MR. CONWAY: Read back that question.

MS. DIXON: I'll restate it.

BY MS. DIXON:

Q. Can you give me one advantage of intentionally

delaying the renal cell? It's a yes or no.

MR. CONWAY: Objection. That is an improper question.

MS. DIXON: Based on what?

MR. CONWAY: It's argumentative.

MS. DIXON: Absolutely not. It's a yes or no. He has given us a standard of care. It clearly delayed the diagnosis. My question is --

MR. CONWAY: Then argue that to the jury.

MS. DIXON: I'm entitled to an answer today.

MR. CONWAY: Doctor, you know what our position is.

MS. DIXON: Certify the question.

MR. CONWAY Go ahead. Let's call the judge right now.

MS. DIXON: Go get her on the phone.

MR. CONWAY: You get her. You want the question. The question insinuates that he did it intentionally. There was no intentional delay in diagnosis.

(Thereupon, a discussion was had off the record.)

BY MS. DIXON:

Q. Doctor, I have one final question for you.

Doctor, based on your review of the medical record of

Nancy Farkas and knowing what you know of the IVP from 10/20/98, is it within the standard of care for a physician to pursue gynecological workup on a patient prior to ruling in or ruling out renal cell carcinoma?

MR. CONWAY: Objection.

A. I don't think I could comment on standard of care, but I was just happening to go through here. I note Dr. Noble mentioned specifically that patient requested a Pap smear and a gynecologic evaluation, so he was simply complying with a request for a lab test. So the intent was not to divert one's attention to working up a different problem but rather to comply with a request, a reasonable request, by a patient to have an additional study because she had not had one for some period of time.

Q. Correct me if I'm wrong, but the Pap smear was done in conjunction with the pelvic ultrasound which was done at Dr. Noble's request; correct?

A. No. The Pap smear, as I saw here, was done at the time of her retrograde which was in surgery supposedly -- I just saw that in here -- not separately at the time of her ultrasound.

Q. But there was a supplemental pelvic ultrasound done on 12/7?

A. There was a separate ultrasound done later, but in the operative note of Dr. Noble on 11/23, he says specifically

it should be mentioned that prior to the actual prep, a Pap test was taken at the request of the patient.

Q. Would you agree that a pelvic ultrasound is more likely to have gynecologic information than it would urologic information?

A. It's difficult to say because we frequently use pelvic ultrasounds to evaluate the bladder, too, but in general, one could make an argument that there may be more of a likelihood of use of pelvic ultrasound in gynecologic applications, but urologists frequently use it, as well.

Q. Was there any information gleaned by way of a pelvic ultrasound that would provide Dr. Noble with additional information as to the obstructive uropathy that was identified in the October 20th IVP?

A. I don't believe the ultrasound showed anything specifically related to her urologic status.

Q. As a general principle, would a pelvic ultrasound provide a physician such as Dr. Noble information relative to the obstructive uropathy identified?

A. Yes, it could, certainly, because a pelvic ultrasound can show a dilated bladder, dilated ureter it can show. It can also reflect by sound the presence of a stone, too, as well.

Q. Would a pelvic ultrasound provide any information relative to the cyst or mass?

A. Not in a kidney, unless an ultrasound was directed at the kidney itself.

MS. DIXON: Okay. Pending the Court's ruling, I don't have any further questions.

MR. CONWAY: You don't have any more?

MS. DIXON: I said pending the Court's ruling, I do not have any further questions.

MR. CONWAY: Let me, in the spirit of being reasonable, reconsider.

MS. DIXON: You should have thought about it before I called.

MR. CONWAY: What?

MS. DIXON: Nothing.

MR. CONWAY: If she rules in your favor, I do not want to have my client come back down here.

MS. DIXON: Absolutely not.

MR. CONWAY: I still think it's an improper question. I'm willing to be practical about things, as well.

If you could read back the question that I vociferously objected to.

MS. DIXON: I can give it back to you. I can place it in a format that would be more palatable to Mr. Conway.

BY MS. DIXON:

Q. Can you tell me one advantage to delaying the diagnosis of renal cell carcinoma?

A. In general, there are no advantages to delaying diagnosis of renal cell carcinoma.

MS. DIXON: I don't have anything else. Thank you.

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(Thereupon the deposition was concluded at 5:00 p.m.)

State of Ohio) SS.
County of Cuyahoga)

~~CERTIFICATE~~

I, Denise C. Winter, a Notary Public within and for the State aforesaid, duly commissioned and qualified, do hereby certify that the above-named witness, LOUIS D'AMICO, M.D., was by me first duly sworn to testify the truth, the whole truth and nothing but the truth in the cause aforesaid; that the testimony then given by him was by me reduced to stenotypy in the presence of said witness, afterwards transcribed upon a computer; that the foregoing is a true and correct transcript of the testimony so given by him as aforesaid, and that this deposition was taken at the time and place in the foregoing caption specified.

I do further certify that I am not a relative, employee or attorney of any of the parties hereto, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto or financially interested in the action.

IN WITNESS WHEREOF, I have hereunto set my hand this 31st day of July, 2000.

Denise C. Winter

Denise C. Winter
Notary Public

My commission expires March 3, 2001.

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