In The Matter Of:

Therese Pruitt, etc., et al. v.
Mahesh Ochaney, M.D.

Keith B. Armitage, M.D.
May 24, 2004

Mehler & Hagestrom
Court Reporters
1750 Midland Building
101 West Prospect Avenue
Cleveland, OH 44115
(216) 621-4984 FAX: (216) 621-0050

Original File 040524KA.V1, 57 Pages
Min-U-Script® File ID: 0589091938

Word Index included with this Min-U-Script®

IN THE CIRCUIT COURT FOR BALTIMORE CITY

THERESE PRUITT, etc,
et al.,
Plaintiffs,
-vs- CASE NO. 24-C-03-006098
MAHESH OCHANEY, M.D.,
Defendant.

Deposition of KEITH B. ARMITAGE, M.D., taken as if upon cross-examination before Linda A. Astuto, a Registered Merit Reporter and Notary Public within and for the State of Ohio, at the University Hospitals of Cleveland, 11100 Euclid Avenue, Cleveland, Ohio, at 9:00 a.m. on Monday, May 24, 2004, pursuant to notice and/or stipulations of counsel, on behalf of the Defendant in this cause.

MEHLER & HAGESTROM
Court Reporters

CLEVELAND
1750 Midland Building
Cleveland, Ohio 44115
216.621.4984
FAX 621.0050
800.822.0650

AKRON
1015 Key Building
Akron, Ohio 44308
330.535.7300
FAX 535.0050
800.562.7100

APPEARANCES:

Tina DiFranco, Esq.
Cook & DiFranco, LLC
120 East Baltimore Street, Suite 1810
Baltimore, Maryland 21202
(410) 223-1590,
On behalf of the Plaintiffs;

Robert S. Morter, Esq. (Via Telephone)
Wharton, Levin, Ehrmantraut & Klein, P.A.
104 West Street
P.O. Box 551
Annapolis, Maryland 21401
(410) 263-5900,

On behalf of the Defendant.

WITNESSINDEX

EXHIBITINDEX

KEITH B. ARMITAGE, M.D., of lawful age, called by the Defendant for the purpose of cross-examination, as provided by the Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposed and said as follows:

CROSS-EXAMINATION OF KEITH B. ARMITAGE, M.D.

BY MR. MORTER:

Q: Good morning. My name is Bob Morter on behalf of Dr. Ochaney.

Have you had your deposition taken before?

A: I have.

Q: How many occasions?

A: I really haven't kept track. I'd say, you know, between, you know, 30 and 70 or somewhere in there.

Q: Okay. And you're familiar with the ground rules, I assume?

A: Yes.

Q: I've been provided, previously provided by Miss DiFranco with a copy of your curriculum vitae. The one that I have, on the very last page it ends with your presentations in 2003, the last one being Case Studies of Infection in Adolescents and Elderly presented in Sanibel

Page 5

Island, Florida.
Have you updated your CV recently or is this the most up-to-date version?
A: There's a more up-to-date version. I have one in my hand that was from March, 2004. There's a few more things on it.
MR. MORTER: Madam Court Reporter, can you mark that as Dr. Armitage Exhibit No. 1, please, and append it to the deposition transcript.

(Thereupon, Defendant's Armitage Exhibit 1, the Curriculum Vitae of Keith B. Armitage, M.D., was marked for purposes of identification.)

Q: Relative to your curriculum vitae, are there any publications or presentations that you've done that you believe are particularly relevant to the issues in this case?
A: There's a chapter I wrote on, in a book called Experts Guide to Common Infectious Diseases on enteropathogens. I think it dealt with bacterial infections.
There's a few presentations that deal with C.

Page 6

diff, Case Studies in Infectious Diarrhea, Case Discussions in Infectious Diarrhea. That's from 1995. We covered C. diff.
Q: And that's a book chapter?
A: That's a presentation.
Q: Okay.
A: The book chapter was, I think, the only article.
Q: That's the Experts Guide to the Management —
A: Experts Guide to Management of Common Infectious Diseases.
Q: That's with you and Dr. Salata or you and Dr. Colecraft?
A: Salata.
Q: Okay.
A: And I think that's it.
Q: Did you say that was it?
A: Yes. Of things that are referenced on my CV, I think that's it.
Q: And could you point me to the presentation you had reference before, you said 1995?
A: You know what, I'm sorry, it's 1996. It's the last one under 1996.
Q: Case Discussions in Infectious Diarrhea?
A: Right.
Q: Do you have any materials from that Case

Page 7

Discussions in Infectious Diarrhea presentation?
A: I think I do.
MR. MORTER: Tina, could I ask you to hopefully gather that while you're there and provide me with copies?
MS. DiFRANCO: Sure. I'll be happy to. If Dr. Armitage can put his hands on it relatively —
MR. MORTER: That's what I was thinking.
A: That one is so old, I think it is actually in printed form, not something on my computer. I think I probably can.
MS. DiFRANCO: Will you look for it?
THE WITNESS: I think I know where it is. Shocking.
MR. MORTER: Can you hold on one second, please?

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

Q: I'm sorry about that. So the way we stand, we're not certain whether we have that Case Discussions

Page 8

in Infectious Diarrhea but we'll look?
A: I'm pretty sure we can find it.
Q: Thank you. And I believe you said you thought you had given some treatment to C. diff colitis in that presentation?
A: I know in that presentation I think we did a C. diff case. So it's really a case discussion. That's the way we teach in these settings.
Q: Do you recall anything about that case?
A: No.
Q: I think your CV probably sets out your education and training in some detail.
Why don't you just give me a nutshell from your graduation from college and then on forward to the present.
A: Well, I went to medical school in Colorado. Then I came here, in 1986 here to Cleveland Case Western Reserve University and did the initial three years of internal medicine, two years of infectious diseases. I was a chief resident for a year and then joined the faculty at Case Western and the staff of University Hospitals and the Cleveland VA in 1992 and I've been here since then.
Q: Okay.

Page 9

A: And I have a couple roles in the medical school in the Department of Medicine. I've been the residency training director since '92 and the vice-chairman for education since, I think '99 and I divide my time between, permanently between education and clinical care. So it's probably about 75 percent clinical care and about 25 percent worth of education, administration.
Q: And is part of that educational time subsumed within your clinical care, that is training residents, interns and the like?
A: There is overlap in the clinical care obviously.
Q: I assume you're licensed to practice in Ohio?
A: Correct.
Q: Any other states?
A: No.
Q: Have you ever been so licensed in any other state?
A: No.
Q: Relative to your licensure, I assume you've had no adverse actions, those being suspension, revocation, restrictions, et cetera?
A: Correct.
Q: You're board certified in internal medicine and infectious diseases, correct?

Page 10

A: Correct.
Q: When did you become board certified in internal medicine?
A: 1989.
Q: Did you pass that exam on your first attempt?
A: Yes.
Q: And then thereafter when did you become board certified in infectious diseases?
A: 1994.
Q: And did you pass that exam on your first attempt?
A: Yes.
Q: Tell me a little bit about your clinical practice.
Are you 100 percent infectious diseases or do you practice both internal medicine and infectious diseases or perhaps some other subspecialty?
A: It's pretty much evenly divided between infectious diseases and internal medicine. So I'm sure you're familiar with people who work at teaching hospitals, our practice patterns really are kind of episodic. So one month we might attend inpatient infectious disease consultation service or an inpatient infectious disease ward team. I have at least three half days a week in

Page 11

outpatient hospitals. It involves both internal medicine and infectious diseases and a half day a week supervising residents at the Urgent Care Center at the Cleveland VA. That's in addition to my inpatient activities.
Q: Do you maintain a private office practice or are all of your patients seen in conjunction with Case Western?
A: Well, the internal medicine physicians who work here at the hospital are a private group, an entity that is not owned by Case Western or the hospital.
So I guess it's organized, I don't know all these details, it's a non-profit corporation, 200 physician group. In that way I guess it's private. The only office I have here is at the hospital but I see patients as a private doctor.
Q: Got it. What's the name of that group? I think you may have told me and I let it just slip by me.
A: I didn't. I believe, these things are changing because we're reorganizing, University Physicians, Inc., I believe.
Q: And do you hold any positions with University Physicians, Inc.?

Page 12

A: No.
Q: So you're an employee, correct?
A: Yeah. I think I'm an employee. It's complicated. I'm an employee of Case Western. My paycheck comes from Case Western but I think the money for my paycheck comes from University Physicians, Inc.
Q: I got you. What type of patient population do you deal with? Do you do adults only or do you do pediatric and adult work? How does that break down?
A: I do adults only.
Q: And do you have any subspecialties within your specialty?
A: No. I don't do much HIV work just because I'm so, there's other people here who really specialize in that in our institution and so I don't consider myself an expert in HIV. I consider myself a generalist infectious disease physician. There are some areas where I think I do more than others, pneumonia, bone and joint and diarrhea.
Q: Are you able to estimate for me the percentage of time you spend attending hospital patients versus attending patients in clinic?

Page 13

A: You know, it's varies from month-to-month. So, you know, I guess over a year, roughly 50/50.
Q: Okay. I think you told me about 25 percent of your time you spend in education and administration, is that correct?
A: Correct.
Q: And I assume the education component, you're talking about grand rounds and didactic lectures?
A: Yeah. And having to do with the educational programs, running the educational programs in the Department of Medicine.
Q: Okay. What percentage of that 25 would you estimate that you spend in your administrative activity?
A: I don't know. Maybe a third.
Q: Okay.
A: There's a lot of overlap there.
Q: Got it. At which hospitals are you privileged to practice?
A: At University Hospitals of Cleveland and the Cleveland VA Medical Center.
Q: How many hospitals are there affiliated with the university?
A: Around 20.
Q: Okay. The VA. Relative to any privilege that

Page 14

you've held to practice in any hospital, I assume there have been no adverse actions, revocations, restrictions, et cetera?
A: There have not.
Q: There's one thing on your CV I want to ask you about on the first page under education and training, 2003, Academic Alliance for Internal Medicine, Merck Executive Leadership Program, tell me a while bit about what that program was.
A: The Academic Alliance for Internal Medicine is a professional group for people that are active chairmen, division chairs, program directors, administrators, clerkships, I guess through an arrangement that's somehow supported by Merck, they put on a week long course every year for people who have leadership positions in departments of medicine and I applied to participate in the course and I participated last year.
Q: Is it fair to summarize it as like a management training, that type of thing?
A: Yeah. It has to do with, I guess there's three, there's three parts of it. Leadership skills in general, healthcare finance and some on marketing. The healthcare finance was, I

Page 15

thought, the major part, at least the part that I found the most interesting.
Q: I notice something on the CV, I can't put my fingertips on it right now, having to do, you mentioned it in response to the previous question about clerkships.
Do you have a clerkship program there at Case Western?
A: Of course.
Q: What does that entail?
A: Well, traditionally the third year medical school student spends time rotating through various clinical services and those are called the core clerkships and we, of course, have a core clerkship for third year students from Case Western.
Q: And that's a precursor to the rotations that these folks will expect when they move into residency?
A: Right. It's a core part of, it's a core part of medical school.
Q: Do you have any research interests?
A: Yeah, I guess a couple areas. I was involved with pneumonia and pneumonia care path here but now it's probably more medical education than

Page 16

clinical care, although I do participate in studies, but the way my time is divided between clinical care and other responsibilities I don't have a lot of time for research.
Q: And when you're talking about medical education, are you meaning the content and the methodology as far as how to go about teaching medical students and residents?
A: Correct.
Q: Estimate for me approximately how many patients you personally have treated for C. difficile colitis.
A: Boy. That's going to be tough because it's pretty common. I treat patients with C. diff colitis both as a primary, you know, physician in the inpatient or outpatient setting and I also get consulted on cases and maybe 20 or more a year for the last 15 years. I've seen a lot of C. diffs. It's an interest of mine.
Q: We can agree that C. difficile colitis cannot be diagnosed radiologically, is that correct?
A: That is not correct. There are, when patients truly have full-blown pseudomembranous colitis, a CAT Scan is pretty pathognomonic. Having said that, it's not a usual way of diagnosing it and

Page 17

in this case there wasn't pseudomembranes but there is an appearance on CAT Scans of full-blown pseudomembranous colitis that really can't be anything else.

Q: I think what you're telling me is as a general rule, one just simply just can't take a CT Scan of the abdomen and pelvis, take a look at it and say this patient has C. diff colitis without more —

A: You can certainly interpret a clinical CAT Scan. A diffuse colitis is highly suggestive of C. diff.

Q: And if there is a gold standard, what is the gold standard for defining and diagnosing C. difficile colitis?

A: Well, there's really three ways you can diagnose C. diff. You can, in the case of pseudomembranes, you can diagnose it on a CAT Scan. You can diagnose it endoscopically as pseudomembranes or you can isolate the organism or the toxin in the stool.

Q: Relative to a stool assay, in order to make the diagnosis of C. difficile colitis, you would need a finding of the toxin, is that correct?

A: That is not correct.

Page 18

Q: How do you go about defining it or diagnosing C. difficile colitis based upon a stool assay?

A: Well, I'm not sure the second question is tied to the first question, but if I can just explain.

C. diff colitis is very often a clinical diagnosis. So a patient who has been on antibiotics, who has diarrhea, depending upon the other findings, can be highly suggestive of C. difficile colitis. So the toxin can sometimes give additional information and is the most common lab test used. But the diagnosis can be made quite confidently on the basis of clinical grounds. The assay of toxins are imperfect. There are technical issues with the assay.

So quite frequently we treat patients with C. diff colitis with a negative assay when the clinical picture is so clear.

Q: So is the assay for the toxin not specific enough for someone to place reliance upon it in making a diagnosis of C. difficile colitis?

A: Well, it's specific but not sensitive. Those are medical terms. So sensitivity means the ability to detect something and specificity means if you detect it, how accurate is it. A positive test is fairly accurate but a negative test isn't very

Page 19

sensitive.

Q: And that's irrespective of how many times you do an assay or does the sensitivity increase proportionally with the number of assays that one does?

A: It would increase somewhat.

Q: I'm going to shift gears just a little bit just to get a flavor for your expert work.

When did you first begin reviewing cases in the medical/legal context?

A: I believe it was around 1996.

Q: Currently approximately how many cases do you have under review for litigation purposes?

A: That's a hard one to answer because there's cases that I'm sent material on that I never hear about them. Active cases, four or five.

Q: Are you able to estimate for me how many cases you're sent for review on an annual basis?

A: Probably around 20. Maybe a little more than 20.

Q: And how long have you been at the level of receiving approximately 20 cases per year in your medical/legal review activities?

A: Probably the last three or four years.

Q: Have you testified in trial?

A: Yes, I have.

Page 20

Q: How many times?

A: Probably about 10 or 11 times.

Q: And when was the last time?

A: Last time was once this year so far.

Q: And where was that case pending?

A: That was in Ohio.

Q: You testified for the plaintiff or the defendant in that case?

A: That case was for the plaintiff.

Q: How does your work break down for plaintiffs versus healthcare providers?

A: 60 percent for defense or healthcare providers and 40 percent for plaintiffs.

Q: And in what states have you accepted medical/legal work, from what states?

A: Well, the majority of cases are from Ohio but also Illinois, West Virginia. I believe this is the first case I've ever been involved in from Maryland.

Q: Do you know how Miss DiFranco or someone from her office came to contact you?

A: I do not recall.

Q: Have you ever provided expert review and testimony in a case with issues similar to the ones that we're discussing today?

Page 21

A: I have.
Q: On how many occasions?
A: I can give at least one.
Q: Tell me a little bit about that case.
A: Well, I was a defense expert and there was an eight hour delay in treating C. diff and the allegation, and the patient ended up dying and the allegation was the eight hour delay directly lead to the patient's death and I was asked to review that case.
Q: And you defended it on the basis that if indeed there was an eight hour delay, then that would have had no effect on the patient's outcome?
A: Well, the patient had a sudden cardiac arrest which I don't think was necessarily related to the colitis. But I didn't think eight hours was critical in this patient's illness.
Q: Did you go to trial in that case or was that deposition testimony?
A: No trial.
Q: So you did give a deposition in that case?
A: I think there was a deposition.
Q: And where was that case pending? Ohio or elsewhere?
A: In Ohio.

Page 22

Q: Any other C. difficile cases that come to mind?
A: None that come to mind.
Q: Doctor, have you ever been the subject of a claim for medical negligence?
A: No, I have not.
Q: Take me through your fee schedule, records review, deposition time and trial testimony.
A: For records review, it's $250 an hour. For deposition it's $350 an hour and for trial testimony it's $1,250 per half day.
Q: Could you estimate for me what percentage of your annual income is derived from your activities in medical negligence cases?
A: Probably 10 or 15 percent.
Q: Up to the time of your deposition but not including it, are you able to tell me how much time you spent in the review of materials in your deposition preparation for this case?
A: Total time in this case is probably between four and six hours.
Q: Do the materials that you have there with you indicate when it was you were first contacted with regard to reviewing this matter on behalf of Mr. Brown's estate?
A: Well, I have two letters from the firm Cook &

Page 23

DiFranco, one dated November 17th and one dated April 28th, 2004. November 17th, 2003 was their first letter. So I would say I was probably contacted in the weeks before that.
Q: By telephone?
A: I imagine.
Q: With the letter of November 17th, 2003, were medical records enclosed?
A: There were.
Q: Would you chronicle for me what was included in that first contact letter?
A: It's St. Agnes Hospital records, the office records of Dr. Ochaney, the Charlestown Home Health Care notes, the North Arundel Hospital admission and University Hospital of Maryland admission.
Q: Did that come to you in a binder?
A: Yes, it did.
Q: Since that time have you received additional records?
A: Yes, I have.
Q: Would you tell me about those records, where did they come from, et cetera?
A: The only other thing I received was the deposition transcript of Dr. Ochaney.

Page 24

Q: And that's the only deposition transcript you've reviewed to date?
A: That's correct.
Q: I assume you've not reviewed any radiology films?
A: I have not.
Q: And we talked briefly off the record before we got started, you said you had taken some notes on the back of a couple of letters, correct?
A: Well, there's two letters from Miss DiFranco and there's some scribbling on the back of those letters. I'd be happy to copy front and back for you if you'd like.
Q: That would be great. And those are the letters of November, 2003 and February, 2004?
A: April, 2004.
Q: April of 2004. Okay. Relative to the medical records that you reviewed, did you annotate or write on the medical records or did you simply take whatever notes you were going to take on that separate piece of paper we were talking about?
A: I did not write on the records.
Q: You're familiar with the medical/legal litigation process. Basically there are several areas in which expert witnesses are asked to testify.

Page 25

I assume you'll be offering standard of care opinions, correct?
A: Correct.
Q: And causation opinions?
A: Correct.
Q: Any other areas in which you will be rendering expert testimony?
A: Not that I'm aware of. I don't know what other areas there were than those two.
Q: Okay. Have you reviewed any medical literature, be it textbooks, Internet, treaties, peer review literature in conjunction with your review of this case?
A: Not specifically for this case. I've done quite a bit of teaching about C. diff and I have read widely about it.
Q: And when you teach with regard to C. diff, are there any particular materials upon which you rely?
A: No.
Q: And did you consult with any other physicians or peers relative to your review of this particular case?
A: No.
Q: You said you had the records from Mr. Brown's

Page 26

admission to St. Agnes Hospital.
I believe it was during that time that Dr. Ochaney first encountered Mr. Brown, correct?
A: Correct.
Q: Did you have any problems with Dr. Ochaney's management of this patient from November 23rd through November 29th, 2001 at St. Agnes Hospital?
A: No.
Q: I assume you hold an opinion that Dr. Ochaney deviated from the standard of care with regard to some treatment of his of Mr. Brown, is that correct?
A: That's correct.
Q: Take me through your standard of care opinions as they relate to Dr. Ochaney and then I'll follow up with you accordingly.
A: Okay. I guess there was three separate occasions or dates when I thought the standard of care issue came into play.
On December 10th I think, on December 10th the patient presented to Dr. Ochaney with, quote, unquote, burst of liquid stools, uncontrolled since discharge. Again this is a patient who had been in the hospital on broad spectrum

Page 27

antibiotics, was discharged on broad spectrum antibiotics. I think his chief complaint at that visit was diarrhea.
So I think the standard of care called for the physician to consider C. diff at that point and either do testing or provide empiric therapy given the clinical context of again someone who had been in the hospital, people pick up C. diff in the hospital, they pick up the bug, who have been on antibiotics, discharged on antibiotics, who is complaining of lots of diarrhea, that's number one. Should I keep going?
Q: Before you leave that, why don't you provide me with the basis for your opinion to the extent you haven't already. If you tell me that's everything, that's fine. But if you have a further basis for that opinion, I'd appreciate hearing it.
A: I just expect an internist who is taking care of a patient who has recently been hospitalized, been given broad spectrum antibiotics, who presents with a chief complaint of diarrhea or significant complaint of diarrhea to think about C. diff and to either provide empiric therapy or testing for it. And that's probably it in a

Page 28

nutshell.
Q: And before we leave that, that date, is it any diarrhea that raises the concern or does it have to be, you know, chronic or consistent diarrhea? Is there a way to quantify that or is that based pretty much on the physician's critical judgment when he encountered the patient and takes the history?
A: Well, any change in stools or any diarrhea after hospitalization on broad spectrum antibiotics and discharged on antibiotics should raise the suspicion for C. diff.
Q: Okay. Have we fairly covered all of your opinions as they relate to December 10th, 2001?
A: I believe we have.
Q: Let's move on to the next date.
A: Next date is December 14th and I believe that there's a family member phone call who actually asked about C. diff at that date and again there wasn't any action taken regarding either therapy or diagnosis of C. diff and there was a prescription for Imodium and again I think the standard of care would call for an investigation and/or empiric therapy and for not giving Imodium.

Page 29

Q: And I want to make sure that I understand your opinion as it relates both to December 10th and December 14th. The standard of care, I believe what I hear you telling me is the physician has a choice in order to comply with the standard of care.

You could either do C. diff testing or you can institute empiric therapy, is that correct?

A: Correct.

Q: Now if one were to employ C. diff testing, and when you're talking about testing, what specifically are you referring to?

A: In that case I would ask the patient and family to provide a stool sample and would probably order one of the toxin assays.

Q: All right. Now if one performed a toxin assay for C. diff and the result was negative, what if anything would the standard of care require based on that finding?

A: Well, if the patient's symptoms persisted or worsened, the standard of care would require empiric therapy or timely consultation.

Q: And when you say consultation, are you referring to referral to an infectious disease specialist or gastroenterologist or both?

Page 30

A: Probably both.

Q: You mentioned a prescription for Imodium.

Is it your belief that that is a deviation from the standard of care?

A: I think if it is an isolated action, no. But in the context of not recognizing what's going on with this patient it was.

(Thereupon, a recess was had.)

Q: Just to summarize where we left off, you said the Imodium as an isolated incident would not be a violation, but I believe in this context you would have to assign a deviation from the standard of care by Dr. Ochaney prescribing Imodium in response to the phone call on December 14th, 2001, is that fair?

A: Yeah. You know, a specific phone call about C. diff in a patient who was hospitalized on broad spectrum antibiotics, discharged on antibiotics and Prednisone and not, prescribing Imodium without thinking about C. diff or taking any appropriate action is a deviation.

Q: And why would it be a violation of the standard of care in this context for Dr. Ochaney to have

Page 31

prescribed the Imodium?

A: Well, I have seen people prescribe Imodium along with specific therapy for C. diff or along with the workup for C. diff. I would not give Imodium and I don't think in general it's a good idea. But I think the isolated act of giving Imodium, to me, as an isolated action isn't significant compared to putting in context of the overall approach to this patient.

Q: You are losing me just a little bit.

Is it a problem with the Imodium in this case or not?

A: There is in the sense it reflects not working up the patient for C. diff and not taking any further actions.

Q: Would Imodium be contraindicated in a patient in whom one suspected C. difficile colitis? I think you said no.

A: I think most people would not give Imodium to someone with C. diff and certainly I would never give it unless I was giving anti-C. diff therapy. I'm not aware of any literature that specifically says or has shown it to be harmful, however.

Q: So the fact, and this is going to touch on causation a little bit, but the fact that the

Page 32

patient was prescribed Imodium and assuming that he took the Imodium, you couldn't relate that to any harm to the patient, is that fair?

A: I would not specifically make the Imodium a major issue, no.

Q: Okay.

A: What I would make a major issue is the next date, which I guess we're coming to.

Q: All right. Have we fairly covered December 14th, 2001?

A: We have.

Q: All right. Why don't you go ahead with the next date.

A: On December 17th I believe the doctor prescribed Augmentin and I consider this, I guess I would almost call it an egregious violation of standard of care.

What happened on December 10th and 14th, I would expect a reasonable and prudent internal medicine doctor to think about C. diff or do the things I talked about. I think giving someone Augmentin, which is a major, major offender when it comes to the normal bowel flora, giving Augmentin to this patient in this context who has had these repeated complaints of diarrhea where

Page 33

there should have been a concern about C. diff, I think that's, you know, just a huge error.
Q: And why is that?
A: Well, Augmentin, you know, if you look at all oral antibiotics that cause C. diff, Augmentin is one of the worst. It may be the worst in that it is used more than other drugs like clindamycin and to prescribe Augmentin, you know, to a patient in whom you should be concerned about ongoing C. diff without doing anything for the C. diff is a major error.
Q: I assume that you hold the opinion that this patient, Mr. Brown, in fact suffered from C. difficile colitis, correct?
A: In my opinion there is no question.
Q: And when in your opinion did Mr. Brown contract C. difficile colitis?
A: Well, it's really important that we get our terms right for my opinion. Because there's C. diff diarrhea, C. diff colitis and C. diff pseudomembranes colitis.
I think he had C. diff diarrhea at least from the 10th on. The colitis, you know, the true colitis probably occurred later, more towards or around the time of the 17th.

Page 34

But, you know, C. diff is a very heterogeneous disease. Some have mild, some have severe diarrhea. I would expect an internist to know it is heterogeneous.
Q: I believe you told me earlier there is no evidence that he ever had pseudomembranous colitis as a result of C. difficile, is that fair?
A: That's fair.
Q: And you're aware that the Augmentin was prescribed for an infected ankle, is that right?
A: Well, I'm aware that one of the home nurses I think called the doctor and said there was some redness over the malleolus.
Again if I was getting a phone call like that, I would think this might be just as likely a stasis change than an infection. But it was related to a phone call from a visiting nurse, not examination by a physician.
And my recollection was when he was admitted a few days later there wasn't any mention of cellulitis, although I'd have to look at the records to be 100 percent sure.
Q: So is your criticism on the 17th the type of antibiotic or is it the prescription of any

Page 35

antibiotic?
A: Well, Augmentin is particularly bad. Again there are antibiotics that you could use to treat cellulitis that are not associated with C. diff but I think any antibiotic at that time in a patient with ongoing and specific concerns about C. diff and ongoing, you know, bursts of liquid stools, I think any antibiotic in that setting without thinking about C. diff is inappropriate.
Q: All right.

(Thereupon, a recess was had.)

MR. MORTER: We're back on the record.
Q: Doctor, was there anything else relative to December 17th, 2001 as it relates to your standard of care opinions and the bases thereof that we've not talked about?
A: No.
Q: All right. Are there any other, do you have any other standard of care opinions as it relates to Dr. Ochaney?
A: The only other question I have, and this is based upon maybe incomplete information at this time,

Page 36

other phone calls from the family to the office about diarrhea?
Q: Okay.
A: But I haven't read the family's depositions and so if there were more phone calls, and I'm not saying there were, if there were more phone calls about diarrhea, I would also cite those phone calls as concerns.
Q: Based on the information you have at this point, you'd not be able to assign any deviation from the standard of care?
A: That's correct.
MS. DiFRANCO: To any other phone calls other than the ones you've already discussed.
A: Right.
Q: Doctor, if you're ultimately provided with the family depositions and you have opinions based thereon that rise to a level of deviation from the standard of care, I'd ask that you let Miss DiFranco know so we can take a short deposition to flush those out. Is that fair?
A: Sure.
Q: Thank you. Assuming Dr. Ochaney had referred Mr. Brown to a gastroenterologist on December 10th,

Page 37

2001, would that have complied with the standard of care as it related to the patient's complaints of diarrhea?

A: No.

Q: Why not?

A: Well, I would expect an internist to know or recognize the clinical situation in which you would suspect C. diff and if he picked up the phone and said can you see this patient tomorrow it would have helped.

But I think C. diff is something that an internist should recognize and know how to either work up or treat.

Q: Okay. Before we leave the standard of care area, the notes that you have on the back of those two letters, could you simply read them into the record and in doing so reference which notes appear on which, you know, the back of which letter so I'll know when I look at them.

A: Okay. The first letter is the letter of November 17th, 2003. These are just jottings that don't have any specific significance as to any opinions. I just sort of did it just to concentrate, jot things down as I go.

11/23/01 to 11/29, I think it says Cefoxitin

Page 38

IV 10 slash Z. Decrease 02. Daughter nurse. '79, diabetes, neuropathy, COPD. NQWWS. Steroids. DC'd Levaquin. 12/10, Ochaney. Depression. Diarrhea. Colonoscopy. 12/17, 12/14, Lomotil. I can't read that. Some of it I can't read. 12/17, Augmentin. Infection, left malleolus. 12/19, diarrhea. Question going back to primary M.D. 12/21, IV Flagyl. Wolf consult. Severe somewhat chronic persistent diarrhea. White cell count, 27,000. That's it for the first letter.

The next letter says med school Bombay. IM St. Agnes. Private practice 1991. 11/23/01, admitted under him, new patient. Shortness of breath, chest pain. NSSTWI. Possible consult. GI for tarry stools. ETD, gastritis. Cefoxitin. DC Levaquin, Prednisone. I can't read that. GI colonoscopy. 11/29, he called Grobotney, PMD. 12/7, home care call. 12/10, office visit. Burst of liquid stool. I can't read that. Question depression. Something I can't read. Possible plan, see GD as planned. Chief complaint, diarrhea. Something I can't read. Question not taking Levaquin. 12/14, family called, re C. diff. See GI, gave Imodium.

Page 39

12/17, Augmentin. Question cellulitis. Usual fever, pain. Lomotil makes C. diff worse.

That's the last note. I believe that last statement was again something that the doctor said in his deposition.

Q: Okay. When we were talking about the standard of care violations, I don't have in my notes that you mentioned anything about Lomotil.

Do you have any opinions relative to the administration of Lomotil?

A: Well, my global opinions would be the same as we talked about for Imodium.

Q: And would your causation opinion as it related to Lomotil be the same as it was as to Imodium?

A: Yes.

Q: All right. Before we move then into your causation opinions, do you have an opinion as to what the cause of Mr. Brown's death was?

A: Complications from C. diff colitis.

Q: What's the basis for that opinion?

A: Well, he was admitted to, let me look at the records here, he was admitted to North Arundel Hospital December 24th and transferred to Maryland and just had a continued downhill course related to his C. diff colitis.

Page 40

Q: And what complications from C. diff colitis do you identify which caused the patient's death?

A: Well, C. diff colitis causes sort of a systemic inflammatory response, it causes your nutrition to go south, it causes exacerbation of other medical problems and, in his case, it led to a surgery which further weakened him.

Q: All right. What evidence is there in the Maryland records or the North Arundel records relative to systemic inflammatory response?

A: Well, a very high white count.

Q: Anything else?

A: His serum albumin continued to drop.

Q: Is that related to inflammatory problems or is that the nutritional problem you referenced?

A: That would be both.

Q: Okay. Any other parameters there reflecting problems with inflammatory response or nutritional problems?

A: Those are the main ones. I think that Mr. Brown had some frailty and the C. diff colitis just created a stress to his system that led to a downhill course.

Q: I assume the appropriate treatment for C. difficile colitis is oral Vancomycin, is that

Page 41

correct?
A: Well, there's three basic treatments. IV or oral Flagyl or oral Vancomycin. Oral Vancomycin is somewhat expensive and sometimes hard to find. So most often people use oral metronidazole or if the patient has nausea or vomiting or can't take oral, intravenous.
Q: Is it fair to say the oral route is more efficacious than IV?
A: I would say without question for Vancomycin. I'm not sure that is true for metronidazole.
Q: Which is Flagyl?
A: Right.
Q: I believe you told me earlier that the sensitivity of the C. difficile stool assay increases with repeated testing, is that a fair statement?
A: It can in some cases.
Q: How do you explain the finding on, I count four separate assays where the toxin result is negative?
A: Which hospitalization are you talking about?
Q: I've got a stool assay done at North Arundel Hospital where the C. difficile antigen is positive and the toxin is negative and that at

Page 42

the University of Maryland Hospital, I believe beginning on December 25th and then thereafter three separate stool assays are done, all of which come back negative for the toxin.
A: Yeah. You know, there's different toxins and there's different assays and all the assays, you know, lack really high sensitivity. There's also the issue about the time Mr. Brown went to the University of Maryland where he had been on therapy for a while which cuts down on the sensitivity.
You know, it's well-known among people who have an interest in C. diff that sometimes the toxin assay is negative in patients who have pseudomembranous colitis. I've seen many patients and the toxin always says, it is not the be all and end all in making the diagnosis. There is very strong evidence in this patient, which I'm sure you'll ask me about, pointing to C. diff.
Q: Why don't you take me through, you're exactly right, I do want to know exactly what it is about this patient that leads you to the opinion that he unquestionably had C. difficile diarrhea and then C. difficile colitis.

Page 43

A: Well, the clinical context, you know, is highly suggestive of C. diff, that is someone who is in the hospital and C. diff is a spore forming gram-positive rod. The spores are pretty hardy. Unfortunately it's not uncommon to find the spores in a hospital environment. So people who haven't been previously colonized with C. diff pick it up in the hospital and at the same time they're in a hospital getting, picking up the spores and getting colonized with C. diff, they're put on broad spectrum antibiotics that wipe out the normal flora.
So in the context of this patient being somewhat elderly, being in the hospital, on broad spectrum antibiotics and then developing diarrhea, I think if you look at those findings and ask what their positive predictive value for this diarrhea being associated with C. diff is extremely high.
And the patient goes on, this diarrhea that gets worse on Augmentin, when he comes into the North Arundel Hospital on the 21st he has a white count during the hospitalization that's around 27,000, 28,000. Leukocytosis is one of the hallmarks of C. diff colitis. There is very few

Page 44

infectious processes that cause that high of a white blood count. It is almost like a leukemoid. There's been literature on this, the higher the white count in a patient like this, again the stronger the positive predictive value is for C. diff colitis, particularly in the absence of any other reason to have a high white count.
All the physicians at North Arundel thought, you know, without question that this person had C. diff colitis. The CAT Scans showed diffuse colitis.
The only other alternative diagnosis that might cause this would be ischemic colitis but the clinical course is not consistent with ischemic colitis, the presentation isn't, the endoscopic findings weren't consistent with ischemic colitis.
So there's no question in my mind that the patient had C. diff.
Q: Would there be any other inflammatory bowel problems that would produce the type of result that you've just referenced to me other than ischemic colitis?
A: You know, a plain colitis in a patient with a

Page 45

28,000 white count who has been on antibiotics, recently been in the hospital, I can't think of any other condition that would cause a plain colitis that presents that way other than ischemic colitis.

But if a patient presented with ischemic colitis with a white count of 28,000, initially those patients are going to die in the next day or two because if they have that much inflammation from ischemic colitis, they usually go on and get necroses. I don't know if I ever saw a patient with ischemic colitis present with a white count that high.

But when patients do present with ischemic colitis, it is an acute presentation that gets worse rapidly. The clinical course is much more consistent with C. diff colitis, as were the CAT Scans. All the physicians who saw him contemporaneously before there was any litigation believed he had C. diff colitis.

Q: Is pseudomembranous colitis the end stage of C. diff colitis or can it occur at any time?

A: Well, it's really — C. diff colitis or the diseases associated with C. diff are a spectrum and C. diff colitis is one presentation and I

Page 46

don't know if it's continuum or spectrum, it's just one presentation.

Q: So there would be no difference in the bowel's ability to absorb nutrients as between a C. diff colitis that has not progressed to a pseudomembranous colitis?

A: I guess I think in general that a pseudomembrane colitis is worse than C. diff colitis without pseudomembranes. We see plenty of really sick patients who don't have pseudomembranes.

Q: If one is going to expire as a result of C. diff colitis, is one more likely to expire if one has pseudomembranous colitis versus non-pseudomembranous colitis?

A: I don't know.

Q: What could have accounted for the positive antigen finding at North Arundel and the negative toxin finding at North Arundel?

A: Well, I think we already discussed this. I think the antigen proves that the patient had C. diff. The toxin assays are imperfect. There's different toxins, different subtypes of toxins, different strains of C. diff and the toxin assay didn't pick up the toxin.

Q: So is it your testimony that if stool is assayed

Page 47

for C. diff, a finding of a positive antigen equals the diagnosis of C. difficile diarrhea or C. difficile colitis?

A: No, that's not what I'm saying.

Q: Then I'm confused. Maybe you could help me square that away.

A: Well, you can find C. diff in people who don't have disease. The finding of C. diff in someone who has been on antibiotics, been in the hospital, has a white count of 27,000 and is having very significant diarrhea and colitis is, you know, in my mind, diagnostic.

The toxin assay, you know, is more specific for being associated with disease but the detection of C. diff in the stool in the right patient is also highly diagnostic.

Q: So you're saying then the antigen can increase your suspicion about the disease provided that you're seeing other things clinically that would support that?

A: That's correct.

Q: Is there anything else relative to the cause of Mr. Brown's death that we've not talked about?

A: Not that I can think of.

Q: Is there any evidence on surgical pathology that

Page 48

the patient had C. difficile colitis, surgery from the University of Maryland?

A: Well, the pathology findings are completely consistent with C. diff colitis.

Q: And what is that? What does one expect to see pathologically?

A: It is a heterogeneous disease, acute inflammation, ulceration are completely consistent with C. diff.

Q: Do you have any opinion as to whether or not this patient had a GI bleed at the time he was at the University of Maryland?

A: I believe he did.

Q: Do you have an opinion as to the cause of that?

A: No.

Q: Do you believe that the fact that the patient had a GI bleed while at Maryland contributed to his demise?

A: No, it did not.

Q: I assume you'll not be offered on any issues of life expectancy?

A: Well, if I was asked about it I'd give an opinion.

Q: What's your opinion?

A: I would expect someone like this to live, you

Page 49

know, at least five more years.
Q: And what's the basis for that opinion?
A: 17 years clinical experience.
Q: Have you ever had any of your own patients succumb to C. difficile colitis?
A: I have.
Q: In what clinical circumstance?
A: I mean I can think of some specific patients. I can think of a specific patient that was sent in from a nursing home with, much like Mr. Brown and, you know, the patient came in with a really high white count and diarrhea, had been in the hospital, had been on antibiotics and we suspected C. diff colitis, gave appropriate therapy and the patient continued to go downhill and died.
This tends to occur more often in elderly patients. The disease tends to be more severe in general in elderly patients.
Q: And that patient that you just described to me, was there a delay in diagnosis or delay in the implementation of therapy?
A: I don't know. There was no delay on our part because we recognized on admission that this was C. diff colitis. She was transferred from a

Page 50

skilled nursing unit. I don't know if there had been issues that should have raised the suspicion earlier or not.
Q: Do you recall based on the history you were provided of how many days duration her diarrhea was?
A: I don't recall.
Q: Is it your opinion that had appropriate therapy been administered to Mr. Brown, that he would not have succumbed to this C. diff colitis?
A: Well, I think there's two things that really put him over the edge. One was not instituting therapy. Augmentin, I think giving him Augmentin on the 17th was literally throwing fuel on the fire.
Those two things, not giving therapy and then the addition of an antibiotic that further set up the right substrate for C. diff, I think those two things contributed to his death.
Q: Do you have a sense from reviewing the medical record when the latest time in which therapy, appropriate therapy could have been instituted and averted the outcome?
A: Well, I think if he had not been given Augmentin, you know, certainly around the 17th or 18th, in

Page 51

the absence of Augmentin might have averted the outcome. I think once he was given Augmentin, I don't think any therapy after that, you know, was going to make any difference.
Q: And why is that? I mean what is it about the Augmentin that rendered him not susceptible to the treatment that was instituted first at North Arundel Hospital?
A: Well, C. diff can improve in the absence of specific therapy if the normal flora in the colon is allowed to re-establish itself and the severity of the disease is somewhat related to the degree of inhibition of the normal flora.
So there are patients, usually younger patients who have diarrhea from C. diff, usually not full-blown colitis but just have diarrhea, for C. diff in young patients who are otherwise healthy where just time and stopping any offending antibiotics can lead to the re-establishment of the normal flora and resolution of the diarrhea.
Further insults in patients who are already having diarrhea from C. diff, further insults to the normal flora, just to allow a rapid escalation of the pathologic process, they allow

Page 52

C. diff to further replicate, multiply and cause illness.
Q: But if that's occurring, why would you not see the presence of either the antigen or the toxin on subsequent stool assays at the University of Maryland?
A: Well, I think we already discussed why the toxin wasn't detected. I don't believe they tested for the antigen at Maryland. There's a lot of reasons why I don't see the toxin in patients and I could repeat those if you like.
Q: No. I heard you earlier. I just, in relation to your opinion about Augmentin, I was just trying to further clarify that.
A: Well, you know, we know Mr. Brown had severe colitis in the context that we've already discussed and we've discussed why sometimes the toxin assay just doesn't detect it. Some strains produce toxins not detected by the assays.
In my clinical practice I've seen plenty of patients whom we made a clinical diagnosis of C. diff and the assays were negative for the toxin.
Q: In general what is the sensitivity of the stool assay for C. diff?
A: I think in general it's 60 or 70 percent.

Page 53

Q: By what factor, if any, would you increase that sensitivity in light of multiple assays?
A: I couldn't give you a number but I would say if it's a toxin not picked up by the assay, then repeat specimens would not help. Repeat specimens are more helpful in patients who have perhaps a low level of assay or technical issues with the collection of the specimens.
Q: How many different toxins are there for the C. diff bug?
A: There's at least two.
Q: And do most commercially available lab tests assay both of those toxins?
A: I don't know if I would say most. Some do, some don't.
Q: Doctor, as you're sitting there, are there any other areas that you and Miss DiFranco may have discussed relative to your opinions in this case that you and I have not talked about?
A: I don't think so. I think we hit on, we hit on most of them.
Q: So as it relates to the standard of care, you and I have covered all your standard of care opinions, is that fair?
A: That's fair.

Page 54

Q: As it relates to the cause of Mr. Brown's death, you and I have touched upon all of your causation opinions, is that fair?
A: That's fair.
Q: And as it relates to life expectancy, we have touched upon all of your opinions in that regard as well, is that fair?
A: That's fair.
Q: Would you just give me a couple of minutes to review my notes? I think I'm just about done.
A: Sure.

(Thereupon, a recess was had.)

Q: Just a little thing in one area, I just wanted to pin this down with you before I let you go.
As it relates to your opinions relative to Imodium and Lomotil, you are not going to testify that the prescription and the taking of those medications by the patient caused or contributed to the cause of Mr. Brown's death, is that fair?
A: Yes. My opinion regarding Lomotil and Imodium is that I don't think they should be prescribed and most people don't, but I don't think the isolated prescription as a stand-alone event is a critical

Page 55

criticism I have and most people, I think there's a general opinion that prescribing anti-motility agents in any kind of infectious colitis can lead to worse outcomes but I'm not aware of any specific literature that supports that for C. diff colitis and, therefore, I'm not going to offer that as a specific opinion.
Q: I just wanted to clear that up, that you weren't going to be saying that those medications caused or contributed to the cause of Mr. Brown's death.
A: No. I think the critical issue here was lack of appropriate therapy and the Augmentin was critical.
Q: Okay. I think I understand that now.
MR. MORTER: You have the right to read and sign your deposition or you can waive that.
THE WITNESS: I'd just as soon waive but I'll ask Miss DiFranco.
MS. DiFRANCO: That's fine.
THE WITNESS: Who is nodding it's okay to waive.
MR. MORTER: Those are all the questions I have. I thank you for your time and patience.

Page 56

(Thereupon, Defendant's Armitage Exhibit 2, one page letter dated November 17, 2003 addressed to Keith Armitage, M.D. from Tina DiFranco, was marked for purposes of identification.)

(Thereupon, Defendant's Armitage Exhibit 3, one page letter dated April 28, 2004 addressed to Keith Armitage, M.D. from Tina DiFranco, was marked for purposes of identification.)

(The reading and signing of the deposition was expressly waived by the witness and by stipulation of counsel.)

CERTIFICATE

The State of Ohio,) SS:
County of Cuyahoga.)

I, Linda A. Astuto, a Notary Public within and for the State of Ohio, authorized to administer oaths and to take and certify depositions, do hereby certify that the above-named witness was by me, before the giving of their deposition, first duly sworn to testify the truth, the whole truth, and nothing but the truth; that the deposition as above-set forth was reduced to writing by me by means of stenotypy, and was later transcribed into typewriting under my direction; that this is a true record of the testimony given by the witness; that said deposition was taken at the aforementioned time, date and place, pursuant to notice or stipulation of counsel; and that I am not a relative or employee or attorney of any of the parties, or a relative or employee of such attorney, or financially interested in this action; that I am not, nor is the court reporting firm with which I am affiliated, under a contract as defined in Civil Rule 28(D).

IN WITNESS WHEREOF, I have hereunto set my hand and seal of office, at Cleveland, Ohio, this _____ day of _____ A.D. 20 _____.

Linda A. Astuto, Notary Public, State of Ohio
1750 Midland Building, Cleveland, Ohio 44115
My commission expires October 25, 2007

Lawyer's Notes

D

E

F

G

H

I

J

K

Q

R

S

T

U

V

W

Y

Z

Lawyer's Notes