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COMMONWEALTH OF MASSACHUSETTS
MIDDLESEX, SS SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT

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RONALD T. LARIVIERE and *
MARIANNE LARIVIERE, *
*
Plaintiffs, *
*
v. *
*
*
MALCOLM A. CREIGHTON, M.D., *
MICHAEL C. BERARDUCCI, M.D., *
LAI HA YEE and *
LAHEY CLINIC HOSPITAL, INC., *
*
Defendants. *
*
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BEFORE THE HONORABLE KENNETH J. FISHMAN
DOCKET NUMBER 1281CV-01825
TRIAL BY JURY

EXPEDITED TESTIMONY OF PAUL GENECIN, M.D., F.A.C.P.

Woburn, Massachusetts
Courtroom: 610
Date: Friday, July 22, 2016

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I N D E X

WITNESS:	DIRECT	CROSS	REDIRECT	RECROSS
PAUL GENECIN, M.D.				
By Mr. Clapp	4,65		164	
By Mr. Reidy		77		

P R O C E E D I N G S

(Testimony of Paul Genecin, M.D., F.A.C.P. commences at 9:17 a.m.)

(Jury present)

(WITNESS SWORN)

PAUL GENECIN: Yes.

THE CLERK: Please state your name and spell your last name for the record.

DR. GENECIN: Paul Genecin, G-E-N-E-C-I-N.

THE COURT: C-I-N?

DR. GENECIN: C-I-N, yes.

MR. CLAPP: Could I put a set of --

THE COURT: Certainly.

MR. CLAPP: -- exhibits on the stand, Your Honor?

THE COURT: Yes.

(DIRECT EXAMINATION OF PAUL GENECIN, M.D., F.A.C.P)

BY MR. CLAPP:

Q Dr. Genecin, what is your profession?

A I'm an Internal Medicine physician. I

see adult patients in the hospital and in clinic and in appointments.

Q And are you employed?

A Yes, I work at Yale University. I have an administrative job in which I am director of a clinic where I also practice.

Q And what is the nature of the clinic in which you practice?

A The clinic is called Yale Health. Yale Health is a healthcare organization providing both healthcare and coverage to the faculty staff, dependents, and retirees at Yale University, as well as its students.

We have approximately 30,000 non-student members. My practice consists of adult patients ranging in age from 20'ish to end of life. I take care of patients in the hospital who are members of the general public.

Q How long have you been in that position, Doctor?

A My current position -- well, I've been

at Yale Health, including it had a different name, since 1999. I've been in my current position, I'm in my 20th year.

Q Do you have teaching responsibilities?

A I do, yes. I'm a clinical associate professor of medicine at Yale School of Medicine.

And in that capacity, I regularly teach both hospital medicine -- Internal Medicine relating to sick patients in the hospital -- as well as patients in a clinic setting.

I teach students, residents, which include interns and trainees in Internal Medicine.

Q Are you admitted to practice medicine at any hospitals?

A Yes. The teaching hospital for Yale is Yale-New Haven Hospital. That's the one hospital where I now practice. It's also the one hospital in New Haven, Connecticut.

Q And what's the nature of your practice

at Yale-New Haven Hospital?

A I work as an attending physician on a teaching service. And in that capacity, for two months of the year, I am the physician of record, admitting patients who are members of the general public.

They can be admitted from home, from a nursing home, from -- transferred from the Intensive Care Unit, all comers to the medical service. In that capacity, I also supervise and teach students and residents.

Q Are you associated with a medical group?

A Yes. Yale Medical Group is the faculty practice of Yale School of Medicine, and I'm also a member of that group.

Q And, Doctor, would you tell the jury the -- your educational background?

A Starting with college or --

Q Yes.

A I went to college at Princeton in New Jersey. I graduated in in '77. I went to Columbia University for coursework in order to be qualified to apply for

medical school.

And I applied to medical school, was accepted and stayed at Columbia University, graduating in 1983. I remained at Columbia for three more years for my internship and residency, and then in 1986 moved to Yale University, where I finished my education and training in a fellowship.

And that takes us up to 1989. I went to work at that point.

Q And would you tell us what your background -- your employment background has been since then?

A I've worked only really for Yale University since then, beginning as a primary care Internal Medicine doctor, following patients both in office, as well as in the hospital.

I also was working for part of my week at the West Haven VA Hospital, where I did liver disease work and worked on the consult service for liver disease at Yale-New Haven Hospital.

In 1997, with the change of my job to job to more administration, I dropped liver disease. I focused on general Internal Medicine.

I kept inpatient hospital attending duties, as well as teaching in outpatient clinic, and continued my practice of Internal Medicine on a part-time basis and took an administrative job, which I continue to have.

Q After you graduated from medical school, did you serve an internship?

A I did. I did my internship training at Columbia-Presbyterian Hospital in New York City.

Q And what is an internship?

A An internship is the first year out of medical school, the first year in which a young doctor can be called doctor, working under direction of more senior residents and attending doctors who are doctors out of training.

A good bit of that year was spent on inpatient work and, in fact, my

whole residency training, the primary focus was on hospital medicine.

Q And did you serve a residency?

A Also at Columbia. That's the junior resident, senior resident. Those are the three years of residency.

Q And what is the nature of the practice of a junior and senior resident?

A Junior and senior residents in medicine acquire increasing levels of responsibility and autonomy, become responsible for supervising more junior physicians, as well as students.

They acquire increasing responsibility for work in Intensive Care Units, in the emergency room, and other settings.

Q And following your residency, did you do postdoctoral studies also?

A Postdoctoral training at Yale, yes.

Q And would you describe that?

A Yes. For the first year, I did a fellowship at Yale University in digestive diseases. My intention was to

be a hepatologist, which is a liver disease specialist. At Yale, within the gist of diseases, there are two tracks, one for Gastroenterology, the other for Hepatology.

The first year is the same for everyone; I did clinical digestive diseases, including GI, as well as liver disease. In the third and fourth year, though,

I -- I'm sorry -- in the second and third-year fellowship, I specialized in liver disease. I worked in a lab, and the clinical work was all pertaining to liver.

Q Doctor, have you received any professional honors or recognition?

A A variety of school honors relating to -- starting with, you know, college and medical school as well as miscellaneous others.

Q And are you certified in any branch of medicine?

A Yes. I'm board-certified in Internal

Medicine.

Q And what is the nature of board certification?

A To be qualified for -- to sit for board certification examinations, a doctor has to -- obviously has to be to medical school and then has to do residency training in the field of medicine.

And that may be Pediatrics, Surgery, Psychiatry, Dermatology. There are a number of different possible fields. Mine is Internal Medicine. And board examination for me was a two-day examination, which included written exam as well as oral.

And then I became board-certified. That entitled me to be -- hold myself out as an Internal Medicine physician with board certification.

Q Dr. Genecin, have you written any papers or articles or other publications in your profession?

A Yes, back when I worked in laboratory and pertaining to work I was doing in

liver disease.

Q And, Dr. Genecin, have you testified as an expert witness in Massachusetts before?

A I have, yes.

Q And have you testified in other states as an expert witness?

A Yes. I've been working as an expert witness for I think approximately 20 years. And over the course of that time, I think I've testified in I think 25 or 26 different states.

Q And, Doctor, do you serve as an expert witness for plaintiffs or defendants or both?

A For both.

Q And what is your percentage of plaintiffs to defendants?

A It seems to vary by year, but I would say at the moment about two-thirds of the cases I read are plaintiff cases. And I always have read more plaintiff cases than defense, but at the moment about a third are defense cases.

I have testified more often in plaintiff cases, that is cases for the patient. But I've also testified for the doctor as well.

Q Dr. Genecin, at my request, did you review the case of Ronald T. Lariviere concerning his admission to Lahey Clinic in May and June of 2009?

A Yes, you did.

Q And what did you do specifically to prepare for that review?

A My recollection is that in approximately 2012, you contacted me about reading this case. I read Lahey Clinic records, both hard copy of the admission in May 2009 and then subsequent care through July of 2009.

You also sent me a CD with several-thousand pages of records, which I looked at, pharmacy records, deposition transcripts. That was the -- there were various legal documents that were also sent to me to read.

Q And what was the purpose for your

review?

A The purpose for my review was to determine whether the care that Mr. Lariviere received in Lahey Clinic met the standard of care for doctors practicing in my field and with specific reference to choice of medications used to treat an infection.

Q And are you able to tell the jury what you found from reviewing the records concerning Mr. Lariviere's admission to Lahey Hospital, which is plaintiffs' Exhibit 1 in front of you?

A Yes.

Well, in brief, at the time of the admission, he was a 57-year-old man working as a construction supervisor with a number of past and current health problems, including Crohn's disease, which is a form of inflammatory bowel disease for which he took prednisone, which is an oral steroid medication that suppresses the immune system and decreases inflammation in inflammatory

bowel disease.

He had recently undergone surgery for a problem he was born with in the aortic valve, so he had undergone an aortic valve replacement, as well as a graft of the ascending aorta. So, that's a major operation and he had recently undergone that.

And that was then. His somewhat recent history, he was, as I said, steroid-dependent. He became ill on May 30th, feeling chills and weakness. And his wife took him to the ER at Lahey Clinic Hospital, assuming that the problem was infection relating to the recent cardiac surgery.

It turned out, though, that the problem was a urinary tract infection and that he did have a fever and possibly diagnosis of urosepsis, which is a systemic infection relating to bacteria coming from the urinary tract.

It was thought that he could have a diagnosis of pyelonephritis,

which is a kidney infection and upper urinary tract infection. And so, he was given an antibiotic called ciprofloxacin in the emergency room.

And he was dehydrated; he needed to have some fluid in order to correct borderline blood pressures and some abnormal kidney function tests, which did improve with hydration.

But it was felt that he needed to be admitted to the hospital, and he was admitted to the medical service for further treatment.

Q And would you describe what the record says concerning his further treatment?

A Sure. In the hospital, of course one of the things that they did was a workup to make sure that things were okay with the heart valve and the aortic graft, which they were, thankfully.

The results of an imaging study suggested a problem in the kidney. He did have kidney stones as well. He was treated -- because of the fact that he

was on long-term therapy with prednisone, which is an oral steroid medication, he was treated with a somewhat higher dose of IV steroid medication in order to deal with the stress of -- that this infection placed on him.

And he was given IV ciprofloxacin, which is an antibiotic of -- a class of antibiotics called fluoroquinolones. He was in the hospital and had an uneventful recovery. He did well and was able to be discharged after switching from IV Cipro to oral, to the pills.

He was then discharged from the hospital basically three days later on June 2nd on oral ciprofloxacin to take for two weeks.

Q Doctor, the steroid that he was given in the hospital, what was that called?

A The steroid that he was given was hydrocortisone, and that was an IV formulation given in a higher dose than

the chronic daily dose of prednisone.

Because patients on chronic prednisone therapy, their adrenal glands, which are the glands that make our normal cortisol, which is the hormone that we have circulating, they become suppressed, they go to sleep when patients are on prednisone.

And when the patient becomes ill and would normally be able to -- normal adrenal glands would be able to secrete a high level of cortisol, since a patient on prednisone won't do that because his adrenal glands are asleep, we give IV steroids in that situation to tide him over until he recovers from an acute illness.

Q Is hydrocortisone a corticosteroid?

A Yes, it's a corticosteroid that can be given by vein. Prednisone is a corticosteroid that's taken by mouth.

Q What is a corticosteroid?

A A corticosteroid is a medication derived from the -- a molecule that our body's

produce called cortisol. It's a hormone that normal people use for regulation of normal body functions.

Given as a medication in large doses, it has very potent effects on the body, particularly with respect to inflammation. So, patients with inflammatory diseases, such as Crohn's disease, ulcerative colitis, a variety of lung diseases, skin diseases.

There's a host of different type of medical conditions for which steroid medications are used in higher doses because of their anti-inflammatory properties.

Q Were there any other significant events that occurred before he was discharged on, did you say June 2nd?

A No, he did well actually. And it was an uneventful hospital course. He was able to be discharged. When he appeared in the ER, the question of whether he might be septic was raised.

Sepsis is a much more serious,

more advanced form of infection than what it turned out, which was that he had an infection with fever, but not sepsis.

And giving IV fluids in the ER was sufficient to normalize his blood pressure to improve his kidney function, and he was admitted to a regular hospital bed and did quite well.

Q And would you proceed with your review of the record from discharge?

A Yes. So, what happened after discharge is that with the -- he developed a problem with tendons in his Achilles tendons.

The pharmacist outside the hospital informed him that ciprofloxacin and drugs like it shouldn’t be used in patients on chronic steroid therapy.

Unfortunately, the complication that it causes, which is called tendinopathy, most commonly affects the Achilles tendons, and Mr. Lariviere suffered, first, spontaneous rupture of

one of his Achilles tendon, and then at some -- a week or two later, the other, and unfortunately had to undergo two surgeries to repair the injured tendons or ruptured tendons.

That was an avoidable complication because doctors are supposed to know not to give ciprofloxacin to patients who are on chronic steroid therapy.

Q Was he discharged with any prescriptions or medications on June 2nd?

A June 2nd, he was provided a prescription for ciprofloxacin 500 milligrams with instructions to take one twice a day for two weeks.

Q Dr. Genecin, in May of 2009, what were the average qualified physicians who would be prescribing medications such as ciprofloxacin and corticosteroids, what did they know or should know about that -- those drugs?

A There was a -- what's called a black box warning. A black box warning is a

warning about the safety concern that's arisen as a result of use of the medication under certain circumstances.

So, after a drug comes on the market, we find out more about the drug as it's used in large populations of people.

And one of the important findings about ciprofloxacin, as well as drugs of its class, was that there was a tendency to be associated with tendinopathy -- that's injuries and disease of tendons -- but particularly, most frequently, Achilles tendinitis and tendon rupture in patients taking ciprofloxacin and drugs like it, with a most heightened level of concern because of increased risk in patients with advanced age, both patients who had organ transplant or kidney failure, and patients who take long-term corticosteroids.

So, in -- I'm sorry -- in 2008, the FDA mandated or required that the

drug company manufacturing Cipro communicate to doctors and other prescribers in what's called the Dear Health Care Professional Letter, and that this black box warning be the topic of that letter so the doctors prescribing Cipro would become aware of that drug interaction and potential for harm with -- for patients on chronic steroid therapy using this antibiotic.

And then the labeling information in the *Physician's Desk Reference* and available to doctors online would now contain what's called a boxed warning or a warning that's literally in a box written in a box in the instructions about the medicine.

Doctors are expected to be aware of not only the benefits of medicines and how they may act in order to treat a patient to make them better, but also the different ways in which medication may be associated with harm.

Any drug may cause harm in an

unpredicted way or unpredictable way. But there are drugs for which harm may be predictable if a dose is too high or if a patient has a certain underlying health condition or the patient is taking a medication for which there is now a known drug -- adverse drug interaction. So, doctors are expected to know that.

Q Dr. Genecin, you mentioned the Dear Health Care Provider Letter. What's the function of that letter?

A It's to alert doctors who prescribe -- and I say doctors.

It includes nurse practitioners, it includes physician assistants and other kinds of professionals who have prescriptive authority so that they can prescribe safely, also to notify of course pharmacists and pharmacies, so that patients can be protected from an avoidable mishap or injury that could have been avoided by managing patients'

medications more safely.

So, you might think of a black box warning kind of like a red light for a physician or other prescriber looking at a certain combination of drugs or if the patient had been a kidney transplant patient or otherwise vulnerable to problems with tendons not to use a drug that causes tendon problems.

But the same could be for a lot of other drugs for other reasons. And those are what are called contraindications, warnings, and problems that are associated with medications that are published, shared with doctors in order that they will practice safely.

Q Doctor, who sends out the Dear Health Care Provider letter?

A Well, the FDA mandates it, but the drug company -- I think it was Johnson that made Cipro, and I think -- but it’s the drug company that has to send the Dear Doctor letter.

Q And who does it go to?
A It goes to prescribers. It goes to doctors who are licensed, to other licensed professionals who are legally allowed to prescribe.
Q Now, are you familiar with the Dear Health Care Provider Letter that was sent out on Cipro in 2008?
A Yes, it got a lot of attention. And I am familiar with it.
Q Is that something that any doctor, the average qualified doctor who would be prescribing Cipro in May of 2009 was required to know?
A Absolutely. Any black box warning -- the black box warning, I should note, is the FDA's highest level of warning.

So, it's not a -- something that's buried in a list of things that might happen. It's the highest level of warning that's mandated by the Food and Drug Administration to inform doctors about a drug safety concern.

It's something then that

doctors -- doctors are required not just to learn medicine in training, but also to read medical literature, to attend to issues about drug safety that are brought to their attention, to have continuing medical education, and to read journals and so forth so that their knowledge evolves with the evolution of knowledge in their field.

So, when an important development like a black box warning on a commonly prescribed drug comes up, it does get a good bit of attention. Because these fluoroquinolone antibiotics are very useful and very commonly prescribed.

And as a consequence, a black box warning is something that would come to the attention of many, many people and get a good bit of attention.

Q And does the Dear Health Care Provider Letter serve a function?

A It does. It puts doctors on notice to observe the recommendations that fall

out of that warning, i.e., avoid fluoroquinolones.

Use a different kind of drug than Cipro in a patient who has had a kidney transplant, who is extremely elderly, who has a disease associated with tendon problems, and a patient on long-term steroids.

That would be what would be expected, would be that doctors prescribing would avoid fluoroquinolones because of the risk that they pose of tendon injury, severe enough that it rises to the level of a black box warning.

Q Did you and other doctors at the Yale Health Center receive such things in late 2008?

MR. REIDY: Objection, relevance.

THE COURT: Sustained.

BY MR. CLAPP:

Q Are you familiar with the Dear Health Care Provider Letter that was sent out

in October of 2008 by Bayer HealthCare Pharmaceuticals --

A Bayer, right.

Q -- concerning -- concerning Cipro?

A Yes, I am. I am familiar with it, yes.

Q And how long have you been familiar with that letter?

A Since it came out, it was the focus of a pharmacy and therapeutics committee discussion, of which I was a part. Back in that year, it's something that all doctors who prescribe medicine received.

It became part of the mandatory labeling for the drug, so it was -- papers on the topic were published and cited so that references were available for doctors to read about this.

So, that -- and I should say that that particular black box warning got a lot of attention for two reasons. One of them is that fluoroquinolone antibiotics are very widely prescribed, millions of prescriptions per year.

But also, that tendinopathy is

an unusual side effect and a lot of people were surprised by that, you know, that Achilles tendon rupture from an oral antibiotic. So, that was a topic of a lot of discussion and was reviewed in continuing medical education.

Papers were written about it. There had already been papers about it, but when it became a boxed warning, what that did was put doctors on notice that there is a red light with respect to prescribing that drug for patients who have these chronic conditions.

MR. CLAPP: May I approach the witness, Your Honor?

THE COURT: You may.

BY MR. CLAPP:

Q Dr. Genecin, I'll show you a document. Do you recognize this document?

A Yes. This is the Dear Health Care Provider -- Dear Health Care Professional Letter dated October 22nd.

It was written by a doctor named Paul MacCarthy -- that's M-A-C

Carthy -- who is the vice-president head of US Medical Affairs for Bayer HealthCare, which was the Bayer Pharmaceuticals.

Q And is that a true copy of the letter that was sent out in 2008?

MR. REIDY: Objection, Your Honor.

THE COURT: Overruled. You may answer it.

A Yeah, this is a photocopy of a letter that I received and that I'm familiar with.

MR. CLAPP: I will offer that as the next exhibit, Your Honor.

MR. REIDY: Objection, Your Honor. Hearsay.

THE COURT: I'm going to admit it.

Ladies and gentlemen, this particular document is being admitted solely on the question of whether the doctors -- defendant doctors in this case had notice of the warning, not for

the truth of the statements that are contained within the letter itself, but just on the question of whether they received warning through this letter.

So, let's give that to the court reporter, please. She'll mark it.

(Exhibit 1, so-marked)

MR. CLAPP: May copies be distributed to the jury or --

THE COURT: Actually, were some pre-marked? Were other exhibits pre-marked in this case?

MR. CLAPP: They haven't been pre-marked.

THE COURT: Okay. So, that will be Exhibit 1 then?

MR. CLAPP: Well, in the book, we have them numbered. This would be six.

THE COURT: Okay. I'm sorry, can we make that six and we'll sort of backfill this a little bit?

(Exhibit 6, so-marked)

MR. CLAPP: May we distribute

copies to the jury for their --

THE COURT: Yes, with the aid of the court officer. All right. Everybody has a copy?

BY MR. CLAPP:

Q Doctor, in May of 2009, what did the average qualified physician prescribing Cipro and a corticosteroid, what was that average qualified physician required to know about those medications?

MR. REIDY: Objection, Your Honor. Can we have a sidebar, a quick one?

THE COURT: Yes, yes.

(SIDEBAR CONFERENCE NOT TRANSCRIBED)

BY MR. CLAPP:

Q Doctor, in this case we’re dealing with two different subspecialties. We’re dealing with Internal Medicine with Dr. Berarducci and Emergency Medicine with Dr. Creighton.

Would there be a difference in what doctors prescribing in one

subspecialty or the other would be required to know concerning ciprofloxacin and corticosteroid prescriptions?

A No, it would be the same across all specialties.

Q And what would it be that the average qualified physicians in those subspecialties, what would they be required to know concerning those medications?

A First of all, in a situation where a patient has an infection, where using a fluoroquinolone comes to mind, a doctor must know to choose an alternative antibiotic, of which there are many, that do not have that risk of tendon problems.

In addition, a doctor would know that tendinitis and tendon rupture are very -- are to be avoided because they are serious complications. They can only be repaired surgically. They cause the patient to become disabled and

in pain.

A ruptured and repaired tendon is never as good as the tendon that the patient started out with. Patients become disabled in terms of their ability to basically what's called plantar flex or to make their foot go down. This way is up; foot up is called dorsiflexion. Plantar flexion.

The muscle in the back of the calf, the calf muscle, the gastrocnemius, becomes weak and makes it difficult for patients to walk. While the tendon is ruptured, they have to be in a boot and getting around on crutches.

They tend to lose strength in the gastrocnemius, have to go through physical therapy in order to try to recover as much function as possible. A patient who had, for example previously been a runner, his running career would be over.

For an average person, the

distance that they'd be able to walk, how they feel at the end of the day, their ability to climb stairs, activities of that sort would be impaired. How they'd feel would be worse.

Q And what would the significance of bilateral Achilles tendon ruptures be and what should those doctors have known about that?

A Well, what happens to one tendon -- and this complication tends to involve both. And for a patient with that, it's a double whammy. They have to undergo two surgical procedures.

They have a prolonged period where they really can't get around on their feet. They have to undergo a lot of physical therapy and they're never really as good as new.

Although patients, with a lot of physical therapy can eventually rehab, they'll feel ongoing problems with tightness and difficulty

stretching, again problems with stairs, possibly ladders, weakness and things of that nature, that are both sides and require surgery bilaterally.

In addition to the risks of surgery, there are also the risks of unsuccessful surgery and ongoing problems with a risk of permanent disability, although patients who have a good repair and a good result may be able to resume a lot of what they were able to do before.

Q Dr. Genecin, what were the average qualified physicians prescribing those medications at that time required to know concerning the probability of tendinopathy with those two drugs?

A Well, they were required to know that the risk of tendinopathy was high enough that a black box warning came into existence.

They would be able to find out that the risk of tendinopathy and tendon rupture were increased several fold

relative to the risk of having a tendon rupture from random circumstances or causes that are other than fluoroquinolone.

So, for example, approximately fivefold increase in risk of a tendon rupture is a risk to a patient that -- resulting from a treatment with a medication for which an alternative could have been chosen that wouldn't have caused that.

Q So, are you talking about a combination of medications that would have that fivefold risk?

A Yes.

Q And what medications were you talking about specifically?

A Well, I was talking about for a patient given fluoroquinolone who is on a corticosteroid, so a patient like Mr. Lariviere. That would be the order of risk.

Q Was there a risk associated with just taking Cipro and tendinopathy?

A Yeah, Cipro -- in fact, the warning was really -- the black box warning is that fluoroquinolones are associated with tendon rupture.

The factors that were most risk -- most important risk factors for tendon rupture in patients taking fluoroquinolones included the transplants, the people with tendon disease, and then people on corticosteroids.

Q And are you familiar with what the percentage of risk would be for just taking fluoroquinolones and tendinopathy?

A Yes. Up to 0.4 percent, which is four in a thousand.

Q And you mentioned a fivefold increase if you’re taking both corticosteroid and fluoroquinolone; is that correct?

A Yes, up to fivefold increase.

Q Fivefold times the 0.4?

A Right.

Q Dr. Genecin, in May of 2009, what were

the average qualified physicians who were prescribing Cipro, what should they have known a patient -- a Cipro and corticosteroid -- what should they have known a patient in Mr. Lariviere's position, what sort of information that patient would need to make a decision as to whether to take that medication?

A I'm sorry, could you ask that question again?

Q Yes. In May of 2009, what was an average qualified physician prescribing Cipro to a patient taking corticosteroids supposed to know concerning what his patient would need in the way of information to make his own decision?

A I think actually the black box warning gave guidance on that, that the patient should be informed in the rare circumstance where a patient had an infection that couldn't be treated by any other means.

So, say for example, a patient

had so many drug allergies that they couldn't take anything but a fluoroquinolone, or that the bug had so many -- was resistant -- the bacteria was so resistant that only a fluoroquinolone was a possible option, then patients should at least be told, you know, to look out for problems with tendinopathy.

Because early recognition and discontinuation of the medication if possible is -- will lead to a better outcome.

Q Doctor, I'd like you to assume that Dr. Creighton and Dr. Berarducci will give certain testimony in this case. And I'm going to ask you a question to assume the facts in Plaintiff's Exhibit One, which is the Lahey Record, and certain facts that I believe Dr. Creighton and Dr. Berarducci will testify to in this case.

I'd like you to assume that Dr. Creighton was an emergency department

physician and was aware of the possibility of adverse drug interaction between Ciprofloxacin and corticosteroids, but did not recall whether he was aware of the boxed warning on 5/31/09, and did not recall that he knew that the patient had taken Ciprofloxacin in the past, that he does not recall speaking to the patient about the risks of tendon injury, that he approved the use of Ciprofloxacin because he felt that that was the best medicine, and that the fact that Mr. Lariviere had taken steroids in the past, and quinolones, either together or separately meant that the use of these drugs was not contraindicated.

And that he will testify that more likely than not, Mr. Lariviere's bilateral Achilles tendon ruptures were induced by Mr. Lariviere's regimen of Ciprofloxacin in May and June of 2009.

And then I'd like you to assume these facts concerning what I believe

Dr. Berarducci will testify to.

That he was aware of the boxed warning at the time, but felt that the risks were outweighed by the benefits in Mr. Lariviere's case, and that his use, Dr. Berarducci's use of Cipro is a common thing and that he didn't believe it violated any policies.

He states -- or he will state that if he had been contacted by the pharmacy with a request that he change to another antibiotic, it would have been an opportunity to discuss the interaction and how to handle it with other doctors who had been treating Mr. Lariviere.

And with those assumptions -- first of all, are you familiar with the standard of care that applied to the treatment that Dr. Berarducci was giving Mr. Lariviere at that time?

A Yes.

Q And are you familiar with the standard of care that Dr. Creighton -- for the

treatment he was giving to Mr. Lariviere at the time?

A Yes. I'm not an ER doctor, but with respect to the prescription of a drug like Cipro, the standard of care is the same for ER doctors and internists.

So, with respect to the choice of antibiotic, I am familiar with the standard of care.

Q So, with those three assumptions, do you have an opinion, based on a reasonable degree of medical certainty, as to whether either Dr. Creighton or Dr. Berarducci deviated from the standard of care applicable to their care --

A Yes.

Q -- of Mr. Lariviere?

A I do have an opinion, yes.

Q Would you tell us what that opinion is?

A My opinion is that each doctor, Dr. Creighton and Dr. Berarducci, deviated from the standard of care in using a medication about which there is a black box warning, because of the

characteristics of Mr. Lariviere's condition, which included that he was on chronic corticosteroid therapy because of his Crohn's Disease.

Q And Doctor, what's the basis for your opinion?

A The basis for my opinion is, in the first place, that the standard of care requires that doctors be aware of black box warnings and heed those warnings, because they're there in order to protect patient safety.

In the second place, the doctors are required to know their antibiotics and to choose those that have a safety profile that doesn't pose a special risk to a patient because of a condition that he presents with.

And in a case such as this, there are antibiotics of other classes that are perfectly safe and equally effective, that a patient with tendinopathy, or tendon rupture, would be disabled and injured.

Those were the things that a doctor was required to know.

The issues that relate to the fact that he had had it before, Cipro in the past, it's well established that the fact that it did not cause this tendon injury in the past, that doesn't protect the patient from it happening.

Using that combination of medicines increases the risk of harm. It doesn't guarantee that at each occurrence that harm will occur. So, sort of think of it in terms of running red lights. A four-car collision doesn't happen every time someone runs a red light, but running red lights does increase the risk that that will happen.

There is no safety pass that was there for Mr. Lariviere with respect to Cipro, just because he had used it in the past. It was not the only drug or best drug. He was not critically ill and could only be rescued by using Cipro. All of that is not true. Drugs

of classes including cephalosporins, beta lactams of a penicillin derivative, drugs of -- I mean, ovicides, drugs that are called penems; Meropenem, and so forth, are all great drugs in this situation, in which a patient can't use a fluoroquinolone.

When Mr. Lariviere's results culture came back, he got something called an antibiogram, which every culture comes with, which is what are the antibiotics to which this bacteria is sensitive or resistant. This was a sensitive e-coli. A whole list of routine antibiotics would have been fine for the purpose of treating Mr. Lariviere. He did not need a fluoroquinolone, so there was no life or death decision there.

And doctors deviate from the standard of care when they ignore black box warnings. There are instances in which someone might be forced to run a red light. There may be ambulances

coming from behind, and there may be a reason to do it.

There may be a situation, as I said, in which a fluoroquinolone may be the only possible drug. Those are very unusual circumstances, and this was not one of those.

Q Doctor, you referred to an antibiogram. Would you look at page 86 in the loose-leaf folder of Exhibit One?

Is that an antibiogram shown on that page?

A Yes, it’s the first half of the page to the left. Basically, it gives Mr. Lariviere’s name, phone number, date of birth, age, etcetera. It gives the collection date for the urine culture. It gives the results, which is that there were greater than 100,000 e-coli per milliliter of urine.

And the antibiogram is a table, where you can read from the left. There’s ampicillin sulbactam, ampicillin cefazolin, cefepime, ceftriaxone,

Ciprofloxacin, which is the one drug listed here that is a fluoroquinolone. But then gentamycin, nitrofurantoin, tobramycin, and trimethoprim sulfa.

And this was a bacteria that was susceptible. It was a drug for which any of these antibiotics, apart from ampicillin, which wouldn't be used for this purpose. So, there were many choices of antibiotics.

Q Now, the last drug on that list, trimethoprim sulfa, is that commonly called Bactrim?

A Yes. Trimethoprim sulfamethoxazole is Bactrim, or Septra is the other name for it. That's an oral antibiotic. It can be given IV, but is seldom given in the hospital IV. It's an oral antibiotic.

Q Now, when the word susceptible is used, does that mean that the organism is susceptible to the medication?

A Yes, right. In other words, it means that it's not resistant. So, you've heard of like methicillin resistant

anthrax oxide, or MRSA, methicillin resistant staph aureus; it's not resistant, it's sensitive -- susceptible.

Q Now, these results take time to be produced once the collection is made, isn't that correct?

A That is a key point. And the antibiogram in this case was only finalized on June 2nd, which was the date of discharge from the hospital. But was soon enough to recognize the error of continuing Cipro, and to guide the choice of a safe alternative drug.

So, Mr. Lariviere could have gone home with a prescription for Bactrim or for any of these others which are available as oral agents for use against urinary tract infection.

Q What would the significance be if the antibiogram didn't come out until after Mr. Lariviere had left Lahey that day and had gone back to Rhode Island?

A Well, it does not have significance. He

did not leave for Mars. He has a telephone number right at the top of the page.

A patient for whom information becomes available after discharge, responsible clinicians are still responsible for the labs they order.

A patient can be reached, his provider can be called, a pharmacy can be called for a prescription to be provided that's a safe prescription for the patient.

Q Dr. Genecin, do you have an opinion as to whether or not the use of Ciprofloxacin was appropriate because of the severity of Mr. Lariviere's illness, during his admission to Lahey on May 31st through June 2nd?

A I do have an opinion, yes.

Q And what is that opinion?

A I agree that he needed to be admitted to the hospital for IV antibiotic therapy.

I do not agree that a fluoroquinolone was the safest or best

or only antibiotic choice. A perfectly acceptable alternative would have been ceftriaxone or cefepime, a penicillin with a penicillin ace inhibitor; a variety of other routinely prescribed medications used in antibiotic therapy in hospital settings.

So, there was no reason that it was either the best or the most effective, because that's not true. And there was a black box warning.

And I should add that when doctors prescribe, using electronic systems in hospitals, a window comes up that gives you a warning when there's a box warning. So, you have to ignore that in order to prescribe a medicine for which there's a drug interaction.

So, I mean, there's no way that that could be within the standard of care.

Q But the decision that had to be made in the emergency room had to be made before the antibiogram data was available?

A Right, but it wasn't before the information about chronic prednisone therapy was available. The fact of chronic prednisone therapy meant that for Mr. Lariviere's urinary tract infection, a fluoroquinolone was not a safe or good choice.

Q Dr. Genecin, do you have an opinion as to whether or not the deviations from the standard of care that you've described were a substantial factor in Ronald Lariviere developing bilateral tendon rupture?

A Yes.

Q And what is that opinion?

A Well, my opinion is that Ciprofloxacin was an important contributing factor to tendon rupture, and that the fact that Mr. Lariviere was taking prednisone put him in a category of patients who tended to be covered by that black box warning; that that was with a high degree of medical probability the cause of the tendon rupture.

Q And what's the basis for that conclusion, Doctor?
A Well, aside from my education, training, experience, the data that we've looked at, the Dear Doctor Healthcare professional letter, journal articles, warnings that come up in prescription system, I'm not sure what else you're asking.
Q Did Mr. Lariviere, according to the records you reviewed, have a history of any tendon injury before coming to Lahey on the 31st of May?
A No, he did not.
Q And does Exhibit One relate to treatments that he received at Lahey after he noticed some stiffness in his legs?
A Yes, the history is included, including procedures that he had to undergo because of tendon rupture.
Q And did the other doctors who treated Mr. Lariviere after his discharge discuss their impression concerning what

was the cause of his injuries?

A Well, when you develop tendon problems, then Bactrim was substituted, because it was recognized that Cipro was a cause.

And the surgeons, of course, that operated on his tendons, recognize that the tendon injury was due to the fact that he was on Cipro and chronic steroid.

Q Doctor, would you turn to page 94 of Plaintiff's Exhibit One?

Is this a record of Mr. Lariviere's visit to the Lahey on June 6th of 2009?

A Yes, correct.

Q And --

A This is the visit -- I'm sorry, I'll wait for the question.

Q On page 98, would you look at the middle of the page where it says Clinical Impression?

A Yes.

Q It says, "Right lower extremity pain and left lower extremity pain (medication

induced."

What does that impression mean?

A That means that the complication of tendon injury, tendinopathy, from Cipro, was recognized, and that the problem that Mr. Lariviere was presenting with before he actually ruptured his Achilles tendons was already recognized to be due to the fact that he'd been given Cipro in the context of long-standing prednisone therapy.

Q Would you look at page 71 of Exhibit One?

Is that a note that was made by the orthopedic physician at Lahey concerning Mr. Lariviere's coming to Lahey on July 1, 2009?

A I think I misunderstood the page number.

What number?

Q Oh, I'm sorry, 172. Or I'm sorry, 171 is the page.

A Yes.

Q Is that the record of his June 23rd, 2009 visit?

A This is an orthopedic surgeon, Paul Smiley, M.D. And Dr. Smiley saw him the day after he ruptured his right Achilles tendon.

Q And did Dr. Smiley express an opinion as to what the cause of those tendon ruptures were?

A Yes. Of course, he had already had a left tendon repair.

Dr. Smiley stated, “I think it is a combination of being on steroids and Cipro he was taking, which weakened his tendons. That is why he has bilateral Achilles tendon ruptures.”

Q Dr. Genecin, when Mr. Lariviere testified yesterday, he used a chalk to show what his history of prednisone use and corticosteroid use was.

MR. CLAPP: May I show that to the doctor, Your Honor?

THE COURT: Okay.

BY MR. CLAPP:

Q Doctor, do you see that that chalk refers to the dates that he was on

prednisone and the dates that he received corticosteroids?

A Yes.

Q It looks like between ‘83 and ‘96, there was a Cipro prescription in June -- June 11th of ’93, while he was on prednisone?

A Yes.

Q What’s the significance of that? Or what was the risk of that incident?

A Well, remember that that’s many years before the black box warning. It was an instance in which he was on chronic steroids and used Cipro without injury, as will happen. It doesn’t happen with every exposure to Cipro, but it also doesn’t mean that he was safe from it in the future.

Q Is age a risk factor in that combination of drugs?

A It is, and being 41, of course, it makes the risk less than 57. The risk goes up with age, and so, age is an important risk factor.

Q And would you look at number two on that

timeline? Much Cipro from 11/19/96 to 3/16/05; I believe the testimony was, it could have been as much as 1,600 tablets of Cipro during that time?

A Yes.

Q What would the significance of that course of Cipro have been?

A Well, not much significance, in the sense that he was not using steroids at that time. He did not experience adverse tendon effects from that long course of Cipro.

Q And would you look at number three, Levaquin?

A Yes.

Q What was the significance of that, in terms of risk?

A Well again, it’s before the black box warning, but on prednisone, Levaquin, levofloxacin, it’s like Ciprofloxacin, and there was an increased risk that he would experience tendinopathy as a consequence of chronic steroid use, when he received Levaquin.

Q And would you look at number four? Five days of Cipro in August of 2008?
A I'm sorry? What's the --
Q I'm still on the timeline, I'm sorry.
A Yes.
Q And I'm looking at parenthesis four, Cipro, five days, age 56.
A Well, he was not on prednisone at that point, so the issue with the black box warning also wasn't yet published. He did not have any problem with it at that time, but he was not on chronic corticosteroids at that time.
Q Did you review the record concerning that instance where he was prescribed Cipro at urgent care in Rhode Island?
A Yes.
Q And does that record reflect that he was not on Cipro at that time?
A It listed his medications. It did not list prednisone, which to me was an indication that he was not taking prednisone at that time.
Q Doctor, there's an Exhibit, which is

Defendants' Exhibits, and its Tab F.

MR. CLAPP: May I show it to the witness, Your Honor?

THE COURT: Yes. Do you have that book in front of you?

DR. GENECIN: Is it the black notebook?

THE COURT: Yes.

BY MR. CLAPP:

Q Yes, that's it. Tab F in that notebook. Page 166B.

A Yes.

Q Is that the record concerning Mr. Lariviere's visit to the urgent care when he was prescribed five days of Cipro, at age 56?

A Yes.

Q And can you point out to the jury where the prescriber listed the medications he was on?

A At the very top, in the middle, there's three sections across the top. First few lines, there's like an address and identifying information on the left.

Then the next column, it states at the top, “dehydrated.” But just under that, it says meds. For unknown reasons, they list Crohn’s Disease there, but they list Lomotil, and a drug called Humira, which is a drug that we give to try to -- as an alternative to prednisone. So, he was off of prednisone.

Q So, those two drugs would be inconsistent, prednisone and Humira?

A Well, I mean it’s possible to take them both at the same time, but he was not taking them both at that time. And it’s unusual to take them together, because you’re trying to use Humira to avoid steroids.

Q Now, the fact that prednisone isn’t listed in that box, does that have significance?

A Yes, it tells me that he was not taking prednisone then.

Q Doctor, when Dr. Creighton and Dr. Berarducci prescribed Ciprofloxacin for

Mr. Lariviere, what should they have known concerning what Ron would want for information in making the decision?

A I think any patient frankly needs his Achilles tendons. We need it to walk and to ambulate.

My understanding is that Mr. --

Q I mean any patient. I don't mean him. But any patient in his position?

A In his position? Well, in a situation where there's no other drug available on a desert island, except for that, a patient should be told to look out for problems with tendons, certainly, and to stop the medication.

But if there's a possibility of informing a patient about the medication and its side effects, you're supposed to tell the patient.

Q Now, Mr. Lariviere testified that he has noticed some changes in his legs since the bilateral Achilles tendon rupture, including his calves getting smaller and difficulty using stairs, going up and

down, uneven ground, climbing ladders.

Are those symptoms connected to Achilles tendon rupture?

MR. REIDY: Objection, Your Honor.

THE COURT: On what grounds? Do you want to be heard?

MR. REIDY: Yes.

THE COURT: I'll see you at sidebar.

(SIDEBAR CONFERENCE NOT TRANSCRIBED)

THE COURT: All right, what we're going to do, ladies and gentlemen, is take our morning recess at this time.

So Doctor, you can step down if you would, please.

(Court in recess at 10:42 a.m.)

(Court reconvenes at 11:06 a.m.)

THE COURT OFFICER: All rise, jury entering.

(JURY ENTERS)

THE COURT OFFICER: Please be seated. Court is in session.

(DIRECT EXAMINATION OF PAUL GENECIN,

M.D., F.A.C.P., CONTINUED)

BY MR. CLAPP:

Q Dr. Genecin, what are the usual physical effects from an Achilles tendon rupture?

A Well, immediate effects may include pain, spasm and shortening of the gastrocnemius muscle and difficulty walking.

Long-term, after a patient has undergone surgery, they really can’t be using their leg until they’re healed, and that’s a variable amount of time, but months.

And they then have a lengthy course of physical therapy in order to recover their gait, their strength, ability to stretch the tendon, and to exercise the muscle in order to shorten -- in order to enough to be able to, for example climb stairs or walk uphill. Tightness or chronic pain, loss of strength and power in the leg are frequent.

Patients don’t have a tendon

that is as good as new and it tightens up on them and they need to go back for therapy intermittently in order to be able to loosen up the tendon and be able to walk and climb without pain and recover as much strength as they can in that calf muscle, which is called the gastroc, the gastrocnemius muscle.

MR. CLAPP: Your Honor, can I approach the witness?

THE COURT: Yes.

BY MR. CLAPP:

Q Dr. Genecin, I'd like you to explain to the jury exactly what an Achilles tendon rupture is and mechanically how it's repaired.

I'll show you anatomical drawings and ask you if those would assist you in describing that?

A Yes. An Achilles tendon is something that we learn in basic anatomy. If you have a picture in front of you, the tendon is a -- basically a fibrous collection of --

THE COURT: They don't have that in front of them.

A Okay.

MR. CLAPP: Could I give it to them, Your Honor?

THE COURT: You want to use this as a chart?

MR. CLAPP: Yes.

THE COURT: Any objection?

MR. REIDY: No objection, Your Honor.

THE COURT: All right. You want to distribute those, please? Is it both of these diagrams? Yes.

THE COURT OFFICER: Your Honor, there is one of each of these?

THE COURT: Yes, please.

THE COURT OFFICER: Okay.

A So, trying to --

THE COURT: Hold on for a second please.

All right. Ladies and gentlemen, you probably heard me refer to drawings such as this as charts. And

that’s a term we use for items that are not in evidence.

This is not an exhibit, but rather it’s a drawing that may help you understand -- better understand the testimony of the witness. And testimony about items contained in charts are evidence.

At the end of this, we’re going to have you return the charts and they won’t be considered exhibits in this matter. Go ahead, Doctor. Why don’t you ask the right question first?

BY MR. CLAPP:

Q Doctor, would you address the description of the Achilles tendon rupture mechanically?

A Sure. Just beginning with anatomy, when you look here, in cross-section, you can see that the calf muscle, sort of up the leg to the left, behind the bones, which are the tibia and fibula, the tendon, if it were intact, attaches to a bone called the heel bone or calcaneus.

So, the other name for Achilles tendon is tendon calcaneus. It's intended to connect the muscles of the calf with the heel. And that muscle is intended to contract and enable your foot to go up, like not pushing down on the pedal, but up from the pedal.

When the tendon is not -- it's not a soft tissue like muscle or fat. It's actually a rather tough, ropey, tendinous or fibrous kind of a structure that's meant to take considerable mechanical stress and is critical for us to be able to walk and to climb.

The rupture of that tendon often happens in sports and in sporting injuries and recovery is -- involves a surgical procedure to reattach it.

In a situation where a patient is on chronic corticosteroids, it slows healing and it weakens our tissue so that the kind of ability to heal for a man pushing 60 with a tendon rupture, on chronic steroids, is a very different

proposition from a 24-year-old basketball player in terms of ability to bounce back.

The repair is shown on the second page. And I will make a plea here. I am not a surgeon or an orthopedist. I do not do these repairs.

But what it basically shows you is that the surgeon has to expose the ends of the tendon where it has ruptured and put them back together, doing a tailoring job basically using suturing.

And you can understand that in a tissue that is not richly vascular, it doesn't have lots of blood supply, the healing is slow and the tendon that the patient ends up with is not as good as the tendon that he started out with.

Q Doctor, I believe you said that Mr. Lariviere went to Lahey on the 31st of May 2009 because he was concerned about complications from his recent heart surgery?

A Well, he was feeling sick, and that was

their first hypothesis, was that there was some complication of the surgery.

Q Does the record reflect that he was seen by a cardiothoracic specialist at that time?

A Yes. It reflects it both in the ER note, where a discussion with the cardiovascular surgeon is documented, and also in the discharge summary.

But I confess, I've had trouble finding any actual written consult note of that hospitalization.

Q Could you look at page 2 of Exhibit 1 --

A Page 2.

Q -- in the large book?

A Is Exhibit 1 the black book?

Q The big one.

A Big blue book?

Q Blue book. Blue for you.

A I'm sorry, page 2?

Q Page 2. Is there a reference to cardiothoracic surgery?

A Yes. This is the discharge summary, and this is the summary of the hospital

admission to Lahey Clinic from May 31st to June 2nd, 2009.

And if you look where the text starts, there is a first paragraph beginning History of Present Illness, then a second paragraph, then in the third paragraph, on the second sentence, after the hydration that he got and Cipro, then CT surgery, which is cardiothoracic -- that's a familiar abbreviation for cardiothoracic surgery -- was involved in patient's care.

They evaluated him while he was in the Emergency Department given his recent history of cardiothoracic surgery. A CT scan -- that's computer -- CT then is computerized tomography, it's not cardiothoracic.

But that's CT scan of the thorax was performed to rule out any involvement of aortic valve for endocarditis, which is infection on the heart valve, given the patient's history of recent procedure and fevers.

And there also were no findings of problems in the lungs. That paragraph goes on to say that they did note some problems with the kidney and that led to the diagnosis of pyelonephritis, which is a kidney infection.

And, fortunately, the heart valve and the aortic graft were in good shape.

Q And, Doctor, would you look at page 40 and tell me if there is another reference to the cardiothoracic consult that occurred?

A Yes. This is an ER note in which the ER physician documented basically under -- towards the bottom, it says progress and procedures, then ED, which is Emergency Department, course. And towards the end, “D/W CT Surg,” means discussed with cardiothoracic surgery. And then it says, “We’ll see him in the Emergency Department.”

Q And does it say, “No clinical findings

of --

A "Of endocarditis." Endocarditis is a heart valve infection. Patients with a new heart valve are at risk of infection, and that's called endocarditis.

Q Doctor, would the suspicion of kidney infection affect a physician's choice of antibiotic in Ron Lariviere's situation?

A Yes.

The kinds of bacteria that affect the kidney or urinary tract are different, for example from the kinds of bacteria that cause respiratory infection, wound infection, other kinds of infection.

So, the choice of antibiotics would be guided with respect to what the likely source of infection was and then covering for a spectrum of possible infecting organisms, treating empirically, that is making a best guess, until culture information comes back.

Q How would Cipro fit into that analysis?
A Cipro, for a patient who is otherwise healthy and not taking chronic steroids, is a great choice. It's a drug of choice.

It's a first-line drug, as fluoroquinolones in general are, for urosepsis. But, as I said, there are some red lights there in that and not every patient is a candidate for fluoroquinolones.

And when they are not, we have, in the hospital pharmacies, a host of other antibiotics of equivalent value in terms of their effect on infection in the kidney.

Q Thank you, Doctor. I have no other questions. Mr. Reidy does, I'm sure.

MR. REIDY: Your Honor, I'd like to offer at this time what was previously marked for identification as Exhibit A. It's the defense --

THE COURT: I assume no objection to Exhibit A becoming a full

exhibit?

MR. CLAPP: One of the defendant's exhibits?

THE COURT: Yes.

MR. CLAPP: Fine.

THE COURT: Okay. So, you don't want to do the items individually; you want the book itself to be a single exhibit?

MR. REIDY: It's more convenient, Your Honor. If I could have it as one exhibit, that's fine.

THE COURT: All right. So, Exhibit A will be the --

(Exhibit 7, so-marked)

THE COURT: -- Exhibit 7. Thank you.

(CROSS-EXAMINATION OF PAUL GENECIN, M.D., F.A.C.P.)

BY MR. REIDY:

Q Good morning, Doctor.

A Good morning.

Q And we've never met before, correct?

A Not that I can recall.

Q All right. And just to be clear, you're not licensed to practice medicine in Massachusetts, correct?
A No, I'm licensed in Connecticut.
Q All right. You've never practiced in Massachusetts?
A That's right.
Q And you've never practiced at the Lahey Clinic in Burlington, correct?
A That is correct.
Q Now, without a Massachusetts license, you're not permitted to practice medicine or to practice at the Lahey Clinic in Massachusetts, correct?
A Correct. I would have to obtain a Massachusetts license.
Q All right. And you've never examined Mr. Lariviere, correct?
A Say that again.
Q You've never examined Mr. Lariviere, correct, or participated in his treatment?
A That's correct.
Q And you weren't present in May and June

of 2009 at the Lahey Clinic, correct?
A Correct.
Q And you don’t have any relationship to either Mr. Lariviere or his attorneys?
A That’s correct.
Q All right. Have you ever worked for Attorney Clapp or Attorney Ovoian before?
A No.
Q And it’s a true statement that in May and June of 2009, you didn’t have the ethical or professional responsibility to treat Mr. Lariviere, correct?
A That’s correct. His treating physicians were doctors at the Lahey Clinic.
Q Right. And the only time that you became involved in this case is when you were hired by his attorney, correct?
A That’s right. Mr. Clapp asked me to read the records in 2012.
Q Right. And do you require a retainer?
A Yes. For a new client, I do.
Q All right. And what’s the amount of the retainer?

A One thousand one hundred dollars. That covers two hours of work.
Q And so, if that covers two hours of work, you charge 550 dollars an hour for record review?
A Yes.
Q And do you know if Attorney Clapp found you through you advertising your services?
A No, I don't. I did not, not that I'm aware of.
Q All right. But you do advertise your services as reviewing records and testifying in medical cases, correct?
A I personally do not advertise. I have in the past worked with a couple of firms that help attorneys find experts. And although I'm not currently working with either MedQuest or TASA, those are two that I have over the years taken cases from. I'm not currently.
Q All right. So, in the past, you've allowed other entities to let attorneys know that you're willing to review cases

and testify in medical cases?

A Yes. My understanding is that attorneys commonly look to firms to help them to identify witnesses in various medical fields.

So, in that capacity, I have been approached about cases in the past.

Q All right. And the advertising that MedQuest and TASA have done, identifying you as a witness in medical cases, that was done with your authorization, correct?

A I'm not aware of advertising concerning me specifically. However, I have been referred cases by both TASA and MedQuest, and on occasion I did accept them.

Q Now, in other cases in Massachusetts, you have indicated that you actually do advertise your services, correct?

A I personally don't advertise my services. You know, I'm not sure about companies that I -- like TASA and MedQuest. I don't have ads or a website

or anything of that nature.
Q Now, Doctor, you'd agree that you've testified that you're available through advertising referral services for plaintiffs in medical malpractice cases, correct?
A Yes, I was. As I stated, MedQuest and TASA, they must market to attorneys. I myself don't personally advertise.
Q And you've testified in the past that you've made between 15 and 20 percent of your income from this -- the business of reviewing records and testifying, correct?
A Yes.
Q And that remains the same today?
A Yes, actually, quite very much the same.
Q Right. And you've testified under oath in other cases that you derive substantial income from your work testifying and reviewing records?
A Yes.
Q And I think you explained earlier that you testified in more than half of the

states in the United States?
A Yes, I believe 26 states.
Q And in the past, you've testified under oath that upwards of 90 percent of the cases that you reviewed were on behalf of plaintiffs or the plaintiffs' attorneys, correct?
A No, I think that number pertains to testimony. The number of cases I review at the moment is about two-thirds. And over the years, it's fluctuated, three quarters -- two-thirds to three quarters. That's been quite stable for at least seven or eight years.
Q All right. So, at some time in the past, however, you've testified that 90 percent of the time you review cases it was for plaintiffs?
A Maybe at one point in the past I may have been asked that. But when I look over the long haul, that's not -- certainly not true.
Q As of last year, it was approximately 70 percent, correct?

A That's right.
Q And it remains true today?
A Yes, I would estimate two-thirds.
Q And I think you testified earlier today that the vast majority of the cases that you testified to in Massachusetts have been on behalf of the patient or the plaintiff, correct?
A That's correct.
Q And what percentage of the cases have you testified on behalf of the patient or plaintiff in Massachusetts?
A In -- I'm sorry, what percent --
Q What percent of the cases have you testified in Massachusetts were for the patient or plaintiff?
A That I can recall in Massachusetts, 100 percent.
Q So, you've never provided any testimony in Massachusetts on behalf of a doctor or healthcare provider?
A Not that I can recall.
Q Now, in this case, when you were retained, you knew you were being

retained by a plaintiffs' attorney representing a patient, correct?

A I don't think I knew Mr. Clapp when he first contacted me. However, I would have known in short order, generally from a phone conversation, that he represented a patient rather than a doctor.

Q Right. And Attorney Clapp would have told you that the case involved a situation where the patient had Achilles tendon ruptures, correct?

A I don't honestly remember the exact nature. Sometimes an attorney sends me a case and says please read this and doesn't send any kind of summary or theory of the case.

Other times, I have a written summary and a lengthy statement and a complaint to review. And I honestly don't recall in this case whether I had information already formulated or whether I just had the medical record.

Q All right. It's important for you to

receive the entire medical record before you do your evaluation and render an opinion, correct?

A Yes, although understand that an entire medical record in some cases involves records from remote past that may not be material. But it's certainly important to review all relevant records, all records of that time period that are available.

Q And the opinions that you first made in this case when you were retained and the opinions that you first documented were opinions that you rendered without reviewing the depositions of Dr. Berarducci or Dr. Creighton, correct?

A Well, it's understood in the review of cases that the opinions rendered are provisional, pending additional information, and that an expert always reserves the right to change his opinions based on availability of new information.

And that might come in the form

of additional medical records -- often does -- or in the form of deposition testimony.

And so, when I get additional information, then I have an additional conversation with an attorney about where I am at after having reviewed that new material.

Q Now, Doctor, my goal is to get you finished today without requiring you to come back on Monday. If you can focus on my question, this might go a little bit quicker.

Now, would you agree with me then, when you first documented and wrote your opinions in this case, you did not have the deposition transcripts of Dr. Creighton and Dr. Berarducci?

A I don’t recall exactly.

MR. REIDY: Your Honor, if I may approach?

THE COURT: Yes.

BY MR. REIDY:

Q Doctor, what I’m showing you is an

affidavit of Paul Genecin, M.D. And I just wanted to get to the signature line. I apologize. Is that your signature on the last page on page 14?

A Yes, it is.

Q And the date is August 27th, 2012, correct?

A That's correct.

Q Now, that's before the depositions of the defendants, correct?

A I don't recall, but if you say so, yes.

Q And, also, I think you explained that you were provided with the May and June and subsequent records in 2009 when you first reviewed this case, correct?

A Yes, that is correct.

Q And it was only more recently, towards the end of last year, that you were provided with a complete copy of the Lahey Clinic chart, correct?

A I can't remember exactly the date when I received, so you might have an accurate register of when the materials became available.

I do not, so I have to answer I don't know to dates of when materials became available.

Q When you were first retained in this case, did the plaintiff or his attorney provide you with the information that he had taken Cipro approximately 1,600 times before May of 2009?

A I don't recall whether I knew 1,600 times, but I was able to tell from medical records that he had taken it on frequent occasions in the past. So, that well-known to me.

Q All right. And you would agree with me that if Mr. Lariviere was interested in obtaining the information regarding the side effects of Cipro, that one of the sources of information would be the doctors that had prescribed the medication over the years, correct?

A That's one source, sure. You'd expect the doctor to be able to talk knowledgably about side effects of drugs.

Q Right. And another source of the information was the written instructions and warnings that the retail pharmacies included with the prescriptions that were written by the doctors, correct?
A Yes.
Q And there is no dispute in this case that Mr. Lariviere had that written instruction when he received the Cipro in the past, correct?
A It's always given with prescriptions. Patients always get some -- an enclosure with medication information.
Q Right. And that's the law?
A My understanding, yes.
Q And there is no doubt in this case that Mr. Lariviere had received those written instructions and warnings relative to Cipro?
A Not that I know of.
Q Now, as far as appearing today and testifying in court today, what's your charge to plaintiff?
A Seven thousand dollars.

Q And that's a flat fee?
A Yes.
Q And that would be seven thousand dollars a day?
A It's for 24 hours.
Q And does that include your travel expenses?
A My travel expenses were covered by Mr. Clapp, so that 7,000 dollars does not include travel expenses. But that -- travel expenses are included in what I bill.
Q All right. So, there would be the flat fee of 7,000 dollars for an appearance fee?
A Yes.
Q Plus whatever the travel expenses are to get you here?
A Yes.
Q And approximately how many hours did you spend reviewing this case?
A I don't recall. I'd have to look at my billing record. In terms of preparation for trial, four hours.

Q And you'd agree with me as far as your business of reviewing records and appearing at trial and testifying, that that 7,000-dollar fee is a significant portion of the money that you make reviewing cases and testifying?
A It is. There aren't very many trials compared to the number of cases one reads, and many states require reports, so -- many states require depositions, so it's variable from state to state.
Q And I think you explained earlier that you are not an emergency room physician?
A That's correct.
Q All right. You're not specialized in Emergency Medicine?
A Correct.
Q And you have never been board-certified in Emergency Medicine?
A Yes.
Q And you've not supervised residents in the emergency room setting?
A No. I've certainly had ER residents rotating in medicine on my service, but

I do not supervise and haven't since I was a resident, when I trained internists, were the doctors in the ER. ER Medicine became a specialty subsequently.

Q All right. My question is a little bit more specific. You have never had the role of an attending in the emergency room setting that had the responsibility to supervise an emergency room resident?

A Correct.

Q And you don't hold yourself out as an expert in Emergency Medicine?

A That's correct.

Q And you'd agree with me that you're not qualified to work in an Emergency Department even as an internist?

A I'm not sure how to answer that. I regularly admit patients from an emergency room.

When I work in the hospital, a patient like Mr. Lariviere would be someone I would regularly go to the ER to see and admit and do so and enter

orders in the ER. So, I'm not sure what you mean by your question.

Q Now, you were up in Massachusetts last year, correct?

A Yes.

Q You testified in Lawrence?

A I can't hear.

Q Did you testify in Lawrence?

A I can't remember the town, but I do remember I was here.

Q All right. You were retained by an attorney, Michael Harris?

A Yes.

Q All right. And you were asked questions during that trial under oath as to whether or not you were qualified to give opinion testimonies as to an emergency room physician, correct?

A I don't recall the specifics. If you give me the specifics, I'll -- you can -- it may jog my memory.

Q The name of the case was *Abegg versus Esdale*; does that refresh your memory?

A I need to look that up. Yes.

Q And you testified in court under oath on September 24th, 2015?
A I did.
Q And you were asked, “And I’ll repeat the question: And you’re qualified to work in an Emergency Department as an internist, aren’t you?”
Answer: “No.”
Did I read that correctly?
A Yes. I think the context, though, was, was I qualified as an internist to work as an ER physician, and the answer is no to that. I’m certainly qualified as a physician to walk into an ER in a state where I’m licensed and see a patient.
Q Now, you’d agree that with seeing a patient in the emergency room, you would defer to an emergency room expert to determine whether they met the standard of care?
A Yes. I would not reach out. But, yes, I would anticipate in an ER case that, in general, that there be an ER doctor serving as an expert relating to that

doctor's care.

Q Well, last September, you specifically testified that, "I would defer to an ER expert to determine whether they met the standard of care," correct?

A Yes.

Q And that's because you're not an Emergency Medicine physician?

A That's correct.

Q And that's because you yourself are not qualified to work in an Emergency Department as an emergency room physician?

A Well, I would leave that to you, I guess, to decide. I'm certainly qualified to opine about the prescription of a medication that a variety of different types of doctors prescribe.

Q Doctor, I understand what you're trying to say, but if you can just focus on my question, we can get through this.

A I'm not an ER doctor and I don't do ER cases as an expert because I'm not an ER

doctor.

Q And you're also on record in Massachusetts under oath that, with respect to standard of care, you don't go beyond your own field?

A I don't go beyond --

Q Yes or no, Doctor?

A It's not a yes or no answer.

Q You can't answer that question?

A I can answer it, just not yes or no.

Q You can't answer it yes or no?

A That's correct.

Q Now, you'd agree with me that in this particular case, when Mr. Lariviere presented to the Lahey Clinic on May 31st, 2009, he was examined by an emergency room resident, correct?

A That is correct.

Q And that was Dr. Allison Sullivan, correct?

A Yes.

Q And the records clearly reflect that Dr. Sullivan saw and examined and spoke with Mr. Lariviere, correct?

A Correct.
Q And you also agree with me that the records that you reviewed in this case indicate that it was Dr. Sullivan who ordered the Cipro for Mr. Lariviere, correct?
A Yes.
Q And as a licensed M.D., even if you're a resident, you're authorized to order prescriptions such as Cipro, correct?
A Yes.
Q Now, in this case, you haven't expressed any criticism of Dr. Sullivan, correct?
A I haven't been asked, but --
Q You have not testified under questions from Attorney Clapp that Dr. Sullivan did anything wrong?
A That's correct.
Q And as far as the responsibility of an emergency room attending supervising a physician, you've already explained that that's not something that you've ever done before, correct?
A No, I'm not an ER attending supervising

ER residents. I'm an Internal Medicine resident supervising Internal Medicine residents and other kinds of residents, including ER residents rotating on my service.

Q So, in our situation involving Dr. Creighton involving the standard of care of an emergency room physician in the emergency room setting for a patient that presents to the emergency room, you'd agree with me that you'd defer to the opinions of an emergency room specialist to evaluate that care?

A Yes, in general, that's true.

Q And you understand in this case that Dr. Creighton has practiced Emergency Medicine for approximately 30 years, correct?

A Yes.

Q And that he's board-certified?

A Correct.

Q He's been recertified a number of times?

A Yes.

Q And that he's been involved in the

teaching of medicine for most of his career, correct?

A Yes.

Q Now, he's one of those Emergency Department Emergency Medicine experts that you would defer to as far as what the standard of care is in the emergency room setting, correct?

A Yes. In many areas of emergency room medicine, there is very little or limited overlap with Internal Medicine. In areas where the --

Q You've answered the question, Doctor. Now, the same way you don't represent yourself to be an emergency room physician, you don't represent yourself to be an Infectious Disease expert, correct?

A That's correct.

Q Now, an Infectious Disease expert is a doctor who has specialized training in the area of infections, as well as the treatment for such infections, correct?

A Yes, with the understanding --

Q Yes?
A -- that an Infectious Disease physician is an internist first, and that considerable amount of Infectious Disease care is provided by internists.
Q All right. Now, my question to you is, you're not an Infectious Disease expert, correct?
A That's correct.
Q All right. And you're not board-certified in Infectious Diseases, correct?
A Yes. Those are different ways of asking the same question.
Q Right. And as far as a specialist in Infectious Diseases, someone who is board-certified in Infectious Diseases, you would agree with me generally that that type of a specialized physician would have specialized knowledge regarding infections and the treatment of infections, correct?
A That's correct.
Q And in complex cases, even in your own

practice, it would be appropriate to defer and consult with an Infectious Disease expert in situations involving infections and treatment of infections, correct?

A Yes. And I do collaborate with Infectious Disease physicians regularly.

Q And in the situation involving a complex infection, you'd agree with me that it would be appropriate to defer to a board-certified ID specialist in the evaluation and treatment of that patient, correct?

A It may be appropriate to do so. It's not invariably necessary to do so. I don't reflexively refer to an ID expert on all questions. I deal with ID matters within my own field of expertise comfortably and don't use ID physicians for that.

Q All right. My question is, with respect to complex infections --

A It depends on the complex infection. There are some where I feel fine to

manage. I use an ID physician in others.

Q All right. In situations that you believe are complex, --

A Yeah.

Q -- you would refer to an ID specialist, correct?

A In situations where I have a specific question for a consultant, then I obtain a consultant. Where I don't have a question for a consultant, generally I do not get a consultant.

Q Now, on a different matter, you'd agree with me that the FDA doesn't create the standard of care and put it in a book for you to review and to apply to all patients, correct?

A That's correct.

Q You have to, you're required to -- to comply with the standard of care as to examine the patient, speak with the patient, apply your education, training and experience, and come up with what you believe is the best plan of course

of treatment, correct?

A Yes.

Q Right. And in doing that, the physician has a fair amount of judgment as far as what the physician may believe is the best course of treatment for a specific patient, correct?

A As long as a doctor uses judgment within the standard of care, then a doctor may take alternate paths to the same destination. A doctor never has the option to use judgment to do something substandard. That's not exercising judgment.

Q All right. Now, going back to the FDA, the Federal Drug Administration, you'd agree with me that the Federal Drug Administration regulates how the retail pharmacies and manufacturers of prescription drugs must include warnings and instructions on the prescription drugs that they dispense, correct?

A That's correct. The Food and Drug Administration does regulate labeling

and does regulate how drugs are prescribed.

Q Thank you. I think I was calling it the Federal Drug. The Food and Drug Administration.

And so, if we look specifically to what you were talking about, Exhibit 6, the letter dated October 22, 2008, now --

A I don’t have it in front of me, but --

Q I think it’s --

A That became an exhibit it’s over here.

Q Now, just to look at the specific language of Exhibit 6, if you look at the second paragraph on the first page, it goes, “To reinforce the warning information that is already included in the prescribing information for fluoroquinolone antibiotics.” Did I read that correctly?

A Yes.

Q So, you’d agree with me that the existing written materials for Cipro included information regarding tendon

rupture?

A Yes. Reports about tendon rupture preceded the development of the black box warning and does -- that information was included in the information before it rose to the level of a black box warning.

Q So, for many years before 2008, the written material that was included with Cipro included information regarding tendon rupture?

A That's correct.

Q All right. So, if Mr. Lariviere had been interested in the side effects of Cipro, that would have been an appropriate source of information to get information about that, correct?

A Sure. But the *Physician's Desk Reference* is for doctors. Patients can access it, but PDR, where these are published, is a *Physician's Desk Reference*.

Q No. My question was, the information that the retail pharmacy provides with

the drug, that would include the risk of tendon rupture before 2008, correct?

A Yes.

Q So, that's not the PDR, that's the pieces of paper that the retail pharmacy would give to Mr. Lariviere with the prescription of Cipro. Those pieces of paper would have information about tendon rupture associated with Cipro, correct?

A Yes.

Q And one of the reasons why the FDA requires Bayer to have that instruction is to allow the patients to be aware of those side effects, correct?

A Actually, it's primarily for prescribers. Yes, it's also for patients, but if you look at those, the very large amount of small print creating every -- with every reported thing that's ever happened with the drug, so not a useful --

Q Let's go down to the last paragraph, Doctor.

A Sorry?
Q Let’s go down to the last paragraph of the page.
A Yes.
Q “To ensure that you and your patients are fully informed.”
A Yes, that’s the reason for the black box.
Q Right. And that’s the reason why the FDA requires the retail pharmacies to have written information about tendon rupture in the written materials even before 2008, correct?
A Yes, but this -- the reason for the black box, the boxed warning --
Q We’ll get to that. I’m talking about the general information about tendon rupture was available before 2008 in the written materials that the retail pharmacy would provide to patients when they picked up Cipro?
A Yes. My recollection, though, was that it was embedded in a lot of other text. It wasn’t picked out in a black box,

which is how important warnings are conveyed in prescribing information.

Q Mr. Lariviere hasn't presented you with all the written instructions that he had been provided over the years regarding Cipro, correct?

A No.

Q You don't know what form they were with him, correct?

A Yeah. Well, the information is exactly the same information as how the PDR read. It's the same exact language literally.

It's available for Cipro up until the black box warning. So, what he was able to see, because it was provided by the pharmacist, is identical to what the doctor read in the PDR.

Q Now, let's go back down to the actual warning that you've been talking about this morning. That's the very bottom of that first page.

A Yes.

Q And it's bold and it's included within a

box, correct?

A That's right.

Q Now, "Warning: Fluoroquinolones, including Avelox/Cipro, are associated with an increased risk of tendinitis and tendon rupture in all ages.

This risk is further increased in older patients usually over 60 years of age and patients taking corticosteroid drugs and in patients with kidney, heart, or lung transplants. See warnings."

I read that correctly, correct?

A Yes.

Q And nothing within that box shows any indication that Cipro should not be ordered or prescribed for any patient, correct?

A No, nothing within that box did, no.

Q There is no language to that, correct?

A Not in the box, no.

Q It doesn't say that Cipro should not be ordered or prescribed, correct?

A That's correct.

Q And, Doctor, you understand that you had to review what you're expected disclosure was in this case and that that would be filed with the Court to advise all the parties what your expected testimony was going to be, correct?
A Yes.
Q And you reviewed your disclosure in this particular case, correct?
A Yes.
MR. REIDY: I'm just referring to Exhibit A, page 4.
MR. CLAPP: In the pretrial?
MR. REIDY: Pretrial. May I approach, Your Honor?
THE COURT: Yes.
BY MR. REIDY:
Q Let me just show you what's been marked as Exhibit A -- it's not in the book -- entitled Supplemental Answers of Ronald Lariviere to Defendants' Expert Interrogatory 16. And it identifies you as an expert, correct?

A Correct.

Q And then if we go to page 4, it indicates, “Dr. Genecin will testify that in May of 2008, the average qualified physicians prescribing ciprofloxacin and corticosteroid medications and pharmacists and pharmacies filling orders for these drugs should have known that since 2008, the FDA mandated the Bayer HealthCare Pharmaceuticals publish a black box warning (‘box warning’) placing healthcare providers on notice of (addition of boxed warning and medication guide regarding tendinitis and tendon rupture) ‘and patients treated with ciprofloxacin at older age, on oral corticosteroid drugs, and renal disease, and following solid organ transplants.’”

And at the top, it was in May of 2008; that’s what’s written there, correct?

A That is what’s written there.

Q All right. And if we turn to page 11, is that the signature of Ronald T. Lariviere?
A Yes.
Q And above it, what's written above it?
A "Signed under the penalties of perjury this 13th day of August 2015."
Q And then if we turn the next page, there is something called a Superior Court Rule 30B Certification?
A Yes.
Q And that's signed by you?
A Yes.
Q It certifies that the disclosure accurately states the subject matter upon which you're expected to testify, "The substantive facts, and the opinions in which you expect to testify, and actually summarizes the grounds for each opinion upon which I expect to testify at trial," correct?
A Yes.
Q So, in the disclosure that you provided to this Court -- and when you reviewed

that disclosure and you signed that certification, you knew it was important to be accurate and truthful in that disclosure, correct?

A I think you're alluding to a mistake relating to the date, which was October rather than May. Yes.

Q Let's focus on my question.

A It is important to be accurate, and there is that error, and I'm sorry for it.

Q In the disclosure, you indicated that as of May of 2008, that warning was available, correct?

A Right, October.

Q In the disclosure that you signed, reviewed, and Mr. Lariviere signed, you indicated that that warning about the tendon rupture was available as of May of 2008, correct?

A Yes.

Q Now, you're aware that Mr. Lariviere was seen at the Urgent Care Center on August 1st, 2008, correct?

A Are you referring me to a specific page? Because I don't have dates in mine.
Q You can put the big jury notebook to the side. We're going to refer to the smaller one. And if you can -- Tab F, page 166B.
A Yes.
Q Now, that's the urgent care records that -- for when Mr. Lariviere went to the Urgent Care Center on August 1st of 2008, correct?
A Yes.
Q Now, at that point in time, regardless as to whether or not you made an error with the disclosure and signing it, at that point in time, it was also known that Cipro could cause tendinitis and tendon rupture regardless of the black box warning, correct?
A Yes.
Q And that would be information that the pharmacies would provide regardless as to your error as to when the black box warning came out?

A Yes. It would have been the pre-black box warning, in which it was embedded in a lengthy list of possible side effects.
Q It was known to physicians at that time that Cipro can cause tendinitis and tendon rupture, correct?
A Certainly not at the level that it became now when it became a black box warning.
Q All right. Well, focus on my question. It was known by physicians as of August of 2008 that Cipro could be associated with tendinitis and tendon rupture, correct?
A Certainly not at the level that it became known in October 2008 with the black box warning.
Q Let's focus on my question. Would you agree with me that it was generally known by physicians as of August 1st, 2008, that Cipro would be -- could be associated with tendinitis and tendon rupture?
A It was known to some physicians. It was

not generally known in the sense that it had not been picked out as a black box warning.

Doctors reading literature about Cipro looking into it might have been able to find information on it. But the black box warning was the point at which it was up in neon lights.

Q So, August 1st, 2008 --

A Yes.

Q -- in Cumberland, Rhode Island.

A Yes.

Q That's not an exotic island somewhere, correct?

A No. It's a state nearby.

Q All right. And you haven't expressed any criticism of either the nurse practitioner or the supervising physician at the Urgent Care Center who prescribed Cipro for Mr. Lariviere on August 1st, 2008, correct?

A That's correct. It looks appropriate under the circumstances. He was not on steroids.

Q But he had been on steroids on and off for the last 20 years, correct?
A Chronic steroids means on steroids, not off steroids.
Q He's been on and off steroids since approximately 1983, correct?
A That is correct. Black box warning referred to patients taking steroids, not patients who at one time took steroids.
Q I'm not talking about the black box warning, Doctor. Just focus on my question, all right?
A Yes.
Q All right. I know what you want to say, but let's focus on this.

Now, based upon the nurse practitioner and/or the doctor that saw Mr. Lariviere on August 1st, 2008, that doctor or nurse practitioner made a decision that Cipro was the appropriate medication to treat Mr. Lariviere on that date, correct?
A Yes.

Q And Cipro was prescribed?
A That's correct.
Q And to pick up that Cipro, Mr. Lariviere would have to go to the pharmacy, correct?
A Generally.
Q Mr. Lariviere went to the pharmacy to pick up the Cipro on August 2nd, 2008, correct?
A I don't have the exact date, but I'll take your word for it.
Q Well, there's the Rite Aid records if you want to look at them.
A I'm not debating. I just don't have it committed to memory.
Q Do you have any reason to disagree with me that Mr. Lariviere obtained the Cipro at the Rite Aid Pharmacy on or about August 1st, 2008?
A No, of course not.
Q All right. Now, when Mr. Lariviere picked up the prescription at the Rite Aid Pharmacy, he would be provided with written instructions and warnings,

correct?
A Yes.
Q And whether it’s the old warnings or the new warnings, those warnings would include information regarding tendinitis and tendon rupture; can you answer that yes or no?
A Yes.
Q Now, if we believe what you wrote and what was written in the disclosure, what you reviewed to make sure that it was accurate, what you certified was accurate and truthful and what Mr. Lariviere certified was accurate and truthful, the black box warning would have been available as of May of 2008, if we believe what you wrote and submitted to this Court through the plaintiff, correct?
A Yes. But that was in error and he wasn’t on steroids.
Q If we believe what you had been disclosed to talk about, the black box warning would have been available as of

August 1st, 2008, correct?
A If what was written in error was -- had in fact been true, yes, that would have been true. It wouldn't have applied because he wasn't on steroids, but that would be true.
Q Now, when Mr. Lariviere presented to the Lahey Clinic Emergency Department on May 31st, 2009, and when he was evaluated, you would agree with me that there was a serious question at that point in time whether he had a potentially life-threatening infection?
A Yes.
Q And it would be appropriate to consider a potentially life-threatening situation when the emergency room staff evaluate, speak with consultants, make plans of care, correct?
A Of course.
Q And that's because -- I don't know if you ever heard worst first? Have you ever heard that in the medical context?
A Worst first is a phrase that applies to

differential diagnosis, yes.

Q All right. So, the basic proposition is, is that you would look at what's an imminent threat to a patient's life or survival and consider and manage those before considering those that might be less minor that could be repaired later on, correct?

A That's right.

Q Now, in this particular case, it would be appropriate for all the physicians in the emergency room setting, including Dr. Creighton, if they believed that there was a potentially life-threatening infection with Mr. Lariviere, it would be appropriate for those physicians to use what they believed was the best medication to treat that infection, correct?

A Yes, understanding the best, though, includes a consideration of the weighing of risks and benefits and not using drugs that would harm a patient because of specific contraindications.

Q Let's address that. Now, in this particular case, the injury that Mr. Lariviere claims to have is the Achilles tendon rupture, correct?
A I guess more than a claim. It's a fact. But, yes, it did happen, Achilles tendon rupture.
Q Right. The claim for damage is that he had the Achilles tendon rupture.
A I understand, yes.
Q Correct?
A Yes.
Q Now, the Achilles tendon rupture versus death from septic shock --
A I'll take the rupture. However, that's an artificial choice.
Q No. But as far as weighing the risks and benefits and evaluating a patient in the emergency room setting, putting the vast weight on saving the patient's life and preventing the patient from dying is absolutely the way to go, correct?
A Yes, but you're weighting that on a ridiculous statement that only Cipro

would have saved his life, whereas a cephalosporin, --

Q Doctor, focus on my question.

A -- a beta-lactam, --

Q Doctor --

A -- an aminoglycoside would have all done very nicely.

Q Focus on my question, Doctor. I'm talking generally. I didn't mention Cipro, I didn't mention medications or any specifics in mind. So, the basic proposition in a potentially life-threatening situation, weighing the patient's survival and preventing the patient from getting into septic shock, that would vastly outweigh the potential rare complication of a tendon rupture that could be repaired, correct?

A Wrong. Absolutely wrong.

Q So, you would weigh tendon rupture versus the patient dying?

A Not at all. What you're saying is that the --

Q No, no.

A -- only antibiotic available is a fluoroquinolone. What I'm saying is --
Q Doctor.
A -- a life-saving antibiotic is mandatory.
Q Focus on my question, please. Focus on the general proposition that I'm giving to you.
A A general proposition is that an antibiotic and admission were appropriate and mandatory. I have no difference about that. It's the choice of antibiotic.
Q Now, focus on my question. The general proposition, weighing the risk of death versus the risk of tendon rupture, avoiding the risk of death wins every time, correct?
A No, because there's an artificial distinction. In a situation where a patient --
Q Can you answer that question yes or no?
A -- has contraindications and other antibiotics are available, then save the

life with the other antibiotic.

Q Well, let's focus on my question. All right? I know what you want to say, but --

A A hypothetical where there is only Cipro and no other antibiotic available?

THE COURT: Actually, he didn't mention the word Cipro in his question. You have to listen carefully to the question. If you can't answer it yes or no, then just don't.

DR. GENECIN: Okay.

THE COURT: Okay?

BY MR. REIDY:

Q And if you're having trouble understanding, I can repeat it. Just let me know.

The general proposition, avoidance of death through an infection spreading, becoming septic shock, multi-organ failure, versus the risk of tendon rupture.

A I'll choose the save my life over the tendons, definitely.

Q In every situation, that's what you would choose?
A Personally, I would, yes.
Q And that's the appropriate thought process that a physician is supposed to make when a physician is considering what treatment plan to pursue, correct?
A Yes.
Q And in this case, you just merely disagree with what the emergency room physician believed was appropriate, correct?
A Well, I guess the FDA and a lot of other people also don't agree. It's the black box warning.
Q Do you disagree? You --
A But, yes, I do disagree.
Q All right. Now, in this particular case, you'd agree with me that Dr. Sullivan, who ordered the Cipro, she disagrees with you, correct?
A Yes.
Q All right. Dr. Creighton disagrees with you, correct?

A Yes.
Q And then the patient was admitted, correct?
A Yes.
Q The patient was seen by a resident, a Dr. Norris, correct?
A Correct.
Q Dr. Norris with Dr. Hamway, the attending, made the decision that Cipro was appropriate, correct?
A That’s correct.
Q Dr. Norris disagrees with you, correct?
A That’s correct.
Q Dr. Nichole Hamway, the Internal Medicine attending physician who saw and examined and reviewed the patient with Dr. Norris, she reviewed Dr. Norris’s plan for Cipro and hydrocortisone, correct?
A Yes.
Q And she disagrees with your view, correct?
A A whole series of doctors ignored the black box warning. That’s a fact.

Q Focus on my question. They disagree with you.
A Well, they made a decision that omitted to consider a black box warning.
Q Well, you understand that Dr. Hamway was aware of the risk of tendon rupture when she did this, correct?
A Yes.
Q And so, that's not ignoring it, correct?
A Well, she must have decided to ignore it, right? Consciously disregarding and warning about safety is deciding to use a drug that she consciously knows can cause harm.
Q Doctor, you've read Dr. Hamway's deposition, correct?
A I did, yes.
Q And she believed that the Cipro was the best medication to treat Mr. Lariviere's condition, correct?
A Yes, and she testified to that.
Q Right. And that is what Dr. Norris, a licensed doctor, had determined as well, correct?

A Correct.
Q And then when Dr. Berarducci took over the -- and you agree with me that Dr. Berarducci did not order the IV Cipro and did not order the IV hydrocortisone, correct?
A No, but they were ordered on his watch and he was the attending of record.
Q Well, let’s be more specific. You’d agree with me that Dr. Berarducci did not order the IV Cipro, correct?
A Correct.
Q You would agree with me that Dr. Berarducci did not order the IV hydrocortisone, correct?
A Correct.
Q And that is because Dr. Hamway and Dr. Norris ordered the IV Cipro and ordered the IV hydrocortisone, correct?
A That is correct.
Q And when asked at the beginning of this case by Attorney Clapp, you didn’t even mention Dr. Hamway, you didn’t even mention Dr. Norris, correct?

A Correct.
Q You didn’t express any criticism of them, correct?
A I don’t remember that they came up.
Q All right. You didn’t express any criticism of Dr. Norris or Dr. Hamway when you presented testimony earlier this morning?
A That’s correct.
Q The same way that you didn’t present any criticism of Dr. Sullivan when you were asked questions this morning?
A Well, trainees work under direction, so the attending physicians are the --
Q Focus on my question.
A Yes.
Q Now, if a resident, who is a licensed physician, does what’s appropriate, there would be no reason for the attending to change that, correct?
A That is correct.
Q And that applies to Dr. Creighton, who was the attending in the emergency room. That applies to Dr. Hamway, who was the

attending that handled the admission. And that would also apply to Dr. Berarducci, who was the attending on the subsequent days up until discharge, correct?

A Is that -- the hypothetical is if?

Q If what the residents did was appropriate, there is no need for the attending --

A Then there would be no reason, right.

Q That’s just a general proposition?

A Yes.

Q And also, a doctor or nurse practitioner form the Urgent Care Center on August 1st, 2008, those individuals believed that Cipro was the appropriate medication for Mr. Lariviere, correct?

A They did, yes.

Q And for the 20-plus years that Mr. Lariviere was being prescribed Cipro by Dr. Warner and potentially by Dr. Schutz, those doctors believed that Cipro was safe and appropriate for Mr. Lariviere, correct?

A Yes. All that was while he was not on chronic steroids.
Q Right. And the Cipro hasn't changed. It's the same Cipro that's been from the get-go, correct?
A Correct.
Q And you're also aware that in April of 2009, when Mr. Lariviere was undergoing his cardiac surgery, --
A Correct.
Q -- the valve replacement and the graft, there was an issue with the Foley catheter, correct?
A Yes.
Q And the anesthesia team gave him IV Cipro, correct?
A Yes.
Q And that was appropriate, correct?
A I do not agree that it was appropriate. What I think is that red light was run a number of times. The accident didn't happen until it happened.
Q All right. Let me rephrase the question then. The anesthesia team who ordered

the IV Cipro and gave Mr. Lariviere the IV Cipro in April of 2009 disagree with your point of view?

A Yes.

Q You'd also agree with me that while Mr. Lariviere was in the Emergency Department on May 31st, 2009, the emergency room staff did not prescribe any steroid, correct?

A I don't recall. If they didn't, they didn't. I don't dispute it. I just don't recall.

Q All right. They didn't order any steroid, correct?

A I don't recall.

Q Wouldn't that be something important for you to know if you're going to come here and testify?

A Yes. I'm sure when I read the case, I'm sure I knew it. I just don't recall.

Q All right. So, as you sit here today in front of this jury explaining what you believe this case is about, you can't tell the jury one way or the other

whether Mr. Lariviere was prescribed or ordered for steroids while he was in the Emergency Department?

A It doesn't make any difference and that's why I can't recall.

Q Now, when you received the records and were retained and received your retainer in this case, you had more information available to you than the physicians who were treating Mr. Lariviere at the time had, correct?

A Yes.

Q You had the benefit of hindsight, correct?

A Right, so --

Q No, no. Focus on my question. We'll get through this. You knew at that point in time that Mr. Lariviere survived his infection, didn't have septic shock, and didn't die, correct?

A Correct.

Q And that's a good result just focusing on that aspect of it, correct?

A Correct.

Q Now, the people who were treating Mr. Lariviere at the time, including in the emergency room, including when he was admitted to the hospital, didn't have that benefit, correct?
A No, but they had something else of great importance.
Q No, focus on mine. They didn't have the benefit of hindsight?
A Correct.
Q They did not know that Mr. Lariviere was going to survive the infection, correct?
A They didn't have a reason to think he wouldn't, but, right, they didn't have -- what was going to happen to him in the future was unknowable.
Q Let's go back. As far as evaluating a patient in the emergency room setting, you've already explained that you're not an emergency room physician, you're not qualified to work in the emergency room setting to evaluate those emergency situations, correct?
A Okay. Yes.

Q So, as far as somebody who is trained in Emergency Medicine, that person would be more skilled, more trained, have more knowledge as to those Emergency Medicine situations, correct?
A Yes. But a patient in this condition is admitted to the medical service of doctors like me who come to the ER to see them regularly.
Q I'm talking about the emergency room, Doctor.
A Yeah.
Q Now, you don't work in the Emergency Department?
A That's correct.
Q And we've gone through this before. Because as an internist, you're not qualified to be an emergency room physician in an Emergency Department, correct?
A That's right.
Q And so, when you may or may not get involved in cases is after the patient is admitted?

A Also to evaluate patient. I sometimes don't admit them, but, yes, to evaluate a patient that the ER would like to admit.
Q All right. So, you'd send this patient home?
A Certainly not.
Q And the reason why you wouldn't have sent him home is because there was a significant concern that if they didn't get the infection under control, Mr. Lariviere would be at risk of death?
A My reasons are more specific than that, but, yes, in brief, that's a fair way to sum it up.
Q And he had to have some antibiotic. You just disagree with what antibiotic he should have gotten, correct?
A That's correct.
Q All right. So, as far as presenting Mr. Lariviere with the option of not having any antibiotic, you wouldn't expect any physician in this circumstance to provide Mr. Lariviere with that option?

A That's correct.
Q Not a valid option?
A Not a valid option.
Q And you also would agree with me that with any antibiotics there are risks?
A Yes. There are --
Q Yes?
A -- some risks which are predictable --
Q Focus, focus.
A -- and some that are --
Q Focus on my question.
A -- not predictable.
Q Well, the risk of tendon rupture, that's an idiosyncratic risk?
A Yes, but it's well enough known that it's a black box warning.
Q No. Just focus on my question. You don't know which dose, if any, is going to actually cause tendinitis or tendon rupture. It could be the first, it could be the five thousandth, correct?
A That's correct.
Q There is no rhyme or reason to it as far as predicting which one?

A Which course of antibiotics or which dose exactly, there is no way to know that.
Q With Cipro, if a patient is on it, you can't tell if it's the first or the last that would cause the tendon rupture?
A Right. And you can look at it as a betting proposition, in which case you can hope the patient doesn't have that, but we don't do that in medicine.
Q Focus on my question, Doctor. I didn't suggest that at all, did I?
A Well, you don't use Cipro when we know it might harm a patient because they have chronic underlying contraindications.
Q Focus on my question. Now, with all antibiotics, there are risks, correct?
A Yes.
Q And some of those risks are severe?
A Yes.
Q Some antibiotics work better than others in certain situations?
A Yes.

Q An Infectious Disease specialist would have specialized knowledge as to which antibiotics can work better in some situations than others, correct?
A They may have knowledge to supplement what doctors practicing in ERs and on medical services, yes.
Q And it’s important to know the pharmacological properties of certain antibiotics in order to make a decision as to whether a physician believes one antibiotic versus the other is more effective, correct?
A Yes.
Q Now, you’ve read the depositions in this case, right?
A I have.
Q Now, you know, the doctors in this case, their belief was that the drug that they had chosen was more effective, correct?
A Yes.
Q Now, you just disagree with that?
A Absolutely.
Q All right. Now, with every antibiotic

having a risk -- and you'd agree with me, correct?

A Yes.

Q Particularly with Bactrim, you'd agree with me that that antibiotic is not risk-free?

A No, of course not. No antibiotic is risk-free.

Q All right. Now, with Bactrim, you can have a risk of an anaphylactic reaction?

A Any drug may cause a severe allergic reaction. That's correct.

Q So, any drug can have that?

A Yes, any drug.

Q And with Bactrim, you can also have a simple rash?

A You can get a simple rash or a severe rash. There are many side effects of sulfonamides.

Q I'll call it Bactrim.

A Bactrim is a sulfonamide.

Q All right. And with Bactrim, you could have also what's called Stevens-Johnson syndrome?

A Rarely you can, yes.
Q All right. And that's a potentially life-threatening situation?
A Yes.
Q And you know, similar to not knowing which particular dose of a Cipro may cause tendonitis or tendon rupture, you can't predict with Bactrim whether or not a particular patient, even if the patient had been on Bactrim before, whether that patient could then, at that dose, experience one of those complications, even if it's rare?
A Addressing Stevens-Johnson specifically, since you asked, Stevens-Johnson Syndrome is rare and idiosyncratic. There's no box warning telling doctors to be aware of it in prescription of Bactrim.

If a patient develops a rash, they need to stop their Bactrim immediately, and that dramatically reduces the risk that they'll go on to develop Stevens-Johnson Syndrome. And

that's many other drugs that also have the potential to cause that dreaded complication.

There are some drugs that have a black box warning relative to Stevens-Johnson Syndrome, though, and those drugs, then a patient has to be advised about that possibility, and informed about what to do in the event that a rash occurs.

Q Now, if Mr. Lariviere had been interested in the risks and side effects of Cipro, as of June 2nd, 2009, he could have asked Dr. Berarducci, correct?

A He could have.

Q He could have asked Dr. Tibbetts, who wrote the prescription for Cipro, correct?

A Yes.

Q He could have asked any of the nurses that were involved in his admission, that he needed to be educated and wanted some more information, or please get me the doctor. He could have done that,

correct?

A He could have, yes.

Q Now, you understand that Mr. Lariviere has no memory whatsoever of any conversations that he had at any time while he was in the ER or during his admission to Lahey from May 31st to June 2nd, 2009, correct?

A Yes, I read that in his deposition.

Q All right. And you also know that he did not deny by saying that, that conversations took place, correct?

A That's right.

Q He just couldn't say who said what, what he said, or anything else. He couldn't tell anything about the substance of the conversation?

A Couldn't recall.

Q Right. Now, you'd agree with me that this documentation within the Lahey ER record, that there was a warning given to Mr. Lariviere before he was given the Cipro, correct?

A I don't recall what you're referring to.

You'd have to show me the page.
Q Well, you're not familiar with the Lahey ER records?
A I am. I just don't recall what specifically you're referring to.
Q All right. Well, if an allergic reaction warning was given to the patient, would you consider that to be information that you should know, to be able to talk about today in front of the jury?
A Sure. In drug allergies, it's mandated that drug patients give a history of drug allergies, and that those be recorded in an ER record.
I didn't realize that's what you were referring to, but yes, drug allergies and are you allergic to the drug I'm about to give you --
Q You misunderstood, Doctor.
A -- are part of that.
Q You misunderstood.
A Yes.
Q I'm talking about something different.

In this particular case, you would agree with me that there's documentation in the ER chart that a nurse provided Mr. Lariviere with an allergic drug reaction warning --

A Right.

Q -- before he gave the Cipro?

A Right.

Q You'd agree with me then?

A Yes, he was not allergic to Cipro.

Q Focus on the question. I'm not saying he was allergic to Cipro.

There is reference in the record that an allergic reaction warning was given to Mr. Lariviere; you would agree with that, correct?

A Yes, anytime medicine is given, the patient is always asked, "Are you allergic to the medicine," before it's administered.

Q So, you don't know what Nurse Church discussed with Mr. Lariviere, correct?

A Of course not.

Q All right. And as far as your

understanding of what an allergic reaction warning is, your belief is that that's, "Are you allergic to Cipro?"

That's what you believe that is?

A "Do you have a history of an adverse reaction to Cipro," but tendinopathy is not an allergy.

Q That's your belief of what the allergic reaction warning is; the nurse asking Mr. Lariviere, "Are you allergic to Cipro?"

A That's my understanding, yes.

Q All right. Now, did you review any deposition from Nurse Church?

A I did not read the nurse's deposition that I can recall. I'd have to look.

Q Did you ask Attorney Clapp that that person should be deposed?

A No, it didn't occur to me.

Q Now, at the time of discharge, you would agree with me generally that there's a time when the physician and the nursing staff and the patient got together and

discussed the discharge instructions?
A Correct.
Q And at that point in time, if the patient has any questions, if the patient is asking questions about the medication or how to take it, that’s an opportunity for the patient to let the medical providers know if they have any questions or concerns, correct?
A Yes.
Q Now, in this case, there were discharge instructions, correct?
A Yes.
Q And documented within the discharge instructions was a reference to not take a vitamin, correct?
A Yes.
Q And you would agree with me that it would be important not to take a vitamin when you’re taking -- finishing a course of antibiotics, correct?
A Under some circumstances.
Q All right. Well, if the vitamin binds with the antibiotic, then the antibiotic

is not going to do its job, correct?
A That's correct.
Q And if the antibiotic doesn't do its job, there's a potential that the infection is not fully treated, correct?
A Yes.
Q And if the infection is not fully treated, it can come back?
A It can.
Q And in that situation, it could come back, and it could come back and be worse?
A It could.
Q And that's generally, with a course of antibiotics, as to why a full course has to be given, correct?
A Yes.
Q Now, when you received this case from Attorney Clapp, and I think you may have alluded to it earlier today, by the time of discharge on June 2nd, 2009, Mr. Lariviere was doing well?
A Correct.
Q So, he had improved on the Cipro,

correct?
A Yes.
Q There was no longer, you know, much of a threat that he was going to becoming septic and succumbing to septic shock and dying, correct?
A That’s correct.
Q But what the physicians knew at that time was that the Cipro worked, correct?
A Yes.
Q He was better?
A Yes.
Q At the time that he was at Lahey, he would have been monitored by the nursing staff?
A Yes.
Q Didn’t exhibit any adverse signs or reactions to the Cipro?
A That’s correct.
Q And that’s even at the same time he’s getting the high dose IV hydrocortisone, correct?
A That’s correct.
Q And the IV hydrocortisone, that’s

steroid -- that's mandatory in a patient such as Mr. Lariviere, because of his chronic prednisone use, correct?

A Yes.

Q If he had not received the hydrocortisone, he wouldn't have been able to produce the cortisol, or his adrenal gland may have shut down, and that could be a potentially significant or serious condition, correct?

A That's right. Neglecting to give stress steroids in a patient who is on chronic prednisone will make the patient what's called Addisonian, and we can't let that happen with patients. That's why we give them stress steroids.

Q All right. So, when Dr. Norris and Dr. Hamway had written that order and recommended it, that was good medical thinking?

A Yes.

Q It was appropriate?

A Absolutely.

Q And then same way when Mr. Lariviere was

being considered for the endocarditis related to his prior heart and heart graft surgery, to be concerned that he might have endocarditis, that was appropriate for the emergency room staff to consider, and that was also appropriate for Dr. Norris and Dr. Hamway to consider, correct?

A Yes. You use the term “worst first.” That would have been a worst case scenario, and that was very appropriate to consider and rule out.

Q And it shows that they were attentive to that concern?

A They were.

Q And it showed that, at least with that specific aspect, their thought process was sound?

A Absolutely.

Q And for the emergency room staff and/or the hospital staff to consult with cardiothoracic surgery, that was appropriate?

A Yes.

Q And that shows that they were attentive?
A Absolutely.
Q And that shows that they had the good thought process?
A Yes.
Q Now, when Mr. Lariviere was discharged on June 2nd, 2009, he had not exhibited any signs of pain, or any adverse reaction to the Cipro, correct?
A That's correct.
Q And that's borne out by the records of admission?
A There was nothing in the records to suggest that he had any symptoms, and when he developed symptoms, the time course was after he was discharged.
Q And you understand that some antibiotics in IV form have an equivalent in the oral pill form, correct?
A Yes.
Q And now, some IV antibiotics don't have that corresponding pill form that's as effective, correct?
A IV antibiotics give a higher

concentration faster. So, for patients who are very ill, we use IV antibiotics. Transitioning from IV to oral regimen, some antibiotics have an oral form that you can continue for outpatient use; some don't, in which case you have to choose another medicine.

Q Right. And you know, to consider whether the oral dose is equivalent to the IV, or as close to the IV as possible, that's an important consideration for a physician to make when discharging a patient, correct?

A It has to be an effective drug for the problem. It doesn't have to be the same drug, but it needs to be effective.

And so, of course, completing a course of oral therapy after IV antibiotics, it is important for a doctor to choose a drug and a dose that are appropriate to the treatment of the infection.

Q And the prescription that Dr. Tibbetts made for Cipro at the time of discharge

of Mr. Lariviere, that was for two pills for two weeks -- two pills a day for two weeks?

A Yes, one pill twice a day for two weeks.

Q And he was also provided with the instruction regarding not to take a multivitamin?

A Yes.

Q And within the written discharge instructions, there would be information as to who to call if he had any questions, and that would actually be on the prescription as well, correct?

A Correct.

Q And he wasn’t provided -- well, you would agree with me that he was also provided with instructions regarding prednisone?

A Yes.

Q And that was, start up the prednisone again in seven days?

A I can’t remember. I think he resumes prednisone -- oral prednisone already at discharge. He wasn’t getting IV

steroids at home.

Q All right. So, you would disagree with me that the discharge instructions advise Mr. Lariviere to start up on the prednisone in seven days?

A I need to look at what you're referring to, because our understandings are different.

Q Well, that seems to be a very significant part of the case.

You can't tell the jury without looking at the records right now?

A I know that he was on chronic steroids and was discharged from prednisone.

I'm trying to understand what you mean by taking it in seven days.

Q Do you remember seeing that written in the instructions anywhere?

A I don't recall. I know he was on a steroid. I don't think he went home on IV steroids, an oral antibiotic. That wouldn't make any sense.

Q Well, it's important for you to review the records and be familiar with them

before appearing in court and testifying, correct?

A Yes. All I'm saying is, what you're saying doesn't make any sense to me. So, if you could show me the cite where you're referring to it, I'll be able to understand what you're talking about.

Q All right, if you look in the small notebook, page 138 on Tab D.

Now, you've reviewed that page before, Doctor, correct?

A Page 138?

Q 1-3-8, Tab D.

A Tab D.

Q Wrong book. Small book.

A Yes. Now understand, he went home on prednisone. They were tapering his prednisone. All that instruction was, was that he was supposed to decrease it.

Q Well, let's read it?

A Yes.

Q "Prednisone, 20 milligrams daily, start in seven days."

Did I read that correctly?

A Yes.
Q So, they did not discharge him taking prednisone when he was discharged? “Start in seven days?”
A No, that’s not correct. You can’t stop steroids for seven days. He was on a tapering regimen of prednisone.
My understanding is, he was sent with prednisone and then told to take a lower dose beginning seven days after discharge. He wouldn’t have survived stopping all steroids for seven days. That wouldn’t have been medically a very probable scenario. So, I think you’re misunderstanding.
Q The record is right there?
A No, I see what it says, but I understand that a patient --
Q Did I read it correctly?
A What’s that?
Q Did I read it correctly?
A Yes, you read it correctly, but I don’t think you’re understanding the medicine.
Q I read it correctly, correct?

A Yes.
Q Now, before Mr. Lariviere could take the oral Cipro pills that had been prescribed by Dr. Tibbetts, he would have to obtain them from the retail pharmacy, correct?
A Yes.
Q And at the same time that the pills in oral form were handed to either Mr. Lariviere or his wife, he would have been handed the warnings and instructions relating to Cipro, correct?
A Yes, I think that actually the pharmacist did notify him that there was a problem with Cipro. That was something a pharmacist did tell him, I thought.
Q All right. So, your testimony here today is that when Mr. Lariviere picked up the drug at the Rite Aid, he was told by the pharmacist that there was a risk of tendon rupture, correct?
A I have to remind myself. I just read this yesterday, but I don’t recall.

Q What are you referring to?
Doctor, what are you referring to right now?
A What I wrote about the case.
Q Well, put that aside for now.
And I think you testified earlier today that --
A I know he found out from a pharmacist that this drug was contraindicated, but he must have picked up, because he did take oral Cipro for several days after.
Q Well, let me ask you this.
A Yes.
Q It makes sense that Mr. Lariviere would have found out about the risk of tendon rupture taking Cipro from the pharmacist who gave him the Cipro when he picked it up?
A I don’t recall.
Q Does that make sense?
A Apparently not. Apparently, he went home with the Cipro, then developed the problem with -- and then tried to determine what it was due to.

I think then he was switched to Bactrim.

Q You sure you've got it straight now?

A I think that's right.

Q So, when Mr. Lariviere or his wife presented to the Rite Aid pharmacy, you'd agree with me that their pharmacist at the Rite Aid pharmacy would provide Mr. Lariviere with written instructions, including the warnings regarding tendon rupture?

A Yes, that's for sure.

Q Now, if Mr. Lariviere or his wife were interested in the side effects, they could review that, correct?

A They could.

Q And you know, you presented some testimony that there's a prominent warning and the information is right there so that you can see it, correct?

A Yes, it's called a box warning.

Q All right. And that means that you have to see that warning to basically get to the pill?

A No, no. It's a piece of paper that comes in the bag. You don't have to --
Q And there's a box in it that says "warning?"
A Well, you have to look at what the labeling looks like, but when you get a prescription, it's very easy to ignore the paper warning -- the paper labeling information.
Q If you believe Mr. Lariviere, he ignored that warning, correct?
A Yes.
Q If he was interested in the warning, or to find out instructions as to how to take the Cipro and when to take the Cipro, what foods to avoid when taking the Cipro, what are the possible side effects of Cipro, what to do if you have a side effect, he could have read that to be aware of that information, correct?
A He could have, but what the important caveat that --
Q No, my question is, he could have done

that, correct?

A He could have.

Q All right. And he could have done that each and every time over the last twenty years when he received Cipro, correct?

A Yes.

THE COURT: All right, counsel, I'm just going to advise --

MR. REIDY: No, I was going to say, Your Honor --

THE COURT: I appreciate it. I just want to advise both counsel to remember that we have to leave time for the juror's questions, if they have any.

MR. REIDY: Your Honor, no further questions.

THE COURT: All right, thank you. And so just, with redirect, have that in mind, counsel.

MR. CLAPP: Sure.

THE COURT: Unless you want the witness back on Monday.

(REDIRECT EXAMINATION OF PAUL GENECIN, M.D.)

BY MR. CLAPP:

Q Doctor, an error was pointed out to you in your disclosure in this case?

A Yes.

Q Can I show you that again?

A Yes.

Q Who typed that disclosure?

A The disclosure was typed by you or your office.

Q And would you look -- the error is the date May 2008, is that correct?

A Yes.

Q Would that make sense if it said May 2009?

A Yes.

Q So, it could be a typo that the 8 is there instead of the 9, is that correct?

A I believe that’s the case, yes. But that’s not how it was asked.

Q Now also, you I think were asked about, if you expressed any criticism of Dr. Hamway in your disclosure?

A Yes.

Q Would you look at the last page, page

11, first paragraph, and tell me if you did express some --

MR. REIDY: Your Honor, sidebar, please?

THE COURT: Yes, sidebar.

(SIDEBAR CONFERENCE - NOT TRANSCRIBED)

BY MR. CLAPP:

Q Doctor, in that first paragraph on page 11, did you express a criticism of Dr. Hamway's care?

A Yes.

Q Thank you.

Doctor, I think you were asked about comparing one dose of corticosteroid to another dose when multiple doses are given in a short period of time?

A Yes.

Q Can you isolate the cause of tendon rupture by thinking about which dose caused it, when there's six doses or so?

A No, of course not.

Q And why is that?

A It's not -- it's an idiosyncratic

reaction. One course it won't happen; it will happen in another. It may take six doses; it may take twelve doses. It's not predictable.

MR. CLAPP: Thank you.

THE COURT: Mr. Reidy, anything further?

MR. REIDY: No, Your Honor.

THE COURT: And do any of the jurors have any questions for this witness? If so, just raise your hand and the court officer will collect your written question.

If you've written a question down, just make sure you have your seat number on the piece of paper, as well, please.

And counsel, join me at sidebar and we'll take a look. Actually, I'm going to ask the court reporter to mark these for identification. Or the Clerk, or whoever is doing it.

(Identification C, so-marked)

(Identification D, so-marked)

THE COURT: Thank you.

(SIDEBAR CONFERENCE - NOT TRANSCRIBED)

THE COURT: So Doctor, there was some reference to 1983 to 1996. There were some thirteen years that the plaintiff was on prednisone.

Does that mean that he was taking prednisone every day during that period of time?

DR. GENECIN: I don't know whether it was continuously, or whether it was mostly on prednisone. I don't have the exact answer to that.

THE COURT: Okay. And would that be true with the other dates that are indicated he was on prednisone? You're not able to say whether it was every day or not?

DR. GENECIN: In other words, whether there were interruptions of therapy, I don't know.

THE COURT: Well normally, what would happen? There was some testimony about tapering down?

DR. GENECIN: Well, patients can take prednisone for its anti-inflammatory effects, but usually, we try to get patients off of prednisone because of its side effects. So to do that, we taper.

THE COURT: So, is it unlikely it would be every day for thirteen years?

DR. GENECIN: It would be unlikely that there would have been no attempts to get him off of prednisone in thirteen years. And there may have been periods without it, in which he needed to then start it again. But I don’t know, because I don’t have the exact information.

THE COURT: Okay. So, on a different topic.

If someone takes a prescription drug, reads the leaflet the first time that they take it, let’s say in 1983, are they expected to read the leaflet each time they receive the prescription?

DR. GENECIN: I don't know about expected. In my experience, patients don't tend to read them because they're very small print. They tend to rely on their doctor to prescribe safely.

THE COURT: And to the extent that they may read them, if the leaflet changes, what alerts a patient that warnings have changed, that a black box warning has been added?

DR. GENECIN: A black box warning, on the leaflet or material, actually is shown in a black box.

In my experience, patients are not oriented to black boxes and don't know to look for them. So, the information, in terms of how it's made available, is a lot more available to doctors and pharmacists than it is to patients. It's one of the reasons why we have to be so careful.

THE COURT: All right. Do the answers to those questions suggest any

further questions from the plaintiff?

MR. CLAPP: No, Your Honor.

THE COURT: From the defendant?

MR. REIDY: No, Your Honor.

THE COURT: All right, you may step down and thank you. You're excused.

DR. GENECIN: Okay.

(Testimony of Paul Genecin, M.D. concludes at 12:52 p.m.)

C E R T I F I C A T I O N

I, JESSICA GALARNEAU, A PER DIEM COURT REPORTER, DO HEREBY CERTIFY THAT THE FOREGOING IS A TRUE AND ACCURATE TRANSCRIPT FROM THE RECORD OF THE COURT PROCEEDINGS IN THE ABOVE-ENTITLED MATTER.

I, JESSICA GALARNEAU, FURTHER CERTIFY THAT I NEITHER AM COUNSEL FOR, RELATED TO, NOR EMPLOYED BY ANY OF THE PARTIES TO THE ACTION IN WHICH THIS HEARING WAS TAKEN, AND FURTHER THAT I AM NOT FINANCIALLY NOR OTHERWISE INTERESTED IN THE OUTCOME OF THE ACTION.

JESSICA GALARNEAU, PER DIEM COURT REPORTER
PROCEEDINGS RECORDED BY STENOMASK. TRANSCRIPTS PRODUCED FROM COMPUTER.

_____ _____

JESSICA GALARNEAU DATE

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