IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW JERSEY

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HELSINN HEALTHCARE, S.A., and ROCHE PALO ALTO, LLC,	:	Civil Action DOCKET NO. 12-2867 (MLC)
Plaintiffs,	:	
v.	:	
DR. REDDY'S LABORATORIES, LTD., et al.,	:	
Defendants.	:	

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Friday, April 15, 2016

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Videotaped deposition of DR. CHRISTOPHER A. FAUSEL, taken pursuant to notice, was held at the law offices of Lerner David Littenberg Krumholz & Mentlik, 600 South Avenue West, Westfield, New Jersey, beginning at 8:47 a.m., on the above date, before Constance S. Kent, a Certified Court Reporter, Registered Professional Reporter, Certified LiveNote Reporter, and Notary Public in and for the State of New Jersey.

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that. So granisetron, I think was in the neighborhood of maybe 70 or 80 bucks. So it was a significant difference.

Q. Okay.

A. So for inpatient population where you're concerned with controlling costs, we talked about this before, if you had two drugs which were -- and these from a toxicity standpoint there's no difference between the IV and the oral formulations of the 5-HT3 antagonist, and if the efficacy was the same and you could gain a little bit of cost benefit, you would consider using the oral agents preferentially in the inpatient setting in the patient populations that it was appropriate for.

Q. Okay. So I'm going to -- there was a lot in that answer.

A. Sorry.

Q. I'm going to try to ask some focused questions.

A. Okay.

Q. Are there advantages to

oral -- to the use of oral antiemetics over IV antiemetics? Yes or no?

A. Yes. At the time they were cheaper.

Q. Okay.

A. That's not the case anymore, with these specific agents because they're all now all generic and they're all almost free. In some instances, it may be easier -- and from an insurance standpoint, and we still run into this -- this problem today, there are some insurance companies that won't cover oral medications well, and so patients have a bigger copay out of pocket, so it may be you can -- you can bill for the IV formulation, get it covered under their hospital benefits when they come into a clinic and get IV therapy, so even today there's -- there's reasons to use one versus another.

Q. I'm going to put myself back in 2002.

A. Okay.

Q. If a patient is in the outpatient setting, he is being given a setron, okay? Are they given that setron on multiple -- are they given it only on day one or are they given it afterwards?

MR. FAEGENBURG: Objection to the form.

THE WITNESS: So in 2002, it was -- it was an interesting time and I had, you know, I was involved with developing our own institutional guidelines at the time for this. The rule of thumb was -- and it's -- it's articulated in much better detail in here in this document.

BY MR. ASHKENAZI:

Q. In the ASCO guidelines?

A. In the ASCO guidelines. And -- but the rule of thumb is if you had somebody getting highly emetogenic chemotherapy or moderately emetogenic chemotherapy for acute chemotherapy-induced nausea and vomiting, the either

granisetron, ondansetron, or dolasetron, any one of those three could be given either IV or orally for prophylaxis.

Q. Okay. Let me just cut through all this.

There are advantages to an oral route of administration for a setron in -- in 2002, correct?

A. There are advantages for certain patient populations and there are advantages for other patient populations for IV.

Q. Okay. And the cells, the -- the 5-HT3 receptor antagonists that setrons are believed to work on, or were believed to work on in 2002, those are located in the gut, correct?

A. Not entirely. So some of them are in the central nervous system. So there's something called the chemoreceptor trigger zone, pretty clear name. It is a group of neurons for which there are serotonin receptors and also neurokinin 1 receptors, that's why it's

believed the neurokinin 1 receptor antagonists work for chemotherapy-induced nausea and vomiting.

If you give someone a dose of a cytotoxic chemotherapy drug, it's going to release serotonin from these enterochromaffin cells in the gut, which are -- these cells are just big vacuoles or big storage bags of serotonin. When the drug is -- when the chemotherapy drug is given systemically, a lot of the serotonin is released, so it's released locally, but a lot of it goes into the central nervous system and then starts hitting the chemoreceptor trigger zone. The chemoreceptor trigger zone then sends a signal to some -- another spot in the brain called the vomiting center. The vomiting center says, Oh, wait, I'm being exposed to some sort of toxic moiety, I need to start the process of getting rid of this compound.

So that's what starts the process of first nausea, and then

retching, and them ultimately emesis.

Q. Okay. All right. Sir, a couple of questions.

Do you prescribe palonosetron? Do you work with doctors to prescribe palonosetron?

A. Yes.

Q. And in what -- do you prescribe palonosetron more than you do ondansetron?

A. So I dispense it. I want to clarify that.

Q. Okay.

A. So in my outpatient clinic of -- so there are several outpatient -- I don't know if we get into this before, but I managed pharmacies for several outpatient cancer clinics in Indianapolis that are a part of Indiana University Health.

Our workhorse 5-HT3 receptor antagonist -- when I say workhorse, I mean the one that we use most of the time in our outpatient clinics exclusively is

palonosetron, and we use that for prophylaxis for highly emetogenic and moderately emetogenic chemotherapy.

We also stock ondansetron, and the reason why we stock ondansetron is there are some patients that get either low emetogenic potential chemotherapy or minimal emetogenic chemotherapy, but, you know, you may be giving them a drug that doesn't have a highly likelihood of causing emesis, but because they've gotten a lot of chemotherapy with other regimens in the past, and because of where the tumor may be located in the GI tract, they may have a lot of nausea to begin with.

Q. Okay.

A. So we'll give ondansetron for those folks, and if someone has a headache with palonosetron -- so there's a class effect with palo -- with 5-HT3 receptor antagonists where they all cause headache. And anywhere between 5 and 20-ish percent, depending on which

clinical trial you read, but it's reproducible, it happens.

What is interesting is you can actually give another one of the 5-HT3s. So if I'm given palo and get a headache with palo, you can switch me over to ondansetron, and about half the time the headache doesn't come back.

Or you -- if I'm getting ondansetron and then I get a headache and then you switch me over to granisetron, if you switch me to the granisetron after I've had a headache with ondansetron, the headache will go away.

Q. Okay.

A. So I think it's always wise to have two of these drugs around because of this side effect.

Q. All right. Let's -- let's break this down, and I'm going to try to make it into specific questions --

A. Okay.

Q. -- that you can answer yes or no, if you can't, you'll explain you

can't, but I want to get you out of here for your flight and the question is getting a little long.

A. Fair enough.

Q. I understand. So let's just try to keep it -- I'll try to keep it focused.

The workhorse antiemetic that you use, you've described as palonosetron, correct?

MR. FAEGENBURG: Objection to the form.

THE WITNESS: So the -- the main 5-HT3 receptor antagonist that we use at our clinics at Indiana University Health for our cancer centers is palonosetron for prophylaxis of highly emetogenic and moderately emetogenic chemotherapy.

BY MR. ASHKENAZI:

Q. Great.

Now you use granisetron you said for certain -- ondansetron?

A. Yeah.

Q. Okay. So you use ondansetron for certain patients, either they're given minimally emetogenic chemotherapy or the patient had a side effect to palonosetron; is that correct?

A. Yes, that's fair.

Q. Okay. Now, the -- the side effects that you discussed with the headache, as long as you have two setrons available, you're in -- you're in good shape? Let me make -- let me clarify that question.

For patients who had headaches back in 2002 and they were on granisetron, most of those patients would not have the headache if you switched them to the ondansetron?

A. I'd say about half.

Q. Okay. And then dolasetron also?

A. Yeah, it's a class effect. So whichever two of these drugs that you were stocking in your hospital, if a

patient had a headache to one, hopefully when you switched them over to the second one, the headache would go away. In some cases it still stuck around, that headache, and you may even have to try and order in special the third one.

Q. So there's really no distinct advantage to having a fourth setron with respect to that -- to avoiding the headaches because you were basically able to treat a patient by using the other alternatives of the other of the three setrons that were available, correct?

A. You need -- you need at least a second agent available, at least that's always been my long-standing clinical belief on formulary at a hospital or in a clinic to manage the headache situation.

Q. So to be clear, for setrons, in order to manage any toxicity issues or headache, side effect issues, having a second setron available is all that you

needed to ensure the safety of your patients?

MR. FAEGENBURG: Objection to form.

THE WITNESS: From the hospital's standpoint, having two agents would be best. I mean, it would be great to have three but there's a cost associated with having too many drugs in stock. So most -- most hospitals would say, All right, let's just carry two, if we need a third one we'll order it in.

BY MR. ASHKENAZI:

Q. So back in 2002 with granisetron, ondansetron and dolasetron available, there would be no need for a fourth setron just for take -- treating patients who may have gotten a headache to the first use of a setron, correct?

A. So long as you have two, you should be good to go for most patients.

Q. Okay. Next, with respect to

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