

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

Friday, April 15, 2016
- - -

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
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Public in and for the State of New
Jersey.

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

4 Q. Okay.

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

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

20 A. Sorry.

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

23 A. Okay.

24 Q. Are there advantages to

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

3 A. Yes. At the time they were
4 cheaper.

5 Q. Okay.

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

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

24 A. Okay.

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

6 MR. FAEGENBURG: Objection
7 to the form.

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

17 BY MR. ASHKENAZI:

18 Q. In the ASCO guidelines?

19 A. In the ASCO guidelines.

20 And -- but the rule of thumb is if you
21 had somebody getting highly emetogenic
22 chemotherapy or moderately emetogenic
23 chemotherapy for acute chemotherapy-
24 induced nausea and vomiting, the either

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

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

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

9 A. There are advantages for
10 certain patient populations and there are
11 advantages for other patient populations
12 for IV.

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

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

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

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

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

1 retching, and then ultimately emesis.

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

4 Do you prescribe
5 palonosetron? Do you work with doctors
6 to prescribe palonosetron?

7 A. Yes.

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

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

13 Q. Okay.

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

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

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

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

17 Q. Okay.

18 A. So we'll give ondansetron
19 for those folks, and if someone has a
20 headache with palonosetron -- so there's
21 a class effect with palo -- with 5-HT3
22 receptor antagonists where they all cause
23 headache. And anywhere between 5 and
24 20-ish percent, depending on which

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

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

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

15 Q. Okay.

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

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

22 A. Okay.

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

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

4 A. Fair enough.

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

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

11 MR. FAEGENBURG: Objection
12 to the form.

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

21 BY MR. ASHKENAZI:

22 Q. Great.

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

1 A. Yeah.

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

7 A. Yes, that's fair.

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

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

19 A. I'd say about half.

20 Q. Okay. And then dolasetron
21 also?

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

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

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

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

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

1 needed to ensure the safety of your
2 patients?

3 MR. FAEGENBURG: Objection
4 to form.

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

15 BY MR. ASHKENAZI:

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

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

24 Q. Okay. Next, with respect to

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