UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,
vs.
ABBOTT DIABETES CARE INC.
Patent owner.

Case IPR2023-01251
Patent 11,298,056 B2

DEPOSITION OF EUGENE E. WRIGHT JR., M.D.

Chicago, Illinois

Thursday, July 25, 2024

Reported by:
JENNIFER L. BERNIER, CSR, RMR, CRR
JOB NO. J11371636

DEXCOM EXHIBIT 1053
Dexcom v. Abbott
IPR2023-01251

July 25, 2024
9:03 a.m.

The deposition of EUGENE E. WRIGHT JR., M.D., called as a witness herein for examination, taken pursuant to the rules of the Patent Trial and Appeal Board of the United States Patent and Trademark Office pertaining to the taking of depositions, taken before Jennifer L. Bernier, a Certified Stenographic Reporter of the State of Illinois, CSR License No. 084-004190, Registered Merit Reporter and Certified Realtime Reporter.

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INDEX OF EXHIBITS
(Attached to transcript.)

NUMBER	DESCRIPTION	MARKED
Exhibit 1050	Ambulatory Glucose Profiling	73
Exhibit 1051	Fingersticks show only part of the picture	75

(Witness sworn.)

EUGENE E. WRIGHT JR., M.D.,

called as a witness, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. MASON: 09:02

Q. Good morning, Dr. Wright. 09:02

Can you please state your name for the record. 09:02

A. Yes. My name is Eugene Edward Wright, Jr. 09:02

Q. And what is your current occupation? 09:03

A. I'm currently a consulting associate, Department of Medicine at Duke University Medical Center. And I serve as the medical director for performance improvement at the South Piedmont Area Health Education Center in Charlotte, North Carolina. 09:03

Q. Great. 09:03

And how long have you been employed at Duke? 09:03

A. I'm currently not employed at Duke. I was employed at Duke between 1995 and 2000. 09:03

Q. Oh, okay. Have you been deposed before? 09:03

A. Yes, I have. 09:03
Q. Okay. Roughly, how many times, if you can remember? 09:03
A. Well, the one I remember most is the one recently, January of 2023. 09:03
Q. Okay. And have you been deposed more than five times? 09:03
A. I don't think so. 09:03
Q. You don't think so, okay. 09:03
And do you feel comfortable with the deposition process? That's a loaded question. 09:03
Do you feel that you understand the deposition process? 09:04
A. I believe I do. 09:04
Q. Okay. And, you know, I think maybe as counsel has told you, I'll be asking questions. He might have some objections; but if he objects, you still have to answer the question. Do you understand that? 09:04
A. I understand. 09:04
Q. Yeah. 09:04
And then do you agree to testify truthfully today? 09:04
A. I do. 09:04
Q. You do, okay. 09:04

And is there anything that would prevent you from testifying truthfully today, like medications or anything else? 09:04

A. No. 09:04

Q. Okay. Do you agree to testify accurately today? 09:04

A. Accurately, yes. 09:04

Q. Okay. Is there anything that would prevent you from providing accurate testimony today? 09:04

A. No. 09:04

Q. Okay, great. 09:04

And do you understand that the rules of the United States Patent and Trademark Office forbid you to talk to counsel on breaks about the substance of your testimony here today? 09:04

A. I understand. 09:05

Q. Okay. And do you agree to follow those rules? 09:05

A. I do. 09:05

Q. Excellent. 09:05

I see that you have a binder right in front of you there. What is in that binder? 09:05

A. (Indicating). 09:05

Q. Oh, yeah. I'm sorry. 09:05
MR. CARROZZA: Could you read it? 09:05
BY MR. MASON: 09:05
Q. This is tough. Yeah, yeah, no. So you're holding it up. 09:05
But just for the reporter, yeah, if you can just tell me what's inside that binder. 09:05
A. This is a copy of my declaration. 09:05
Q. Okay. And is that Exhibit 2013? 09:05
A. That is accurate. 09:05
Q. Okay, great. 09:05
And then do you also have a copy of your CV, Exhibit 2014, in that binder? 09:05
A. Yes, I do. 09:05
Q. Okay, excellent. Thank you. 09:05
And then to your left here, do you have a stack of binders that includes all of the exhibits that you considered in preparing your declaration? 09:05
MR. CARROZZA: And just to clarify, counsel, they're not all exhibits. Some are documents like papers from the parties. 09:05
MR. MASON: Okay, excellent. 09:06
(Reporter clarification.) 09:53
MR. CARROZZA: Papers from the

parties.

MR. MASON: And I'll ask him about those. 09:06

THE WITNESS: Yes, I believe they are. 09:06

BY MR. MASON:

Q. Yeah, okay. Can I see that real quick? Thank you, sir. 09:06

And do these binders also include a copy of DexCom's Petition for Inter Partes Review of U.S. PN 11,298,056? 09:06

A. U.S. PN 11,298,056, yes. 09:06

Q. Thank you. 09:06

And do they also contain a copy of Abbott's Patent Owner's Preliminary Response (POPR)? 09:06

A. Yes, they do. 09:06

Q. Excellent. 09:06

And does Tab 3, do they also include a copy of DexCom's Reply to Abbott's POPR? 09:06

A. Yes. 09:06

Q. Excellent. 09:07

And then do they also include, as Tab No. 4, Abbott's Surreply ISO in Support of POPR? 09:07

A. Yes. 09:07
Q. And then finally, as Tab No. 5, do they also include Decision Granting Institution of Inter Partes Review? 09:07
A. Yes. 09:07
Q. Okay, great. 09:07
And you see there that that institution decision you were just looking at, that lists on its face Patent No. 11,298,056; is that correct? 09:07
A. 11,298,056 B2. 09:07
Q. Oh, yeah, yeah. The B2 is something that they add on to that. I asked you to be accurate. 09:07
So can we agree to refer to that Patent No. 11,298,056 B2 as the '056 patent today? 09:07
A. Yes. 09:08
Q. And you understand that's been submitted as Exhibit 1001 in this proceeding? 09:08
A. Yes. 09:08
MR. MASON: Tell me if you need me to slow down. 09:08
THE REPORTER: Yes, you do. Thank you. 09:08

MR. MASON: I'm sorry. 09:08

BY MR. MASON:

Q. And you can tell me, too, 09:08

Dr. Wright, if you need me to slow down. 09:08

A. Excuse me. One question. You 09:08

said -- what is the -- Exhibit 1001 is under 09:08

Tab 6. 09:08

Q. Oh, yeah, it's under Tab 6. But is 09:08

that the '056 patent -- 09:08

A. Yes -- 09:08

Q. -- that we discussed? 09:08

A. -- the '056 B2.

Q. Oh, yeah. And then in its lower 09:08

right-hand corner, it's got the exhibit 09:08

marker -- 09:08

A. Gotcha.

Q. -- 1001. All right. 09:08

And if I could have you just look at 09:08

your declaration, which is Exhibit 2013, 09:08

correct? 09:09

A. I'm sorry. The question? 09:09

Q. Oh, yeah. My question is -- yeah -- 09:09

looking at Exhibit 2013, is that your signature 09:09

on the last page of the declaration -- prior to 09:09

the appendix? 09:09

A. Yes, that is. 09:09
Q. All right, great. 09:09
And did you read your declaration 09:09
carefully before signing it? 09:09
A. Oh, yes, I did. 09:09
Q. You did, great. 09:09
And did you review it again in 09:09
preparing for this deposition? 09:09
A. Yes, I have. 09:09
Q. You have, okay. 09:09
Did you notice any errors in your 09:09
declaration? 09:09
A. I did not. 09:09
Q. Okay. And then how long did you 09:09
spend drafting your declaration? 09:09
A. That's a good question. The 09:09
drafting of the declaration was an iterative 09:09
process, and I worked with counsel. So we 09:10
prepared drafts. We looked at it. I reviewed, 09:10
revised. So it's over several sessions. So... 09:10
Q. Okay. Would you estimate you spent 09:10
more than ten hours working on the declaration? 09:10
A. Oh, yes. Yes. 09:10
Q. More than 20 hours? 09:10
A. Probably close to that. 09:10

Q. Okay. And then in preparing for today's deposition, what did you do? 09:10
A. I've reviewed my declaration, as I've noted, and reviewed some of the exhibits that were referred to in them. 09:10
Q. Did you meet with anybody in preparation for your deposition? 09:10
A. I met with counsel. 09:10
Q. And by counsel, are you referring to Mr. Carrozza? 09:10
A. Mr. Carrozza, yes. 09:10
Q. Okay. Did you meet with any other counsel? 09:11
A. One of the meetings was with Mr. McAndrews. 09:11
Q. Okay. Is that Peter McAndrews? 09:11
A. Peter McAndrews, yes. 09:11
Q. Okay. And did you meet with Leland Hansen in preparation for your deposition? 09:11
A. I have met Mr. Hansen, yes. 09:11
Q. Okay. Did you meet or speak with anybody at Abbott in preparation for your deposition? 09:11
A. I have not. 09:11

Q. Okay. And did you -- strike that. 09:11
Have you met or spoken with anybody 09:11
at Abbott in preparing your opinions in this 09:11
matter? 09:11
A. In preparing my opinions? No. 09:11
Q. Okay. Have you met with anybody at 09:11
Abbott, aside from counsel, in relation to this 09:11
IPR? 09:11
A. No. 09:11
Q. Anybody else that you met with in 09:11
preparation for your deposition? 09:11
A. I can't think of anyone else. 09:12
Q. Okay. Did you meet with 09:12
Dr. Aaron Striegel? 09:12
A. I have met Dr. Aaron Striegel. 09:12
Q. Okay. And when did you meet 09:12
Dr. Striegel? 09:12
A. Maybe two days ago. 09:12
Q. Okay. And how long did you meet 09:12
with Dr. Striegel two days ago? 09:12
A. It was a short time, over lunch. 09:12
Q. Okay. And did you discuss your 09:12
opinions in this matter with Dr. Striegel? 09:12
A. In my -- no. 09:12
Q. Okay. Did you discuss his opinions 09:12

in this matter? 09:12
A. I have reviewed his declaration. 09:12
Q. Okay. And in meeting with him and 09:12
in person two days ago, did you discuss the 09:12
substance of his testimony in this IPR? 09:12
A. I don't recall. I don't recall 09:12
discussing the substance of my declaration or 09:12
the IPR with him. 09:12
Q. Okay. And aside from that lunch 09:12
meeting with Dr. Striegel, have you had any 09:13
phone conversations with Dr. Striegel? 09:13
A. Oh, no. 09:13
Q. Okay. Have you met him via Zoom or 09:13
any other in-person meetings? 09:13
A. I saw him briefly yesterday at 09:13
breakfast. 09:13
Q. Oh, okay. And in your meetings with 09:13
Dr. Striegel, did you learn anything that 09:13
informed your testimony today? 09:13
A. Oh, no. 09:13
Q. Okay. In meeting with Dr. Striegel, 09:13
did you learn anything that informs your 09:13
opinions or affects your opinions in this 09:13
matter? 09:13
A. No. 09:13

Q. Okay. Are you aware that Dr. Striegel was deposed yesterday? 09:13
A. I am. 09:13
Q. Okay. Have you been provided with a transcript of that deposition? 09:13
A. I have not. 09:13
Q. Okay. Have you spoken with Dr. Striegel since his deposition yesterday? 09:13
A. I said good-bye to him as he was leaving. 09:14
Q. Okay. Fare thee well. 09:14
Yeah, did you -- strike that. 09:14
Did you speak with Dr. Striegel about any substance related to this matter after his deposition? 09:14
A. I have not. 09:14
Q. Okay. In your declaration, do you use the term PWD as a shorthand for persons with diabetes? 09:14
A. That is accurate, yes. 09:14
Q. Okay. And can we agree to use that acronym throughout today as well? 09:14
A. Absolutely. 09:14
Q. All right, great. 09:14
And in your declaration, do you also 09:14

use the term CGM to refer to continuous glucose monitoring? 09:14

A. Continuous glucose monitor or continuous glucose monitoring. 09:14

Q. Fair enough, yeah. And can we agree to use that acronym CGM today? 09:14

A. Right. 09:14

Q. Okay.

A. I make the distinction because a continuous glucose monitor is a device. Continuous glucose monitoring is a process. 09:14 09:15

Q. Okay. And what does CGM typically refer to in the field? 09:15

A. The device. 09:15

Q. The device, okay.

A. Continuous glucose monitor. 09:15

Q. Okay. And do you use the term SMBG to refer to self-monitored blood glucose measurements? 09:15

A. SMBG, yes, that's self-monitored blood glucose. 09:15

Q. Mm-hmm. And is that also sometimes referred to as a "fingerstick measurement"? 09:15

A. Yes. 09:15

Q. Okay. In your declaration, you 09:15

discuss the treatment of diabetes. Based on your experience, what does diabetes treatment include or encompass? 09:15 09:15 09:16

A. That's a broad question. Can you be a bit more specific? 09:16 09:16

Q. Yeah. Do you consider diabetes treatment to include dosing insulin? 09:16 09:16

A. Yes. That is one form of diabetes treatment. 09:16 09:16

Q. Okay. And do you consider diabetes treatment to include deciding whether or not to perform one or more SMBG measurements? 09:16 09:16 09:16

A. That would be a part of diabetes management. 09:16 09:16

Q. Okay. 09:16

A. I think of treatment as providing a medication. 09:16 09:16

Q. Okay. And then how would you -- you mentioned the term "diabetes management"; is that correct? 09:16 09:16 09:16

A. Yes. 09:16

Q. Yeah. And what would you consider diabetes management to be? 09:16 09:16

A. Think of diabetes management as the process of assimilating the information and 09:16 09:16

making decisions about how and what -- when to treat. 09:17

Q. Okay. And I think, as you said, diabetes management then includes determining when to take a fingerstick measurement; is that correct? 09:17

A. That would be one, yes. 09:17

Q. And what else would diabetes management include? 09:17

MR. CARROZZA: Object to the form. 09:17

THE WITNESS: It would include activity, lifestyle, sense of well-being. 09:17

BY MR. MASON: 09:17

Q. Okay. And is diabetes management largely performed by the patient, or PWD? 09:17

A. Diabetes management is typically a team process. The patient is at the center. 09:18

Q. And what do you mean by the patient is at the center? 09:18

A. The patient is the person for whom the diabetes management is directed. 09:18

Q. Okay. And does the patient or the PWD, as you refer to them, play an active role in management of their -- his or her diabetes? 09:19

A. That would be accurate, yes. 09:19

Q. And you discuss in your declaration the concept of a person of ordinary skill in the art? 09:19
A. Yes. 09:19
Q. Okay. And do you understand that that term can be shorthanded as POSITA? 09:19
A. Yes, I do. 09:19
Q. And can we agree to use that terminology today, POSITA? 09:19
A. Yes, that would be fine. 09:20
Q. Okay. In paragraph 122 of your declaration, do you quote the definition of a POSITA, at least in part, as provided by a Mr. Brian Gross? 09:20
A. Yes, I do. 09:20
Q. And in paragraph 123, do you state disagreement with his opinion, insofar as, in your mind, a POSITA must be part of an interdisciplinary team? 09:20
A. Yes, I do. 09:21
Q. Other than that disagreement, do you have any other disagreement with Mr. Gross's definition of a POSITA? 09:21
A. I do not. 09:21
Q. Okay. Do you believe that you were 09:21

at least a POSITA in 2009? 09:21
A. Yes. 09:21
Q. Okay. And why is that -- or strike that. 09:21
What -- in your mind, what qualified you as a POSITA in 2009? 09:21
A. Well, according to Mr. Gross's definition, I was a part of -- in my amendment to this deposition, I was a part of an interdisciplinary team working on these types of -- with these -- team composed of these components. 09:22
Q. Okay. And what was the interdisciplinary team that you were a part of in 2009? 09:22
A. In 2009, we were working on what was the unmet need for patients with Type 2 diabetes. And so the team included engineers, clinicians. 09:22
Q. Anybody else? 09:23
A. That's a long time ago. 09:23
Q. I know, yeah. And what was -- what were the -- strike that. 09:23
What medical device were you working on with these engineers and other clinicians in 09:23

2009? 09:23
A. In 2009, that would have been the 09:23
Abbott devices. 09:23
Q. And in 2009, you were working then 09:23
with engineers and other clinicians on Abbott 09:23
CGM devices; is that correct? 09:23
A. That is accurate, yes. 09:23
Q. Okay. And when did you begin work 09:23
on -- strike that. 09:23
When did you begin working with 09:23
Abbott CGM devices? 09:23
A. It was around that 2009 time frame; 09:23
2008, 2009. 09:24
Q. And was your work in that time frame 09:24
focused on Type 2 diabetes? 09:24
A. Yes, as is my work now. 09:24
Q. Okay. And then -- strike that. 09:24
In 2009, was your work limited to 09:24
Type 2 diabetes? 09:24
A. My work in which capacity? 09:24
Q. Oh, it -- yeah, strike that. 09:24
So in 2009, was your -- was your 09:24
work on CGM devices and with CGM devices 09:24
limited to Type 2 diabetes? 09:24
A. You know, I don't think we limited 09:24

to Type 2. The focus work for me, my interest, was Type 2. 09:24

Q. Okay. In 2009, were you working on Type 1 -- strike that. 09:25

In 2009, were you working on issues related to Type 1 diabetes? 09:25

A. Issues related to diabetes affect patients both with Type 1 and Type 2 diabetes. 09:25

Q. Okay. Given that your focus was on Type 2 diabetes, were you seeing any Type 1 diabetics at the time? 09:25

A. Very few. 09:25

Q. And in 2000 -- strike that. 09:25

Beginning in 2008 when you began working with Abbott, did you receive funding from Abbott? 09:26

A. My work in 2008 or early 2009 with Abbott was related to advising and consulting. 09:26

Q. And were you paid an hourly rate by Abbott then at that -- during that time period? 09:26

A. For my advising and consulting work, yes. 09:26

Q. Okay. And did that advising and consulting work for Abbott continue beyond 2008, 2009? 09:26

A. As long I had been advising and consulting them, yes. 09:26

Q. Okay. So is it fair to say that that advising and consulting for Abbott has continued from 2008, 2009 up until the present? 09:26

A. That is accurate. That would be accurate. 09:27

Q. Okay. And understanding that passage of time can limit our memories, but do you -- do you recall roughly how much annually you would make in consulting fees from Abbott? 09:27

A. I could not tell you that with any certainty. 09:27

Q. Okay. And in 2009, do you know if you made -- even were paid more than $10,000 by Abbott? 09:27

A. That's a tough number. That's been 14 years ago, so I couldn't tell you with great certainty. And I want to be accurate, so... 09:27

Q. Okay. And do you remember what your hourly rate for Abbott would have been in 2008 or 2009? 09:27

A. I don't. That would have been what the fair market value was, as determined. 09:27

Q. Yep, okay. 09:27

Do you recall roughly how many hours you would spend each year working for Abbott, say -- let's just start with 2009. Do you recall how many hours you might have worked on Abbott projects? 09:27

A. Probably less than 20. 09:28

Q. Less than 20 for the entire year? 09:28

A. Yeah. It would... 09:28

Q. And were there any years that you worked more than 20 hours in consultation for Abbott? 09:28

A. Were there any years? 09:28

Q. Mm-hmm. 09:28

A. Since 2009? 09:28

Q. Yes, 2009. 09:28

A. Yes. 09:28

Q. Okay. Was there a point at which your consulting work for Abbott increased markedly? 09:28

A. Yes. One of the consulting things we talked about were the Glucose Patterns Insight Report. 09:28

Q. You said Glucose Patterns -- 09:28

A. Insight Report. 09:28

Q. -- Insight Report? Oh, you also 09:28

refer to that as GPIR? 09:28
A. That's correct. 09:28
Q. Okay. And when did you begin that work on GPIR? 09:28
A. I couldn't tell you with accuracy. It's been more than three years. 09:28
Q. Okay. 09:28
A. Probably less than 20 -- less than 10. 09:29
Q. Okay. Yeah, and you can -- maybe we can -- let's see here. Feel free to refer to your CV if you want, which is that second tab in that binder you've got there -- 09:29
A. Mm-hmm. 09:29
Q. -- if that's helpful. 09:29
But do you recall -- and have you been paid a consulting fee by Abbott while working on GPIR? 09:29
A. Yes, I was. 09:29
Q. Okay. And do you recall how much annually you've been paid by Abbott in relation to that GPIR work? 09:29
A. I do not recall. 09:29
Q. When you first began working on GPIR, how many hours per year did you spend 09:29

consulting for Abbott? 09:29
A. I would -- I would have to guess at 09:29
that. Because in the first initial set of 09:30
meetings, we would meet occasionally once a 09:30
week, occasionally twice a month, to flesh out 09:30
things. So it's hard to tell you exactly. 09:30
Q. Are you saying that in the first 09:30
couple of years, you were meeting more 09:30
regularly with Abbott than you did in later 09:30
years? 09:30
A. In this capacity as a consultant on 09:30
the GPIR, Glucose Patterns Insight Report, yes. 09:30
Q. Okay. Do you think you spent, in 09:30
the first year on GPIR, more than 100 hours 09:30
consulting for Abbott? 09:30
A. No. 09:30
Q. Okay. Do you think you spent more 09:30
than 50 hours in that first year? 09:30
A. Well, let's see. If we met once a 09:30
week, that would be 52; but we didn't meet once 09:30
a week. So I would say, perhaps, less than 50. 09:31
Q. Okay. More than 25 hours? 09:31
A. Perhaps, yeah. 09:31
Q. Okay. And have you continued to 09:31
meet more than 24 or 25 hours a year with 09:31

Abbott in relation to the GPIR work? 09:31
A. There have been subsequent projects 09:31
that we've worked on after that, yes. 09:31
Q. And aside from any of this 09:31
litigation or patent work, have you -- have you 09:31
worked more than 50 hours in any year for 09:31
Abbott? 09:31
A. Aside from this work? I'm not sure 09:31
I understand the question. 09:31
Q. Oh, yeah. So I just want to make 09:31
sure you understand that my questions are not 09:31
directed to your patent consulting work -- 09:31
A. Right. 09:31
Q. -- for this dispute with DexCom. 09:31
So my question is: Has there been 09:31
any year in which you've consulted for Abbott 09:31
more than 100 hours? 09:31
A. I can't recall exactly. The 09:32
consulting work, as I've mentioned, and then 09:32
the advising and -- advising work, as an 09:32
advisor, I don't know. I can't tell you 09:32
specifically how many hours totally. 09:32
Q. Did you work -- or strike that. 09:32
Have you worked with Abbott 09:32
employees as part of any of your GPIR or other 09:32

work? 09:32
A. Oh, yes, yes. And I think I 09:32
mentioned that in the declaration. 09:32
Q. Yeah. Have you met -- strike that. 09:32
Did you ever work with Wesley 09:32
Scott Harper, the named inventor on the '056 09:32
patent? 09:32
A. I have not. 09:32
Q. Okay. Have you ever met Mr. Harper? 09:32
A. I don't recall. 09:32
Q. Do you have any Abbott stock from 09:32
your work for Abbott? 09:33
A. That granted me stock? 09:33
Q. Yeah, granted you -- 09:33
A. Oh, no. No, I do not. 09:33
Q. Okay. And have you ever been an 09:33
employee for Abbott? 09:33
A. I have not. 09:33
Q. Okay. So coming back to your 09:33
declaration, is it your opinion that Mr. Gross 09:33
is a POSITA? 09:33
A. I think I disagreed. I think I 09:33
disagreed with his definition. 09:34
Q. Yeah. This might be -- if I could 09:34
invite you to paragraph 133 of your 09:34

declaration. 09:34
A. Okay. Thank you. 09:34
Q. Yep. 09:34
A. I was looking at the wrong spot. 09:34
Yes. 09:35
Q. Oh, so -- I'm sorry. I just want to make sure. So is it your opinion that Mr. Gross is a POSITA? 09:35
A. Given his definition, I would say no. 09:35
Q. Okay. Oh, under his definition? 09:35
A. I thought that was what you were asking me. 09:35
Q. Yeah, yeah -- no, that's -- no, no, no. 09:35
My question to you is: Under your view of a POSITA, do you agree that Mr. Gross is a POSITA? 09:35
A. So make sure I understand the question, because I looked at his definition of a POSITA. 09:35
Q. Mm-hmm. 09:35
A. And I disagreed with it for the reasons that I indicated. 09:35
Q. Yeah. 09:35

A. So by disagreeing with that, his definition, I would agree that he is not -- doesn't meet that criteria. 09:35

Q. Okay. Well, even under his definition of a POSITA, because it -- yeah. I want to just make sure we have a clear record. 09:35

You disagree with his definition of a POSITA, correct? 09:35

A. I do. 09:36

Q. Okay. And it's your opinion that a POSITA, under his definition, would need to be a part of an interdisciplinary team, correct? 09:36

A. That is accurate, yes. 09:36

Q. Yeah. And is it your opinion that Mr. Gross is not a POSITA because, in your opinion, he is not a clinician? 09:36

A. No. My opinion was that he was not a part of a multidisciplinary team. That would be a requirement to be a POSITA. 09:36

Q. Okay. And if -- do you agree that Mr. Gross would be at least a POSITA if he had worked on a team or provided -- worked on a team with a clinician? 09:36

A. He would then fulfill what I would consider to be a POSITA. 09:36

Q. Okay. 09:36
A. By his definition here. 09:36
Q. Mm-hmm. But also under your 09:36
definition too? 09:37
A. Well, I didn't define it separately. 09:37
Q. Yeah. 09:37
A. I just -- but by his definition. I 09:37
want to be clear. 09:37
Q. Yeah.
A. I looked at his definition and 09:37
understood that rather than may be a part of a 09:37
interdisciplinary team, that that would be a 09:37
requirement to be. 09:37
Q. Requirement, yeah. 09:37
And if Mr. Gross were informed by a 09:37
clinician, would he be a POSITA under your sort 09:37
of recharacterized definition of a POSITA? 09:37
A. Say that again. I'm not sure I 09:37
understood that. 09:37
Q. I'll restate it, yeah. 09:37
If Mr. Gross were working on a team 09:37
with a clinician, under your recharacterized 09:37
definition of a POSITA, would Mr. Gross be a 09:37
POSITA? 09:37
MR. CARROZZA: Objection. Form. 09:37

THE WITNESS: He would, because, as Mr. Gross has implicated, there are clinical consequences. 09:37 09:37 09:38

BY MR. MASON: 09:38

Q. Yeah. And just to make sure I understand, if Mr. Gross had been informed of the clinical consequences of CGM treatment, would you consider him to be a POSITA? 09:38 09:38 09:38 09:38

MR. CARROZZA: Objection to form. 09:38

THE WITNESS: Mr. Gross, in his declaration, has opined on the clinical consequences without clinical background or part of his definition, so that was my disagreement. 09:38 09:38 09:38 09:38 09:38

BY MR. MASON: 09:38

Q. And -- yeah, fair enough. 09:38

My question is: If he had been provided with clinical background in rendering his opinions, would he then meet the definition of a POSITA? 09:38 09:38 09:39 09:39

MR. CARROZZA: Objection to form. 09:39

THE WITNESS: He would certainly then have the clinical input that would be necessary to be a POSITA and opine on clinical consequences. 09:39 09:39 09:39

BY MR. MASON: 09:39
Q. And in 2009, were you alone a POSITA 09:39
under your definition of that term? Or were 09:39
you a POSITA based on your working with other 09:39
folks as part of a team? 09:39
A. As a part of a team. 09:39
Q. And did a POSITA understand, in your 09:40
opinion, the importance of data reliability? 09:40
MR. CARROZZA: Objection to form. 09:40
THE WITNESS: What do you mean by 09:40
data reliability? 09:40
BY MR. MASON: 09:40
Q. Do you have an understanding of the 09:40
term "data reliability"? 09:40
A. I do, but I want to make sure I 09:40
understand your understanding. 09:40
Q. Yeah. What is -- what is your 09:40
understanding of data reliability? 09:40
A. The ability to reproduce data 09:40
accurately. 09:40
Q. Okay. So with that understanding, 09:40
did a POSITA understand the importance of data 09:40
reliability? 09:40
MR. CARROZZA: Objection to form. 09:40
THE WITNESS: I would think so, yes. 09:40

BY MR. MASON: 09:40
Q. And did a POSITA understand that in 09:40
the context of CGM, communication errors could 09:40
lead to missing data? 09:40
MR. CARROZZA: Objection to form. 09:40
THE WITNESS: Please say that again. 09:40
BY MR. MASON: 09:41
Q. Yes. Yeah. 09:41
So did a POSITA understand that 09:41
communication errors between a glucose monitor 09:41
and a patient device could lead to missing 09:41
data? 09:41
MR. CARROZZA: Objection to form. 09:41
THE WITNESS: Could lead to? 09:41
BY MR. MASON: 09:41
Q. Mm-hmm. 09:41
A. Yes. 09:41
Q. And did a POSITA understand that 09:41
calibration errors in a CGM system could lead 09:41
to inaccurate data? 09:41
MR. CARROZZA: Objection to form. 09:41
THE WITNESS: Yes. 09:41
BY MR. MASON: 09:41
Q. And did a POSITA understand that it 09:41
was important to provide accurate glucose data 09:41

to a user? 09:41
MR. CARROZZA: Objection to form. 09:41
THE WITNESS: Which time frame are you talking about? In 2009? 09:41
BY MR. MASON: 09:41
Q. In 2009, yeah. 09:41
A. No. 09:41
Q. And just to be clear, when -- do you understand that when I discuss a POSITA, it's defined as the time frame 2009? 09:41
A. Right. 09:41
Q. Okay. So with that in mind then, did a POSITA understand that it was important to provide accurate glucose data to a PWD? 09:41
MR. CARROZZA: Same objection. 09:42
THE WITNESS: Yes. 09:42
BY MR. MASON: 09:42
Q. Okay. And did a POSITA understand that it was important to not provide inaccurate data to a PWD? 09:42
MR. CARROZZA: Objection to form. 09:42
THE WITNESS: So in 2009, the issue of accuracy and inaccuracy is an important distinction. Because as we talk about continuous glucose monitors, they were not 09:42

as accurate as they are today. 09:42
BY MR. MASON: 09:42
Q. And so in 2009, is it correct, then, 09:42
that a POSITA would want to avoid providing 09:42
inaccurate data to a PWD? 09:42
MR. CARROZZA: Objection to form. 09:42
THE WITNESS: Generally, yes. But 09:42
in 2009, most of the CGMs and the data that 09:42
they produced -- in fact, all of them could 09:43
not be used to make a treatment decision; 09:43
therefore, the issue of accuracy and 09:43
inaccuracy becomes a bit fuzzy. 09:43
BY MR. MASON: 09:43
Q. In 2009, would you want to avoid 09:43
providing PWDs with any CGM data? 09:43
MR. CARROZZA: Objection to form. 09:43
THE WITNESS: No. 09:43
BY MR. MASON: 09:43
Q. In what context would you want -- 09:43
strike that. 09:43
Would you -- strike that. 09:43
Would a POSITA know that CGM data in 09:44
2009 could help patients make decisions 09:44
relating to diabetes management? 09:44
MR. CARROZZA: Objection to form. 09:44

THE WITNESS: If we use the broad term of management, perhaps. However, insulin treatment or medication treatment could not be made based on CGM data in 2009. 09:44

BY MR. MASON: 09:44

Q. And in 2009, would a POSITA know that CGM data then could be used to make management decisions other than insulin treatment? 09:44

MR. CARROZZA: Objection to form. Incomplete hypothetical. 09:45

THE WITNESS: No. There are certain medications that are not insulin for which treatment decisions should not be made in 2009 based on CGM data. 09:45

BY MR. MASON: 09:45

Q. And in 2009, would you want to provide CGM data to patients for making decisions on when to perform a fingerstick? 09:45

A. In 2009, any CGM data that was called into question by the patient was recommended -- actually, required to do a fingerstick before making a treatment decision. 09:46

Q. Okay. Did PWDs use CGM data to 09:46

determine whether or not to perform a fingerstick in 2009? 09:46

A. That wasn't the sole reason that they'd use fingersticks, but yes. 09:46

Q. And in 2009, were there any other diabetes management actions that a patient might take based on CGM data? 09:46

MR. CARROZZA: Objection to form. 09:46

THE WITNESS: There probably were other things that they could do with lifestyle. 09:47

BY MR. MASON: 09:47

Q. Did you, in 2009, work with any PWDs who were using a CGM device? 09:47

A. I don't recall. I don't think so. 09:47

Q. And prior to 2009, did you work with any PWDs who were using a CGM device? 09:47

A. There may have been one or two that I worked with an endocrinologist who was prescribing if they had Type 1 diabetes; but I did not, essentially, because my focus was Type 2 diabetes. And in 2009, they were not approved for patients with Type 2 diabetes. It was primarily a Type 1 diabetes device. 09:48

Q. And when you say "they," are you 09:48

referring to CGM devices? 09:48
A. I'm sorry? 09:48
Q. You're referring to CGM devices? 09:48
A. Yes. 09:48
Q. I just want to make sure the record is clear. 09:48
So in 2009, CGM devices were primarily a Type 1 diabetes treatment; is that correct? 09:48
A. That's correct. 09:48
Q. Okay. Did a POSITA know that it was important to avoid providing uncalibrated glucose data to users? 09:49
MR. CARROZZA: Objection to form. 09:49
THE WITNESS: Uncalibrated -- oh, from the CGM? 09:49
BY MR. MASON: 09:49
Q. Correct. 09:49
A. That was certainly in the user's manuals, that they should be -- they needed to be calibrated. 09:49
Q. Yeah. And just to make sure I was clear, because my question wasn't perfect, but did a POSITA know it -- that it was important to avoid providing uncalibrated CGM data to 09:49

users? 09:49
A. Yes. 09:49
Q. In 2009, did a POSITA know that it was important to provide as much accurate glucose data as possible to PWDs? 09:49 09:50 09:50
MR. CARROZZA: Objection to form. 09:50
THE WITNESS: From a CGM? 09:50
BY MR. MASON: 09:50
Q. Correct. 09:50
A. Yes. Yes. 09:50
Q. Could I have you turn to paragraph 42 of your declaration? 09:50 09:51
A. Okay. 09:51
Q. And in paragraph 42, do you discuss the need for PWDs to treat themselves or have a family member do so? Strike that. I'll rephrase my question. 09:51 09:51 09:51
Do you opine in paragraph 42 that nearly all of the interventions used to treat diabetes are managed by the PWD or their loved ones? 09:51 09:51 09:51
A. Yes. 09:51
Q. Okay. And what time period was this in? Or strike that. 09:51 09:51
Are your opinions in paragraph 42 09:51

applicable to from 2009 until the present? 09:52
A. Yes. 09:52
Q. Okay. And if you could turn then, Dr. Wright, to paragraph 48. And in paragraph 48 of your declaration, do you discuss blood glucose monitoring using disposable strips? 09:52
A. I do, yes. 09:52
Q. Okay. And are those opinions here in paragraph 48 applicable to -- strike that. 09:52
Are those opinions here in paragraph 48 applicable from 2009 up until the present? 09:52
A. Yes. 09:52
Q. And then in paragraphs 51 to 54, do you provide certain opinions on CGM? 09:52
A. Yes, I do. 09:53
Q. Okay. And those opinions in paragraphs 51 to 54, do those reflect the state of diabetes treatment from 2009 until the present? 09:53
MR. CARROZZA: Objection. Form. 09:53
THE WITNESS: This was written more contemporaneously and, really, I think reflects more in the recent -- the past 09:53

five to seven years as CGMs have become more accurate. 09:54

BY MR. MASON: 09:54

Q. So if we look at, for example, paragraph 51, are your opinions in that paragraph -- do those reflect -- 09:54

A. Yeah. 09:54

Q. -- the state of CGMs in 2009? And I'm just trying to get a -- 09:54

A. Yes. 09:54

Q. I'm just trying to get a sense of time here. 09:54

A. Yes. 09:54

Q. So I'll repeat my question. 09:54

Looking at paragraph 51, are your opinions in that paragraph reflecting the state of diabetes management in 2009? 09:54

A. Yes, they do. 09:54

Q. Okay. And then in paragraph 52, do those opinions reflect the state of diabetes management in 2009? 09:54

A. Yes, they do. 09:54

Q. And then in paragraph 53, do your opinions reflect the state of diabetes management in 2009? 09:54

A. Yes, they do. 09:55
Q. And then in paragraph 54 of your declaration, do your opinions there reflect the state of diabetes management in 2009? 09:55
A. Yes. 09:55
Q. And could I have you turn to paragraph 78 of your declaration, please, Dr. Wright? 09:55
A. What paragraph? 09:55
Q. 78. When I talk slow, sometimes I also start to whisper. 09:55
Yeah, so my -- please let me know when you're at paragraph 78. 09:56
A. I'm at paragraph 78. 09:56
Q. Okay. And in paragraph 78, do you discuss the accuracy of CGM as compared with SMBG? 09:56
A. Yes, I do. 09:56
Q. And for what time period are these opinions in paragraph 78? 09:56
A. I believe I refer to these as the first generation CGM devices. 09:56
Q. Would that be 2006 and earlier? 09:56
A. Certainly earlier. One might consider 2009 CGM devices to be first 09:56

generation as well. 09:56
Q. Okay. Do your paragraph -- strike that. 09:56
09:57
Do your opinions in paragraph 78 relate to both Type 1 and Type 2 diabetes? 09:57
MR. CARROZZA: Objection to form. 09:57
Those aren't his opinions. 09:57
You are referring to paragraph 78. 09:57
It's a quotation of an article. 09:57
BY MR. MASON: 09:57
Q. Dr. Wright, do you state at the beginning of paragraph 78: Poor accuracy was initially a barrier to adopting CGMs? 09:57
A. Yes. 09:57
Q. Yeah. Is that your opinion? 09:57
A. Yes. 09:57
Q. Okay. And do your opinions in paragraph 78 relate to both Type 1 and Type 2 diabetes? 09:57
A. Yes, they do. 09:58
Q. And by a barrier to adopting CGMs, do you mean that they prevented PWDs from using CGMs entirely? 09:58
A. You know, I think of barrier in this context as being an obstacle. It wouldn't 09:58

prevent necessarily entirely, but it could certainly influence the decision. 09:58

Q. And when you say influence the decision, do you mean influence the decision whether or not to prescribe a CGM or not? 09:58

A. Well, for a person with diabetes, they wouldn't be prescribing. That would be the healthcare practitioner who would prescribe. 09:58

Q. So what -- what did you mean by certainly influence the decision? 09:58

A. It could influence the decision on the part of the patient with diabetes or -- and/or the healthcare professional. 09:58

Q. And by decision, are you talking about the decision to use a CGM or a decision to rely on CGM data? 09:59

A. It could be both. 09:59

Q. Is it true that patients -- strike that. 09:59

Is it true that PWDs were using CGMs prior to 2009? 09:59

A. Yes. 09:59

Q. And is it true that PWDs were using CGMs to assist in diabetes management prior to 09:59

2009? 09:59
MR. CARROZZA: Objection to form. 09:59
THE WITNESS: Yes. 09:59
BY MR. MASON: 09:59
Q. And would a POSITA know that PWDs were using CGMs to assist in diabetes management prior to 2009? 09:59
MR. CARROZZA: Objection to form. 09:59
THE WITNESS: Yes. 09:59
BY MR. MASON: 09:59
Q. Can I have you turn to paragraph 81? 09:59
A. Mm-hmm. 10:00
Q. In paragraph 81, do you discuss -- strike that. 10:00
In paragraph 81, do you quote from an article that describes confirmatory fingersticks, near the middle of that quote? 10:00
A. Yes. 10:00
Q. Do you understand what is meant by confirmatory fingersticks? 10:00
A. Yes. 10:00
Q. Okay. And what is meant by confirmatory fingersticks? 10:00
A. Well, this is in reference to when you get a value from your CGM, that it needs to 10:00

be confirmed with a fingerstick. 10:00

Q. And what might lead a PWD to take a confirmatory fingerstick in 2009? 10:00

A. Typically, if the symptoms they were experiencing did not match the values, the data they were seeing on their CGM. 10:01

Q. And in 2009, would you expect PWDs to perform a confirmatory fingerstick based on CGM readings? 10:01

MR. CARROZZA: Objection to form. 10:01

THE WITNESS: I'm sorry. Would you ask that again? 10:01

BY MR. MASON: 10:01

Q. Yeah. 10:01

In 2009, would you expect PWDs to perform configutory -- confirmatory fingersticks after seeing a trend, for example, on a CGM data? 10:01

MR. CARROZZA: Objection to form. 10:01

THE WITNESS: In 2009, I believe the instruction was that if you have a reading that doesn't match your symptoms, you need to confirm. The further instructions were before making insulin-dosing decisions, you had to confirm. I don't believe that they 10:01

mentioned a trend. 10:02
BY MR. MASON: 10:02
Q. Okay. In your opinion, in 2009, would PWDs rely on glucose trends from a CGM when deciding whether to perform a fingerstick? 10:02
MR. CARROZZA: Objection to form. 10:02
THE WITNESS: The instruction that they were given was if your symptoms do not match the reading, you should perform a confirmatory fingerstick. If you're about to make an insulin-dosing decision, you have to make use -- confirm a fingerstick to make that dosing decision. 10:02
BY MR. MASON: 10:03
Q. And what -- in 2009, what might lead a patient to want to perform a dosing decision based on CGM data? 10:03
A. Well, in Type 1s, they typically dose before a meal or may dose if they determine that they are -- or not dose if they have symptoms of hypoglycemia. 10:03
Q. Would you expect PWDs in 2009 to make decisions on whether to perform a fingerstick based on trends reflected in CGM data? 10:04

A. Not necessarily.
Maybe I can give you an example. If the CGM data was reading a blood glucose of 80 but you were having symptoms of hypoglycemia, you would be required to do a fingerstick. 10:04
Q. Okay. How about if the -- strike that. Maybe I'll offer a different question. 10:04
If the CGM data were trending rapidly downward, would that motivate a PWD in 2009 to perform a fingerstick? 10:04
A. Perhaps, yeah. 10:04
Q. And if -- okay. 10:04
Could I have you turn to paragraph -- are you on paragraph 81? Look at that. You're there already. 10:04
A. Uh-huh.
Q. In paragraph 81, you also note that CGMs were only approved for adjunctive use in 2009? 10:05
A. That is accurate. 10:05
Q. And does that mean that the FDA did not approve CGMs to be used as the sole basis for insulin-dosing decisions? 10:05
A. That's accurate. 10:05
Q. Is it accurate that the FDA did 10:05

approve CGMs to be used for insulin-dosing decisions so long as it was in conjunction with SMBG measurements? 10:05

A. I'm not sure that it said it like that. I'd have to look at it. 10:05

Q. Is it your recollection that the FDA did approve CGMs to be used for insulin-dosing decisions so long as they were used in conjunction with SMBG measurements? 10:06

MR. CARROZZA: Objection to form. 10:06

THE WITNESS: I don't recall that. 10:06

I would have to look. 10:06

BY MR. MASON:

Q. Look, yeah.

A. You know, our instructions to the patients were to use fingersticks for insulin dosing. 10:06

Q. But you'd have to look at the FDA language before offering an opinion to say specifically what was allowed? 10:06

A. Well, you asked me if I recall that was what the FDA said. I'd have to -- 10:06

Q. No, that's fair. 10:06

MR. CARROZZA: We've been going for a little over an hour, if you're thinking 10:07

about a break. 10:07
MR. MASON: Yeah. Yeah, no. I'm 10:07
just seeing if I have any more questions. 10:07
Yeah, I think we can take a break 10:07
right now. 10:07
(Recess had.) 10:07
BY MR. MASON: 10:21
Q. Are you ready to resume your 10:21
deposition, Dr. Wright? 10:21
A. I am ready. 10:21
Q. All right. And while we were on 10:21
break, did you discuss the substance of your 10:21
testimony with Mr. Carrozza? 10:21
A. I did not. 10:21
Q. Okay. Do you recall earlier talking 10:21
about CGM only being approved for Type 1 10:21
diabetes in 2009? 10:21
A. In 2009, Type 1 diabetes -- patients 10:21
with Type 1 diabetes were most commonly using 10:22
CGM. 10:22
Q. Okay. And was -- strike that. 10:22
Were CGMs -- strike that. 10:22
And why was it most -- strike that. 10:22
Why were CGMs most commonly used to 10:22
treat Type 1 diabetes in 2009? 10:22

A. So in 2009, Type 1 diabetes were all treated with insulin. CGM devices in 2009 were used for patients with insulin-requiring diabetes, and Type 1 patients all required insulin. 10:22

Q. And is that in contrast to Type 2 PWDs? 10:22

A. I'm sorry. I don't understand the question. 10:22

Q. Yeah, that was a poor question. 10:22

So why were CGMs not as commonly used to treat Type 2 diabetes in 2009? 10:22

A. That's a good question. 10:23

Inasmuch as there were -- not all patients with Type 2 diabetes required insulin -- 10:23

Q. Okay. 10:23

A. -- in 2009. Many patients with Type 2 diabetes only -- if they were taking insulin, were only taking basal insulin. And it was not felt that they required CGM to help manage their diabetes. 10:23

Q. And when you say basal insulin, do you mean just take it at one or two specific times in the day? 10:23

A. Basal insulin is typically taken once a day. 10:23

Q. And when did you start working with patients on use of CGM devices? 10:24

A. When did I start working with patients? 10:24

Q. Mm-hmm. 10:24

A. I don't recall the exact date. Between 2015, 2016. 10:24

Q. And was that in relation to your work on GPIR? 10:24

A. The work on the GPIR came subsequent to that. 10:24

Q. Okay. And have you -- strike that. 10:24

Was there any particular reason that led you to begin working with CGM devices in that 2015/2016 time period? 10:24

A. There were a number of reasons. One, the patients with Type 2 diabetes did take insulin. Patients with Type 2 diabetes did take other medications that could cause them to be hypoglycemic. And many patients with Type 2 diabetes who may have been taking insulin were not always aware that they were hypoglycemic because it could occur overnight. 10:25

Q. Okay. And then you said shortly after that work, you began working on GPIR with Abbott? 10:25
A. Yes. 10:25
Q. Okay. And what led to the GPIR work? 10:25
A. Well, the Glucose Patterns Insight Report was a report -- is a report to help clinicians who are not familiar with the standard report of glucose -- it's called the AGP, or ambulatory glucose profile -- to help give them a way to quickly review the report and make safe, effective treatment decisions. 10:25
Q. Did you work with Dr. Howard Wolpert, W-O-L-P-E-R-T, in relation to this GPIR work? 10:26
A. Yes, we did. 10:26
Q. Okay. Who is Dr. Wolpert? 10:26
A. Dr. Wolpert is an endocrinologist in Boston. 10:26
Q. Have you worked with him regularly? 10:26
A. I wouldn't say regularly, but we have worked together. 10:26
Q. Is he knowledgeable about CGM? 10:26
A. Yes, he is. 10:26

Q. Is he knowledgeable about the use of CGM data for diabetes management? 10:26 10:27

A. Yes, he is. 10:27

Q. Are you familiar with the Juvenile Diabetes Research Foundation? 10:27 10:27

A. I am familiar with it. 10:27

Q. And can we refer to that as JDRF? 10:27

A. Yes, we can. 10:27

Q. All right. Thank you. 10:27

What is JDRF? 10:27

A. You've just said it's the Juvenile Diabetes Research Foundation. 10:27 10:27

Q. Was JDRF responsible for key research on CGM technology? 10:27 10:27

A. It's one of the organizations, yes. 10:27

Q. Okay. What are some other organizations that are sort of at the center of the CGM technology development? 10:27 10:27 10:27

MR. CARROZZA: Objection to form. 10:27

THE WITNESS: Well, the Type 1 Diabetes Exchange does do some work with CGM, more in deployment of CGM, how to use it. 10:27 10:27 10:28 10:28

BY MR. MASON: 10:28

Q. Have you heard of the 10:28

Sensor-Augmented Pump Therapy for A1C Reduction, also known as STAR studies? 10:28

A. I'm familiar with sensor-augmented pump. I'm not familiar with the specific study. 10:28

Q. Okay. Are you familiar with the Indian Institute of Science at Bangalore? 10:28

A. The -- which one? 10:28

Q. Sorry. I was -- yeah, I'll state that again. 10:28

Are you familiar with the Indian Institute of Science (Bangalore)? 10:28

A. I'm not familiar with that name. I may know the researchers there, but I don't recognize the name of the institute. 10:28

Q. Okay. Are you familiar with the University of Padova, P-A-D-O-V-A? 10:28

A. Not specifically. 10:28

Q. Do you know whether the University of Padova was engaged in CGM research before 2009? 10:29

A. I do not know. 10:29

Q. Okay. Could I have you turn to paragraph 84 of your declaration. Is paragraph 84 the first paragraph in a section 10:29

that's been headered "Historical Reports"? 10:29
A. Yes, it is. 10:29
Q. Okay. And did you choose that term, historical reports, as a section header because it had a well-understood meaning in the art in 2009? 10:29
A. Yes. 10:29
Q. Okay. What was the well-understood meaning in the art of historical reports in 2009? 10:29
A. Well, as in the CareLink system, you downloaded data and you produced a historical report that was sort of a retrospective view of assimilated, organized, analyzed data. 10:29
Q. Yeah. And I might -- might have -- I asked my question uncarefully. 10:30
But so my question is: Is the term historical reports in 2009, was that a well-understood term of art in the field of diabetes care? 10:30
A. I would think so. 10:30
Q. Okay. So historical reports -- strike that. 10:30
Is it your testimony today, then, that the term historical reports would have had 10:30

a precise definition to any diabetes management clinician in 2009? 10:30

MR. CARROZZA: Objection to form. Asked and answered. 10:30

THE WITNESS: I'm not sure what you mean by a precise definition. People who were in the field understood historical reports to mean reports that reflect history. 10:31

BY MR. MASON: 10:31

Q. And by reports, do you just mean presentation of CGM data? 10:31

A. No. 10:31

Q. Was historical reports a term that you used in your publications in 2009? 10:31

A. Which publication are you referring to? 10:31

Q. Oh, I'm just asking if you had publications -- I'm just asking generally, yeah. 10:31

So maybe a better question would be -- my question is: Did you use the term historical reports in any publications prior to 2009? 10:31

MR. CARROZZA: Objection to form. 10:32

THE WITNESS: Prior to 2009? 10:32
BY MR. MASON: 10:32
Q. Yeah. 10:32
A. I really can't recall all of the 10:32
words that I used. I have an understanding of 10:32
what historical report means and meant to me. 10:32
Q. Yeah. And do you specifically 10:32
recall using the term historical reports in 10:32
2009? 10:32
A. I can't recall specifically in a 10:32
publication. If you show me a publication, I 10:32
can tell you if I used it; but I've got a 10:32
number of publications. 10:32
Q. Aside from the exhibits describing 10:32
the Paradigm system, are you aware of any usage 10:32
of the term historical reports? 10:32
MR. CARROZZA: Objection to form. 10:32
THE WITNESS: For my declaration, I 10:32
reviewed, obviously, the Paradigm and the 10:32
CareLink reports; and that's where my 10:32
reference to historical reports comes from. 10:32
BY MR. MASON: 10:32
Q. Okay. And are you aware of any 10:32
usage of that term historical reports outside 10:32
Exhibit 1011 in this proceeding? 10:32

A. I can't tell you that truthfully that I can recall if I've ever seen that -- those terms used in other publications. 10:33

Q. Can you recall ever specifically using that term historical reports in -- in communications with other clinicians prior to 2020? 10:33

MR. CARROZZA: Objection. 10:33

THE WITNESS: Prior to 2020? 10:33

MR. CARROZZA: Objection to form. 10:33

THE WITNESS: Certainly. 10:33

BY MR. MASON: 10:33

Q. Okay. When do you recall specifically using that term historical reports? 10:33

A. Well, for instance, the -- 2016, when we did the study with the blinded CGM, or the PRO, at the end of the wear period, you get a historical report. 10:33

Q. Okay. And Abbott referred to its data as being presented in a "historical report"? 10:33

MR. CARROZZA: Objection to form. 10:34

THE WITNESS: I don't recall. Can you ask that question again? 10:34

BY MR. MASON: 10:34

Q. Yeah. I just -- I'm trying to understand. My questions here are just getting at the specific term -- 10:34

A. Historical report. 10:34

Q. -- historical report as opposed to something else that you might understand is encompassed by historical report. 10:34

So my question is -- I'll come back to it: In 2016, is it your testimony that you can recall specifically using that term historical report? 10:34

A. I don't recall specifically using the term, but I would have used that in the context of a PRO, where you get a report that reflects the history there in a historical report. 10:34

Q. Okay. And so a historical report, in your mind, was a presentation of historical data? 10:34

A. You know -- 10:34

MR. CARROZZA: Objection. Asked and answered that exact question. 10:34

THE WITNESS: I would suggest that the presentation of the data in a report, 10:35

the data has been then organized, summarized, and analyzed to develop the information that comes out of the report. 10:35 10:35 10:35

BY MR. MASON: 10:36

Q. In 2009, was it important for PWDs to understand how their daily choices were impacting blood glucose levels? 10:36 10:36 10:36

A. Yes. 10:36

Q. Okay. And in 2009, was it known that it was helpful to understand the impact of, say, a meal on blood glucose levels? 10:36 10:36 10:36

MR. CARROZZA: Objection to form. 10:36

THE WITNESS: Yes. 10:36

BY MR. MASON: 10:36

Q. And in 2009, was it known that it was helpful to understand the impact of exercise on blood glucose levels? 10:36 10:36 10:36

A. Yes. 10:36

Q. And in 2009, was it known that it was helpful to understand blood sugar levels overnight for a PWD? 10:36 10:36 10:37

A. Yes. 10:37

Q. Would you ever instruct patients to use BGM -- strike that. 10:37 10:37

Would you ever instruct patients to 10:37

perform fingersticks throughout the night? 10:37
A. We have done that before, yes. 10:37
Q. Okay. In 2009, did you instruct patients to use BGM throughout the night? 10:37
A. I did not in 2009. One exception. If -- and I wouldn't instruct the patient. I would instruct the family member. If the patient became seized or had some problem during the night and they had taken insulin previously, they would be instructed to take a blood sugar after they called for emergency. 10:37
Q. Okay. That makes sense, yeah. 10:38
And just to be -- just to make sure I understand, that explanation you were providing is just that anytime there was an event -- 10:38
A. An event. 10:38
Q. -- an emergency event, you would recommend taking a BGM measurement, regardless of the time of day -- 10:38
A. Correct. 10:38
Q. -- or night? 10:38
A. Or night, correct. 10:38
Q. Do you know if Abbott had a CGM device in 2009? 10:39

A. The Abbott Navigator. 10:39
Q. Are you familiar with that device? 10:39
A. Overview of the device, it was used primarily in the UK. It was used a bit in the U.S. 10:39
Q. Did the Abbott Navigator display trend graphs on its receiver device? 10:40
A. I couldn't tell you specifically right here or recall. 10:40
Q. And did the Abbott Navigator backfill data from the sensor to a receiver device? 10:40
MR. CARROZZA: Objection to form. 10:40
Asked and answered. Beyond the scope of his declaration. Again, the scope of anything even relevant to this proceeding. 10:40
THE WITNESS: I don't recall. 10:40
BY MR. MASON: 10:40
Q. Do you recall offering testimony on the capabilities of DexCom and Medtronic devices in the 2009 to 2016 time frame? 10:40
MR. CARROZZA: Objection to form. 10:40
THE WITNESS: Where are you referring to in my declaration? 10:40

BY MR. MASON: 10:40
Q. If you look at paragraph 95, sir. 10:40
A. 95. 10:41
Q. And if we look at paragraph 95, is that a section that you have headered "Data Gaps"? 10:41
A. Yes, I did. 10:41
Q. And that section ends with paragraph 110, correct? 10:41
A. Yes, it does. 10:41
Q. And in these paragraphs, do you discuss your opinions that DexCom's earlier systems did not provide data gaps? 10:41
MR. CARROZZA: Objection. 10:42
BY MR. MASON: 10:42
Q. Strike that. Maybe I'll ask a different question. 10:42
Is there any reason that you did not discuss the Abbott devices in these paragraphs 95 through 110? 10:42
A. Permit me to read them again. 10:42
Q. Yes. 10:42
MR. CARROZZA: I'm going to object to the form of the question. 10:42
THE WITNESS: Okay. Now, your 10:45

question again was?
BY MR. MASON:
Q. Yeah.
In those paragraphs 95 to 110, do you discuss any Abbott devices?
A. I do not.
Q. Is there a reason you did not discuss any Abbott device in paragraphs 95 to 110?
A. I was just giving examples.
Q. Okay. Can I have you turn to paragraph 126, Dr. Wright?
A. Okay.
Q. And in paragraph 126, do you opine on the types of problems facing those skilled in the art?
A. Yes.
Q. Okay. And this is in the context of a POSITA, correct? If we look at the section header prior to paragraph 122, it's the -- under the section "Person of Ordinary Skill in the Art"?
A. Right. Yes, it is.
Q. Now, turning -- and looking at paragraph 126, is it your testimony that one

known problem to POSITAs was "adverse conditions that interrupt the operation of CGMs and result in data gaps appearing on the CGM display in place of glucose values"? 10:47

A. Yes. 10:47

Q. And is it your opinion that this is one of the problems that a POSITA would want to solve? 10:47

MR. CARROZZA: Objection to form. 10:47

THE WITNESS: I don't -- I think in this context, this is certainly something that would need to be considered. 10:47

BY MR. MASON: 10:48

Q. Okay. Could I have you turn to paragraph 151 of your declaration? 10:48

A. Okay. 10:48

Q. And then in paragraph 151, you provide a graph from the Paradigm Exhibit 1011? 10:48

A. Yes. 10:49

Q. Okay. And does that graph compare CGM glucose data with glucose measurements using other technologies? 10:49

A. I believe this graph from Chapter 7 is a representative example of continuous sensor tracing versus reference blood glucose 10:49

readings.
Q. And you reproduced that same graph with annotations in paragraph 152 of your declaration?
A. Yes.
Q. And you reproduced that same graph in paragraph 154 of your declaration with annotations added?
MR. CARROZZA: Counsel, I just want to mention for the record that second one is colored, but we printed it black-and-white.
MR. MASON: Oh.
MR. CARROZZA: He's looking at black-and-white.
MR. MASON: Okay. Fair enough.
BY MR. MASON:
Q. Is it fair to say that what's in paragraph 154 is a reproduction of that same graph that's shown in paragraph 151?
A. Yes.
Q. Am I correct that in that graph shown in paragraph 151, that the solid line is the CGM data?
A. Yes, it is.

Q. And am I correct that the large hollow circles in that graph in paragraph 151 are SBGM data? 10:50

A. SMBG? 10:50

Q. Is that -- sorry -- did I say -- yeah. 10:50

A. So the closed circles or the dots represents reference blood glucose readings. The solid lines represents the sensor glucose values. 10:50

(Reporter clarification.) 09:53

THE WITNESS: Sensor, the sensor glucose values. 09:53

BY MR. MASON:

Q. And what do the larger hollow circles in that graph in 151 represent? 10:51

And it might help you to just look at page 96 of Exhibit 1011. 10:51

A. Okay. Page 90? 10:51

Q. Oh, no, I'm sorry, not on your -- this is -- I think here, you're pulling this from Exhibit 1011. 10:51

A. Okay. 10:51

Q. So it may help you look at -- 10:51

A. It would. 10:51

Q. -- yeah, page 96 of that. 10:51
A. Page 90, you said? 10:52
Q. 96. I think that's what you cite, 10:52
to this page 96. 10:52
A. The open circles on the graph 10:52
represent meter calibration readings from -- 10:52
Q. And what do you understand meter 10:52
calibration readings to mean? 10:52
A. Fingerstick SMBG calibrations. 10:52
Q. And there in the graph that's 10:52
reproduced in paragraph 151 of your 10:53
declaration, do the closed circles represent 10:53
the reference blood glucose readings? 10:53
A. The closed circles represent 10:53
reference blood glucose readings. 10:53
Q. Okay. What is used -- strike that. 10:53
What was used to create those 10:53
reference blood glucose readings? 10:53
A. Typically, they use what's called a 10:53
YSI, Yellow Springs Instrument, blood test to 10:53
reproduce that. But they would note that in 10:53
their manual. 10:53
Q. So is it fair that your best 10:53
expectation is that those reference values 10:54
would be taken using what you said was YSI? 10:54

A. Yellow Springs Instrument, YSI. That's the type of device that measures blood glucose. 10:54

Q. And that's Yellow, the color, Springs Instrument? 10:54

A. (Indicating). 10:54

Q. Okay, YSI. What is YSI? 10:54

A. It's an analyzer that is used for reference. 10:54

Q. And when you say reference, is it an -- strike that. 10:54

Is YSI an analyzer that is used for reference blood glucose levels? 10:54

A. Yes. 10:54

Q. Okay. Is a YSI device something that PWDs use at home? 10:54

A. They would not. 10:54

Q. Okay. Where is a YSI device used? 10:54

A. Typically in a laboratory. 10:54

Q. So just so that I make sure I understand what -- everything that's in paragraph 151's graph, in paragraph 151, that graph you reproduced, the solid line represents glucose measurements taken using a CGM; is that correct? 10:54 10:55 10:55 10:55 10:55

A. Using a CGM sensor, yes. 10:55
Q. And the open circles represent 10:55
glucose measurements taken using a 10:55
fingerstick -- 10:55
A. Yes. 10:55
Q. -- is that correct? 10:55
Okay. And is it correct that the 10:55
small dots -- 10:55
A. Solid. 10:55
Q. Yes, thank you. 10:55
Is it accurate that the solid dots 10:55
represent blood glucose readings taken using a 10:55
YSI? 10:55
A. YSI reference -- 10:55
Q. Okay. 10:55
A. -- analyzer. 10:55
MR. MASON: Can you mark this as 10:56
Exhibit 10 -- do you mind a double-sided 10:56
copy of the exhibit? 10:56
THE REPORTER: It's up to you, 10:57
counsel. I don't mind either way. 10:57
MR. MASON: All right. Can I have 10:57
you mark this, Jennifer, as Exhibit 1050? 10:57
(Deposition Exhibit 1050 was marked
for identification.) 10:57

BY MR. MASON: 10:57

Q. Please let me know when you have a chance to review Exhibit 1050, Dr. Wright. 10:57

A. I briefly reviewed it. Is there some specific area you wish me to -- 10:58

Q. No. Do you recognize Exhibit 1050? 10:58

A. Yes, I do. 10:58

Q. Yeah, you do. 10:58

And what is Exhibit 1050? 10:58

A. It's a published paper from the supplement of the Journal of Family Practice from December of 2015. 10:59

Q. Okay. And are you one of two authors on this paper? 10:59

A. Yes, I am. 10:59

Q. Okay. And do you recall writing this paper? 10:59

A. I do. 10:59

Q. And do you recall publishing this paper in 2015? 10:59

A. Yes. 10:59

Q. Okay. Or rather, do you recall this paper being published? 10:59

A. Being published. I didn't publish it, that's correct. 10:59

Q. Okay. And is this Exhibit 1050 an accurate copy of that article as it was published in 2015? 10:59

A. It appeared to be. I haven't read it completely, but it certainly appears to be. 10:59

Q. I can just give you a couple more minutes to look at it if you want to, just to make sure that you don't see any issues with it. 10:59

MR. CARROZZA: Objection. Form. 10:59

What issues are you referring to? 10:59

BY MR. MASON:

Q. Just let me know when you're finished. 11:00

A. Okay. I think I'm confident that this is my paper. 11:00

Q. Thank you. Let's see... 11:00

MR. MASON: Can I have you mark this as Exhibit 1051? 11:01

(Deposition Exhibit 1051 was marked for identification.) 11:01

BY MR. MASON: 11:01

Q. Do you have in front of you Exhibit 1051? 11:01

A. Yes, I do. 11:01

Q. Okay. And I'll represent to you that this is a -- an excerpted graph showing, with solid squares, fingerstick readings taken by a PWD. Do you understand? 11:01 11:01 11:01 11:02

MR. CARROZZA: Hold on, Andy, before we go further. An excerpt of what? What are we looking at here? And where is this in his report? What is this in response to? How is this even relevant to his opinions? 11:02 11:02 11:02 11:02 11:02 11:02

MR. MASON: Well, he's opined on the relevance of fingersticks to glucose management. 11:02 11:02

BY MR. MASON: 11:02

Q. So, Dr. Wright, do you see Exhibit 1051? 11:02 11:02

A. I see it. 11:02

Q. Okay. And are you able to understand the graph presented on Exhibit 1051 and, in particular, the indications of fingerstick glucose measurements indicated by the solid squares? 11:02 11:02 11:02 11:02 11:02

MR. CARROZZA: Hold on before you answer. 11:02

MR. CARROZZA: Objection to form. I'm going to 11:02

make a few objections here.

First of all, you haven't explained what he's looking at. You're asking him to appreciate what it is. So I'm going to object to the fact that you haven't explained where this is an excerpt from, number one.

Number two, this is outside the scope of his declaration because this figure is not in Mr. Gross's declaration, nor is it in any other reference or paper in this proceeding. This is outside the scope of his direct examination -- direct testimony. Excuse me.

MR. MASON: Okay. Are you instructing the witness not to answer?

MR. CARROZZA: No. I just stated my objections, because you haven't explained what this is from.

BY MR. MASON:

Q. So, Dr. Wright, in your declaration, have you offered opinions on the value of fingersticks glucose measurements as compared to CGM glucose measurements?

A. I offered an opinion that for --

fingersticks were required for treatment decisions. 11:03

Q. Okay. 11:03

A. May I ask where this is from? 11:03

Q. I'm -- 11:03

A. I have not seen this before. 11:03

Q. Yeah, yeah. No, I understand. I understand you have not seen this before. 11:03

And I will represent to you that what's shown here is a graph for a single day depicting, in solid squares, four different fingerstick measurements taken by a -- by a patient. Do you understand? 11:04

A. I think I do. 11:04

Q. Okay.

(Reporter clarification.) 09:53

MR. CARROZZA: I was just going to say same objections. 11:04

BY MR. MASON: 11:04

Q. And do you see on the left hand -- or sorry -- in the Y axis of the graph, it indicates glucose levels in milligrams per deciliter? 11:04

A. I see these words, yes. 11:04

Q. Yeah. Is that an annotation or is 11:04

that a measurement that you understand? 11:04
A. It is. 11:04
Q. Okay. And do you see the time of day represented there on the "X" axis? 11:04
A. Yes, I do. 11:04
Q. Okay. And do you understand that representation indicating times throughout the day? 11:04
A. I do. 11:05
Q. Okay. And what -- do you see that first solid square on the left-hand side? 11:05
A. Yes. 11:05
Q. And what does that solid square tell you about glucose levels at that time? 11:05
MR. CARROZZA: Objection to form. Incomplete hypothetical. Incomplete description of what we're looking at. Outside the scope of his direct testimony. Outside the scope of this proceeding. 11:05
THE WITNESS: I would need to see the rest of this so that I know what this is in context of. It's just a picture with four blocks on it and a scale, but I don't have any context for this. 11:05

BY MR. MASON: 11:05
Q. Okay. And do you understand that 11:05
those four blocks are -- are fingerstick 11:05
readings, as I represent to you today? 11:05
MR. CARROZZA: Objection to form. 11:05
BY MR. MASON: 11:05
Q. Each of those -- strike that. 11:05
Each of those -- I represent to you 11:05
today that each of those four blocks is a 11:05
fingerstick reading. Do you understand that? 11:05
A. Yes. 11:05
MR. CARROZZA: Objection. 11:05
(Reporter clarification.) 09:53
MR. CARROZZA: Your representations 11:05
are meaningless. It doesn't make this any 11:05
relevant. 11:06
BY MR. MASON: 11:06
Q. Have you reviewed graphical data in 11:06
similar format? 11:06
MR. CARROZZA: Objection to form. 11:06
Vague. 11:06
THE WITNESS: In similar format to? 11:06
BY MR. MASON: 11:06
Q. To Exhibit 1051. 11:06
MR. CARROZZA: Objection to form. 11:06

Vague.

THE WITNESS: When you say graphical data, please help me --

BY MR. MASON:

Q. Yeah. I'm sorry. I --

A. I want to give you an accurate --

(Reporter clarification.) 09:53

THE WITNESS: So I asked what does he mean by graphical data. This is a plot.

BY MR. MASON:

Q. And if I represent to you that the red square just prior to 9:00 a.m. -- strike that.

If I represent to you that the solid square just prior to 9:00 a.m. is a fingerstick glucose reading, do you understand that?

MR. CARROZZA: Objection to form.

THE WITNESS: Yes.

BY MR. MASON:

Q. And are you able to tell, at least roughly, what a person's glucose level would be based on that solid square?

MR. CARROZZA: Objection to form.

THE WITNESS: When you say roughly, please be more specific.

BY MR. MASON: 11:07
Q. Oh, yeah, yeah. 11:07
Are you able to determine a person's 11:07
glucose level based on if -- if that solid 11:07
square represents a fingerstick reading taken 11:07
at that time, are you able to determine what 11:07
the patient's glucose level is at that time? 11:07
A. I am not. 11:07
Q. You're not, okay. 11:07
Would you understand that first 11:08
square to represent a blood glucose level of 11:08
just under 100 milligrams per deciliter -- 11:08
MR. CARROZZA: Objection. 11:08
Speculation. 11:08
BY MR. MASON: 11:08
Q. -- at just prior to 9:00 a.m.? 11:08
MR. CARROZZA: Objection. Calls for 11:08
speculation. Asked and answered. 11:08
THE WITNESS: Just under 100? 11:08
BY MR. MASON: 11:08
Q. Mm-hmm. 11:08
A. That's a lot of territory. 11:08
Q. How would you characterize that? I 11:08
guess -- well, my question to you is: Is it 11:08
your testimony today, then, that you're unable 11:08

to analyze glucose levels based on the presentation here in Exhibit 1051? 11:08

A. So typically with a fingerstick, we get a number, not a range. So a fingerstick would not give you just under 100. It would give you a number like 95, 90, 92. 11:08

I cannot see that on this representation, which is why I asked for the broader context so that I could understand what was being represented here. 11:08

Q. Yeah. And, you know, with that understanding -- and thank you for that -- with that understanding, would you be able to make treatment recommendations based on just an estimate of glucose -- 11:09

MR. CARROZZA: Objection. 11:09

BY MR. MASON: 11:09

Q. -- levels -- 11:09

MR. CARROZZA: Objection. 11:09

Speculation.

BY MR. MASON:

Q. -- on this --

(Reporter clarification.) 09:53

BY MR. MASON: 11:09

Q. And with that understanding, would 11:09

you be able to make treatment recommendations based on what's shown here in this graph? 11:09

MR. CARROZZA: Objection. Calls for speculation. 11:09

MR. MASON: Please limit your objections to form only, Mike. If I ask, you can tell me. But it's form only at the PTAB, so let's stop the talking objections. Form, scope, that's fine. Anything else, that's beyond the rules. 11:09

MR. CARROZZA: Andy, you know what's happening here. You know this is -- you know what's happening. 11:09

THE WITNESS: I would not make a treatment decision without knowing precise -- 11:09

BY MR. MASON: 11:09

Q. Value? 11:10

A. -- value. 11:10

Q. Okay. And you can set that aside now. You can set aside 1051. 11:10

Turning back to your report, you've discussed in -- and I'm not actually going to ask about any specific paragraph right now. 11:10

But in your report, do you discuss 11:10

the Paradigm REAL-Time system and its FDA approval? 11:10

A. Can you tell me where? 11:10

Q. I believe in paragraph -- well, strike that. 11:10

If you look in paragraph 82, I believe you discuss -- 11:11

A. 82? 11:12

Q. Yeah. I believe you first discuss the DexCom system. And then, am I correct that after that, you discuss FDA approval of the Medtronic Paradigm REAL-Time system? 11:12

A. Okay. I've read it. 11:12

Q. Do you know when the Paradigm REAL-Time system was originally approved by the FDA? 11:12

A. I don't. 11:12

Q. Okay. Do you know the times of any supplemental FDA -- strike that. 11:12

Do you know whether the FDA issued any supplemental approvals for the Paradigm REAL-Time system? 11:13

A. I do not specifically recall that, no. 11:13

Q. Your declaration discusses FDA 11:13

approval of the Paradigm REAL-Time system for adjunctive use. Do you know if the FDA approved the Paradigm REAL-Time system for any other use? 11:13

A. It's my understanding that the Medtronic still has an adjunctive claim. It's not -- doesn't have a nonadjunctive claim. 11:13

Q. Do you know if the Paradigm REAL-Time system was approved to make therapy adjustments? 11:14

A. That would be nonadjunctive. And to my knowledge, it does not have nonadjunctive approval. 11:14

MR. MASON: We've been going for about an hour. I think we can take a break. 11:14

(Recess had.) 11:14

MR. MASON: We can go back on the record. 11:28

BY MR. MASON: 11:28

Q. Are you ready to resume your deposition, Dr. Wright? 11:28

A. I am ready. 11:28

Q. All right. And when we were on break, did you discuss the substance of your 11:28

testimony with anyone? 11:28
A. I did not. 11:28
Q. All right. Thank you. 11:28
Do you recall earlier discussing how 11:28
hypoglycemia, I think you said, can occur 11:28
overnight? 11:28
A. Yes. 11:28
Q. Okay. Was it common for 11:28
hypoglycemia to occur overnight in diabetes 11:28
patients? 11:28
A. In diabetes patients in general or 11:28
specific diabetes patients? 11:28
Q. Oh, yeah. So -- strike that. 11:28
That's a fair question. 11:28
Is it common -- is hypoglycemia a 11:28
common concern for PWDs? 11:28
A. Yes. 11:28
Q. And is hypoglycemia overnight a 11:28
common concern for PWDs? 11:28
A. In patients who are taking 11:28
medications that can cause hypoglycemia, it is. 11:29
Q. Would it have been important -- 11:29
strike that. 11:29
Would it be important for a PWD to 11:29
know if hypoglycemia had occurred overnight? 11:29

A. Yes, it would. 11:29
Q. And was that the case in 2009 as well? 11:29
A. Yes. 11:29
Q. Okay. What are some causes of nocturnal hypoglycemia? 11:29
A. The most common cause would be someone who is taking insulin and the insulin is acting at a time when there is insufficient substrate and it would -- blood sugar would drop overnight. It can also occur with other medications that people take for diabetes. 11:29
Q. Okay. So is it -- strike that. 11:29
Do I understand correctly, then, that if -- strike that. I think I understood what you were saying. 11:29
But yeah, my question is: With the knowledge that nocturnal hypoglycemia had occurred, would a patient be able to adjust those medications? 11:30
A. The patient would be instructed to confer with their healthcare professional to make adjustments. 11:30
Q. Were there any other causes other than medication that might need to -- lead to 11:30

nocturnal hypoglycemia? 11:30
(Reporter clarification.) 09:53
BY MR. MASON: 09:53
Q. Lead to nocturnal hypoglycemia? 11:30
A. Yes. There's other causes. 11:30
Q. Okay. Well, what are some of those other causes? 11:30
A. Alcohol ingestion. 11:30
Q. Does alcohol cause a lowering of blood glucose levels? 11:30
A. It can. It can lead to hypoglycemia overnight. 11:30
Q. Okay. 11:30
A. Missed meals. If you take insulin and miss the meal, that could lead to hypoglycemia overnight. 11:30
Q. And would knowing about nocturnal hypoglycemia allow patients to make decisions about whether and when to ingest alcohol? 11:31
A. In consultation with a healthcare professional to look at the circumstances in which this occurred would lead to a better decision about what to do. 11:32
MR. MASON: Dr. Wright, I have no further questions. 11:32

MR. CARROZZA: Okay. Can we have a short break? 11:32

(Lunch recess had.) 11:57

EXAMINATION 12:28

BY MR. CARROZZA: 12:28

Q. Dr. Wright, do you recall Mr. Mason asking you questions about an Exhibit 1050? 12:28

A. I do. 12:29

Q. And is Exhibit 1050 an article that you are one of the authors on? 12:29

A. It is. 12:29

Q. The title is "Ambulatory Glucose Profiling." Is that often abbreviated as AGP? 12:29

A. It is. 12:29

Q. Do you have an understanding of what an AGP is? 12:29

A. Yes, I do. 12:29

Q. What is an AGP? 12:29

A. AGP is the ambulatory glucose profile, and it is a report that is generated from a large stream of glucose data that is collected over time and organized, analyzed, and displayed in report format. 12:29

Q. And what sort of data would be provided in an AGP report? 12:29

A. Typically, we have the -- what's called the "modal day," which is multiple days of data displayed as if it were in one day. We have number of statistics; such as the glucose management indicator, glycemic variability, the mean average glucose are just some of them. And we also display what are the target ranges, the highs and the lows, for that particular period of time and that data stream. 12:29 12:29 12:29 12:30 12:30 12:30 12:30 12:30 12:30

Q. You mentioned glycemic variability. What does that relate to? 12:30 12:30

A. Glycemic variability is the concept that blood glucose is not static. And it typically rises and falls both interday and intraday, so inside of one day and then over multiple days. 12:30 12:30 12:30 12:30 12:30

We try to conceptualize that for patients as that, as your blood sugar rises and falls during the course of a day, you really want to look at that over time to see if there is a pattern or a trend that is occurring that you then can recognize as something that would require making an adjustment. 12:30 12:30 12:30 12:30 12:30 12:30 12:30

Q. So you used the term "trend" just now to refer to the AGP report. What's your 12:31 12:31

understanding of the word trend in that context? 12:31

A. Well, a trend is that -- on any given day, a patient with diabetes is not the same. So we really look for these changes over time, over multiple days, as we make recommendations for treatment or management. 12:31

So, for instance, on any given day, if I eat two cookies, I may have a spike in the blood sugar; and the next day, I don't eat any, I may not. That will show up as part of my variability. But looking at it over time, it may even out. 12:31

Q. So when you were answering Mr. Mason's questions that used the word trend, was that your understanding of the word trend in your answers? 12:31

MR. MASON: Objection. Form. Scope. 12:31

THE WITNESS: I used the word trend with glycemic patterns as looking at trends of data over time. 12:31

BY MR. CARROZZA: 12:32

Q. Okay. Switching gears a little bit. 12:32

Do you recall -- 12:32

If a PWD were using a CGM in the 2009 time frame and they have data missing such that there is now a data gap on their CGM display, in what ways would that missing information be useful to the PWD for diabetes management -- 12:32

MR. MASON: Objection -- 12:32

BY MR. CARROZZA: 12:32

Q. -- if any at all? 12:32

MR. MASON: -- form. Objection to form. Scope. 12:32

THE WITNESS: In 2009, all treatment decisions were based on a fingerstick. So missing data from a CGM would be useful to me as a healthcare professional, as I said, with an AGP report so that I could look to see if there were periods or points in time where there potentially was a problem. 12:32 12:32 12:33 12:33 12:33

(Reporter clarification.) 09:53

THE WITNESS: Potentially was a problem. Sorry. 12:33

BY MR. CARROZZA: 12:33

Q. Okay. And let's switch gears slightly. 12:33 12:33

Do you recall Mr. Mason asking you 12:33

questions about a graph that is shown on page 96 of Exhibit 1011? 12:33

A. 1011 or -- yeah, I'm sorry. Wrong one. Page 96, yes. 12:33

Q. And do you recall Mr. Mason asking you questions about the open circles that are displayed or indicated on the graph on page 96? 12:34

A. The open circles represent self-monitored blood glucose readings that were used for calibration. 12:34

Q. And do you see the ones open circle that -- far to the left, but very near the top of the graph? It sort of looks like it corresponds to Day 1 at approximately, maybe, 1600 hours. 12:34

MR. MASON: Objection to form. 12:34

THE WITNESS: I do see that. 12:34

BY MR. CARROZZA: 12:34

Q. Do you have any thoughts on why that one open circle is so far off of the graph versus all of the other open circles? 12:34

MR. MASON: Objection. Form. 12:34

THE WITNESS: Clinically, when we see this pattern, it typically represents some sort of a -- I'll use the word user 12:34

error, that the patient didn't perform the fingerstick accurately. And there are a number of reasons why that might happen. 12:35

BY MR. CARROZZA: 12:35

Q. For example, like what? 12:35

A. The alcohol doesn't dry on the finger. They stuck -- they didn't wash their hands thoroughly before they performed the test, which is why we instruct them to do that, to wash their hands thoroughly, use -- allow the alcohol to dry before you do the fingerstick. 12:35

Q. And so the data point that's shown at about 1600 on page 96 of Exhibit 1011, the open circle, in your opinion, does that appear to be an inaccurate test result? 12:35

MR. MASON: Objection. Form. 12:35

THE WITNESS: To me, it appears to be -- if I look at the time that it occurred, it would be an after-lunch; and perhaps the person didn't wash their hand or something. I don't know. But it does not appear to be accurate when I look at the YSI. 12:35

MR. CARROZZA: We have no further 12:36

questions. 12:36
MR. MASON: I just have one question 12:36
on recross. 12:36
EXAMINATION 12:36
BY MR. MASON: 12:36
Q. Dr. Wright, were fingerstick user 12:36
errors, as you describe them, a known issue in 12:36
2009? 12:36
A. Oh, yes. 12:36
Q. And would those fingerstick user 12:36
errors in 2009 lead to inaccurate glucose 12:36
measurements? 12:36
A. On the fingerstick? Yes. 12:36
MR. MASON: That's all I have. 12:36
MR. CARROZZA: I have one question 12:36
on re-redirect. 12:36
EXAMINATION 12:36
BY MR. CARROZZA: 12:36
Q. In 2009, besides CGMs and 12:36
fingerstick measurements, were PWDs able to use 12:36
any other tools to measure their glucose 12:36
levels? 12:36
MR. MASON: Objection. Form. 12:36
Scope. 12:36
THE WITNESS: In 2009, other than 12:36

CGM and fingerstick? Well, if they came to the office, we would do a venous blood sample; but no. 12:37

MR. CARROZZA: Okay. I have no further questions. 12:37

MR. MASON: I'm done. We can go off the record. 12:37

(Off the record.) 12:37

THE REPORTER: Does anybody want a rough? 12:37

MR. CARROZZA: I'll take a rough. 12:37

MR. MASON: Sure, yeah. But otherwise, standard delivery is fine. 12:37

(Deposition concluded at 12:37 p.m.)

CERTIFICATE OF SHORTHAND REPORTER

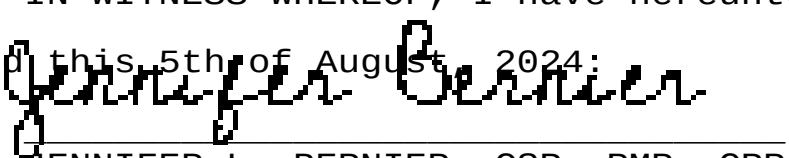
I, JENNIFER L. BERNIER, Certified Shorthand Reporter within and for the State of Illinois do hereby certify:

That EUGENE E. WRIGHT JR., M.D., the witness whose deposition is hereinbefore set forth, was duly sworn by me before the commencement of such deposition and that such deposition was taken before me and is a true record of the testimony given by such witness.

I further certify that the deposition of EUGENE E. WRIGHT JR., M.D., occurred at the offices of McAndrews, Held & Malloy, Ltd., on Wednesday, July 25, 2024 commencing at 9:03 a.m. to 12:37 p.m.

I further certify that I am not related to any of the parties to this action by blood or marriage, I am not employed by or an attorney to any of the parties to this action, and that I am in no way interested, financially or otherwise, in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 5th of August, 2024.



JENNIFER L. BERNIER, CSR, RMR, CRR