UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

U.S. Patent No.: 11,298,056

DECLARATION OF ANDREW AHMANN M.D.
IN SUPPORT OF DEXCOM'S REPLY

DEXCOM EXHIBIT 1055
Dexcom v. Abbott
IPR2023-01251

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I, Dr. Andrew Ahmann, do hereby declare as follows:

I. INTRODUCTION

1. My name is Andrew Ahmann, M.D., and I have been retained as an independent expert on behalf of Petitioner DexCom, Inc. in connection with the above-captioned Inter Partes Review ("IPR"), which I understand involves U.S. Patent No. 11,298,056 (hereinafter "the '056 Patent").

2. I submit this report in response to certain opinions of Patent Owner Abbott's expert, Dr. Eugene E. Wright, Jr., in the above-captioned IPR.

3. I am being compensated at my usual and customary rate for the time I spend in connection with this IPR. My compensation is not affected by the outcome of this IPR.

II. BACKGROUND AND QUALIFICATIONS

4. I completed a Master of Science degree in pharmacy and clinical pharmacy residency as well as a hospital pharmacy residency. I received my MD degree with honors at the University of Colorado in 1980 and completed my specialty training with a Fellowship in Endocrinology at Walter Reed Medical Center in Washington, D.C., including an extra research year that resulted in the Bailey K. Ashford Award for clinical research. I became board certified in Endocrinology and Metabolism after my initial fellowship.

5. After 4 years as a staff endocrinologist at Walter Reed and Assistant Professor at the Uniformed Service University for Health Sciences, Bethesda, Md., I moved to Oregon in 1990 where I had a clinical practice and served as medical director of a comprehensive diabetes program at Providence Medical Center.

6. In 1993, I was recruited to the Oregon Health & Science University where I became the Director for Diabetes Services and had a busy endocrine practice that eventually evolved into a diabetes specific practice. In addition to clinical practice, I functioned as the local principal investigator for more than 200 clinical research studies over the years. In 2007, I became the initial Director of the Harold Schnitzer Diabetes Health Center, a newly formed comprehensive diabetes center that serves nearly 8000 active patients with diabetes including both pediatric and adult patients. The center staff includes 20 physicians, 9 advanced practice providers, 15 certified diabetes educators, two psychologists, two pharmacists and a social worker. I was promoted to the rank of Professor in 2009.

7. Beyond my academic practice, I have been very involved with the American Diabetes Association (ADA), with a long record of regional leadership, service on the Professional Practice Committee that publishes the ADA Standards of Care for Diabetes each year, and the scientific session planning committee. In 2018, I received the ADA National Outstanding Physician Clinician in Diabetes Award. Activities with the ADA and the Endocrine Society have included several

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committees and projects addressing diabetes technology and particularly CGM education and practice guidelines. I have published over 70 peer-reviewed articles including over 25 articles that address use of CGM. I have presented many educational sessions locally, regionally, nationally and internationally including many on the topic of diabetes technology and CGM. I feel confident that my vast clinical experience, clinical research experience and national involvement in the standards of care around technology use in diabetes provide appropriate qualifications for me to offer the below opinions regarding diabetes care and CGM use.

8. My publications, along with other information, are listed in my CV, attached as Appendix A.

III. SCOPE OF OPINION

9. I have been asked to consider the May 22, 2024, Declaration of Eugene E. Wright, Jr. MD (EX2013, "Wright Declaration") and to provide my opinions and analysis regarding some of Dr. Wright's opinions.

10. My declaration does not respond to every opinion in Dr. Wright's declaration. The omission of any particular response, however, does not imply that I agree or acquiesce to the corresponding opinion or argument. Rather, to the extent permitted under the PTAB's rules, I reserve the right to address opinions and arguments for which a response subsequently becomes necessary or helpful.

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11. I understand that in patent law a person of ordinary skill in the art ("POSITA") is a hypothetical person who has the experience and skills of a typical person working in the field of the alleged invention at the time the invention was allegedly made. As discussed further below in paragraphs 16-18, for purposes of this declaration I have been asked to make certain assumptions regarding a POSITA. *Also see generally*, *infra* Section V.A (paragraphs 15-22 below).

12. As noted above, this declaration responds to certain opinions presented in the Wright Declaration, including Dr. Wright's testimony on aspects of the declaration of Mr. Brian Gross (EX1008, "Gross Declaration"). I do not offer opinions on the meaning of '056 patent claim language or the ultimate legal question of obviousness. Rather, my opinions here focus more on the diagnosis, treatment, and management of diabetes for the time period leading up to, and including, April 2009 (which I have been informed is the alleged date of invention). My opinions would not materially differ if the alleged invention date were in April 2010. Unless otherwise noted, my opinions in this declaration present the viewpoint of an ordinary clinician involved in diagnosis, treatment, and management of diabetes during in the relevant 2009 (or 2010) time period.

13. I am not an attorney and do not offer legal opinions. As noted in the preceding paragraphs, my focus in this declaration is responding to certain of Dr.

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Wright's opinions as they relate to the diagnosis, treatment, and management of diabetes for the time period leading up to, and including, April 2009 and April 2010.

IV. MATERIALS CONSIDERED

14. In forming my opinions expressed in this declaration, I have relied on my professional experience, as well as the materials discussed herein, including at least portions of the following materials bearing exhibit numbers that I understand have been used in the above-noted IPR:

No.	Description
1008	Declaration of Brian Gross, dated July 24, 2023 ("Gross Decl.")
1009	Curriculum Vitae of Brian Gross
1011	Exhibits A and B to Affidavit of Nathaniel E Frank-White ("Paradigm® REAL-Time Archive")
1012	U.S. Patent Application Publication No. 2009/0085768 to Patel et. al. ("*Patel*-2009")
1029	John J. Mastrototaro. *The MiniMed continuous glucose monitoring system*. Diabetes Technology & Therapeutics 2.1 (2000)
1039	Bruce Buckingham, M.D., et al., *Real-Time Continuous Glucose Monitoring*, Current Opinion in Endocrinology, Diabetes & Obesity 14.4 (2007)
1040	Bruce Buckingham, M.D., *Clinical Overview of Continuous Glucose Monitoring*, Journal of Diabetes Science and Technology 2.2 (2008)
1041	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Paradigm Real Time System, Premarket Approval, dated April 7, 2006. Retrieved from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980022S013 on July 21, 2023.

1044	Medtronic Inc., News Release: Medtronic Receives FDA Approval for World's First Insulin Pump with Real-Time Continuous Glucose Monitoring, dated April 13, 2006. Retrieved from https://web.archive.org/web/20060427084431/http://wwwp.medtronic.com:80/Newsroom/NewsReleaseDetails.do?itemId=1144875806140&lang=en_US on July 21, 2023.
1046	Mark R. Burge, M.D. et al., *Continuous Glucose Monitoring: The Future of Diabetes Management*, Diabetes Spectrum 21.2 (2008)
1050	Eugene Wright, Jr., M.D., et. al., *Ambulatory Glucose Profiling*, The Journal of Family Practice 64.12 (Supp., 2015)
1052	Affidavit of Nathaniel E Frank-White, Exhibit A ("Supplemental Paradigm REAL-Time Archive")
1053	Deposition Transcript of Eugene E. Wright Jr., M.D. (July 25, 2024)
1058	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Medtronic MiniMed Guardian RT, Premarket Approval P980022/S011, dated July 18, 2005. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022S011A.pdf on August 26, 2024.
1059	U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Medtronic MiniMed Guardian RT, Summary of Safety and Effectiveness Data (SSED). Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf/P980022B.pdf on August 26, 2024.
1061	The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group, *Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes*, New England Journal of Medicine 359:14 (2008)
1062	Richard M. Bergenstal, M.D., et. al., *Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes*, New England Journal of Medicine 363:4 (2010)

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1063	Howard Wolpert, M.D., *Establishing a Continuous Glucose Monitoring Program*, Journal of Diabetes Science and Technology, 2:2 (2008)
1064	John Mastrototaro, et. al., *Accuracy of Real-Time Continuous Glucose Monitoring in the MiniMed Paradigm System*, American Diabetes Association 67th Scientific Sessions, Diabetes 56 (Supp. 2007)
2013	Declaration of Eugene E. Wright, Jr. M.D.
2014	Curriculum Vitae of Eugene E. Wright, Jr. M.D.

V. OPINIONS ON DIABETES MANAGEMENT

A. My Understanding of a POSITA and My Perspective As a Clinician Who Has Researched and Worked With Patients on the Use of CGM To Manage Type 1 Diabetes Since Before 2009

15. I understand that claim construction, obviousness, and other legal issues relating to patent law are viewed from the perspective of a person of ordinary skill in the art ("POSITA"). I further understand that a POSITA is a hypothetical person who has the experience and skills of a typical person working in the field of the alleged time of invention.

16. Here, I understand that DexCom's expert, Mr. Brian Gross, provided the following definition of a POSITA:

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> As of April 2009, persons of ordinary skill in the art ("POSITAs") would have had a Bachelor of Science degree in biomedical engineering, or a similar field, such as electrical, or software, or computer engineering, and two years of industry experience or research working with medical devices and systems for measuring biomedical signals. Such systems might include those for determining levels of blood analytes, such as glucose, in a patient and transmit indications of such levels to a receiving device for reporting the measurements. Additional education, such as a Master's degree could substitute for the industry experience, or vice versa.
>
> POSITAs may be part of an interdisciplinary team with others having relevant experience in the areas set forth above and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals. This definition of a POSITA would not differ materially for a date of April 2010.

See EX1008, ¶¶ 51-52.

17. I understand that Dr. Wright does not disagree that a POSITA could have this educational level but that Dr. Wright opines "it would be imperative that a POSITA be a part of such an interdisciplinary team." EX2013, ¶¶ 122-123. Without agreeing to Dr. Wright's definition that an interdisciplinary team would be "imperative," I assume that modified definition for purposes of this declaration unless stated otherwise.

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18. My opinions in this declaration reflect the perspective of an ordinary clinician involved in diagnosis, treatment, and patient management of diabetes, such as might be part of the above-noted interdisciplinary team. As noted above in paragraph 12, I offer opinions on the diagnosis, treatment, and management of diabetes for the time period leading up to, and including, April 2009 (which I have been informed is the alleged date of invention). My opinions would not materially differ if the alleged invention date were in April 2010.

19. As explained in the following paragraphs, I meet Dr. Wright's "clinician" as it relates to his definition of a POSITA. I also note how those clinicians who treat only Type 2 diabetes—such as Dr. Wright—would have had little to no experience working with PWDs ("patients with diabetes") on use of CGMs ("continuous glucose monitors") prior to 2015 or 2016, when the FDA approved these devices for Type 2 PWDs. I understand that this is consistent with Dr. Wright's deposition, as I have been informed that he testified at deposition that he did not "start working with patients on use of CGM devices" until 2015 or 2016. *See also* EX1053 (Wright Deposition Transcript), 54:3-9.

20. Dr. Wright opines that "a POSITA who is a clinician on the interdisciplinary team should have at least an advanced degree in a medical science, such as a doctor of medicine (MD), doctor of osteopathic medicine (DO), nurse practitioner (NP), or physician assistant (PA), and a few years of supervised training

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in diabetes management, including interpreting reports and providing clinical decision support." EX2013, ¶ 129. In 2009, I met and exceeded Dr. Wright's definition of a "POSITA who is a clinician" based at least on my work and research relating to diabetes treatment and management, and to this day meet and exceed that definition. *Supra* Section II (paragraphs 4-8 above).

21. I also note that in 2009, I had prescribed a CGM before, helped PWDs select a CGM that was right for them, instructed a PWD on how to use a CGM, and helped PWDs determine target thresholds to manage their glucose levels. *See* EX2013, ¶ 132. I primarily treated (and to this day, treat) Type 1 PWDs, many of whom used CGM devices, and in 2009 CGM devices were only approved for Type 1 diabetes. *See also* EX1053, 40:7-10 (agreeing that, "in 2009, CGM devices were primarily a Type 1 diabetes treatment."), 52:15-20 (same). Dr. Wright testified that he did not think he worked with PWDs using a CGM in 2009 (*id.*, 39:13-15) as his focus was Type 2 diabetes and in 2009 CGMs were "not approved for patients with Type 2 diabetes" (*id.*, 39:16-24; *see also id.*, 22:14-23:12). My understanding from Dr. Wright's testimony is that he did not begin working with patients on use of CGM devices until 2015 or 2016. *Id.*, 54:3-9.

22. I agree with Dr. Wright that, in the 2009 timeframe, clinicians would understand the various conditions discussed in paragraphs 127–128 of his declaration, and would "understand the causes for these types of conditions and the

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potential impact they could have on a patient's health and safety." EX2013, ¶¶ 127-128. With full awareness of these problems, there was motivation to address them and the literature indicates that POSITAs indeed had addressed them.

B. By 2009, Continuous Glucose Monitoring Greatly Aided PWDs in Diabetes Treatment and Management and One Would Want To Provide PWDs With As Much Accurate Data As Possible To Assist In That Treatment And Management

23. Dr. Wright criticizes paragraphs 54-61 of Mr. Gross's declaration (EX1008), on the apparent basis that Mr. Gross lacks clinical experience. *See*, *e.g.*, EX2013, ¶¶ 135-155.

24. I see no issue with the aspects of Mr. Gross's report that Dr. Wright appears to criticize for lacking clinical experience. To the extent they relate to clinical treatment of diabetes, Mr. Gross's opinions are sound and consistent with my own clinical experience, as well as the supporting literature, as discussed further herein. For example, even if not working directly with a clinician on a team, a POSITA might—from past interactions with clinicians or through working with PWDs or through reading literature relating to diabetes treatment and management—have knowledge about diabetes treatment and management. For example, Mr. Gross cites Exhibits 1039 and 1040, which are publications authored by Bruce Buckingham M.D., a renowned physician at Stanford Medical Center and one of the pioneers of continuous glucose monitoring. EX1008, ¶¶ 60, 80 (citing EXs1039-1040).

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25. I have reviewed **paragraphs 51-61 and 80 of Exhibit 1008**, the declaration of Brian Gross, signed and dated July 24, 2024. As discussed below, I agree with the following statements from Mr. Gross's declaration, although as a clinician I would use the term person with diabetes ("PWD") instead of diabetic, given that the American Diabetes Association and other advocacy groups indicate that using "diabetic" as a noun objectified those living with diabetes:

- "POSITAs would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia." EX1008, ¶ 60 (citing EX1011, 15, 18, 23-27; EX1012, [0004], [0006]; EX1029; EX1037, 17; EX1039-1040).
- "One purpose of continuous glucose monitoring is to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia by providing accurate glucose concentrations and trend information in real-time." EX1008, ¶ 80 (citing EX1011, 15, 18, 23-27; EX1012, [0004], [0006]; EX1029; EX1037, 17; EX1039-1040).
- "POSITAs would also know that not every diabetic would require an insulin pump but would still require a mechanism to display glucose

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values, and alerts/alarm to assist with diabetes management." EX1008, ¶ 80.

- "POSITAs would have been motivated to detect missing or inaccurate glucose data and convey as much accurate glucose information to a user as possible without providing inaccurate information." EX1008, ¶ 80.

26. Further, I have reviewed the references that Mr. Gross cites in support of the above opinions, including EX1011, EX1012, EX1029, and EXs1039-1040, which I understand all pre-date April 2009. It is my opinion that these references support the opinions in paragraphs 60 and 80 of Mr. Gross's report, including as excerpted immediately below and in the following table, with highlighting added.

a. EX1011, 15:

Exclusive capability of integrating with continuous glucose monitoring technology

When used with the available glucose sensor and MiniLink™ Transmitter components, the MiniMed Paradigm 522 or 722 Insulin Pump displays on-screen REAL-Time data to help you understand more about your glucose control

- Displays updated glucose values every five minutes.
- Displays 3-hour and 24-hour glucose trend graphs, as well as arrows that indicate how fast, and in what direction, glucose is moving.



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b. EX1011, 23:

REAL-Time Continuous Glucose Monitoring System

REAL insights help you take action sooner to improve your glucose control[1-3]

Feature	Specification	Benefit
Glucose Sensor	The glucose sensor is inserted, virtually painlessly, through the skin, usually in the stomach area. The glucose sensor sends an electronic signal measuring the amount of glucose in your interstitial fluid. Replace the glucose sensor every three days.	Measures your glucose levels continuously, as an addition to fingerstick measurements. Displays a five-minute average, 24 hours a day. Numerous studies have proven the accuracy of the sensor.[4-6]
Calibration	Calibrate your MiniMed Paradigm REAL-Time System at least once every 12 hours. In addition, make sure you always confirm with a fingerstick before making any adjustments in your therapy.	Simple and easy.

c. EX1011, 24

MiniMed Paradigm® 522/722 Insulin Pump

REAL-Time features give you insights you need to take action

Feature	Specification	Benefit
REAL-Time Trend Graphs	Your insulin pump displays glucose trend graphs for 3-hour and 24-hour periods.	Shows you the effects of meals, exercise, insulin, and medication on your glucose control.
REAL-Time Readings	Monitors your glucose every minute and displays a five-minute average, 24 hours a day.	Continuous glucose monitoring is proven to improve glycemic control,[1-3] which reduces your risk of long-term complications including eye, nerve, kidney, and heart disease.[7,8]
REAL-Time Alarms	Audible or vibrating alarms occur when glucose levels go out of your preset target range. Personalize alarms to meet your specific needs and preferences. You also can turn off your alarms, if you prefer.	Warns you of high or low glucose levels. Use of continuous glucose monitoring is proven to detect highs and lows that fingersticks and A1C testing alone may miss.[1-3,9]
REAL-Time Trend Arrows	Single and double arrows point up and down to show the degree and direction of glucose trends. One arrow indicates that glucose has risen or fallen 20-40 mg/dL during the last 20 minutes. Two arrows indicate that glucose has risen or fallen >40 mg/dL during the last 20 minutes.	Up arrows reveal increases in glucose levels. Down arrows reveal decreases in glucose levels. Double arrows suggest a more rapid increase or decrease. Use of continuous glucose monitoring helps reduce the duration of high and low blood glucose and A1C.[1-3,9]

Reference Cited by Mr. Gross	**Support for the clinical utility of providing CGM data to patients in real time**
Exhibit 1012, [0005] (patent application filed March 2008 and published April 2009)	Recently, a variety of implantable electrochemical sensors have been developed for detecting and/or quantifying specific agents or compositions in a patient's blood or interstitial fluid. For instance, glucose sensors are being developed for use in obtaining an indication of blood glucose levels in a diabetic patient. These glucose sensors connected (wired or wirelessly) to a blood glucose monitor can provide continuous glucose readings over a period of time, such as 3 to 5 days. Such readings are useful in monitoring and/or adjusting a treatment regimen which typically includes the regular administration of insulin to the patient.
Exhibit 1012, [0040]	FIG. 1 is a perspective view illustrating a subcutaneous sensor insertion set and telemetered characteristic sensor transceiver device embodying the novel features of the invention. FIG. 2 is an enlarged longitudinal vertical section of FIG. 1. Referring to FIGS. 1 and 2, a telemetered characteristic sensor system, in accordance with a preferred embodiment of the present invention includes a percutaneous sensor set 10, a telemetered characteristic sensor transceiver device 100 and a characteristic monitor 200. Description of the telemetered characteristic sensor is further found in commonly owned co-pending application Ser. No. 11/322,568 entitled "Telemetered Characteristic Monitor System and Method of Using the Same" filed on Dec. 30, 2005, which is incorporated by reference in its entirety. Preferably, the telemetered characteristic sensor system provides for better treatment and glycemic control in an outpatient or home-use environment. For example, the sensor system can provide indications of glucose levels, hypoglycemia/hyperglycemia alerts and outpatient diagnostics. It is also useful as an evaluation tool under a physician's supervision or use in a hospital environment to monitor a patient's health status.
Exhibit 1029, pg. S-13 (Mastrototaro article,	There is a tremendous need to develop and commercialize a truly simple, accurate method of measuring glucose that can provide a basis for more accurate and directed disease self-management. Generally, it is not practical to perform SMBG frequently enough throughout the day to accurately identify every blood glucose

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Reference Cited by Mr. Gross	Support for the clinical utility of providing CGM data to patients in real time
published 2000)	excursion. MiniMed® has taken a first step in advancing the practice of glucose self-monitoring by developing a short-term, continuous glucose sensor. The sensor is inserted subcutaneously and is capable of reliable operation for up to 3 days, followed by replacement with a new sensor at a different location, if necessary. The assay method is based on electrochemical detection of glucose through its reaction with glucose oxidase. Data are collected once every 5 min by a pager-sized monitor device and can be periodically downloaded into a computer for analysis and interpretation.
Exhibit 1039, 288 (Buckingham article, published 2007)	**Recent findings** Real-time continuous glucose sensors are new tools to assist in diabetes management. Several devices are currently being sold and additional monitors are expected to be available shortly. These sensors measure interstitial glucose – a distinct physiologic space when compared with the blood glucose. The ability to recognize trends in blood glucose levels provides a new paradigm for making insulin dose decisions and treating hypo- and hyperglycemia.
Exhibit 1039, 292	**Sensor function during hypoglycemia** From a patient perspective, one of the critical functions of a real-time continuous glucose sensor is the ability to detect clinically significant events, both hyper- and hypo-glycemic. Avoidance of nocturnal hypoglycemic seizures is particularly important. Individuals vary in how long they can tolerate hypoglycemia before having a seizure. We are aware of three cases in which a patient was wearing a sensor and had a nocturnal hypoglycemic seizure, and in all cases the sensor was reading below 40 mg/dl for 3–4 h prior to the seizure. From these data, it would appear that, if a sensor detected hypoglycemia within 30 min and it was able to awaken the patient, most individuals would not have a seizure. The DirecNet study group has, therefore, evaluated hypoglycemic alarms using an event-based analysis allowing the sensor 30 min to recognize hypoglycemia [15]. In this study of the GlucoWatch, the value of using a predicted alarm (the trend of glucose values projects hypoglycemia) was compared with a threshold alarm (the

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Reference Cited by Mr. Gross	Support for the clinical utility of providing CGM data to patients in real time
	measured glucose drops below the level set by the user). The predicted alarm detected significantly more hypoglycemic events, but also had a higher false-positive rate. Table 4 provides a summary of the incidence of true-positive and false-positive alarms using real-time sensors. There is substantial variability in the frequency of the alarms, which is mostly dependent on whether threshold and/or predicted alarms were used, and the definition of what constituted a true-positive alarm. Some definitions allow ±30 min for the sensor to recognize a hypoglycemic event and also allow a 10–15 mg/dl 'cushion' for the glucose threshold (i.e. if sensor was reading 78 mg/dl and alarm threshold was set to 70 mg/dl this value was considered a true-positive alarm). These various definitions make it difficult to compare the false-positive and true-positive rate of alarms in the current literature.
Exhibit 1039, 293	In a 3-month feasibility study to assess the use and acceptance of the FreeStyle Navigator continuous glucose monitoring, 30 children using insulin pumps (mean age 11, range 4–17 years) were assigned to wear a Navigator daily [20]. Mean Hb A1c improved from 7.1% at baseline to 6.8% at 13 weeks (P = 0.02), and the percentage of glucose values between 71 and 180 mg/dl increased from 52% to 60% (P = 0.01). There was no control group. Subjects and parents reported high satisfaction with the Navigator on the DirecNet Continuous Glucose Monitor Satisfaction Scale [21] and nearly all subjects chose to continue using the sensor in the subsequent extension phase of the study. They were not overwhelmed by the amount of information provided by real-time monitoring, and 70% thought the use of the Navigator made adjusting insulin doses easier, gave them more confidence in making diabetes decisions and showed them patterns in their blood glucose levels they had not previously been aware of. This study demonstrates that incorporating real-time continuous glucose monitoring into the daily management of type 1 diabetes in children is feasible, and the sensor was perceived as providing valuable information regarding glycemic control by parents and patients. The majority of subjects were using the

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Reference Cited by Mr. Gross	**Support for the clinical utility of providing CGM data to patients in real time**
	sensor for at least 6 days a week throughout the duration of the study, indicating the device was well accepted.
Exhibit 1039, 293-294	**Clinical experiences with real-time continuous glucose monitoring** Real-time continuous glucose monitoring allows for insulin doses to be based not only on a single glucose value, but with knowledge of which direction the blood glucose is trending. Thus, the premeal dose of short-action insulin can be increased or decreased depending on the direction and speed of glucose changes at the time of the meal. Currently available insulin pumps utilize algorithms to incorporate current glucose levels and the expected carbohydrate intake into suggestions for bolus doses (the 'bolus calculator' or 'bolus wizard' features). With the availability of glucose trend information and rate of change arrows, more sophisticated algorithms can be developed. As an example, a patient might increase a premeal bolus by 20% if the glucose were rising faster than 2 mg/dl-min (this rate of change can be easily determined using trend arrows).
Exhibit 1039, 294	One of the keys to achieving a significant benefit in glycemic control when using a real-time sensor is to look at sensor glucose levels and glucose trends frequently throughout the day. Patients who were most successful in using a real-time sensor were looking at the sensor 10–20 times a day and greatly missed the comfort of knowing their glucose levels when they were not wearing the sensor.

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Reference Cited by Mr. Gross	Support for the clinical utility of providing CGM data to patients in real time
Exhibit 1039, 295	**Conclusion** Real-time continuous glucose monitoring offers a great benefit to patients who want to actively manage their diabetes; however, widespread adoption of this technology will be delayed until insurance plans authorize this treatment. Continuous monitoring may be of particular benefit to patients with hypoglycemia unawareness, inpatients, athletes and pregnant women. Both patients and physicians need to learn how to best utilize the real-time data and pending hypo- and hyperglycemic alarms to make treatment decisions. Ongoing randomized controlled studies will help to determine if near-continuous use of real-time sensors over extended periods of time will result in significant improvements in Hb A1c levels, a decrease in the incidence of hypoglycemia and an improvement in the quality of life for people with diabetes.
Exhibit 1040, 300-301 (Buckingham article, published 2008)	**Introduction** This article contains an overview of continuous glucose monitoring (CGM) in general and covers basic concepts focusing on how to use this technology in everyday clinical practice. There are two major ways people use these devices. Patients use real-time CGM (RT-CGM) throughout the day, looking at their glucose trends and making adjustments in real time to their diabetes management, and they use the alarms to alert them during the day and night of possible hypoglycemic and hyperglycemic events. A second way to look at CGM data is in the retrospective analysis of CGM reports; this information is beneficial to the patient but also has great potential benefit to the health care provider when making treatment recommendations. One of the main contributions of CGM is to reveal glucose excursions, including lows during sleep and numerous postprandial highs that would be missed by finger stick blood glucose monitoring. In a Diabetes Research in Children Network (DirecNet) study comparing CGM with eight-point testing, the postprandial glucose peaks were two to three times higher using CGM data compared to eight-point glucose testing using a glucose meter.[] A second important reason for using CGM is for the

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Reference Cited by Mr. Gross	**Support for the clinical utility of providing CGM data to patients in real time**
	detection and possible prevention of hypoglycemia. Seventy-five percent of hypoglycemic seizures occur at night,[] which is of great concern to many patients and parents of children with diabetes. By measuring interstitial glucose levels overnight, CGM is able to provide an alarm system to alert the patient of pending or actual hypoglycemia. Since 2002 we have been one of five centers participating in DirecNet, a National Institutes of Health-funded study group to assess continuous glucose monitoring in children. From analysis of DirecNet CGM outpatient data, there is about a 25% incidence of nocturnal hypoglycemia, a much higher incidence than commonly detected by discrete home glucose monitoring.
Exhibit 1040, 304	A study done by Garg and colleagues[] using the DexCom sensor evaluated glycemic control when subjects were initially blinded to the RT-CGM readings for 3 days and then the sensors w[e]re worn unblinded for 6 days so the subjects could see their glucose readings. When subjects were able to see and react to their RT-CGM glucose values, they spent 26% more time in the target glucose range (80–140 mg/dl) compared with blinded wear ($P < 0.0001$), and they also spent 21% less time in the hypoglycemic range (240 mg/dl)[.]

27. I also note that at least some of Mr. Gross's conclusions are consistent with an article authored by Dr. Howard Wolpert (EX1063), as shown in the following table. Dr. Wright acknowledged during deposition that Dr. Wolpert is "knowledgeable about the use of CGM data for diabetes management." EX1053, 55:14-56:3.

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Mr. Gross's Declaration (EX1008)	EX1063 (Wolpert Article)
¶ 59: POSITAs would have known that the failure to convert sensor signals to calculated analyte concentrations could be caused by a variety of conditions, including faulty or interrupted sensor readings and calibration errors based on, for example, sensor instability, extreme temperatures, extreme glucose levels, rapid glucose changes, and issues with blood glucose reference values.	(At 308) One of the important issues that needs to be strongly emphasized in patient education is the fact that the sensor should only be calibrated when the glucose level is relatively stable and there is steady-state equilibration between glucose concentrations in the blood and interstitial fluid compartment… If the CGM is calibrated with a blood glucose measurement postprandially, this will result in an upward bias of the sensor readings and compromise the accuracy of the device in detecting hypoglycemia.
¶ 60: When failed communication or failed/delayed calibration is resolved and previously missing data becomes available, POSITAs would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia. ¶ 80: One purpose of continuous glucose monitoring is to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia by providing accurate glucose concentrations and trend information in real-time.	(At 307) Real-time continuous glucose monitoring (RT-CGM) devices provide detailed information on glucose patterns and trends, and alarms that alert the patient to both hyper- and hypoglycemia. This technology can dramatically improve the day-to-day management of patients with diabetes and promises to be a major advance in diabetes care. To derive the full potential benefit from RT-CGM the patient needs to have good diabetes self-management skills.

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28. Paragraphs 147 and 148 of Dr. Wright's declaration criticize the premise in paragraph 60 of Mr. Gross's declaration that: "When failed communication or failed/delayed calibration is resolved and previously missing data becomes available, POSITAs would have found it obvious to display previously missing data to the user in order to present as much accurate data as possible to assist in diabetes management, insulin dosing decisions, and prevention or treatment of hyper and hypo-glycemia." EX1008, ¶ 60. I agree with Mr. Gross's assertion and disagree with Dr. Wright's criticisms, which appear driven by either a misreading of Mr. Gross's statement or a misunderstanding of how CGMs were used in 2009 and earlier, or both. I further note that Dr. Wright appeared to retreat or correct his opinion, as he agreed during deposition that in 2009, POSITAs knew "that it was important to provide as much accurate glucose data as possible to PWDs … from a CGM." EX1053, 41:3-10.

29. Dr. Wright also opines in his paragraph 148 that POSITAs would not have wanted to present patients with as much data as possible because "as of 2009, all CGMs were approved for adjunctive use only." Ex2013, ¶ 148. But, as discussed below, the FDA approved Paradigm REAL-Time "for continuous or periodic monitoring of glucose levels … for the purpose of improving diabetes management," including by "provid[ing] real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood

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glucose episodes." *See infra* Section V.F (paragraphs 50-51 below). Therefore, I disagree with Dr. Wright; contrary to his opinions, POSITAs would have wanted to provide patients with as much accurate data as possible to support Paradigm REAL-Time FDA approved indications, including assistance in diabetes management and the identification or prevention of hyper and hypo-glycemia as listed in paragraph 60 of Mr. Gross's report. EX1008 at ¶ 60. I do not understand Mr. Gross to opine that patients would use CGM as the sole, non-adjunctive basis for dosing insulin. Rather, he opines, consistent with pre-2009 publications and knowledge of a typical clinician, that providing as much reliable CGM data as possible would "assist in" diabetes treatment and management, which would include the adjunctive treatment of diabetes.

30. Moreover, as I explain further below, the teachings in the pre-2009 references and the opinions of Mr. Gross are consistent with the well-known understanding within the clinical diabetes community that doctors would want PWDs to have as much up-to-date accurate data as possible, and to avoid presenting inaccurate CGM data. *Infra* Sections V.G-H & V.K-L (paragraphs 52-62 and 76-85 below). This was especially so for persons with Type 1 diabetes, who are dependent on insulin and thus need to more closely monitor their blood glucose levels. *See also e.g.*, EX1053, 39:16-24 ("my focus was Type 2 diabetes. And in 2009, [CGM devices] were not approved for patients with Type 2 diabetes"), 40:7-10 (agreeing

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that "in 2009, CGM devices were primarily a Type 1 diabetes treatment"), 41:3-10 (agreeing that in 2009, POSITAs knew "that it was important to provide as much accurate glucose data as possible to PWDs … from a CGM"), 52:15-20 ("In 2009 … patients with Type 1 diabetes were most commonly using CGM."). Even in the year 2000 it was recognized that providing as much CGM data as frequently as possible helped identify (and thus manage) every "blood glucose excursion," i.e., potentially adverse change in blood glucose level:

> There is a tremendous need to develop and commercialize a truly simple, accurate method of measuring glucose that can provide a basis for more accurate and directed disease self-management. Generally, it is not practical to perform SMBG frequently enough throughout the day to accurately identify every blood glucose excursion.

EX 1029 at S-13. For the same reasons that infrequent SMBG fingersticks might lead to adverse blood glucose events, so too could the failure to provide as much CGM data as quickly as possible to the user.

C. Dr. Wright's Criticisms Of Mr. Gross Reflect An Incomplete And Inaccurate Understanding Of The Development Of Real-Time CGM From 2004 to 2009

31. I have reviewed paragraphs 42 to 61, 75 to 83, and 136 to 155 of Dr. Wright's declaration (Exhibit 2013) and disagree with his opinions to the extent they:

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- conflict with my experience using CGM technology during the relevant 2004 to 2009 timeframe to help treat persons with type-1 diabetes (*see* paragraphs 47-49 below; *also see* paragraphs 53, 55, 82 below);

- undervalue how CGM data in conjunction with SMBG confirmatory fingerstick measurements assisted PWDs in the management and adjunctive treatment of diabetes, including by helping patients determine when to take fingerstick readings, when to consult with their physician, and by informing other treatment- or management-related decisions (*see* paragraphs 47-49, 51, 55-61, 66-69, 73-75, 78-80 below);

- assume that patients would not manage diabetes based on information displayed by a CGM receiver (*i.e.*, monitor, insulin pump) (*see* paragraphs 47, 49, 51, 57 below; *see also* paragraphs 79-81 below);

- fail to consider Paradigm REAL-Time's FDA approved indications and the clinical utility of CGM data to these indications, including "improving diabetes management," "provid[ing] an indication of when a finger stick may be required," and "track[ing] patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose" (*see* paragraphs 50-51 below);

- assess the 2009 accuracy of Paradigm REAL-Time based on an August 2004 study of Guardian RT accuracy (*see* paragraphs 63-65 below);

- criticize Paradigm REAL-Time's accuracy by comparing CGM measurements to yellow springs instrument (YSI) reference glucose readings that would not have been available to a patient (*see* paragraphs 70-74 below; *also see* paragraph 55 below);

- suggest that displaying CGM to a PWD lacked clinical utility due to less than perfect accuracy or FDA approval for use only with SMBG fingerstick readings (*see* paragraphs 48, 50, 63, 66-68 below);

- largely omit research and developments from the most relevant 2004-2009 timeframe when continuous glucose monitoring technologies implemented real-time display of CGM data. (*see* paragraphs 82-85 below).

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In short, even if CGMs were not used for "standalone" treatment, they provided important information that allowed PWDs to manage glucose levels and make important in-the-moment decisions.

D. Reviewing the Paradigm Documentation, A Clinician Would Expect Re-Populated CGM Data To Be Displayed To Assist With Imminent Management And Adjunctive Treatment Decisions

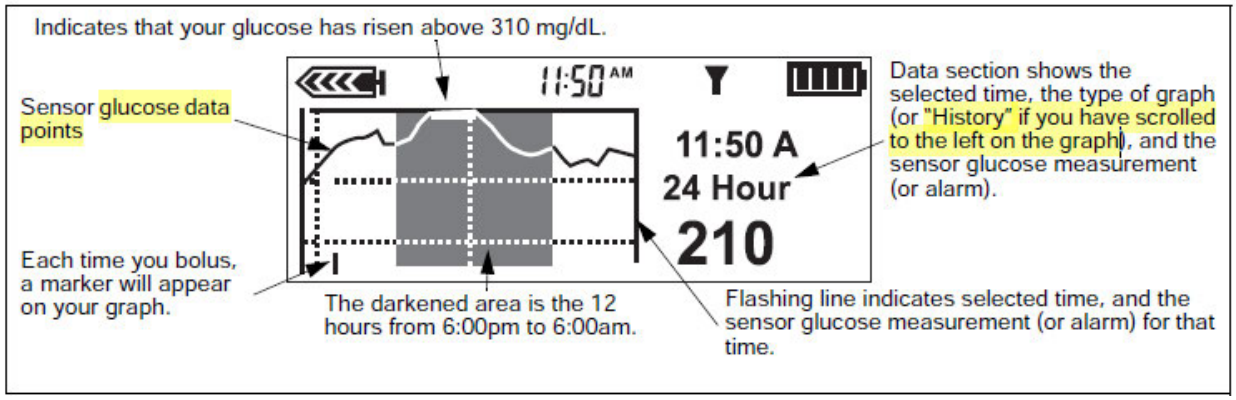
32. For at least the following reasons, a clinician looking at the Paradigm documentation would expect re-populated CGM data to be displayed to patients in the trend graphs. *See* paragraphs below 33-39 below. This expectation is consistent with, and further supported by, my opinions further below regarding the benefit derived by patients having access to as much CGM data as possible. *See infra* Sections V.E, V.G-H, V. J-K (paragraphs 47-49, 52-62, 66-81 below).

33. Paradigm describes displaying graphs of "the most recent 24 hours of data" and "the most recent three hours of data" on the pump receiver unit. These 3- and 24-hour trend graphs (example below) show "glucose data points," with the word "History" indicating on the display when a user has scrolled to look at past glucose values. EX1011, 64.

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24 hour graph

To view the current glucose and a graph of the most recent 24 hours of data, press **ESC** twice from the HOME screen:



Id., 64 (excerpted, highlighting added). A 24-hour trend graph can also be seen in this photo from the Paradigm User Guide:



Id., 30.

34. Paradigm also describes repopulating data in the context of displaying data on the screen of the insulin pump. For example, under the Paradigm MiniLink FAQ Section, it describes how the transmitter "holds 40 minutes worth of memory"

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so that "continuous glucose monitoring (CGM) data can be re-populated in the insulin pump." EX1011, 8 (FAQ, "How much data does the . . . Transmitter store? …").

35. I understand Dr. Wright to suggest that the pump receives and stores this repopulated data but does not display it in the trend graphs because users may optionally display it later after uploading to a PC with separate CareLink software. EX2013, ¶¶ 173-175. Not only does this assertion defy logic by suggesting that the system deviates from default, described behavior and withholds important data from a user, it is also belied by the next FAQ, which describes the continuous *display* of data and the repopulation of that data:

> As long as the transmitter is within 6 feet (approximately 2 meters) of the insulin pump, continuous glucose monitoring (CGM) ***data will be displayed on the insulin pump's screen***. If the MiniLink REAL-Time Transmitter and insulin pump are out-of-range for longer than 40 minutes, ***only the last 40 minutes will be re-populated***.

EX1011, 8 (emphases added) (quoted by Paper 11 ("DI"), 31); *see also* Petition, 25-28, 45; EX1008, ¶ 76; Paper 9, 2. The first sentence describes how CGM "data will be displayed on the insulin pump's screen" so long as the pump and transmitter are within 6 feet. EX1011, 8. And the next sentence then indicates that "the last 40 minutes will be re-populated" once the transmitter and pump reconnect after being

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"out-of-range." *Id.* Simply put, a data gap up to 40 minutes is repopulated to the screen of the user device (in this case, a pump).

36. Given that the trend graphs display "the most recent 24 hours of data" and "most recent three hours of data" (EX1011, 64), in context, the FAQs teach that up to the last 40 minutes of data is repopulated in the trend graphs once the devices are back in range. The FAQs predictably explain when data would be *missing*. EX1011, 8. If there were an exception to normal operation that excluded available, repopulated data from the trend graphs, Paradigm would likely have noted that. Instead, it simply explains that the most recent 3 or 24 hours "of data" are displayed. EX1011, 64; *id.*, 30. Thus, any reader would expect that all available data for a given period—including repopulated data—is displayed in the trend graphs.

37. This natural reading aligns with Paradigm's repeated emphasis—including in the FAQs—on providing continuous real time data to users. This is reflected in the below excerpted FAQ on page 9, as well as other passages:

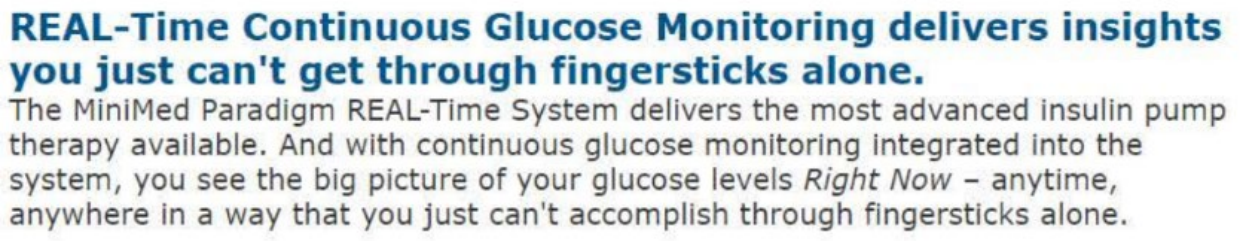
> An important benefit of using a CGM system is REAL-Time readings and trend graphs. They allow you to be proactive in your diabetes treatment so you can avoid severe highs and lows. You can see if your glucose is trending up or trending down and take action much earlier. With this information, you will be able to confidently make changes to your daily glucose management to improve your heath.

E.g., EX1011, 9 ("An important benefit … is REAL-time readings and trend graphs. … The trend graphs allow you to see when glucose is trending up or trending down and how fast it is moving … [T]hese things help you manage your diabetes more

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effectively …"); *see also id.*, 15 ("displays on-screen REAL-Time data to help you understand more about your glucose control [including] 3-hour and 24-hour glucose trend graphs"), 18 ("help prevent lows and highs").

38. This emphasis on providing recent data to users as promptly as possible is also reflected in other documents describing the Paradigm system:



EX1052, 27.

39. When Paradigm teaches that its trend graphs display "the most recent 24 [or three] hours of data," the expected behavior is ***display of all data, including repopulated data***. There was no reason for Paradigm to belabor expected behavior (displaying all stored and available data in the trend graphs). This is consistent with my clinical experience, Paradigm's FDA approved indications, and the clinical utility of providing patients with real-time CGM data as discussed in paragraphs 47-51 and 55-61 below. *Generally*, *see infra* Sections V.E-H, J-K (paragraphs 47-62, 66-81 below). Reporting this real-time data to patients as immediately as possible enhances the user experience for acute diabetes management (unlike data reported

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later via separate software on a separate device, which required additional steps of scanning / downloading data to that separate device).

1. Reference to CareLink Does Not Change Paradigm's Teachings On Display of Re-Populated Data in Trend Graphs

40. As just explained, a clinician reading Paradigm would expect that re-populated data is displayed in the trend graphs. I disagree with Dr. Wright to the extent he opines otherwise based on Paradigm's reference to CareLink and use of the term "historical reports." *E.g.*, EX2015, ¶¶ 173-184. Regardless of what "historical reports" encompass, Paradigm teaches that the trend graphs display the most recent 3 and 24 hours "of data" and the accompanying FAQs teach that display data is repopulated. Even if "historical reports" were wrongly limited to CareLink PDFs, that would not change Paradigm's other teachings—including in the FAQs—that repopulated data fills data gaps and is displayed on trend graphs, in line with its teachings on the benefits of providing real-time data to the user. *See supra* Section V.D (paragraphs 33-39 above). While separate reports such as those created by the CareLink software could provide additional benefits, in my experience the extra steps needed to create and review these separate reports meant that they often were not utilized as much as the recent historical glucose data reported on the user's pump or other handheld device.

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41. Similarly, I disagree to the extent Dr. Wright opines that the "historical reports" mentioned in Paradigm are *limited to* only PDF reports separately created by CareLink. Nothing in the FAQs uniquely associates "historical reports" with CareLink. Rather, the FAQs suggest that "historical reports" encompass the glucose "History" reported to users via trend graphs. In particular, the *second* FAQ explicitly teaches repopulating "(CGM) data … displayed on the insulin pump's screen." EX1011, 8. A clinician would understand that this repopulated displayed data included the display of trend graphs described in the Paradigm documentation.

42. The two page FAQs that discuss re-populated data both inform users of what happens to *missing* data that is not re-populated (e.g., weak signal for longer than 40 minutes), "when reviewing historical reports, you would notice 'data gap'." EX1011, 8. Dr. Wright appears to suggest that this "review" of "historical reports" must be done on later-accessed, downloaded data through the CareLink software (*e.g.*, EX2013, ¶¶ 172-175), but nothing in either FAQ suggests that all data stored by the pump (original and repopulated) is not *also* displayed on the trend graphs. This is consistent with the pump's labeling of the historical data on these graphs as "History." EX1011, 64.

43. Dr. Wright points to another FAQ on disconnecting the transmitter on an airplane, which also refers to "historical reports" and appears under a section entitled "Travel and Environmental Exposure." EX2013, ¶ 173 (citing EX1011, 12-

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13). That FAQ warns users that when the transmitter is disconnected during an airplane flight (pursuant to FAA requirements), no data will be reported and "[w]hen downloading data and reviewing historical reports, you will notice 'data gap' where information is missing during this period of time." EX1011, 12-13. This FAQ does not restrict "historical reports" to only data downloaded and displayed using CareLink. Indeed, the FAQ does not mention CareLink. Rather, it relates to situations where the transmitter is disconnected from the sensor and thus has no data to later repopulate, as distinct from the first two FAQs, which relate to repopulation of data stored on the transmitter (up to 40 minutes).

44. Moreover, the above-noted two FAQs on page 8 reference "historical reports" without mention of "downloading" or of CareLink. These two page 8 FAQs and the FAQ spanning pages 12-13 also appear under FAQ sections related to the Paradigm pump system, *not* the CareLink software. And the FAQ section that does relate to CareLink never mentions historical reports. EX1011, 11-12.

45. Finally, another Paradigm document discusses trend graphs and CareLink in a way that suggests the trend graphs display the same data as the CareLink software, as any reasonable reader would expect. EX1052, 17. As shown in the following screen shot excerpt, a section titled "REAL-Time Trend Graphs" includes a bullet point explaining how CareLink helps "easily manage *this data* online" (emphasis added).

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EX1052, 17. This suggests that the data shown in the trend graphs over time is the same data managed using the CareLink software.

46. For at least these reasons, clinicians would have read the description of "historical reports" as including the "History" of glucose data points displayed in real-time trend graphs.

E. The Clinical Utility of Providing CGM Data To Patients is Highlighted By My Own Experience In the Relevant 2004-2009 Timeframe

47. First, I disagree with Dr. Wright's opinions relating to the clinical utilization and benefit of CGM in 2009 and earlier. Based on my abundant experience as a clinician scientist working with diabetes-management technology, and specifically CGM, in 2009 and earlier, it is my firm opinion that the state of the art for those who utilized CGM (referring to providers, clinical researchers and patients who chose this technology) included recognition of the benefits of CGM for monitoring patterns and trends, and using recent trend data to make fingerstick and other diabetes management decisions in acute situations, i.e., without waiting to speak with one's physician or review longer-term summaries of data. *See also e.g.*,

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EX1063, 309 (discussed in paragraphs 49, 57, 66 below). The technology was in its early stages but the value of abundant data sometimes demonstrating critical events or trends that impact decision making in intensive insulin therapy was fully appreciated.

48. As discussed below, continuous glucose monitors were accurate enough in 2009 to assist with diabetes management. For example, they served as a screening tool to indicate when a fingerstick glucose value should be taken, allowing patients to identify incidents of hypoglycemia and hyperglycemia that would have been missed by fingerstick glucose values alone. *See also e.g.*, EX1053, 18:10-14 (defining diabetes management to encompass "whether or not to perform one or more SMBG measurements"); EX1063, 308 (discussed in paragraph 73 below); EX1053, 38:25-39:11, 46:21-47:9 (same), 50:8-11 (agreeing that "If the CGM data were trending rapidly downward," this would perhaps "motivate a PWD in 2009 to perform a fingerstick").

49. While neither CGM nor fingersticks were as accurate as today, an analogy is with present day use of CGM in the hospital setting where it is not presently approved for general use. Yet, in pregnant patients with diabetes where we strive for tight control, when they are admitted to the hospital, we allow the patients to use their CGM. They are told not to take an insulin dose without checking the glucose on the hospital meter but they insist that they feel insecure without the CGM

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and they can inform the nurse whenever they see a pattern that makes them concerned. The nurse then checks the glucose at those critical times and the dosing is completed as indicated. It is indisputable that having extra information with the CGM devices available prior to 2009 led to more therapy decisions based on indicators from the sensor values or trends, even when confirmed by a standard meter, i.e., "fingerstick." EX1063, 309 ("Before taking extra insulin to treat postprandial hyperglycemia the patient should consider the following… The direction of the 'trend' arrow on the glucose sensor."); *see also* EX1046, 112-113 (discussing the importance of a glucose trend even in the presence of a fingerstick). Missing data could cause missed opportunities for improved glucose control or reduced hypoglycemia, and this was known and understood prior to 2009.

F. The Full-Scope Of Paradigm REAL-Time's FDA Approval Encompassed Management and Adjunctive Treatment of Diabetes

50. Second, paragraphs 80-83 and 148 of Dr. Wright's declaration relate to FDA approval of CGM systems for adjunctive and non-adjunctive use. EX2013, ¶¶ 80-83, 148. However, I understand that during his deposition Dr. Wright admitted that he did not "know when the Paradigm REAL-Time system was originally approved by the FDA," or whether the FDA issued any supplemental approvals. EX1053, 85:14-24. Nor does it appear that Dr. Wright considered the FDA's approved indications for Paradigm REAL-Time and other continuous glucose monitors as discussed in paragraph 51 below.

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51. I have reviewed the FDA original approval of Paradigm REAL-Time as a modification to the Medtronic Guardian RT Continuous Glucose Monitoring System ("Guardian RT") on April 7, 2006, by supplemental pre-market approval ("PMA") number S013 to original Medtronic CGMS PMA number P980022 (*i.e.*, supplemental approval no. P980022/S013). EX1041. Based on this supplemental PMA, I referred to the FDA's corresponding Guardian RT approval (P980022/S011) for Paradigm REAL-Time's originally approved indications. *Id.*; EX1058; EX1059. The FDA approved indications include:

- "continuous or periodic monitoring of glucose levels in the fluid under the skin in adults (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management;"
- "provid[ing] an indication of when a finger stick may be required;" including
- "real-time glucose values that allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose episodes."

EX1058, 1; EX1059, 1 (same); *see also supra* Section V.D (paragraph 37-38 above); *infra* Section V.K (paragraphs 80-81 below); EX1041. Further, this is consistent with Paradigm REAL-Time's discussion of the "Differences Between Blood Glucose Meter and Continuous Glucose Monitoring Readings," including that "[t]he System helps you discover when is the best time to take a fingerstick" and that "REAL-Time readings and trend graphs … allow [patients] to be proactive in [their] diabetes treatment so [they] can avoid severe highs and lows." EX1011, 9. In fact,

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the same Paradigm FAQ goes on to discuss the benefits of providing CGM data to users, including that they "can see if [their] glucose is trending up or trending down and take action much earlier," and "confidently make changes to [their] daily glucose management to improve [their] health." *Id.*

G. Contemporaneous Research Showed That Patient CGM Use Improved Clinical Outcomes

52. Third, before and leading up to April 2009, the use of continuous glucose monitoring data and trends to tailor insulin dosing was a known utility and contemplated benefit of CGM technology. Multiple studies done with sensors in the pre-2009 era consistently showed that increased use with added information drove success. For example, the JDRF study published in New England Journal of Medicine in 2008 and the Star 3 Study published in the New England Journal of Medicine in 2010 clearly showed frequency of use to be a predictor of success. EX1061; EX1062. In other words, more information led to improved A1c. *See e.g.*, EX1052, 7-8, 12 ("Continuous glucose monitoring has been shown to help guide therapy adjustment and, therefore, reduce HbA1c levels versus the use of fingersticks alone."), 25 ("Data from the GuardControl Trial was published in the December 2006 issue of *Diabetes Care.* The study demonstrated that patients using Medtronic REAL-Time continuous glucose monitoring had better control of their glucose than patients using fingersticks alone."); *see also* EX1053, 56:4-15

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(acknowledging that the JDRF was one of the organizations "responsible for key research on CGM technology").

53. I was an investigator in the Star 3 study that was designed in 2006 and initiated in January 2007. EX1062, 314. The treatment protocols including patient instructions were based on input from a group of clinicians familiar with the available CGM clinical research data and experienced in CGM use who formed the planning group. The patients were randomized to the sensor-augmented pump (SAP) based on that state of the art in 2007 and were instructed in standard principles of insulin pump therapy and CGM use but were also instructed in how to use the CGM patterns to improve self-management. *Id.*, 312, 314. Thus, the design of this study gave testament to the fact that CGM data was considered valuable to pattern management at that time. Although the use of the pump with sensor augmentation (MiniMed Paradigm REAL-Time System) showed significant improvement versus intensive therapy with multiple daily insulin injections and self-monitored blood glucose (SMBG), not mentioned in most discussions of this study was that almost all the improvement could be attributed to the CGM use rather than the pump itself. *Id.*, 315-316, 317, Fig. 2. The frequency of the CGM use drove the success. For example, those who were using the CGM at least 81% of the time had a reduction in HbA1c of 1.21% while those who used it 21-40% of the time only experienced a 0.19% reduction in HbA1c. *Id.*, 316, 317, Fig. 2. It is true that these sensors were

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approved for adjunctive use only but the value of "adjunctive use" is critical in understanding the benefits of CGM. Note that more SMBG readings were done in the control group who did not use CGM. That control group had the same access to the pre-meal glucose values as the sensor augmented pump group (SAP). Yet, there was highly significant improvement in those using the CGM because the exact glucose before a meal is only part of the story in dosing insulin. *Id.*, 315, 317. Obviously, the CGM greatly impacted insulin dosing with the level of accuracy available at that time. *Id.*, 317.

54. The 2008 JDRF study published similar results for PWDs over the age of 25 for which CGM monitoring was highest, to a lesser extent for PWD between 8 and 14 years of age, but found that compliance was limited among PWD between 15 and 24 years of age. EX1061, 1468, 1470, 1473-74. This correlation between sensor usage and improved glucose control is consistent with the finding of the Star 3 study.

H. There Were Recognized Clinical Benefits to Providing Patients With Historic CGM Trends in Real-Time

55. Fourth, before and leading up to April 2009, the use of continuous glucose monitoring data and trends to predict and prevent hypo and hyper-glycemia was a known utility and contemplated benefit of CGM technology. It is true that CGM of the 2009 time would give results that vary from the gold standard YSI measurement. As explained below, however, even standard meter ("fingerstick")

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measurements were inaccurate compared to YSI reference measurements. And in fact, present day CGM devices continue to experience some significant deviations. However, the difference between situational single point fingerstick monitoring four or less times daily and CGM with, e.g., 288 measurements per day allows for response to patterns and trends that mitigate the negative effect of inaccuracies. Indeed, this is reflected in the Paradigm discussion of the "Differences Between Blood Glucose Meter and Continuous Glucose Monitoring Readings," which notes the value of trend graphs to "proactive" diabetes management, including determining "the best time to take a fingerstick." EX1011, 9. My early experiences with CGM at the time prior to 2009 were highly valuable, providing excellent training of patients on the circumstances that created high, low or variable blood glucose results. I would direct them to review segments of the CGM from the recent hours in explaining problem foods, problem activities, inappropriate insulin dosing or missed dosing. If data were missing from key events, it would be a lost opportunity to guide adjustments in the standard single point dosing.

56. In fact, insulin dosing based on a single point in time uses ratios for food (what does 1 unit of insulin cover in terms of grams of carbohydrate) and sensitivity (how much does 1 unit of insulin cause the glucose to drop). Those ratios are determined by historical glucose responses to insulin as rendered by CGM. Those ratios often vary for different parts of the day based on changes in insulin

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sensitivity seen with CGM patterns. Beyond the fact that CGM experience leads to changed ratios used for dosing at the time of single point testing, what has happened in the interval since the last dose of insulin influences the dose. For example, if the patient exercised and the glucose has been running low, the dose is modified. If the patient experienced a significant level of hypoglycemia and then the glucose rebounded to a high level due to hepatic glucose production the dose would be modified. If illness or a medication precipitated a high glucose seen on CGM, the dose would be modified. If that data is missed, the decisions can be impacted. Based on my experience as a clinician treating Type 1 PWDs, and regular review of diabetes literature, it is my opinion that patients in the pre-2009 era used the real-time CGM data effectively and safely to adjust insulin dosing and improve glucose control without increasing hypoglycemia.

57. CGM data assisted patients in managing diabetes in other ways too. For example, CGM data would help PWDs notice certain glucose level trends after a certain type of activity or consuming a certain type of food or beverage, thus reinforcing a treatment plan or helping to remind them to stick with a treatment plan. *See e.g.*, EX1053, 63:5-18 (agreeing that it was important and helpful for PWDs to understand how daily choices, including meals and exercise, impacted blood glucose levels); *see also* EX1063, 309 ("Continuous glucose monitoring provides the patient with added information about postprandial glucose patterns, which can be extremely

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helpful in guiding the patient about when additional insulin coverage is required to reach the target glucose range.") As another example, if a PWD had been told by their doctor to be careful with evening alcohol consumption to minimize risk of hypoglycemia, and then saw morning CGM data indicating an overnight downward trend in glucose levels after consuming more alcohol, the PWD would be reminded to be more careful with evening time alcohol consumption and would adjust their behavior accordingly. *See also e.g.*, EX1053, 89:6-23. In short, the CGM data would help patients stick with the management plan that their clinician had prescribed. *See also e.g.*, EX2013, ¶ 42 ("Across all of the illnesses and conditions I have seen over my years as a physician, diabetes is unique in that nearly all of the interventions used to treat diabetes are managed by the PWD or their loved ones."); EX1053, 18:18-19:25 (agreeing that the patient or PWD "play an active role in the management of their – his or her diabetes."), 41:18-42:2. PWDs used CGM data presented on the screen of their monitoring device to manage diabetes and inform diabetes-management decisions, including decisions based on the preceding day (*i.e.*, 24 hours of data).

58. CGM devices were particularly helpful for assisting in preventing nighttime hypoglycemia, when blood sugar drops to dangerous levels while a PWD is sleeping. These events can be deadly. But they are also hard to detect in advance using fingersticks alone because patients tend not to be in the habit of regularly

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waking up and performing fingerstick measurements. I understand Dr. Wright testified at deposition that he finally began using CGM devices with patients because, using just fingersticks alone, PWDs "were not always aware that they were hypoglycemic because it could occur overnight." EX1053, 54:14-25. While this was Dr. Wright's experience with Type 2 PWDs in 2015 (*id.*, 54:3-9), clinicians treating Type 1 diabetes in 2009 and earlier (like myself) knew of this benefit of CGMs much earlier. *See also e.g.*, *id.*, 39:16-24 ("my focus was Type 2 diabetes. And in 2009, [CGM devices] were not approved for patients with Type 2 diabetes"), 40:7-10 (agreeing that "in 2009, CGM devices were primarily a Type 1 diabetes treatment"); 52:15-20 (same). CGMs were (and remain) helpful for preventing nighttime hypoglycemia because they allow for alarms that wake a patient with low blood sugar, allow the patient to quickly see whether their glucose levels have trended downwards, perform a confirmatory fingerstick, and then administer treatment to head off any adverse events that might be caused by the low blood sugar (such as shock). Moreover, I understand that Dr. Wright agreed at deposition that it would have been important in 2009 for a PWD to know if hypoglycemia had occurred overnight. *id.*, 87:24-88:4; *see also id.*, 63:19-22 (agreeing that "in 2009, was it known that it was helpful to understand blood sugar levels overnight for a PWD"). For example, Dr. Wright agreed that knowledge of a hypoglycemic event would help patients determine when it might be good to contact their doctor. *id.*, 89:17-23.

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59. Multiple scenarios show the potential and obvious value of avoiding gaps in sensor information before 2009 or now. When paged by a patient in the morning reporting a very high glucose value prior to breakfast, I routinely ask that they look at the CGM data for the hours prior. In some cases that can be a low glucose that was not recognized by the patient during sleep or due to hypoglycemic unawareness. *See e.g.*, EX1053, 54:14-24 (noting that patients with Type 2 diabetes "were not always aware that they were hypoglycemic because it could occur overnight."). The body's response is to produce glucagon to stimulate glucose production from the liver, trying to protect the subject from prolonged hypoglycemia. If the problem is interpreted as hyperglycemia in the morning due to a rising glucose overnight from inadequate insulin, the response is to increase the long-acting insulin. However, if there was hypoglycemia followed by rebound hyperglycemia, the action to increase insulin would in fact increase the risk of more severe hypoglycemia the following night. If there is a gap in that in CGM tracing during the night or in the short term before morning dosing there is no help in differentiating the two potential causes for the morning hyperglycemia. Data gaps that missed hypoglycemia at night could make it more difficult to determine what caused the morning hyperglycemia. Individuals with diabetes frequently have nocturnal hypoglycemia. Nighttime hypoglycemia is harder for PWDs to recognize. Hypoglycemia at night has been documented to cause falls, seizures, or arrhythmias.

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If one has a hypoglycemic event at night the risk of a repeat severe hypoglycemic event the next night is increased more than two-fold. Thus, it was known as desirable to provide a PWD with as much data as possible on his or her CGM to be able to assess nighttime glucose levels.

60. Another case where CGM data is useful is when administering one's typical pre-meal dose of rapid acting insulin, which can cause significant hypoglycemia if the CGM shows a pattern of decreasing glucose for the time prior to the dose. That hypoglycemia could come even before the individual has an opportunity to start their meal. Hypoglycemia could also occur after beginning a meal, especially when the meal is high in fat and protein or in PWDs who have gastroparesis (delayed stomach emptying that delays absorption of carbohydrate). We would therefore delay meal dosing until the patient has started eating rather than giving it prior to the meal as is usually recommended. The blood sugar could be normal (e.g., 120 mg/dl) at the time but if it had been 180 mg/dl 30 minutes earlier, the patient will be at risk for insulin induced hypoglycemia. It was known that presenting as much information as possible would likely enhance PWDs' experience by showing them these potential pitfalls.

61. In general, there are situations where presenting as much historical data as possible to PWDs can help them understand their glucose trends better, and thus make better decisions.

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62. Dr. Wright also cites to certain later-arising patents in opining that there may be "reasons why backfilling data gaps might not always be the best idea." EX2013, ¶ 160; *see also id.*, ¶¶ 159-163. Even if there were reasons to not backfill data gaps under certain circumstances in 2016, for the reasons explained above the over-all the benefits of backfilling as quickly as possible on user displays—especially for Type 1 PWDs—would outweigh any drawbacks. The supposed drawbacks noted by Dr. Wright, if they even arose, could be resolved by patient education. In any event, the existence of any potential drawbacks would not change that Paradigm (EX1011) would have been understood by clinicians to describe displaying repopulated data in trend graphs.

I. Dr. Wright Mis-Assesses Paradigm REAL-Time's Accuracy

63. Fifth, paragraphs 76 to 79 and 149 to 155 of Dr. Wright's declaration critique the accuracy of Paradigm REAL-Time and other CGM devices. EX2013, ¶¶ 76-79, 149-155. For example, Dr. Wright refers to the 15-25% MARD of CGM devices prior to 2009. *Id.*, ¶¶ 76, 150. Then, to assess Paradigm REAL-Time's accuracy, Dr. Wright relies on an August 2004 "Sample Accuracy Evaluation of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus" as reported in Chapter 7 of the Paradigm REAL-Time Sensor Features Guide. *E.g.*, *id.*, at ¶¶ 77, 151-155 (citing EX1011 at 85, 96); EX1011 at 83, n.1 (referencing "Sample Accuracy Evaluation" clinical

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study). Yet, as discussed in paragraphs 64-65 below, the accuracy of Paradigm-REAL Time steadily improved and by 2007 Paradigm REAL-Time was 23% more accurate with 87% less bias than the accuracy results considered by Dr. Wright. *See* paragraph 64-65 below; *see also* EX2013, ¶ 77.

64. Dr. Wright correctly notes that the Medtronic Guardian RT CGM components were used with the Paradigm insulin pump and that this "[w]hen the Paradigm insulin pump included the CGM components, Medtronic referred to it as the Paradigm® REAL-Time System, which is the subject of Exhibit 1011." EX2013, ¶ 57. Thus, information on Guardian RT informs the CGM aspects of the Paradigm REAL-Time System. Along with the Guardian RT approval order (P980022/S011) (EX1058), the FDA issued a Guardian RT summary of safety and effectiveness (SSED) (EX1059). As copied into the below table, this Guardian RT SSED discusses a "Performance Evaluation Of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus." *Id.*, 6-12. The below table compares this Guardian RT SSED Study with the "A Frequent Sample Accuracy Evaluation of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus, August 2004" study of the "Accuracy of Guardian RT readings" as recited in Chapter 7 of Paradigm Sensor Features User Guide. *Compare* EX1059, 6-8; EX1011 at 83-87.

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Performance Evaluation Of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus EX1059, 6.	Medtronic MiniMed, A Frequent Sample Accuracy Evaluation of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus, August 2004. EX1011 at 83, n.1.
This study was conducted at one investigational site and involved a total of 16 subjects with Type 1 Diabetes Mellitus. EX1059, 6.	The performance of the Guardian RT was evaluated in a clinical study... Sixteen subjects with Type I diabetes participated in a single-site in-clinic study. EX1011 at 84.
Each subject wore two MMT-7002 sensors (modified version without outer hydrophilic membrane) simultaneously. EX1059, 6.	Each subject wore 2 Guardian RT systems simultaneously. EX1011 at 84.
Venous blood samples were drawn every 30 minutes and glucose concentrations were measured using a YSI STAT Plus Glucose Analyzer. EX1059, 6.	Guardian RT results were compared to plasma glucose values from a reference method, the YSI 2300 STAT Plus™ glucose analyzer (referred to as YSI). EX1011 at 84.
The dataset from this study consisted of a total of 3941 paired YSI reference values and corresponding Guardian RT glucose concentrations when the BD Logic measurements were used as calibration values… The mean and median ARE (Absolute Relative Error) between the glucose concentration calculated by the Guardian RT and the corresponding YSI Analyzer reference value were … 19.67% … the BD Logic capillary glucose measurements were used as	<table><tr><td>Number of Paired Glucose Measurements</td><td>3941</td></tr><tr><td>Mean Absolute Percent Difference (± SD)</td><td>19.7 ± 18.4%</td></tr><tr><td>Bias</td><td>-15.0 mg/dL (-0.8 mmol/L)</td></tr></table> EX1011 at 85.

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calibration values. On average, the Guardian RT glucose values were … 15.0 mg/dL less than the YSI Analyzer reading when the BD Logic measurements were used for calibration.

EX1059, 7.

The following table shows the percent of Guardian RT readings within 20% and 30% of the YSI values (or within 20 mg/dL for values < 80 mg/dL), broken down into various glucose ranges.

Plasma Glucose Range (mg/dl)	Percent Within 20%	Percent Within 30%
40-80*	68%	68%
>80-120	60%	77%
>120-240	62%	81%
>240	61%	82%

*For the Low glucose range, 40-80 mg/dl (2.2-4.4 mmol/l), the value shown is the percent within 20 mg/dl (1.1 mmol/l).

EX1059, 7 (excerpted, highlighted).

The accuracy of the Guardian RT was also evaluated by calculating the percentage of Guardian RT readings within 20% and within 30% of the YSI reading (or within 20 mg/dL (1.1 mmol/L) in the low glucose range). Results are shown below.

Plasma Glucose Range (mg/dL)	Plasma Glucose Range (mmol/L)	Number of Paired Readings	Percent Within 20%	Percent Within 30%
Overall		3941	62%	79%
40-80*	2.2-4.4	356	68%	68%
>80-120	>4.4-6.7	769	60%	77%
>120-240	>6.7-13.3	2362	62%	81%
>240	>13.3	454	61%	82%

*For the Low glucose range, 40-80 mg/dL (2.2-4.4 mmol/L), the value shown is the percent within 20 mg/dL (1.1 mmol/L).

EX1011 at 85 (excerpted, highlighted).

The following table shows the percentage of points falling within each zone, stratified according to the range of glucose concentrations.

Glucose Range (mg/dl)	Number and (%) of Data Points Evaluated	A+B	A	B	C	D	E
40-80	356 (9)	271 (76.1)	214 (60.1)	57 (16.0)	2 (0.6)	80 (22.5)	3 (0.8)
81-120	769 (20)	768 (99.9)	463 (60.2)	305 (39.7)	1 (0.1)	N/A*	N/A
121-240	2362 (60)	2352 (99.6)	1476 (62.5)	876 (37.1)	4 (0.2)	N/A	6 (0.2)
>240	454 (11)	394 (86.8)	277 (61.0)	117 (25.8)	N/A	59 (13.0)	1 (0.2)
Overall	3941 (100)	3785 (96.0)	2430 (61.7)	1355 (34.4)	7 (0.2)	139 (3.5)	10 (0.2)

*N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range

EX1059, 8.

The percent of Guardian RT readings in the above graph are presented in the following table according to the percentage of points falling within each zone (A-E). Results are further broken down (stratified) according to the range of glucose concentrations.

Glucose Range (mg/dl)	Number and (%) of Data Points Evaluated	A+B	A	B	C	D	E
40-80	356 (9)	271 (76.1)	214 (60.1)	57 (16.0)	2 (0.6)	80 (22.5)	3 (0.8)
81-120	769 (20)	768 (99.9)	463 (60.2)	305 (39.7)	1 (0.1)	N/A*	N/A
121-240	2362 (60)	2352 (99.6)	1476 (62.5)	876 (37.1)	4 (0.2)	N/A	6 (0.2)
>240	454 (11)	394 (86.8)	277 (61.0)	117 (25.8)	N/A	59 (13.0)	1 (0.2)
Overall	3941 (100)	3785 (96.0)	2430 (61.7)	1355 (34.4)	7 (0.2)	139 (3.5)	10 (0.2)

*N/A means that the Clarke Error Grid does not consider the possibility of these zones in that concentration range.

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	EX1011 at 88.

Based on the above comparison, it appears that the results reported in Chapter 7 of the Paradigm REAL-Time Sensor Features Guide (EX1011 at 83-97) relate to the "Accuracy of the Guardian RT" and "Guardian RT Sensor Performance" (EX1011 at 85-97) as assessed in August 2004. *See also e.g.*, EX1011 at 83, n.1 ("Medtronic MiniMed, A Frequent Sample Accuracy Evaluation of the Medtronic MiniMed Telemetered Glucose Monitoring System II (TGMS II) in Subjects with Type 1 Diabetes Mellitus, August 2004.").

65. These August 2004 Guardian RT accuracy results and Dr. Wright's corresponding assessment do not reflect the accuracy of Paradigm REAL-Time in 2007, 2008, or 2009 because the sensor accuracy of Medtronic systems improved from 2004 to 2009. For example, a 2007 study titled "Accuracy of Real-Time Continuous Glucose Monitoring in the MiniMed Paradigm System" evaluated 60,000 paired sensor/meter readings to determine a MARD of 15.8% with a bias of -2.3 mg/dl. EX1064, 2. Meanwhile, for adults, the study determined a MARD of 15.2% with a bias of -2.0 mg/dl. *Id.* This study demonstrates that by 2007, the Paradigm REAL-Time was 23% more accurate with 87% less bias than the Guardian RT accuracy results considered by Dr. Wright. *See* EX2013, ¶ 77.

J. The Accuracy of Paradigm REAL-Time's Continuous Monitoring Data Was Sufficient To Support Its Clinical Utility To Patients

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66. Sixth, while CGMs have certainly gotten more accurate over the years, even in 2009 (and before) they were accurate enough to greatly aid treatment and management decisions. At that time, CGM provided much more information than fingersticks, allowing patients to observe recent trends that allowed more informed and proactive decisions in acute diabetes management. Though the adjunctive use approval required confirmation via standard meter (i.e., fingerstick), the CGM trend data provided for much more informed and calculated use of standard meter readings. *See also e.g.*, EX1063, 309 ("Before taking extra insulin to treat postprandial hyperglycemia the patient should consider the following… The direction of the "trend" arrow on the glucose sensor.").

67. Indeed, the Paradigm documentation explains what was generally known: that trend information was often more helpful than any given glucose measurement, especially since any given measurement (whether made by CGM or standard meter) could vary widely. EX1011, 9. The Paradigm documentation notes potential differences in accuracy between CGM and standard meter readings, and also notes the known variation even in meter readings. *Id.* As that document explains, it was known to be "unlikely that two consecutive meter readings from the same blood sample will match" and that "[p]erfectly matched readings - whether they come from meters or CGM systems, are unlikely to happen." *Id.* Thus, the real value in CGMs was in continuously collecting glucose data and informing PWDs of

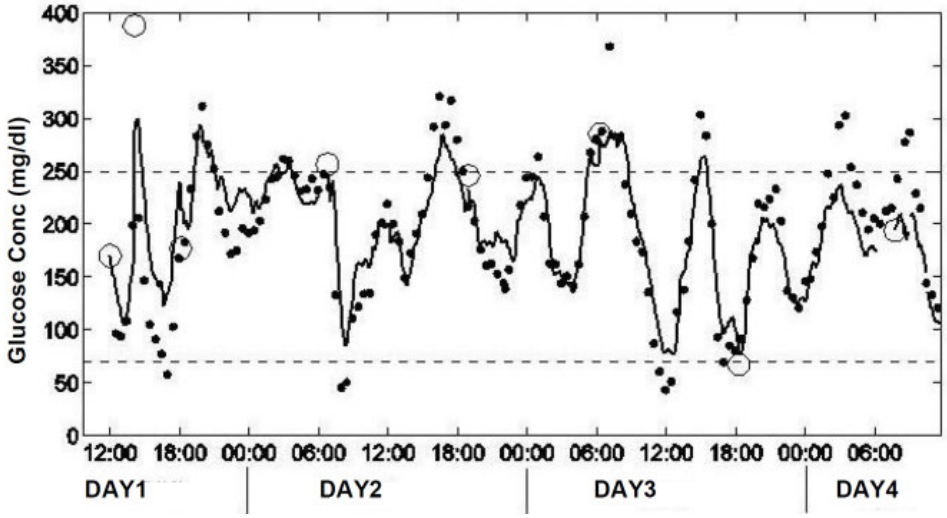
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glucose trends. As Paradigm notes, "[t]he advantages of REAL-Time CGM [we]re the trend graphs," which allowed PWDs "to see when glucose is trending up or trending down and how fast it is moving." *Id.* This helped PWDS "manage [their] diabetes more effectively" and "live a healthier life." *Id.*

68. For example, consistent with its FDA approved indications, the Paradigm REAL-Time guide "requires patients to take a fingerstick measurement before adjusting therapy" and then notes what clinicians and others already knew: that one great value of a CGM system is that it "helps [patients] discover when is the best time to take a fingerstick." EX1011 at 9; *see also e.g.*, EX1063, 308 (as discussed in paragraph 73 below); EX1053, 38:25-39:11, 46:21-47:9 (same). It further explains, as was known, that trend graphs "allow[s patients] to be proactive in [their] diabetes treatment so [they] can avoid severe highs and lows. Patients can see if [their] glucose is trending up or trending down and take action much earlier." EX1011 at 9. This allowed PWDs to "confidently make changes to [their] daily glucose management to improve [their] health." *Id*.

69. The figures provided by Dr. Wright to demonstrate liabilities of the CGM of that era could be interpreted quite differently if considered in the context of monitoring options at that time and the decision making that goes with availability of important trending data.

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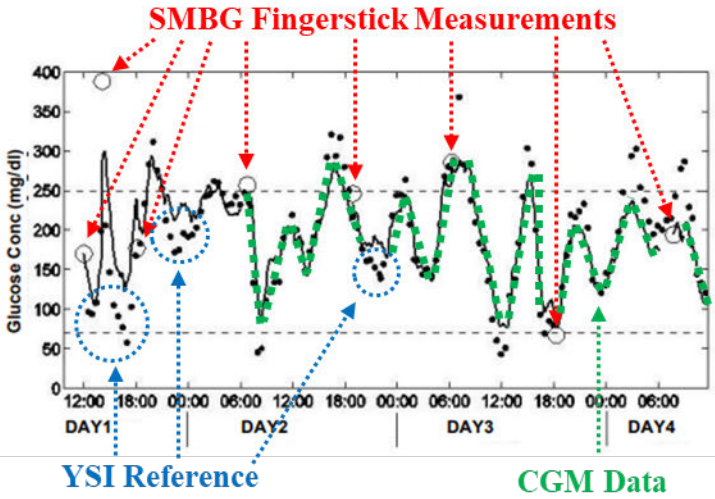


EX2013, ¶ 151 (citing EX1011 at 96). This time-elapsed plot demonstrates that even the 2004-era accuracy of Guardian RT provided patients clinically useful CGM data that would have assisted with the management and adjunctive treatment of diabetes. For example, as discussed in paragraphs 71-75 below, this 2004-era Guardian RT time-elapsed plot demonstrates how CGM data allowed users to identify impending hyper- and hypo-glycemia, sometimes prevent these conditions and sometimes correct them—often in the absence of timely self-monitored blood glucose ("SMBG") fingerstick measurements. EX1011 at 96.

70. Before discussing how the 2004-era Guardian RT time-elapsed plot would assist a user in the management and adjunctive treatment of diabetes, I want to clarify the nature of displayed glucose data:

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The plot graph below is a representative example of continuous sensor tracing vs. reference blood glucose reading, where sensor showed average (typical) performance. The open circles (o) on the graph represent the meter calibration readings. The closed circles (•) represent the reference blood glucose readings, and the solid line (—) represents the sensor glucose value.



EX1011 at 96. First, there are eight open circle (o) standard blood glucose meter (SMBG) fingerstick measurements indicated with red arrows. *See also* EX1053, 71:5-9, 73:2-5. Second, the small closed circles or dots (·) indicated in blue are "reference blood glucose readings" (EX1011, 96) collected by a Yellow Springs Instrument (often called "YSI"). EX1053, 71:12–72:14, 73:11-16. For example, Chapter 7 of the Paradigm REAL-Time sensor features guide discusses how "Guardian RT results were compared to plasma glucose values from a reference method, the YSI 2300 STAT Plus™ glucose analyzer (referred to as YSI)." EX1011 at 84. A YSI is a highly-specialized benchtop medical analyzer device that for at least the past 20 years has been used almost exclusively in research settings. YSI reference blood glucose readings are the gold standard for blood glucose

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measurement, they are not taken by a PWD, not taken in a PWD's home, and are not typically available to patients. *See also* EX1053, 72:12-19. *See also* EX1053, 72:12-19. Finally, CGM data is indicated by the solid line (–) roughly traced in green. EX1011 at 96; *see also* EX1053, 69:22-25, 72:23-73:1.

71. I disagree with Dr. Wright to the extent he relies on the above graph as suggesting that a clinician would not want to provide CGM data to users because confirmatory fingerstick measurements were necessary to make a treatment decision. EX2013, ¶¶ 81, 148. Note that any inaccuracies in CGM data (vis-à-vis the YSI gold standard) shown in the above graph would not lead to inappropriate dosing nor to adverse outcomes. Rather, the power of 288 glucose tests per day with CGM means the patient doesn't rely on a single number over a few minutes of time but rather follows a trend for at least 15 minutes or longer. The low CGM values in the above graph that appear lower than the fingerstick glucose would still have utility for patients—the precipitous drop demonstrated in the CGM trend line would lead the PWD to take action, such as performing a fingerstick and perhaps taking glucose to avoid dangerously low blood sugar levels.

72. Likewise, the high or upward-trending CGM values provided helpful guidance, even if they tracked imperfectly to the corresponding YSI reference glucose readings. For example, high YSI values are associated with CGM sensor readings at or near 250 mg/dl and often accompanied by a steep upwards trend,

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which would lead to an intervention (e.g., fingerstick and administration of insulin). If the intervention was not adequate to bring the glucose down to target, it would still reduce the glucose into a safe range and subsequent treatment could be added if indicated.

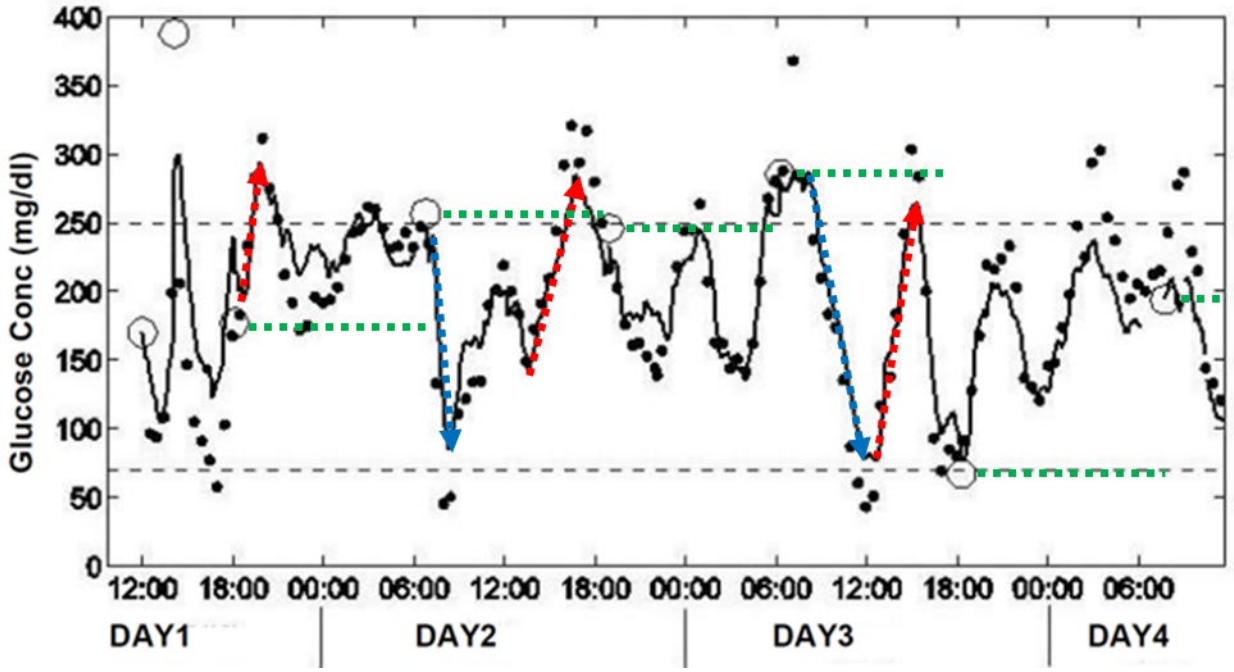
73. Understood properly, the Guardian RT time-elapsed plot referenced in Dr. Wright's declaration illustrates that despite deviating from YSI reference blood glucose readings, CGM values indicated when glucose was heading higher or lower, including identifying impending and sometimes actual hyper- or hypo-glycemia. This data would have assisted a PWD in the management and adjunctive treatment of diabetes, including indicating when to take a confirmatory fingerstick. *See e.g.*, EX1063, 308 ("The practical implication is that in situations when the glucose is declining …, even if the sensor glucose is normal, the patient needs to perform finger stick glucose measurements before driving. Usually in this situation the trend graph on the sensor display or the rate of change arrows would indicate that the glucose is falling, which would serve as a prompt for the patient to check the finger stick blood glucose."); EX1053, 38:25-39:11 ("Did PWDs use CGM data to determine whether or not to perform a fingerstick in 2009?" "That wasn't the sole reason that they'd use fingersticks, but yes." "And in 2009, were there any other diabetes management actions that a patient might take based on CGM data?" "There probably were other things that they could do with lifestyle."); 47:5-9 (agreeing that POSITAs would

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know that "PWDs were using CGMs to assist in diabetes management prior to 2009"); 63:5-18 (agreeing that it was important and helpful for PWDs to understand how daily choices, including meals and exercise, impacted blood glucose levels).

74. For example, between 18:00 (6pm) and 00:00 (midnight) of Day 1, the CGM trace exceeds 250 mg/dl glucose indicating hyper-glycemia and very close to the YSI blood glucose reference values while the most recent SMBG fingerstick value is still showing a glucose concentration between 150 and 200 mg/dl. Similarly, the steep downward trend between 6:00 and 12:00 on the second and third days indicated impending hypo-glycemia when the most recent SMBG fingerstick value would have indicated glucose between 250 and 300 mg/dl at 6:00 am. Likewise, the steep upward trend between 12:00 and 18:00 on the second and third days indicated actual hyper-glycemia when the most recent SMBG fingerstick was still from 6:00 am.

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EX1011 at 96 (excerpted, annotated in red, blue, green). The above figure overlays CGM trends projecting or indicating hyperglycemia (annotated in red) or hypoglycemia (annotated in blue) against SMBG values that would be known to the patient in the absence of CGM (annotated in green). As noted in paragraphs 71-73 above and 77 below, both the absolute values and trends of this CGM data provide clinical value when displayed to a user, including identifying impending or actual hyper- and hypo-glycemia not apparent from SMBG measurements alone. In addition to indicating impending hypo-glycemia, the steep downward trends between 6:00 and 12:00 of the second and third days maybe in response to insulin dosed according to the 6:00 am confirmatory fingerstick (*e.g.*, 250 to 300 mg/dl). If

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so, these steep declines towards hypo-glycemia could inform a patient's response to a 250 to 300 mg/dl 6:00 am fingerstick measurement on future days.

75. In summary, the CGM values of that time were quite informative for the engaged user allowing for interventions (e.g. glucose or insulin) that could safely prevent the potential severe low or high glucose values.

K. The Clinical Benefits Provided By CGM Were Not Available With SMBG Fingerstick Measurements Alone

76. Seventh, SMBG fingerstick measurements and other alternatives for glucose monitoring in that pre-2009 era did not provide the same clinical benefits as CGM. For example, Dr. Wright's own 2015 article on "Ambulatory Glucose Profiling" provides that:

> For decades, self-monitoring of blood glucose (SMBG) has been the standard measure of glycemic control to guide day-to-day adjustment of therapy. Limitations of SMBG include underreporting (omission of undesirable values), over-reporting (addition of values within target), imprecise reporting, lack of overnight glucose readings, and its episodic nature, all of which result in missed significant hypo- and hyperglycemic events.

EX1050 at S44; *see also* EX1046 at 112 ("Even when applied conscientiously, self-monitoring of blood glucose (SMBG) provides only a snapshot blood glucose concentration without providing any information about the direction or rate of blood glucose change. As a result, many patients are unable to achieve blood glucose

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targets despite testing their blood glucose multiple times daily."). Dr. Wright then contrasts these limitations of SMBG fingerstick values with the benefits of CGM:

> CGM can provide real-time feedback on current glucose levels as well as retrospective data that provides a more accurate view of glucose patterns over a given time period compared with SMBG. A number of studies, including 2 meta-analyses, have demonstrated the efficacy of CGM in improving glycemic control (including reduced HbA1c) and reducing hypoglycemia.

EX1050 at S44-45 (citing EX1061); *see also e.g.*, EX1053, 74:6-75:16 (Dr. Wright agrees that Exhibit 1050 is his paper that he wrote and was published in 2015); EX1046 at 112 ("CGM represents a significant advance because it 1) provides real-time information about current blood glucose (or, more accurately, interstitial fluid glucose) concentrations, 2) provides short-term feedback about the effectiveness of diabetes interventions (such as insulin administration)…").

77. The Guardian RT time-elapsed plot also shows that SMBG fingerstick measurements were not perfectly accurate. For example, it was not disclosed in Dr. Wright's description of this figure but the open circle seen at the upper left end of the figure was actually a glucose measurement done with a glucose meter. None of the CGM values are as divergent from the reference values as that meter value that is near 400 mg/dl while the YSI blood glucose reference reading is under 300 mg/dl. Dr. Wright hypothesized that this SMBG measurement, which occurs between 12:00

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and 18:00 on DAY1, was an "error." EX1053, 94:5-95:24. In fact, Dr. Wright admitted that fingerstick user errors were a "known issue" in 2009. EX1053, 96:5-13.

78. While SMBG accuracy was a concern, a much bigger issue with relying on SMBG without CGM is that patients were left without any indication of whether and how much glucose values had changed since the most recent SMBG measurement or of the direction in which glucose had been trending. For example, despite their glucose levels dropping into hypoglycemia then returning to hyperglycemia between 6:00 and 18:00 on both days 2 and 3, the only information known to the patient would have been a 6:00 am glucose value between 250 and 300 mg/dl. But as Dr. Wright agrees, this rapid downward trend might also motivate a PWD to take a confirmatory fingerstick measurement. EX1053, 50:8-11.

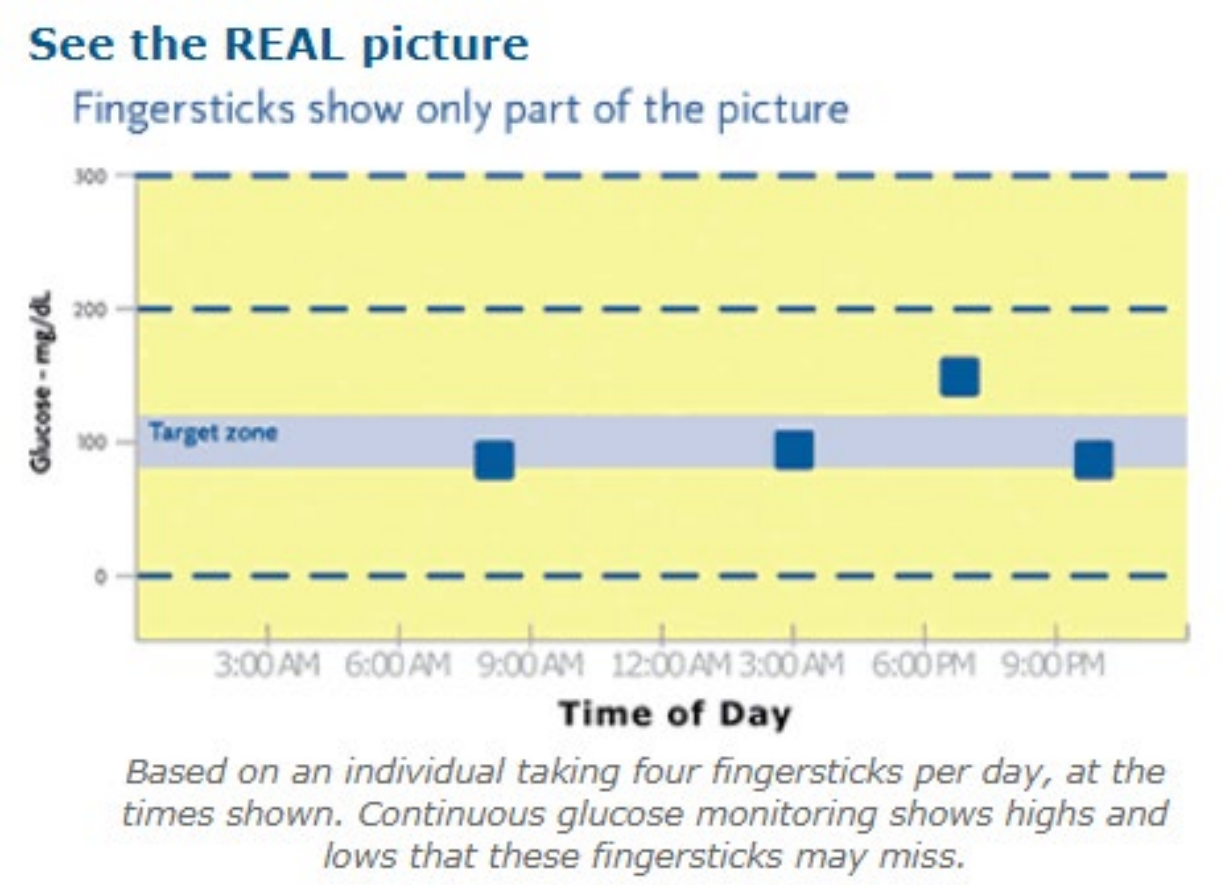
79. Consistent with this concern, the following images show the benefit of adjunctive CGM usage for assisting in treatment and management (including performing fingersticks in response to CGM trends, which would then often lead to insulin dosing treatment). EX1052; *see also id.*, at 6, 11 ("Continuous glucose monitoring as an adjunct to fingersticks is proven to improve these outcomes versus fingersticks alone."; "Continuous Glucose Monitoring is an Important Supplement to Fingersticks and HbA1c Testing"). These images illustrate how the use of only fingersticks (as shown in the first image by four squares) would lead to missed lows

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and highs (as shown in the overlaid CGM graphic of the second image). These highs and lows would have clinical significance in both a patient's own self-treatment in the short-term and when reviewing long-term trends with a clinician. The graphs are valuable to see trends and compare changes in glucose with near real-time behavior. Studies and personal experience as a treating physician all support that more data to a patient from a CGM, including recent 3-hour and 24-hour trend graphs leads to better diabetes management and lifestyle decisions overall, even if the CGM data is not used alone to decide whether and how much insulin to administer. The need for more data in the near-term was especially so because PWDs were largely responsible for managing their diabetes. *See e.g.*, EX2013, ¶ 42 ("Across all of the illnesses and conditions I have seen over my years as a physician, diabetes is unique in that nearly all of the interventions used to treat diabetes are managed by the PWD or their loved ones."); EX1053, 18:18-19:25 (agreeing that the patient or PWD "play an active role in the management of their – his or her diabetes."), 41:18-42:2. And this need for data was even higher for those with Type 1 diabetes because the consequences of acute therapeutic errors were typically much greater than in the Type 2 population. For example, Type 1 PWDs faced the acute risk of potentially deadly keto-acidosis, which was not a problem commonly faced by Type 2 PWDs.

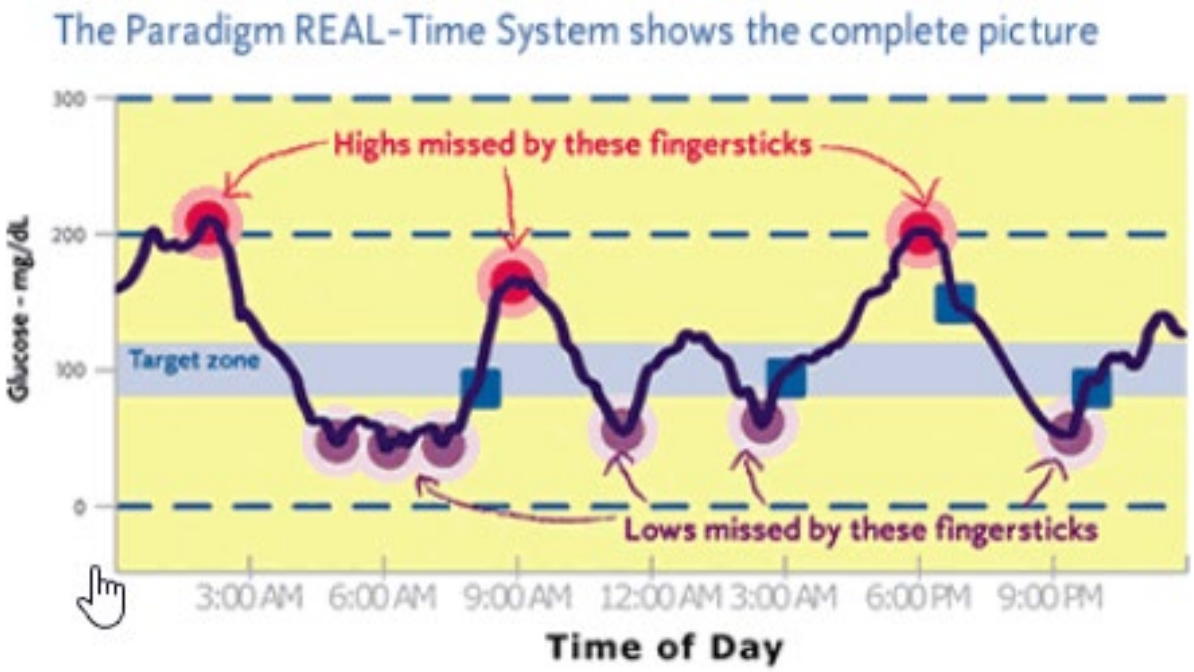
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80. These images are available as Internet Archive captures taken from the Medtronic website in 2007. *See* https://web.archive.org/web/20070715214458/http:/www.medtronicdiabetes.com/products/insulinpumps/benefits.html:



EX1052, 6, 11, 27. I reproduce the following image showing the overlaid CGM graphical data overlaid, illustrating the highs and lows missed by using only fingerstick measurements. While the below image is not captured in EX1052, it appears when one hovers over the above image on the Internet Archive. Regardless of its origin, the following figure provides a good example of the glucose highs and lows that would be missed by fingersticks alone in the time period before 2009:

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Id., 6, 11, 27. That 2007 Medtronic page also directly explains this well-known utility of CGM in detecting highs and lows that fingersticks alone might otherwise miss, thus allowing PWDs to be more proactive in their diabetes interventions:

And did you know that fingersticks alone may not even reveal up to 60% of lows - lows that the MiniMed Paradigm REAL-Time System *can* reveal? 1

Fingerstick measurements reveal a blood glucose value at a single moment - a "snapshot" - in time. An A1C test, which measures blood glucose control over a two to three month period, reveals an average glucose value. Both can miss highs and lows in your blood glucose present at various times during the day highs and lows that may lead to diabetes-related complications. 2

Intervene Proactively

The MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System displays glucose readings, offers safety alarms, and displays 3- and 24-hour trend data that help you proactively intervene to improve your glucose control, and reduce the severity and duration of low and high blood sugars. Additionally, you can analyze historical glucose patterns by uploading your glucose trend data to CareLink™ Personal software, a FREE online tool. Over time, you may gain valuable understanding of the effects of meals, exercise, and medication on your glucose levels.

REAL-Time information is ideal for people trying to cope with the challenges of controlling high and low glucose levels, including people who are:

- Prone to nighttime lows ("nocturnal hypoglycemia") 3
- Prone to post-meal highs ("postprandial hyperglycemia") 4
- Experiencing morning highs ("dawn phenomenon") 5,6
- Pregnant, or who are planning to get pregnant 2

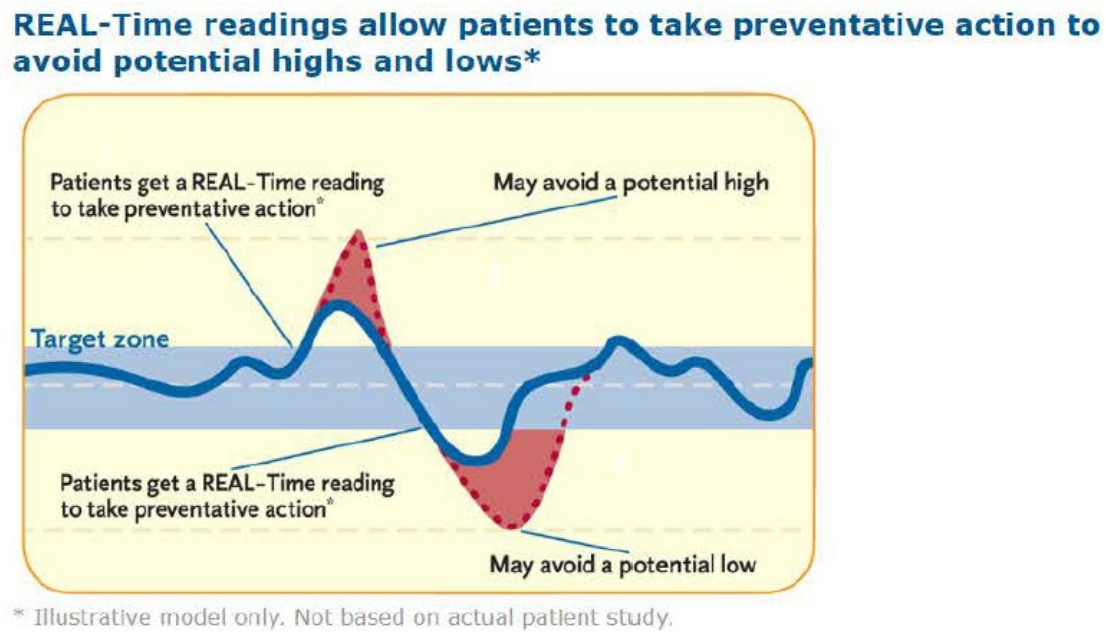
With this information, your healthcare provider can customize your diabetes treatment and reduce your A1C levels. And *that* reduces your risk of long-term health complications. 2

EX1052, 27. In addition, Medtronic marketed additional benefits of CGM to patients and clinicians, including:

- "Just as the body uses this information to guide insulin release, continuous glucose monitoring helps patients to guide therapy decisions" *Id.*, 6, 11;

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- "By offering the clinical benefits of both insulin pump therapy and continuous glucose monitoring, the MiniMed Paradigm® REAL-Time system enables you and your patients to achieve the following: Better detection of hypoglycemia and hyperglycemia vs. fingersticks alone" *Id.*, 6, 11;
- "Better Reveals Dangerous Glucose Variability[:] Continuous glucose monitoring helps reveal glucose variability not tracked by fingersticks or HbA1c testing … Continuous glucose monitoring identifies 4 times more glucose excursions requiring therapy adjustment versus fingersticks alone" *Id.*, 7, 12;
-



Id., 7, 12;

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- "MiniMed Paradigm 522 or 722 Insulin Pump Offers REAL Innovations[:] On-screen REAL-Time glucose readings, trend arrows, and trend graphs to help patients understand more about their glucose control and improve their diabetes management" *Id.*, 16;
- "REAL Benefits - Day and Night - for You and Your Patients[:] With the MiniMed Paradigm REAL-Time System, patients have access to REAL-Time glucose readings, trending and alarms around the clock so they can intervene more quickly... This information can help you and your patients better detect and manage incidents of hypo- and hyperglycemia, which can reduce HbA1c and related diabetes complications." *Id.*,17;
- "REAL-Time Trend Graphs[:] … Show patients the effect of meals, exercise, insulin and medication on their glycemic control" *Id.*, 17;
- "REAL-Time Continuous Glucose Monitoring delivers insights you just can't get through fingersticks alone[:] … with continuous glucose monitoring integrated into the system, you see the big picture of your glucose levels *Right Now* - anytime, anywhere in a way that you just can't accomplish through fingersticks alone." *Id.*, 27.

81. As an additional example, less than a week after Paradigm REAL-Time's April 7, 2006 approval, Medtronic announced on April 13, 2006 the "FDA

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approval of the MiniMed Paradigm® REAL-Time Insulin Pump and Continuous Glucose Monitoring System" and promoted it as:

- "new technology will help patients take immediate corrective or preventive action to maintain healthy glucose levels;"
- "REAL-Time glucose information displayed on the insulin pump allows patients to take immediate action to improve their glucose control after taking a confirmatory fingerstick";
- "Glucose measurements obtained by the sensor are relayed every five minutes from a transmitter to the insulin pump, which displays the glucose value, three-hour and 24-hour trend graphs, as well as arrows to indicate how quickly glucose is moving up or down;" and
- "fingerstick measurements only reveal a glucose value at a single moment in time. As a result, patients are unable to detect approximately 60 percent of low glucose (hypoglycemia) events, and have difficulty assessing glucose fluctuations while they sleep. In contrast, REAL-Time CGM allows patients to view glucose trends throughout the day and night, and understand how fast, and in what direction, their glucose levels are heading. By discovering how diet, exercise, medication and lifestyle affect their glucose levels, patients can make more informed self-management decisions and achieve a greater sense of confidence when managing their disease."

EX1044.

L. Contrary to Wright's Criticisms, The Benefits of Providing CGM to Patients were Known to Clinicians before 2009

82. From their first clinical experiences with continuous glucose monitoring, clinicians as well as patients and system designers recognized that missed data could result in lost opportunities for improvement. That was true in 2008 and remains true today. Once CGM use is initiated, users look for critical events that

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inform them, not just at the time of dosing but at any time. Patterns of glucose that were revealed through CGM in 2008 were just as significant as they are today and providers as well as patients quickly came to look for such events and lessons.

83. I have reviewed paragraphs 51 to 61 of Dr. Wright's declaration, which appear to assess the development and basic function of continuous glucose monitors. EX2013, ¶¶ 51-61. Based on my experience with CGM technology during the relevant 2004-2009 period and my review of contemporaneous articles and other references that were published during this 2004-2009 period, it is my opinion that Dr. Wright's assessment appears to be based on 2004-era CGM technology while glossing over and largely ignoring research and development that occurred from 2004 to 2009. For example, Dr. Wright skips from discussing the 1999-era Medtronic CGMS in paragraph 55, to summarily listing CGM systems available in 2009 in paragraphs 56 through 58, before jumping to later developed CGM technology in paragraphs 59 and 60. *Id.*, ¶¶ 55-60.

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I, Andrew Ahmann, do hereby declare and state, that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: 09/04/2024, 2024

Andrew Ahmann, MD

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CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY

NAME	**Andrew J. Ahmann**	**DATE**	6/18/2024

PRESENT POSITION AND ADDRESS

Academic Rank:	**Professor of Medicine**
Department/Division:	**Department of Internal Medicine, Division of Endocrinology, Diabetes and Metabolism** **Harold Schnitzer Diabetes Health Center**
Professional Address:	**Oregon Health & Science University** **3181 SW Sam Jackson Park Road, OP05-DC** **Portland, OR 97239**
E-Mail Address:	**ahmanna@ohsu.edu**

I. BIOLOGICAL

Birthdate*:	**04/16/1950**
Marital Status/ Children*:	**Married/2 adult children**
Home Address*:	**2768 SW Sherwood Dr.** **Portland, Oregon 97201**

II. EDUCATION

Undergraduate and Graduate:

University of Colorado School of Medicine	MD	1980
North Dakota State University College of Pharmacy	MS	1976
North Dakota State University College of Pharmacy	BS	1973

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Postgraduate:

Endocrinology Research Fellowship	1985-1986
Walter Reed Army Medical Center, Washington, DC	
Endocrinology Fellowship	1983-1985
Walter Reed Army Medical Center, Washington, DC	
Internal Medicine Internship and Residency	1980-1983
Fitzsimons Army Medical Center, Denver, CO	
Hospital Pharmacy Residency	1974-1976
VA Hospital, Fargo, N.D.	
Clinical Pharmacy Residency	1973-1974
VA Hospital, Palo Alto, CA	

Certification:

Diplomat, Endocrinology and Metabolism, American Board of Endocrinology and Metabolism; #92927; 1987
Diplomat, Internal Medicine, American Board of Internal Medicine; #092927; 1983
Diplomat, National Board of Medical Examiners; #16524; 1981

Licenses:

Licensed Physician, State of Oregon, # 16524
Initial licensure, June 1990. Continuous to date.

III. PROFESSIONAL EXPERIENCE

Academic:

Professor of Medicine, OHSU	2009-present
Associate Professor of Medicine, OHSU	2001 - 2009
Assistant Professor of Medicine, OHSU	1993 - 2001
Clinical Assistant Professor of Medicine, OHSU	1990 - 1993
Assistant Professor of Medicine	1986 - 1990
Uniformed Service University for Health Sciences, Bethesda, Maryland	

Administrative:

Interim Division Head; Division of Endocrinology, Diabetes and Clinical Nutrition	2021 - present
Director, Harold Schnitzer Diabetes Health Center	2007 - present
Medical Director, OHSU Diabetes Center	2000 - 2007
Director, OHSU Diabetes Inpatient Care Team Project	1997 - 2001
Director, Diabetes Services, OHSU	1993 - present
Co-Director, Diabetes Treatment Center, Providence Portland Medical Center	1990 - 1992

Other:

NIDDK Type 1 Diabetes in Acute Pancreatitis Consortium Review Panel, July 2, 2020, Virtual Meeting through NIH.	*2020*
Advisory Board, Medtronic	2019 - present
Expert Evaluators Panel (CPDPC), NIH/ NIDDK Bethesda, Md	2018
Advisory Board, Mannkind	2018
Advisory Board, Sanofi	2018

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Advisory Board, Novo Nordisk	2017 -2019
Consultant, Dexcom	2015-2018
Advisor Dexcom DIAMOND study planning group	2015-2016
Consultant, Trividia Health	2017
Sanofi Advisory Board (Afrezza and Lantus U300)	2015
Eli Lilly Advisory Board	2015, 2017- 19
AstraZeneca Advisory Board	2014
Janssen Advisory Board	2013
Scientific Advisory Board, MannKind	2013
Abbot Scientific Advisory Board	2009 - 2011
Orexigen Scientific Advisory Board	2008 - 2011
Novo Nordisk Translational Advisory Board	2008 - present
Hospital Task Force, Novo Nordisk	2008 - 2009
Scientific Advisory Board, GLP-1 Technosphere, MannKind	2007 – 10, 2018
Hospital Advisory Board, Novo Nordisk	2006 - 2007
Scientific Advisory Board, Ortho Clinical Diagnostics Metabolic Disease	2006 – 2007
Society of Hospital Medicine Inpatient Glycemic Control Task Force	2006 - 2007
Sanofi-Aventis "Inpatient in Hospital Use" Advisory Board	2005 - 2008
President, American Diabetes Association Portland Area Leadership Board	2005 - present
ODS Health Plans, Diabetes Program Advisory Group	2004 - 2010
Advisory Board, Exenatide Clinical Applications, Amylin Pharmaceuticals & Eli Lilly	2003 - 2007
Consultant, Sensys, non-invasive glucose sensor	2003 – 2010
Am Coll of Endocrinology Inpatient Diabetes and Metabolic Control Task Force	2003
Consultant, Regence Blue Cross/Blue Shield on diabetes	2002, 2004 -05
Physician Advisory Board, NuMedics Software	1997 - 1998
Medical Director, Fred Meyers, Healthy Options Diabetes Education Program	1996 - 1999
Consultant, Pharmacy Services Group/ODS, Pharmacist Diabetes Case Management Program	1996 - 1998
Consultant, Asante Heath System, Medford, OR, Diabetes Services	1997
Endocrinology Practice in Portland, OR	1990 - 1993
Staff Physician, Diabetes Clinic, OHSU	1990 - 1992
Staff Physician, Walter Reed Army Medical Center, Washington, DC	1986 - 1990
Assistant Director, Diabetes Center Walter Reed Army Medical Center, Washington, DC	1986 - 1990
Co-Director, Lipid Clinic Walter Reed Army Medical Center, Washington, DC	1989 - 1990

IV. SCHOLARSHIP AND AWARD

Castle Connolly America's Top Doctors award.	10 years to date
ADA Outstanding Physician Clinician in Diabetes Award	***2018***
Career Teaching Achievement Award, Department of Medicine, OHSU	2009
Oregon and Southwest Washington ADA Special Medicine Service Award	2009
Hope Award, Juvenile Diabetes Research Foundation, Oregon and Southwest Washington	2007
Designated a Portland "Top Doctor", Portland Monthly	2004-09,15-17.
The Macleod Award, American Diabetes Association, OR	1994
The President's Honor Roll, American Diabetes Association of Oregon	1994
Bailey K. Ashford Award (for clinical research) Walter Reed Army Medical Center, Washington, DC	1986

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Lange Award (outstanding performance in medicine) 1980
All Degrees awarded with honors

Grants and Contracts:

Federal (Include Title, Source, PI, Amount Period, and % Effort)

1. ***TrialNet Natural History Study of the Development of Type 1 Diabetes and Oral Insult Study; Source: NIDDK, NIAID, NICHD; PI Andrew J. Ahmann, MD; 2009-present***

2. A Phase 1 Trial of Proleukin® and Rapamune® in Recent-onset Type 1 Diabetes Mellitus; Source: NIAID; PI: Andrew J. Ahmann, MD; Period: 2009- 2012

3. ***Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE Study). Source: NIDDK; PI Andrew Ahmann, MD (0.2 FTE) 2013-present***

State and Local (Include Title, Source, PI, Amount Period, and % Effort)

1. HSDHC Rural Outreach Program. Sponsor: Meyer Memorial Trust. $500,000 Program Director: Andrew J. Ahmann, MD 2008-2011.

2 Evaluating alternative methods for transitioning from intravenous to subcutaneous insulin in the hospital; Sponsors: Eagles; $10,000 PI: Andrew J. Ahmann, MD; 2006 – 2007

3 Measuring progress and identifying problems in glucose control during hospitalization; Source: Eagles; $10,000 PI: Andrew J. Ahmann, MD; 2005

4 Identifying treatment patterns and patient perceptions of inpatient diabetes care; Source: Eagles; $10,000 PI: Andrew J. Ahmann, MD; 2004

5 Pre-diabetes identification and intervention; $10,000 Source: Eagles; PI: Andrew J. Ahmann, MD; 2003

Other Research Support – non-Industry Sponsored

1. Type 1 Diabetes Exchange. Sponsor: Helmsley Charitable Trust/ The Jaeb Center for Health Research PI: Andrew Ahmann 2010 – 2019
2. Effect of Continuous Glucose Monitoring on Hypoglycemia in Older Adults with Type 1 Diabetes Research PI: Andrew Ahmann 2017-2019. Helmsley Charitable Trust, JDRF.
3. The T1D Exchange type 1 diabetes network ancillary study: Residual C-peptide in patients with type 1 diabetes. Sponsor: Helmsley Charitable Trust/ The Jaeb Center for Health Research 2012 – present
4. A Randomized Trial Comparing Contiuous Glucose Monitoring with and Without Blood Glucose Monitoring in Adults with Type 1 Diabetes. T1D Exchange/ Helmsley Charitable Trust 2015 - 2016 PI= Andrew Ahmann
5. Efficacy and Safety of Once Weekly Semaglutide in Adults with Obesity and Inadequately Controlled type 1 Diabetes Using Hybrid Closed-Loop system. Sponsor: JDRF. PI at OHSU = Andrew Ahmann 2023-present.

Clinical Trials, Multicenter, Industry Sponsored: (partial list)

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1. A parallel-group, randomized, prospective, interventional, double-blind, multicenter global Phase 3 study to investigate the efficacy and safety of finerenone versus placebo, in addition to standard of care, in participants with chronic kidney disease and type 1 diabetes. Bayer Pharma AG Local PI = Andrew Ahmann 2024 -
2. A Randomized Trial Evaluating the Efficacy and Safety of Control-IQ Technology in Adults with Type 2 Diabetes Using Basal-bolus Insulin therapy (2IQP) Sponsor :Jaeb Ctr For Health Research/ Tandem. Local PI = Andrew Ahmann 2023- present
3. T1D Exchange QI Collaborative Data Use Program. Sponsor: T1D Exchange Local PI = Andrew Ahmann 2022-present
4. Study of Hypercortisolism in Patients with Difficult to Control Type 2 Diabetes Despite Receiving Standard-of-Care Therapies: Prevalence and Treatment with Korlym (Mifepristone) (CATALYST). Sponsor = Corcept Therapeutics Local PI = Andrew Ahmann, MD 2023- present
5. DiabeteS AUtoimmuNity WithdRawn In New OnSEt and in Established Patients (SUNRISE), Tolerion, PI = Andrew Ahmann 2020-
6. Efficacy and Safety of LY3298176 Once Weekly versus Insulin Glargine in Patients with Type 2 Diabetes and Increased Cardiovascular Risk (SURPASS-4). Eli Lilly and Company. PI = Andrew Ahmann 2018-present
7. YSI Feasibility Session Study of the Dexcom G7 Continuous glucose Monitoring System in Adults and Pediatrics with Diabetes Mellitus. Dexcom PI: Andrew Ahmann, 2019
8. A Phase3, Randomized, Double-blind Placebo-Controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of LX4211 as Adjunct Therapy in Adult Patients with Type 1 Diabetes Mellitus Who have Inadequate Glycemic Control with Insulin Therapy. Lexicon PI= Andrew Ahmann 2015
9. PTL-901148 Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes: DiaMonD study. Dexcom PI = Andrew Ahmann 2014
10. PTL-901200 Version 01: Effectiveness and Safety Study of the Dexcom G4Platinum with Spritz Algorithm Continuous Glucose Monitoring System in Pediatric Subjects with Diabetes Mellitus. Dexcom PI = Andrew Ahmann 2014
11. Post Approval Study of TS (Threshold Suspend) Feature with a Sensor-Augmented Pump System, CEP266/Z25/B. PI = Andrew Ahmann 2014
12. A randomized, 30 week, active-controlled open-label, 3-treatment arm, parallel-group multicenter study comparing the efficacy and safety of insulin glargine/lixisenatide fixed ratio combination to insulin glargine alone and to lixisenatide alone on top of metformin in patients with type 2 diabetes mellitus. LixiLan PI = Andrew Ahmann 2014
13. Efficacy and safety of semaglutide once-weekly versus exenatide ER 2.0 mg once-weekly as add-on to 1-2 oral antidiabetic drugs (OADs) in subjects with type 2 diabetes. Sustain 3. PI: Andrew Ahmann 2013
14. YSI Feasibility Study of the Dexcom CGM System in Adults and Pediatrics with Diabetes Mellitus. Dexcom 2013 PI = Andrew Ahmann
15. Efficacy and Safety of Intranasal glucagon for Treatment of Induced Hypoglycemia in Adults with Diabetes. Novo Nordisk 2013 PI = Andrew Ahmann
16. Efficacy and Safety of FIAsp compared to insulin aspart both in Combination with insulin detemir in Adults with Type 1 Diabetes. Onset 1. NovoNordisk PI: Andrew Ahmann 2013
17. A Randomized, Open-Label, Long-Term, Parallel-Group, Comparator-Controlled, Multicenter Study to Compare the Glycemic Effects, Safety, and Tolerability of Exenatide Once Weekly Suspension to Exenatide Twice Daily in Subjects With Type 2 Diabetes Mellitus Sponsor: Amylin PI:Andrew Ahmann 2013
18. A 6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus Injected in the Morning or Evening in Patients with Type 1 Diabetes Mellitus with a 6-month Safety Extension Period

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Sponsor: Sanofi Aventis PI:Andrew Ahmann 2012

19. FLAT SUGAR (FLuctuATion reduction with inSUlin and Glp-1 Added together) Sponsor: Sanofi Aventis through U. Washington PI: Andrew Ahmann 2012 -present
20. ASPIRE (Automation to simulate pancreatic insulin response): Pivotal in home study to determine safety and efficacy of the low glucose suspend (LGS) feature in sensor augmented pumps. Sponsor Medtronic PI: Andrew Ahmann 2012
21. A performance evaluation of the Enlite glucose sensor to support a full 144 hours (6 days) of use. Sponsor: Medtronic PI: Andrew Ahmann 2012
22. MKC-IT-171: A Phase 3, multicenter, open-label, randomized, forced-titration clinic trail evaluating the efficacy and safety of Technosphere insulin inhalation powder in combination with a basal insulin versus insulin aspart in combination with a basal insulin in subjects with type 1 diabetes mellitus over a 24-week treatment period. Sponsor: MannKind PI: Andrew Ahmann,

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2012-

23. MKC-TI-175: A Phase 3, multicenter, double-blind, placebo-controlled, randomized clinical trial evaluating the efficacy and safety of prandial Technosphere insulin inhalation powder versus Technosphere inhalation powder placebo in insulin naïve subjects. Sponsor: MannKind PI: Andrew Ahmann 2012-2013
24. A 26-week, multinational, multi-centre, open-labelled, two-arm, parallel, randomised, treat-to-target, efficacy and safety comparison of soluble insulin analogue combination (SIAC) once daily (OD) and insulin glargine OD both in combination with metformin in insulin-naive subjects with type 2 diabetes inadequately controlled on oral antidiabetic drugs (OADs/ PI: Andrew J. Ahmann, MD; 2010
25. STAR 3: A prospective, randomized, two-arm study to compare the efficacy of the MiniMed Paradigm REAL-Time System versus multiple daily injection (MDI) in subjects with type 1 diabetes mellitus naïve to insulin pump therapy; Sponsor: Medtronic MiniMed; PI: Andrew J. Ahmann, MD; 2007 - 2010

26. Home use testing of a continuous glucose monitoring system in persons with insulin-treated diabetes; Sponsor: iSense; PI: Andrew J. Ahmann, MD; 2006 - 2008

27. Metformin, exenatide, and glargine insulin in combination for treatment of patients with type 2 diabetes (MEXELIN Trial); Sponsor: OHSU / Lilly-Amylin Alliance; PI: Andrew Ahmann, MD; 2006 - 2010

28. A randomized, open-label, multicenter, comparator-controlled study to examine the effects of exenatide long-acting release on glucose control (HbA1c) and safety in subjects with type 2 diabetes mellitus managed with diet modification and exercise and/or oral antidiabetic medications; Sponsor: Amylin; PI: Andrew J. Ahmann, MD; 2006 - present

29. IO meter/controller human factors and clinical accuracy study; Sponsor: LifeScan; PI: Andrew J. Ahmann, MD; 2007

30. Lantus (insulin glargine) plus Apidra (insulin glulisine) MDI versus premix insulin treatment in subjects with diabetes mellitus (type 1 or type 2) evaluating differences in patient reported outcomes: a randomized, multicenter, cross over study; Sponsor: Sanofi-Aventis: PI: Andrew J. Ahmann, MD; 2006 - 2007

31. Apidra (insulin glulisine) administered premeal vs. postmeal in adult subjects with type 2 diabetes mellitus receiving Lantus (insulin glargine) as basal insulin: a multicenter, randomized, parallel, open label clinical study; Sponsor: Sanofi-Aventis; PI: Andrew J. Ahmann, MD; 2004 - 2007

32. A comparison of prandial insulin lispro mixtures therapy to glargine basal-bolus therapy with insulin lispro on the overall glycemic control of patients with type 2 diabetes previously treated with oral agents combined with insulin glargine; Sponsor: Eli- Lilly; PI: Andrew J. Ahmann, MD; 2004 - 2007

33. A phase 2, randomized, double-blind, placebo-controlled multicenter study to examine the safety and pharmacokinetics of exenatide in subjects with type 2 diabetes mellitus; Sponsor: Amylin; PI: Andrew J. Ahmann, MD; 2005 - 2006

34. A phase 3, randomized, three-arm, double-blind, active controlled, parallel group, multicenter trial to evaluate the safety and efficacy of muraglitazar in combination with metformin compared to

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glimepiride in combination with metformin in subjects with type 2 diabetes who have inadequate glycemic control on metformin therapy alone; Sponsor: Bristol-Myers Squibb; PI: Andrew J. Ahmann, MD; 2004 - 2006

35. A multicenter, double-blind study to evaluate the effect of pre-treatment with a daily dose of Viagra (sildenafil citrate) on the PRN efficacy of Viagra in men with erectile dysfunction and type 2 diabetes; Sponsor: Pfizer; PI: Andrew J. Ahmann, MD; 2003 - 2005

36. A phase 2, randomized, double-blind, placebo-controlled multicenter study to examine the safety and pharmacokinetics of two formulations of AC2993 LAR in subjects with type 2 diabetes mellitus; Sponsor: Amylin; PI: Andrew J. Ahmann, MD; 2002 - 2003

37. Efficacy and safety of inhaled compared with subcutaneous human insulin therapy in subjects with type 1 diabetes mellitus; Sponsor: Pfizer; PI: Andrew J. Ahmann, MD; 1999 - 2005

38. Multicenter, double-blind, randomized, placebo-control parallel-group study to evaluate the safety and efficacy of three dose groups of Trileptal in patients with neuropathic pain due to diabetic neuropathy; Sponsor: Novartis; PI: Andrew J. Ahmann, MD; 2001 - 2003

39. A multinational, randomized, double-blind, placebo-controlled, forced-titration, 2 x 2 factorial design study of the efficacy and safety of long term administration of nateglinide and valsartan in the prevention of diabetes and cardiovascular outcomes in subjects with impaired glucose tolerance (IGT); Sponsor: Novartis; PI: Andrew J. Ahmann, MD; 2002 - 2003

40. Safety and efficacy of fixed combination metformin/glyburide products as first line therapy in patients with type 2 diabetes mellitus who have inadequate glycemic control with diet and exercise; Bristol-Myers Squibb; PI: Andrew J. Ahmann, MD; 1998 - 2001

41. A randomized, double-blind, placebo-controlled, multi-center, fixed-dose, parallel group, three month comparison study to investigate the efficacy and safety of the phosphodiesterase type V inhibitor BAY 38-9456 in males with erectile dysfunction; Sponsor: Bayer; PI: Andrew J. Ahmann MD; 2000 - 2001

42. Insulin delivery using a new Lilly 3.0mL disposable pen device; Sponsor: Eli Lilly; PI: Andrew J. Ahmann, MD; 1998 - 2000

43. A multicenter, double-blind, placebo-controlled, parallel-group, dose-ranging clinical evaluation of oral G1262570X in patients with type II diabetes mellitus; Sponsor: Glaxo Wellcome; PI: Andrew J. Ahmann, MD; 1998 - 2000

44. A multi-center, randomized parallel group comparison of the efficacy and safety of treatment with once-daily biphasic insulin aspart 30 in combination with metformin to human insulin NPH with metformin and biphasic human insulin 70/30 with metformin; Sponsor: Novo Nordisk; PI: Andrew J. Ahmann, MD; 2000 - 2002

45. rhIGF-I administration once daily for the treatment of type II diabetes mellitus; Sponsor: Genentech; PI: Andrew J. Ahmann, MD; 1994 - 2002

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46. A randomized, placebo-controlled, parallel group, multiple-dose study of the effects of NID525 and troglitizone in non-insulin dependent diabetic patients; Sponsor: Rhone-Poulenc Rorer; PI: Andrew J. Ahmann, MD, 1998 - 2000

47. A multicenter, randomized, dose-response study to compare the efficacy and tolerability of simvastatin and atorvastatin in patients with type 2 diabetes mellitus and hypercholesterolemia; Sponsor: Merck; PI: Andrew J. Ahmann, MD; 1998 - 2000

48. A 52-week, double blind, randomized, placebo controlled study to evaluate the efficacy of orlistat treatment in obese patients with type 2 diabetes inadequately controlled with insulin; Sponsor: Roche; PI: Andrew J. Ahmann,, MD; 1998 - 2000

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Non-peer-reviewed

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Ahmann AJ, Comi R. Managing the major complications of diabetes. Patient Care. 37: 46, 2004

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Ahmann A, Hellman R, Maynard G. Building and Implementing an Insulin Infusion Order Sets and Protocols In Workbook for Improvement: Improving Glycemic Control, Preventing Hypoglycemia, And Optimizing Care of the Inpatient with Hyperglycemia and Diabetes, Society of Hospital Medicine 2007. Available online at www.hospitalmedicine.org

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Ahmann AJ, Riddle MC. Diabetic Ketoacidosis and Hyperglycemic Hyperosmolar Syndrome. In Rakel RE, Bope ET. Conn's Current Therapy. W.B. Saunders Co. 2001.

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Reviews

ESAP 2008 -2012 Endocrine Self-Assessment Program. The Endocrine Society. Contributed all of the diabetes material and edited all other content.

Standards of Medical Care in Diabetes --- 2008. Diabetes Care 2008; 31(suppl 1)S12-S55. Edited all parts as part of the professional practice committee with special responsibility for sections on diagnosis of diabetes and pre-diabetes, prevention of diabetes and monitoring diabetes.

Oregon Population-Based Guidelines for Diabetes Mellitus. Oregon Department of Human Services. 1997, 2002 and 2006. I chaired the Diabetes Guidelines Advisory Group that developed and updated these guidelines. My involvement included significant scientific review, writing, and editing. Is available as hard copy and online at: www.oregon.gov/DHS/ph/diabetes/docs/2006guidelinesfinal.pdf.

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Abstracts

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Joarder F, Nagra H, Rocha L, Andreas L, Guttmann-Bauman I, Ahmann AJ. Characteristics of Type 1 Diabetes (T1D) Patients Attending a Young adult Diabetes Clinic (YADC) as a Component of Transition from Pediatric to Adult Diabetes Care. ADA 79th Scientific Sessions, San Francisco, CA June 7-11, 2019.

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Hypoglycemia in Type 1 Diabetes. ADA 76th Scientific Sessions, New Orleans, LA, June 10-14, 2016

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Laffel LM, Bailey TS, Ahmann AJ, Tsalikian E, Chase P. Glucose Levels Assessed by Continuous Glucose Monitoring (CGM) across the Pediatric Age Range in Youth with Type 1 Diabetes (T1D). ADA 75th Scientific Sessions, Boston, MA, June 5-9, 2015

Weiss R, Schwartz FL, Weinstock RS, Bode BW, Bailey T, Ahmann AJ, Kaufman F. 2369-PO - Bolus Insulin Dosing and Nocturnal Hypoglycemia in the ASPIRE In-Home Study View session detail. ADA 74th Scientific Sessions, San Francisco, CA, June 13-17, 2014

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Davis A, Haller MJ, Miller K, Dubose S, Carpenter C, Dimeglio L, Liljenquist DR, Ahmann A, Marcovina SM, Greenbaum C, Beck RW. 1616P Presidual C-Peptide in pateints 3-81 years from diagnosis of T1D: A T1D Exchange Study. ADA 73rd Annual Scientific Sessions, Chicago, ILL June 21-25, 2013.

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Bergenstal RM, Tamborlane WV, Ahmann A, Buse JB, Dailey G, Davis, SN, Joyce C, Peoples, T, Perkins BA, Welsh JB, Willi SM, Wood MA. Sensor-Augmented Pump Therapy for A1c Reduction (STAR 3) Study: Results from the 6-Month Continuation Phase. American Diabetes Association 71st Annual Scientific Sessions, San Diego, CA, June 24-28, 2011.

Ahmann A, Buse JB, Berganstal RM, Tanenberg. HbA_{1c} and Sensor Use in Adults During a 1-year Randomised Controlled Trial Comparing Sensor-Augmented Pump Therapy and Multiple Daily Injection Therapy. Pending presentation at the 46th European Association for the Study of Diabetes (EASD) Annual Meeting, Stockholm, September 20-24, 2010.

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Yuen KCJ, Lester LR, Hohn SB, Ahmann AJ. Efficacy and Patient Satisfaction of Human U-500 Insulin Administration by Multiple Daily Injections Versus Continuous Subcutaneous Insulin Infusion Regimen in Obese, Severely Insulin Resistant Patients with Type 2 Diabetes. Presented at the 92nd Annual Endocrine Society Meeting, San Diego, CA, June 19-22, 2010.

Riddle M, Andrew A, Basu A, Vanita A, Ratner R. Metformin+Exenatide+Basal Insulin vs Metformin+Placebo+Basal Insulin: Reaching A1c<6.5% Without Weight-Gain or Serious Hypoglycemia. Presented at the American Diabetes Association 70th Scientific Sessions, Orlando, FL, June 25-29, 2010.

Ahmann A, Jiang H, Martin SA. Hypoglycemia Rates with Titration of Prandial or Basal Bolus Insulin Therapy in Patients with Type 2 Diabetes. Diabetes 2008; 57 (Suppl 1): 490-P.

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Hsu W, Laffel L, McGill BJ, Meneghini L, Kaiserman K, Donner T, Counts D, Ahmann A, Einhorn D. Improved HbA1c levels through the use of an electronic logbook incorporating data displays: A multicenter, randomized, controlled trial. Diabetes 2005; 54 (suppl 1) A99.

Medak, R, Lucas J, Ahmann, AJ. Diabetes Management of Medicare patients Enrolled in Managed Care: A Patient Centered Analysis. Diabetes 2003; 52 (suppl 1): A622.

Riddle MC, McDaniel PA, Mitchell ML, Ahmann AJ, Karl DM. Low dose Metformin Added to Sulfonylures: Comparison of Two Regimens. Presented at the International Society of Endocrinology, June 12-15, 1996.

Ahmann AJ, Barnes S, Galloway R. Species-Specific and Age-Related Heterogeneity in 125-I ANP Binding to Thyroid Tissue. Presented at the 71st Annual Endocrine Society Meeting, Seattle, WA, June 21-24, 1989.

Tseng YL, Schaudies RP, Ahmann AJ, D'Avis J, Geelhoed GW, Burman KD, Wartofsky L. Effects of Epidermal Growth Factor on Thyroglobulin and Cyclic AMP Production by Human Thyrocytes in Long-Term Culture. Presented at the American Thyroid Association Meeting, Montreal, Canada, September 27-October 1, 1988.

Ahmann AJ, Tseng YL, Sellitti DF, Wartofsky L. 125-I Atriopeptin Binding to Cultured Procine Thyrocytes: Influenced of Iodine and Thyrotropin. Presented at the 70th Annual Endocrine Society Meeting, New Orleans, LA,
June 8-11, 1988.

Ahmann AJ, Solomon B, Duncan WE, Wartofsky L. Normal Bone Mineral Density in Premenopausal Women on Suppressive Doses of L-Thyroxine. Presented at the American Thyroid Association Meeting,

Washington DC, September 16-18, 1987.

Smallridge RC, Ahmann AJ, Fein HG. Long-term Control of TSH-Secreting Macro Adenoma with a Somatostatin Analog (SMS 201-995). Presented at the 62nd American Thyroid Association Meeting. Washington DC, September 16-18, 1987.

Tseng YC, Baker JR, Saunders NA, Ahmann AJ, Burman KD, Wartofsky L. A Human Monoclinal Antibody from Lymphocytes of a Patient with Graves Disease which Demonstrates Thyroid Stimulating Activity. Presented at the 69th Annual Endocrine Society Meeting. Indianapolis, IN June 9-12, 1987.

Baker JR, Saunders NB, Tseng YC, Wartofsky L, Ahmann AJ, Burman KD. Isolation of the Immune Response in Hashimoto's Disease to Intrathyroidal Lymphocytes and the Production of Human Monoclinal Antibodies From there Lymphocytes. Abstract. 61st Meeting of the American Thyroid Association, September 1986.

Ahmann AJ, Baker JR, Wartofsky L, Burman KD. Development of an Antigen-Responsive Intra Thyroidal T-Cell Population: Evidence that Thymocyte Antigens and OKT 3 T-Cell Receptor Mediate Cellular proliferation. Abstract, 61st Meeting of the American Thyroid Association, September 1986.

Ahmann AJ, Baker JR, Weetman AP, Wartofsky L, Nutman T, Burman KD. Serum Immunoglobulins in Patients with Graves Ophthalmopathy Directed against Unique Determinants of Porcine Eye Muscle. Annual Meeting American Federation for Clinical Research, Washington, DC, January 1986.

Fein HG, Ahmann AJ, Hennessey JB, Butkus NE, Kornhauser DM, Petty BG, Smallridge RC. Cholinergic Suppression TSH Secretion: Therapeutic Applications. Presented at the First International Congress of Neuroendocrinology, San Francisco, CA July 9-11, 1986.

Ahmann AJ, Baker JR, Wartofsky L, Weetman AP, Burman KD. Evidence for Antibodies for Porcine Eye Muscle in Endocrine Ophthalmopathy. Regional ACP meeting, San Francisco, CA 1985.

Selected, Recent Invited Lectures, Conference Presentations or Professorships:

National/ International:

Using SGLT2 Inhibitors in Patients With T1DM. Endocrine Society Annual Meeting. March 20, 2021. Virtual meeting.

Shifting the Global Paradigm for Managing CV Risk in Diabetes. American Diabetes Association and American Cardiology Cardiometabolic Program Update. Virtual program for Mexico (originally scheduled for Oaxaca, Mexico). July 20- July 22, 2020.

"What an Administrator Can Do to Advocate for Behavioral Health in Diabetes Care." 80th Annual American Diabetes Association Scientific Sessions, Virtual program (originally scheduled for Chicago, Ill) June 12, 2020.

Case Studies in Diabetes Care. An Alliance for Cardio Metabolic Exchange. ADA and ACC. Mumbai, India. February 15-16, 2020.

"CGM or Pump: Which is More Important?" ATDC Keystone Conference, Keystone, CO. July 12, 2019
"When and If CGM Will Replace SMBG" ATDC Keystone Conference, Keystone, CO July 13, 2019
"Why Are Rates of Complications Going Down?.Keystone Conference, Keystone, CO July 14, 2019

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"Update on Diabetes Management Technology for The Non-endocrinologist". Oregon Health & Science University Medical Grand Rounds, Portland, OR, May 23, 2017

"Semaglutide Provides Superior Glycemic Control across SUSTAIN 1-5 Clinical Trials." 77th Annual American Diabetes Association Scientific Sessions, San Diego,CA June 11, 2017.

"Continuous Glucose Monitoring (CGM) In Patients Treated With MDI". 10th Internation Conference on Advanced Technologist & Treatments For Diabetes (ATTD), Paris, France, February 16, 2017

"The Value of Continuous Glucose Monitoring in Patients with Type 1 Diabetes Using Multiple Daily Injections --- DiaMonD Study: Design, Methods, and Baseline Demographics" 76th Annual American Diabetes Association Scientific Sessions, New Orleans, LA June 12, 2016.

"Efficacy and Safety of Once-weekly Semaglutide vs Exenatide ER in Subjects With Type 2 Diabetes (SUSTAIN 3)". 76th Annual American Diabetes Association Scientific Sessions, New Orleans, LA June 12, 2016.

"Approaches to Reducing Hypoglycemia and Hypoglycemic Unawareness". Endocrine Society, Dimensions in Diabetes Chennai, India, November 21, 2015.

"Update in Basal Insulins: Your Questions Answered". Endocrine Society Board Review. Miami, Fl, September 11, 2015.

"Review of Newer Medications For Type 2 Diabetes: Seeing Clearly Through the Fog" Oregon Health & Science University Medical Grand Rounds, Portland, OR, July 21, 2015.

"Management of NODAT with Oral Therapies and Insulin." 75th Annual American Diabetes Association Scientific Sessions, Boston, MA, June 6, 2015.

"Evolving Insulin Therapy: Optimizing Care Through Proper Selection and Use". Pri-Med West Annual Conference. Anaheim Convention Center. Anaheim, CA April 8, 2015.

"Back to Basals: Optimizing Basal Insulin Therapy". 97th Annual Meeting of The Endocrine Society, San Diego, CA, March 5, 2015.

PriMed CME Programs 2015 - - Evolving Insulin Therapy: Optimzing Care Through Proper Selection and Use.

- Anaheim, CA, April 8, 2015
- Dallas, Tx, May 20, 2015
- Rosemont, Il, October 13, 2015
- Tampa, Fl, December 9, 2015

"Update on Oral Agents for T2DM" American Association of Clinical Endocrinologists Diabetes Day for Primary Care Clinicians. Seattle, WA, February 28, 2015
"Type 2 Diabetes Mellitus", MER Primary Care Conference, Key West, Florida, November 13, 2014

PriMed CME 2014 lectures: Insulin Therapy in Patients with Type 2 Diabetes: Current and Emerging Basal Insulins.

- Anaheim, CA, 3/27/2014
- Raleigh, NC, 9/10/2014

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- Boston, MA, 9/11/2014
- Chicago, Ill, 10/15/2014

"Type 2 Diabetes in Pediatrics: Medication Update". Pediatric Endocrine Society Annual Meeting, Vancouver, BC, May 1, 2014.
"Inpatient Management of Diabetes: Case Management Forum" The Endocrine Society's 94th Annual Meeting, Houston, TX, June 24, 2012.

"Utilizing What We Know to Change The Impact of Diabetes Care Delivery". Grand Rounds presentation, University of Nevada School of Medicine Grand Rounds Presentation, Reno, Nevada, February 17, 2012.

"Advances in Technology and Systems for Inpatient Management of Hyperglycemia". 71st American Diabetes Association Scientific Sessions, San Diego, CA, June 26, 2011.

Guides Audio Poster Tour Moderator for Pharmacologic Treatment Of Diabetes – Novel Therapies. American Diabetes Association Scientific Sessions, San Diego, CA, June 26. 2011.

Chair, Oral Session entitled "Cardiometabolic Risk: Inflammation & Insulin Resistance" at the 93rd Annual Endocrine Society Meeting, Boston, MA. June 6, 2011.

"Inpatient Diabetes Care". Union Hospital CME Program, Terre Haute, IN, March 11, 2010.

"Type 1 Diabetes Mellitus", Type 2 Diabetes Mellitus", "Management of Hyperlipidemia". Clinical Endocrinology for Primary Care Physicians", Hilton Resort, San Dietgo, California. July 16-18, 2010.

"Strategies for Preventing Hypoglycemia" and "Improving Glycemic Control: Strategies and Protocols". Critical Pathways CME, Chicago, Illinois. October 13, 2009.

"Type 1 Diabetes Mellitus", "Type 2 Diabetes Mellitus", "Calcium Case Presentations". Clinical Endocrinology for Primary Care Physicians. An Endocrine Society CME program. Monterey Plaza, Monterey California. August 28-30, 2009 - - also at the Fiestamericana Coral Beach Resort, Cancun, Mexico. February 8-10, 2007.

"Hyperlipidemia and Obesity Management Update", "Type 1 Diabetes Mellitus", Type 2 Diabetes Mellitus" Clinical Endocrinology for Primary Care Physicians. An Endocrine Society CME. Westin Resort, Seattle, Washington. June 20-22, 2003.

Chair, Oral Session entitled "In-Patient Hospital Management and Closed-Loop Insulin Delivery" at the 68th Scientific Sesssions of the American Diabetes Association, San Francisco, CA, June 7, 2008.

"Endocrine reviews for primary care on Type 1 diabetes, Type 2 diabetes, hyperlipidemia and obesity with the Medical Education Resources CME program, Phoenix, AZ, April 10-12, 2008.

" Managing the Complexities of Type 2 Diabetes: A Roadmap for Patient Care." National Diabetes Education Initiative CME Meeting, Seattle, WA March 26. 2008

"The Butterfly Effect: Resurrection of the Beta Cell in Type 2 Diabetes." Dannemiller Memorial Educational Foundation CME Program, San Francisco, CA, 2007

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"Glycemic Control In The Hospital: A Case-Based Team Approach" American Diabetes Association CME Program, San Francisco, CA, October 25, 2007.

"Focus On Inpatient Diabetes Management" American Association of Clinical Endocrinologists "Clinical Conversations" online at www.aace.com, videotaped April 13, 2007.

"Initiation, Integration, and Implementation of Insulin In the Hospital" American Association of Clinical Endocrinologists (AACE) 16th Annual Meeting, Seattle, WA, April 11, 2007

"Advancing Insulin therapy in Type 2 Diabetes: A Focus on Basal-Prandial Therapy. Pharm Med Update Donald E Stephens Convention Center, Rosemont, IL December 1, 2006.

"Systematically Improving the Management of Diabetes: A Review of Current Guidelines, recommendations, and Performance Measures", BIMARK Center for Medical Education, Chicago, IL, October 5, 2006.

"Catching the Wave"; St. Joseph's Hospital/ Marshfiled Clinic, Marschfild, WS; September 28, 2006

"Diabetes and Heart Disease: The Deadly Connection." Cardiovascular Update & Metabolic Syndrome Symposiuim; Alaska Regional Hospital, Anchorage, AK; May 19, 2006

Pharm Med Updates; Pri-Med Institute.' Los Angeles, Ca; May 11,2006

"Examining Insulin therapy in Type 2 Diabetes"; Rocky Mountain Metabolic Syndrome Symposium; University of Colorado School of Medicine, Denver, CO; April 21, 2006

"The Endocannabinoid System: A New Target for the Reduction of Cardiovascular Risk Factors" Endocrine Society CME Program; San Diego, CA; May 2, 2006

"Insulin Therapy in the Hospital: Strategies for Improving Patient Outcomes"; Banner Mesa Medical Center, Mesa, AZ; December 5,2005

"Diabetes Education Initiative: Collaboration for Intervention", American College of Cardiology Foundation and Washington Chapter of the ACC, Seattle, WA; December 3, 2005

"Outpatient Insulin in Managing Type 2 Diabetes: Why Sooner Rather Then Later", ADA, Honolulu HA, November 19, 2005

"Insulin Therapy in the Hospital", UCLA-Santa Monica Hospital Grand Rounds, Santa Monica, CA; November 2, 2005.

"State of the Heart Management of Type 2 Diabetes and CVD: Latest Evidence from Clinical Trails"; ACC, Seattle, WA. October 11, 2005

"Insulin Therapy in the Hospital: Strategies for Improving Patient Outcomes"; Sharp Chula Vista Medical Center; Chula Vista, CA; October 4, 2005

"Inpatient management of hyperglycemia." St. Luke's Episcopal Hospital Grand Rounds/ Baylor University, Houston, TX. October 2, 2005

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"Improving Outcomes Through Glucose Control in the Hospital" VHA Live Televised CME Program, Dallas, Tx: September 20, 2005.

"Evidence for Tight Control: Review of Current Literature" in Inpatient Management of Hyperglycemia CME Symposium. Scottsdale, AZ February 19, 2005

"Managing Special Situations in Inpatient Diabetes Care." Postgraduate Program, American Diabetes Association, New York City, NY. January 8, 2005.

"New Hormonal Therapies For Diabetes Mellitus". Oregon Diabetes Educators A nnual Meeting, Seaside, OR. October 23, 2004.

"Protocols for IV Insulin Therapy for Inpatients Requiring Intensive Blood Sugar Control" Overland Park Regional Medical Center Diabetes CME Program, October 22, 2004.

"Diabetes Mellitus: A Progressive Disease." North American Women's Healthcare Forum, Dallas, TX. September 18, 2004

"The Obesity Epidemic: A Connection to Addictions?" The Foundation for Medical Excellence Cascadia Conference, Vancouver, British Columbia. September 10, 2004.

"Reduction of hospital costs and length of stay by good control of blood glucose levels." Consensus Development Conference on Inpatient Diabetes and Metabolic Control, Washington, D.C. December 6, 2003.

"Getting To The Heart of Type 2 Diabetes and the Metabolic Syndrome". National Diabetes Education Initiative, St. Paul, MN, May 1 2003

Regional and Local

Team-based Approaches to Diabetes Care Management ECHO Program. 2020-2022. Diabetes specialist lead for this 12 session ECHO program offered by the Oregon ECHO Network, supported by funds from the Oregon Health Authority.

Series of 3 lectures (Webinars) developed and presented for OHA Transformation Center on "Addressing Poor A1C Control" in January and February 2020 (CME program)

"Everything You Need to Know on the New EASD/ ADA Guidelines for Type 2 Diabetes". OHSU Ashland Endocrine Conference. Ashland, OR, August 3, 2019

Type 2 Diabetes Mellitus Treatments: 2018 Update. UCLA Endocrinology Conference. Santa Monica, CA, December 1, 2018.

"Treating Diabetes Beyond A1C: Considerations for Cardiovascular Protection". Diabetes Trends by Horizon CME. Portland, Oregon. October 27, 2018.

"Non-Insulin Treatment of Type 2 Diabetes: An Update". OHSU Primary Care Review. Sentinel Hotel, Portland, Oregon. February 12, 2016.

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"Type 2 Diabetes Treatment Guidelines: Recent Changes That Matter" Salem Clinic Annual Meeting. Skamania, WA, November 14, 2015.

"Type 2 Diabetes Treatment Guidelines: Changes That Matter". Salem Health Diabetes Symposium for Primary Care. Salem, OR, November 13, 2015

"Biological Beta Cell Replacement: What you need to know when your patients ask" OHSU Ashland Endocrine Conference. Ashland, OR, August 1, 2015.

"Diabetes Prevention: The Evidence". Oregon Health & Science University Primary Care Review, Portland, OR, February 10, 2015.

"Case Studies in Type 2 Diabetes" OHSU Annual Primary Care Review, Governor Hotel, Portland, OR, February 12, 2014.

"Type 1 Diabetes Treatment for Primary Care". OHSU 41st Annual Primary Care Review, Governor Hotel, Portland, OR, February 24, 2012.

"Incretin Impairment and GLP-1: The Short Story", Grand Rounds at Samaritan Hospital, Lebanon, OR, November 15, 2011.

"Diabetes Pathophysiology and Complications" for Oregon State University School of Pharmacy, October 26, 2011 (and for 2007-2010 as well).

"Glucose Monitoring: When, Where, Why and How" Diabetes Academic Rountable and Peer Exchange Symposium. Embassy Suites, Portland, Oregon, May 6, 2011

"Glucose Monitoring Guidelines and Caveats" and "Class Dismissed: Your Take-Home Message" at the CME Conference "Diabetes" Dealing with a Rising Pandemic", CME of Southern Oregon Conference, Grants Pass, OR, October 29, 2010.

"Diabetes: The Growing Lifelong Threat for Latinos". Inishgt of Diabetes management in the Latino Population. Portland Chapter, National Ass of Hispanic Nurses. Linfield College-School of Nursing, Portland, OR October 23, 2010

"Pharmacology Update" and "2012 Clinical Practice Guidelines Update" at the American Diabetes Association Annual Practice Update, October 8, 2010.

"Recent Issues and Controversies in Diabetes Management" and "Prevention, Diagnosis and Initial Treatment of Type 2 Diabetes", the PeaceHealth Primary Care Conference, Eugene, OR, March 6, 2010.

"2010 Clinical Practice Guidelines Update" and "Pharmacology Update". American Diabetes Association Anuual Diabetes Practice Update, Oregon Convention Center, Portland, OR, October 8, 2010.

"Diabetes Update". Internal Medicine Review, OHSU CME, Governor Hotel, Portland, OR, April 8, 2010.

"Highlights of the Standards of Medical Care in Diabetes – 2010. Grand Rounds at Willamette Valley Medical Center, McMinville, OR, February 29, 2010.

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"Type 1 Diabetes: Pointers and Pitfalls", OHSU 41st Annual Primary Care Review, Governor Hotel, Portland, OR, February 24, 2010

"Diabetes 2010 Update: What's New & What's True". Grand Rounds at Sacred Heart Medical Center, Eugene, OR, February 12, 2010.

"Case Studies In Type 1 Diabetes" OHSU Family Medicine Review, Portland, OR February 28, 2008.

"Clinical Diabetes Guidelines Update" ADA Annual Diabetes Practice Update, Oregon Convention Center, Portland, OR, October 24, 2008.

"Update on New Insulin and Diabetes Therapies", American College of Physicians CME, Eugene, OR, November 16, 2007.

"Perioperative Management of Diabetes", OHSU Womens Health CME Conference, Portland, OR, November 2, 2007.

"The Big Picture: Perspectives On Diabetes", The American Diabetes Association Annual Update, Portland, OR, October 19. 2007

"Re-evaluating Options in Type 2 Diabetes Treatment." Medical Grand Rounds, Providence Medical Center, Portland, OR October 3, 2007

"Diabetes: Managing the Ultimate Risk Factor." Salishan Conference: Cardiology for the PCP, September 29, 2007.

"Re-evaluating Options In Treating Type 2 Diabetes". Providence Portland Grand Rounds, September 26, 2007

"Update on New Insulin and Diabetes Therapies" Annual Sacred Heart Cardiovascular Disease Symposium, Eugene, OR. September 22, 2007.

"Update on New Insulin and Diabetes Therapies" Ashland Endocrine Conference. Ashland, OR, August 4, 2007.

"Overview of Diabetes in the Elderly". Oregon Geriatric Society Conference. Sunriver, Oregon. October 13, 2006,

"Hot Topics in Pharmacology" The American Diabetes Association Annual Update, Portland, OR October 20, 2006.

"Seeing Clearly Through The Fog: Do Recent Studies Clarify Treatment Issues in Diabetes?" 15th Annual Ashland Endocrine Conference, Ashland, OR; August 2-5, 2006

"Diabetes After Transplant". Oregon Health and Science University's combined Transplant Conference; Oregon Health & Science University, Portland, OR; June 29, 2006

The Endocannabinoid System: A New Target for the Reduction of Cardiovascular Risk Factors; Endocrine

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Society CME, Portland, OR; June 14, 2006

"the Emerging Face of Diabetes and Heart Disease" Anchorage Cardiovascular Symposium, Anchorage, Alaska, Mary 19, 2006

"New Hormonal Therapies in Diabetes.," Oregon Diabetes Educators Annual Meeting, Cannon Beach, OR: April 22, 2006.

"Type 1 Diabetes Update." 13th Annual Internal Medicine Review, Oregon Health & Science University, Portland, OR; April 20, 2006

"Update in Type 1 Diabetes" 13th Annual Internal Medicine Review, OHSU, Portland, OR April 20, 2006.

"Type 2 Diabetes Update" 37th Annual Family Med. Review, Oregon Health & Science University, Portland, OR; February 15, 2006

"Advanced Research in T2DM and Incretin Hormones", Medical Grand Rounds, St. Vincent Medical Center, Portland, OR; January 17, 2006

"Insulin Therapy in the Hospital: Strategies for Improving Patient Outcomes." Southwest Washington Medical Center Grand Rounds, Vancouver, WA, November 10, 2005

"Diabetes Update". 29th Annula Pacific Northwest Update in Obstetrics & Gynecology & Womens Health, Hilton Hotel, Portland, OR November 4, 2005.

"New Diabetes Treatments on the Horizon" American Diabetes Association Annual Update, Portland, OR; October 13, 2005.

"State of the Heart Management of Type 2 Diabetes and CVD: Latest Evidence from Clinical Trials." NDEI CME; Grand Hyatt, Seattle, WA. October 11, 2005.

"Catching the Wave: The New Emphasis on Improving Glucose Control in the Hospital." Providence Medical Center Grand Rounds, Anchorage, Alaska: September 15, 2005

"Treating Hyperglycemia in the Hospital" Anchorage Regional Medical Center Grand Rounds, September 16, 2005

"Management of Obesity" Foundation for Medical Excellence, Vancouver, B.C., September 9, 2005
"Glucose Control in the Surgical Patient", OHSU Surgical Grand Rounds, August 15, 2005.
"Diagnosis and Management of Diabetes in Transplant Patients" OHSU Combined Transplant Conference. Portland, Oregon. May 19th, 2005.

"Hospital Meanagement of the Diabetic Patient". Southern Oregon Review of Medicine. Rogue Valley Medical Center, Medford, Oregon. April 8, 2005

"Case Studies in Type 2 Diabetes". OHSU Annual Family Medicine Review, Portland, Oregon, February 15 2005.

"Metabolic Aspect of Treatment with Psychiatric Medication". Oregon Psychiatric Association CME,

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February 25, 2005.

"Inpatient Management of Hyperglycemia: Why All The Fuss" American Diabetes Association Annual Update, Portland, OR; October 15, 2004.

"Defeating Diabetes: The Deadly Diffuse Disease" OHSU Diabetes Center, Marriott Residence Inn, Portland, Oregon. September 24, 2004.

"Diabetes Treatment Guidelines and Complications". Oregon State Pharmacists Association. Skamania Lodge, Stevenson, WA October 10, 2003

"Update in Type 2 Diabetes". OHSU Annual Family Medicine Practice Review. Portland, Oregon, February 12, 2003

"Defining Diabetes: Type 1,2 and LADA"; Review of Currently Available Insulins; Inpatient Diabetes Management". Making the Transition to Insulin: A Practical Approach an OHSU CME program. Benson Hotel, Portland, Oregon. October 25, 2002 –

"The Role of Insulin Resistance in Type 2 Diabetes and Associated Vascular Disease". Getting to the Heart of Type 2 Diabetes, and OHSU CME program. Doernbecher Hospital Auditorium, Portland, Oregon. September 14, 2002

"Diabetes 1&2". OHSU Annual Internal Medicine Review. Marriott Hotel, Portland, Marriott. April 4, 2002.

"Management of Type 2 Diabetes" Annual Family Practice Review, OHSU, Marriott Hotel, Portland, OR February 14.2002

"Type 2 Diabetes: Achieving Sustained Glycemic Control". St. Charles Medical Center Grand Rounds, Bend, Oregon. February 4, 2000.

"Managing the Common Complications of Type 2 Diabetes". OHSU Endocrinology CME. Embassy Suites, Portland, Oregon. September 25, 1999.

"Treatment of Type 2 Diabetes: Focus on Combination Therapy". Type 2 Diabetes and the Metabolic Syndrome: Tactics for Improved Outcomes. OHSU CME program. Embassy Suites, Portland, Oregon. October 10, 1998.

V. SERVICE

Membership in Professional Societies:
American Diabetes Association
American Thyroid Association
American Association of Clinical Endocrinologists
Alpha Omega Alpha National Honorary Medical Society
Endocrine Society

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Granting Agency Review Work:

Sanofi-Aventis "Inpatient in Hospital Use" Advisory Board	2005 - 2008
Fund Allocation Committee, American Diabetes Association Oregon Affiliate (Chairman, 1992-1995)	1992-1996

Editorial and Ad Hoc Review Activities:

Editorial Board, Diabetes Technology and Therapeutics	**2019 -**
Editorial Board, Diabetes Care	2018 - 2021
NIH Grant Application Reviewer	2009-2010, 2020
Abstract Review for Endocrine Society Annual Meeting	2010-2012
Reviewed the Thiazolidinedione Drug Class Review for the Oregon Evidence-based Practice Center at OHSU (Susan L Norris MD, MPH And Susan Carson, MPH) Commissioned for The Agency for Healthcare Research and Quality.	July 2008, January 2011
Reviewed Management of Inpatient Hyperglycemia: A Systematic Review. for the Portland Veterans Affairs Healthcare System and Oregon Evidence-based Practice Center (by D. Kanasagara, F. Wolf, M Freeman and M Helfand commissioned for the Department of Veterans Affairs	June 2008
Abstract review for American Diabetes Association Scientific Sessions	2004, 2007-2020
Editorial board, The Endocrinologist	2000-2003

Ad Hoc Reviews

Diabetes Care, Journal of Clinical Endocrinology And Metabolism, American Family Physician, Vascular Health and Risk Management, Diabetes Technology and Therapeutics, Metabolism, Diabetologia, Mayo Clinic Proceedings, Diabetes Obesity and Metabolism, Diabetes Technology And Therapeutics, New England Journal of Medicine,

Associate Editor for Endocrinology, Metabolism and Genetics

Section of Kelley's Essentials of Internal Medicine
2nd Edition

Committees:

International/National

Outcomes Committee for NIH GRADE study	***2015-present***
American Diabetes Association Scientific Sessions Planning Committee	***2017-2019***
Endocrine Society Diabetes Technology Task Force, Chair	2017-2018
Endocrine Society Special Programs Committee	2016-2019
Endocrine Society Committee for Endocrine Device Guidelines	2014- 2016
Early Self Assessment Program (EASP) Committee	2007- 2012

Endocrine Society
Primary board review method of the Endocrine Society

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National Professional Practice Committee, American 2008 Diabetes Association, Washington, DC Sets national standards for diabetes care	2006 -
Glycemic Control Task Force of the Society 2010 of Hospital Medicine (national collaborative effort to develop a web-based comprehensive manual for guiding inpatient diabetes programs).	2006 -
Inclusion Committee, American Diabetes Association	2005 -
2006 American Diabetes Association Writing Committee for Inpatient Diabetes Management	2003 -
2004 Task Force of the American Assn. of Clinical Endocrinologists, Consensus Development Conference on Inpatient Diabetes and Metabolic Control, Washington, DC	2003
National Annual Meeting Committee, American Diabetes Association	1994-1996

Regional

Planning Committee for OHA Echo Diabetes Program	***2020***
Planning committee for Oregon Health Authority Transformation Center On Addressing Poor A1C control aimed at 3 different view points	***2019-2020***
Executive Committee of the Oregon Diabetes Coalition	2008- 2010
Oregon Diabetes Collaborative II, Clinical Expert	2003- 2004
Oregon Diabetes Collaborative (Chair)	2001- 2003
Oregon Diabetes Coalition (First Professional Chair) Developed and initiated Oregon coalition	1998 -2001
Oregon State Diabetes Guideline Advisory Group, Chair Developed and later revised diabetes guidelines in state Last revision 2006	1995-present
OHSU Annual Ashland Endocrine Conference, CME Planning Committee	1995-2000
Nominations Committee, American Diabetes Association, Oregon Affiliate	1995-1996
Fund Allocation Committee, American Diabetes Association Oregon Affiliate (Chairman, 1992-1995)	1992-
1996 Professional Education Committee, American Diabetes Association, Oregon Affiliate (Chairman, 1995)	2000-
2018 Executive Committee, American Diabetes Association, Oregon Affiliate	1992-1995
Auction Committee, American Diabetes Association, Oregon Affiliate	1993-1997
Finance Committee, American Diabetes Association, Oregon Affiliate	1994-1995
Corporate Advisory Board Steering Committee, American Diabetes Association, Oregon Affiliate	1993-1995

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Institutional

OHSU TPIAT Program Committee	***2018-present***
OHSU Department of Medicine Endocrine Recruitment	2008-
2010 Committee for Division Head, Endocrinology, Diabetes and Clinical Nutrition	
OHSU Pancreas Transplant Committee	2007 -
OHSU Inpatient Diabetes Interdisciplinary Committee	2002-present
OHSU Clinical Research Administrative Task Force	2005
Faculty Senate, Oregon Health & Science University	1999-2001
Oregon Health & Science University Outpatient	
Diabetes Critical Path Committee	1996-2000
Oregon Health & Science University Diabetes	
Education Program Advisory Committee	1996-
present Faculty Council, Oregon Health & Science University	1994-1996
Physicians Computer Advisory Committee,	
Oregon Health & Science University	1994-
1995 Pharmacy and Therapeutics Committee,	
Portland Adventist Medical Center, Portland, OR	1991-
1993 Diabetes Subcommittee, Providence Medical	
Center, Portland, OR	1990-1998
Hospital Product Review, Walter Reed Medical Center,	
Washington, DC	1986-1990
Department of Medicine Quality Assurance,	
Walter Reed Medical Center, Washington, DC	1986-1990

Departmental

Community Service:

Developed and oversees the annual Pacific Northwest Diabetes Health Summit	2008-2010
Research update for Family Camp at Gales Creek Diabetes Camp	2005, 2006
Speaker for American Diabetes Association Expo	2002, 2005, 2006, 2007, 2008, 2009, 2010
Member of American Diabetes Association	2004 – present
Portland Area Leadership Board (President 2009-2017)	
ADA Professional Education Committee, Portland Area	2014 - 2018
ADA Spokesperson on Everyday Choices Campaign	2004 -
2010 Portland, Oregon region	
Chris Dudley Basketball Camp for Children with Diabetes,	
Camp Physician (national camp held yearly)	1998-2018
Board of Directors, Gales Creek Diabetes Camp	1995-2001
Gales Creek Diabetes Camp for Children,	
Camp Physician	1991-92, 1994-95

VI. TEACHING (OHSU Educator=s

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Portfolio): Overview of your Role as an

Educator:

First Year Medical Students:
Principles of Clinical Medicine
1997
PCM Preceptor
2000,2001,2002,2003, 2004, 2006

Second Year Medical Students:
Pathophysiology lectures in diabetes
6-7 hours lecture per year
Section leader for pathophysiology course on diabetes for 9 years

Third Year Medical Students:
Diabetes lectures for medicine rotation 3-4 times yearly

Fourth Year Students:
Precept students in diabetes clinic weekly, 2-4 months yearly

Internal Medicine Residents:
Precept in diabetes clinic an average of 2 times weekly
Noon lecture series 1-2 times yearly
Precept on endocrine consult service 3-6 weeks yearly

Endocrine Fellowship:
Developed a new diabetes fellows continuity clinic starting 2007 (attending 95% of clinics)
Precept in diabetes clinic twice weekly
Precept on endocrine consult service 3-6 weeks yearly

Physician Assistant Students:
Endocrinology Clinical Lectures Series (endocrine section coordinator 1996-1998)
Diabetes comprehensive lecture series yearly, 1996 – 2010.
PA Board Review Course lectures 2005, 2006,2008

Pharm D Students
Diabetes Lecture Series – Oregon State University Pharm D Program
Yearly 1997-2004, 2009-present

Scholarship of Teaching:

<u>Curriculum Development</u>

Section leader for diabetes curriculum in Pathophysiology course for 2nd year students 2004 – 2013

Chaired and developed at least 5 accredited CME programs including the following large programs:

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Type 2 Diabetes Across the Continuum of Care: Current Approaches for Glycemic Control in the Inpatient and Outpatient Setting. A Princeton Teleconference Series.
Accredited through University of Kentucky College of Medicine and the North American Center for Continuing Medical Education- Princeton CME
I developed the slide kit and presented the core lecture that reached over 1600 physicians and Pharm Ds over 4 teleconference sessions.

Inpatient Glycemic Control Program: Champion Training Course October 11-12, 2007
Hilton Conference Center, Vancouver, WA
Co-sponsored with SW Washington Medical Center
Attended by nearly 300 attendees from 25 states.
Recruited faculty representing national leadership on the topic

Diabetes Update September 14, 2007
Half day programs at Riverside Conference Center, Grants Pass and Smullin Education Center, Medford
Intensive review of diabetes developed for Assante/Providence CME of Southern Oregon

Diabetes and Heart Disease: Exploring the Deadly Connection November 17, 2006
Ambridge Event Center, Portland, OR
Organized and conducted by the diabetes center, including cardiology and endocrinology speakers

Additional Clinical Research Experience as PI for Industry Sponsored Studies over last 15 years

1. A Phase II, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study of the Safety and Efficacy of XXX Administered Once Daily for the Treatment of Type II Diabetes Mellitus.

2. Two-Week, Multicenter, Double-Blind, Parallel, Placebo and XXX Study of Plasma Glucose Profiles and Pharmacokinetics in Subjects with Juvenile-Onset Diabetes Mellitus.

3. Thirteen-Week, Multicenter, Double-Blind, Parallel Group, Placebo-Controlled and AC 137 Dose Ranging Study to Evaluate Glycated Hemoglobin and Plasma Glucose Profiles in Patients with Type II Diabetes Mellitus.

4. A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Multidose Study of the Combined Effects of Subcutaneously Administered Insulin and XXX in Subjects with Insulin-Dependent Diabetes Mellitus.

5. Fifty-Two Week, Multicenter, Double-Blind, Parallel Group, Placebo-Controlled and XXX Dose-Ranging Study to Evaluate Glycated Hemoglobin in Patients with Type II Diabetes Mellitus.

6. A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multidose Study of the Safety and Pharmacokinetic/ Pharmacodynamic Effects of XXX Administered Twice Daily for the Treatment of Type II Diabetes Mellitus in Subjects Receiving XXX Treatment.

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7. A Multicenter, Double-Blind, Randomized, Parallel-Group Study to Prospectively Evaluate the Post-Grandial Glucose Excursion (PPGE), the Daytime Glucose and Insulin Profile, Safety, and Tolerability of a Fixed Dose of XXX, a Force Titrated Dose of XXX and Placebo in Subjects with NIDDM on Diet Alone.

8. A 26-Week, Randomized, Double-Blind, Multicenter, Study to Evaluate the Safety, Efficacy, and Tolerability of XXX when Administered Twice Daily to Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM) who are Inadequately Controlled on Insulin Monotherapy.

9. An Open-Label Extension Study to Assess the Long-Term Safety, Tolerability and Efficacy of XXX when Administered Once or Twice Daily in Combination with Insulin to Patients with Non-Insulin Dependent Diabetes Mellitus (NIDDM).

10. A Double-Blind, Placebo-Controlled, Randomized Trial to Determine the Effects of a Range of Doses of XXX Administered Either Once or Twice a Day in Patients with Type 2 Diabetes who have Inadequate Glycemic Control with Diet and Exercise.

11. A Multicenter, Double-Blind, Randomized, Parallel-Group Study to Evaluate the Efficacy, Safety and Tolerability of Three Fixed Dose Levels of XXX and Placebo in Type 2 Diabetes Mellitus Patients with Minimally Elevated Fasting Plasma Glucose Levels.

12. A Randomized, Double-Blind, Placebo-Controlled, Dose-Finding Study of XXX in Type 2 Diabetic Patients.

13. A Phase III, Randomized, Double-Blind, Active Control Trial to Evaluate the Safety and Efficacy of a Fixed Combination XXX in Patients with Type 2 Diabetes Mellitus who have Inadequate Glycemic Control on XXX.

14. A Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Safety and Efficacy of Subcutaneously Administered XXX in Obese Subjects.

15. A Double-Blind, Randomized Study of the Safety and Efficacy of a Combination of Insulin and XXX Compared to a Combination of Insulin and XXX in the Treatment of Patients with Type 2 Diabetes Mellitus.

16. A Randomized, Multicenter, Double Blind, Placebo- Controlled, Parallel Group, Multiple-Dose Study of the Safety and Efficacy of XXX in Patients with Mild Thyroid Failure.

17. A Double-blind, Placebo-controlled, Parallel Group, Dose-Response Study to Evaluate the Efficacy and Safety of XXX versus Placebo in the Relief of Pain In Diabetic Peripheral Polyneuropathy

18. A Randomized, Double-Blind Study to Compare the Durability of Glucose Lowering and Preservation of Pancreatic Beta-Cell Function of XXX Compared to XXX in Patients with Drug-Naive, Recently Diagnosed Type 2 Diabetes Mellitus (< 2 years)

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19. A Phase 2, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Subcutaneously Administered XXX in Obese Subjects

20. Efficacy, Dose-Ranging and Safety for XXX in Type 2 Diabetic Subjects Inadequately Controlled on Diet, XXX or XXX: A 24-Week Double-Blind Randomized Placebo-Controlled Study

21. A Randomized, Double-Blind, Placebo Controlled trial to Evaluate the Safety and Efficacy of XXX Added on to a Background of XXX in Subjects with Type 2 Diabetes Mellitus Who have Inadequate Glycemic Control on XXX Therapy

22. A Multicenter, Randomized, Double-Blind, Parallel Group Trial Comparing the Safety and Efficacy of XXX to XXX as First Line Therapy in patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control with Diet and Exercise

23. Open-Label, Long-Term Study of the Antihypertensive Activity and Safety of XXX, A Dual Metalloprotease Inhibitor, in the Treatment of Hypertension

24. Phase III Double-Blind Efficacy and Safety Study of XXX in Addition to XXX Compared to Placebo in Subjects with Primary Hypercholesterolemia

25. A Multi-Center Study of Calibration/Calibration Stability and Accuracy and Precision Measurements in a Diabetic Population using XXX

26. XXX Cardiovascular Treatment Assessment vs. XXX

27. A Phase 2, Randomized, Triple-Blind, Placebo-Controlled, Multicenter, Forced Dose-Escalation Study to Examine Dose Tolerability in Subjects with Type 2 Diabetes Mellitus Given XXX Subcutaneously

28. XXX versus XXX in Subjects with Type 2 Diabetes Mellitus and Dyslipidemia

29. Evaluation of the safety and efficacy of XXX in the treatment of chronic pain in patients with painful diabetic neuropathy

30. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose, Multicenter Study of Weight-Reducing and Prevention of Weight Regain Effects and Safety of XXX in Obese Patients with or without Comorbidities

31. A Phase III, 12-Month, Double Blind, Randomized, Parallel Group, Placebo Controlled, Efficacy and Safety Study of XXX in Overweight and Obese Subjects With a 12-Month Open-Label Extension Phase

32. A Double-blind Feasibility Study to Estimate and Compare the Effect of XXX in Parallel with XXX on Cognition in Patients with Type 2 Diabetes Mellitus

33. A Multicenter, Double-Blind, Randomized, Placebo-and Active-Controlled, Parallel Study to Evaluate the Glucose and Lipid-Altering Efficacy and Safety of XXX in Patients with Type 2

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Diabetes

34. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Balanced, Three-Way Crossover Study to Evaluate the Efficacy of XXX in Elevating HDL-C Levels In Patients with Type 2 Diabetic Dyslipidemia and Low HDL-C

35. Effects of XXX on Lipoproteins In Subjects with Type 2 Diabetes Mellitus Who Are Receiving Statin Therapy

36. XXX vs. XXX as Add On Therapy in Type 2 Diabetes Patients Failing XXX and XXX

37. 12-Week, Multinational, Multicenter, Controlled, Open, 1:1:1 Randomized, Parallel Clinical Trial to Assess Noninferiority Between Pre- and Post-Meal Administration of XXX and Pre-Meal Regular Human Insulin in Subjects with Type 1 Diabetes Mellitus Receiving Insulin Glargine as the Basal Insulin Therapy

38. Long-Term, Open-Label, Safety and Tolerability Study of XXX in Addition to XXX in Subjects with Primary Hypercholesterolemia Who Have Previously Completed the 12-Week Double-Blind Study

39. A randomized, double-blind, placebo-controlled, parallel-group, fixed-dose, multicenter study of weight-reducing effect and safety of XXX in obese patients with type 2 diabetes

40. A Phase 3, Randomized, Triple-Blind, Parallel-Group, Long-Term, Placebo-Controlled, Multicenter Study to Examine the Effect on Glucose Control (HbA1C) of XXX Given Two Times a Day in Subjects with Type 2 Diabetes Mellitus Treated with XXX Alone

41. A Phase 3, Randomized, Triple-Blind, Parallel-Group, Long-Term, Placebo-Controlled, Multicenter Study to Examine the Effect on Glucose Control (HbA1C) of XXX Given Two Times a Day in Subjects with Type 2 Diabetes Mellitus Treated with a XXX Alone

42. A Phase 3, Randomized, Triple-Blind, Parallel-Group, Long-Term, Placebo-Controlled, Multicenter Study to Examine the Effect on Glucose Control (HbA1C) of XXX Given Twice Daily in Subjects With Type 2 Diabetes Mellitus Treated with XXX and a XXX

43. A Randomized, Triple-Blind, Placebo-Controlled, Multicenter Study to Investigate the Safety of XXX Treatment Employing XXX Dose-Titration Followed by XXX in Subjects with Type 1 Diabetes Mellitus Who Have Not Achieved Glycemic Targets With Intensive Insulin Therapy

44. A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Short-Term Safety and Efficacy Study of Two Doses of XXX in Overweight and Obese Patients with Type 2 Diabetes Mellitus

45. A Multicenter, Eight-Week Treatment, Single Step Titration, Open-Label Study Assessing the Percentage of Dyslipidemic Patients Achieving LDL Cholesterol Target with XXX Starting Doses of 10mg, 20mg, 40mg, and 80mg

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46. A Pilot Study to Evaluate the XXX Device as a Tool in the Assessment of Carbohydrate Metabolism Disorders

47. A Multicenter Study, Open-Label, Extension Study of the Long-Term Safety of XXX in Subjects with Type 1 Diabetes Mellitus Completing Protocol XXX

48. A Phase II randomized, double-blind, placebo-controlled dose ranging study to determine the efficacy, safety, tolerability and pharmacokinetics of XXX in patients with type 2 diabetes mellitus

49. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of the Addition of XXX to Patients with Type 2 Diabetes with Inadequate Glycemic Control on Combined XXX and XXX

50. An Open-Label Extension Study of Protocol XXX to Examine the Long-Term Effect on Glucose Control (HbA1c) and Safety and Tolerability of XXX Given Two Times a Day to Subjects Treated With XXX Alone

51. An Open-Label Extension Study of Protocol XXX to Examine the Long-Term Effect on Glucose Control (HbA1c) and Safety and Tolerability of XXX Given Two Times a Day to Subjects Treated With a XXX Alone

52. An Open-Label Extension Study of Protocol XXX to Examine the Long-Term Effect on Glucose Control (HbA1c) and Safety and Tolerability of XXX Given Two Times a Day to Subjects Treated With XXX and a XXX.

53. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX Added to Sulfonylurea in Patients With Inadequately Controlled Type 2 Diabetes Mellitus

54. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX Added to Metformin in Patients With Inadequately Controlled Type 2 Diabetes Mellitus

55. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of XXX Added to Insulin in Patients with Inadequately Controlled Type 2 Diabetes Mellitus

56. The Evaluation of Cardiac Biomarkers in Normal Healthy and NIDDM Men and Women

57. A Phase 2, Randomized, Triple-Blind, Parallel-Group, Placebo-Controlled Multicenter Study to Examine the Effect of XXX on Glucose Control in Subjects With Type 2 Diabetes Mellitus

58. A Phase 3, Randomized, Double-Blind, Active Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of XXX in Combination with XXX Compared to XXX in Combination with XXX in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on XXX Therapy Alone

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59. XXX Test Strip Multi-Site Alternative Site Testing Clinical Study

60. A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Safety and Pharmacokinetics of XXX in Subjects With Type 2 Diabetes Mellitus

61. A Randomized, Triple-Blind, Placebo-Controlled, Multicenter study to Investigate the Safety and Tolerability of Progressive Dose-Escalation of XXX in Obese Subjects With Non-Insulin Treated Type 2 Diabetes and Obese Non-Diabetic Subjects

62. Long-Term Effects of Insulin plus Metformin Regimens on the Overall and Postprandial Glycemic Control of Patients with Type 2 Diabetes: A Comparison of Premeal XXX Mixtures To Once-Daily XXX

63. A Randomized, Double-blind, Placebo-controlled, 4-Week Study to Evaluate the Safety and Efficacy of XXX in Subjects with Type 2 Diabetes Mellitus

64. A Multicenter, Double-Blind, Placebo-Controlled, Randomized Study of the Safety of XXX in the Treatment of Patients with Type 2 Diabetes Mellitus

65. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Assess the Efficacy and Safety of XXX in Subjects with Painful Distal Diabetic Neuropathy

66. An Open-Label Study to Examine the Long-Term Effect on Glucose Control (HbA1c) and Safety and Tolerability of XXX Given Two Times a Day to Subjects With Type 2 Diabetes Mellitus

67. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XXX in Type 2 Diabetics with Inadequate Glycemic Control on Metformin Monotherapy

68. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of XXX in Type 2 Diabetics with Inadequate Glycemic Control on Insulin Therapy Alone or Insulin Therapy in Combination with Other Oral Anti-Diabetic Agents

69. A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of XXX Compared with XXX Sulfonylurea Therapy in Patient with Type 2 Diabetes with Inadequate Glycemic Control on Metformin Monotherapy

70. A Double-Blind, Randomized, Placebo-Controlled, Parallel Study to Evaluate the Efficacy and Safety of XXX as an Adjunct to Oral Hypoglycemic Therapy, in the Treatment of Hypogonadal Men with Type 2 Diabetes

71. A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of XXX Compared With XXX in Patients With Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy

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72. A Randomized, Double-Blind, Placebo-Controlled Factorial Study Evaluating the Efficacy and Safety of XXX in Patients with Mild to Severe Hypertension

73. A Multi-Center, Open-Label, Follow-On Trial to Assess the Long-Term Safety and Efficacy of XXX in Subjects with Painful Distal Diabetic Neuropathy

74. A randomized, double-blind, placebo-controlled, parallel-group, fixed-dose, multicenter study of long-term glycemic control with XXX in treatment-naïve patients with type 2 diabetes

75. A Double-Blind, Randomized, Multicenter, Placebo-Controlled, Parallel-Group Efficacy and Safety Extension Study of XXX in the Treatment of Adult Outpatients With Primary Insomnia

76. A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Subjective Response To Treatment With XXX in Adult Subjects With Chronic Insomnia by Utilizing an Interactive Voice Response System (IVRS) For Collecting Diary Data

77. A multicenter, double-blind, randomized, placebo controlled dose ranging phase 2 study to investigate efficacy, safety, tolerability and pharmacokinetics of XXX in patients with type 2 diabetes

78. A multicenter, double-blind, randomized, placebo controlled dose ranging phase 2 study to investigate efficacy, safety, tolerability and pharmacokinetics of XXX in patients with type 2 diabetes, who are treated with a stable dose of metformin

79. A Safety, Tolerability, and Efficacy Study of XXX Administered for Ninety Days in Subjects with Probable Alzheimer's Disease of Mild to Moderate Severity

80. A Phase 2B, Randomized, Double-Blind, Placebo-Controlled, Dose Ranging, Multicenter Study to Examine the Effect of XXX on Body Weight and It's Safety and Tolerability in Obese Subjects

81. A Multi-Center, Randomized, Double-Blind, Placebo Controlled, Parallel Evaluation of the Efficacy and Safety of XXX in the Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia

82. A Phase I/II, Randomized, Placebo-Controlled, Double-Blind, Dose-Escalation Study of Safety, Pharmacokinetics and Efficacy of Single Intravenous Doses of XXX in Adults with Moderate-to-severe Pain from Osteoarthritis of the Knee

83. A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Single Dose Comparison of the Analgesic Activity of XXX and Placebo in Subjects with Shoulder Pain

84. A double-blind, placebo-controlled study exploring the safety, tolerability, and pharmacodynamic effect of XXX in centrally obese subjects with insulin resistance

85. A Randomized Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Effects of XXX on Body Composition in Patients with Type 2 Diabetes

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86. A Study to Assess the Efficacy and Tolerability of XXX Administered with Insulin in Patients with Type 2 Diabetes

87. A US Randomized Questionnaire-Based Trial Assessing the Impact of the Availability of Inhaled Insulin on Therapeutic Choice in Patients with Suboptimally Controlled Type 2 Diabetes

88. RANDOMIZED DOUBLE-BLIND PLACEBO-CONTROLLED PHARMACODYNAMIC EVALUATION OF XXX IN PATIENTS WITH TREATMENT NAÏVE TYPE 2 DIABETES MELLITIS

89. An Open-Label Study Evaluating the Safety and Tolerability of Long Term Administration of XXX Extended Release Tablets in Subjects with Moderate to Severe Chronic Non-Malignant Pain

90. A Multi-Center Open-Label Evaluation of the Safety of XXX in the Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia

91. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 3 Trial to Evaluate the Efficacy and Safety of XXX as Monotherapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercise

92. A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of XXX in Combination with Metformin in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control in Metformin Alone

93. A Prospective, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety of a Bivalent Vaccine of XXX in Healthy Adults

94. A Randomized, Double-Blind, Placebo-Controlled, Forced-Titration, Phase IV Study Comparing XXX Taken Orally For 8 Weeks In Patients With Stage 2 Hypertension

95. A Pilot Study to Evaluate the Lipid-modifying Effect and Safety of XXX in Subjects with Mild-to-Moderate Hypercholesterolemia.

96. Extension Study of XXX to Examine the Long-Term Effect of XXX on Body Weight and Its Safety and Tolerability in Obese Subjects

97. A 2-Panel, 2-Period, Double-Blind Study of the Safety, Tolerability and Pharmacokinetics of XXX Following Oral Administration in Patients During and Between Acute Migraine Attacks

98. A Phase 2, Randomized, Double-blind, Placebo-Controlled, Multicenter Study of the Safety and Effects on Lipids of 12-Weeks of XXX in Subjects with Primary Hypercholesterolemia

99. A Study to Assess the Efficacy and Tolerability of XXX Co-Administered with Insulin in Subjects with Type 2 Diabetes

100. A Double-Blind, Randomized Placebo-Controlled Study to Evaluate the Efficacy and Safety of

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XXX when Co-administered with XXX in Subjects with Primary Hypercholesterolemia

101. An Open-Label Extension Study to Evaluate the Safety and Tolerability of XXX in Subjects with Primary Hypercholesterolemia or Combined Hyperlipidemia

102. A 16 week randomized, double-blind, parallel group study to evaluate the efficacy and safety of a new medication to lower LDL-c and HBA1c in subjects with type 2 diabetes mellitus

103. A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study Evaluating The Efficacy And Safety Of Adding XXX In Subjects With Type 2 Diabetes Who Are Not Achieving Glycemic Targets

104. Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Study of XXX in Patients with Moderate to Severe Psoriasis

105. XXX with Chronic Low Back Pain Patients with or without Lower Extremity Pain

106. Efficacy and Safety of XXX on Sleep Maintenance Insomnia: A 12-week Multicenter, Randomized, Double-Blind, Placebo-Controlled Study

107. A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of XXX in Subjects with Osteoarthritis

108. A randomized, double-blind, double-dummy, placebo-controlled, 3x4 factorial design trial to evaluate XXX after eight weeks of treatment in patients with Stage I or II hypertension with an ABPM sub-study.

109. A Multicenter, Randomized, double-Blind, Prospective Study Comparing the Safety and Efficacy of XXX in Subjects with mixed Dyslipidemia

110. A Long-Term, Open-Label, Safety Extension Study of the Combination of XXX for Subjects with Mixed Dyslipidemia

111. A Phase 3 Study of the Analgesic Efficacy and Safety of XXX: A Parallel, Randomized, Double-Blind, 13-Week, XXX in Patients with Osteoarthritis of the Knee

112. A Randomized, Double-Blind, Parallel Group, Multi-Center, Vehicle-Controlled, Multiple-Dose, Combined Phase1/Phase 2 Trial of XXX Applied Topically to Scalp of Subjects with Oily Skin

113. "A Phase 1/2a, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Study Of Safety, Tolerability, Pharmacokinetics And Activity Of XXX In Subjects With Type 2 Diabetes Mellitus"

114. "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX as Monotherapy for Type 2 Diabetes"

115. A 13-week Multinational, Randomized, Double-Blind, Placebo-Controlled, Dose-Response Trial Assessing the Safety, Tolerability and Efficacy of XXX in Metformin-Treated Subjects with Type

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2 Diabetes Mellitus

116. A Prospective, Multi-Center, Open-Label, Randomized, Controlled Clinical Trial Comparing the Efficacy and Safety in Subjects With Type 2 Diabetes Receiving XXX Over a 52-Week Treatment Period and a 24-Week Follow-up

117. A Single-Blinded Randomized, Placebo-Controlled, Staggered-Parallel, Escalating-Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Type 2 Diabetes Mellitus

118. A randomized, double-blind, placebo-controlled, cross-over study to evaluate the effects of XXX on polysomnographic sleep recordings, subjective sleep assessment, and daytime cognitive function in elderly and nonelderly subjects with primary insomnia

119. A RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY TO EXAMINE THE EFFECTS OF XXX AND SAFETY IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS MANAGED WITH DIET MODIFICATION AND EXERCISE AND/OR ORAL ANTIDIABETIC MEDICATIONS

120. A randomized, placebo controlled, parallel group, double-blind study of the efficacy and safety of XXX in abdominally obese subjects with type 2 diabetes mellitus and multiple cardiovascular and metabolic risk factors and with LDL-cholesterol at NCEP ATP III treatment goal

121. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Weight Loss, Safety, Tolerability and Pharmacokinetics in Obese Subjects Following 12-Week Dosing of XXX

122. "A 36 week randomized, double-blind, parallel group, multicenter, active-controlled, optional titration study comparing XXX in patients ≥ 65 years old with systolic essential hypertension"

123. A Prospective, Multi-Center, Open-Label, Randomized, Controlled Clinical Trial Comparing the Efficacy and Safety in Subjects with Type 1 Diabetes Receiving XXX Over a 52-Week Treatment Period and a 4-Week Follow-up

124. A Phase 2A, Randomized, Controlled, Double-Blind, Multicenter study to Evaluate the Safety, Tolerability, and Effect on Body Weight of XXX Adminidtered in Conjunction with XXX in Overweight and Obese Subjects.

125. A 104 Weekk, double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of XXX in Obese Patients.

126. A Phase 3, 24 Week, multi-Center, Open-Label, Randomized, Controlled Trial Comparing the Efficacy and Safety of XXX in Combination with XXX in Subjects with Type 2 Diabetes XXX Sub-Optimally Controlled on Combination of XXX and a XXX.

127. A Randomized, Placebo-Controlled, Double-Blind, Multi-Center, Six Week Study to Evaluate the Safety and Pharmacodynamic Effects of XXX in Subjects with Type 2 Diabetes.

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128. A Phase 4, Randomized, Open-Label, Parallel-group, Multicenter Study to Characterize Regimins of XXX Intensified with Either XXX or XXX in Patients with Type 2 Diabetes.

129. A Randomized, Double-blind, Active-Controlled, Multicenter Study to Compare the Effect of 24 Weeks Treatment with a Fixed Combination Therapy of XXX and XXX to the individual Monotherapy Components in Drug Naïve Patients with Type 2 Diabetes.

130. A Phase 2b, Randomized, Double-Blind, Parallel-Group, Study of Safety and Efficacy of 16 Weeks of Treatment with XXX or XXX Placebo in Addition to XXX and XXX or XXX Placebo in Participants with Type 2 Diabetes Mellitus.

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